
YALE LAW & POLICY REVIEW

The Prescription Abuse Prevention Act: A New Federal Statute to Criminalize Overprescribing Opioids

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The United States is experiencing an epidemic of opioid abuse and overdose deaths. In addition to the hundreds of thousands of lives lost, the opioid epidemic has shattered local communities, overwhelmed the health care system, and devastated families across the country in ways that will have profound effects for multiple generations of Americans. Even now, an average of 130 people die every day from an opioid overdose, making it a leading cause of injury-related death in the United States. Seventy percent of those deaths involve an opioid that a doctor legally prescribed and the COVID-19 pandemic has only made the opioid epidemic worse.

Amidst this national crisis, there is a growing sense that those responsible for the epidemic—specifically doctors who overprescribe these drugs—are not being held accountable. In the last decade, criminal charges against doctors have numbered only in the few hundred nationwide. Given the increasing number of opioid overdose deaths nationally, why are charges and convictions of doctors so rare and why have existing legal mechanisms failed to punish the improper prescribing practices? This Article argues that the problem of overprescribing opioids persists because the existing federal law in this area is unclear and lacks uniform application among the states. Additionally, it is the first Article in legal scholarship to offer a concrete solution rooted in common sense and federal criminal law. Specifically, the Article recommends the adoption of a new federal criminal statute aimed directly at those doctors who knowingly violate acceptable health care norms in prescribing opioids. Not only will the novel federal homicide law proposed

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here deter and punish physicians whose reckless prescription practices cause their patients' deaths, but it will also provide clarity to doctors engaged in legitimate pain management practices.

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INTRODUCTION

The United States is experiencing an epidemic of opioid abuse and overdose deaths. From 1999 to 2016, drug overdose deaths per year more than tripled.¹ An analysis of the Centers for Disease Control’s (CDC) 2018 drug overdose data shows that the overdose epidemic in the United States is spreading geographically and increasing across all demographic groups; deaths increased for men and women, ages 15 and older, all races and ethnicities, and across all levels of income and urbanization.² As of July 2018, drug overdoses killed approximately 130 people every day in the United States, and nearly two-thirds of these deaths involved a prescribed or illicit opioid.³ In addition to the lives lost, the opioid epidemic also has significant financial and societal costs. It has shattered communities, overwhelmed the health care system, and devastated families across the country in ways that will have profound effects across multiple generations

1. Holly Hedegaard et al., *Drugs Most Frequently Involved in Drug Overdose Deaths: United States, 2011-2016*, 67 NAT’L VITAL STAT. REP. 9, (Dec. 12, 2018), https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_09-508.pdf [<https://perma.cc/D8XV-HPNV>].
2. Lawrence Scholl et al., *Drug and Opioid-Involved Overdose Deaths – United States, 2013-2017*, 67 MORBIDITY & MORTALITY WKLY. REP. 1419 (2019), https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w#suggestedcitation [<https://perma.cc/E9ZG-EQRA>]; *Drug Overdose Deaths*, CDC, <https://www.cdc.gov/drugoverdose/data/statedeaths.html> [<https://perma.cc/W72N-SHUT>].
3. *Benzodiazepines and Opioids*, NAT’L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/drug-topics/opioids/benzodiazepines-opioids#Reference> [<https://perma.cc/7K8D-3497>]. The number of opioid prescriptions dispensed by doctors steadily increased from 112 million prescriptions in 1992 to a peak of 282 million in 2012; the number of prescriptions dispensed has since declined slightly, falling to 236 million in 2016. *Drug and Opioid-Involved Overdose Deaths – United States, 2013-2017*, CDC, https://www.cdc.gov/mmwr/volumes/67/wr/mm675152e1.htm?s_cid=mm675152e1_w [<https://perma.cc/TRV3-WQX9>].

of Americans. The arrival of the coronavirus disease 2019 (COVID-19) pandemic has produced an unanticipated and tragic surge in the opioid epidemic. Nationwide, authorities report an increase in fatal opioid overdoses since the spring of 2020.⁴

There is a growing sense that those responsible for instigating the opioid crisis—drug companies and doctors who prescribe these drugs—are not being held accountable.⁵ Although some pharmaceutical companies and pharmacies have faced civil litigation⁶ and criminal exposure⁷ for their conduct in contributing to the opioid epidemic, prescribers have not experienced much scrutiny. In fact, in the last decade, arrests and criminal

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4. Megan Brooks, *US Drug Overdose Deaths Hit a Record High*, *CDC Reports*, MEDSCAPE MED. NEWS (Dec. 18, 2020), <https://www.medscape.com/viewarticle/942917> [<https://perma.cc/XWV9-CHAN>]; Marc Zarefsky, *As COVID-19 Surges, AMA Sounds Alarm on Nation's Overdose Epidemic*, *AMA* (Dec. 14, 2020), <https://www.ama-assn.org/delivering-care/opioids/covid-19-surges-ama-sounds-alarm-nation-s-overdose-epidemic> [<https://perma.cc/67Z6-4XNR>].
 5. Ronald Hirsch, *The Opioid Epidemic: It's Time to Place Blame Where It Belongs*, 114 *MO. MED.* 82 (2017).
 6. More than a dozen pharmaceutical companies and pharmacies are the named defendants in the National Prescription Opiate Litigation, which has consolidated thousands of civil lawsuits pending against opioid manufacturers, distributors, and pharmacies across the United States. *See In re National Prescription Opiate Litigation*, No. 1:17-MD-2804-DAP N.D. Ohio <https://www.ohnd.uscourts.gov/mdl-2804> [<https://perma.cc/SZW6-CYH2>]. The plaintiffs are more than 2,500 state governments, local governments, native tribes, and individuals who are seeking relief for the defendants' role in creating, perpetuating, and profiting from the opioid epidemic. *Id.*; *see also* Sammy Almashat et al., *Twenty-Seven Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2017*, *PUB. CITIZEN* (Mar. 14, 2018), <https://www.citizen.org/wp-content/uploads/2408.pdf> [<https://perma.cc/XLN5-724Y>] (documenting the number and size of criminal and civil settlements and court judgments reached between the federal and state governments and pharmaceutical manufacturers between 1991 through 2017).
 7. *See e.g.*, *United States v. Purdue Fredrick Co.*, 495 F. Supp. 2d 569, 572 (W.D. Va. 2007); Gabrielle Emanuel & Katie Thomas, *Top Executives of Insys, an Opioid Company, Are Found Guilty of Racketeering*, *N.Y. TIMES* (May 2, 2019), <https://www.nytimes.com/2019/05/02/health/insys-trial-verdict-kapoor.html> [<https://perma.cc/FHM2-YX3C>].

charges brought against doctors at both the state and federal level have numbered only in the few hundred.⁸ A disparity exists between the size of the opioid epidemic and the number of people, specifically doctors, who have been disciplined or criminally charged for prescribing these dangerously addictive drugs. Although it is not unusual for a physician to face civil liability for the death of a patient,⁹ it is still exceptional for medical practitioners to face criminal charges for the overdose deaths of patients.¹⁰

One case, however, stands out. On December 14, 2018, the California Court of Appeal affirmed the judgment and conviction of Dr. Hsiu-Ying Tseng, who was sentenced to thirty-years-to-life in prison after a jury found her guilty under California law of second-degree murder for three patient drug overdose deaths.¹¹ Dr. Tseng's prescriptions of high-quantity, high-dose opioids played a role in almost a dozen overdose deaths of her patients.¹² Even after repeated warnings that her patients fatally overdosed on their medication, Dr. Tseng continued to issue prescriptions to hundreds of patients a week.¹³ Her case marked the *first* time in American history that a physician was held criminally liable for the *implied malice murder* of a patient using extreme recklessness in opioid prescribing. Accordingly, *People v. Tseng* serves as an important case study and anomaly, not because

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8. *Criminal Cases Against Doctors*, U.S. DEP'T OF JUST., https://www.deadiversion.usdoj.gov/crim_admin_actions/index.html [<https://perma.cc/Y76C-3MLW>].
 9. See National Practitioner Data Bank, U.S. DEP'T HEALTH & HUMAN SERVICES (Sept. 10, 2020), <https://www.npdb.hrsa.gov/enews/Mar2019Insights.jsp> [<https://perma.cc/Z9X8-QYUE>] (reporting that between 1990 and 2018 more than 453,000 medical malpractice payments, 989,000 adverse actions, and 34,000 judgments had been filed against medical providers).
 10. See Arielle Dollinger & Mihir Zaveri, *Doctor Who Prescribed Pain Pills Is Charged With 5 Counts of Murder*, N.Y. TIMES (Mar. 5, 2021), <https://www.nytimes.com/2021/03/05/nyregion/george-blatti-overdose-deaths.html> [<https://perma.cc/9FTQ-EFZ7>] (discussing the historical infrequency of criminal charges for overprescribing doctors); see also Y. Tony Yang & Rebecca L. Haffajee, *Murder Liability for Prescribing Opioids: A Way Forward?*, 91 MAYO CLINIC 1331-33 (2016) (surveying criminal cases against doctors for overprescribing opioids and recommending a holistic response including clinical prevention measures).
 11. *People v. Tseng*, 241 Cal. Rptr. 3d 194 (Ct. App. 2018), *review denied*, (Mar 20, 2019), *cert. denied*, *Tseng v. California*, 140 S.Ct. 2018 (Oct. 07, 2019).
 12. *Id.* at 203.
 13. *Id.*

of Dr. Tseng's all-too-common conduct in overprescribing opioids, but because of the unique charges filed and the convictions obtained. Although Dr. Tseng's explicit awareness and conscious disregard of the risks resulted in a high-profile murder conviction, the isolated case is unlikely to increase the prospect of criminal charges for opioid prescribers under current state or federal law.

This situation raises several questions. First, given the increasing number of opioid overdose deaths nationally, why are charges against and convictions of doctors so uncommon? Second, what legal and regulatory mechanisms exist at the federal and state levels to address the opioid crisis and, in particular, the prescribing practices of health care professionals like Dr. Tseng? Finally, why have the existing legal mechanisms failed to deter improper prescribing practices and to curb this national epidemic so far? This Article seeks to examine these issues and others, and it is the first article in legal scholarship to offer a concrete solution grounded in federal criminal law. Using the legal principles that the California Court of Appeal in *Tseng* recognized as a dispositive roadmap, this Article proposes a new federal criminal statute aimed directly at those health care professionals who knowingly violate acceptable health care norms in prescribing opioids, resulting in the death of a patient.

Part I of this Article describes the evolution of the law as it relates to the opioid epidemic and briefly explores the root causes of the crisis and collateral events—namely the COVID-19 pandemic—that have exacerbated the crisis. It aims to explain how we got from the medically acceptable practice of prescribing opioids and other controlled substances for legitimate medical purposes to where we are now: hundreds of thousands of drug overdose deaths as a result of addiction to prescription opioids. Part I additionally examines the current federal drug laws, as well as the relevant state statutes in place that seek to address the problem of overprescribing doctors and patient overdose deaths. The legal basis for the arrest and prosecution of physicians in this context, as well as enforcement efforts, are also explored. Currently, when a patient dies as a result of a prescription drug overdose, physicians may be investigated and charged under either the federal Controlled Substances Act (CSA), a state's adopted version of that Act, or other state criminal homicide and felony murder statutes. This Part will articulate distinctive types of criminal liability that have been pursued in both state and federal courts, and will examine other cases, in addition to Dr. Tseng's, that have been brought against doctors. Finally, Part I discusses the relative deterrent effects of the CSA and state homicide laws on physicians participating in this prescription scheme.

Part II considers shortcomings in current legal approaches and asserts that responses under existing federal criminal law and the CSA are

inadequate. As of now, Title 18 of the United States Code contains no specific homicide statute that can address the culpability of doctors who act with conscious disregard for their patients. Instead, federal prosecutions against doctors are pursued—if at all—under the CSA. But scholars and health care advocates have rightfully argued that the CSA standard is both vague and overbroad, and it therefore discourages many physicians from providing medically necessary palliative treatment to patients suffering from chronic pain.¹⁴ Because many physicians fear criminal sanctions under the CSA for prescribing opioids, pain sufferers may not be able to receive adequate pain care.¹⁵ Furthermore, the overwhelming majority of state criminal laws fair no better in terms of providing predictable results and holding overprescribing doctors accountable. This Part concludes by examining the current conflict that pits physicians and others who advocate for palliative care drug therapy against drug-enforcement personnel, and it briefly

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14. See, e.g., Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS UNIV. J. HEALTH L. & POL'Y 231, 235 (2008); Yang & Haffajee, *supra* note 10, at 1331–33.
 15. See Michael C. Barnes & Stacy L. Sklaver, *Active Verification and Vigilance: A Method to Avoid Civil and Criminal Liability When Prescribing Controlled Substances*, 15 DEPAUL J. HEALTH CARE L. 93, 95 (2013) (examining the concern that criminal liability for physicians for improper prescribing “create[s] a chilling effect: physicians would refrain from properly treating patients who legitimately needed certain prescription medications out of fear of criminal sanctions”); Danielle M. Nunziato, *Preventing Prescription Drug Overdose In The Twenty-First Century: Is The Controlled Substances Act Enough?*, 38 HOFSTRA L. REV. 1261, 1269 (2010) (arguing that overprescribing doctors should be prosecuted under the CSA and state involuntary manslaughter laws when their prescribing practices result in a patient’s death); Rima J. Oken, *Curing Healthcare Providers’ Failure to Administer Opioids in the Treatment of Severe Pain*, 23 CARDOZO L. REV. 1917, 1941–43 (2002) (discussing the causes of the “nationwide palliative care crisis” that included a lack of physician training in pain management, unwarranted fears of drug addiction and prosecution for prescribing, “overly broad drug regulations,” and urging legislative remedies to “ensure compliance by holding healthcare providers accountable for their failure to provide adequate palliative care to their patients”); M.M. Reidenberg & O. Willis, *Prosecution of Physicians for Prescribing Opioids to Patients*, 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 903, 904 (2007) (finding a reduction in the prescription of opioids due to fear of legal action); Yang & Haffajee, *supra* note 10, at 1333–34.

discusses the inherent racial and socio-economic bias baked in to the tough-on-crime drug laws.

Part III addresses why a consistent, national response grounded in federal criminal law is the right approach. When physicians knowingly prescribe various controlled substances in excessive doses to their patients for an unarticulated medical purpose, enabling drug dependency or recreational use that ultimately results in that patient's death, the physician's behavior may rise to the level of homicide. Therefore, based on the legal standards applied in *Tseng*, this Article recommends legislative action. It specifically proposes the enactment of a new federal statute to criminalize a physician's overprescription of opioids that causes the death of a patient. This Part highlights cases with outcomes that would have rightfully changed if the new proposed statute were enacted, and it details how the law will both deter and punish physicians whose prescription practices cause their patients' deaths while simultaneously providing clarity to doctors engaged in legitimate and medically necessary pain management practices.

I. EVOLUTION OF THE OPIOID EPIDEMIC AND THE LAW'S RESPONSE

A. *Historical Efforts to Regulate the Use of Opioids*

Before the early 1900s, drugs derived from opioids were generally available without a prescription and prepared for patients by pharmacists on their own initiative or upon a physician's recommendation. The Opium Exclusion Act of 1909, which banned all smoking of opioids, was the first government regulation of opioids.¹⁶ Over the next fifty years, government regulation increased as knowledge about the harms and addictive properties of opioids emerged. For example, in 1914, the Harrison Narcotics Tax Act required physician and pharmacist approval for the distribution of opioids.¹⁷ In 1924, the Heroin Act criminalized heroin, banning its

16. Dale Gieringer, *The Opium Exclusion Act of 1909*, COUNTERPUNCH (Feb. 6, 2009), <http://www.counterpunch.org/2009/02/06/the-opium-exclusion-act-of-1909> [https://perma.cc/ZX4S-4R5U].

17. Michael Waldrop, Note, *A Little Less Regulation: Why Federal Pain Management Laws Are Hurting State Efforts to Combat the Opioid Epidemic*, 43 MITCHELL HAMLINE L. REV. 881, 888-89 (2017).

manufacture, import, and possession.¹⁸ And, in 1938, Congress created the Food and Drug Administration (FDA) to monitor and regulate drugs and their safety before sale in the United States.¹⁹

Despite the known risks of addiction from opium-based drugs, the 1950s and 1960s saw large increases in both prescription opioids and heroin.²⁰ Oxycodone was touted as a “safe” pain-relieving treatment²¹ and became a widely used prescription opioid.²² However, in the second half of the 1960s the public’s perception of these drugs began to evolve. Opiates became symbols of rebellion, social discord, and political dissent. As a result of these connotations, the federal government stopped funding scientific research into the medical safety and efficacy of opium-based drugs.²³ The 1970s ushered in the “War on Drugs” and with it the first and most comprehensive regulation of illicit and prescription drugs specifically enacted to combat the expansion of illegal drug use and abuse: The Controlled Substances Act of 1970.²⁴ The Act was intended to criminalize

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18. Richard D. deShazo et al., *Backstories on the US Opioid Epidemic: Good Intentions Gone Bad, an Industry Gone Rogue, and Watch Dogs Gone to Sleep*, 131 AM. J. OF MED. 595, 597 (2018) [https://www.amjmed.com/article/S0002-9343\(18\)30084-6/pdf](https://www.amjmed.com/article/S0002-9343(18)30084-6/pdf).
 19. Waldrop, *supra* note 17, at 890.
 20. *Id.*
 21. *Id.* at 889.
 22. *Id.* Oxycodone is an opioid first produced in 1916 by German scientists who hoped to provide the same pain-relieving benefits of morphine and heroin without the same harm of addiction. Mohammad Moradi et al., *Use of Oxycodone in Pain Management*, 1 ANESTHESIOLOGY & PAIN MED. 262 (2012).
 23. *A Brief History of the Drug War*, DRUG POL’Y ALLIANCE, <http://www.drugpolicy.org/issues/brief-history-drug-war> [<https://perma.cc/E88M-S3J3>] (last visited Aug. 20, 2019); *see also* Don Lattin, *The War on Drugs Halted Research Into the Potential Benefits of Psychedelics*, SLATE (Jan. 3, 2017, 5:55 AM), <https://slate.com/technology/2017/01/the-war-on-drugs-halted-research-into-the-potential-benefits-of-psychedelics.html> [<https://perma.cc/K4AQ-HGQT>] (reflecting on the federal government’s support of drug research from the 1940s through the 1960s and noting the subsequent decline in government funding for research during the “War on Drugs”).
 24. In 1971, President Richard Nixon declared a “war on drugs,” increasing both the size and presence of federal drug control agencies while also pushing

the importation, distribution, possession, and use of controlled substances, which Congress found to have a substantial and detrimental effect on the health and general welfare of the American people.²⁵ Notwithstanding the “War on Drugs” and the enactment of the CSA, the number of opioid prescriptions rose from 76 million annually in 1991 to a peak of 219 million prescriptions a year in 2011.²⁶ The following Section explains what happened between these years to account for the dramatic increase in opioid prescriptions.

