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INTRODUCTION

"*Progress on public health problems in a democratic society requires agreement about the mission and content of public health sufficient to serve as the basis for public action.*"[1]

The emergence of the COVID-19 pandemic in January 2020 not only brought its own burden of death, disease, and economic hardship, but also exacerbated many existing public health and social problems. In particular, the misuse of opioids,[2] an issue the United States has been struggling with for many years,[3] has been a cause for concern. Recently, the country has seen a dramatic rise in deaths associated with the use of synthetic opioids.[4] By May of 2020,

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[1] INST. OF MED. (US) COMM. FOR THE STUDY OF THE FUTURE OF PUB. HEALTH, THE FUTURE OF PUBLIC HEALTH 108 (1988).

[2] There is no universal agreement on a vocabulary related to harm associated with drug use beyond the defined terms specific to individual pieces of legislation. Unless quoting a source using a different definition, this paper will use terms as defined by the Centers for Disease Control and Prevention. *Commonly Used Terms*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 26, 2021), https://www.cdc.gov/drugoverdose/opioids/terms.html [https://perma.cc/Y6VK-E9TE].

[3] *See* David A. Fiellin & Patrick G. O'Connor, *New Federal Initiatives to Enhance the Medical Treatment of Opioid Dependence*, 137 ANNALS INTERNAL MED. 688, 688 (2002).

[4] *See* Lucy W. Halpern, *Update: COVID-19 Upends Progress on Opioid Crisis*, 120 AM. J. NURSING 16, 16 (2020) (linking measures to reduce infection by reducing human contact "have increased the chances of relapse, since many addiction patients depend on comprehensive care that includes housing and social services. The pandemic has forced some treatment centers to close or scale back operations precisely when their patients are suffering economic hardships—job loss, food insecurity, homelessness—and urgently need human connection.

the United States had seen the "largest number of drug overdoses for a 12-month period ever recorded."[5] January 2020 to January 2021 exceeded that record with a 30 percent increase in drug overdose deaths.[6] The most recently available provisional figures, those for the twelve months ending in April 2021, show a 29 percent increase, amounting to an estimated 100,306 deaths,[7] the most ever reported in a single year.[8]

Dr. Sarah Wakeman, one of the nation's leading experts in addiction medicine, predicted this early on in the pandemic when she noted that the social distancing measures needed to control COVID-19 create social isolation and despair, "both of which are known risk factors for the development and exacerbation of addiction."[9] Therefore, "[substance users] are at greater risk than ever."[10] It may be several years before we fully understand the impact of the pandemic, but one thing we know already is that the number of cases of opioid overdoses increased during this time.[11]

While no one has suggested that COVID-19 itself increases opioid-associated deaths, this sharp rise in deaths highlights the

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Loneliness, isolation, anxiety, and unemployment are significant factors fueling the resurgent opioid epidemic."); Jesse C. Baumgartner & David C. Radley, *The Spike in Drug Overdose Deaths During the COVID-19 Pandemic and Policy Options to Move Forward*, COMMONWEALTH FUND (Mar. 25, 2021), https://www.commonwealthfund.org/blog/2021/spike-drug-overdose-deaths-during-covid-19-pandemic-and-policy-options-move-forward [https://perma.cc/DQ9P-CTWY] ("Overdose deaths increased in almost every state; 24 states and the District of Columbia had an estimated increase of at least 30 percent, and the overall U.S. total increased by 33 percent."); *see also* Jasmina Mallet et al., *Addictions in the COVID-19 Era: Current Evidence, Future Perspectives a Comprehensive Review*, 106 PROGRESS NEURO-PSYCHOPHARMACOLOGY & BIOLOGICAL PSYCHIATRY 1, 7 (2020).

[5] CDC Health Alert, Ctrs. for Disease Control & Prevention, Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic (Dec. 17, 2020, 8:00 AM), https://emergency.cdc.gov/han/2020/han00438.asp [https://perma.cc/UQ5J-BY2P].

[6] Farida B. Ahmad et al., *Provisional Drug Overdose Death Counts*, NAT'L CTR. FOR HEALTH STATS. (Oct. 13, 2021), https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm [https://perma.cc/QXK4-XF9V].

[7] Steven Ross Johnson, *CDC Data: Drug Overdose Deaths Top 100K for First Time*, U.S. NEWS & WORLD REP. (Nov. 17, 2021, 10:00 AM), https://www.usnews.com/news/health-news/articles/2021-11-17/drug-overdose-deaths-top-100k-over-12-months-for-first-time (last visited Jan. 12, 2022).

[8] *See id.*; Ahmad et al., *supra* note 6.

[9] Sarah E. Wakeman et al., *An Overdose Surge Will Compound the COVID-19 Pandemic if Urgent Action Is Not Taken*, NATURE MED. (May 1, 2020), https://www.nature.com/articles/s41591-020-0898-0 [https://perma.cc/3YG2-5SEV].

[10] *Id.*

[11] *See* LISA N. SACCO & ERIN BAGALMAN, CONG. RSCH. SERV., R44987, THE OPIOID EPIDEMIC AND FEDERAL EFFORTS TO ADDRESS IT: FREQUENTLY ASKED QUESTIONS 2 (2017), https://crsreports.congress.gov/product/pdf/R/R44987/4 [https://perma.cc/SB9M-EUMA]; *see also* Maryann Mason, *Opioid Deaths Are Helping Fuel the Pandemic's Death Toll*, US NEWS & WORLD REP. (Mar. 26, 2021, 6:00 AM), https://www.usnews.com/news/health-news/articles/2021-03-26/opioid-deaths-are-increasing-the-covid-pandemics-death-toll (last visited Oct. 30, 2021) (noting the increase in non-COVID-19 related deaths during the pandemic and citing evidence linking the deaths to opioid overdoses).

fundamental failure of existing federal[12] and state[13] legislative schemes. These schemes prioritize reducing the number of opioids prescribed rather than reducing the harm associated with opioid use. The result has been what some experts are calling the "opioid paradox," in which prescriptions for opioids have significantly decreased even while deaths continue to rise.[14]

This article creates a framework for analyzing existing and proposed legislation in terms of its likelihood to reduce opioid-associated deaths. In particular, it looks at the United States' continued commitment to attach criminal penalties to the use of some of the drugs responsible for this harm, and that a considerable gap remains between endorsing what former Senior Counselor to the President Kellyanne Conway described as "a whole-of-government approach to treat the whole person"[15] and implementing public health problem solving techniques. This article is the first to evaluate the legislative response to the harms caused by substance use from a public health perspective in order to better identify why laws that do not incorporate the public health method are doomed to fail. Public health approaches are more effective because they take people as they are, rather than as they wish them to be.

This article proceeds from the premise that the law can, and should, be a powerful tool in promoting public health.[16] In a 2000

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[12] *See* SACCO & BAGALMAN, *supra* note 11, at 1, 6.

[13] *See Drug Overdose Immunity and Good Samaritan Laws*, NAT'L CONF. OF STATE LEGISLATURES (June 5, 2017), https://www.ncsl.org/research/civil-and-criminal-justice/drug-overdoseimmunity-good-samaritan-laws.aspx [https://perma.cc/3SSS-6NWF] (according to the National Conference on State Legislatures: "[i]n 2016 nearly every state enacted legislation addressing opioids, including heroin and prescription drugs, and in 2017 the majority of states have again enacted legislation on this issue. Policymakers have sought solutions that will help curb use and overdose by expanding access to treatment, increasing diversion opportunities and funding, modifying penalties, expanding Good Samaritan immunity, and increasing naloxone access.").

[14] *See* Aaron Glickman & Janet Weiner, *Why Deaths Continue to Rise in the Opioid Epidemic*, PENN LEONARD DAVIS INST. OF HEALTH ECON. (Jan. 22, 2019), https://ldi.upenn.edu/our-work/research-updates/why-deaths-continue-to-rise-in-the-opioid-epidemic/ [https://perma.cc/G85A-9KN4] ("Deaths continue to soar, even as states and health systems implement policies to curb the overprescribing of opioids that led to the epidemic in the first place. It's hard not to be discouraged by these numbers and our failure to reduce overdose deaths."); *see also Unintended Consequences of State Opioid Policies*, SCI. DAILY (Feb. 17, 2021), https://www.sciencedaily.com/releases/2021/02/210217134802.htm [https://perma.cc/VS7N-5XMB] (describing an Indiana University study of the impact of opioid policies on "various opioid adverse outcomes" which found that "the so-called opioid paradox—the rise of opioid-related deaths despite declines in opioid prescriptions—may arise from the success, not the failure, of state interventions to control opioid prescriptions").

[15] Transcript of *Press Briefing by Senior Counselor Kellyanne Conway, ONDCP Director Jim Carroll, and Assistant Secretary of Public Health ADM Brett Giroir*, THE WHITE HOUSE (Jan. 30, 2020), https://trumpwhitehouse.archives.gov/briefings-statements/press-briefing-senior-counselor-kellyanne-conway-ondcp-director-jim-carroll-assistant-secretary-public-health-adm-brett-giroir/ [https://perma.cc/WX8G-4NH2].

[16] *See* Lawrence O. Gostin & Madison Powers, *What Does Social Justice Require for the Public's Health? Public Health Ethics and Policy Imperatives*, 25 HEALTH AFFS. 1053,

article in the *Journal of the American Medical Association*, Professor Larry Gostin, a founder of the field of public health law, wrote that "public health law should be seen broadly as the authority and responsibility of government to ensure the conditions for the population's health."[17] Picking up this theme, Professor Scott Burris advanced the field by bringing together the work of scientists who evaluated the law's "impact in areas such as traffic safety, gun violence, and tobacco control" as part of the general work of public health law.[18] In so doing, he created the field of "legal epidemiology"—the study of law's incidental or unintended effects on health.[19] But using law as a tool to promote public health is very different from using public health principles to develop legislation. Even as the federal government declares the challenge met and the war won, deaths and other serious harm associated with the use of opioids and other drugs continue to rise.[20]

The current federal and state legislative approach to the ever-rising deaths associated with synthetic opioid use has failed because it has prioritized reducing the use of opioids rather than the harm caused to those who use them. By not prioritizing reducing the most serious harms associated with opioid use—namely, death and disease—existing legislation has had the perverse effect of magnifying harm by creating a cascade of unintended consequences. To effectively address these legislative inadequacies, a public health framework must be incorporated in the lawmaking process, which requires identifying the primary harms to be mitigated, utilizing the

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1054, 1057 (2006) (arguing that using the "justice perspective" to improve the public's health reflects an understanding that "health threats" are "multicausal [and] interactive" and therefore require "a system of overlapping and shared responsibility among federal, state, and local governments").

[17] Lawrence O. Gostin, *Public Health Law in a New Century Part I: Law as a Tool to Advance the Community's Health*, 283 JAMA 2837, 2841 (2000).

[18] Scott Burris et al., *A Transdisciplinary Approach to Public Health Law: The Emerging Practice of Legal Epidemiology*, 37 ANN. REV. PUB. HEALTH 135, 136 (2016).

[19] Michelle M. Mello, *Peeping into Hidden Worlds: The Past and Future of Legal Epidemiology*, 92 TEMP. L. REV. 837, 844 (2020) ("There are many pioneering thinkers and supporting organizations to thank for the progress the field [legal epidemiology] has made. We should particularly acknowledge the leadership of Professor Scott Burris. In partnership with champions at the Robert Wood Johnson Foundation and other thought leaders, he articulated a vision for the new field of PHLR, and in the decade since he has thrown himself into making it happen.").

[20] Steven Rich et al., *How the Opioid Epidemic Evolved*, WASH. POST (Dec. 23, 2019), https://www.washingtonpost.com/graphics/2019/investigations/opioid-pills-overdose-analysis/ [https://perma.cc/2ULC-DR8K] (describing the timeline: "[opioids] have killed more than 400,000 Americans since the turn of the century" and 25 percent, or approximately 100,000 people, died in the six years between 2011 and 2017). Recent evidence suggests that deaths attributable to opioids were undercounted "between 1999 and 2016" and therefore possibly delayed an effective response that targeted nonprescription drug synthetic opioid use. *See* Meryl Kornfield, *The Death Toll of the Opioid Epidemic Is Higher than Originally Thought, Researchers Say*, WASH. POST (Feb. 28, 2020), https://www.washingtonpost.com/health/2020/02/28/opioid-deaths [https://perma.cc/HB22-B3WR].

law to effectively address these harms, and continuously evaluating the outcomes of implemented solutions.

Part I of this article provides an overview of opioid use and regulation in the United States, along with an exploration of the justifications for widely used regulatory strategies. Part II will then introduce the methodology necessary to remedy current inadequacies of state and federal law to tackle the opioid epidemic from an evidence-based public health perspective. Part III shifts focus to discuss the impacts synthetic opioid use has on individuals, communities, and society more broadly. Finally, Part IV concludes with a proposal calling for the implementation of comprehensive legislative solutions rooted in principles of public health to address these harms at every level.

I. AN OVERVIEW OF HUMAN OPIOID USE AND OPIOID REGULATION IN THE UNITED STATES

A. Brief History of Human Opium Use

By some estimates, humans have known of and used opioids as far back as Neolithic times.[21] Opium is a natural substance secreted by poppy which, when ingested, binds to a receptor in the human brain to induce a feeling of wellbeing while reducing the perception of pain.[22] Once the brain is exposed to opioids, its chemical structure changes immediately, requiring larger doses to replicate the same feeling of relief from physical distress.[23] Recent research supports the theory that, while all humans likely have

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[21] For a review of human use of mind-altering substances from prehistoric times to the present, see Greg Wadley & Brian Hayden, *Pharmacological Influences on the Neolithic Transition*, 35 J. ETHNOBIOLOGY 566, 575 (2015) ("Psychoactive substance use does not represent merely a problematic behavior indulged in by a minority; rather it is an important and routine shaper of behavior for the vast majority of post-Neolithic humans."); *see also* Brij Kishore Mishra et al., *Opium Poppy: Genetic Upgradation Through Intervention of Plant Breeding Techniques*, *in* PLANT BREEDING FROM LABORATORIES TO FIELDS 209, 209 (Sven Bode Andersen ed., 2013) ("Opium Poppy (*Papaver somniferum* L.) has its importance as a plant based natural pain reliever from the time dating back to early civilization till today.").

[22] *See Opioid Facts*, U.S. DEP'T OF JUST. (Dec. 15, 2020), https://www.justice.gov/opioidawareness/opioid-facts [https://perma.cc/5J77-4HP7] ("Opioids bind to mu-opioid receptors on the nerve cells in the brain and body to reduce pain and suppress coughs when used legitimately, but can also cause intense euphoria or intense high that can lead to dependence and/or addiction, whether the drug ingested is heroin or a legally prescribed drug.").

[23] *Comorbidity: Substance Use Disorders and Other Mental Illnesses*, NIH NAT'L INST. ON DRUG ABUSE (Aug. 2018), https://www.drugabuse.gov/publications/drugfacts/comorbidity-substance-use-disorders-other-mental-illnesses [https://perma.cc/76NM-LT9A] ("Addiction changes the brain in fundamental ways, changing a person's normal needs and desires and replacing them with new priorities connected with seeking and using the drug. This results in compulsive behaviors that weaken the ability to control impulses, despite the negative consequences, and are similar to hallmarks of other mental illnesses.").

receptors that react to opioids, the extent and nature of the reaction varies among different people because of their genetics.[24]

Opioid pain killers derived from plants have been available in the United States since the early 1800s.[25] Like many pharmaceuticals originally derived from natural substances, chemists were able to duplicate the structure of the molecules that interacted with the brain, and pharmaceutical companies quickly developed products that could both be manufactured cheaper and calibrated more precisely in terms of dose and effect.[26] It is these man-made, or synthetic, opioids that are responsible for the rise in death rates.[27]

B. How Synthetic Opioids Changed Everything

The harm synthetic opioids cause revealed itself in three waves. The first was an increase in opioid overdose because the pills manufactured by the pharmaceutical companies were much more potent than those derived from poppies.[28] Synthetic opioids were also more available because intense marketing efforts by pharmaceutical companies selling them helped support an already growing attention to providing patients with pain control. Once developed, pharmaceutical companies aggressively marketed synthetic opioids both to physicians already experienced in prescribing opioids[29] and

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[24] *See* Ivone Gomes et al., *Disease-Specific Heteromerization of G-Protein-Coupled Receptors that Target Drugs of Abuse*, 117 PROGRESS IN MOLECULAR BIOLOGY & TRANSLATIONAL SCI. 207, 207–65 (2013).

[25] *See* SACCO & BAGALMAN, *supra* note 11, at 5 (noting that while "[o]pioids have been available in the United States since the 1800s, . . . the market for these drugs shifted significantly beginning in the 1990s").

[26] *See* Sarah DeWeerdt, *Tracing the US Opioid Crisis to Its Roots*, NATURE (Sept. 11, 2019), https://www.nature.com/articles/d41586-019-02686-2 [https://perma.cc/8J59-XCF5] (describing the cheaper opioids, such as fentanyl, developed by pharmaceutical companies as they touted their increased safety and efficacy); *see also* Jonelle Harvey, *Fentanyl, Inc.: How Rogue Chemists Are Creating the Deadliest Wave of the Opioid Epidemic*, CHEMISTRY WORLD (June 19, 2020), https://www.chemistryworld.com/review/fentanyl-inc-how-rogue-chemists-are-creating-the-deadliest-wave-of-the-opioid-epidemic/4011699.article [https://perma.cc/C9FA-45PN] (discussing the 2019 book, *Fentanyl, Inc.: How Rogue Chemists Are Creating the Deadliest Wave of the Opioid Epidemic*, by Ben Westhoff, which illuminates how rogue chemists have created cheaper, more addictive opioids derived from poppies); *Drug Fact Sheet: Synthetic Opioids*, U.S. DRUG ENF'T ADMIN. (Apr. 2020) [hereinafter *Drug Fact Sheet: Synthetic Opioids*], https://www.dea.gov/sites/default/files/2020-06/Synthetic%20Opioids-2020.pdf [https://perma.cc/WV7H-FDMS] (differentiating synthetic opioids from natural opioids as laboratory created drugs that act on the brain in the same way as natural opioids); *Opioid Facts*, *supra* note 22.

[27] For a timeline of the shift in the number and cause of opioid-associated deaths, see *Opioid Data Analysis and Resources*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 10, 2021), https://www.cdc.gov/drugoverdose/data/analysis.html [https://perma.cc/L6L3-WPCU].

[28] *See Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 17, 2021), https://www.cdc.gov/opioids/basics/epidemic.html#three-waves [https://perma.cc/8R6S-H79Q]; *see also Drug Fact Sheet: Synthetic Opioids*, *supra* note 26.

[29] Scott Higham et al., *The Fentanyl Failure*, WASH. POST (Mar. 13, 2019), https://www.washingtonpost.com/graphics/2019/national/fentanyl-epidemic-obama-administration/

to a broader range of general practitioners who had been concerned about the dangers of addiction and overdose.[30] Pharmaceutical companies promoting these new synthetic opioids portrayed them as safer alternatives to naturally derived opioids.[31] However, because synthetic opioids were far more concentrated than those derived from poppies, respiratory suppression could result after ingestion of only a handful of pills.[32] These effects were magnified by other substances causing respiratory suppression, such as alcohol or other prescription drugs.[33]

As a result, more patients were being prescribed opioids for pain control, and with the increased volume came increased opportunities for patients, doctors, and pharmacists to divert the pills to which they had access outside the healthcare system.[34] Consequently, the number of people who became dependent on opioids grew. The most visible consequence of more people taking a much more powerful drug was a rapid increase in deaths associated with opioid use, even though these individuals had not been treated for pain.[35] However, lawsuits brought against the pharmaceutical companies whose marketing was associated with the first wave of

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[https://perma.cc/9CKX-LPRW] ("The first wave of the opioid epidemic began in 1996 after drug manufacturer Purdue Pharma introduced what it claimed to be a wonder drug for pain—OxyContin, a powerful opioid that was aggressively marketed to physicians as less addictive than other prescription narcotics. . . . The DEA started to crack down on the illegal trade in 2005. Two years later, Purdue paid $600 million in fines and its executives pleaded guilty to federal criminal charges for claiming the product was less addictive than other painkillers.").

[30] Lars Noah, *Federal Regulatory Responses to the Prescription Opioid Crisis: Too Little, Too Late?*, 2019 UTAH L. REV. 757, 763–64 (2019) (arguing that it was physicians themselves who created the environment for later abuse citing the "growing normalization of the medical use of such powerful narcotics. . . [by] primary care physicians . . . even though they seem particularly ill-equipped to prescribe them in a careful fashion").

[31] *See, e.g.*, Higham, *supra* note 29 (noting that Purdue Pharma aggressively marketed its powerful opioid, OxyContin, and company executives later pleaded guilty to federal criminal charges for claiming OxyContin was less addictive than other painkillers).

[32] *See Drug Fact Sheet: Synthetic Opioids*, *supra* note 28.

[33] *See Mixing Opioids and Alcohol May Increase Likelihood of Dangerous Respiratory Complication, Especially in the Elderly, Study Finds*, AM. SOC'Y ANESTHESIOLOGISTS (Feb. 7, 2017), https://www.asahq.org/about-asa/newsroom/news-releases/2017/02/mixing-opioids-and-alcohol-may-increase-likelihood-of-dangerous-respiratory-complication [https://perma.cc/3YEM-BQCN] (describing respiratory decompensation as a frequent and serious complication of mixing opioids with alcohol and other drugs). *See generally* Elinore F. McCance-Katz et al., *Drug Interactions of Clinical Importance Among the Opioids, Methadone and Buprenorphine, and Other Frequently Prescribed Medications: A Review*, 19 AM. J. ON ADDICTIONS 4 (2010) (detailing the drug interactions between opioids and other commonly prescribed medication).

[34] *See* Higham, *supra* note 29.