B. Root Causes of the Modern Opioid Epidemic

Four interrelated events coalesced to cause the crisis we now know as the opioid epidemic: (1) the federal government’s diminished role in funding drug research and, beginning in the 1980s, in regulating the pharmaceutical industry; (2) a one-paragraph letter in a medical journal; (3) the marketing of opioids by pharmaceutical companies and their infiltration of the medical establishment in the mid-1990s; and (4) the new focus on pain management and monitoring which affected the prescribing practice of doctors. A fifth event, the COVID-19 pandemic, although not an initial cause of the opioid epidemic, is also examined in this Part because the pandemic has made the opioid epidemic worse.

1. The Federal Government’s Role

The absence of publicly funded research into the efficacy of drug treatment helped create the current opioid epidemic. Beginning in the late

through measures such as mandatory sentencing for drug offenses. DRUG POL’Y ALLIANCE, *supra* note 23.

25. Controlled Substances Act, 21 U.S.C. §§ 801–971 (2018) [henceforth “the Act” or “CSA”].

26. See David W. Baker, *The Joint Commission’s Pain Standards: Origins and Evolution*, JOINT COMM’N (2017) https://www.jointcommission.org/-/media/tjc/documents/resources/pain-management/pain_std_history_web_version_05122017pdf.pdf?db=web&hash=E7D12A5C3BE9DF031F3D8FE0D8509580 [https://perma.cc/5JTK-L933]; *Trends in Opioid Use: History, Background, and Origins of the Epidemic*, AVALERE (Oct. 2018), <https://avalere.com/wp-content/uploads/2018/11/Avalere-20181030-Opioid-Trends-Brief-FINAL.pdf> [https://perma.cc/TH6H-P8WY].

1940s, the federal government, primarily through the Veteran's Administration, began to sponsor research into a variety of pain medications to treat those suffering from debilitating and painful injuries suffered in World War II.²⁷ In the 1950s the federal government played a significant role in funding research and development of a variety of medicines and drugs.²⁸ During this period, the FDA strictly required drug manufacturers to demonstrate that their products were both safe and effective before they were marketed.²⁹ As described above, the government's sponsorship of research began to wane in the mid-1960s as the public's and the political establishment's perceptions of drug use began to change. By the end of the decade, many of the drugs actively researched using public funds in the 1950s had become linked with the 1960s counterculture, the civil rights and Vietnam antiwar movements, and the crusade for sexual liberation. The Nixon Administration's new focus on criminalization of drugs became part of a broader political reaction against the liberation movements of the 1960s.

The fact that funding for opioid research was swept into that current reflects the broader reality that public funding for drug development and research has always been tied to changes in the public's perceptions of drug use. In the last fifty years, public funding for drug research has declined,³⁰ and the lack of funding has detrimentally affected research programs that have relied on ongoing support to maintain research projects.³¹ With the "War on Drugs" during the 1970s and 1980s, the government and public's attention on drugs moved from funding of research and development to

27. David F. Musto, *Drug Abuse Research in Historical Perspective*, in *PATHWAYS OF ADDICTION: OPPORTUNITIES IN DRUG ABUSE RESEARCH* 284, 289 (1996).

28. *A History of the Pharmaceutical Industry*, PHARMAPHORUM (Sept. 1, 2020), https://pharmaphorum.com/r-d/a_history_of_the_pharmaceutical_industry [<https://perma.cc/3VBQ-N2ZU>]. The development of new drugs and the growth of the pharmaceutical industry were fueled by funding from the United States government, with the National Institutes of Health seeing its federal funding rise to nearly \$100 million by 1956. *Id.*

29. Margaret A. Hamburg, *Innovation, Regulation, and the FDA* 363 *NEW ENG. J. MED.* 2228 (2010).

30. Michelle Llamas, *Big Pharma's Role in Clinical Trials*, *DRUGWATCH* (Apr. 24, 2015), <https://www.drugwatch.com/featured/clinical-trials-and-hidden-data> [<https://perma.cc/V3GZ-4ZDF>].

31. *See* Musto, *supra* note 27.

enforcement of the new drug criminalization laws.³² This shift in priorities and resources left a void in the knowledge of the safety and efficacy of opioids that was ultimately filled by the private sector, specifically the research of pharmaceutical companies and trade-groups who sought to promote their opioid products.³³

An equally significant factor in the genesis of the opioid epidemic was the change in the relationship between the federal government and the pharmaceutical industry that occurred during the 1980s. With the election of Ronald Reagan in 1980, the federal government deregulated many sectors of the economy.³⁴ The pharmaceutical industry was no exception. As it did with other federal agencies, the new administration cast the FDA regulatory process as hampering private markets, discouraging innovation, and inhibiting consumer choice.³⁵ Led by free-market conservatives, the administration consolidated regulatory policy under the Health and Human Services Secretary Richard Schweiker, who abandoned the prior administration's rules for such tasks as tracking of adverse drug reactions and defective medical devices. The Reagan Administration also limited the authority of regulatory agencies, pushed for faster drug approval, and began to see itself as a partner in the drug innovation process. In the ten years that followed, pharmaceutical regulatory policies aimed to cut "bureaucratic red tape" in drug approvals, to permit drug companies to market their drugs directly to consumers, and to overall speed up the flow of products from drug maker to consumer.³⁶

Deregulation of the pharmaceutical industry was followed by the FDA's systematic failure to exercise the authority it had retained. Specifically, at least one scholar has argued that the FDA failed to curtail the opioid epidemic in three ways.³⁷ First, the FDA failed to police false marketing claims by opioid manufacturers. For example, the FDA allowed Purdue Pharma to mislabel its opioids in a manner that suggested that they were indicated for a broader range of conditions than supported by medical

32. *See id.*, n. 21.

33. *See id.*, n. 29.

34. KEITH WAILOO, *PAIN: A POLITICAL HISTORY* 172-73 (2014).

35. *Id.*

36. *Id.*

37. Andrew Kolodny, *How FDA Failures Contributed to the Opioid Crisis*, 22 *AM. MED. ASS'N J. ETHICS* 743 (2020).

evidence.³⁸ Second, the FDA did not require sufficient and well-controlled clinical trials for opioids.³⁹ This practice contravened the FDA's general requirement of at least two randomized, controlled trials demonstrating clear efficacy for a proposed indication of a drug.⁴⁰ The FDA approved extended release oxycodone based on only one study, a two-week clinical trial in osteoarthritis patients.⁴¹ Finally, the FDA did not manage conflicts of interest between agency staff and industry. A revolving door has existed between the FDA and the pharmaceutical manufacturers for the last twenty years, as agency officials responsible for drug approvals, opioid oversight, and opioid manufacturing have left the FDA to work for opioid makers.⁴²

The absence of a functioning regulatory environment within which the pharmaceutical industry operated during the 1980s, coupled with the general decrease in publicly funded drug research, meant that there were fewer government watchdogs, a dearth of scientific studies and fewer scientific voices to countervail the efforts of the industry to market opioids to clinicians and the public. The absence of government oversight and funding in this space resulted in a lack of meaningful critique of the evidence the pharmaceutical industry presented to demonstrate the efficacy and safety of the group of opioids that it developed in the 1980s and 1990s.

2. The "Porter and Jick" Letter

The misrepresentation of one study in particular further laid the groundwork for the marketing practices that spawned the opioid epidemic in the United States.⁴³ In 1980, Dr. Hershel Jick and his assistant, Jane Porter,

38. *Id.* at 744-45.

39. *Id.* at 745.

40. Nicholas S. Downing et al., *Clinical Trial Evidence Supporting FDA Approval of Novel Therapeutics, 2005-2012*, 311 JAMA 368 (2014).

41. Kolodny, *supra* note 37, at 745; see also *Approval Package for Oxycontin 80 mg, Application Number: NDA 20-552/S-002*, CTR. FOR DRUG EVAL. & RSRCH. (Dec. 9, 1996), https://www.accessdata.fda.gov/drugsatfda_docs/nda/96/020553s002.pdf [<https://perma.cc/YNU6-NFNH>] (describing the clinical trial conducted for the 80 mg. OxyContin time-released tablet).

42. Kolodny, *supra* note 37, at 746.

43. Greg H. Jones, et al., *The Opioid Epidemic in the United States—Overview, Origins, and Potential Solutions*, 124 CANCER 4279 (2018).

reviewed hospital records at Boston University Medical Center to assess whether hospital patients became addicted to their narcotic pain medications when treated in the hospital.⁴⁴ Their review stated that only four out of nearly 12,000 hospital patients treated with such painkillers under the supervision of hospital personnel had become addicted.⁴⁵ They described the results of their review in a five-sentence letter to the *New England Journal of Medicine* (NEJM), which concluded: “[D]espite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.”⁴⁶ The Porter and Jick letter became characterized as a landmark study: it was cited 608 times between 1980 and 2017 as support for prescribing opioids regularly to non-terminally ill outpatients for routine treatment.⁴⁷ Seventy percent of the citations used the letter as evidence that addiction was rare among patients treated with opioids. More than 80% did not mention that patients from the original study were exclusively hospitalized while receiving the medication, and thus under the supervision of medical personnel.⁴⁸ Some even claimed that the Porter and Jick letter proved that there was no risk of addiction with opioids.⁴⁹

44. Sonia Moghe, *Opioid History: From ‘Wonder Drug’ to Abuse Epidemic*, CNN (Oct. 14, 2016), <https://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html> [<https://perma.cc/RQ3B-PL8X>].

45. Derek Hawkins, *How a Short Letter in a Prestigious Journal Contributed to the Opioid Crisis*, WASH. POST (June 2, 2017), https://www.washingtonpost.com/news/morning-mix/wp/2017/06/02/how-the-opioid-crisis-traces-back-to-a-five-sentence-scholarly-letter-from-1980/?utm_term=.665071c2634c [<https://perma.cc/H8AH-2EXN>].

46. *Id.*

47. Pamela T.M. Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 *NEW ENG. J. MED.* 2194 (2017). Nearly 500 articles citing the letter failed to note that the letter concerned only hospitalized patients whose treatments were overseen by medical staff, rather than people prescribed take-home painkillers. Other articles “grossly misrepresented” the letter’s findings. *Id.*; see also Hawkins, *supra* note 45 (describing the effect of the Porter & Jick letter on the opioid epidemic).

48. *Id.*; Jones et al., *supra* note 43.

49. Hawkins, *supra* note 45.

Publications such as *Time Magazine* and *Scientific American* characterized this letter as an “extensive study”⁵⁰ that portrayed “the exaggerated fear that patients would become addicted to opioids” as “basically unwarranted.”⁵¹ The misinterpretations and inaccurate citations understated the dangers of opioid addiction.⁵² In reliance on the letter, the Drug Enforcement Agency (DEA) did not prosecute licensed medical professionals for prescribing opioids unless it appeared that they were engaged in drug trafficking.⁵³ During this time, prescriptions of opioids grew by two to three million more per year for all manner of conditions, such a chronic back pain, broken bones, and oral surgery.⁵⁴

3. Purdue Pharma, OxyContin, and the Marketing Infiltration of the Medical Establishment

Another causal element in the current opioid epidemic was the release of Purdue Pharma’s drug, OxyContin. In 1995, the FDA approved the slow-release opioid.⁵⁵ As soon as it was approved, the company began an

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50. Ronald Melzack, *The Tragedy of Needless Pain*, 262 *SCI. AM.* 27 (1990).
 51. Sam Allis Boston, *Less Pain, More Gain*, *TIME* (June 21, 2001).
 52. See David S. Egilman et. al, *The Marketing of OxyContin: A Cautionary Tale*, 4 *INDIAN J. MED. ETHICS* 183, 185 (2019). The Porter and Jick letter was the most frequently cited evidence that the pharmaceutical industry relied upon to show the efficacy and safety of its new batch of opioid drugs. It was the first of a few of studies that have subsequently been assailed as scientifically invalid for the purpose for which they were used. *Id.* at 184.
 53. See Kathryn Foxhall, *DEA Enforcement Verses Pain Practice*, 5 *PRACTICAL PAIN MGMT.* (2016), <https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/dea-enforcement-versus-pain-practice> [<https://perma.cc/ZWU5-BYXP>] (highlighting that DEA enforcement efforts in the early and mid-2000s focused on a small number of doctors who ran pill mills).
 54. Teresa A. Rummans et al., *How Good Intentions Contributed to Bad Outcomes: The Opioid Crisis*, 93 *MAYO CLINIC PROC.* 344, 346 (2018).
 55. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 *AM J. PUB. HEALTH* 221 (2009). OxyContin was touted by the manufacturer as having less potential for addiction and abuse than other formulations of opioids because OxyContin had a slow-release delivery mechanism in the form of a digestible coating that caused the delayed absorption of the drug over the course of several hours and thus allowed for

aggressive marketing campaign.⁵⁶ Throughout this campaign, the company was able to increase sales by misrepresenting the addiction potential of their new drug, claiming that addiction risk was extremely small by citing the Porter and Jick letter.⁵⁷ Purdue also convinced the FDA to label the drug as having an addiction level of “very rare.”⁵⁸

These advertising tactics made a lasting impression: the number of OxyContin prescriptions increased significantly in the late 1990s. In 1997 OxyContin prescriptions were about 670,000, and by 2002 they had

long-lasting pain relief. BETH MACY, *DOPESICK: DEALERS, DOCTORS, AND THE DRUG COMPANY THAT ADDICTED AMERICA* 19 (2018).

56. Van Zee, *supra* note 55, at 221. Between 1996 and 2001 the company had sponsored forty national all-expenses-paid symposiums about OxyContin, which reached an audience of over 5,000 doctors. *Id.*

57. *Id.* at 223.

58. Baker, *supra* note 26, at 5.

skyrocketed to 6.2 million.⁵⁹ By 2004, OxyContin had become the leading drug prescribed and abused⁶⁰ in the United States.⁶¹

As Purdue earned billions of dollars from sales, other drug companies took note; they introduced their own opioid products and joined Purdue in funding a campaign that changed the culture of opioid prescribing in the United States. Clinicians who previously understood that the development of tolerance to opioids results in dose escalation, and that dependence on opioids would make discontinuation difficult for users, now began hearing from a virtual army of spokespeople for opioid manufacturers that

59. Van Zee, *supra* note 55.

60. As overdoses and deaths related to OxyContin began to increase in 2003, the efficacy of the drug and manufacturers' claims began to be reexamined. The FDA issued a warning letter to the manufacturer about misleading advertising, lack of warning statements regarding the addictive nature of the drug, and overstating the efficacy of the drug. The FDA added several black box warnings to the package insert, stating that OxyContin exposes patients to the risk of addiction, overdose, and death. Marilyn Bulloch, *How Oxycodone Has Contributed to the Opioid Epidemic*, PHARMACY TIMES (Aug. 02, 2018), <https://www.pharmacytimes.com/contributor/marilyn-bulloch-pharmd-bcps/2018/08/how-oxycodone-has-contributed-to-the-opioid-epidemic> [https://perma.cc/XHS8-H9NR]. In 2017, the FDA placed its most recent warning on the drug requiring that the drug insert disclose that OxyContin is "[a] long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death." *Highlights of Prescribing Information*, FOOD & DRUG ADMIN. (2018), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/022272s040s041bl.pdf [https://perma.cc/5S4Z-SKFY]; *Opioid Overdose Crisis*, NAT'L INST. ON DRUG ABUSE (Mar. 2018), drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis [https://perma.cc/76XL-2T9Z]. By 2007, the first litigation resulted in Purdue Pharma pleading guilty to misrepresenting OxyContin as being less addictive than other prescription opioids, resulting in a judgment of \$634 million. *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007). Purdue, which filed for bankruptcy in 2019, continues to face lawsuits. Joanna Walters, *Purdue Pharma: OxyContin Maker Faces Lawsuits from Nearly Every US State*, GUARDIAN (June 04, 2019), <https://www.theguardian.com/us-news/2019/jun/03/purdue-opioids-lawsuit-oxycotin-california-maine-hawaii> [https://perma.cc/7MYM-F8VN].

61. Van Zee, *supra* note 55.

addiction was rare and that long-term use was safe and effective. Risks were minimized, benefits were exaggerated, and opioid prescribing surged.⁶²

Pharmaceutical companies have played a key role in the current opioid crisis through their advertising and advocating to medical professionals and patients about the beneficial use of their drugs as safe palliative care for chronic pain.⁶³ Pharmaceutical companies' sales representatives spend millions of dollars annually on gifts and other inducements to physicians and medical students in the effort to promote their products.⁶⁴ Company sales representatives provide physicians with everything from pens, lanyards, and notepads, to meals, tickets to entertainment and sporting events, and weekend-long getaway vacations.⁶⁵ One 2007 study from the *New England Journal of Medicine* found that of 3,000 physicians, 83% of physicians accepted food or drink from pharmaceutical companies, 78% accepted drug samples, 35% accepted reimbursement for meeting expenses, 28% accepted money for lectures, and 7% accepted free tickets.⁶⁶ Studies also showed that pharmaceutical companies' gifts noticeably impact doctors' prescribing practices.⁶⁷

62. *Id.*

63. Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 *JAMA* 373 (2000).

64. *See Id.* (describing the efforts and resources companies apply to affect the prescribing practice of doctors and medical students).

65. Amanda L. Conners, Comment, *Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics*, 73 *ALB. L. REV.* 243, 251 (2010).

66. Eric G. Campbell et al., *A National Survey of Physician-Industry Relationships*, 356 *NEW ENG. J. OF MED.* 1742, 1746 (2007).

67. Sheena T. Wheeler, Note, *Under the Influence: An Examination of the Tactics Pharmaceutical Companies Use to Manipulate Physicians*, 7 *IND. HEALTH L. REV.* 89, 92 (2010). One study found that physicians prescribe drugs for which they attended paid conferences 4.5-10 times more often than other drugs. *Id.* at 105. This study, which combined data from 538 similar studies, concluded that the current "extent of physician-industry interactions appear to affect the prescribing and professional behavior" of physicians. Wazana, *supra* note 63, at 373.

4. The Focus on Pain Monitoring and Pain as the “Fifth Vital Sign” and Evolving Prescribing Practices

In the 1970s, the implementation of the CSA, the rhetoric of the “War on Drugs,” and the changing public perception of drug use affected physicians’ prescribing practices and the view of opioids in the medical community.⁶⁸ By the mid-1990s however, the medical community had embraced new standards for assessing patients’ pain.⁶⁹ The evaluation of pain became the “Fifth Vital Sign,” a requirement of proper patient care as important and basic as the assessment and management of temperature, blood pressure, respiratory rate, and heart rate.⁷⁰ This elevation of pain as a human experience that warranted individual attention and treatment by health care professionals did not arise in a vacuum. Rather, the increased focus on pain and its alleviation emerged as part of a broader social movement to acknowledge the rights of individuals to effective medical treatment and greater access to health care in the United States, which began with the return of disabled war veterans in the 1940s through the 1990s with HIV and AIDS activism.⁷¹

Pharmaceutical companies also played a significant role in the new approach to opioids in the medical community. In the early 1990s, large drug manufacturers such as Purdue Pharma, Johnson & Johnson, and Endo Pharmaceuticals began funding nonprofit groups involved in the medicine of pain management, such as the American Pain Society. These organizations drew attention to the view that many individuals with chronic

68. Waldrop, *supra* note 17, at 891.

69. Baker, *supra* note 26, at 2-3. In 1999, based on these standards, California enacted a provision that required that “[e]very health facility licensed pursuant to this chapter shall, as a condition of licensure, include pain as an item to be assessed at the same time as vital signs are taken. The pain assessment shall be noted in the patient’s chart in a manner consistent with other vital signs.” *Id.* In October of 2000, the United States Congress passed H.R. 3244, tit. VI § 1603 which contained similar provisions. *Id.* at 3.

70. Natalia E. Morone & Debra K. Weiner, *Pain as the Fifth Vital Sign: Exposing the Vital Need for Pain Education*, 35 CLINICAL THERAPEUTICS 1728 (2013).

71. Stephen A. Bernard et al., *Management of Pain in the United States—A Brief History and Implications for the Opioid Epidemic*, 11 HEALTH SERVS. INSIGHTS 1 (2018).

pain were being treated inadequately.⁷² Playing on this idea, Purdue Pharma helped to fund a “pain management education program” organized by the Joint Commission on the Accreditation of Healthcare Organizations (known as the “Joint Commission”).⁷³ Eventually, the Joint Commission also adopted pain as the fifth vital sign. Sponsored by Purdue Pharma, the Joint Commission published a guide that proclaimed, “[S]ome clinicians have inaccurate and exaggerated concerns [about risks of addiction] This attitude prevails despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”⁷⁴ The National Cancer Center Network joined in also publishing cancer pain guidelines that included escalating opioid pain treatment according to pain intensity on a scale of 0 to 10.⁷⁵

Furthermore, between 1996 and 2002, Purdue Pharma funded more than 20,000 pain-related educational programs designed to influence physician prescription habits.⁷⁶ As a result, medical associations lobbied the government to allow the use of opioids for all pain treatment,⁷⁷ not just for chronic pain from terminal illness.⁷⁸ In 2004, the Federation of State

72. See Jones et. al., *supra* note 43, at 4280.

73. In 1997, the Robert Wood Johnson Foundation in collaboration with the University of Wisconsin-Madison School of Medicine funded and established the Joint Commission on the Accreditation of Healthcare Organizations (known as the “Joint Commission”) to develop pain standards for health care organizations to improve pain management. Baker, *supra* note 26.

74. *Id.*

75. *Id.*

76. Van Zee, *supra* note 55, at 223.

77. Bernard et. al., *supra* note 71, at 4 (observing that a number of regulatory interventions by governmental and nongovernmental organizations, such as the Veterans Health Administration, the Institute of Medicine, and the Agency for Healthcare Research and Quality of the Hospital Consumer of Healthcare Providers and Systems, propelled increases in opioid use for chronic noncancer pain).

78. Laurie Tarkan, *New Efforts Against an Old Foe: Pain*, N.Y. TIMES (Dec. 26, 2000), <https://www.nytimes.com/2000/12/26/science/new-efforts-against-an-old-foe-pain.html> [<https://perma.cc/6D35-BAQW>]; Baker, *supra* note 26, at 3; see also, Bernard et. al., *supra* note 71 (exploring the efforts of medical associations to influence government drug regulators).

Medical Boards⁷⁹ (FSMB) joined the movement by encouraging state medical boards to scrutinize and punish physicians for the under-treatment of pain.⁸⁰ The FSMB also published a book, subsidized by manufacturers including Purdue Pharma and Endo Pharmaceuticals, that outlined policies designed to encourage the broad use of opioids for non-terminal patients.⁸¹ The FSMB's policies were developed by several individuals with ties to narcotics manufacturers, some of whom were also members of an industry speakers' bureau and later became company executives.⁸² Finally, the World Health Organization and other health organizations began advocating for more pain control for anyone who experienced pain.⁸³ Thus,

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79. The Federation of State Medical Boards (FSMB) is a national non-profit organization that represents the 71-state medical and osteopathic boards of the United States and co-sponsors the United States Medical Licensing Examination. See FSMB, <https://www.fsmb.org/about-fsmb/> [<https://perma.cc/QMB2-FMPD>]. According to its website, the FSMB "supports its member boards as they fulfill their mandate of protecting the public's health, safety and welfare through the proper licensing, disciplining, and regulation of physicians and, in most jurisdictions, other health care professionals." *Id.*
80. Jones, et al., *supra* note 43; see also Diane E. Hoffmann & Anita J. Tarzian, *Achieving the Right Balance in Oversight of Physician Opioid Prescribing for Pain: The Role of State Medical Boards*, 31 J. OF LAW, MED. & ETHICS 21-40 (2003) (describing the Oregon Medical Board's 1999 discipline of a physician for failure to prescribe adequate pain relief medication. The board disciplined the doctor for several pain undertreatment infractions including prescribing insufficient pain medication for a terminally ill cancer patient (i.e., only Tylenol) and prescribing only a fraction of the dose of morphine that another patient needed and the hospice nurse suggested. The medical board ordered the doctor to complete an educational program on physician-patient communication and undergo mental health treatment).
81. John Fauber, *Follow the Money: Pain, Policy, and Profit*, MEDPAGE TODAY (Feb. 19, 2012), <https://www.medpagetoday.com/neurology/painmanagement/31256> [<https://perma.cc/66TB-Y9KX>].
82. *Id.*
83. Rummans et al., *supra* note 54, at 345. In 1996, the American Academy of Pain Medicine and the American Pain Society issued statements that opioids should be used to treat patients with chronic noncancer pain. *Id.*

by the early 2000s, pain had gone from being hardly monitored to liberally and aggressively treated using prescription opioids.⁸⁴

Although the conduct of the pharmaceutical industry influenced the adoption of a new approach to the treatment of pain, which laid the groundwork for the opioid epidemic that followed, doctor's prescribing practices also contributed to the crisis. Throughout the 1990s and 2000s, medical professionals deferred to the messaging of pharmaceutical representatives on the efficacy and safety opioids. Prescribers did not question the paucity of evidence, including the mischaracterization of the Porter and Jick letter, because they lacked training and medical education in pain management sufficient to critique the evidence and because regulators had also accepted the evidence.⁸⁵ Additionally, the profit-oriented structure of the American health-care system furthered the overprescription of opioids. Because many doctors are in private practice, they may benefit financially by increasing the volume of patients that they see, as well as by ensuring patient satisfaction, which can incentivize the overprescription of pain medication.⁸⁶ For example, some physicians have operated "pill mills,"⁸⁷ serving a high volume of patients with large dose opioid prescriptions that have been dispensed for illegitimate medical reasons.⁸⁸ Pill mill doctors and pain clinics, however, are not the only

84. For instance, a 2003 study found that 90% of post-operative patients were satisfied with their pain medications, even though doctors continued to report that "many patients experience intense pain after surgery." Baker, *supra* note 26, at 4.

85. Sarah DeWeerd, *The Natural History of an Epidemic*, 573 NATURE S10, S11 (2019).

86. *Id.*

87. See Pia Malbran, *What's a Pill Mill?*, CBS NEWS (May 31, 2007), <https://www.cbsnews.com/news/whats-a-pill-mill> [<https://perma.cc/6DNZ-F3QN>]. Some typical signs of a pill mill are prescribers who accept only cash, require no medical records, physical exams, or testing, and allow the patient to choose their medicine. *Id.*

88. See *e.g.*, *People v. Tseng*, 241 Cal. Rptr. 3d 194, 197 (Ct. App. 2018) (describing the practice of Dr. Tseng, a California doctor whose cash-only medical practice involved examining multiple unrelated patients simultaneously for only a few minutes and failing to question patients about prior treatments or request medical records to substantiate claims of pain and medical problems); see also *Documents and Resources from the April 17, 2019 Press Conference*, U.S. DEP'T OF JUSTICE (Jan. 30, 2020), <https://www.justice.gov/opa/documents-and->

sources that have contributed to the national epidemic of opioid abuse and overdose.⁸⁹ Medical scholars have also concluded that although most physicians are “well-meaning,” they often prescribe “30 or 60 pills when 5 or 20 would have been adequate.”⁹⁰ In fact, primary care physicians and dentists have been a major source of opioid overprescription.⁹¹

5. The COVID-19 Pandemic

The four initial causes of the opioid epidemic discussed above did not occur independently. Instead, they cascaded from each other: the diminished role of the federal government in funding drug science left a research gap filled to a large extent by the Porter and Jick letter. The Porter and Jick letter provided the evidence the pharmaceutical industry needed to fuel the marketing of opioid products as safe and effective. In turn, the focus on pain management highlighted in the marketing efforts triggered the explosion of opioid prescription. Thus, the initial causes of the opioid epidemic represent a chain of related events each building upon the momentum created by the others into a major public health crisis. The COVID-19 pandemic has made the opioid epidemic even worse.

Although the COVID-19 pandemic did not cause the opioid epidemic, it has accelerated the pace of the crisis, and the pandemic’s effects underscore the urgent need to address the opioid epidemic. Addiction and recovery advocates say the United States is now battling two epidemics at once.⁹²

resources-april-17-2019-press-conference [https://perma.cc/3GKR-ND3Q] (describing the 2019 federal indictments in seven states for violations of the CSA by more than hundreds of doctors, many of whom allegedly operated pill mills).

89. Karsten Bartels, Ingrid A. Binswanger & Christian J. Hopfer, *Sources of Prescription Opioids for Nonmedical Use*, 10 J. ADDICTION MED. 134 (2016).

90. Hirsch, *supra* note 5.

91. *See Id.*; Brian Mann, *Doctors and Dentists Still Flooding U.S. with Opioid Prescriptions*, NPR (July 17, 2020), <https://www.npr.org/2020/07/17/887590699/doctors-and-dentists-still-flooding-u-s-with-opioid-prescriptions> [https://perma.cc/D8A6-XVJ8].

92. Dan Vergano, *Fatal Drug Overdoses Are Likely Increasing Again Because of the Coronavirus Pandemic*, BUZZFEED NEWS (July 14, 2020), <https://www.buzzfeednews.com/article/danvergano/coronavirus-overdose-fentanyl> [https://perma.cc/BE8S-NGV3].

Epidemics, natural disasters, global conflicts, and societal strife have been shown to induce stress across populations as people somaticize disasters into physical pain.⁹³ For many, the COVID-19 pandemic has brought grief, anxiety, isolation, financial challenges, disruptions to daily routines, and an ongoing sense of uncertainty—all of which can threaten individuals with a substance use disorder and aggravate those at risk of developing one.⁹⁴

Specific consequences of the COVID-19 pandemic that have contributed to recent spikes in opioid and other substance-use cases and overdoses include disrupted access to treatment, limited access to peer support and the loss of employment.⁹⁵ Because of shutdowns designed to reduce the spread of the coronavirus, numerous substance-use treatment programs closed their doors. This left many recovering individuals without access to the critical substance-use counseling and support they need. Social distancing limits individuals' contact with friends, mentors and other close members of their community, fostering feelings of isolation and loneliness that can contribute to substance use. Social distancing and lockdowns also interfere with individuals' ability to attend group therapy sessions, which are an important part of the treatment process for substance use disorders. Job loss can lead to a lack of daily structure and home foreclosures and evictions, all of which can increase psychological stress and, in turn, increase substance use. According to a Kaiser Family Foundation poll from mid-May 2020, 46% of adults in households that had experienced income or job loss as a result of the pandemic said that the pandemic had negatively impacted their mental health.⁹⁶ Finally, as the opioid epidemic was forced to cede priority to the more immediate crisis of COVID-19, many of the

93. Nabarun Dasgupta, Leo Beletsky & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182 (2018).

94. Marcelina Jasmine Silva & Zakary Kelly, *The Escalation of the Opioid Epidemic Due to COVID-19 and Resulting Lessons About Treatment Alternatives*, 26 AM. J. MANAGED CARE 202 (2020).

95. Kate Briquetelet, *Don't Forget the Other Pandemic Killing Thousands of Americans*, DAILY BEAST (May 3, 2020), <https://www.thedailybeast.com/opioid-deaths-surge-during-coronavirus-in-americas-overdose-capitals> [https://perma.cc/6MWC-J8TH].

96. *KFF Health Tracking Poll - May 2020*, KFF (May 27, 2020), <https://www.kff.org/report-section/kff-health-tracking-poll-may-2020-health-and-economic-impacts> [https://perma.cc/7RF2-NJKQ].

resources devoted to treatment and research of opioid abuse were curtailed or put on pause. Combined with the interruption of outpatient services in hospitals and clinics, and socioeconomic changes that can lead to relapse, these disruptions have experts worried that recent progress on the opioid front may be jeopardized.⁹⁷

Although definitive data on the pandemic's effects on substance use is not yet available, early numbers demonstrate an increase in the reliance on substances to help people cope. In the first few months of the pandemic, alcohol sales rose by 27%.⁹⁸ National laboratory service Millennium Health also reported a 32% increase for nonprescribed fentanyl, a 20% increase for methamphetamine, and a 10% increase for cocaine from mid-March through May 2020.⁹⁹ A national tracking system at the University of Baltimore further supports these findings, having identified an 18% increase in suspected drug overdoses during the same time period.¹⁰⁰

The climate of desperation, despair and isolation created by the COVID-19 pandemic creates an atmosphere where health care providers face greater pressure to prescribe opioids. Prescribing drugs has always been an easier fix than other treatments that are more costly. In the short term, prescription opioids are also inexpensive compared to alternative, more labor-intensive therapies. Patients' health insurance plans often cover pain medication but not pain-management approaches such as physical therapy, mindfulness and yoga.¹⁰¹

97. Annalisa Merelli, *COVID-19 Is Undoing a Decade of Progress on the Opioid Epidemic*, QUARTZ (Aug. 11, 2020), <https://qz.com/1889798/covid-19-is-making-the-opioid-crisis-much-worse/> [<https://perma.cc/K5DH-3TXJ>].

98. Jordan Valinsky, *Budget Beers and Spiked Seltzer Dominated During the Pandemic*, CNN BUSINESS, (June 20, 2020), <https://www.cnn.com/2020/06/09/business/budget-beer-spiked-seltzer-sales-coronavirus/index.html> [<https://perma.cc/MF3F-JFG5>].

99. *COVID-19 Special Edition: Significant Changes in Drug Use During the Pandemic*, 2.1 MILLENNIUM HEALTH (2020), https://resource.millenniumhealth.com/signalsreportCOVID?utm_source=presrelease [<https://perma.cc/SK82-K3AV>].