[35] *See Understanding the Epidemic*, *supra* note 28; Michael A. Yokell et al., *Presentation of Prescription and Nonprescription Opioid Overdoses to US Emergency Departments*, 174 JAMA INTERNAL MED. 2034, 2035 tbl.1 (2014) (finding that less than 13 percent of patients admitted to US emergency rooms for prescription opioid overdoses had a pain diagnosis). For further discussion of the narrative of opioid overdose deaths as a result of prescriptions for pain medications, see Taleed El-Sabawi, *The Role of Pressure Groups and Problem Definition in Crafting Legislative Solutions to the Opioid Crisis*, 11 NE. L. REV. 372, 385–90 (2019).

deaths are primarily about the harm caused by legal products manufactured legally in facilities subject to federal regulation.[36]

During this first wave of the epidemic, rising overdose deaths were associated with prescription synthetic opioids, even if diverted from the patient for which they were originally prescribed.[37] Because those synthetic opioids were less powerful than the ones being manufactured illegally today, there was more time to interrupt an overdose by administering naloxone (Narcan), an instantly effective antidote.[38] Therefore, modifying laws restricting the sale and distribution of naloxone became an early harm reduction priority.[39]

However, while making naloxone available to counter the effects of an overdose continues to be important, it is nonetheless critical to prevent overdoses before they happen. This is because pharmaceutical companies have now developed more powerful forms of synthetic opioids, such as fentanyl,[40] and because these formulations can now be manufactured illegally outside of the pharmaceutical chain of supply, resulting in the second wave of the epidemic.

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[36] *See generally* JENNIFER A. STAMAN, CONG. RSCH. SERV., LSB10226, STATE AND LOCAL GOVERNMENTS PURSUE JUDICIAL SOLUTIONS TO THE OPIOID EPIDEMIC 1 (2018), https://crsreports.congress.gov/product/pdf/LSB/LSB10226 (last visited Feb. 4, 2022) ("Despite the array of federal and state law claims advanced in these lawsuits, what is at the heart of these cases is the same: questions about who is legally accountable for the devastating consequences of the opioid epidemic."). Concerns have been raised over the secrecy of the multidistrict litigation into which nearly 2000 of these cases have been consolidated. *See* Jennifer D. Oliva, *Opioid Multidistrict Litigation Secrecy*, 80 OHIO ST. L.J. 663, 664–65 (2019) ("[S]cant attention has been consigned to the opioid MDL's most salient and, arguably, most disturbing feature: its insidious secrecy. The clandestine nature of the MDL has prevented the public from understanding the plaintiffs' allegations and legal arguments, the basic facts concerning the scope of corporate marketing, distribution, and sales of prescription opioids, and the DEA's confounding failure to detect suspicious sales of the drugs and, thereby, mitigate diversion.").

[37] *See* El-Sabawi, *supra* note 35, at 385 (recounting attribution of the "cause of the opioid crisis to physician over-prescribing" with the result that "left-over prescriptions were diverted to the black market or misused by family members and friends" (footnote omitted)).

[38] *See* Scott Burris et al., *Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone to Prevent Opioid Overdose*, 1 DREXEL L. REV. 273, 277 (2009) (describing almost all overdose deaths as "preventable" because of the long window of time between ingestion and death from cardiac suppression).

[39] *Id.* (describing almost all overdose deaths as "preventable" because of the long window of time between ingestion and death from cardiac suppression, "leav[ing] plenty of time for effective medical intervention").

[40] *See* Higham et al., *supra* note 29 ("A synthetic opioid developed in 1960 by a Belgian physician, fentanyl is normally reserved for surgery and cancer patients . . . For traffickers, illicit fentanyl produced in labs was the most lucrative opportunity yet, a chance to bypass the unpredictability of the poppy fields that produced their heroin. The traffickers could order one of the cheapest and most powerful opioids on the planet directly from Chinese labs over the Internet. It was 20 times more profitable than heroin by weight. By lacing a little of the white powdery drug into their heroin, the dealers could make their product more potent and more compelling to users.").

While there are many pharmaceutical formulations of synthetic opioids, the one most responsible for the initial increase in deaths from opioids is fentanyl.[41] Not only do fentanyl and other forms of synthetic opioids come from a different place, but they are also much more powerful than their prescription counterparts.[42] As a result, death happens more quickly after ingestion.[43]

Initially, fentanyl manufactured for medical use was diverted for direct purchase, but over time it was made so easily and cheaply in China and Mexico that the product was produced to be smuggled into the United States and sold directly to consumers.[44] Because the fentanyl on the market was no longer produced to pharmaceutical standards, it became impossible for any consumer to know the strength or quality of the substance she was ingesting.[45] As such, synthetic opioids had an immediate destabilizing effect in that they turned a drug that was taken with little ill effect on a daily basis by patients (and recreational users) into a widely available, deadly poison. Moreover, because it has become so inexpensive to manufacture, fentanyl powder is often mixed, without any disclosure to users, into a variety of other illegal drugs including heroin,[46] methamphetamine,[47] and cocaine.[48] In a further escalation of lethality, the fentanyl smuggled into the United States has become increasingly potent in new formulations, one of which is known as "gray death"—an "illicit synthetic opioid mix that is reportedly 10,000 times more powerful than morphine."[49]

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[41] U.S. DRUG ENF'T ADMIN., DEA-DCT-DIR-008-21, 2020 NATIONAL DRUG THREAT ASSESSMENT 4 (Mar. 2021) [hereinafter DEA 2020 DRUG THREAT ASSESSMENT], https://www.dea.gov/sites/default/files/2021-02/DIR-008-21%202020%20National%20Drug%20Threat%20Assessment_WEB.pdf [https://perma.cc/5SHX-LUM8].

[42] *See Fact Sheet: Fentanyl and Synthetic Opioids*, DRUG POL'Y ALL. 1 (Sept. 2016), https://drugpolicy.org/sites/default/files/Synthetic-Opioids-Fact-Sheet.pdf [https://perma.cc/7ZBE-8EYK] ("Fentanyl, its analogues, and other synthetic opioids, though similar in effects to longer-acting opiates like morphine, heroin, or oxycodone, are riskier in use due to their increased potency.").

[43] *See id.* at 2 ("Fentanyl has a rapid onset with a shorter duration of effects, so there is some limited evidence that may suggest compulsive use and repeated administration, which increases the risk of fatal overdose. However, the risk of fatal overdose is highest when people unknowingly snort or inject heroin that has been adulterated with a synthetic opiate like fentanyl, and not because people who use opiates crave a stronger high from fentanyl.").

[44] U.S. DRUG ENF'T ADMIN., DEA-DCT-DIR-007-20, 2019 NATIONAL DRUG THREAT ASSESSMENT 5 (Dec. 2019) [hereinafter DEA DRUG THREAT ASSESSMENT], https://www.dea.gov/sites/default/files/2020-01/2019-NDTA-final-01-14-2020_Low_Web-DIR-007-20_2019.pdf [https://perma.cc/85C3-APZ9].

[45] *Id.* at 14–15.

[46] *Id.* at 12–13 (noting that "[i]n August 2018, Tucson Police Department (PD) officers arrested an individual in possession of . . . a black tar substance" that turned out to be not black tar heroin, but rather "fentanyl, most likely mixed with sugar").

[47] *Id.*

[48] *Id.*

[49] *See* SACCO & BAGALMAN, *supra* note 11, at 7 & n.34.

In addition to fentanyl, there are other drugs with similar chemical compositions, some of which cannot be identified by current testing procedures.[50] Carfentanil, one of the new analogs that can now be tested, is so potent that it is used as a tranquilizer for large zoo animals.[51] On August 30, 2016, twenty-four men and women nearly died after injecting heroin mixed with carfentanil over a twenty-four-hour period in Louisville, Kentucky.[52] In the period between July to December 2016, Ohio reported four hundred deaths involving carfentanil.[53] It is this illicitly produced fentanyl, as opposed to pharmaceutical fentanyl, that "remains the primary driver behind the ongoing opioid crisis, with fentanyl involved in more deaths than any other illicit drug."[54] According to the Drug Enforcement Administration (DEA), rather than diverted prescription opioids,

> Illicit fentanyl—produced in foreign clandestine laboratories and trafficked into the United States in powder and pill form—is primarily responsible for fueling the ongoing opioid crisis. Fentanyl-laced counterfeit pills continue to be trafficked across the country and remain significant contributors to the rates of overdose deaths observed across the country.[55]

The death toll from synthetic opioids is dramatic, global, and terrifying. The Centers for Disease Control and Prevention (CDC) reports the more than 36,000 deaths "involving synthetic opioids" in the United States in 2019 were "more deaths than from any other type of opioid."[56] Whether the availability of these synthetics actually increased drug use is still a matter of considerable debate, but there is no question that it made drug use visible just as AIDS made homosexuality visible.[57] But even though deaths caused by synthetic opioids occur all over the world, the US

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[50] *Synthetic Opioid Overdose Data*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 25, 2021), https://www.cdc.gov/drugoverdose/data/fentanyl.html [https://perma.cc/AVF4-3K8R].

[51] *Alert Issued in Ohio for Human Use of Animal Sedative Carfentanil, with Cases Also Seen in Florida*, NIH NAT'L INST. ON DRUG ABUSE (Aug. 2016), https://archives.drugabuse.gov/emerging-trends/alert-issued-in-ohio-human-use-animal-sedative-carfentanil-cases-also-seen-in-florida [https://perma.cc/54F9-8WND].

[52] Beth Warren, *DEA Chemists Solved Mystery of Drug Causing Mass Overdoses*, AP NEWS (Mar. 2, 2019), https://www.apnews.com/a41e90f8c9c64ecc9c45eaac440a8c18 [https://perma.cc/8RJ5-A9HY].

[53] Julie O'Donnell et al., *Notes from the Field: Overdose Deaths with Carfentanil and Other Fentanyl Analogs Detected—10 States, July 2016–July 2017*, 67 MORBIDITY & MORTALITY WKLY. REP. 767, 767 (2018); Julie K. O'Donnell et al., *Deaths Involving Fentanyl, Fentanyl Analogs, and U-47700—10 States, July–December 2016*, 66 MORBIDITY & MORTALITY WKLY. REP. 1197, 1199 (2017).

[54] DEA 2019 DRUG THREAT ASSESSMENT, *supra* note 44, at 9.

[55] *See* DEA 2020 DRUG THREAT ASSESSMENT, *supra* note 41, at 4 (footnote omitted).

[56] *Synthetic Opioid Overdose Data*, *supra* note 50; *see also Overdose Death Rates*, NIH NAT'L INST. ON DRUG ABUSE (Jan. 29, 2019), https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates [https://perma.cc/F7GN-KCNB].

[57] *See id.*

legislative response is distinctive because it has been built on the foundation of highly punitive, if not vindictive, laws created during the war on drugs and the failure to develop a comprehensive system for providing healthcare.[58]

Because the link between opioid-associated deaths and the pervasive availability of synthetic opioids illegally manufactured outside of the pharmaceutical supply chain is so well established, any serious legislative effort that prioritizes reducing deaths must make illegally manufactured synthetic opioids the focus of attention.

C. How Opioids Are Regulated in the United States

The United States' response to drugs used outside of the US Food and Drug Administration (FDA) regulated sphere of substances approved to promote health has, like much of the world, centered on punishment.[59] These laws, intended to reduce the harm caused by drug use, fall into a category often described as "Social Regulations" in that they aim to "protect public interests such as health, safety, the environment, and social cohesion."[60] Opioids have been regulated differently than other illegal drugs because they are recognized to have a legitimate medical use.[61] As discussed in Section I.B, by focusing on prescribed opioids, these laws ignore the driving force behind the increase in opioid-associated deaths: the use of illegally manufactured and obtained synthetic opioids for nonmedical purposes.[62]

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[58] Josh Bowers & Daniel Abrahamson, *Kicking the Habit: The Opioid Crisis, America's Addiction to Punitive Prohibition, and the Promise of Free Heroin*, 80 OHIO ST. L.J. 787, 788–89 (2019). *See generally* BETTINA MUENSTER & JENNIFER TRONE, WHY IS AMERICA SO PUNITIVE? A REPORT ON THE DELIBERATIONS OF THE INTERDISCIPLINARY ROUNDTABLE ON PUNITIVENESS IN AMERICA (2016), https://www.jjay.cuny.edu/sites/default/files/news/Punitiveness_in_America_Report_March2016.pdf [https://perma.cc/TU23-UTTB] (discussing the reasons and mechanisms behind America's punitive system).

[59] Nora D. Volkow et al., *Drug Use Disorders: Impact of a Public Health Rather than a Criminal Justice Approach*, 16 WORLD PSYCHIATRY 213, 213 (2017) ("The Outcome Document of the 2016 United Nations General Assembly Special Session on drugs (UNGASS 2016), unanimously approved by the 193 Member States, has recognized 'drug addiction as a complex multifactorial health disorder characterized by chronic and relapsing nature' that is preventable and treatable and not the result of moral failure or a criminal behavior.").

[60] ORG. FOR ECON. CO-OPERATION & DEV., THE OECD REPORT ON REGULATORY REFORM 6 (1997) [hereinafter OECD REPORT ON REGULATORY REFORM], https://www.oecd.org/gov/regulatory-policy/2391768.pdf [https://perma.cc/EK6F-UWHR].

[61] *See generally* D.E. Joranson, *Federal and State Regulation of Opioids*, 5 J. PAIN SYMPTOM MGMT. (SUPPLEMENT–ISSUE 1) S12 (1990) (discussing federal and state policies on opioids as balancing the control of drug use with continued availability for legitimate medical needs).

[62] Higham et al., *supra* note 29.

The rapid increase in deaths associated with opioid use has triggered a significant legislative response by the federal government and all fifty states.[63] These legislative initiatives cover the gamut of available governmental powers, including the allocation of funds to support existing programs and create new ones. At least two major pieces of federal legislation, the 21st Century Cures Act[64] and the Comprehensive Addiction and Recovery Act of 2016,[65] and hundreds of state and local laws currently exist or are being proposed to address the bundle of harms caused by drug use.[66] Both the federal and state legislative responses to the harm caused by drug use have become so numerous that, like the multiplying buckets of water nearly drowning a young Mickey Mouse portraying the Sorcerer's Apprentice in the Disney classic, "buckets of law" are flooding society, causing considerable incidental harm and failing to achieve their purported goal.[67] What distinguishes this response from others mounted against past threats is that it is hampered in its effectiveness due to a lack of consensus about the nature of the problem to be solved.

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[63] For a comprehensive overview of both the federal and state legislative responses to the emerging opioid crisis, see Noah, *supra* note 30, at 764–74; and Lars Noah, *State Regulatory Responses to the Prescription Opioid Crisis: Too Much to Bear?*, 124 DICK. L. REV. 633, 636–54 (2020) [hereinafter, Noah, *State Regulatory Responses*]. *See also* Lev Facher, *What's In, What's Out, and What's Still on the Table in the Opioids Packaged Passed by the Senate*, STAT NEWS (Sept. 17, 2018), https://www.statnews.com/2018/09/17/senate-opioid-bill-content [https://perma.cc/2PP6-F2JR] (discussing new Senate opioid bill).

[64] 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016) (codified in scattered sections of 42 U.S.C. and other titles); *see also* Press Release, Energy & Com. Comm., E&C Leaders Highlight Release of Remaining State Grants to Combat the Opioid Crisis as Part of 21st Century Cures (Apr. 18, 2018), https://republicans-energycommerce.house.gov/news/press-release/ec-leaders-highlight-release-of-remaining-state-grants-to-combat-the-opioid-crisis-as-part-of-21st-century-cures/ [https://perma.cc/3NFH-AE79].

[65] Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, 130 Stat. 695 (codified in scattered sections of 42 U.S.C. and other titles); *see also* Press Release, Energy & Com. Comm., #RecordOfSuccess: Sweeping Bipartisan Opioid Package Now Law (July 22, 2016), https://republicans-energycommerce.house.gov/news/press-release/recordof success-sweeping-bipartisan-opioid-package-now-law/ [https://perma.cc/9FNT-4A88].

[66] *See Injury Prevention Legislation Database: Opioid Abuse Prevention*, NAT'L CONF. OF STATE LEGISLATURES (July 5, 2021), https://www.ncsl.org/research/health/injury-prevention-legislation-database.aspx [https://perma.cc/SZL9-LQ88] (searchable database of injury prevention legislation proposed or enacted in the 50 states and the District of Columbia).

[67] In the classic Disney movie *Fantasia*, "The Sorcerer's Apprentice," portrayed by a young Mickey Mouse, is assigned the task of carrying two buckets of water. Seeking a shortcut, the mischievous Mickey tries his own hand at magic by enchanting a nearby broom to do the work for him. The spell works, the broomstick sprouts hands, takes the empty buckets to the well, and brings them back. Pleased with himself, Mickey falls asleep. On awakening, however, he finds that the broomsticks have multiplied until there are dozens of them bringing bucket after bucket of water into the workshop creating a roaring ocean of water until the sorcerer finally returns to end the spell and restore order. FANTASIA (Walt Disney Productions 1940); *see also* GamePlay, *Fantasia 1940 The Sorcerer's Apprentice Walt Disney Cartoon Movie*, YOUTUBE (Mar. 19, 2015), https://www.youtube.com/watch?v=Rrm8usaH0sM (last visited Feb. 5, 2022).

D. Justifications for Laws Restricting Drug Use

Laws restricting drug use in the United States have traditionally been justified on moral grounds, not on the preservation of life.[68] Until very recently, opioids were not a significant cause of death, and the resulting fatalities were instead seen as a consequence of bad choices or poor character.[69] To the extent that there are now serious legislative efforts to change the circumstances that lead to drug use and to treat, rather than punish, those who become addicted, it is because both the kinds of drug being abused (synthetic opioids rather than primarily heroin and cocaine[70]) and the types of people affected have changed.[71] Those dying today are primarily white people living in rural areas.[72]

Today, laws regulating opioid use are predicated on reducing the supply of prescription opioids. However, it is not clear that overprescribing synthetic opioids ever contributed to the rise in overdose deaths.[73] Whatever may have been the state of knowledge in the past, the sources of information produced today by the federal government for policy makers are uniform in their conclusion that

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[68] For a broader discussion on the justification for laws to prevent people from hurting themselves, without directly hurting others, see John Kaplan, *The Role of the Law in Drug Control: Self-Harming Conduct and Society*, 1971 DUKE L.J. 1065, 1071 (1972) ("The fact is that most of the situations where the criminal law is used to prevent an individual from harming himself are situations where his conduct is also felt to be immoral. There is thus an ever present temptation to enforce a dominant morality without looking to see whether the conduct to be prohibited is sufficiently harmful in terms of secondary harms . . . .").

[69] GLOB. COMM'N ON DRUG POL'Y, THE WORLD DRUG PERCEPTION PROBLEM: COUNTERING PREJUDICES ABOUT PEOPLE WHO USE DRUGS 8 (2017), https://www.globalcommissionondrugs.org/wp-content/uploads/2018/01/GCDP-Report-2017_Perceptions-ENGLISH.pdf [https://perma.cc/T55C-YPQU].

[70] *See* Holly Hedegaard et al., Drug Overdose Deaths in the United States, 1999–2017, CTRS. FOR DISEASE CONTROL & PREVENTION 5 (Nov. 2018), https://www.cdc.gov/nchs/data/databriefs/db329-h.pdf [https://perma.cc/2WH9-F96M]. ("The pattern of drugs involved in drug overdose deaths has changed in recent years. The rate of drug overdose deaths involving synthetic opioids other than methadone . . . increased 45%.); *id.* at 1, 4 & fig. 4 ("In 2017, there were 70,237 drug overdose deaths in the United States . . . . The age-adjusted rate of drug overdose deaths increased from 6.1 per 100,000 standard population in 1999 to 21.7 in 2017" and the form of opioid used was primarily a synthetic product.).

[71] For a discussion of the changing demographics of those dying from drug overdoses, see Kumiko M. Lippold et al., Racial/Ethnic and Age Group Differences in Opioid and Synthetic Opioid-involved Overdose Deaths Among Adults Aged ≥ 18 Years in Metropolitan Areas, 68 Morbidity & Mortality Wkly. Rep. 967–73 (2019).

[72] *The Drug Overdose Epidemic Affects All Communities*, NAT'L INST. ON MINORITY HEALTH & HEALTH DISPARITIES (Oct. 25, 2019), https://www.nimhd.nih.gov/news-events/features/community-health/overdose-epidemic.html [https://perma.cc/7FS7-R96J] ("The number of deaths from drug overdoses has skyrocketed, particularly among White people and people who live in rural areas.").

[73] *See* Anne Case & Angus Deaton, *Mortality and Morbidity in the 21st Century*, BROOKINGS PAPERS ON ECON. ACTIVITY 4 (Mar. 17, 2017), https://www.brookings.edu/wp-content/uploads/2017/03/6_casedeaton.pdf [https://perma.cc/E3US-YA4U] ("Although we do not see the supply of opioids as the fundamental factor, the prescription of opioids for chronic pain added fuel to the flames, making the epidemic much worse than it otherwise would have been.").

prescription opioids are no longer a primary factor in deaths from opioids. Instead, "illicitly produced fentanyl as opposed to pharmaceutical fentanyl" remains the primary driver behind the ongoing opioid crisis, with fentanyl involved in more deaths than any other illicit drug.[74] This is in spite of the considerable success of current programs designed to reduce the supply of pharmaceutical fentanyl for illicit use.[75] But even if prescription of synthetic opioids for pain control was a factor in rising overdose deaths, attributing the harms associated with opioid use to the overprescription of pain medication is a "simple solution to a complex challenge."[76] Thus, laws that are designed to reduce the supply of opioids miss the mark significantly by ignoring the impact of illicitly produced opioids.[77]

E. Current Laws Are Not Effective in Reducing the Harms Associated with Opioid Use Due to Disagreement About the Harm to Be Prevented

We know the current laws that target prescription opioid misuse are not working because opioid-associated deaths, including those directly attributable to restrictions on prescription opioids,[78] continue to rise even as the number of prescriptions for opioids falls.[79] Using CDC guidelines as a standard, states, the DEA,

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[74] *See* LISA N. SACCO ET AL., CONG. RSCH. SERV., R45790, THE OPIOID EPIDEMIC: SUPPLY CONTROL AND CRIMINAL JUSTICE POLICY—FREQUENTLY ASKED QUESTIONS 2–3, 13 (2019) (quoting U.S. DRUG ENF'T ADMIN., 2018 NATIONAL DRUG THREAT ASSESSMENT 21 (Oct. 2018), https://www.dea.gov/sites/default/files/2018-11/DIR-032-18%202018%20NDTA%20final%20low%20resolution.pdf [https://perma.cc/CAP6-MDF6]).