100. See Zarefsky, *supra* note 4; Stacy Weiner, *COVID-19 and the Opioid Crisis: When a Pandemic and an Epidemic Collide*, AAMC (July 27, 2020) <https://www.aamc.org/news-insights/covid-19-and-opioid-crisis-when-pandemic-and-epidemic-collide> [<https://perma.cc/48T5-KU87>].

101. See Deweerdt, *supra* note 85.

These circumstances—the prescribing practices of doctors and the renewed focus on pain relief and recently, the effects of the COVID-19 pandemic—account for the explosive increase of opioid prescriptions and abuse in the last twenty-five years.¹⁰² However, the question remains: why has the crisis occurred despite the existence of the CSA and other laws implemented to prevent it? Finding the answer to this question begins with a closer examination of the current law, existing regulatory framework, and law-enforcement bias governing opioids.

C. The Current Legal Approach to Confronting the Overprescription of Opioids

This Section details the current federal drug laws, the relevant state statutes and regulatory mechanisms, and other professional practices in place to address the problem of patient overdose deaths as the result of an opioid prescription.

1. Federal Law and Regulatory Approaches Governing Controlled Substances

As recently as 2017, the federal government promulgated regulations declaring that

[i]t shall be the policy of the United States to use all lawful means to combat the drug demand and opioid crisis currently afflicting our country. Individuals, families, and communities across the United States continue to be devastated by an unprecedented epidemic of

102. Gery P. Guy, Jr. et al., *Vital Signs: Changes in Opioid Prescribing in the United States 2006-2015*, 66 MORBIDITY & MORTALITY WKLY REP. 697-704 (July 7, 2017), <https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm> [<https://perma.cc/E364-MYZR>]. According to the CDC, annual opioid prescribing rates increased from 72.4 to 81.2 prescriptions per 100 persons from 2006 to 2010 and remained constant through 2012. They began decreasing in 2012 and have since decreased to 70.6 per 100 persons in 2015. *Id.*

drug abuse and overdose, including of [sic] prescription opioids, heroin, and illicit synthetic opioids.¹⁰³

This aspiration notwithstanding, Title 18 of the United States Code currently contains no specific homicide statute that can address the culpability of doctors who act with conscious disregard for their patients in overprescribing opioids.

The CSA, which remains the primary federal law regulating controlled substances, categorizes prescription narcotics and opioids into five schedules (I-V) based on their potential for abuse and addiction, their acceptance for medical applications, and their safety.¹⁰⁴ The drugs listed in Schedule I are considered the most dangerous and are deemed illegal under all circumstances because they have a high potential for abuse, lack accepted safety for use even under medical supervision, and have no currently accepted medical use in treatment in the United States.¹⁰⁵ The drugs in Schedules II-V also have potential for abuse but have medical uses in treatment in the United States or a currently accepted medical use with severe restrictions.¹⁰⁶ The class of drugs listed in Schedule II include commonly prescribed opioid drugs such as morphine, methadone, oxycodone, and injectable forms of methamphetamine that have been used

103. Memorandum on Combatting the National Drug Demand and Opioid Crisis, 82 Fed. Reg. 50,305 (Oct. 26, 2017).

104. *Controlled Substance Schedules*, U.S. DEP'T OF JUSTICE, <https://www.deadiversion.usdoj.gov/schedules> [<https://perma.cc/2RNA-LZUS>].

105. Waldrop, *supra* note 17, at 890. Schedule I drugs include heroin (diacetylmorphine), LSD (Lysergic acid diethylamide), marijuana (cannabis, THC), Mescaline (Peyote), MDMA (3,4-methylenedioxymethamphetamine or "ecstasy"), GHB (gamma-hydroxybutyric acid), ecstasy (MDMA or 3,4-methylenedioxymethamphetamine), Psilocybin, synthetic marijuana and analogs (spice, K2), Methaqualone (quaalude), Khat (Cathinone), and bath salts (3,4-methylenedioxypropylone or MDPV). *See Drug Scheduling*, DRUG ENFORCEMENT AGENCY (Apr. 26, 2019), <https://www.dea.gov/drug-scheduling> [<https://perma.cc/B5H7-ADN3>]; *Controlled Substance Schedules*, *supra* note 104.

106. *Controlled Substance Schedules*, *supra* note 104.

to treat chronic and acute pain. Schedule II drugs have been most closely associated with abuse in the opioid epidemic.¹⁰⁷

When federal prosecutions are pursued against doctors, they are generally brought under the CSA, which makes it “unlawful for any person knowingly or intentionally (1) to manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or (2) to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.”¹⁰⁸ Compliance with the CSA requires medical professionals prescribing substances listed under Schedules II-V to issue prescriptions only for “legitimate medical purposes” within “the usual course of his professional practice.”¹⁰⁹ The CSA also requires prescribers to register with the United States Attorney General,¹¹⁰ and only those registered are exempt from CSA’s criminal penalties for prescribing the drugs in these schedules.¹¹¹ Although registration under the CSA authorizes registrants to prescribe opioids, registration does not immunize a violation of the CSA. In other words, a doctor licensed to prescribe opioids under the CSA may still be prosecuted for a violation of the statute if the doctor issues a prescription outside of the usual course of practice or without a legitimate medical purpose. Depending on the nature of the offense, any person who violates the CSA may be subject to five years to life in prison.¹¹² If death or serious bodily injury “results from” the use of

107. See 21 C.F.R. § 1308.12 (2019); Marsh L. Meldrum, *A Capsule History of Pain Management*, 290 JAMA 2470, 2474 (2003). Schedule II drugs include common opioid painkillers such as morphine, opium, codeine, hydrocodone, hydromorphone, methadone, meperidine, oxycodone, and fentanyl. See *Controlled Substance Schedules*, *supra* note 104.

108. 21 U.S.C. § 841(a)(1)-(2) (2018).

109. 21 C.F.R. § 1306.04. *e.g.*, Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716, 52,717 (Sept. 6, 2006); Hoffmann, *supra* note 14, at 235; *Controlled Substances Act Prosecutions Against Physicians and Other Medical Professionals*, BURNHAM & GOROKHOV (July 19, 2019), <http://www.burnhamgorokhov.com/criminal-defense-resources/federal-crimes/csa-prosecutions-against-physicians> [https://perma.cc/9F6A-ZM4R].

110. 21 U.S.C. § 823 (2018).

111. 21 U.S.C. § 841(a)(1) (2018).

112. 21 U.S.C. § 841(b)(1)(A)-(B) (2018).

a prescribed substance, the prescriber can be sentenced to a term of imprisonment of between fifteen years to more than life in prison.¹¹³

Federal prosecutions of doctors and other medical professionals under the CSA for prescribing practices that result in patient deaths are not common. Beginning in 2017, however, the United States Department of Justice began focusing investigative and prosecutorial resources on doctors' prescribing practices in certain areas of the country, including the Midwest, the Appalachian region, and Florida, which are some of the areas hardest hit by the opioid crisis.¹¹⁴ In 2018 and 2019, those efforts resulted in federal criminal indictments of more than 100 medical professionals across seven states, including doctors, pharmacists, and nurses involved in the fraudulent prescription and distribution of opioids.¹¹⁵ Recent prosecutorial and investigative efforts have focused largely on "pill mills" and pain clinics¹¹⁶ rather than primary care physicians, surgeons, and dentists, who currently issue a significant number of prescriptions and are now, according to some reporting, the main drivers of the opioid crisis.¹¹⁷

The fact that prosecutors have secured high-profile indictments does not, however, demonstrate the effectiveness of the CSA as an enforcement mechanism because criminal indictments do not always result in convictions, and such high-profile indictments may only comprise a small number of the health care providers engaged in dangerous prescribing activities. As Part II describes, the problems with the application of the CSA persist, and securing convictions under the CSA has historically proven difficult because its elements are broad and ambiguous, making the burden of proof challenging.

113. See 21 U.S.C. § 841(b)(1)(C) (2018); 21 U.S.C. § 841(b)(1)(E)(i) (2018).

114. Campbell Robertson, *Doctors Accused of Trading Opioid Prescriptions for Sex and Cash*, N.Y. TIMES (Apr. 17, 2019), <https://www.nytimes.com/2019/04/17/us/doctor-arrested-prescription-drugs.html> [https://perma.cc/3455-WGZE]; *Documents and Resources from the April 17, 2019 Press Conference*, *supra* note 88.

115. Robertson, *supra* note 114.

116. Brian Krans, *More 'Pill Mill' Doctors Prosecuted During Opioid Epidemic*, HEALTHLINE (Oct. 16, 2019), <https://www.healthline.com/health-news/pill-mill-doctors-prosecuted-amid-opioid-epidemic> [https://perma.cc/FG63-777R] (reporting that pill mills and pain clinics are the focus of criminal investigators).

117. See Mann, *supra* note 91.

2. State Laws Governing Controlled Substances

The majority of states also regulate the manufacturing, distribution, and selling of controlled substances. No single uniform approach among the states exists for prosecuting doctors who improperly prescribe opioids. States employ different approaches, including: (1) prosecution under a state's controlled substance laws, (2) prosecution under specific drug-induced homicide laws, and (3) prosecution under general manslaughter or murder laws. At least one state, Alabama, imposes no criminal liability upon the conduct.

In the next sections, analysis of these approaches and evidence of states' enforcement of their drug laws and criminal prosecution of over-prescribers is viewed through the lens of anecdotal cases. In contrast to the federal government, the states do not systematically catalog or maintain lists of their criminal cases.¹¹⁸ Moreover, there is a lack of reliable statistics on state prosecutions due to variations in the state laws and rules described below. Given variations in individual prosecutors' inclinations or styles, charges brought against physicians are also classified differently among states or even within a state.¹¹⁹ That said, the available data show that states prosecuted more cases than the federal government against those who overprescribe opioids.¹²⁰ A study conducted by the Academy of Pain Medicine in conjunction with the Henry Ford Health System examined data gleaned from the DEA, state medical licensing boards, and 43 state attorney general offices. It showed that between 1998 and 2006 nationwide physicians had been criminally charged in state criminal court, and/or had been administratively reviewed, for "offenses involving the prescribing of opioid analgesics" in 178 cases.¹²¹ The individual physicians involved in

118. Donald M. Goldenbaum et al., *Physicians Charged with Opioid Analgesic-Prescribing Offenses*, 9 PAIN MED. 737 at 739 (2008).

119. *Id.* at 739.

120. *Id.* at 741.

121. *Id.*; In 2020 the Henry Ford Health System published a follow-up study covering 2004 to 2017. The update sought to determine "if there have been any changes in the numbers, demographics, physician risk factors, charges, and sanctions involving the DEA against physicians who prescribe opioids, when compared to [the] previous DEA database review from 1998 to 2006." The update did not conduct a state-by-state comparison or gather statistics on individual states' prosecution rates. However, the update found that the

these cases over the study time period represented only 0.1% of the total 691,873 patient-care physicians active during that time period.¹²² With this context in mind the states' various approaches are briefly examined here.

a. Prosecutions Under State Controlled Substance Law

Thirty states, including California,¹²³ Connecticut,¹²⁴ Florida,¹²⁵ Illinois,¹²⁶ Louisiana,¹²⁷ Maryland,¹²⁸ Kansas,¹²⁹ New York,¹³⁰ and West Virginia¹³¹ have controlled substances laws and regulatory frameworks modeled on the federal CSA. Violations of these state statutes are often characterized as a misdemeanor or low-level felony.¹³² Prosecutions of medical professionals under state-controlled substances laws are often

“risk of DEA action as a percentage of total physicians is small,” but the overall rates of DEA prosecution have increased from 14 per review year to 18 per year. David Daewhan Kim & Nabil Sibai, *The Current State of Opioid Prescribing and Drug Enforcement Agency (DEA) Action Against Physicians: An Analysis of DEA Database 2004-2017*, 23 PAIN PHYSICIAN 293 (2020).

122. See Goldenbaum et al., *supra* note 118, at 741.
123. CAL. HEALTH & SAFETY CODE §§ 11350 (West 2018), 11351 (West 2011), 11351.5 (West 2015), 11352 (West 2015), 11352.5 (West 1983), 11357 (West 2018), 11358 (West 2017), 11359 (West 2017), 11360 (West 2017), 11372 (West 2003), 11375 (West 2002), 11377 (West 2018), 11378 (West 2014), 11378.5 (West 2011), 11379 (West 2015), 11379.2 (West 1991), 11379.5 (West 2016), 11379.6 (West 2016), 11550 (West 2015).
124. CONN. GEN. STAT. ANN. § 21a-243 (West 1989).
125. FLA. STAT. ANN. §§ 775.082 (West 2019), 775.083 (West 2017), 893.033 (West 2016), 893.13 (West 2019), 893.135 (West 2019), 893.149 (West 2016).
126. 720 ILL. COMP. STAT. ANN. 550/4 (West 2019), 550/5 (West 2019), 550/6 (West 1971), 550/8 (West 2019), 550/10.3 (West 2019), 570/401 (West 2018), 570/402 (West 2018), 570/411.2 (West 2019); 730 ILL. COMP. STAT. ANN. 5/5-8-1 (West 2020), 5/5-8-3 (West 2015), 5/5-9-1 (West 2019).
127. LA. STAT. ANN. §40:961 (2019).
128. MASS. GEN. LAWS ANN. ch. 94C, §§ 32-32E, 34 (West 2012).
129. KAN. STAT. ANN. §65-4101 (West 2019).
130. N.Y. PENAL LAW § 220.65 (McKinney 2014).
131. W. VA. CODE §§ 60A-1-101 to 60A-6-605 (2017).
132. See *e.g.*, N.Y. PENAL LAW § 220.65 (West 2014) (classified as a “Class C Felony”); CAL. HEALTH & SAFETY CODE § 11350 (West 2018) (classified as a misdemeanor).

brought in conjunction with other charges in the case where the patient dies as a result of a drug overdose.¹³³ In most states, prosecutors have the option to charge physicians either under the state or the federal version of the CSA.¹³⁴

b. Prosecutions Under State Drug-Induced Homicide Laws

Twenty-four states have targeted drug-induced homicide laws to prosecute culpable parties in opioid overdose deaths.¹³⁵ Most of these laws, however, are aimed at prosecuting drug dealers rather than medical professionals who improperly prescribed opioids to patients who subsequently die from

133. *See e.g.*, *People v. Tseng*, 241 Cal. Rptr. 3d 194 (Cal. Ct. App. 2018) (explaining that in addition to three second-degree murder charges, Dr. Tseng was charged with nineteen counts under California's controlled substances laws); *People v. Stan XuHui Li*, 155 A.D.3d 571, 574 (N.Y. App. Div. 2017) (explaining that Dr. Li was charged with 170 counts of criminal sale of a prescription in addition to second-degree manslaughter charges).

134. *See, e.g.*, *Scotland v. Attorney Gen.*, 342 F. App'x 851, 854 (3d Cir. 2009) (holding that a conviction under New York penal law was analogous to an offense under the CSA); *Cadet v. Attorney Gen.*, 339 F. App'x 273, 275 (3d Cir. 2009) (per curiam) (arguing that New Jersey generally proscribes the same conduct as the federal analog). *See generally Criminal Cases Against Doctors*, *supra* note 8, (cataloging investigations of physician registrants in which DEA was involved that resulted in the arrest and prosecution and listing concurrent charges under state law).

135. Lindsay LaSalle, *An Overdose Death Is Not Murder: Why Drug-Induced Homicide Laws Are Counterproductive and Inhumane*, DRUG POL'Y ALLIANCE 56-65 (2017), https://www.drugpolicy.org/sites/default/files/dpa_drug_induced_homicide_report_0.pdf [https://perma.cc/LVY4-89FF]; *see also Drug Induced Homicide Laws*, HEALTH IN JUST. ACTION LAB & LEGAL SCI. (AUG. 16, 2019), <http://www.pdaps.org/datasets/drug-induced-homicide-1529945480-1549313265-1559075032> [https://perma.cc/PC2F-X9WS] (explaining that states with drug-induced homicide laws include Alaska, Arizona, Colorado, Delaware, District of Columbia, Florida, Illinois, Kansas, Louisiana, Michigan, Minnesota, Nevada, New Hampshire, New Jersey, North Carolina, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Vermont, Washington, West Virginia, Wisconsin, and Wyoming). States that have proposed drug-induced homicide legislation include Connecticut, Idaho, Maine, Maryland, Massachusetts, Ohio, South Carolina, and Virginia. *Id.*

a drug overdose.¹³⁶ Illinois,¹³⁷ Pennsylvania,¹³⁸ and West Virginia¹³⁹ (states with the highest rates of opioid-related deaths)¹⁴⁰ have such statutes. Likewise, certain highly populated states, such as New York¹⁴¹ and

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136. See e.g., Zachary A. Siegel & Leo Beletsky, *Charging Dealers with Homicide: Explained*, APPEAL (Nov. 2, 2018), <https://theappeal.org/the-lab/explainers/charging-dealers-with-homicide-explained> [https://perma.cc/8MNM-6CCF].
137. “A person commits drug-induced homicide when he or she violates Section 401 of the Illinois Controlled Substances Act or Section 55 of the Methamphetamine Control and Community Protection Act by unlawfully delivering a controlled substance to another, and any person’s death is caused by the injection, inhalation, absorption, or ingestion of any amount of that controlled substance.” 720 ILL. COMP. STAT. 5/9-3.3 (2018).
138. “A person commits a felony of the first degree if the person intentionally administers, dispenses, delivers, gives, prescribes, sells or distributes any controlled substance or counterfeit controlled substance in violation of section 13(a)(14) or (3) of the act of April 14, 1972 (P.L. 233, No. 64), known as The Controlled Substance, Drug, Device and Cosmetic Act, and another person dies as a result of using the substance.” 18 PA. CONS. STAT. § 2506(a) (2016). A person who has violated section 2506(a) is subject to a prison term up to forty years, unless the victim is less than thirteen years old. 18 PA. CONS. STAT. § 2506(b) (2016).
139. “Murder by . . . a felony offense of manufacturing or delivering a controlled substance as defined in article four, chapter sixty-a of this code, is murder of the first degree.” W. VA. CODE § 61-2-1 (2019).
140. “The largest relative changes [in prescription opioid-involved deaths] included a 29.7% increase in Illinois and a 39.2% decrease in Maine. The highest prescription opioid-involved death rates in 2017 were in West Virginia (17.2 per 100,000), Maryland (11.5), and Utah (10.8).” *Drug and Opioid-Involved Overdose Deaths – United States, 2013-2017*, supra note 3; “In 2017, the states with the highest rates of death due to drug overdose were West Virginia (57.8 per 100,000), Ohio (46.3 per 100,000), Pennsylvania (44.3 per 100,000), the District of Columbia (44.0 per 100,000), and Kentucky (37.2 per 100,000).” *Drug Overdose Deaths*, supra note 2.
141. New York Senate Bill No. 3902, also known as Laree’s Law, proposes the following amendment to the penal code: “A person is guilty of homicide by sale of an opiate controlled substance when he or she unlawfully transports by importing into the state or transporting within the state from one county into another, or unlawfully sells as defined by subdivision one of section 220.00 of this chapter, an opiate controlled substance as defined by subdivision twenty-one of section 220.00 of this chapter, and such opiate

Florida,¹⁴² also have drug-induced homicide statutes. However, these statutes use language not specifically directed at the conduct of physicians, but rather at any *person*. The drug-induced homicide law in Illinois, for example, provides that “[a] *person* commits drug-induced homicide . . . by unlawfully delivering a controlled substance to another, and any person’s death is caused by the injection, inhalation, absorption, or ingestion of any amount of that controlled substance.”¹⁴³ One notable prosecution of a doctor under a drug-induced homicide statute occurred in Florida.¹⁴⁴ In 2015, Florida prosecuted Dr. Gerald Klein under a state statute¹⁴⁵ for first-degree murder in connection with the 2009 overdose death of his twenty-four-year-old patient, whom Dr. Klein had proscribed opioids and a sedative.¹⁴⁶ Dr. Klein’s clinic, described by the prosecution as a “pill mill,” was also accused of prescribing hydromorphone and oxycodone pills daily without sufficient medical justification.¹⁴⁷ Dr. Klein faced life in prison if

controlled substance causes the death of another person.” S.B. 3902, 2019 Leg., 242d. Sess. (N.Y. 2019).

142. “The unlawful killing of a human being . . . [w]hich resulted from the unlawful distribution by a person 18 years of age or older of any of the following substances, or mixture containing any of the following substances, when such substance or mixture is proven to be the proximate cause of the death of the user . . . [a] substance controlled under s. 893.03(1) . . . is murder in the first degree and constitutes a capital felony, punishable as provided in § 775.082.” FLA. STAT. § 782.04(1)(a)(3) (2019).
143. 720 ILL. COMP. STAT. § 5/9–3.3(a) (2019) (italics added); *see also* 720 ILL. COMP. STAT. 5/9–3.3(a-5) (2019) (“A person commits drug-induced homicide when he or she violates the law of another jurisdiction, which if the violation had been committed in this State could be charged under Section 401 of the Illinois Controlled Substances Act or Section 55 of the Methamphetamine Control and Community Protection Act, by unlawfully delivering a controlled substance to another, and any person’s death is caused in this State by the injection, inhalation, absorption, or ingestion of any amount of that controlled substance.”).
144. Marc Freeman, *Jury Acquits Former Pain Clinic Doctor of Murder, Convicts Him of Minor Drug Charge*, S. FLA. SUN SENTINEL (Sept. 16, 2015), <https://www.sun-sentinel.com/local/palm-beach/fl-doctor-murder-trial-verdict-watch-20150915-story.html> [<https://perma.cc/5N98-BW47>].
145. FLA. STAT. § 782.04(1)(a)(3) (2019).
146. Freeman, *supra* note 144.
147. *Id.*

convicted under the state first degree murder statute,¹⁴⁸ but the jury acquitted Dr. Klein on the first-degree charge because it concluded that the patient's negligence contributed to his death.¹⁴⁹

c. Prosecutions Under Pre-existing State Manslaughter/Murder Laws

Several states prosecute overdose deaths under general manslaughter and homicide laws.¹⁵⁰ More than a dozen states prosecute overdose deaths under pre-existing homicide laws.¹⁵¹

Prosecutions under these statutes have seen mixed results. Some have resulted in acquittals, like Dr. Klein's case, as well as another publicized case: *State of Iowa v. Baldi*. In *Baldi*, after prescribing high doses of prescription opioids for five years, the defendant doctor was charged with seven counts of manslaughter in connection with the overdose deaths of patients, including a founding member of the Grammy-Award winning band Slipknot, Paul Gray.¹⁵² Although the prosecution argued that the doctor had prescribed more medication than was medically necessary to patients whom he should have known were abusing the drugs, the jury acquitted the

148. FLA. STAT. § 782.04(1)(a)(3) (2019).

149. Freeman, *supra* note 144. The jury convicted Dr. Klein of a single minor count involving an anti-anxiety drug prescribed to a patient. *Id.*

150. LaSalle, *supra* note 135, at 61–63.

151. These states include: California (CAL. PENAL CODE §§ 192(b) (West 2015), 193(b) (West 2011)); Connecticut (CONN. GEN. STAT. ANN. §§ 21a-277 (West 2017), 21a-279 (West 2015)); Georgia (GA. CODE ANN. § 16-5-3(a)–(b) (West 1984)); Indiana (IND. CODE § 35-42-1-5 (2014)); Iowa (IOWA CODE § 707.5 (2013)); Kentucky (KY. REV. STAT. ANN. § 507.050 (West 1974)); Maryland (MD. CODE ANN. CRIM. LAW § 2-207 (LexisNexis 2002)); Massachusetts (MASS. GEN. LAWS ANN. ch. 265 § 13 (West 2018)); Michigan (MICH. COMP. LAWS § 750.317 (2020)); Missouri (MO. REV. STAT. § 565.024 (2017)); Nevada (NEV. REV. STAT. § 200.070 (2005)); New York (N.Y. PENAL LAW § 125.10 (McKinney 1965)); Ohio (OHIO REV. CODE ANN. § 2903.04 (LexisNexis 2019)); and Texas (TEX. PENAL CODE ANN. § 19.02 (West 1994)).

152. See Deborah Hastings, *Iowa Doctor Charged in Death of Slipknot Bassist Paul Gray Acquitted of Manslaughter*, N.Y. DAILY NEWS (May 1, 2014), <https://www.nydailynews.com/news/national/iowan-dr-daniel-bandi-acquitted-patient-death-charges-including-linked-slipknot-founder-paul-gray-article-1.1776239> [https://perma.cc/5GGJ-ACZT].

defendant. As in Dr. Klein's case, the jury accepted the defense's theory that the patients shouldered responsibility for their deaths by taking more than the prescribed amounts of the medication. The jury consequently concluded that the patients did not die solely as a result of the drugs prescribed by the doctor, a finding that is required under state law for a guilty verdict.¹⁵³ However, prosecutions under general manslaughter and murder statutes in other states, such as Georgia and California, have resulted in several convictions.¹⁵⁴

Georgia prosecutes overdose deaths as involuntary manslaughter¹⁵⁵ and felony murder.¹⁵⁶ For example, in *Chua v. State*, the defendant was a physician who wrote prescriptions to the victim for morphine, oxycodone,

153. *See id.*

154. *See, e.g.,* *People v. Stan XuHui Li*, 155 A.D.3d 571, 574-75 (N.Y. App. Div., 2017), *appeal granted sub nom.* *People v. Li*, 31 N.Y.3d 1119 (2018) (finding that evidence that defendant doctor consciously disregarded risk that victims, who were patients at defendant's pain clinic, would die as a result of his practice of prescribing opioids was sufficient to support defendant's second-degree manslaughter convictions).

155. In Georgia, a person is guilty of involuntary manslaughter if "in the commission of an unlawful act when he causes the death of another human being without any intention to do so by the commission of an unlawful act other than a felony" or "in the commission of a lawful act in an unlawful manner when he causes the death of another human being without any intention to do so, by the commission of a lawful act in an unlawful manner likely to cause death or great bodily harm." GA. CODE ANN. §16-5-3(a)-(b) (1984).

156. *Silver v. State*, 79 S.E. 919, 922 (Ga. Ct. App. 1913) (affirming defendant's conviction of involuntary manslaughter for providing morphine to another, resulting in death); *Hulme v. State*, 544 S.E.2d 138 (Ga. 2001) ("In Georgia, although we have no controlled-substance homicide statute, a person may be convicted of felony murder in this State 'when, in the commission of a felony, he causes the death of another human being irrespective of malice.'"); *Chua v. State*, 710 S.E.2d 540 (Ga. 2011) (finding sufficient evidence to convict defendant physician of felony murder and violation of the Controlled Substances Act for improperly prescribing opioids); *Ayers-Jones v. State*, 829 S.E.2d 878 (Ga. Ct. App. 2019) (finding defendant guilty of the lesser included offense of involuntary manslaughter, even though the state prosecuted defendant drug user under the felony murder statute).

and methadone, among other drugs.¹⁵⁷ The court found that there was sufficient evidence to convict the defendant for felony murder¹⁵⁸ and that “an inappropriate relationship beyond that of physician and patient had developed between [defendant] and [victim]” because the victim lived with the defendant.¹⁵⁹

In 2015, when California brought criminal charges against Dr. Tseng in connection with the overdose deaths of three of her patients, California was one of the first states to proceed successfully against a medical professional under implied malice second-degree murder.¹⁶⁰ A general practitioner in southern California since 2007, Dr. Tseng’s prescribing practices played a role in the deaths of nine patients between 2009 and 2010, all by prescribing opioids.¹⁶¹ She prescribed high quantities and dosages of multiple drugs, conducted perfunctory medical examinations, often saw unrelated patients in the same exam room at the same time, kept virtually no patient records, had limited knowledge of patient symptoms or history, and accepted only cash payments for her services. Although she had been

157. *Chua*, 710 S.E.2d at 540.

158. *Id.*

159. *Id.* at 543.

160. Marisa Gerber, *Doctor Convicted of Murder for Patients’ Drug Overdoses Gets 30 Years to Life in Prison*, L.A. TIMES (Feb. 5, 2016), <https://www.latimes.com/local/lanow/la-me-ln-doctor-murder-overdose-drugs-sentencing-20160205-story.html> [<https://perma.cc/ZD6L-UKPP>]. In California, second-degree murder is any murder that is not “perpetrated by means of a destructive device or explosive, a weapon of mass destruction, knowing use of ammunition designed primarily to penetrate metal or armor, poison, lying in wait, torture, or by any other kind of willful, deliberate, and premeditated killing, or that is committed in the perpetration of, or attempt to perpetrate, arson, rape, carjacking, robbery, burglary, mayhem, kidnapping, train wrecking, or any act punishable under Section 206, 286, 288, 288a, or 289,” or murder that is not “perpetrated by means of discharging a firearm from a motor vehicle, intentionally at another person outside of the vehicle with the intent to inflict death.” The key difference between manslaughter and murder is malice, which can either be express—“when there is manifested a deliberate intention to unlawfully take away the life of a fellow creature”—or implied—“when no considerable provocation appears, or when the circumstances attending the killing show an abandoned and malignant heart.” CAL. PENAL CODE § 189 (West 2020).

161. *People v. Tseng*, 241 Cal. Rptr. 3d 194, 203 (Cal. Ct. App. 2018).

informed by coroners as well as law enforcement officials that her patients fatally overdosed on their medication and that many pharmacies refused to fill prescriptions for her patients, Dr. Tseng failed to alter her prescribing practices. In 2016, a jury found her guilty of three counts of second-degree murder for three patient drug overdose deaths, and she was sentenced to 30-years-to-life in prison. In December 2018, the California Court of Appeal affirmed the convictions.¹⁶² Her case marked the first time in American history that a physician was held criminally liable for the murder of a patient through extreme recklessness in opioid prescribing.

d. States Declining to Prosecute

In at least one state, Alabama, it appears that a licensed physician prescribing a controlled substance cannot be criminally prosecuted under state law, even where the doctor had no legitimate medical purpose for issuing the prescription. In *State v. Hankins*,¹⁶³ the court, relying on precedent from the Alabama Supreme Court,¹⁶⁴ affirmed the trial court's order dismissing an indictment against a doctor who allegedly violated the state's controlled substances laws and engaged in unlawful drug distribution and drug trafficking.¹⁶⁵ The court, interpreting the state's controlled substances laws, concluded as a matter of law that a physician cannot be charged with unlawful distribution of a controlled substance or

162. *Id.* at 209.

163. 155 So. 3d 1043, 1046 (Ala. 2013).

164. *See Ex parte Evers* 434 So. 2d 813, 816–817 (Ala. 1983) (finding that because writing a prescription for a controlled substance is within the scope of the defendant's registration to write prescriptions, the prescribing doctor was immune from prosecution under the state's controlled-substances act even though the doctor admitted that he did not have a legitimate medical purpose for writing the prescription). In *Evers*, the Alabama Supreme Court narrowly construed the state's controlled-substances act, reasoning that the normal sense of the words "selling furnishing or giving away" amphetamines in the act did not encompass crimes not indicated by their wording and did not "sufficiently describe the action of a physician prescribing a controlled substance within the scope of his registration." *Id.* at 816.

165. *State v. Hankins* 155 So. 3d 1043, 1048 (2013) (stating that the statute did not apply to a licensed physician who writes a prescription within the scope of his registration).

drug trafficking where the doctor was properly registered to write prescriptions under the act.¹⁶⁶

Although most states regulate the manufacture, distribution, and sale of controlled substances, no uniform approach exists for prosecuting doctors who improperly prescribe opioids. As shown, states take different approaches from prosecution under state controlled-substance laws, to using homicide and murder laws, to immunizing doctors' prescribing practices. The lack of consistency among the states is concerning especially because of the scope of the opioid epidemic. The next Parts highlight the shortcomings of the existing law and underscore the need for a new national approach.

II. THE INADEQUACY OF THE EXISTING LAW

As described in Part I, federal and state prosecutors have criminal remedies and enforcement mechanisms available to punish healthcare professionals who prescribe controlled substances without a legitimate medical purpose. However, even though indictments of some over-prescribers have increased,¹⁶⁷ these efforts to address overprescribing practices have proven unsuccessful in halting the current opioid epidemic. In fact, data compiled by the CDC suggests that although some opioid prescribers "have become more cautious in their opioid prescribing practices" in the last fifteen years, prescribing rates are still three times higher than they were two decades ago.¹⁶⁸ As recently as 2017 prescribers were issuing 58 prescriptions per 100 Americans; nearly twenty percent of all Americans had at least one prescription for an opioid; and the number of overdose deaths attributable to opioid prescriptions continued to be three times higher than it was in 1999.¹⁶⁹ In addition, all indications from the increasing number of opioid overdoses and deaths during the COVID-19 pandemic suggest that the coronavirus crisis has only exacerbated the

166. *Id.*

167. *See Robertson supra*, note 114; *Krans, supra* note 116.

168. *See Opioid Overdose Prescribing Practices*, CDC, <https://www.cdc.gov/drugoverdose/data/prescribing/prescribing-practices.html> [<https://perma.cc/HP8T-CR9X>] (disclosing that prescribing rates have varied between 2006 and 2017, but is still three times higher than it was in 1999).

169. *Id.*

problem.¹⁷⁰ The CDC found that in the twelve months ending in May 2020, roughly 81,230 people died of a drug overdose in the United States, which is the “largest number of drug overdoses for a twelve-month period ever recorded.”¹⁷¹ These statistics suggest that enforcement of the drug laws meant to address the crisis remain ineffective, and that the legal tools, namely the statutory framework regulating opioid prescribers, are inadequate. This Part analyzes the failings and inherent unfairness of the existing legal approaches that seek to combat dangerous over-prescription practices and the opioid epidemic.

A. The Federal Legal Framework and Law Enforcement Mechanisms Fail to Provide Clear Guidance

Prosecution of doctors under the federal CSA has been problematic in several respects: the lack of clarity in the language of the statutory scheme creates challenges for enforcement, causes healthcare providers to refrain from prescribing opioid drugs even for legitimate medical purposes, and fails to deter doctors who overprescribe opioids. Since the mid-1970s, the courts have struggled with the elements in the CSA¹⁷² that require the

170. *Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic*, CDC HEALTH ADVISORY (Dec. 17th, 2020), https://emergency.cdc.gov/han/2020/han00438.asp?ACSTrackingID=USCDC_511-DM44961&ACSTrackingLabel=HAN%20438%20-%20General%20Public&deliveryName=USCDC_511-DM44961 [https://perma.cc/4V9A-JGU6]. Of the 38 jurisdictions for which synthetic opioid data are available, 37 reported increases in overdose deaths involving synthetic opioids for this period; 18 reported increases topping 50%; and 10 Western states reported an increase of 98% in synthetic opioid-involved deaths. *Id.*

171. *Id.*

172. *See, e.g.*, *United States v. Moore*, 423 U.S. 122, 124 (1975) (interpreting “usual course of practice” under the CSA for those already addicted by looking to other acts to provide insight into congressional intent); *United States v. Feingold*, 454 F.3d 1001, 1008 (9th Cir. 2006) (analyzing the *mens rea* element, and concluding that a conviction appears to require more than a showing of professional negligence); *United States v. Rosenberg*, 515 F.2d 190, 198 (9th Cir. 1975) (Ely, J. dissenting) (“[I]t is difficult to see how the language can be made more precise and at the same time ban the undesirable conduct on the part of physicians which Congress intended to make illegal and

prosecution to prove that the doctor prescribed the substance without a “legitimate medical purpose” and outside “the usual course of his professional practice.”¹⁷³ Courts have also struggled to determine the appropriate test for causation when a prescription results in a patient’s death. Neither the CSA nor its corresponding regulations defines these concepts.¹⁷⁴

In 1975, the Supreme Court first interpreted the “usual course of practice” language in *United States v. Moore*.¹⁷⁵ Dr. Moore was convicted of

subject to sanctions.”); *United States v. Collier*, 478 F.2d 268, 272 (5th Cir. 1973) (“[W]hat constitutes *bona fide* medical practice must be determined upon consideration of evidence and attending circumstances.”) (quoting *Linder v. United States*, 268 U.S. 5, 18 (1925)); *see also* *United States v. Schneider*, 704 F.3d 1287, 1295 (10th Cir. 2013) (following *Feingold*); *United States v. Armstrong*, 550 F.3d 382, 401 (5th Cir. 2008) (attempting to locate the mens rea requirement within the statute).