[75] *See* U.S. DEP'T OF HEALTH & HUM. SERVS., REPORT TO CONGRESS ON OPIOID PRESCRIBING LIMITATIONS 30, 37, 54, https://www.fda.gov/media/147152/download [https://perma.cc/4DGR-342W].

[76] Leo Beletsky, *Deploying Prescription Drug Monitoring to Address the Overdose Crisis: Ideology Meets Reality*, 15 IND. HEALTH L. REV. 139, 162 (2018); *see also* El-Sabawi, *supra* note 35, at 397 ("Although cloaked in medical and health terminology, many of the causal stories used by pressure groups emphasized the supply, or availability, of prescription opioids as the cause of the crisis and substituted actors in the medical industry for the street drug dealers of past narratives.").

[77] *See* Press Release, U.S. Drug Enf't Admin., Leader of Conspiracy that Manufactured Illegal Drugs on an Industrial Scale Sentenced to 20 Years in Federal Prison (Aug. 7, 2020), https://www.dea.gov/press-releases/2020/08/07/leader-conspiracy-manufactured-illegal-drugs-industrial-scale-sentenced [https://perma.cc/6CUK-H2S2] ("'The illegal manufacture and distribution of opioids can result in overdoses and deaths, fueling the national opioid crisis,' said Special Agent in Charge Justin C. Fielder, Food and Drug Administration (FDA) Office of Criminal Investigations Miami Field Office. 'The FDA remains committed to working with our law enforcement partners to disrupt and dismantle illegal prescription drug manufacturing and distribution networks, including those that import illicit raw materials from overseas to make counterfeit drugs, and misuse the internet to distribute those drugs with reckless disregard of the risk to public health and safety.'").

[78] Kate M. Nicholson et al., *Overzealous Use of the CDC's Opioid Prescribing Guideline Is Harming Pain Patients*, STAT NEWS (Dec. 6, 2018), https://www.statnews.com/2018/12/06/overzealous-use-cdc-opioid-prescribing-guideline/ [https://perma.cc/463R-7HGW].

[79] AM. MED. ASS'N, 2021 OVERDOSE EPIDEMIC REPORT: PHYSICIANS' ACTIONS TO HELP END THE NATION'S DRUG-RELATED OVERDOSE AND DEATH EPIDEMIC—AND WHAT

Medicare,[80] Medicaid,[81] and the Veteran's Administration (VA) system have adopted systems to monitor the prescribing behavior of individual physicians through electronic databases that track prescribing patterns.[82] Called Prescription Drug Monitoring Programs (PDMP), these are electronic databases operated by individual states to track prescriptions for controlled substances.[83] Almost every state has adopted some version of a PDMP which tracks the controlled substance prescriptions written for individual patients.[84] The data comes from the information collected by the pharmacists who fill the prescriptions.[85] Depending on how a state chooses to use it, this information can be used to monitor both prescribers and patients.[86] In some states, the information from a PDMP can be made available directly to providers and to pharmacists so that both can be aware of a patient receiving prescriptions for opioids from more than one provider.[87]

In an article highly critical of PDMP's violation of individual rights, Professor Leo Beletsky makes the larger point that the program's presence in all fifty states reflects "the zeal with which we have traditionally pursued supply reduction measures to address drug-related harms."[88] He argues that "the success of PDMPs has for too long been measured primarily by their impact on suppressing medication supply, with too little regard for the more meaningful metrics anchored to reducing risky drug use and overdose."[89] His work reflects a growing consensus that, while PDMPs may have had an effect on reducing the number of opioids prescribed, there is still no data that they have had any effect on reducing deaths or other harms.

STILL NEEDS TO BE DONE 2 (2021), https://end-overdose-epidemic.org/wp-content/uploads/2021/09/AMA-2021-Overdose-Epidemic-Report_92021.pdf [https://perma.cc/6222-S2GN].

[80] CONG. RSCH. SERV., R45449, THE SUPPORT FOR PATIENTS AND COMMUNITIES ACT (P.L.115-271): MEDICARE PROVISIONS 3 (2019), https://sgp.fas.org/crs/misc/R45449.pdf (last visited Feb. 4, 2022) (among the many provisions in the SUPPORT Act related to opioid use are several specific to Medicare patients, including a form of opioid prescription monitoring).

[81] U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., CMS ROADMAP: STRATEGY TO FIGHT THE OPIOID CRISIS (2020), https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf [https://perma.cc/YPD6-RN7S].

[82] For a recent overview of PDMPs, see generally Ashley Monzel, Note, *The Hydra Paradox of the Opioid Epidemic: Why Supply Side Responses Will Fuel Rather than Curb the Opioid Epidemic*, 28 ELDER L.J. 145 (2020).

[83] *What States Need to Know About PDMPs*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 19, 2021), https://www.cdc.gov/drugoverdose/pdmp/states.html [https://perma.cc/L7PD-Q754].

[84] *Id*. at 59.

[85] *Id.*

[86] *Id.*

[87] *See id*.

[88] Beletsky, *supra* note 76, at 141.

[89] *Id*. at 141–42.

Such laws have fallen under heavy criticism for both their failure to reduce deaths and their trigger of a cascade of unintended consequences.[90] This failure comes from the premise that "[r]educing the supply of opioids should reduce the number of people who newly develop opioid use disorders," which therefore "[i]n the long run . . . will likely reduce overdose deaths."[91] However, "staunch[ing] the 'flow'" of new drug users "does not address the risk faced by people who already have the disorder—the 'stock' of people now at greatest risk for overdoses."[92]

Human Rights Watch issued a report in 2018 that found "that doctors were abruptly reducing or eliminating chronic pain patients' opioid medication without their consent, even when they believed patients benefited from the medication and weren't misusing it."[93] The laws also impose administrative hurdles on healthcare providers by limiting the number of patients to whom a physician can prescribe opioids, the length of time they can be prescribed, and the number of pills that can be prescribed at any one time.[94] Many of the laws passed over the last fifteen years are targeted at patients seeking relief from acute pain and represent levels of intrusion into the doctor-patient relationship more common to issues of pregnancy and abortion.[95] The effect has been that "[m]any doctors now refuse to prescribe any opioids because of the fear of sanctions."[96]

Writing about the consequences of current laws, such as invasions of privacy caused by the creation of a database that tracks

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[90] *See, e.g.*, Byungkyu Lee et al., *Systematic Evaluation of State Policy and Interventions Targeting the US Opioid Epidemic, 2007-2018*, JAMA NETWORK OPEN (Feb. 12, 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2776301 [https://perma.cc/6EFZ-6FAK] (describing state policies as effective at mitigating prescription drug abuse, but as also pushing individuals to use illicit opioids); *see also* Kelly K. Dineen & James M. DuBois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J.L. & MED. 7, 12–13 (2016).

[91] Glickman & Weiner, *supra* note 14.

[92] *Id*.

[93] Kate M. Nicholson & Laura Mills, *The Problems with One-Size-Fits-All Laws on Opioid Prescriptions*, WASH. POST (Apr. 4, 2019), https://www.washingtonpost.com/outlook/2019/04/04/problems-with-one-size-fits-all-laws-opioid-prescriptions/ [https://perma.cc/FH4C-7V4V]; *see US: Fears of Prescribing Hurt Chronic Pain Patients*, HUM. RTS. WATCH (Dec. 18, 2018, 12:01 AM), https://www.hrw.org/news/2018/12/18/us-fears-prescribing-hurt-chronic-pain-patients [https://perma.cc/BG3J-8MFH]; LAURA MILLS, HUM. RTS. WATCH, NOT ALLOWED TO BE COMPASSIONATE 32 (Dec. 2018), https://www.hrw.org/sites/default/files/report_pdf/hhr1218_web.pdf [https://perma.cc/HJE3-DTGV].

[94] Nicholson & Mills, *supra* note 93; *US: Fears of Prescribing Hurt Chronic Pain Patients*, HUM. RTS. WATCH, *supra* note 93; Mills, *supra* note 93, at 22–31.

[95] *See* Michael Shermer, *Abortion Is a Problem to Be Solved, Not a Moral Issue*, SCI. AM. (Sept. 1, 2018), https://www.scientificamerican.com/article/abortion-is-a-problem-to-be-solved-not-a-moral-issue/ (last visited Jan. 5, 2022) (arguing that rather than encouraging unwanted pregnancy, access to birth control reduces unwanted pregnancies and abortions).

[96] *What New Opioid Laws Mean for Pain Relief*, HARV. HEALTH LETTER, Oct. 2018, at 6, 7 (overview of the legal restrictions on physicians who prescribe opioids).

opioid prescriptions nationwide, commentators note that such "supply-side" solutions are the result of an "ongoing and flawed framing of the overdose crisis as a prescription-drug problem."[97] Current laws intended to reduce the harms caused by drug use focus primarily on reducing both the supply of and demand for drugs.[98] They do so based on a premise that the "demand" for drugs is caused by the prescribing practices of physicians.[99]

The primary activity of demand side interventions is to find and reduce the causes of drug addiction. As related to addiction to prescription synthetic opioids, this effort has always been hampered by the myth that the primary source of addiction is unnecessary prescriptions.[100] This narrative is fostered in popular media by books like *Dreamland,* which chronicles the story of people who became addicted to opioids after being prescribed large doses for relatively minor conditions.[101] It is not, however, supported by evidence.[102] Instead, "[a]ddiction occurs in only a small percentage of persons who are exposed to opioids—even among those with preexisting vulnerabilities."[103]

When asked for her opinion on recently passed legislation intended to address the opioid epidemic, "Dr. Leana Wen, the former health commissioner of Baltimore," explained that she was not hopeful of its success because "the legislation 'is simply tinkering around the edges,' and that a far more comprehensive, ambitious

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[97] Jennifer D. Oliva, *Prescription Drug Policing, The Right to Health-Information Privacy Pre-and Post-Carpenter*, 69 DUKE L.J. 775, 779 (2020).

[98] *See* FLA. DEP'T OF HEALTH, STATEWIDE DRUG POL'Y ADVISORY COUNCIL 2017 ANN. REP., at 5–6 (Dec. 1, 2017) ("The Council proposes the following recommendations for improving the health and safety of all Floridians by promoting strategic approaches and collaboration to reduce the demand for drugs, reduce the supply of drugs, broaden prevention efforts, expand treatment options, and improve data collection and surveillance.").

[99] *See* Cassandra Rivais & Bruce D. White, *The Opioid Epidemic Is Not New: Time to Change the Practice of Medicine*, 11 ALB. GOV'T L. REV. 58, 58 (2018) ("To date, this matter has been addressed primarily by policy makers as a legal issue, with the creation of more legislation and regulation. However, it is at its heart and core a medical issue, since prescribing opioids is an almost essential component of the practice of medicine, and it must be addressed as one.").

[100] For an example of the persistence of this belief, see Andrew Kolodny, *How FDA Failures Contributed to the Opioid Crisis*, 22 AMA J. ETHICS 743, 747 (Aug. 2020), wherein Kolodny argues that "a critical step toward abating the opioid crisis" is to correct "past mistakes" and implement "preventative measures . . . to ensure that public health is consistently prioritized ahead of industry interests."

[101] *See* SAM QUINONES, DREAMLAND: THE TRUE TALE OF AMERICA'S OPIATE EPIDEMIC 6–9 (2015).

[102] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 NEW ENG. J MED. 1253, 1256–57 (Mar. 31, 2016); Jacob Sullum, *Courts Debunk Cash-hungry Governments' Harmful Opioid Myths*, N.Y. POST (Nov. 16, 2021), https://nypost.com/2021/11/16/courts-debunk-governments-harmful-opioid-myths/ [https://perma.cc/88HX-V7UF].

[103] *See* Volkow & McLellan, *supra* note 102, at 1256.

response is needed to really deal with the crisis."[104] Contrasting the federal response to past legislative initiatives to combat public health problems, Dr. Keith Humphreys of Stanford University pointed out that opioid legislative initiatives were less likely to be effective due to a lack of shared agreement about the nature of the problem and the appropriate response to it.[105] Without agreement about whether the problem was that too many people were using opioids or that too many people were being harmed by opioid use, "Congress did the next best thing—which is to find agreement on as many second-tier issues as they could."[106]

However, these interventions are mostly disconnected from the underlying factors promoting and sustaining drug use.[107] Contemporary authors have expanded on this idea by considering the relationship between law and the society in which it operates.[108] When is a public health law effective?[109] Issues of evaluating the effectiveness of legal interventions are, in the United States at least, not generally of concern to legal scholars, but instead are seen more as within the purview of political scientists and economists.[110] If any

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[104] German Lopez, *Trump Just Signed a Bipartisan Bill to Confront the Opioid Epidemic*, VOX (Oct. 24, 2018, 3:13 PM), https://www.vox.com/policy-and-politics/2018/9/28/17913938/trump-opioid-epidemic-congress-supportact-bill-law [https://perma.cc/FN26-U7ZP].

[105] *Id*. (noting that Dr. Humphreys explained that "[t]his reflects a fundamental disagreement between the parties over whether the government should appropriate the large sums a massive response would require").

[106] *Id*. (quoting Dr. Humphreys).

[107] *See* El-Sabawi, *supra* note 35, at 374–75.

[108] STEVEN VAGO & STEVEN E. BARKAN, LAW AND SOCIETY 231 (Routledge, 11th ed. 2018) ("Law is both a dependent and an independent variable in social change. . . . Some maintain that law is a reactor to social change; others argue that it increasingly is an initiator of change. . . . [L]aw alone cannot deal effectively with social problems such as drug addiction . . . .").

[109] *See, e.g.*, Anthony D. Moulton et al., *The Scientific Basis for Law as a Public Health Tool*, 99 AM. J. PUB. HEALTH 17, 17–18 (2009) (addressing the benefits of public health laws on health impacts and identifying the previous research gaps in data-informed policy making); Burris et al., *supra* note 18, at 135–36 (describing the process for turning an evidence-based public health idea into an actionable and codified policy or law); Megan C. Lindley et al., *Association of State Laws with Influenza Vaccination of Hospital Personnel*, 56 AM. J. PREVENTATIVE MED. 177, 177 (2019) (discussing vaccination laws); Maureen Lichtveld et al., *Preparedness on the Frontline: What's Law Got to Do With It?*, 30 J.L. MED. & ETHICS 184 (2002) (identifying core competencies in public health lawmaking and providing a framework for practice); David P. Fidler, *Legal Issues Surrounding Public Health Emergencies*, 116 PUB. HEALTH REP. 79, 82–85 (2001) (providing approaches to development and implementation of legal strategies in public health law); Wendy E. Parmet, *Quarantine Redux: Bioterrorism, AIDS and the Curtailment of Individual Liberty in the Name of Public Health*, 13 HEALTH MATRIX 85, 87–88 (2003); *What Science Tells Us About the Effects of Gun Policies*, RAND CORP. (Apr. 22, 2020), https://www.rand.org/research/gun-policy/key-findings/what-science-tells-us-about-the-effects-of-gun-policies.html [https://perma.cc/6CBN-RC22] (describing effective gun policies as being rooted in data and fact, as well as being drafted by policymakers that consider any potential trade-offs if a policy is implemented).

[110] *See* CHRISTINE PARKER, ORG. FOR ECON. CO-OPERATION & DEV., REDUCING THE RISK OF POLICY FAILURE: CHALLENGES FOR REGULATORY COMPLIANCE 11 (2000) ("Regulatory compliance in this report refers to o*bedience by a target population with regulations.* Why do people obey any rule? Several conditions are needed. The first condition is that the target group

intervention aimed at reducing the harm from synthetic opioids is to be successful, however, it must be analyzed for its effectiveness in achieving this overarching goal.

II. USING PUBLIC HEALTH TO SOLVE SOCIETAL PROBLEMS

Public health is a field of study that develops the information and implements the strategies needed to prevent conditions that diminish the health of a population as a whole.[111] It is most clearly seen in contrast to medicine, which is focused on treating conditions that diminish the health of individual patients.[112] The first principle of the American Public Health Association's (APHA) code of ethics is that "[p]ublic health should address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes." [113] Within the field of public health are people who take actions like monitoring toxin levels in the water or even organizing distribution of vaccines during a pandemic—they are called public health practitioners.[114] These practitioners depend on the work of public health scientists who conduct research and develop strategies. Public health research involves experts in many different disciplines, such as nutrition, virology, and environmental toxins.[115] But the primary tool of public health researchers' preventive actions is the science of epidemiology.[116]

Every public health textbook includes the story of Dr. John Snow who, in 1854, well before there was agreement about how germs caused disease, was able to stop a cholera outbreak in a London neighborhood by creating a map that traced cases back to a

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has to be *aware of the rule* and *understand* it. For example, lack of clarity in a rule may bring about unintentional non-compliance. Second, the target group has to be *willing to comply*. Economic incentives can motivate compliance. A strong enforcement programme can discourage noncompliant behaviour. The third condition is that the target group is *able to comply*.").

[111] Thomas R. Frieden, *A Framework for Public Health Action: The Health Impact Pyramid*, 100 AM. J. PUB. HEALTH 590, 590 (2010) ("[P]ublic health involves far more than health care.").

[112] *See id*.

[113] *Principles of the Ethical Practice of Public Health*, PUB. HEALTH LEADERSHIP SOC'Y 4 (2002), https://www.apha.org/-/media/files/pdf/membergroups/ethics/ethics_brochure.ashx [https://perma.cc/YNZ7-BMVN].

[114] *See generally What Do Public Health Professionals Do, Exactly?*, GOODWIN UNIV. (June 10, 2019), https://www.goodwin.edu/enews/what-do-public-health-workers-do/ [https://perma.cc/6V42-T6SY].

[115] Richard Riegelman, *Evidence-Based Problem Solving: Liberal Education and Preparation for the Health Professions*, 98 LIBERAL EDUC. 54, 54 (2012) (It is well described by Dr. Richard Riegelman, founding dean of the George Washington University School of Public Health and Health Services, who advocated "an integrative approach to the application of scientific principles across the natural, behavioral, and social sciences.").

[116] Haroutune K. Armenian, *Epidemiology: A Problem-Solving Journey*, 169 AM. J. EPIDEMIOLOGY 127, 127 (2009) (describing epidemiology as "not just a scientific discipline but a professional practice area").

well where the community got their water.[117] When, at his insistence, the handle of the pump was removed to make the well inaccessible, no new cases emerged and the outbreak ended.[118] This act is cited as the paradigm of public health problem solving since it depended on developing a plan of action based on data analysis .[119]

For researchers today, a "public health approach" is one that prioritizes information gathering—also called surveillance—for the purpose of identifying risk factors that make the problem more likely and protective factors that make it less likely.[120] This is in contrast to a "biomedical approach" which might begin by designing a study.[121] A final distinguishing feature of public health problem solving is that it involves those affected in the process of developing a solution. As one commentator explains, developing a public health solution often means working "with a range of stakeholders, across a range of problems."[122]

A. Sources of Legal Authority

Any federal intervention in matters of drug supply or policy must be justified by a specific enumerated clause of the US Constitution.[123] Over time, the result has been the creation of an overlapping system with the individual states and the federal government, each having some distinct and some intersecting authority when it comes to regulating the use of opioids for healthcare.[124]

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[117] John Snow is usually described as the father of epidemiology, see generally SW Newsome, *The History of Infection Control: Cholera—John Snow and the Beginnings of Epidemiology*, 6 BRITISH J. INFECTION CONTROL 12 (2005).

[118] *See* Mitali Banerjee Ruths, *The Lesson of John Snow and the Broad Street Pump*, 11 AM. MED. ASS'N J. ETHICS 470, 470 (2009) ("Although Dr. Snow could not identify the culprit under his microscope, the bean-shaped bacteria *Vibrio cholera* that thrives in brackish water, he had his map as evidence."). *See generally* STEVEN JOHNSON, THE GHOST MAP: THE STORY OF LONDON'S MOST TERRIFYING EPIDEMIC—AND HOW IT CHANGED SCIENCE, CITIES, AND THE MODERN WORLD (2006) (further linking the cholera epidemic to current public health practices).

[119] *See* JOHNSON, *supra* note 118, at 162–63.

[120] Roberto Hugh Potter & Richard Tewksbury, *Sex and Prisoners: Criminal Justice Contributions to a Public Health Issue*, 11 J. CORR. HEALTH CARE 171, 175 (2005) ("The first step in the public health approach is surveillance, the systematic, continuing observation of a particular phenomenon.").

[121] *Id.* at 177 ("Surveillance activities ideally enable us to identify risk factors or markers that differentiate those at high risk of developing a disease or becoming a victim or perpetrator of violence.").

[122] Jim McManus, *A Framework for Public Health Problem Solving in the New World*, COMMONPLACE BOOK (June 11, 2013), https://jimmcmanus.wordpress.com/2013/06/11/a-framework-for-public-health-problem-solving-in-the-new-world/ [https://perma.cc/DET6-CSBD].

[123] For an overview of the relevance of enumerated powers to public health law, see generally SCOTT BURRIS ET AL., THE NEW PUBLIC HEALTH LAW: A TRANSDISCIPLINARY APPROACH TO PRACTICE AND ADVOCACY 122–24 (2018).