173. 21 C.F.R. § 1306.04 (2020); *see e.g.*, Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,715 & 52,717 (Sept. 6, 2006) (containing guidance the meaning of the CSA “to make clear that the longstanding requirement under the law that physicians may prescribe controlled substances only for legitimate medical purposes in the usual course of professional practice should in no way interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate pain treatment”); Yang & Haffajee, *supra* note 10, at 1331–33; Hoffmann, *supra* note 14, at 235.
174. *See* 21 U.S.C. § 801(1) (2000) (outlining congressional findings, which include that many controlled substances have a legitimate medical purpose); Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,715, 52,719 (Sept. 6, 2006) (“Throughout the 90 years that this requirement has been a part of United States law, the courts have recognized that there are no definitive criteria laying out precisely what is legally permissible, . . . DEA cannot modify or expand upon this longstanding legal requirement through the publication or endorsement of guidelines.”).
175. 423 U.S. 122 (1975). Two years before the Supreme Court decided *Moore*, the language “in the course of his professional practice” survived a Fifth Circuit challenge on the grounds that the language was unconstitutionally vague in violation of the Due Process Clause. *United States v. Collier*, 478 F.2d 268, 270–71 (5th Cir. 1973). The *Collier* court recognized “[w]hat constitutes bona fide medical practice must be determined upon consideration of evidence and attending circumstances.” *Id.* at 272. However, the court concluded that such circumstantial evidence can be sufficiently clear so as not to be unconstitutionally vague. *Id.* *See also* *United States v. Birbragher*, 603 F.3d

“distribution and dispensation of methadone . . . in violation of 21 U.S.C. § 841 (a)(1)” based on prescribing “large quantities of methadone” for patients with “only the most perfunctory examination” and minimal instructions.¹⁷⁶ He charged fees based on the quantity of drugs prescribed rather than the medical services performed.¹⁷⁷ Moore argued that he used unique protocols in prescribing to treat narcotic addiction, claiming that his patients reduced their use of heroin as a result of his treatment.¹⁷⁸ The Court considered whether Moore’s acts were “outside the usual course of professional practice,”¹⁷⁹ and in doing so it referred to the Narcotic Addict Treatment Act of 1974 (NATA).¹⁸⁰ The Court observed that Congress “sought to ‘cure’” the difficulty in prosecuting physicians under the CSA “because of the intricate and nearly impossible burden of establishing what is beyond ‘the course of professional practice’ for criminal law purposes when such a practitioner speciously claims that the practices in question were ethical and humanitarian.”¹⁸¹ NATA sought to solve the problem by setting up a separate set of explicit requirements that a practitioner must meet to dispense narcotic drugs for maintenance or detoxification treatment for addicts.¹⁸² Although the new law helped clarify what constituted “legitimate medical practice” when treating those already addicted, the phrase has not been defined in other contexts.

478, 489 (8th Cir. 2010) (citing *United States v DeBoer*, 966 F.2d 1066, 1068–69 (6th Cir. 1992)) (holding that CSA and its implementing regulation, is sufficiently clear to provide adequate notice of what conduct is prohibited).

176. *Moore*, 423 U.S. at 124, 131.

177. *Id.* at 126–27.

178. *Id.*

179. *Id.* at 124. In *Moore*, the Court also considered whether registrants under the CSA were exempt from prosecution under section 841(a)(1) and held “that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice.” *Id.* at 124.

180. *Id.* at 139 n.16; Narcotic Addict Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124 (1974).

181. *Moore*, 423 U.S. at 139 n.16 (quoting S. Rep. No. 93-192, at 14 (1973)).

182. Michaela Poizner, *50 Years of Policy-Driving Legislation and the Growing Role of MAT in Combatting the Opioid Crisis*, BAKER OBER HEALTH LAW (Nov. 2, 2020), <https://www.jdsupra.com/legalnews/50-years-of-policy-driving-legislation-45142> [<https://perma.cc/BZ5B-62HL>].

More recently in *Gonzales v. Oregon*¹⁸³ the Supreme Court examined the “legitimate medical purpose” language of the CSA. In *Gonzales*, the Court considered an interpretive rule of the Attorney General of the United States providing that physician-assisted suicide did not qualify as a “legitimate medical purpose,” and that a person violates the Act by prescribing, dispensing, or administering controlled substances to assist suicide.¹⁸⁴ The interpretive rule conflicted with an Oregon law that permitted doctors to dispense or prescribe a lethal dose of drugs upon the request of a terminally ill patient.¹⁸⁵ The Supreme Court recognized that the term “legitimate medical purpose” was not defined in the statute and found that the United States Attorney General did not have the authority under the CSA to define that term. The Court explained that “there is no question that the Federal Government can set uniform national standards”¹⁸⁶ of medical practice, but the Court concluded that the Act “manifests no intent to regulate the practice of medicine generally.”¹⁸⁷ Additionally, because “[t]he structure and operation of the [Act] presume and rely upon a functioning medical profession regulated under the states’ police powers,”¹⁸⁸ the Act does not empower the Attorney General to declare that physician-assisted suicide is not a legitimate medical purpose.¹⁸⁹ At least one court has subsequently interpreted *Gonzales* to state that, “[w]hen Congress enacted the [Act], it thus manifested its intent to leave it to the states to define the applicable standards of professional practice.”¹⁹⁰

Post-*Gonzales*, the lack of a uniform and clear definition of “legitimate medical purpose” in the context of doctors prescribing opioids has arisen in cases in which doctors facing prosecution for their prescribing practices under the CSA have complained that neither the Act nor the relevant case

183. 546 U.S. 243 (2006).

184. *Gonzales*, 546 U.S. at 254.

185. *Id.* at 249.

186. *Id.* at 271.

187. *Id.* at 270.

188. *Id.* at 270, 271.

189. *Id.*

190. *U.S. v. Tobin*, 676 F.3d 1264, 1275 (11th Cir. 2012).

law interpreting it contains clear guidance on what constitutes “legitimate medical purpose” in the context of prescribing opioids.¹⁹¹

*United States v. Miller*¹⁹² is illustrative. In *Miller*, the evidence of criminality was weak, and thus the vague definition of “legitimate medical practice” resulted in the conviction of Dr. Miller, a small-town doctor in rural Colorado who ran a general practice of around 2,500 patients whom he saw for all manner of medical conditions.¹⁹³ In contrast to the fee-driven “pill mill” or “pain clinic” business run by the likes of Dr. Tseng, Dr. Miller ran a legitimate family medicine practice and was well known and liked in the small community.¹⁹⁴ At trial he was depicted as a doctor who spent extra time with his patients and became involved not only in their care, but also their personal lives. He was regarded as a caring doctor, who never turned someone away because they could not pay or because they had complicated conditions or histories that required time to manage.¹⁹⁵ Even the government conceded that Dr. Miller helped many people in his practice.¹⁹⁶ Nevertheless, Dr. Miller eventually ended up accused of improperly prescribing controlled substances to a handful of his patients and was ultimately convicted of six counts of unlawfully distributing a controlled substance, each based on a single prescription written between 2009 and 2012 to five of Dr. Miller’s over 2,500 patients.¹⁹⁷

Miller appealed his convictions and argued, among other things, that the court erred in failing to instruct the jury on the meaning of the term

191. See *U.S. v. Joseph*, 709 F.3d 1082, 1094 (11th Cir. 2013) (rejecting the defendant’s complaint that the court’s instruction on “legitimate medical purpose” failed to adequately define the terms because it instructed the jury to evaluate the doctor’s conduct against a national standard of practice); *U.S. v. Volkman*, 736 F.3d 1013, 1019-1022 (6th Cir. 2013) (assailing the jury instruction and the expert testimony on the standard of care that equated legitimate medical purpose with “usual standard of practice”); *U.S. v. Miller*, 891 F.3d 1220, 1227-30 (10th Cir. 2018) (same).

192. 891 F.3d 1220, 1227-30 (10th Cir. 2018).

193. *United States v. Miller*, Brief of Appellant at 3-5; 2016 WL 7383416, Docket No. 16-1231.

194. *Id.* at p. 5-6

195. *Id.*

196. *Id.* at 13.

197. *Id.* at 9-14; *United States v. Miller*, 891 F.3d 1220 (10th Cir. 2018).

“legitimate medical purpose.”¹⁹⁸ He argued that the court compounded this error by allowing the prosecution’s expert witness to opine on the matter, which he suggested left a gray area in which a doctor may be found criminally liable for prescriptions made within the bounds of a legitimate doctor-patient relationship.¹⁹⁹ Miller asserted the government’s expert failed to properly comprehend and describe the difference between criminal conduct and bad medical practice because “he did not clearly delineate where he would draw the line between bad conduct that only amounts to civil malpractice and bad conduct that violates the criminal standard, opining only that the criminal standard is much more stringent.”²⁰⁰

The Tenth Circuit disagreed and concluded that the district court did not abuse its discretion in admitting the government expert’s testimony. In doing so, however, the court conceded that the CSA had “no specific guidelines concerning what is required to support a conclusion” that a doctor acted outside the usual course of professional practice, or to support a conclusion on whether the medical practitioner’s conduct had no legitimate medical purpose.²⁰¹ Additionally, this case made clear that it was appropriate to leave these matters to the jury.²⁰²

Given the CSA’s lack of specificity in its elements, it appears that courts have resorted to an *ad hoc* analysis to determine whether physicians prescribed opioids for a legitimate medical purpose.²⁰³ Courts have

198. *Miller*, 891 F.3d at 1226.

199. *Id.* at 1227-1229.

200. *Id.* Relatedly, in other cases defendants have complained that the jury instructions on the issue of the “legitimate medical purpose” have failed to sufficiently distinguish between a civil and criminal standard of proof. *See United States v. McIver*, 470 F.3d 550, 557 (4th Cir. 2006).

201. *Miller*, 891 F.3d at 1229.

202. *Miller*, 891 F.3d at 1227-229.

203. *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995) (“[T]here are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice. Rather, the courts must engage in a case-by-case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts.”) (quoting *United States v. August*, 984 F.2d 705, 713 (6th Cir. 1992)). *See also United States v. Sabeau*, 885 F.3d 27, 46 (1st Cir. 2018) (citing *Singh* and recognizing that there is “no pat formula describing what proof is required to

referenced the following factors: whether (1) an inordinately large quantity of controlled substances was prescribed, (2) a large numbers of prescriptions were issued, (3) no physical examination was given, (4) the physician warned the patient to fill prescriptions at different drug stores, (5) the physician issued prescriptions knowing that the patient was delivering the drugs to others, (6) the physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment, (7) the physician used street slang rather than medical terminology for the drugs prescribed, (8) there was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing, and (9) the physician wrote more than one prescription on occasions in order to spread them out.²⁰⁴ Because these factors are ad hoc, they may not provide sufficient guidance to physicians as to which prescribing practices should be used to avoid the risk of criminal investigation and charges. And because “legitimate medical purpose,” as used in the CSA, is undefined by regulation, it is thus subject to different interpretations amongst physicians, prosecutors, and courts. Reliance on precedent-driven factors alone invites inconsistent results in physician prosecutions because jurors, who possess

ground a finding that a defendant acted outside the usual course of professional practice Rather, inquiring courts must approach the issue on a case-by-case basis and sift the evidence in a given case to determine whether a specific set of facts will support a guilty verdict”).

204. *Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52,715, 52,720 (Sept. 6, 2006) (citing *United States v. Rosen*, 582 F.2d 1032, 1036 (5th Cir. 1978)). *Accord Hoffmann*, *supra* note 14, at 277–78; *Yang & Haffajee*, *supra* note 10, at 1333. Courts applying at least one of the ad hoc indicators identified in *Rosen*, which support the inference that a prescription was written for an illegitimate medical purpose under the CSA, include: *United States v. Kohli*, 847 F.3d 483, 490 (7th Cir. 2017) (prescriptions that are repeatedly refilled early for no legitimate reason); *United States v. Joseph*, 709 F.3d 1082, 1104 (11th Cir. 2013) (prescribing excessively large amounts of opioids); *United States v. Armstrong*, 550 F.3d 382, 390 (5th Cir. 2008) (writing multiple prescriptions for overlapping treatment periods in order to “spread out” the prescriptions); *United States v. Merrill*, 513 F.3d 1293, 1297–98 (11th Cir. 2008) (failure to perform a physical examination or diagnostic testing, or performing only minimal examination or diagnostic testing, on patients); *United States v. Hurwitz*, 459 F.3d 463, 474 (4th Cir. 2006) (continuing to prescribe opioids to patients despite the physician’s understanding that the patients were redistributing the opioids prescribed to them).

little to no medical expertise, are placed in the impossible position of having to determine the validity of a medical professional's prescribing practices.

In addition, the courts have struggled to define other elements of proof under the CSA, including the challenge of the requisite *mens rea* standard of "knowingly" or "intentionally."²⁰⁵ Judges often reference objective practices to infer the physician's state of mind, especially in instances where the physician was willfully blind to avoid the requisite guilty knowledge.²⁰⁶ Moreover, courts have seemingly agreed that the knowledge requirement applies to the third element of the crime, *i.e.*, that the prosecution must prove that the physician knowingly or intentionally prescribed outside the usual course of professional practice, or not for a legitimate medical purpose.²⁰⁷ Because determining what the physician knew or intended is difficult, courts have resorted to other *mens rea* theories to determine if a defendant has requisite knowledge to support a conviction under the CSA. For instance, physicians have been convicted under a theory of "willful blindness,"²⁰⁸ which examines whether the defendant has engaged in a

205. Hoffmann, *supra* note 14, at 276.

206. *Id.* (citing Deborah Sprenger, Annotation, *Propriety of Instruction of Jury on "Conscious Avoidance" of Knowledge of Nature of Substance or Transaction in Prosecution for Possession or Distribution of Drugs*, 109 A.L.R. FED. 710, 713, § 2[a] (1992)); Yang & Haffajee, *supra* note 10, at 1333; *see also* United States v. McIver, 470 F.3d 550, 564 (4th Cir. 2006) (affirming a conviction based on evidence that the practitioner "freely distributed prescriptions for large amounts of controlled substances that are highly addictive, difficult to obtain, and sought after for nonmedical purposes," including prescribing one patient more than 20,000 pills in a single year); United States v. Nelson, 383 F.3d 1227, 1230 (10th Cir. 2004) (upholding a conviction of a pharmacist who signed thousands of prescriptions for sale through an online pharmacy).

207. *See, e.g.*, United States v. Feingold, 454 F.3d 1001, 1007-08 (9th Cir. 2006) ("We agree with Dr. Feingold's contention that a practitioner who acts outside the usual course of professional practice may be convicted under § 841(a) only if he does so intentionally Simply put, to convict a practitioner under § 841(a), the government must prove . . . that the practitioner acted with intent to distribute the drugs and with intent to distribute them outside the course of professional practice. In other words, the jury must make a finding of intent not merely with respect to distribution, but also with respect to the doctor's intent to act as a pusher rather than a medical professional.").

208. Sprenger, *supra* note 206, at 713. In these cases, the trial court may issue to the jury a "conscious avoidance" charge, also known as a "willful blindness" instruction. The charge has also been referred to as "an ostrich instruction,

knowing act to avoid learning that a prescription would be improper; the knowing act substitutes for actual knowledge of the criminal endeavor.²⁰⁹ The willful blindness doctrine has been applied in CSA cases, for example, when a doctor has “ignored many warning signs and red flags and consciously eschewed performing the most rudimentary screening that would have revealed many . . . patients’ ruses.”²¹⁰ In *United States v. Katz*, the physician “sought no patient medical history and never ordered diagnostic or laboratory tests for any of the patients . . . [and] provided patients access to controlled substances by routinely refilling 30-day prescriptions when only two weeks had expired.”²¹¹

Finally, the CSA has proved to be an ineffective deterrent because neither the CSA nor its implementing regulations provide specific guidance on the issue of causation. When the government seeks to charge a doctor in the death of a patient—in addition to having to prove the prescription of a controlled substance was outside the usual course of medical practice or without a legitimate medical purpose—the government also has to prove that the patient died “as a result of” taking the prescribed medications.²¹² In the absence of legislative guidance on the intended meaning of these terms, courts had interpreted the term “as a result of” as suggesting a causation

because the defendant is considered by the court to have, figuratively, stuck his head in the sand to avoid learning truths that would otherwise have been patently obvious to the average reasonable person.” *Id.*; see also JULIE R. O’SULLIVAN, *FEDERAL WHITE COLLAR CRIME: CASES AND MATERIALS* 100-01 (2001) (discussing the willful blindness jury instruction).