[124] For an explanation of the concurrent and exclusive roles of state and federal government, see generally *The Role of State and Federal Governments*, NAT'L GEOGRAPHIC

1. State Power to Legislate for Health

Individual states in the United States retain the power originally granted to the sovereign in England to act in the welfare of the people.[125] The primary source of state power to regulate on behalf of the public's health is the police power reserved to the states.[126] The Tenth Amendment to the US Constitution affirms that after ratification, individual states retained "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the [s]tates."[127] In 1905, the US Supreme Court described the power to regulate public health as a "police power" that includes "the authority of a state to enact . . . 'health laws of every description.'"[128] Courts frequently cite to the police power on issues regarding medical care, such as licensing healthcare professionals.[129]

2. Federal Power to Legislate for Health

The federal government has no inherent power to regulate health and safety. Instead, it must link legislation to one of its enumerated powers explicitly granted in the text of the Constitution.[130] Primarily, these are the power to spend money[131] and the power to regulate interstate commerce.[132] There are two

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(July 24, 2020), https://www.nationalgeographic.org/article/roles-state-and-federal-governments/7th-grade/ [https://perma.cc/FH3R-3ZXK].

[125] *See* Alfred L. Snapp & Son, Inc. v. Puerto Rico, 458 U.S. 592, 600 (1982).

[126] Zucht v. King, 260 U.S. 174, 176 (1922) ("[I]t is within the police power of a state to provide for compulsory vaccination."); *see also* Lawrence O. Gostin, *Law and the Public's Health*, ISSUES SCI. & TECH. (2005), https://issues.org/gostin/ [https://perma.cc/DVG5-ZHEH] ("The police powers include all laws and regulations directly or indirectly intended to reduce morbidity and mortality in the population. These powers have enabled states and localities to promote and preserve the public's health in areas ranging from injury and disease prevention to sanitation, waste disposal, and water and air pollution.").

[127] U.S. CONST. amend. X. *See generally* Elizabeth Y. McCuskey, *Body of Preemption: Health Law Traditions and the Presumption Against Preemption*, 89 TEMP. L. REV. 95, 114–17 (2016) (tracing development of application of health regulation activities to the police power).

[128] Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905).

[129] Dent v. West Virginia, 129 U.S. 114, 122 (1889); *see also* Nadia Sawicki, *Character, Competence, and the Principles of Medical Discipline*, 13 J. HEALTH CARE L. & POL'Y 285, 289–94 (2010) (citing *Dent*, 129 U.S. at 122) (tracing state authority to establish medical licensing boards through its history and practice).

[130] *See generally* ANDREW NOLAN ET AL., CONG. RSCH. SERV., R45323, FEDERALISM-BASED LIMITATIONS ON CONGRESSIONAL POWER: AN OVERVIEW (2018), https://sgp.fas.org/crs/misc/R45323.pdf (last visited Jan. 5, 2022) ("There are two central ways in which the Constitution imposes federalism-based limitations on Congress's powers. First, Congress's powers are restricted by and to the terms of express grants of power in the Constitution, which thereby establish internal constraints on the federal government's authority . . . . That said, Congress's enumerated powers nevertheless do authorize the federal government to enact legislation that may significantly influence the scope of power exercised by the states.").

[131] Helvering v. Davis, 301 U.S. 619, 640 (1937) (rejecting a challenge to the federal government's New Deal initiatives and holding that the federal government could use its power to spend money in areas historically controlled by the states).

[132] U.S. CONST. art. I, § 8, cl. 3.

primary federal statutes relevant to prescriptions: the Controlled Substances Act (CSA),[133] which is administered by the DEA, a division of the US Department of Justice, and the Federal Food, Drug, and Cosmetic Act (FD&CA),[134] administered by the US FDA.

The federal government plays a particularly prominent role in addressing the opioid crisis because it has already preempted the states' underlying power to regulate drugs.[135] This includes the power to control the availability of pharmaceutical products intended to treat or impact the effects of disease through the FDA[136] and the power to enforce federal criminal drug laws through the DEA.[137] In the case of opioids, which have both legal uses to treat medical conditions and illegal uses, these two sources of authority often overlap.[138] A physician who prescribes opioids following surgery must comply with federal laws regarding the registering of the prescription in a national database operated by the federal government.[139]

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[133] Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1242 (1970) (codified as amended at 21 U.S.C. §§ 801–971).

[134] Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399(f)); *see also* 21 U.S.C. § 321f(g)(1) (2016) ("The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).").

[135] McCuskey, *supra* note 127, at 134–35.

[136] *See Laws Enforced by FDA*, U.S. FOOD & DRUG ADMIN. (Apr. 19, 2021), https://www.fda.gov/regulatory-information/laws-enforced-fda [https://perma.cc/C2ED-VPEN]. For a history of how drugs came to be regulated by the federal government in the United States, see Taleed El-Sabawi, *Why the DEA, Not the FDA? Revisiting the Regulation of Potentially-Addictive Substances*, 16 N.Y.U. J.L. & BUS. 317, 323–29 (2020), wherein the author traces the start of federal regulation in the tax code, the development of the Federal Narcotics Control Board and the development of the DEA.

[137] For a history of how the FDA and DEA came to have authority over non-narcotic drugs and an argument for why control of drug regulation should be shifted from the DEA to the FDA, see El-Sabawi, s*upra* note 136, at 342 ("Since Congress has reconsidered the use of the criminal justice approach to address problem drug use, it should also revisit its reliance on a criminal justice agency to regulate and enforce the regulation of potentially-addictive substances.").

[138] For example, under the CSA, "the schedule of a drug or other substance may be initiated by the Drug Enforcement Administration (DEA), the Department of Health and Human Services (HHS), or by petition from any interested party." *The Controlled Substances Act*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/drug-information/csa [https://perma.cc/8DBB-2DXW].

[139] *See Prescription Drug Monitoring Programs (PDMPs): What States Need to Know*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/pdmp/states.html [https://perma.cc/GS8W-H7YB].

3. State and Federal Laws Working Together

The entire enterprise of drug regulation is quite complex because both the state and federal government are regulating the same activities, but from very different inherent powers. So, for example, states regulate the practice of medicine, and the federal government has added layers of constraints based on its powers to regulate drugs.[140] To make things more complicated, states extend their reach into matters usually reserved to the FDA, such as setting guidelines for the use of narcotics or limiting the number of pills that can be prescribed.[141] Increasingly, these state and federal regulations become intertwined. For example, new legislation requires physicians to check the federal prescription registry before prescribing opioids to individual patients.[142] These laws, which target physicians,[143] have had their intended effect of reducing the number of prescriptions because violations could mean a physician loses their medical license,[144] and even ends up in prison.[145] But all credible sources agree that prescription opioids are not the cause of current rising overdose deaths.

In the United States, at both the federal and state level, laws are drafted and passed by politicians who are subject to the direct vote of the public. The content of these laws is controlled by individual legislators.[146] Once a law is passed, it leaves the domain of Congress and is turned over to administrative agencies who are

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[140] Valarie Blake, *Fight Prescription Drug Abuse with Federal and State Law*, 15 AMA J. ETHICS 443, 443–48 (2013).

[141] Many, but not all, states have implemented a PDMP to collect data about substances prescribed in the state. *See* Rivais & White, *supra* note 99, at 59.

[142] Oliva, *supra* note 97, at 780.

[143] *See* Dineen & DuBois, *supra* note 90, at 38 (noting that although these laws apply to all physicians who prescribe opioids, pain clinics have been the target of "numerous additional state imposed restrictions" and "pain physicians, in particular, fear investigations and false arrest").

[144] *See* Jayne O'Donnell & Ken Alltucker, *Pain Patients Left in Anguish by Doctors 'Terrified' of Opioid Addiction, Despite CDC Change*, USA TODAY (June 30, 2019, 3:54 PM), https://www.usatoday.com/story/news/health/2019/06/24/pain-patients-left-anguish-doctors-who-fear-opioid-addiction/1379636001/ [https://perma.cc/VY2C-627J].

[145] *See* Adam M. Gershowitz, *The Opioid Doctors: Is Losing Your License Sufficient Penalty for Dealing Drugs?* 72 HASTINGS L.J. 871, 874 (2021) (arguing that while many doctors are afraid, the prosecution of doctors who use their prescribing powers to profit does not occur frequently enough).

[146] *See Who Writes Our Law?*, GOVTRACK.US SITE NEWS (Mar. 24, 2010), https://govtracknews.wordpress.com/2010/03/24/who-writes-our-law/ [https://perma.cc/6ZTN-KZCQ] (Marci Harris, staffer for then US Representative Peter Stark explained: "There are lots of little bills pending at any time before both the House and Senate, and the ideas behind these small bills come from many sources. Lots of bills start as news clippings: a Member may read a newspaper article and come in the next morning and tell his staffer to draft a bill to address the issue. And it's not hard to imagine the origins of bills that would require . . . . Others originate from a constituent letter about a particularly compelling issue, or a request from a professional advocate representing a trade association, union, nonprofit, or corporation.").

tasked with implementing it to achieve the purpose the legislature intended.[147] Once implemented, however, these laws are never reevaluated to determine their efficacy. Many commentators have pointed out that this process will "inevitably yield unintended consequences."[148] This is exactly what has happened with legislation intended to prevent harm associated with opioid use.[149] The most notable exceptions are laws with "sunset" provisions that "establish dates for the termination of government agencies and programs" for "[t]he purpose of . . . promot[ing] and encourag[ing] program evaluation."[150]

B. How Does Public Health Develop Policy to Solve Problems?

The phrase "public health approach" means different things to different people depending on the context.[151] But one point of general agreement is that a public health approach seeks to prevent problems at their earliest stages instead of imposing penalties after the harm has already occurred.[152] Public

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[147] *See, e.g.*, Jason J. Fichtner & Patrick A. McLaughlin, *Legislative Impact Accounting*: *Rethinking How to Account for Policies' Economic Costs in the Federal Budget Process* 3 (Mercatus Ctr. at George Mason Univ., Mercatus Working Paper June 2015), https://www.mercatus.org/system/files/Fichtner-Full-Cost-Budgeting.pdf [https://perma.cc/H3ML-P5SZ] ("Government actions have multiple direct and indirect impacts on the economy. Yet despite byzantine budgeting and regulatory processes, there is no systematic way for Congress to comprehensively track and assess the economic impact of legislative actions—including the regulatory progeny of legislation."); *see also* Rena I. Steinzor, *The Legislation of Unintended Consequences*, 9 DUKE ENV'T L. & POL'Y F. 95, 95–96 (1998) (providing examples of unintended consequences of environmental protection laws).

[148] Fichtner & McLaughlin, *supra* note 147, at 5; *see also* JP Cortez, *When Government Acts, Unintended Consequences Follow*, MISES INST. (Feb. 24, 2017), https://mises.org/wire/when-government-acts-unintended-consequences-follow [https://perma.cc/U3ZG-5YWS] (discussing the 1850 essay of economist Frédéric Bastiat, *That Which Is Seen, and That Which Is Not Seen*).

[149] For further discussion of the effect of laws intended to reduce opioid prescriptions on the treatment of chronic and acute pain, see Robert Davidson, *Opioid-Use Policies Causing Unintended Consequences*, U.S. PHARMACIST (Mar. 9, 2021), https://www.uspharmacist.com/article/opioiduse-policies-causing-unintended-consequences [https://perma.cc/3S3U-GDVM].

[150] Lewis Anthony David, *Review Procedures and Public Accountability in Sunset Legislation: An Analysis and Proposal for Reform*, 33 ADMIN. L. REV. 393, 393 (1981). *See generally* Brian Baugus & Feler Bose, *Sunset Legislation in the States: Balancing the Legislature and the Executive*, MERCATUS RSCH. (2015), https://www.mercatus.org/system/files/Baugus-Sunset-Legislation.pdf [https://perma.cc/8DLA-YXU6] (providing over of sunset laws across all states).

[151] *See, e.g.*, Alex Mold, *Framing Drug and Alcohol Use as a Public Health Problem in Britain: Past and Present*, 35 NORDIC STUD. ON ALCOHOL & DRUGS 93, 94 (2018) ("Defining 'public health' is a difficult enterprise.").

[152] *Defining and Implementing a Public Health Response to Drug Use and Misuse*, AM. PUB. HEALTH ASS'N (Nov. 2013) [hereinafter *Defining and Implementing a Public Health Response*], https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/08/08/04/defining-and-implementing-a-public-health-response-to-drug-use-and-misuse [https://perma.cc/BM7J-76GN] ("Criminalization of substance use further stigmatizes people who use drugs, making it more difficult to engage people in health care

health problem solving is described as a method that seeks population-based solutions by identifying a problem, applying epidemiological methods of analysis, implementing evidence-based solutions to mitigate harm, and evaluating the efficacy of the intervention once it has been put into practice.[153] Similarly, the CDC describes its "analytical framework" for solving public health problems as a series of key steps that begin with "identify[ing] the problem or issue."[154] It recommends starting that process by "[s]ynthesiz[ing] data on the characteristics of the problem or issue, including the burden (how many people it affects), frequency (how often it occurs), severity (how serious of a problem is it), and scope (the range of outcomes it affects)."[155] Yet when it comes to opioid use, the CDC does not take its own advice in that it still emphasizes reducing the prescription of opioid pain medication despite evidence that these are not the forms of opioids leading to overdose. Nor, in light of this evidence, has it criticized state laws like prescription drug registries that are solely designed to track opioids prescribed for pain control.[156]

These actions, which depend on punishing rather than preventing behavior, contribute to harm that is antithetical to public health problem solving. This Section first identifies distinguishing features of public health problem solving. As a starting point, these features include public health's rejection of stigma and criminalization and its incorporation of lessons from the past. Building on this foundation, public health problem solving's distinctive features include the emphasis on identifying, prioritizing, and preventing harms. Finally, having developed strategies, public health also evaluates them by measuring their effectiveness in achieving their goals and then making changes if these goals are not being met. These features of public health problem solving are then contrasted with the process for drafting and implementing US law and policies.

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and other services, a tendency that is often compounded by sociocultural factors associated with problematic drug-using populations, such as fear, lack of information and education, general physical and mental health problems, homelessness, and incarceration. Criminalization also exacerbates social marginalization and encourages high-risk behaviors such as poly-drug use, binging, and injecting in unhygienic, unsupervised environments.").

153 Riegelman, *supra* note 115.

154 *CDC's Policy Analytical Framework*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 29, 2015), https://www.cdc.gov/policy/analysis/process/analysis.html [https://perma.cc/S4X6-NLZB].

155 *Id.*

156 For an overview of state laws controlling the sale and distribution of prescription opioids, see Noah, *supra* note 63, at 634–35 (considering constitutional objections to state laws "designed to prevent opioid addiction and diversion" by limiting the quantity of opioids prescribed).

1. Public Health Rejects Stigma

A primary feature of true public health methodology is that it does not stigmatize those in need of help, but rather focuses on identifying and then developing strategies to prevent the causes of harm.[157] Substance use stands apart from most public threats in that it is perceived by current law as both a disease, a moral failure, and a crime.[158] Those who use drugs have traditionally been subject to moral judgement beyond that of those who smoke or drink in excess.[159] As a result, measures such as providing clean needles to reduce the harm of using injection drugs meet the same objections today as they did when first implemented in the late 1980s to stop the spread of HIV/AIDS.[160]

In developing policies to reduce harm associated with opioids, it is particularly important to note that opioids associated with death are already illegal and their use carries significant social stigma.[161] As bioethicist Nathan Emmerich wrote recently, "the idea of 'health' and 'wellbeing' have recently taken on a moral hue and contemporary norms are such that smoking and obesity are increasingly understood as reflecting

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[157] GLOB. COMM'N ON DRUG POL'Y, *supra* note 69, at 37 ("Putting health and safety first requires the medical community and healthcare professionals to be vocal in promoting evidence-based prevention, treatment, and harm reduction services, and to urgently address perception-based stigma in healthcare settings. Doctors, nurses, and other healthcare workers who are in contact with people who use drugs have a major role to play in changing the perceptions on drugs. They are often the first point of contact with people who use drugs, and can be influential in feeding evidence back to the public.").

[158] For further discussion of justifications for criminalizing drug use, see generally Taleed El-Sabawi, *Carrots, Sticks, and Problem Drug Use: Law Enforcement's Contribution to the Policy Discourse on Drug Use and the Opioid Crisis*, 80 OHIO ST. L.J. 765 (2019).

[159] *Why Aren't More People with Opioid Use Disorder Getting Buprenorphine?*, PEW (July 31, 2019), https://www.pewtrusts.org/en/research-and-analysis/articles/2019/07/31/why-arent-more-people-with-opioid-use-disorder-getting-buprenorphine [https://perma.cc/3E3V-9QWZ]. Explaining that stigma permeates the entire process of providing medical care, Dr. Rebecca Haffajee, an assistant professor of health management and policy at the University of Michigan's School of Public Health, explains that these restrictions and the stigma of treating patients with OUD are substantial barriers. *Id.* She notes that providers such as "physicians, nurse practitioners, and physician assistants express concerns about the lack of institutional and peer support" that are also based on stigma. *Id.*

[160] *Defining and Implementing a Public Health Response*, *supra* note 152.

[161] *See* Holly Jespersen, *Shatterproof Releases National Addiction Stigma Strategy as the COVID-19 Pandemic Continues to Worsen the Addiction Public Health Crisis*, SHATTERPROOF (July 16, 2020), https://www.shatterproof.org/press/shatterproof-releases-national-addiction-stigma-strategy-covid-19-pandemic-continues-worsen [https://perma.cc/85DS-WPMG] ("'Most people mistakenly believe that addiction is the fault of those with this disease, that it is caused by a lack of willpower, and that addiction is not treatable,' said Shatterproof Founder and CEO Gary Mendell. 'As a result, many will not seek treatment because they fear their family, friends or employer will find out they have addiction. And those who do seek treatment may not be able to have access or find quality treatment.'").

the moral failings of individuals."[162] There is substantial evidence that people of whom medical personnel think less get worse medical care.[163]

On the positive side, there is evidence that the stigma associated with some forms of drug use is receding. Surveys consistently find that Americans distinguish among kinds of drugs, with as many as 67 percent surveyed agreeing that marijuana should be made legal.[164] Also, while the legalization movement has not stretched to opioids, there have been increased calls for decriminalization.[165]

2. Public Health Takes Lessons from the Past

Public health's attachment to the story of John Snow and the Broad Street pump represents a deep commitment to remembering the lessons of history. Because developing and implementing public health strategies depends on understanding human behavior, it is, as a discipline, more interested in history than other scientific fields which primarily look forward.[166] Similarly, the current response to COVID-19 relies on lessons from the 1918 flu pandemic.[167] In contrast, there are so many parallels between the current harm opioid use causes and the harm that comes with infection with HIV/AIDS that the failure to adopt similar solutions undercuts any claim of taking a public health approach.[168] Just as serious

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[162] Nathan Emmerich, *Sex and Other Sins: Public Morality, Public Health, and Funding PrEP*, BMJ BLOGS (Oct. 8, 2016), https://blogs.bmj.com/medical-ethics/2016/10/08/sex-and-other-sins-public-morality-public-health-and-funding-prep/ [https://perma.cc/5FTH-5KM6]; *see also* Peter Conrad, *Wellness as Virtue: Morality and the Pursuit of Health*, 18 CULTURE MED. & PSYCHIATRY 385, 385–86 (1994) (noting the roots of linking "health" and "virtue" in nineteenth century "health crusaders").

[163] *See, e.g.*, S. Lochlann Jain, *Be Prepared*, *in* AGAINST HEALTH: HOW HEALTH BECAME THE NEW MORALITY (Jonathan M. Metzl & Anna Kirkland eds., 2010) 170, 173 ("Part of Americans' dismal life expectancy results from the broad lack of access to health care as well as the broader and well-documented discrimination in health care against the usual suspects: African Americans, women, younger people, and queers.").

[164] Andrew Daniller, *Two-Thirds of Americans Support Marijuana Legalization*, PEW RSCH. CTR. (Nov. 14, 2019), https://www.pewresearch.org/fact-tank/2019/11/14/americans-support-marijuana-legalization/ [https://perma.cc/U5B5-YACE].

[165] Ryan Hampton, *Note to Jeff Sessions: Criminalizing Addiction Is Like Criminalizing Cancer*, HILL (May 15, 2017), https://thehill.com/blogs/pundits-blog/crime/333423-note-to-jeff-sessions-criminalizing-addiction-is-like-criminalizing [https://perma.cc/5CBM-W5ZR] ("People with addiction are not criminals—and criminalizing addiction is about as useful as criminalizing breast cancer. It merely raises the stakes and threatens the most vulnerable members of our community.").

[166] History is part of the core public health curriculum while history of medicine or science are usually specialized fields.

[167] Prakash Mallappa Munnoli et al., *Post-COVID-19 Precautions Based on Lessons Learned from Past Pandemics: A Review*, J. PUB. HEALTH (2020), https://link.springer.com/content/pdf/10.1007/s10389-020-01371-3.pdf [https://perma.cc/V4EN-D32U].

[168] *See* Stephanie Pappas, *HIV Laws that Appear to Do More Harm than Good*, 49 AM. PSYCH. ASS'N 32, 34 (2018) (noting a growing consensus that laws making it illegal to expose

legislative attention to address the consequences of HIV/AIDS infection did not come until the emergence of a population with the disease which could be identified as "blameless"—primarily hemophiliacs and others who acquired the virus through blood transfusions[169]—it was not until the deaths were perceived as a problem affecting white, middle-class people who had become dependent on prescription opioids that it became a matter of legitimate legislative concern.[170] Some of the harms associated with infection from the increased use of injection drugs could easily have been resolved decades ago by assuring the availability of clean needles or even safe injection sites.[171] Equally, medication-assisted therapy (MAT) in the form of methadone has been available since the 1970s[172] but remained difficult to access when it was thought to serve a less-deserving population.[173]

Had there been an infrastructure based on harm prevention, including needle exchange programs and safe use locations, both the transmission of blood borne pathogens and the increased death from overdoses could have been prevented. That is because, before heroin became adulterated with synthetic opioids like fentanyl and its derivatives, death from overdose was not the serious risk it is today.

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others to HIV have not been effective in reducing transmission of HIV and "may actually increase risky sexual behavior among people at risk for HIV.").

[169] As late as 1988, seven years after AIDS was first recognized in the United States, the Secretary of Health and Human Services assured the public that "we do not expect any explosion into the heterosexual population." Judith Areen, *A Need for Caring*, 86 MICH. L. REV. 1067, 1069, 1071, 1082 (1988); *see also Elizabeth's Story*, ELIZABETH GLASER PEDIATRIC AIDS FOUND., https://www.pedaids.org/about/elizabeths-story/ [https://perma.cc/N6CW-DKNJ].

[170] *See* Julie Netherland & Helena Hansen, *White Opioids: Pharmaceutical Race and the War on Drugs that Wasn't*, 12 BIOSOCIETIES 217, 217–18 (2017) (noting that criminal penalties for the mostly white Americans who use synthetic opioids are less than for Black Americans who use other illicit drugs); Ryan Faircloth, *These Two Minnesota Moms Will Be Sen. Amy Klobuchar's Guests at 2020 Presidential Debate*, TWIN CITIES PIONEER PRESS (June 25, 2019, 7:59 PM), https://www.twincities.com/2019/06/25/these-two-minnesota-moms-will-be-sen-amy-klobuchars-guests-at-2020-presidential-debate/ [https://perma.cc/39LS-LMAU] ("Shelly Elkington of Montevideo lost her 26-year-old daughter Casey because Casey got hooked on opioids as she coped with Crohn's disease.").

[171] *See generally* AIDS AND THE LAW: A GUIDE FOR THE PUBLIC (Harlon L. Dalton et al. eds., 1987) (collection of essays reviewing the need for legal interventions that if heeded would be saving lives today).

[172] SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEPT. OF HEALTH & HUM. SERVS., HHS Publication No. (SMA) 12-4214, TREATMENT IMPROVEMENT PROTOCOL (TIP) SERIES 43, MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION IN OPIOID TREATMENT PROGRAMS 211 (2005), https://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/Bookshelf_NBK64164.pdf [https://perma.cc/9EC7-2B8R].

[173] *See* Anne Corbett, *The Locality's Case for Safe Injection Facilities: Legal Obstacles and Ways to Overcome Them*, 24 U. PA. J.L. & SOC. CHANGE 37, 45 (2021) (discussing history of syringe exchange programs to efforts at combatting HIV, "Private charitable organizations opened the first U.S. SEP in 1988 in Tacoma, Washington as a harm reduction response to the HIV epidemic") (citing Scott Burris et al., *Lethal Injections: The Law, Science, and Politics of Syringe Access for Injection Drug Users*, 37 U.S.F. L. REV. 813, 817 (2003)).

In 1987, in one of the earliest books about the law's response to HIV/AIDS, Professor Harlon Dalton and a group of students, including now Professor Scott Burris, published a series of essays that, if heeded, would have prevented many of the most serious consequences of today's epidemic.[174] At that time, faced with widespread fear and stigmatization of people with HIV/AIDS who were already stigmatized because of their race, sexual practices, or drug use, Professor Dalton urged society to "rein in its worst impulses,"[175] writing that

> [s]uch an effort requires healthy doses of . . . "humane imagination," the ability to comprehend, however dimly, how life is lived by people very different from ourselves. We must struggle to see through the eyes and feel with the hearts of those whom AIDS is most likely to fell."[176]

3. Public Health Prioritizes Harms According to the Potential Risk to Human Health

A first step in developing an effective legal approach to the harms caused by illegal drug use is to identify those harms, then prioritize them.[177] Public health prioritizes preventing avoidable harms to a population's quality of life and life expectancy, rather than focusing on economic harms.[178] This is measured by combining both life span and health status by calculating "quality-adjusted life years" (QUALY).[179] Given that deaths directly associated with opioid use are now the leading cause of accidental death in the United States, it would seem self-evident that reducing the death toll should be the first priority of any legislative scheme.[180]

Without preexisting priorities and agreed-upon metrics for achieving them, it is impossible to know whether a particular

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[174] *See* AIDS AND THE LAW: A GUIDE FOR THE PUBLIC, *supra* note 171, at xi–xvi.

[175] Areen, *supra* note 169, at 1071.

[176] AIDS AND THE LAW: A GUIDE FOR THE PUBLIC, *supra* note 171, at xiv; Areen, *supra* note 169, at 1071.

[177] For further discussion of the process of setting priorities among different public health objectives, see generally Jeremy Shiffman, *Agenda Setting in Public Health Policy*, *in* 1 INTERNATIONAL ENCYCLOPEDIA OF PUBLIC HEALTH 16 (2d ed. 2016).

[178] Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 83 (1995).

[179] *Id.* (The measure attempts to consider "both quantitative benefits of health improvement, such as increase in life expectancy, and more qualitative improvements, such as quality-of-life benefits.").

[180] NAT'L ACADS. OF SCIS., ENG'G, & MED., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 2 (2017); *National Center for Health Statistics: Accidents or Unintentional Injuries*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nchs/fastats/accidental-injury.htm [https://perma.cc/ZU2C-JSFC].

intervention has been effective in achieving a high-priority goal.[181] So, for example, while laws limiting the number of refills on prescription pain medication have been successful in reducing the amount of pain medication received by individual patients,[182] they have had no effect on the harms caused by use of synthetic opioids manufactured and purchased illegally.[183] This is because the legislature failed to identify and prioritize the principle harm associated with synthetic opioid use—opioid-associated deaths.

4. Public Health Does Not Criminalize the Problems It Is Trying to Solve

"*If Addiction Is a Disease, Why Is Relapsing a Crime?*"[184]

The greatest deviation of current drug laws from a public health approach is that they have at least two very different priorities: reducing drug use by reducing the amount of drugs available versus reducing the harm caused by those who use drugs. Recent laws that treat drug users as patients have been overlain onto current laws that treat them as criminals. By continuing to use the language of waging a "war on drugs," state and federal government entities have adopted an approach described as "punitive prohibition" such that "recreational drugs are still forbidden, and users are still blamed, shamed, and caged."[185]

This is a recipe for policy failure.[186] The results of these two different policies are clusters of laws, primarily criminal, aimed at

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[181] Maria Mousmouti, *The "Effectiveness Test" as a Tool for Law Reform*, 2 IALS STUDENT L. REV. 4, 4–6 (2014), https://sas-space.sas.ac.uk/5752/1/2116-3099-1-SM.pdf [https://perma.cc/32LK-SYK8]; *see also* Stephano Campostrini et al., *Evaluating the Effectiveness of Health Promotion Policy: Changes in the Law on Drinking and Driving in California*, 21 HEALTH PROMOTION INT'L 130, 132–33 (2006) (measuring effectiveness of drinking and driving laws in California). *See generally* Christopher James McGrath, How to Evaluate the Effectiveness of an Environmental Legal System (2007) (Ph.D. thesis, Queensland University of Technology), https://eprints.qut.edu.au/16661/1/Christopher_James_Mcgrath_Thesis.pdf (last visited Feb. 5, 2022).

[182] *New Prescribing Law for Treatment of Acute and Chronic Pain*, N.J. ACAD. FAM. PHYSICIANS, https://njafp.org/new-prescribing-law/ [https://perma.cc/6QP9-63QJ]; Thaddeus Mason Pope, *New Laws Limiting Opioid Prescriptions Create Undue Barriers for Patients with Cancer and Cancer Survivors*, ASCO POST (Sept. 25, 2018), https://ascopost.com/issues/september-25-2018/new-laws-limiting-opioid-prescriptions-create-undue-barriers/ [https://perma.cc/74WH-FTCU].

[183] *See* Lee et al., *supra* note 90.

[184] The Editorial Board, *If Addiction Is a Disease, Why Is Relapsing a Crime?*, N.Y. TIMES (May 29, 2018), https://www.nytimes.com/2018/05/29/opinion/addiction-relapse-prosecutions.html [https://perma.cc/8V5Y-22HT].

[185] Bowers & Abrahamson, *supra* note 58, at 788 (describing federal efforts to cut opioid prescriptions through increased prosecutions).

[186] Scholars argue that effective regulation requires that the government "accurately defines the causes of the problem and clearly defines its policy objective" so that

decreasing the amount of drugs available and the number of people using them, as well as laws targeted at reducing the harm caused by drugs to people who use them and to society.[187] These two competing goals are often described as targeting either the "supply" or "demand" for opioids.[188] Under this conceptualization, decreasing "supply" means reducing access to opioids, usually through criminal enforcement, while legislation that decreases "demand" addresses the factors that lead individuals to access opioids in the first place.[189]

In the face of these two competing goals, public health has endorsed those laws reducing harm from drugs and has soundly denounced those targeting supply. In 2013, just as officials began to identify synthetic opioids as the cause of the rise in deaths associated with drug use, the APHA issued a policy statement describing the "war on drugs," implemented by then President Nixon in 1971, as a "severely flawed" approach based on "misplaced priorities and strategies."[190] The APHA further noted that despite "spen[ding] an estimated $1 trillion on drug war policies . . . national rates of drug use have remained relatively stable . . . [while] drug-related harms, such as the spread of blood-borne diseases and accidental overdose deaths, have grown severely worse."[191] Given the ineffectiveness of the "war on drugs" and the associated risk of drug-related harms, the APHA called for eliminating criminal penalties for personal drug use and possession and implementing a public health response reflecting best practices other countries were already beginning to successfully implement.[192] It also directly identified the "war on drugs" as "a major driver of the HIV/AIDS pandemic among people who inject drugs and their sexual partners" because it prevented implementation of highly effective harm reduction strategies, such as providing sterile needles.[193] Finally, the APHA concluded that

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"the government can then use the least coercive and most effective means to achieve that objective." PARKER, *supra* note 110, at 21. But such action is impossible when the features of the problem change, but the policy and regulations based on that policy do not.

187 *See* Kaplan, *supra* note 68, at 1096.

188 For a comprehensive overview of the federal government's actions to reduce the supply of opioids in the United States, see SACCO ET AL., *supra* note 74, at 1 ("Over the last several years, the public and lawmakers in the United States have been alarmed over the increasing number of drug overdose deaths, most of which have involved opioids. Congress has responded to the issue through legislative activity, oversight, and funding, while the Administration has sought to reduce the supply and demand of illicit drugs through enforcement, prevention, and treatment.").

189 *Id.* at 1, 6.

190 *Defining and Implementing a Public Health Response*, *supra* note 152.

191 *Id.*

192 *Id.*

193 *Id.* ("The criminalization of people who use illicit drugs, along with the mass incarceration of people for nonviolent drug law violations, has restricted access to sterile syringes and opioid substitution treatments, and aggressive law enforcement practices have promoted risky practices that facilitate the spread of HIV/AIDS and other diseases while creating barriers to drug and HIV treatment.").

> APHA believes that national and state governments and health agencies must reorient drug policies to embrace health-centered, evidence-based approaches that reduce the individual and community harms deriving from current policies and from illicit drug misuse, respect the human rights of people who use drugs, and allow for the redirection of financial resources toward where they are needed most.[194]

It is my contention that by calling for a "reorientation" of policy from criminalizing drug use, which focuses on the harm that those using drugs cause others, towards the needs of the individuals who were themselves at risk of infection, APHA was rejecting criminalization as an effective means of promoting the "human rights of people who use drugs."[195]

Yet, despite the APHA's clear call for a complete change in policy and the rapidly growing number of people harmed by drug use, not only were their recommendations ignored, but the legislative response was to adopt the language of public health solutions while increasing the role of law enforcement.[196] For example, the DEA has a "360 Strategy" to "combating heroin/opioid use through Law Enforcement, Diversion, and Community Outreach."[197]

5. Public Health Adapts Its Solutions as the Nature of the Threat Changes

The harm caused by opioids today is almost exclusively traceable to a kind of drug yet unknown at the time then President Nixon launched his war on drugs in 1971: synthetic opioids manufactured illegally and sold outside the medical chain of supply.[198] These synthetic forms of the compounds found naturally in opium poppies did not reach the commercial market

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[194] *Defining and Implementing a Public Health Response*, *supra* note 152.

[195] *Id.*

[196] *See generally* Lawrence O. Gostin, *Law and Policy*, *in* DIMENSIONS OF HIV PREVENTION: NEEDLE EXCHANGE 1, 2 (Jeff Stryker & Mark D. Smith eds., 1993), *reprinted in* PROCEEDINGS WORKSHOP ON NEEDLE EXCHANGE AND BLEACH DISTRIBUTION PROGRAMS 113, 113 (1994) (calling for the repeal of drug paraphernalia laws that made it illegal to operate needle exchange programs and thus prevented taking a "public health approach to controlling the dual epidemics of drug dependency and the acquired immune deficiency syndrome (AIDS) in the United States").

[197] *DEA 360 Strategy*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/divisions/360-strategy [https://perma.cc/T5EC-ADYD].

[198] *See* Chris Delcher et al., *Carfentanil Outbreak—Florida, 2016–2017*, 69 MORBIDITY & MORTALITY WKLY. REP., 125, 125 (Feb. 27, 2020) ("Increased prevalence of illicitly manufactured fentanyl and fentanyl analogs has contributed substantially to overdose deaths in the United States."); *see also* Meghan Ross, *7 Things to Know About Carfentanil*, PHARMACY TIMES (Sept. 13, 2016), https://www.pharmacytimes.com/news/7-things-to-know-about-carfentanil [https://perma.cc/XHV9-KQJG].

in the form of a pharmaceutical product until 2016.[199] At that time, pharmaceutical companies began marketing their new products to physicians. At first, these synthetic opioids manufactured by pharmaceutical companies were diverted illegally either by physicians writing prescriptions or pharmacists reselling the products they were supposed to discard. However, once discovered that it was fairly easy to manufacture these synthetic opioids outside the regulated pharmaceutical industry, this became the major source of supply.[200] As such, most of today's drug laws targeting diversion of prescription synthetic opioids are obsolete.[201] This is evidenced in the language still used to describe the harms these laws are supposed to prevent, such as referring to deaths associated with opioids as "overdoses." This is because "overdose" implies a product prescribed at a specific therapeutic dose. Since illicitly manufactured synthetic opioids responsible for the majority of today's opioids have not gone through the FDA approval process, there is no therapeutic "dose" and therefore no possibility of "overdose."[202] However, because the CDC categorizes deaths associated with both legal and illicit opioids together,[203] whatever amount of drug results in death is, by this definition, an "overdose" since death was not the intended result.[204]

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[199] *See* Delcher et al., *supra* note 198, at 125 ("Deaths involving carfentanil, an analog reportedly 10,000 times more potent than morphine and 100 times more potent than fentanyl, were first reported in Florida, Michigan, and Ohio in 2016 and described in an August 2016 CDC Health Advisory.").

[200] *See Drug Fact Sheet—Synthetic Opioids*, *supra* note 28.

[201] *See* Oliva, *supra* note 97, at 778 ("Journalists, public-health experts, and pundits frequently frame this public-health catastrophe as a *prescription-drug*-overdose crisis primarily attributable to the overprescribing of opioid analgesics. Even assuming this description of the overdose crisis was once accurate, the national health-data statistics tell a much different story today. According to the Centers for Disease Control and Prevention ('CDC'), nearly two-thirds of overdose deaths in 2016 were attributable to *illicit* substances, such as heroin, fentanyl, methamphetamines, cocaine, or some lethal combination thereof, and not *prescription* drugs."); *see also* Nabarun Dasgupta et al., *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182, 183 (2018).

[202] *See Development and Approval Process: Drugs*, U.S. FOOD & DRUG ADMIN. (Aug. 19, 2021), https://www.fda.gov/drugs/development-approval-process-drugs#FDA [https://perma.cc/MYE2-2NTW] ("FDA approval of a drug means that data on the drug's effects have been reviewed by CDER, and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population.").

[203] *See Drug Overdose Deaths*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 28, 2021, 9:49 PM), https://www.cdc.gov/drugoverdose/deaths/index.html [https://perma.cc/YB3X-J8JA].

[204] *See Intentional v. Unintentional Overdose Deaths*, NIH NAT'L INST. ON DRUG ABUSE (Feb. 13, 2017), https://www.drugabuse.gov/drug-topics/treatment/intentional-vs-unintentional-overdose-deaths [https://perma.cc/DQ6W-ZLBC] ("When a person dies because of a drug overdose, the medical examiner or coroner records on the death certificate whether the overdose was intentional (purposely self-inflicted, as in cases of suicide) or unintentional

6. Public Health Evaluates the Effectiveness of Interventions

As described in Section II.B.3, measuring the effectiveness of an intervention is impossible without first identifying what problem it is supposed to solve. But when there is agreement on the nature of the problem and the indicia or metrics of success, there must be plan in place for evaluating results.[205] Here is where US law falls short in all public policy legislation.

III. APPLYING PUBLIC HEALTH PROBLEM SOLVING METHODS: ASSESSING THE HARM CAUSED BY SYNTHETIC OPIOIDS

This Part examines harms associated with opioid use at both the individual and population or societal level. The National Institute on Drug Abuse notes that "[t]he misuse of and addiction to opioids—including prescription pain relievers, heroin, and synthetic opioids such as fentanyl—is a serious national crisis that affects public health as well as social and economic welfare."[206] These harms occur at both an individual level in terms of death and injury attributable to the effects of opioids on individuals who use them and on the population as a whole. This Part starts with the harm most easily measured, sudden death, because it requires the filing of a death certificate.[207]

(accidental). Unintentional drug poisoning deaths include cases where: a drug was taken accidentally [or] too much of a drug was taken accidentally . . . .").

[205] *See* Cary Coglianese, *Measuring Regulatory Performance: Evaluating the Impact of Regulation and Regulatory Policy* 8 (Org. for Econ. Co-operation & Dev., Expert Paper No. 1, 2012), http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.398.3130&rep=rep1&type=pdf (last visited Feb. 5, 2022) ("The assumption behind the question, 'How well is regulation working?' is that regulation is supposed to 'work', that is, it is supposed to effectuate some improvement in the conditions of the world. 'Improvement' means that the conditions in the world with the regulation are better than what they would have been without the regulation."); Alan Rosenthal, *Beyond the Intuition That Says "I Know One When I See One," How Do You Go About Measuring the Effectiveness of Any Given Legislature?*, NAT'L CONF. OF STATE LEGISLATURES (1999), https://www.ncsl.org/research/about-state-legislatures/the-good-legislature.aspx [https://perma.cc/VC38-BA59].

[206] *Opioid Overdose Crisis*, NIH NAT'L INST. ON DRUG ABUSE (Mar. 11, 2021), https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis [https://perma.cc/RG29-ZAP5]; *What Is the U.S. Opioid Epidemic?*, HHS.GOV (Oct. 27, 2021), https://www.hhs.gov/opioids/about-the-epidemic/index.html [https://perma.cc/2ZQR-LX42].

[207] The CDC uses World Health Organization standards to categorize drug overdose deaths using four different codes "from the Tenth Revision of ICD (ICD–10): X40–X44 (unintentional), X60–X64 (suicide), X85 (homicide), and Y10–Y14 (undetermined)." Ahmad et al., *supra* note 6. While codes exist for the specific kind of drug involved, medical examiners do not always perform extensive postmortem testing to determine which substances contributed to the death. *See* Christine Vestal, *It's Not Just Opioids. Deaths from Cocaine and Meth Are Surging*, PBS (May 16, 2019, 10:00 AM), https://www.pbs.org/newshour/health/its-not-just-opioids-deaths-from-cocaine-and-meth-are-surging [https://perma.cc/B9HV-ZQP5]); *States Can Now Use Federal Opioid Funds to Tackle Meth and Cocaine*, P'SHIP TO END ADDICTION (Jan. 2020),

A. Harms from Opioid Use at the Individual Level

1. Sudden Death from Cardiac Arrest

The most significant harm associated with use of opioids, natural or synthetic, is sudden death from cardiac arrest, which is often described misleadingly as the effects of an overdose. According to the CDC, more than 136 people in the United States die every day after overdosing on opioids.[208] By 2017, drug overdose became the leading cause of death for Americans under age fifty.[209] Between 1999, when opioid use was already identified as a serious problem, and 2017, when it became the leading cause of death for Americans under the age of fifty, there was a significant change in composition of the opioids Americans were using—most deaths involve synthetic opioids manufactured for direct sale to users outside of the healthcare system.[210] Whether the opioids ingested are obtained through a valid prescription and manufactured by pharmaceutical company or purchased and manufactured illegally, their physiological effect on the body is the same.[211]

Opioids are one of the few lethal poisons with an instantly effective antidote, naloxone.[212] Although not effective against the cardiac effects of other drugs such as cocaine, the growing contamination of all illegally sold drugs with synthetic opioids make it a potentially lifesaving antidote even if the patient does not know they have ingested opioids.[213] Within seconds of administering naloxone, it attaches to the brain's opioid receptors and renders them unresponsive,[214] effectively reversing the physiological effect of the drug. Laws that limit access to life saving antidotes to narcotic overdoses have, as a

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https://drugfree.org/drug-and-alcohol-news/states-can-now-use-federal-opioid-funds-to-tackle-meth-and-cocaine/ [https://perma.cc/VU7K-ZFT4].

[208] *Understanding the Epidemic*, *supra* note 28.

[209] Dean Reynolds, *Overdoses Now Leading Cause of Death of Americans Under 50*, CBS NEWS (June 6, 2017, 8:00 PM), https://www.cbsnews.com/news/overdoses-are-leading-cause-of-death-americans-under-50/ [https://perma.cc/8UVJ-2W92].

[210] *See Understanding the Epidemic*, *supra* note 28 (identifying the 1990s as the starting point of the first wave of the opioid epidemic and 1999 as a year with particularly high overdose deaths); *see also Drug Overdose Deaths*, *supra* note 203.

[211] *See Prescription Opioids DrugFacts*, NIH NAT'L INST. ON DRUG ABUSE (June 2021), https://www.drugabuse.gov/publications/drugfacts/prescription-opioids [https://perma.cc/T4H8-C3WW].