209. See, e.g., Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 *Geo. Mason L. Rev.* 701, 716 (2009) (describing situations in which the government relied on circumstantial evidence to argue that a physician willfully blinded himself).

210. *United States v. Katz*, 445 F.3d 1023, 1031 (2006).

211. *Id.*

212. The penalty section of § 841 provides that “[i]n the case of a controlled substance in schedule I or II [i.e., oxycodone], . . . if death or serious bodily injury results from the use of such substance [such person] shall be sentenced to a term of imprisonment of not less than twenty years or more than life.” 21 U.S.C. § 841(b)(1)(C) (2018). “[I]n the case of any controlled substance in schedule III [i.e., hydrocodone mixtures], . . . if death or serious bodily injury results from the use of such substance [such person] shall be sentenced to a term of imprisonment of not more than 15 years.” 21 U.S.C. § 841(b)(1)(E)(i) (2018).

along the lines of a “substantial factor” in, or “contributing to,” the victim’s death.²¹³ This meant that even if other factors, including the abuse of other substances, contributed to the patient’s death, the physician who prescribed opioids that contributed to the patient’s death would still be held accountable. In 2014, however, the Supreme Court rejected that interpretation in *Burrage v. United States*,²¹⁴ which held that to secure a conviction for distributing a drug that “results” in death, the government must prove the victim’s use of the drug “is a but-for cause of the death.”²¹⁵

Assuming that the Court’s interpretation in *Burrage* conforms to the intent of the legislature, the result is that the CSA is an ineffective punishment for some of the most egregious overprescribers, like pill mill doctors, whose patients are often seeking drugs and abusing multiple substances simultaneously. Even where a pill mill doctor’s opioid prescriptions contribute to such a patient’s death, given the causation test announced in *Burrage*, that doctor will likely escape punishment under the CSA enhancement.

*United States v. MacKay*²¹⁶ illustrates this point. Dr. MacKay, originally trained as an orthopedist, ran a pain management practice in Brigham City, Utah from the early 1990s until 2011. During that time period, he saw between 80 to 100 patients a day on average for appointments lasting between two and five minutes.²¹⁷ He conducted cursory examinations, if any, of his patients, and he did not take medical histories or conduct relevant testing.²¹⁸

In 2011, a grand jury indicted MacKay on 129 counts, alleging various violations of the CSA. In two of the counts, Dr. MacKay was charged with the death of his patient, David Wirick, a former firefighter who injured his back on the job.²¹⁹ Dr. MacKay began seeing Wirick in the pain management

213. *See, e.g.*, *United States v. Monnier*, 412 F.3d 859, 861–62 (8th Cir. 2005); *People v. Jennings*, 237 P.3d 474, 496 (Cal. 2010); *Commonwealth v. Osachuk*, 681 N.E.2d 292, 294 (Mass. App. Ct. 1997); *State v. Christman*, 249 P.3d 680, 687 (Wash. Ct. App. 2011).

214. 571 U.S. 204 (2014).

215. *Id.* at 218.

216. *United States v. MacKay*, 20 F. Supp. 3d 1287 (D. Utah 2014).

217. *United States v. MacKay*, 715 F.3d 807, 813 (10th Cir. 2013).

218. *Id.* at 816.

219. *Id.* at 825-26.

practice in 1999 and continued to see him for approximately seven years, prescribing a variety of opioids.²²⁰ In January 2006, Wirick overdosed on methadone that Dr. MacKay had prescribed.²²¹ Dr. MacKay was aware that his prescription had caused Wirick's overdose, but he did not recommend any change in Wirick's course of treatment. As a result, Wirick stopped treatment with MacKay and decided instead to seek pain management treatment through his family physician.²²² However, when his family physician's office refused to give Wirick an early refill of his pain medication, Wirick went back to see Dr. MacKay, who prescribed Wirick with both oxycodone and hydrocodone. Three days later, Wirick died.²²³ An autopsy revealed that Wirick died as a result of the combined effects of oxycodone, hydrocodone, and Valium, as well as pneumonia.²²⁴ At the close of MacKay's trial, the court instructed the jury to decide whether Wirick's death "resulted from" the use of the drugs prescribed by MacKay. The jury was not, however, given any further direction as to the meaning of "resulted from."²²⁵

The jury convicted MacKay of forty federal charges.²²⁶ On appeal, he argued that the trial record contained insufficient evidence to support his convictions on the counts of distributing a controlled substance that resulted in death.²²⁷ The Tenth Circuit disagreed, finding that sufficient evidence existed to support those convictions, but remanded the case on unrelated sentencing errors.²²⁸ While the case was before the district court on remand, *Burrage* came down. The district court subsequently determined that the jury instructions in *MacKay* failed to conform to *Burrage's* newly announced standard and it vacated Dr. MacKay's convictions on the two counts related to Wirick's death.²²⁹

220. *Id.*

221. *Id.*

222. *Id.*

223. *Id.*

224. *Id.*

225. *United States v. MacKay*, 20 F. Supp. 3d 1287 (D. Utah 2014).

226. *MacKay*, 715 F.3d at 813.

227. *Id.* at 813-14.

228. *Id.* at 830, 846-47.

229. *MacKay*, 20 F. Supp. 3d at 1295.

B. The States' Legal Framework and Law Enforcement Mechanisms Lack Uniformity

Prosecution under state law is also variable and unpredictable. As described in Part I, states have adopted different approaches to policing healthcare providers who overprescribe opioids ranging from prosecution under a state's controlled-substance law, drug-induced homicide law, or general manslaughter and murder laws to imposing no criminal liability on healthcare prescribers. Thus, on one end of the spectrum, a doctor who overprescribes opioids which result in the death of a patient in Florida may face serious murder charges and be sentenced to life in prison or death.²³⁰ And on the other end, that same doctor practicing medicine in Alabama would be immune from prosecution for any harms that resulted from an over-prescription of opioids.²³¹ Although this disparity in states' treatment of the same conduct may seem unfair viewed from the patient-victim perspective, the desire to maintain states' autonomy and federal hesitancy to interfere with the states' regulation of the practice of medicine may explain why the differences in the states' enforcement approaches persist.²³² And the American system of federalism certainly contemplates diversity among the states, respecting the ability of the states to act in their own best interests in matters pertaining to criminal law²³³ and the

230. See FLA. STAT. § 782.04(1)(a)(3)-(4) (2019) ("The unlawful killing of a human being . . . [w]hich resulted from the unlawful distribution by a person 18 years of age or older of any of the following substances, or mixture containing any of the following substances, when such substance or mixture is proven to be the proximate cause of the death of the user . . . [a] substance controlled under s. 893.03(1) . . . is murder in the first degree and constitutes a capital felony, punishable as provided in s. 775.082 [prescribing the penalty of death or life in prison without the possibility of parole]").

231. See *State v. Hankins* 155 So. 3d 1043, 1048 (Ala. Civ. App. 2013); *Ex Parte Evers* 434 So. 2d 813, 816 (Ala. 1983).

232. See Jacob C. Hanley, *Illegitimate Medical Purpose: Resolving the Fundamental Flaw in Criminal Prosecutions Involving Physicians Charged with Overprescribing Prescription Opioids*, 58 DUQ. L. REV. 229, 244 (2020).

233. See Wayne A. Logan, *Contingent Constitutionalism: State and Local Criminal Laws and the Applicability of Federal Constitutional Rights*, 51 WM. & MARY L. REV. 143, 146 (2009) (recognizing the decentralizing effect of federalism which preserves the authority of the states to enact and enforce laws,

regulation of the practice of medicine.²³⁴ But reliance on the individual states to enact laws to address the overprescription of opioids has thus far not been a successful response to the crisis.²³⁵

Moreover, given that the opioid epidemic is a national rather than a regional crisis,²³⁶ the disparity in punishment for overprescribing among the states is troubling. Varied legal standards among states make it unclear what conduct would render a prescriber criminally liable. Indeed, even in states that have statutes that criminalize drug-induced homicide, doctors have not been consistently charged for their deadly prescribing practices. In some instances prosecutors appear hesitant to bring such charges against doctors because statutes either: (1) do not include “prescribing” among the acts triggering liability,²³⁷ (2) express the clear legislative intent to single out street drug dealers and drug traffickers, rather than licensed medical

especially relative to police power, thereby making nonuniformity of laws an unavoidable reality in a federalist system).

234. Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716 (Sept. 6, 2006) (acknowledging that the “DEA does not act as the Federal equivalent of a State medical board overseeing the general practice of medicine. State laws and State licensing bodies (such as medical licensing boards) collectively regulate the practice of medicine”).
235. See Liz Essely Whyte & Ben Wieder, *Politics of Pain: Drugmakers Fought State Opioid Limits Amid Crisis*, CTR. FOR PUB. INTEGRITY (Sept. 18, 2016), <https://publicintegrity.org/politics/state-politics/politics-of-pain-drugmakers-fought-state-opioid-limits-amid-crisis> [https://perma.cc/LSF2-XQX5] (describing how grassroots efforts to strengthen state laws aimed at opioid prescribing practices were unsuccessful in the face of a pharmaceutical companies’ 50-state strategy to oppose those efforts).
236. *Opioid Summaries by State*, NAT. INST. ON DRUG ABUSE (May 27, 2020), <https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state> [https://perma.cc/NR92-8UA6]; Nabarun Dasgupta, Leo Beletsky & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH. 182, 183 (2018) (recognizing that the opioid epidemic is a national public health emergency); see also *U.S. Opioid Overdose Death Maps*, CDC, <https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html> [https://perma.cc/4Q6A-CU42] (showing that opioid overdose deaths from 2015-2018 affect every county and region of the United States).
237. See e.g., 720 ILL. COMP. STAT., 5/9-3.3(a) (West, 2019).

professional prescribers,²³⁸ or (3) are controversial and unpopular with the public.²³⁹ The absence of a clear, predictable, and consistent response at the state level that can address the crisis lends support for a uniform national effort.²⁴⁰

The national response grounded in federal criminal law described in Part III does not, however, seek to preempt or supplant the states' regulation of the practice of medicine or the criminalization of healthcare professionals who overprescribe opioids. Rather, the proposal here is intended to augment and supplement the states' laws and in so doing bring clarity for well-meaning practitioners and predictability for prosecutors to hold wrongdoers accountable.

C. Consequences of the Lack of Clarity in the Law

Opioid-related drugs have medically efficacious applications that were unimaginable at the outset of the "War on Drugs" in the 1970s, and acceptable prescribing practices for opioids have dramatically changed in that time.²⁴¹ Yet, as cases such as *Miller* illustrate, the CSA and its interpretations have remained vague and inconsistent. This Section demonstrates why the lack of clarity in the law has resulted in troublesome

238. *See e.g.*, S.B. 3902, 2019 Leg., 242nd Sess. (N.Y. 2019).

239. *See* Claire Goforth, *Florida in Debate Over Murder Charges for Drug Dealers Whose Buyers Die*, JUV. JUST. INFO. EXCHANGE (July 29, 2019), <https://jjie.org/2019/07/29/florida-considers-murder-charge-for-drug-dealers> [<https://perma.cc/VZA8-G8WQ>]; Jack Shuler, *Overdose and Punishment*, NEW REPUBLIC (Sept. 26, 2018), <https://newrepublic.com/article/150465/prosecutors-reviving-reagan-era-drug-induced-homicide-laws> [<https://perma.cc/KBV6-EPPD>]; *Rethinking the Drug Dealer*, DRUG POL'Y ALLIANCE (2019), http://www.drugpolicy.org/sites/default/files/dpa-rethinking-the-drug-dealer_0.pdf [<https://perma.cc/7M7M-ZN7G>].

240. *See* National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy, PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 226 (Richard J. Bonnie et al. eds., 2017), https://www.ncbi.nlm.nih.gov/books/NBK458660/pdf/Bookshelf_NBK458660.pdf [<https://perma.cc/7L77-BEYK>] (recognizing that a national systems approach led by the federal government would most effectively address the national opioid crisis).

241. *Id.* at 25-26 (chronicling the history of opioid prescribing practices).

consequences. On the one hand, the imprecision in the law may deter doctors who fear criminal sanctions under the CSA from issuing prescriptions for legitimate purposes. On the other hand, the lack of clarity and the variation in the laws among states hamper effective and consistent enforcement. Finally, the ambiguity exacerbates the tension between the law enforcement and medical communities, as well as perpetuates the perception that the law is biased.

1. The CSA Discourages Physicians from Providing Medically Acceptable Palliative Treatment While Also Failing to Effectively Deter Doctors Who Overprescribe Opioids

Recent studies estimate that 50 million American adults suffer from chronic pain while 19.6 million suffer from high-impact chronic pain.²⁴² Chronic-pain management is a predominant objective of palliative care and is one of the most common reasons Americans seek medical treatment.²⁴³ Those who have experienced chronic pain understand how the pain, and attempts to manage it, dominate one's daily life,²⁴⁴ and the Supreme Court has implicitly recognized the liberty interest of pain treatment.²⁴⁵ Chronic pain has notoriously been undertreated because of a lack of physician

242. James Dahlhamer et al., *Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults — United States, 2016*, MORBIDITY & MORTALITY WEEKLY REP. (Sept. 14, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm?s_cid=mm6736a2_w [<https://perma.cc/KA8X-BDNH>].

243. World Health Organization, *Cancer Pain and Palliative Care*, 804 TECH. REP. SERIES 11 (1990). Palliative care, as defined by the World Health Organization, is “[t]he active total care of patients whose disease is not responsive to curative treatment” and the ultimate goal “is achievement of the best possible quality of life for patients and their families.” *Id.*

244. Oken, *supra* note 15, at 1917 (“All [the patient] can think about is pain: there is no past pain-free memory, no pain-free future, only the pain-filled present. Pain destroys autonomy: the patient is afraid to make the slightest movement. All choices are focused on either relieving the present pain or preventing greater future pain.”).

245. Hoffmann, *supra* note 14, at 291–92 (citing *Washington v. Glucksberg*, 521 U.S. 702 (1997); *Vacco v. Quill*, 521 U.S. 793 (1997)).

education, general fear of opioids, and, in light of the CSA and related laws, the fear of legal repercussions for overprescribing.²⁴⁶

Unfortunately, because the proscriptive scope of the CSA is unclear, it has deterred some physicians from lawfully prescribing controlled substances to patients in desperate need of opioids for chronic pain.²⁴⁷ This fear of prosecution has reduced the already-low number of available physicians willing to prescribe opioids for chronic pain and increased the number of patients who are undertreated.²⁴⁸ Even the DEA acknowledges that the laws regulating physician prescriptions of controlled substances “should in no way interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate pain treatment.”²⁴⁹ And although the ambiguous language of the CSA dissuades some doctors from prescribing all opioids, it does not discourage everyone. At least one scholar has argued that some physicians are not daunted by the CSA because there is no inherent stigma associated with violating the statute.²⁵⁰ The fact that the CSA appears to simultaneously deter some but not others from engaging in the same conduct is not only a function of the individual prescriber’s tolerance for risk of investigation and punishment, but also a result of vagueness in the statute.²⁵¹ The coexistence of these two seemingly contradictory effects of the CSA represents the statute’s failure to consistently eliminate conduct it was intended to prevent. Like other vague laws, it fails to give sufficient guidance to those who intend to comply as well as fair notice to those it is meant to deter, and it creates the possibility of discriminatory enforcement.

246. See Barnes & Sklaver, *supra* note 15, at 95; Oken, *supra* note 15, at 1941-43; Reidenberg & Willis, *supra* note 15, at 904; Yang & Haffajee, *supra* note 10, at 1333-34.

247. Barnes & Sklaver, *supra* note 15; Reidenberg & Willis, *supra* note 15.

248. Hoffmann, *supra* note 14, at 235.

249. Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. at 52,716 (Sept. 6, 2006).

250. See Theodore G. Chiricos et al., *Inequality in the Imposition of a Criminal Label*, 19 SOC. PROBS. 553, 562-64 (1972) (noting that defendants that pled “guilty” and are represented by private counsel are more likely to avoid the stigma attached to a criminal conviction; however, those defendants accused of a personal offense, such as homicide, are least likely to avoid the criminal stigma).

251. See Hoffmann, *supra* note 14.

Lack of clarity in the law also presents challenges for holding wrongdoers accountable. Although Congress enacted the CSA to deter and punish those who illegally distribute and prescribe controlled substances,²⁵² the millions of opioids prescriptions in the last twenty years, as well as the hundreds of thousands of opioid-related deaths, suggest that the CSA is an ineffective deterrent.²⁵³ Because the law is unclear, convincing a jury of guilt and securing a conviction that will withstand appellate scrutiny is less certain. This uncertainty may alter the balance of the negotiating power between prosecutors and defendants. In the face of a vague prohibition against the conduct, doctors engaged in harmful overprescribing may escape with only a minor violation and fine, or perhaps no penalty at all. Moreover, even though certain provisions under the CSA provide for lengthy prison sentences if violated, a physician will only get a long sentence if sufficient evidence to sustain a conviction is presented.²⁵⁴ If physicians believe that they can avoid criminal penal liability, they may continue to engage in illegal practices and violate the CSA.