[212] *Naloxone Drug Facts*, NIH NAT'L INST. ON DRUG ABUSE (Jan. 2022), https://www.drugabuse.gov/publications/drugfacts/naloxone [https://perma.cc/NJT3-YMXM].

[213] *See* Christopher McCall Jones et al., *Recent Increases in Cocaine-Related Overdose Deaths and the Role of Opioids*, 107 AM. J. PUB. HEALTH 430, 432 (2017).

[214] *See How Opioid Drugs Activate Receptors*, NAT'L INSTS. OF HEALTH, https://www.nih.gov/news-events/nih-research-matters/how-opioid-drugs-activate-receptors [https://perma.cc/D94M-QGYL].

natural consequence, contributed to the deaths of those overdosing. It seems increasingly clear that lack of access to naloxone does not discourage drug overdoses[215] any more than a ban on defibrillators discourages heart attacks.

Moreover, naloxone is safe to use on individuals who do not have opioids in their system. Guidance for first responders states that "[w]hen given to individuals who are not opioid intoxicated or opioid dependent, naloxone produces no clinical effects, even at high doses. Moreover, although rapid opioid withdrawal in opioid-tolerant individuals may be unpleasant, it is not life threatening."[216] The more common risk is not recognizing overdose as a cause of unconsciousness and thus not administering naloxone.[217] Of course, the benefit of naloxone is time limited to the overdose it blocks. On its own, naloxone cannot assist with the larger issues of substance dependence. But if the most important goal is to preserve life as is the case with most public health analyses, then every overdose where naloxone was not available is a preventable death.

2. Reduction in Pain Control that Has Been Attributed to Suicides

Laws and policies based on CDC guidelines[218] intended to reduce opioid prescriptions for chronic pain use[219] have had tragic consequences for patients being treated for pain—the symptom which opioids were originally intended to relieve.[220] These

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[215] This finding was endorsed by the National Institute on Drug Abuse, which quoted a national study and concluded that "[t]hese findings underscore the importance of public health strategies, such as broader access to naloxone to reverse opioid overdoses, including providing naloxone to people using cocaine, and expansion of medication-assisted treatment for opioid use disorders." *Opioids Are Driving Increase in Cocaine Overdose Deaths*, NIH NAT'L INST. ON DRUG ABUSE (Feb. 9, 2017), https://archives.drugabuse.gov/news-events/news-releases/2017/02/opioids-are-driving-increase-in-cocaine-overdose-deaths [https://perma.cc/4UH3-7MK3].

[216] *Opioid Overdose Prevention TOOLKIT*, SAMHSA (2018), https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf [https://perma.cc/K8ZB-JLA9] ("Naloxone can be used in life-threatening opioid overdose circumstances in pregnant women.").

[217] *See Naloxone for Opioid Overdose: Life-Saving Science*, NIH NAT'L INST. ON DRUG ABUSE (Mar. 2017), https://www.drugabuse.gov/sites/default/files/opioid_naloxone.pdf [https://perma.cc/NT3A-SN3P].

[218] *See Pocket Guide: Tapering Opioids for Chronic Pain*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/pdf/Clinical_Pocket_Guide_Tapering-a.pdf [https://perma.cc/V5AD-9SMX].

[219] *See* Kelly K. Dineen, *Definitions Matter: A Taxonomy of Inappropriate Prescribing to Shape Effective Opioid Policy and Reduce Patient Harm*, 67 U. KAN. L REV. 961, 971–72 (2019) ("In response to rising rates of opioid related morbidity and mortality after 2000, opioid prescribing laws and policies proliferated. Earliest in the response were laws directed at chronic pain treatment with opioids.").

[220] *See id.* at 962–67 (drawing link between laws passed to combat opioid crisis and prescription of drugs to treat pain).

guidelines recommend that physicians "consider tapering to a reduced opioid dosage or tapering and discontinuing opioid therapy" for patients who take opioids for chronic pain[221] but who do "not have clinically meaningful improvement in pain and function."[222] The FDA has criticized these guidelines as lacking a sound basis in science[223] and, even though the CDC has reinterpreted them[224] because they are the basis for many existing laws and policies intending to limit prescriptions of opioids,[225] they continue to have considerable influence over prescribing practices since they have been codified into state law.[226]

Consequently, patients who had been maintained safely on opioids but who are now being involuntary "tapered off" face considerable stress.[227] In some cases, the distress has led to suicide.[228] The issue of suicide has been particularly well established in the population served by the VA since that agency was an early adopter of the content reflected in the CDC guidelines.[229]

The relationship between opioid use and suicide is difficult to quantify because "[i]n the absence of a suicide note, it is difficult to assess the intentions of an individual who has died of an overdose."[230] But the evidence becomes visible in both suicide

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[221] *See Pocket Guide: Tapering Opioids for Chronic Pain*, *supra* note 218.

[222] *Id.*

[223] *See* Catherine Sharkey, *The Opioid Litigation: The FDA Is MIA*, 124 DICK. L. REV. 669, 675–76 (2020) (discussing the FDA's letter criticizing the guidelines: "The misinterpretation and misapplication of these guidelines, the letter maintained, 'contribut[ed] to substantial harms to patients, particularly patients with chronic pain, who were forced to taper their previously stable opioid doses to lower doses, or who were forced to discontinue their opioids through forced tapers or patient abandonment.'" (alteration in original) (quoting U.S. Food & Drug Admin., Memorandum from Ning Hu, Med. Officer, Ctr. For Drug Evaluation and Research 11 (May 13, 2019)).

[224] Letter from Deborah Dowell, Chief Med. Officer, The Nat'l Ctr. for Injury Prevention & Control & Ctrs. for Disease Control & Prevention, to Robert W. Carlson, Clifford A. Hudis & Martha Liggett (Feb. 28, 2019), https://bit.ly/3rv4in0 [https://perma.cc/CWF7-LQ78].

[225] *See* Dineen, *supra* note 219, at 1001–02 ("The most universally ignored category of misprescribing is underprescribing. It may be a serious contributor to overall morbidity and mortality, for example by contributing to suicides or unintentional poisonings.").

[226] *See* Leo Beletsky & Corey Davis, *Today's Fentanyl Crisis: Prohibition's Iron Law, Revisited*, 46 INT'L J. DRUG POL'Y 156 (2017).

[227] *See supra* note 225.

[228] *Id.* at 1006 ("Serious concerns about suicide in patients with pain is poorly addressed in larger policy discussions, despite the extremely high risk it presents.").

[229] *VA Research Helps Lay Groundwork for New CDC Guidelines on Opioids*, U.S. DEP'T OF VETERANS AFFS. (Nov. 21, 2018), https://www.research.va.gov/research_in_action/VA-research-helps-lay-groundwork-for-new-CDC-guidelines-on-opioids.cfm [https://perma.cc/7YCV-WH47]; *see also* Benjamin Pomerance, *Yet Another War: Battling for Reasoned Responses for Veterans Amid the Opioid Crisis*, 11 ALB. GOV'T L. REV. 147, 162, 172–73 (2017) (criticizing the undertreatment of pain).

[230] Nora Volkow, *Suicide Deaths Are a Major Component of Opioid Crisis that Must Be Addressed*, NIH NAT'L INST. ON DRUG ABUSE (Sept. 19, 2019), https://www.drugabuse.gov/about-nida/noras-blog/2019/09/suicide-deaths-are-major-component-opioid-crisis-must-be-addressed [https://perma.cc/B7YX-UC7H]; *see also Preventing Suicide*, CTRS. FOR DISEASE

notes[231] and research data.[232] Therefore, not only are existing laws that limit opioid prescriptions ineffective in reducing deaths associated with opioid use, they have also exceeded their initial justifications for preserving public health and safety by causing unintended harm, in the form of suicide, to patients being treated for pain.[233]

3. Harm from Increase in Heroin Use

Another harm associated with synthetic opioids has been a drop in the price of heroin, which has resulted in an increase in its use.[234] Both products are chemically similar enough to prescription opioids to be considered complete substitutes for those who had already developed chemical dependencies.[235] And to some extent, the harm caused from this shift to illegal substitutes also had predictable consequences in terms of an

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CONTROL & PREVENTION (Apr. 2021), https://www.cdc.gov/suicide/pdf/preventing-suicide-fact sheet-2021-508.pdf [https://perma.cc/C582-VA6T].

[231] *See, e.g.*, Pat Anson, *Pain Community Mourns Loss of Pain Advocate Erin Gilmer—Pain News Network*, PAIN NEWS NETWORK (July 12, 2021), https://www.painnewsnetwork.org/stories/2021/7/12/pain-community-mourns-loss-of-patient-advocate [https://perma.cc/T4Q6-TC6R] (quoting a note written by Erin Gilmer, "a patient advocate and health policy attorney who intimately knew the problems faced by many chronically ill patients. She was one herself[ ]" who wrote a few days before her death on July 8, 2021, "'I wish I could describe how bad the pain is but nothing seems adequate. I keep thinking it can't possibly get worse but somehow every day is worse than the last,' Gilmer tweeted. 'This pain is more than anything I've endured before and I've already been through too much. Yet because it's not simply identified no one believes it's as bad as it is. This is not survivable.'").

[232] *See FDA Identifies Harm Reported from Sudden Discontinuation of Opioid Pain Medicines and Requires Label Changes to Guide Prescribers on Gradual, Individualized Tapering*, U.S. FOOD & DRUG ADMIN. (Apr. 9, 2019), https://www.fda.gov/media/122935/download [https://perma.cc/GQ4H-KSYC] ("The U.S. Food and Drug Administration (FDA) has received reports of serious harm in patients who are physically dependent on opioid pain medicines suddenly having these medicines discontinued or the dose rapidly decreased. These include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide.").

[233] *See id.*

[234] *See* NAT'L INST. ON DRUG ABUSE, PRESCRIPTION OPIOIDS AND HEROIN RESEARCH REPORT 10–11 (2018) [hereinafter PRESCRIPTION OPIOIDS AND HEROIN RESEARCH REPORT], https://www.drugabuse.gov/download/19774/prescription-opioids-heroin-research-report.pdf?v=fc86d9fdda38d0f275b23cd969da1a1f [https://perma.cc/659E-G9ER] ("While efforts to reduce the availability of prescription opioid analgesics have begun to show success, the supply of heroin has been increasing. . . . It is not clear whether the increased availability of heroin is causing the upsurge in use or if the increased accessibility of heroin has been caused by increased demand. A number of studies have suggested that people transitioning from abuse of prescription opioids to heroin cite that heroin is cheaper, more available, and provides a better high.").

[235] *See id.* at 6, 10. For more information about the similarity between powdered fentanyl and heroin, see *DEA Fact Sheet, Fentanyl*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/factsheets/fentanyl [https://perma.cc/CK7A-KZUP], which states: "Fentanyl is added to heroin to increase its potency, or be disguised as highly potent heroin. Many users believe that they are purchasing heroin and actually don't know that they are purchasing fentanyl— which often results in overdose deaths."

increase in criminal behavior and even the increase of diseases caused by blood borne pathogens as more people became injection drug users.[236]

B. Population-based Harms of Opioid Use

While death, sickness, and disability are all risks for individuals who use opioids, synthetic opioid use also causes substantial harms on a population level. The CDC "estimates that the [annual] 'economic burden' of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement."[237]

There is also considerable evidence that drug use hurts families[238] in that it impairs the ability of parents to take care of their children.[239] Foster care systems across the country have found themselves overwhelmed by the task of finding and funding homes for children whose parents cannot care for them because they have developed substance use disorders.[240] Moreover, a growing body of research shows significant differences in the parent/child relationships between parents who use opioids and those who do not.[241] Parents become less

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[236] *See* PRESCRIPTION OPIOIDS AND HEROIN RESEARCH REPORT, *supra* note 234, at 7.

[237] *Opioid Overdose Crisis*, *supra* note 206 (citing Curtis S. Florence et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, 54 MED. CARE 901,901–06 (2016)).

[238] *Substance Abuse Now Accounts for Nearly One of Three Minnesota Children Being Removed from Their Homes*, KAISER HEALTH NEWS (Dec. 3, 2018), https://khn.org/morning-breakout/substance-abuse-now-accounts-for-nearly-one-of-three-minnesota-children-being-removed-from-their-homes/ [https://perma.cc/FMA5-4NTP].

[239] Laura Lander et al., *The Impact of Substance Use Disorders on Families and Children: From Theory to Practice*, 28 SOC. WORK PUB. HEALTH 194, 195 (2013) ("The negative impacts of parental SUDs on the family include disruption of attachment, rituals, roles, routines, communication, social life, and finances. Families in which there is a parental SUD are characterized by an environment of secrecy, loss, conflict, violence or abuse, emotional chaos, role reversal, and fear.").

[240] Dawn Holden Woods, *PA's Foster Care System Overwhelmed by Opioid Epidemic. New Bill Can Help*, PHILA. INQUIRER (Nov. 5, 2018), https://www.inquirer.com/philly/opinion/commentary/pennsylvania-foster-care-system-opioid-tax-credit-20181105.html [https://perma.cc/5ZQB-NL9Z]; Susie Neilson, *More Kids Are Getting Placed in Foster Care Because of Parents' Drug Use*, NPR (July 15, 2019, 11:27 AM), https://www.npr.org/sections/healthshots/2019/07/15/741790195/more-kids-are-getting-placed-in-foster-care-because-of-parents-drug-use [https://perma.cc/92BJ-UMGL].

[241] Magdalena Romanowicz et al., *The Effects of Parental Opioid Use on the Parent-Child Relationship and Children's Developmental and Behavioral Outcomes: A Systematic Review of Published Reports*, 13:5 CHILD & ADOLESCENT PSYCHIATRY & MENTAL HEALTH 1, 9 (2019) ("In terms of the parent-child relationship, children of parents with opioid use disorders show greater disorganized attachment, they are less likely to seek contact, and they are more avoidant than the control children. Although this finding is based on a limited number of studies, it is worrisome and should be investigated further because of its importance for policy making and programming.").

responsive to their children's needs, setting in motion a cascade of negative consequences, including increased rates of abuse and neglect.[242]

Another population harm from opioid use is the harm caused by motor vehicle accidents. Given that opioid use, like alcohol, affects both dexterity and alertness, it is not surprising that it has become a major cause of traffic accidents.[243] A 2018 study by the Governors Highway Safety Association found that "in 2016, 44% of fatally-injured drivers with known results tested positive for drugs, up from 28% just 10 years prior."[244]

Finally, opioid use has caused considerable harm to the population of individuals incarcerated in our nation's jails and prisons. This harm comes in many forms, from those who suffer from withdrawal when first incarcerated[245] to those who take significant health risks to obtain synthetic opioids while serving their sentence. Not only could appropriate legislation reduce the prison population by reducing demand for opioids outside of prison and removing laws that criminalize drug use, it could also develop effective treatment while people are imprisoned and after their release. By making MAT the standard of care, new laws could mandate opioid treatment immediately when a person who needs it is arrested.[246] They could offer treatment to all who request it during incarceration[247] and make substance use less dangerous for those who will continue to seek it out. But they could also prepare those imprisoned for release into a world where opioids pose an even greater danger. For instance, individuals released from incarceration are particularly susceptible to death by drug overdose within the first few weeks

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[242] Lander et al., *supra* note 239, at 198.

[243] *Drugged Driving*, NIH NAT'L INST. ON DRUG ABUSE (Oct. 30, 2018), https://www.drugabuse.gov/drug-topics/trends-statistics/infographics/drugged-driving-infographic [https://perma.cc/7SSC-D7B6].

[244] *Drug-Impaired Driving*, GOVERNORS HIGHWAY SAFETY ASSOC. (2018), https://www.ghsa.org/resources/DUID18 [https://perma.cc/655S-3PYU].

[245] *See* Sarah E. Wakeman, *Why It's Inappropriate Not to Treat Incarcerated Patients with Opioid Agonist Therapy*, 19 AMA J. ETHICS 922, 922–24 (2017).

[246] As opioid agonist therapy becomes the standard of care, failure to provide it to prisoners could qualify as deliberate indifference. *See* Estelle v. Gamble, 429 U.S. 97, 104 (1976) (holding that the Eighth Amendment to the US Constitution's ban on "cruel and unusual" punishment prevents state and federal officials detaining an individual accused or convicted of a criminal offense from being deliberately indifferent to serious health needs); Wakeman, *supra* note 245, at 925.

[247] *What Role Can the Criminal Justice System Play in Addressing Drug Addiction?*, NIH NAT'L INST. ON DRUG ABUSE (Jan. 2018), https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/frequently-asked-questions/what-role-can-criminal-justice-system-play-in-addressing [https://perma.cc/CS2Y-CT4P].

following release.[248] Given how many people have died from causes directly attributable to their own use of opioids, whether because of exposure to adulterated products or because of the inherent mechanism of a drug that affects breathing, a public health approach mandates a legislative solution prioritizing saving their lives.

IV. IMAGINING A LEGISLATIVE RESPONSE THAT PRIORITIZES REDUCING DEATHS

Measures that reduce untimely deaths have traditionally enjoyed a place of primacy among the harms that public health laws are designed to prevent.[249] As such, reducing the harm associated with using drugs is a top priority public health intervention. This Part considers proposals directly targeted to the factors contributing to these deaths.

While the goal of a criminal penalty is to stop an activity, the goal of harm reduction is to reduce the severity of the consequences of engaging in that activity.[250] In terms of substance misuse, "Harm Reduction" refers to a category of public health interventions that do not prevent drug use or treat substance dependence, but rather make the activity of taking drugs safer in order to reduce death and disease.[251] For example, the United Kingdom has made a significant investment into a "Drug Interventions Programme" (DIP) that offers an array of harm reduction programs for individuals who are "arrested for 'trigger' offences such as drug possession or

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[248] Ingrid A. Binswanger, *Release from Prison—A High Risk of Death for Former Inmates*, 356 NEW ENG. L. MED. 157–65 (2007). Researchers have suggested that barriers to treatment for individuals who become involved in the criminal justice system may be different from the general population and are thus missed in existing surveys. *See* Mandy D. Owens et al., *Barriers to Addiction Treatment Among Formerly Incarcerated Adults with Substance Use Disorders*, 13 ADDICTION SCI. & CLINIC PRAC. 1, 6 (2018).

[249] *See* Dawn Pepin et al., *How Are Telehealth Laws Intersecting with Laws Addressing the Opioid Overdose Epidemic?*, J. PUB. HEALTH MGMT. & PRAC. 5 (2019).

[250] *See, e.g.*, Neil Hunt, *A Review of the Evidence-Base for Harm Reduction Approaches to Drug Use*, FORWARD THINKING ON DRUGS A RELEASE INITIATIVE, https://www.hri.global/files/2010/05/31/HIVTop50Documents11.pdf [https://perma.cc/M3DZ-QHHU] ("In essence, harm reduction refers to policies and programmes that aim to reduce the harms associated with the use of drugs. A defining feature is their focus on the prevention of drug-related harm rather than the prevention of drug use *per se*."); *see also Trends in Harm Reduction and Substance Use in the U.S. Criminal Justice System*, VERA INST. OF JUST., https://www.vera.org/publications/new-normal-opioid-use-criminal-justice-system/new-normal-opioid-use-criminal-justice-system/trends-in-harm-reduction [https://perma.cc/Z4UA-32CD].

[251] *See Principles of Harm Reduction*, NAT'L HARM REDUCTION COAL., https://harmreduction.org/aboutus/principles-of-harm-reduction/ [https://perma.cc/G7QZ-4E35].

dealing, or crimes that are often related to drug addiction, such as fraud or acquisitive crime."[252]

Harm reduction measures frequently encounter strong objections from segments of the public and from law enforcement, who, with little evidence, either challenge the restriction on their freedom to engage in an activity or believe that by making an activity less dangerous the government will actually lead more people into risky behavior.[253] The first set of objections, restrictions on freedom, was addressed by courts across the country in response to laws requiring that motorcyclists wear helmets and that all occupants of cars wear seatbelts.[254] The second set of objections, the encouragement to engage in risky behavior, often comes up in debates about football helmets, with some arguing that wearing the helmet encourages more aggressive play.[255]

Objections to harm reduction measures for substance users fit squarely in the second category in that they are criticized as reducing barriers to drug use. But they go further than concern about unintended consequences or ineffectiveness. The objections to harm reduction measures for substance users are closer to those made against prevention of HIV/AIDS with condoms[256] or PrEP (pre-

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[252] Brendan J. Collins et al., *Assessing the Effectiveness and Cost-Effectiveness of Drug Intervention Programmes: UK Case Study*, 36 J. ADDICTIVE DISEASES 1, 3 (2016). For other examples of European harm reduction programs related to drug use, see generally Canadian Paediatric Society, *Harm Reduction: An Approach to Reducing Risky Health Behaviours in Adolescents*, 13 PAEDIATRICS & CHILD HEALTH 53 (2008).

[253] Rod Knight et al., *Complex and Conflicting Social Norms: Implications for Implementation of Future HIV Pre-Exposure Prophylaxis (PrEP) Interventions in Vancouver, Canada*, PLOS ONE 1 (2016) (studying the conflicting social views of PrEP from a convenient form of protection versus a means to encourage "socially unacceptable" behavior), https://doi.org/10.1371/journal.pone.0146513 [https://perma.cc/DDK2-Q8BJ].

[254] *See* Daniel Ackerman, *Before Face Masks, Americans Went to War Against Seat Belts*, BUS. INSIDER (May 26, 2020, 11:03 AM), https://www.businessinsider.com/when-americans-went-to-war-against-seat-belts-2020-5 [https://perma.cc/VB8D-HD2H]. These objections were also associated with a prevalent but now discredited belief that it was safer to be "thrown clear" of a car than be restrained in an accident. *See* Aaron Martin, *Auto Accident Folklore—Being Thrown Clear and Bracing for Impact*, PATCH (May 21, 2013, 12:23 AM), https://patch.com/iowa/ankeny/bp—auto-accident-folklore being-thrown-clear-and-brac0d1450cef3 [https://perma.cc/9BAN-N6RV].

[255] *See* Lane Wallace, *Do Sports Helmets Help or Hurt?*, ATLANTIC (Feb. 19, 2011), https://www.theatlantic.com/entertainment/archive/2011/02/do-sports-helmets-help-or-hurt/71407/ [https://perma.cc/VJU7-BU89]; *see also* Loren Grush, *How Football Helmets Fail to Protect Against Some of the Most Dangerous Hits in the Game*, VERGE (Feb. 5, 2016, 10:03 AM), https://www.theverge.com/2016/2/5/10919146/nfl-football-helmet-head-injuries-safety-protech-vicis [https://perma.cc/N4FG-GC3Q] (recounting arguments that football helmets give a false sense of security). For a comprehensive response to antihelmet laws, see *Our Response to Some Negative Views on Helmets*, BICYCLE HELMET SAFETY INST. (Mar. 22, 2021), https://www.helmets.org/negativs.htm [https://perma.cc/7YNX-AAAL].

[256] *See* Giuseppe Benagiano et al., *Condoms, HIV and the Roman Catholic Church*, 22 REPROD. BIOMEDICINE ONLINE 701, 701–02 (2011) ("'The Catholic Church has repeatedly criticized programs promoting condoms as a totally effective and sufficient means of AIDS prevention'. He went on to say that the widespread and indiscriminate promotion of condoms

exposure prophylaxis), a "medicine people at risk for HIV take to prevent getting HIV from sex or injection drug use."[257] They are also similar to arguments raised against providing birth control to teenagers in that they equate protection against consequences with encouragement of the activity itself.[258]

A. Reducing Deaths from Overdose

If reducing deaths is the top priority of a legislative strategy, then the first question to ask must be: how do people die from using drugs? The most frequently used term is "overdose" which the CDC defines as an "[i]njury to the body (poisoning) that happens when a drug is taken in excessive amounts."[259] This can be misleading, however, because it suggests that there is a safe dose for every drug. More helpful is a functional definition offered in a training manual developed by the Harm Reduction Coalition stating that "[o]verdose (OD) happens when a toxic amount of a drug, or combination of drugs overwhelms the body."[260] Opioids "affect the body's central nervous system, which slows breathing, blood pressure, and heart rate . . . ."[261] Therefore, an "overdose" of "opioids" is essentially a process whereby the brain can no longer "signal the body to breathe" and the person dies of oxygen deprivation.[262]

The difference between deaths caused by an "overdose" of the synthetic opioids that are mixed with drugs like heroin or cocaine and death caused by an "overdose" of less powerful prescription

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was immoral and a misguided weapon in the battle against HIV/AIDS. He gave several reasons: 'The use of condoms goes against human dignity. Condoms change the beautiful act of love into a selfish search for pleasure – while rejecting responsibility. Condoms do not guarantee protection against HIV/AIDS. Condoms may even be one of the main reasons for the spread of HIV/AIDS.'" (quoting Cardinal Alfonso López Trujillo, *Family Values Versus Safe Sex: A Reflection by His Eminence*, VATICAN (Dec. 1, 2003), https://www.vatican.va/roman_curia/pontifical_councils/family/documents/rc_pc_family_doc_20031201_family-values-safe-sex-trujillo_en.html [https://perma.cc/3764-3CAY]).

257 *PrEP (Pre-Exposure Prophylaxis) Basics*, CTRS. FOR DISEASE CONTROL AND PREVENTION (May 13, 2021), https://www.cdc.gov/hiv/basics/prep.html [https://perma.cc/56W3-QS24] ("When taken as prescribed, PrEP is highly effective for preventing HIV.").

258 Knight et al., *supra* note 253, at 5–8 ("Use of PrEP was often portrayed as being problematic because it was viewed as an 'excuse' from adherence to other risk-reduction practices and, therefore, it was also often viewed as contributing to 'high-risk' lifestyles. . . . [M]oral opinions and prejudicial understandings comprise important aspects of the implementation context that may influence the feasibility, fidelity and equitable reach of interventions such as PrEP.").

259 *Commonly Used Terms*, *supra* note 2.

260 Eliza Wheeler et al., *Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects*, HARM REDUCTION COAL. 9 (2012), https://harmreduction.org/wp-content/uploads/2020/08/Resource-OverdosePrevention-GuidetoDevelopingandManaging OverdosePreventionandTakeHomeNaloxoneProjects.pdf [https://perma.cc/NG6F-FPER].

261 *Id.*

262 *Id.*; *see* Merel Boom et al., *Non-Analgesic Effects of Opioids: Opioid-induced Respiratory Depression*, 18 CURRENT PHARM. DESIGN 5994, 59946004 (2012).

opioids is the speed at which this suffocation happens.[263] As the Harm Reduction's training manual explains, "[f]ortunately, this process is rarely instantaneous; most commonly, people will stop breathing slowly, minutes to hours after the drug or drugs [are] used."[264] So,

> [w]hile people have been "found dead with a needle in their arm," in most cases there is time to intervene between when an overdose starts and before a victim dies. Even in cases where a person experiences overdose immediately after taking a drug, proper response can reverse the overdose and keep the person breathing and alive.[265]

Another aspect to consider when tracking the deaths caused by an overdose of synthetic opioids is that some of these deaths are accidental while others are deliberate.[266]

1. Increasing the Availability of Naloxone: A Drug that Stops Overdose

The most direct approach to preventing death associated with opioid overdose is to administer an antidote that blocks its effect.[267] Long a staple in hospitals for emergency room physicians and anesthesiologists, naloxone was traditionally not available to the general public.[268] Now, thanks to aggressive lobbying by the public health community, all fifty states have made naloxone widely available outside the hospital setting.[269]

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[263] *Transcript of August 6, 2019, CDC Vital Signs: Naloxone*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 6, 2019), https://www.cdc.gov/media/releases/2019/t0806-naloxone.html [https://perma.cc/F6M3-ZVDQ] ("The increase in opioid-related overdoses has led to recent efforts, further expanding access to naloxone through pharmacies based on what we call 'co-prescribing.' To call attention to the importance of co-prescribing naloxone, last year the Surgeon General issued an advisory to raise awareness among providers and the public about naloxone, and last fall the Depart[ment] of Health and Human Services issued a guide for healthcare providers on naloxone prescribing.").

[264] Wheeler et al., *supra* note 260, at 9.

[265] *Id.*; *see also A Shared Approach to Preventing Opioid Overdoses*, CDC: PUBLIC HEALTH MATTERS BLOG (June 10, 2021), https://blogs.cdc.gov/publichealthmatters/2021/06/opioid-overdose/ [https://perma.cc/Q56M-Q8JJ] ("Naloxone is a life-saving drug that can reverse the effects of an opioid overdose when given in time. Naloxone can easily be injected into the thigh or given as a spray into the nose to save a life during an overdose. It can be given by anyone, even if they have no training for this kind of emergency." (footnote omitted)).

[266] Svetla Slavova et al., *Drug Overdose Surveillance Using Hospital Discharge Data*, 129 PUB. HEALTH REPS. 437, 441–42 (2014) ("[Thirty percent] of the drug overdose suicide attempts involved benzodiazepines, and the majority of the drug overdose hospitalizations were related to suicide attempt.").

[267] *The History of Naloxone*, CORDANT HEALTH SOLS. (July 5, 2017), https://cordantsolutions.com/the-history-of-naloxone/ [https://perma.cc/F49G-DEMX] (recounting the history of the development and use of naloxone).

[268] *See id.*

[269] *Legal Interventions to Reduce Overdose Mortality: Naloxone Access Laws*, THE NETWORK FOR PUB. HEALTH L. (2021), https://www.networkforphl.org/wp-content/uploads/2021/05/NAL-Final-4-29.pdf [https://perma.cc/97RC-D3FJ].

It can be administered by anyone without training either as an EpiPen-like injection or a nasal spray.[270] But the antidote is ineffective unless it is administered while the overdose is occurring.[271] Therefore, it is important that naloxone be available to individuals while they are experiencing the effects of overdose.[272]

2. Encouraging Quick Treatment of Overdose by Immunizing Helpers from Prosecution: Good Samaritan Laws

Another arsenal in the legal armory of harm reduction is the passage of Good Samaritan laws that encourage bystander intervention.[273] In order to be effective, naloxone needs to be administered quickly, but laws that place criminal responsibility on those who are with an individual when they overdose have long discouraged witnesses to seek help because of fear that they will be arrested.[274] As a result, some states have passed laws—called Good Samaritan laws—intended to shield those seeking to assist a person who intervenes with the intention of preventing another's death by cardiac arrest after ingesting drugs.[275] The purpose of Good Samaritan laws is to reduce unintentional overdose by

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[270] *Model Universal Access to Naloxone Act*, NAT'L ALL. FOR MODEL STATE DRUG L. 4 (2018), https://namsdl.org/wp-content/uploads/Model-Universal-Access-to-Naloxone-Act.pdf [https://perma.cc/YWE7-5VHM] ("Many opioid-related overdose deaths are preventable if naloxone, a U.S. Food and Drug Administration (FDA)-approved opioid overdose reversal medication, is readily available to, and carried by, all first responders and a greater number of other residents of [state].").

[271] This limitation has led to research in preventive medications that can immunize individuals from the effects of opioids. Madeline McCurry-Schmidt, *Heroin Vaccine Blocks Lethal Overdose*, SCRIPPS RSCH. (Feb. 16, 2018), https://www.scripps.edu/newsand-events/press-room/2018/20180213janda.html [https://perma.cc/WA4P-ETNV] ("The vaccine works by training the immune system antibodies to recognize and bind to heroin molecules, blocking the drug from reaching the brain to cause a 'high.' Researchers believe that blocking the high of heroin will help eliminate the motivation for many recovering addicts to relapse into drug use.").

[272] *See* Jeffrey A. Singer, *Harm Reduction: Shifting from a War on Drugs to a War on Drug-Related Death*, CATO INST. (Dec. 13, 2018), https://www.cato.org/policy-analysis/harm-reduction-shifting-war-drugs-war-drug-related-deaths [https://perma.cc/YL6V-SFLD].

[273] *See Drug Overdose Immunity and Good Samaritan Laws*, *supra* note 13 (noting that such laws have been passed "[t]o encourage people to seek out medical attention for an overdose or for follow-up care after naloxone has been administered").

[274] *See* Chloe Cockburn, *Criminalizing Drug Users Is Killing People*, ACLU (Feb. 12, 2014), https://www.aclu.org/blog/smart-justice/sentencing-reform/criminalizing-drug-users-killing-people [https://perma.cc/454D-626L] ("'Saving a life is far more important than making an arrest,' White House Drug Czar and former Seattle police chief R. Gil. Kerlikowske said at a press conference on Tuesday as he urged states and local communities to pass Good Samaritan laws."). Somewhat different are immunity laws that encourage those in physical proximity to someone experiencing an overdose to help rather than run away in fear of being arrested.

[275] *Id.*; *Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws*, *supra* note 269.

encouraging witnesses to get the victim medical help without fear that they too might be arrested.[276]

3. Reducing Death from All Drug Use by Detecting the Presence of Synthetic Opioids

Many of the people who are now dying after ingesting illegally manufactured synthetic opioids think they are taking something either less potent[277] or safer, such as an illegally diverted prescription opioid pill[278] or a drug that usually contains no opioids, like cocaine or a methamphetamine.[279] For example, while there are many harms associated with long term use of methamphetamine,[280] they do not usually include sudden

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[276] SAMHSA, PREVENTING THE CONSEQUENCES OF OPIOID OVERDOSE: UNDERSTANDING 911 GOOD SAMARITAN LAWS 1 (2017), https://mnprc.org/wp-content/uploads/2019/01/good-samaritan-law-tool.pdf [https://perma.cc/23EG-M4V3].

[277] For more information about the addition of powdered fentanyl to heroin, see *DEA Fact Sheet, Fentanyl*, *supra* note 235, which explains that "[f]entanyl is added to heroin to increase its potency, or be disguised as highly potent heroin. Many users believe that they are purchasing heroin and actually don't know that they are purchasing fentanyl – which often results in overdose deaths."

[278] 2019 NATIONAL DRUG THREAT ASSESSMENT, *supra* note 6, at 14–15 (explaining that "[f]entanyl traffickers use fentanyl powder and pill presses to produce pills that resemble popular prescription opioids" so that "[t]he inconsistent amount of fentanyl present in fentanyl-containing pills is another major contributor to pills' lethality"); *see* U.S. DRUG ENF'T ADMIN., DEA DRUG FACT SHEET, COUNTERFEIT PILLS, https://www.dea.gov/factsheets/counterfeit-pills [https://perma.cc/7V4D-DEHC] ("Counterfeit pills are fake medications that have different ingredients than the actual medication. They may contain no active ingredient, the wrong active ingredient, or have the right ingredient but in an incorrect quantity. Counterfeit pills may contain lethal amounts of fentanyl or methamphetamine and are extremely dangerous because they often appear identical to legitimate prescription pills, and the user is likely unaware of how lethal they can be."); *see also* DEA CHICAGO FIELD DIVISION, DEA-CHI-BUL-167-17, FAKE RX IN INDIANA: CARFENTANIL AND FENTANYL FOUND IN PURPORTED OXYCODONE PILLS 1 (2017), https://www.dea.gov/sites/default/files/2018-07/BUL-167-17%20Fake%20Rx%20in%20Indiana%20-%20UNCLASS.PDF [https://perma.cc/UWE7-XQQ3].

[279] *See* Mbabazi Kariisa et al., *Drug Overdose Deaths Involving Cocaine and Psychostimulants with Abuse Potential—United States, 2003–2017*, 68 MORBIDITY & MORTALITY WKLY. REP. 388, 388 (2019) (reporting that 14 percent of all drug overdose deaths in 2017 involved "psychostimulants" which include cocaine and methamphetamine and that this represented a 37 percent increase in psychostimulant associated deaths from 2016). For an example of the adulteration of cocaine with synthetic opioids, see DEA MIAMI FIELD DIVISION, DEA-MIA-BUL-039-18, DEADLY CONTAMINATED COCAINE WIDESPREAD IN FLORIDA 1 (2018), https://www.dea.gov/sites/default/files/2018-07/BUL-039-18.pdf [https://perma.cc/EH8V-49FT], noting that "[a] review of cocaine exhibits acquired by law enforcement authorities during operations across Florida and analyzed by forensic laboratories during the period from 2016 to 2017 revealed the widespread adulteration of cocaine with fentanyl and fentanyl-related substances" and that "[f]entanyl, a Schedule II opioid analgesic approximately 50 times more potent than heroin and 100 times more potent than morphine, carries a high risk of overdose and can be lethal at the 2-milligram range."

[280] *See Pseudoephedrine: Legal Efforts to Make It a Prescription-Only Drug*, CTRS. FOR DISEASE CONTROL & PREVENTION (2013), https://www.cdc.gov/phlp/docs/pseudo-brief112013.pdf [https://perma.cc/3T4G-GCT9] (summarizing federal, state, and local efforts to limit access to the main ingredient in methamphetamine).

death.[281] Yet in 2017, the CDC reported that "[a]mong 70,237 drug overdose deaths in 2017, nearly a third (23,139 [32.9%]) involved cocaine, psychostimulants, or both."[282]

The issue with the adulteration of synthetic opioids extends beyond products marketed as a form of opioid, either directly as fentanyl or heroin. The CDC attributes rising death rates from nonopioid-based drugs like cocaine and methamphetamine to their being adulterated with synthetic opioids.[283] The formulations of synthetic opioids, such as carfentanil, developed by those selling drugs outside the pharmaceutical chain of command, however, are as much as one hundred times more powerful than fentanyl.[284] Thus, even if a substance is described as "fentanyl," a product with which the user is familiar, it could actually be adulterated with a much more powerful synthetic opioid.[285] Thus, avoiding opioids does not reduce the risk because many other illegal drugs are also adulterated with synthetic opioids.[286]

There are two primary ways to inform people of the contents of the drugs they take. The first is to end the distinction between legal and illegal drugs, thereby tasking the FDA with inspection and quality control. The addition of a single subchapter to the FD&CA could create standards for production of opioids, methamphetamine, and any other drug now being produced illegally just as there are standards for prescription medications, tobacco, alcohol, baby food, milkshakes, and asthma inhalers. The other less-

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[281] Steve Lopez, *Meth Addiction Is an Epidemic, and It's Complicating the Homeless Relief Effort*, L.A. TIMES (June 29, 2019, 5:00 AM), https://www.latimes.com/local/california/la-me-lopez-meth-homeless-20190629-story.html (last visited Jan. 16, 2022).

[282] Kariisa et al., *supra* note 279, at 392–93; *see also DOJ Announces $42M to Combat Illegal Manufacture and Distribution of Methamphetamine and Opioids*, U.S. DEP'T OF JUST. (June 23, 2020), https://www.justice.gov/usao-edva/pr/doj-announces-42m-combat-illegal-manufacture-and-distribution-methamphetamine-and [https://perma.cc/2GBW-MH6L] (announcing a $42 million grant to combat illegal manufacture and distribution of methamphetamine and opioids in Virginia, the US Attorney's Office for the Eastern District of Virginia explained that "[i]llicitly produced fentanyl and fentanyl analogues like carfentanil and acetyl fentanyl are being trafficked at alarming rates on the streets of the Commonwealth. Pills bought on the street and on the dark web are often counterfeit and contain fentanyl or fentanyl analogues, often killing those unaware of the presence of these highly potent drugs.").

[283] *Drug Overdose: Synthetic Opioid Overdose*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 25, 2021), https://www.cdc.gov/drugoverdose/deaths/synthetic/index.html [https://perma.cc/HL2T-DPHZ].

[284] *DEA Issues Carfentanil Warning to Police and Public*, U.S. DRUG ENF'T ADMIN. (Sept. 2016), https://www.dea.gov/press-releases/2016/09/22/dea-issues-carfentanil-warning-police-and-public [https://perma.cc/DSU4-BS7J].

[285] Christopher M. Jones et al., *Changes in Synthetic Opioid Involvement in Drug Overdose Deaths in the United States*, 319 JAMA 1819 (2018) ("Lack of awareness about synthetic opioid potency, variability, availability, and increasing adulteration of the illicit drug supply poses substantial risks to individual and public health.").

[286] *Id.*

comprehensive solution is to increase the availability of testing strips that detect fentanyl in the drug supply. These are already widely available and very popular in Canada.[287]

4. Creating Safe Locations to Use Drugs

Another intervention intended to encourage quick treatment of overdoses is to create monitored locations where people can go to use drugs safely.[288] Called by a number of different names, such as "overdose prevention centers" or "safer consumption spaces," they operate in ten European countries[289] and have become increasingly popular in Canada.[290] This allows for immediate administration of naloxone at the first sign of overdose.[291] Often called "safe injection sites," efforts in the United States to establish safe locations for drug use have been met with considerable opposition.[292] Many of the objections are based on a preference for stopping drug use rather than making it safer. For example, in an op-ed in the *New York Times*, then Deputy Attorney General Rod Rosenstein argued that safe injection sites "create serious public safety risks," "normalize drug use and facilitate addiction," and do not help people who use opioids (PWUO) to stop using.[293]

In contrast, a 2017 report from a group of Catholic ethicists endorsed a "safe injection site" for people who inject drugs (PWID) on the grounds that it would both decrease

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[287] *See* Randy Dotinga, *Take-home Test Strips Allow Drug Users to Detect Fentanyl*, MEDSCAPE (July 3, 2020), https://www.medscape.com/viewarticle/933389 [https://perma.cc/BAP9-T5ZF].

[288] *See* Beau Kilmer et al., *Considering Heroin-Assisted Treatment and Supervised Drug Consumption Sites in the United States*, RAND CORP., 5, 14–17 (2018), https://www.rand.org/pubs/research_reports/RR2693.html [https://perma.cc/JCB7-FXEK] (recommending implementing safe consumption sites in the United States and providing an overview of how other countries are using safe consumption sites); *see also Syringe Services Programs (SSPs) Fact Sheet*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 2019), https://www.cdc.gov/ssp/docs/SSP-FactSheet.pdf [https://perma.cc/ZL6Q-NCD5].

[289] *Overdose Prevention Centers*, DRUG POL'Y ALL. (Jan. 2019), https://drugpolicy.org/sites/default/files/overdose-prevention-centers_0.pdf [https://perma.cc/US2X-4GCR].

[290] *See* Elana Gordon, *What's the Evidence That Supervised Drug Injection Sites Save Lives?*, NPR (Sept. 7 2018, 2:40 PM), https://www.npr.org/sections/health-shots/2018/09/07/645609248/whats-the-evidence-that-supervised-drug-injection-sites-save-lives [https://perma.cc/2LKA-S3WE]; Thomas Kerr et al., *Supervised Injection Facilities in Canada: Past, Present, and Future*, 14 HARM REDUCTION J. 1, 1 (2017).

[291] *See* Mike Ludwig, *Sanders and Warren Back Legalization of Injection Sites for Drug Users*, TRUTHOUT (Aug. 29, 2019), https://truthout.org/articles/sanders-and-warren-back-legalization-of-injection-sites-for-drug-users/ [https://perma.cc/N2SP-GX4P].

[292] Rod J. Rosenstein, *Fight Drug Abuse, Don't Subsidize It*, N.Y. TIMES (Aug. 27, 2018), https://www.nytimes.com/2018/08/27/opinion/opioids-heroin-injection-sites.html [https://perma.cc/933R-GXW3]; Gordon, *supra* note 290.

[293] Rosenstein, *supra* note 292; *see also* Kilmer et al., *supra* note 288, at 7.

harms associated with opioid use and create an environment where people would be "treated with respect and dignity."[294]

B. Reducing Death from the Extended Consequences of Using Opioids

1. Combatting Infection and Disease Associated with Injecting Drugs

Not all deaths associated with opioid use occur immediately after ingestion. The CDC reports that the "increase in substance use" attributable to synthetic opioids has also "resulted in concomitant increases in injection drug use" which "cause[] not only largely increases in overdose deaths" but also result in cases of potentially lethal blood borne pathogens, leading to a substantial increase in cases of viral hepatitis and HIV infection.[295] The primary interests in the health of those who used unsterile needles to inject themselves with substances stemmed from what, at the time, seemed like the unprecedented proliferation of death from HIV.[296] Even then, the solution to this form of transmission was well known and widely available.[297] Yet the path to providing clean needles is blocked by laws intended to reduce drug use by criminalizing the possession of "drug paraphernalia."[298]

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[294] Carol Bayley et al., *Assessing the Ethical Issues in "Safe Injection" Sites*, HEALTH CARE ETHICS USA, Fall 2017, at 21, 22.

[295] *Summary of Information on the Safety and Effectiveness of Syringe Service Programs (SSPS)*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 23, 2019), https://www.cdc.gov/ssp/syringe-services-programs-summary.html [https://perma.cc/R84E-UH6G] (describing the increase in HIV cases as "threatening recent progress made in HIV prevention"). Viral hepatitis, HIV, and other blood-borne pathogens can spread through injection drug use if people use needles, syringes, or other injection materials that were previously used by someone who had one of these infections. *Id.* "Injecting drugs can also lead to other serious health problems, such as skin infections, abscesses and endocarditis." *Id.*; John E. Zibbell et al., *Increases in Acute Hepatitis C Virus Infection Related to a Growing Opioid Epidemic and Associated Injection Drug Use, United States, 2004 to 2014*, 108 AM J. PUB. HEALTH 175, 175 (2018).

[296] *Defining and Implementing a Public Health Response*, *supra* note 152; *see also* Gostin, *supra* note 126.

[297] *See* Tessie Castillo, *Drug Paraphernalia Laws: The "Swiss Army Knife" of the Drug War*, FILTER (Apr. 4, 2019), https://filtermag.org/drug-paraphernalia-laws-the-swiss-army-knife-of-the-drug-war/ [https://perma.cc/7J6B-HNZN]; *see also* Kristina T. Phillips, *Barriers to Practicing Risk Reduction Strategies Among People Who Inject Drugs*, 24 ADDICTION RSCH. & THEORY 62 (2016).

[298] Courts have interpreted "paraphernalia" broadly. The Eighth Circuit upheld a conviction based on labeling a sock as "drug paraphernalia." *See* Mellouli v. Holder, 719 F.3d 995, 998 n.2 (8th Cir. 2013) ("[I]t seems surprising to call a sock 'drug paraphernalia,' but using a sock to store and conceal a controlled substance falls within the [Kansas] statute's literal prohibition."), *rev'd sub nom.* Mellouli v. Lynch, 575 U.S. 798 (2015); *see also* Kevin Johnson, *Argument Preview: Removal for a Misdemeanor "Drug Paraphernalia" Conviction*, SCOTUSBLOG (Jan. 2, 2015),

In addition to facilitating access to clean needles, there are other safe alternatives that help prevent infections from reusing needles. A study conducted at Beth Israel Medical Center in New York found that among a population of drug users, "[i]ntranasal use of heroin and intranasal use of speedball were both significantly associated with lower [hepatitis C virus] prevalence."[299] These results were so positive that the researchers recommended further research on transitioning injection drug users to "non-injecting drug use."[300]

2. Expanding Access to Healthcare, Including Mental Health

While seeking pain control is not the primary cause of opioid-associated harms, a public health approach to reducing the need for synthetic opioids to control pain would involve focusing on preventing and treating the conditions that cause pain by increasing access to healthcare across the life span. This includes both directly addressing the causes of physical pain from accidents or chronic conditions like arthritis and making mental healthcare available to those seeking to manage painful conditions.[301] Even for those aware of the problems of stigma, substance use is often separated from other forms of mental illness.[302] For example, speaking at an event, "former Rep. Patrick J. Kennedy, founder of The Kennedy Forum and former member of the President's Commission on Combatting Drug Addiction and the Opioid Crisis,", stated, "[t]hose with mental health and substance use disorders currently face a separate and unequal system of care in this country."[303]

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https://www.scotusblog.com/2015/01/argument-preview-removal-for-a-misdemeanor-drug-paraphernalia-conviction/ [https://perma.cc/3N4J-XJQ6]. However, this conviction was held insufficient to trigger deportation. *Mellouli*, 575 U.S. at 813.

[299] Don C. Des Jarlais et al., *Can Intranasal Drug Use Reduce HCV Infection Among Injecting Drug Users*, 119 DRUG & ALCOHOL DEPENDENCE 201, 202 (2011).

[300] *Id*.

[301] Ilana Marcus, *Time Is Running Out for Federally Funded Mental-Health Clinics*, WASH. POST (Dec. 27, 2018), https://www.washingtonpost.com/national/health-science/time-is-running-out-for-federally-funded-mental-health-clinics/2018/12/26/1186b35c-fd0c-11e8-862a-b6a6f3ce8199_story.html [https://perma.cc/P94M-8EMR].

[302] Robert Preidt, *Drug Addiction Seen as 'Moral Failing,' Survey Finds*, HEALTHDAY (Oct. 3, 2014), https://www.medicinenet.com/script/main/art.asp?articlekey=184399 [https://perma.cc/AYP7-LELH].

[303] Joann Donnellan, *New Report Identifies Barriers and Policy Options to Integrating Clinical and Mental Health*, BIPARTISAN POL'Y CTR. (Jan. 24, 2019), https://bipartisanpolicy.org/press-release/new-report-identifies-barriers-and-policy-options-to-integrating-clinical-and-mental-health/ [https://perma.cc/DU87-R8CQ] ("Diseases of the brain can and must be treated on par with diseases of the body, such as diabetes and cancer, using evidence-based approaches. There is no health without mental health . . . .").

3. Treating Factors that Cause Drug Dependence

The current scientific understanding of drug dependence describes it as a process that "involves complex, gradual, and enduring changes in the brain's reward circuits and control centers."[304] An increase in the use of psychoactive substances that affect the brain in ways that its users perceive as pleasurable is a global phenomenon.[305]

Laws that limit the supply of prescription synthetic opioids have reduced the number of prescriptions but have reduced neither drug use nor deaths associated with drug use. While the description of the condition of wanting to use substances varies, the United Nations General Assembly has described

> "drug addiction as a complex multifactorial health disorder characterized by chronic and relapsing nature" that is preventable and treatable and not the result of moral failure or a criminal behavior. Historically, most nations' strategies for addressing substance use disorders have centered on punishment, and thus recognition of the need to shift from a criminal justice to a public health approach represent a major shift in mentality by United Nations Member States.[306]

Therefore, a legal response to drug dependence should start with an understanding of what factors cause dependence and how they can be prevented. This may be called a "demand" rather than "supply" approach in that reducing demand for opioids reduces the risk of dependence. Like most serious problems, though, there is no one factor that causes dependence. Research strongly supports what was long suspected: susceptibility to dependence and the extent of dependence

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[304] Jeanette Kennett et al., *Drug Addiction and Criminal Responsibility*, *in* HANDBOOK OF NEUROETHICS 1065, 1067 (Jens Clausen & Neil Levy eds., 2015) ("[D]rug addiction involves complex, gradual, and enduring changes in the brain's reward circuits and control centers. These occur because certain drugs stimulate the release of excessive quantities of the neurotransmitter dopamine. These changes prioritize drug use and sensitize drug users to drug use cues, in effect giving rise to strong and persistent urges to seek out and use these drugs. They also reduce drug users' ability to exercise cognitive control over those urges.").

[305] *See Drugs (Psychoactive)*, WORLD HEALTH ORG., https://www.who.int/health-topics/drugs-psychoactive [https://perma.cc/Y9BA-NMPD] ("Psychoactive drugs are substances that, when taken in or administered into one's system, affect mental processes, e.g. perception, consciousness, cognition or mood and emotions. Psychoactive drugs belong to a broader category of psychoactive substances that include also alcohol and nicotine. 'Psychoactive' does not necessarily imply dependence-producing, and in common parlance, the term is often left unstated, as in 'drug use,' 'substance use' or 'substance abuse.'").

[306] Volkow, *supra* note 59, at 213 (quoting the Outcome Document of 2016 the United Nations General Assembly Special Session on Drugs).

differs according to genetic makeup.[307] Some people are physiologically less affected than others.

4. Treating Drug Dependence Once It Occurs by Increasing Access to MAT

In addition to the interventions designed to mitigate the consequences of a single lethal dose of an opioid, there are also safe and effective medical interventions that reduce the cravings which lead people to inject or ingest drugs that, by the composition or qualities of the drugs, put them at risk of immediate death.[308] MAT targets receptors for opioids in the brain and eliminates the craving for opioids without producing euphoria or clouding the memory or judgment of the individual.[309] Reporting on the result of a national study of 40,885 people diagnosed with opioid use disorder, one research team found a "76% reduction in overdose at 3 months and a 59% reduction in overdose at 12 months" in contrast to a comparable population who were not treated with medication for opioid use disorder (MOUD).[310] Based on these results, the team concluded that MOUD "is effective and improves mortality, treatment retention, and remission."[311]

As the National Institute on Drug Abuse explains, MOUD is effective because "[a]lthough it occupies and activates" "the same receptors that other opioids such as heroin, morphine, and opioid pain medications activate . . . it does so more slowly."[312] In Europe, at least 50 percent of individuals with an addiction to opioids receive pharmacological therapy, buprenorphine or methadone, in outpatient settings.[313]

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[307] *See Genetics and Epigenetics of Addiction DrugFacts*, NIH NAT'L INST. ON DRUG ABUSE 2–6 (Aug. 2019), https://www.drugabuse.gov/download/20362/genetics-epigenetics-addiction-drugfacts.pdf [https://perma.cc/RTK8-S464].

[308] Sarah E. Wakeman et al., *Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder*, JAMA NETWORK OPEN 1, 1–2 (2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2760032 [https://perma.cc/LXK7-GNM2].

[309] Paul N. Samuels, *Confronting an Epidemic: The Case for Eliminating Barriers to Medication-Assisted Treatment of Heroin and Opioid Addiction*, LEGAL ACTION CTR. (Mar. 11, 2015), https://www.lac.org/resource/confronting-an-epidemic-the-case-for-eliminating-barriers-to-medicationassisted-treatment-of-heroin-and-opioid-addiction [https://perma.cc/989G-RNRP]; *see also* Georgi Vasilev et al., *Opioid Use in the Twenty First Century: Similarities and Differences Across National Borders*, 3 CURRENT TREATMENT OPTIONS PSYCHIATRY 293, 293–305 (2016).

[310] Wakeman et al., *supra* note 308, at 8.

[311] *Id*. at 2.

[312] NIH NAT'L INST. ON DRUG ABUSE, MEDICATIONS TO TREAT OPIOID USE DISORDER RESEARCH REPORT 1, 3 (Dec. 2021), https://www.drugabuse.gov/download/21349/medications-to-treat-opioid-use-disorder-researchreport.pdf [https://perma.cc/45FP-DPB9].

[313] *Tackling Opioid Dependence*, EUR. MONITORING CTR. FOR DRUGS & DRUG ADDICTION, http://www.emcdda.europa.eu/best-practice/briefings/tackling-opioid-dependence_en [https://perma.cc/XBB8-F6ZJ]; *see also* Zachary Siegel, *Europe's Solution to the Drug Crisis*

Those seeking treatment for drug dependence face both general barriers to accessing healthcare in the United States, such as lack of insurance,[314] and specific barriers to accessing treatment for substance use, such as laws that limit the availability of MAT.[315] This difficulty in accessing treatment for opioid dependence is in stark contrast to the accessibility of medications intended to aid in smoking cessation.[316] Not only do only a small percentage of people who would benefit from MAT receive it, most people in the United States do not even know that it exists.[317]

Increasing access to MAT requires more than just rescinding the laws that created legal barriers to its use. There is a considerable misinformation about the process of "detoxification" based on the moral views about "substituting one drug for another"[318] or due to the financial interests of residential drug treatment facilities which have benefitted from state decisions to use existing civil commitment laws to mandate forced inpatient "detox."[319] Not only does the complete withdrawal from opioids by people who have become dependent cause physical pain, there is strong evidence that it is completely ineffective as a long-term treatment.[320]

Even if substance users can afford treatment, it is still difficult to find.[321] This is due to laws that restrict the ability of

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Is Working. Why Won't America Follow It?, QUARTZ (Jan. 18, 2018), https://qz.com/1181957/europes-solution-to-the-drug-crisis-is-working-why-wont-america-follow-it [https://perma.cc/D3LT-J6XF].

[314] *See Barriers to Preventing and Treating Substance Use Disorders in Rural Communities*, RURAL HEALTH INFO. HUB (Nov. 23, 2020), https://www.ruralhealthinfo.org/toolkits/substance-abuse/1/barriers [https://perma.cc/XME9-BUL9].

[315] *See* Samuels, *supra* note 309.

[316] Nicotine replacement therapy has long been freely available without a prescription. *See* Saul Shiffman & Christine T. Sweeney, *Ten Years After the Rx-to-OTC Switch of Nicotine Replacement Therapy: What Have We Learned About the Benefits and Risks of Non-prescription Availability?*, 86 HEALTH POL'Y 17, 22 (2008).

[317] *Why Aren't More People with Opioid Use Disorder Getting Buprenorphine?*, *supra* note 159 (noting that although an estimated two million Americans are living with the diagnosis of "Opioid Use Disorder (OUD)" and there are three drugs available that counter the effects of drug craving, few Americans are receiving prescriptions for them).

[318] Stacy Mosel, *Medication Assisted Treatment (MAT): Find MAT Treatment Near Me, Misconceptions About MAT*, AM. ADDICTION CTRS. (Nov. 19, 2021), https://americanaddictioncenters.org/addiction-medications [https://perma.cc/RVZ8-7XNP]; German Lopez, *There's a Highly Successful Treatment for Opioid Addiction. But Stigma Is Holding It Back.*, VOX (Nov. 15, 2017, 2:25 PM), https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone (last visited Feb. 5, 2022).

[319] *See* Philip Marcelo, *In the Addiction Battle, Is Forced Rehab the Solution?*, AP NEWS (May 23, 2018), www.apnews.com/75a4822a714b43a5b6f7b7b988d641f6 (last visited Feb. 5, 2022).

[320] *Id.*

[321] Rebecca Haffajee, *Fight the Urge to Criminalize Opioid Addiction Behaviors*, HEALTH AFFS. BLOG (Mar. 9, 2016), https://www.healthaffairs.org/do/10.1377/hblog20160309.053806/full [https://perma.cc/EY5K-399P] ("The problem with criminalizing opioid addiction is

physicians to easily prescribe MAT and societal prejudices against using drugs. As one provider explained, "[c]linicians and their patients are often bound by the same unscientific, shaming beliefs about substance misuse; these beliefs create barriers to treatment."[322] For example, the Drug Addiction Treatment Act of 2000 requires that healthcare providers receive both additional training and DEA permission before they can prescribe the drug outside of a hospital.[323] This is called receiving an X-Waiver.[324] There are also burdens associated with funding MAT. Many insurance companies require preauthorization which is "almost impossible" to complete in an emergency room setting.[325]

Another barrier to MAT comes in the form of the judicially imposed condition requiring individuals to be "drug free" for the purposes of being granted bail, probation, or child custody. These bans often include MAT, even when legally prescribed by a physician.[326] Thus, even if an individual can afford MAT and can find a physician willing to prescribe it, because MAT is itself an opioid derivative, many of the criminal laws intended to prevent the use of opioids extend to use of MAT. For example, special courts for individuals arrested for drug related offenses (Drug Courts),[327] although described as

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that little moral culpability attaches to individuals who got an opioid prescription (or accessed one second-hand) and had a predisposition to compulsively use these drugs. Locking up opioid addicts seems to achieve little (other than to overcrowd our prisons) and fails to comport with the purposes underlying criminal punishment. These individuals are not 'deserving' of punishment because they likely cannot control their addiction behaviors, nor are they typically violent or rational criminals who must be incapacitated or prevented from committing future harm.").

322 Robert A. Matano & Stanley F. Wanat, *Addiction Is a Treatable Disease, Not a Moral Failing*, 172 W. J. MED. 63, 63 (2000).

323 *Why Aren't More People with Opioid Use Disorder Getting Buprenorphine?*, *supra* note 159.

324 *Id.* ("Without question, the X-waiver—which allows physicians to prescribe buprenorphine for OUD only after completing eight hours of training and obtaining a special license from the DEA— is the biggest hindrance to treatment. For doctors who maybe don't want to treat patients with OUD, it's easy to use the waiver requirement as a way out. But even motivated prescribers face limitations.").

325 *Id.* ("We have a perfect opportunity to reach patients where they are—in our emergency departments, when they have experienced an overdose, when they are in withdrawal, and when they are often desperately seeking help. We can initiate OUD treatment with buprenorphine. But the need for prior authorization can stop me dead in my tracks. Just try to complete a prior authorization request in the middle of the night; it's almost impossible."); *see also* Alison Kodjak, *In Midst of Opioid Crisis, FDA May Block New Addiction Drug from Market*, NPR (May 12, 2019, 12:12 PM), https://www.npr.org/sections/health-shots/2019/05/24/722076165/inmidst-of-opioid-crisis-fda-may-block-new-addiction-drug-from-market [https://perma.cc/B4AU-4KBR].

326 Samuels, *supra* note 315.

327 For more information on drug courts, see *Overview of Drug Courts*, NAT'L INST. OF JUST. (July 22, 2020), https://www.nij.gov/topics/courts/drug-courts/Pages/welcome.aspx [https://perma.cc/N4BY-NSGG]; and Miranda Gottlieb, *3 Barriers to Medication-Assisted Treatment for Drug Court Participants and How They Can Be Overcome*, INST. FOR RSCH., EDUC., & TRAINING IN ADDICTIONS (May 9, 2017),

alternatives to punishment and a gateway to treatment, "require[] [participants] to abstain from substance use,"[328] and effectively ban the use of MAT.[329] This is justified by a "mission . . . to stop the abuse of alcohol and other drugs and related criminal activity,"[330] rather than to reduce harm to the individuals who use drugs. This is despite a claim by the US Department of Health and Human Services that drug courts are intended to help "participants recover from use disorder with the aim of reducing further criminal activity"[331] and another by the National Institute of Justice that "[u]ltimately, drug court programs are designed to rehabilitate drug offenders and teach accountability."[332] Finally, MAT is also often inaccessible to individuals in regulated industries, such as law and medicine, which still cling to a "drug free" ideal.[333]

CONCLUSION

Synthetic opioids, first developed as a more effective method of treating pain, have become the leading cause of drug-associated deaths in the United States. Over the past twenty-five years, legislative efforts to combat these deaths have failed to keep pace with the rapid development of a secondary market that first diverted, then illegally manufactured, synthetic opioids. As a result, the leading cause of drug-related deaths in the United States today are deaths associated with synthetic opioids. But instead of prioritizing a reduction in death and other harms associated with opioid use, these laws have succeeded only in the reduction of prescriptions for synthetic opioids. Thus, not only are deaths continuing to rise, but these laws have also made life so difficult for the patients who rely on

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https://ireta.org/3-barriers-to-medication-assisted-treatment-for-drug-court-participants-and-how-they-can-be-overcome/ [https://perma.cc/2VXM-VDNS].

328 *What Are Drug Courts?*, HHS.GOV (May 15, 2020), https://www.hhs.gov/opioids/treatment/drug-courts/index.html [https://perma.cc/CQ2C-2KX4].

329 Barbara Fedders, *Opioid Policing*, 94 IND. L.J. 389, 438–39 (2019) (arguing that while programs that divert individuals using substances and provide pathways to resources like medical care and housing have some "promising results," they still "remain[] firmly within the contours of the contemporary carceral state" in that they continue to frame drug use as a criminal activity and emphasizing that, "[n]otwithstanding their comparatively benevolent intentions, each of the two forms of opioid policing functions to expand police surveillance").

330 BUREAU OF JUST. ASSISTANCE, DEFINING DRUG COURTS: THE KEY COMPONENTS 1 (1997), https://www.ncjrs.gov/pdffiles1/bja/205621.pdf [https://perma.cc/HL23-R2GF].

331 *What Are Drug Courts?*, *supra* note 328.

332 *Adult Drug Courts*, NAT'L INST. OF JUST., https://www.crimesolutions.gov/PracticeDetails.aspx?ID=7 [https://perma.cc/HNV7-NRQD].

333 Robert D. Ashford et al., *Systemic Barriers in Substance Use Disorder Treatment: A Prospective Qualitative Study of Professionals in the Field*, 189 DRUG & ALCOHOL DEPENDENCE 62, 63 (2018).

opioids for pain relief that many have even turned to suicide. This spectacular failure of legislation to address a public health crisis should be frightening enough to spur a reappraisal of not only the nation's drug policy, but more generally of the dangers of a lawmaking scheme with no attachment to evidence-based methods of crafting effective public health policy.

While many involved in lawmaking pay lip service to using "public health methods" in combating the "opioid crisis," there is still no meaningful integration of public health and lawmaking, or even any serious attempt to mandate measurable markers of success for new legislation. In particular, the lack of a mechanism for reevaluating legislation based on predetermined metrics of success means that once passed, laws remain in effect until they have caused so much harm that public outcry demands their repeal. And even if that public outcry does happen, there remains no mechanism for appropriate replacement. Public health methodology is certainly neither a panacea nor infallible. As we have seen in the response to COVID-19, it is not always possible to get enough information fast enough to make the right decisions. But integrating public health methodology into lawmaking could give the people of the United States something that many other countries already have: an effective infrastructure for crafting legislation to address public health threats based on the best available scientific information and a mechanism to continuously monitor the effects of the legislation so that it can be revised or withdrawn before causing more harm than good. Unless the goal of the war on synthetic opioids was to impose treatable intractable pain on those who suffered through injury or illness, it is the most bitter of victories.