In contrast to the CSA, unambiguous homicide statutes deter generally and specifically by both putting society on clear notice of what acts are proscribed and by punishing after the fact. Imposing homicide charges upon an individual devastates his or her reputation in society, as it is nearly impossible to avoid the criminal stigma associated with the offense.²⁵⁵ A physician will likely be cognizant of behaviors that give rise to criminal homicide charges and will be wary of risking their professional reputation. Most importantly, a clear statute that targets specific and defined conduct will also give physicians the freedom to alleviate legitimate chronic pain without fear of criminal ramifications.²⁵⁶

252. See 116 CONG. REC. 1662-68 (1970).

253. See generally, *Criminal Cases Against Doctors*, *supra* note 8 (containing arrest and conviction information of physicians registered with the DEA from the last seven years and illustrating the number of physicians convicted under the federal CSA or a state's equivalent).

254. See 21 U.S.C. §§ 841, 848 (2006) (potential prison term of twenty years to life for engaging in a continuing criminal enterprise). See generally *Criminal Cases Against Doctors*, *supra* note 8 (detailing punishments ranging from probation to life in prison).

255. See Chiricos et al., *supra* note 250, at 564.

256. Dispensing of Controlled Substances for the Treatment of Pain, 69 Fed. Reg. 67,170-71 (Nov. 16, 2004).

2. The Current Law Has Perpetuated the Tension Between Drug Enforcement Agencies' Approaches and the Medical Community, Highlighting Their Conflicting Goals

Physicians and drug enforcement personnel such as the DEA, along with other government enforcement agencies, disagree about how best to address the opioid epidemic, and the uncertain legal landscape has made matters worse. Some in the medical community promote the use of opioids beyond palliative applications for those that are terminally ill and seek to increase their use to treat addiction.²⁵⁷ For example, the American Medical Association has created an Opioid Task Force, which has published a list of recommendations for how to attack the epidemic.²⁵⁸ This list includes suggestions such as the removal of authorization burdens before allowing the use of medication to treat opioid-use disorder, as well as the removal of administrative and other barriers to comprehensive rehabilitation programs.²⁵⁹ Additionally, one of the main goals of the Task Force is to help provide more education and training for health practitioners.²⁶⁰

In contrast, drug enforcement agencies attempt to limit the number of opioid prescriptions by restricting all uses of the drug, thereby cutting off the source of the addiction. For instance, the DEA's "360 Strategy" is aimed at controlling drug diversion by targeting practitioners, among others, and it consists of using law enforcement and other administrative tactics to curb prescriptions.²⁶¹ The DEA and Department of Justice have also pressured physicians and pharmacists to detect addiction in drug-seeking patients

257. Vivek H. Murthy, *Surgeon General's Report on Alcohol, Drugs, and Health*, 317 JAMA 133-34 (2017), <http://www.ncbi.nlm.nih.gov/pubmed/27854372> [<https://perma.cc/X6C5-76QW>]; Devesh Vashishtha et al., *The North American Opioid Epidemic: Current Challenges and a Call for Treatment as Prevention*, 14 HARM REDUCTION J. (2017), <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-017-0135-4> [<https://perma.cc/GFV2-FN4L>].

258. *Reversing the Opioid Epidemic*, AM. MED. ASS'N (July 29, 2019), <https://www.ama-assn.org/delivering-care/opioids/reversing-opioid-epidemic> [<https://perma.cc/DFK8-HKWF>].

259. *Id.* at 6.

260. *Id.*

261. *360 Strategy*, DRUG ENFORCEMENT AGENCY (July 19, 2019), <https://www.dea.gov/360-strategy> [<https://perma.cc/K44K-U42G>].

when deciding whether to prescribe opioids.²⁶² For instance, the DEA expects pharmacists to be able to spot when a drug prescription was obtained fraudulently or issued for a non-medical purpose.²⁶³

The lack of consistent, clear, and predictable legal mechanisms to regulate and criminalize prescribing practices has prolonged the tension between law enforcement and the medical community. As it stands, neither side has sufficient information to navigate in a manner that meets their respective goals and obligations without constraining the other. The tension between the medical profession and federal and state governments regarding how to best use these powerful opioid drugs without causing abuse and addiction is unresolved, and the current law has not alleviated the strain. In the meantime, hundreds of thousands of Americans have lost their lives as the result of addiction to opioids.²⁶⁴

3. The Current Law Maintains the Perception of Racial and Socio-Economic Inequities in the Criminalization of Similar Drug Offenses

Since the inception of the “War on Drugs” in the 1970s, which culminated into the harsh drug sentencing laws enacted in the Violent Crime Control and Law Enforcement Act of 1994, drug laws have disproportionately impacted poor and urban people of color²⁶⁵ by criminalizing the use and sale of drugs while failing to consistently criminalize the virtually identical conduct of those—generally affluent, white medical professionals—who overprescribe opioids.²⁶⁶ Although people of color are no more likely to use illicit drugs than white people, they

262. *Controlled Substances Act Prosecutions Against Physicians and Other Medical Professionals*, *supra* note 109.

263. *Id.*

264. *See Drug Overdose Deaths*, *supra* note 2.

265. *Punishment and Prejudice: Racial Disparities in the War on Drugs*, HUM. RTS. WATCH (May 2000), <https://www.hrw.org/legacy/reports/2000/usa/index.htm> [<https://perma.cc/JVE4-GQWV>].

266. *Race and the War on Drugs*, ACLU DRUG POL’Y LIT. PROJECT (May 2003), aclu.org/sites/default/files/field_document/ACF4F34.pdf [<https://perma.cc/6JWF-R67C>].

are six to ten times more likely to be incarcerated for drug offenses.²⁶⁷ Due to its association with white individuals,²⁶⁸ opioid use is viewed as a medical necessity while opioid addicts are more likely to be considered victims.²⁶⁹ In contrast, people of color are more closely connected with the use of heroin and are more likely to have their conduct criminalized.²⁷⁰ The inconsistent enforcement of the CSA for overprescribing doctors, caused in part by the insufficiency in the law itself, has done nothing to dispel the perception of unfairness and biased enforcement.

Although a new national homicide statute designed to criminalize the conduct of overprescribing opioids will not remedy the institutional racial stereotyping and bias that has caused the inequitable enforcement of current drug laws against people of color, it may alter the optics and conversation about the issue. Thus, adopting a clear national approach to the criminalization of overprescribing opioids will not only remove the variability of physician prosecution so that equivalent criminal conduct will be treated similarly, but it may also rewrite the narrative that criminalizes urban black and Latino heroin abusers while sympathetically portraying suburban white addicts as victims.

III. THE PROPOSED CRIMINAL LAW SOLUTION

A consistent, national response rooted in federal criminal law is appropriate given the nationwide scope of the opioid crisis, the inconsistent state approaches, and the racial disparities in enforcing existing criminal drug laws. Historically, states have regulated the practice of medicine generally, with the federal government intervening to regulate federally

267. Julie Netherland & Helena Hansen, *White Opioids: Pharmaceutical Race and the War on Drugs that Wasn't*, 12 *Bio. Socs.* 217-238 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5501419/pdf/nihms752948.pdf> [<https://perma.cc/RV3Q-HFSM>].

268. According to data issued by the CDC in 2014, people of color have been prescribed opioid-based pain medication in far lower rates than whites and are less likely to suffer from opioid addiction. Commentators have explained that this disparity in opioid prescriptions resulted from the medical profession's view that people of color could not be trusted to *not* abuse opioids. BETH MACY, *DOPESICK* 254 (2018).

269. Netherland & Hansen, *supra* note 267.

270. *Id.* at 12.

controlled substances specifically with the CSA.²⁷¹ Under state CSAs, physicians must be licensed to prescribe controlled substances in that particular state, and even then the state requires that the prescription be issued for a legitimate medical purpose in the usual course of professional practice.²⁷²

This notwithstanding, the epidemic of opioid abuse and addiction is not confined to one state or national region, and no area of the country is immune from the crisis.²⁷³ Patients have crossed state lines to obtain prescriptions from pill mill doctors, as evidenced by Dr. Tseng's case, where one individual traveled from Arizona specifically to be treated by Dr. Tseng in southern California.²⁷⁴ Given that the opioid crisis encompasses the entire United States,²⁷⁵ a consistent and predictable approach to prosecuting physicians for overprescribing opioids is imperative. The arbitrary fact of where a physician practices medicine should not dictate the legal response to their conduct. California should not be the only state where physicians like Dr. Tseng can be held criminally responsible for the murder of their patients when patients throughout the United States are dying because of opioid overdoses legally prescribed by their physicians.

Accordingly, this Part offers an alternative to the current federal CSA that more accurately calibrates the balance between pain treatment and reduction of drug diversion and abuse by offering a more specific and contextual legal framework focused on the expertise of the medical prescriber as well as their specific knowledge of the patient's circumstances. When physicians knowingly prescribe controlled substances in excessive doses and varieties to their patients for an unarticulated medical purpose, which ultimately results in that patient's death, their behavior is likely to rise to the level of criminal homicide. Although the CSA and related state laws have existed for almost forty years, these laws have proven ineffective in stemming the tide of over-prescription throughout the nation. Consequently, the enactment of a new

271. Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. at 52,717 (Sept. 6, 2006).

272. *Id.*

273. *Opioid Summaries by State*, *supra* note 236.

274. *Tseng*, 241 Cal. Rptr. 3d at 125.

275. See *Opioid Summaries By State*, NIH (2018), <https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state> [<https://perma.cc/833M-PJJS>].

federal statute to criminalize a physician's conduct of overprescribing opioids that cause the death of a patient is required.

Currently, the CSA details that charging a violation of section 841(a) requires that the government "prove: (1) 'that the [physician] distributed... a controlled substance'; (2) that the [physician] 'acted knowingly and intentionally'; and (3) 'that the [physician's] actions were not for legitimate medical purposes in the usual course of his professional medical practice or were beyond the bounds of medical practice.'"²⁷⁶ As discussed earlier, the third element in particular has proved to be problematic for prosecutors and has brought uncertainty to the medical profession. Notably, this element differs from the elements necessary to prosecute under typical homicide statutes, such as California's second-degree murder statute, which requires the unlawful killing of a human being with malice aforethought.²⁷⁷ Unlike the CSA's third element, which focuses on the doctor's purpose in prescribing the medicine and whether it was beyond the bounds of the medical practice, the federal statute proposed here focuses on the doctor's knowledge and intent. The proposed statute is described and then analyzed below.

A. Proposed Federal Criminal Statute: The Prescription Abuse Prevention Act

(a) A health care professional who without express malice to cause death, acting with implied malice, proximately causes the death of another by knowingly and intentionally prescribing, distributing, bartering, delivering, exchanging, or administering a controlled substance classified in Controlled Substances Act, 84 Stat. 1242, 21 U.S.C. § 801 et seq., is guilty of murder in the second degree and may be sentenced to imprisonment for 20 years to life.

(b) "Implied malice," as used in subsection (a), may be shown by the possession of specialized medical or expert knowledge of the dangerousness and the addictive nature of the controlled substances classified in Controlled Substances Act, 84 Stat. 1242, 21 U.S.C. § 801 et seq. in addition to other evidence showing that the actor, knowing the act was dangerous to human life, deliberately acted with conscious disregard for human life.

276. *United States v. Hurwitz*, 459 F.3d 463, 475 (4th Cir. 2006) (quoting *United States v. Singh*, 54 F.3d 1182, 1187 (4th Cir. 1995)).

277. *See* CAL. PENAL CODE §§187 & 188.

(c) The phrase “health care professional” as used in subsection (a), means a physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which they practice or do research, to distribute, dispense, conduct research concerning, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

B. Analysis of the Proposed Statute

The proposed statute, the Prescription Abuse Prevention Act (PAPA), seeks to both punish healthcare professionals who overprescribe controlled substances and deter others from engaging in that practice. It will address scholars’ criticism that the current CSA is ambiguous and has caused well-meaning healthcare providers to choose not to prescribe opioids based on the fear of prosecution.²⁷⁸ The PAPA will provide much-needed clarity in the law, thereby allowing legitimate prescribers to continue to treat patients in pain. Most notably, it codifies in statute the legal principles which the California Court of Appeal recognized as dispositive in *Tseng*.

In *People v. Tseng*, Dr. Tseng argued that there was insufficient evidence to support implied malice second-degree murder because there was no evidence of her actual awareness of the dangerousness of her conduct.²⁷⁹ However, the California appellate court disagreed and cited evidence from which the jury could infer Dr. Tseng’s actual knowledge of the effect of her prescribing practices.²⁸⁰ This included the fact that she was informed by law enforcement that some of her patients had overdosed on the drugs she had prescribed, that pharmacies questioned her about the medical necessity of certain prescriptions, and that others refused to fill the prescriptions she issued.²⁸¹ Additionally, Dr. Tseng knew that some patients appeared to be drug-seeking, and that some were simultaneously obtaining drugs from her, other doctors, and multiple pharmacies.²⁸² In conclusion, the court

278. See Hoffmann, *supra* note 14; Yang & Haffajee, *supra* note 10; Barnes & Sklaver, *supra* note 15.

279. *Tseng*, 241 Cal. Rptr. 3d at 203.

280. *Id.* at 205.

281. *Id.*

282. *Id.*

highlighted that Dr. Tseng’s “expert knowledge of the life-threatening risk posed by her drug prescribing practices” as well as her “experience and medical training regarding opioids and other controlled substances” was substantial evidence to sustain the jury’s verdict on the implied malice murder convictions.²⁸³

Accordingly, the implied malice standard in the PAPA embeds a doctor’s expert knowledge, practice experience, and specialized medical training evidence into the offense, and in so doing serves to elevate the charge from the realm of negligence homicide (involuntary manslaughter) to second degree implied malice murder. This standard is appropriate because a doctor has the necessary expertise and background knowledge, gleaned from practice and medical education, to appreciate the risk of harm from opioids. The implied malice included in PAPA requires the factfinder to consider the subjective risk that the physician was able to assess in light of their knowledge and expertise from their medical training, rather than focusing on the medical purpose for issuing the prescription.

Although focusing on “expert knowledge” to elevate the degree of the crime is new in the context of medical professionals prescribing opioids, the use of special status/expert knowledge finds an analog elsewhere in criminal law. In California, for example, when a drunk-driver kills a person, the driver will typically face vehicular manslaughter or gross vehicular manslaughter charges.²⁸⁴ If, however, the driver is an EMT, nurse, or other healthcare worker, the driver will likely face second-degree implied malice murder charges because, as a matter of their special knowledge and training, the driver is deemed to have a unique appreciation for the risk involved in drunk driving.²⁸⁵ Similarly, in the context of a medical professional prescribing opioids, knowledge of the dangers of the opioid prescription should be imputed upon the prescriber and the law should deem the prescriber to have a subjective understanding of the risk of overdose and addiction from the prescription, which, in addition to other

283. *Id.* at 204.

284. CAL. PENAL CODE § 191.5 (West 2011).

285. In California, a DUI resulting in the death of another human being is known as a “Watson Murder.” The “Watson Murder” or “Watson Murder Rule” originated with the case of *People v. Watson*, in which a multiple-DUI offender’s prior convictions were used to prosecute him for second-degree murder under the legal theory of “implied malice,” based on knowledge of the subjective risk of driving under the influence that was imputed to the defendant based on his prior conduct, special knowledge or training. *See People v. Watson*, 30 Cal. 3d 290 (2018).

case-specific evidence, can be used to prove implied malice and support a second-degree murder charge.

The PAPA includes this presumption of knowledge and provides a viable alternative standard to the CSA and similar state statutes. When looking at the characteristics and scope of the current American opioid crisis, as well as the evolving views on the treatment of pain, it is clear that the elements in the CSA are unworkable. Under the current standard, physicians may see patients who are legitimately in pain and also abusing or diverting narcotics. Thus, doctors who are prescribing to someone legitimately in pain, even if they are aware of signs that they are also diverting or abusing, may be able to escape liability if the prescription of the opioid was also for a legitimate medical purpose. On the other hand, because of the lack of clarity in the CSA's legal standards, physicians such as Dr. Miller may be found criminally liable for prescriptions made within the bounds of a legitimate doctor-patient relationship.

By adopting an "implied malice" standard in the PAPA, factfinders can more accurately convict or acquit prescribers by first evaluating the facts available to the prescriber about the patient, and then evaluating those facts within the context of the prescriber's special knowledge of the risks due to the prescriber's status as a physician. This statute will also provide more guidance to prescribers by including clear definitions of the implied malice standard in the context of current medical practices. Not only will the "implied malice" standard resolve the confusion that the language in the CSA has presented for doctors, but it will also deter those doctors who are effectively dealing narcotics rather than practicing medicine, while also allowing other doctors to continue to use opioids when medically necessary to treat chronic pain.

Indeed, because PAPA is narrowly focused on the prescribing practices of doctors specifically, rather than applicable to any individual who engages in the distribution of controlled substances generally, it is calibrated to create liability for problematic actors, like Dr. Tseng or Dr. MacKay, who have abandoned the ethical practice of medicine.

Under the PAPA, the unjust outcomes afforded to some doctors might well have been different. For instance, for those physicians, like Dr. Miller, who treat pain using opioids but do not operate classic "pill mills," the PAPA would not have resulted in charges and convictions. Rather, Dr. Miller would have rightfully escaped criminal sanction because the implied malice test in the PAPA would have required jurors to evaluate the case through the lens of the physician defendant and their background, rather than based on an expert opinion regarding an undefined "legitimate medical treatment" standard that conflates the criminal and civil standards of care.

The PAPA would also impose criminal liability on pill mill doctors who escaped liability under the CSA and similar state statutes. Importantly, the PAPA avoids the “but for” causation standard of the CSA and the related state statutes, the standard which led to the acquittals of Dr. MacKay, Dr. Klein, and Dr. Baldi.²⁸⁶ As the results in *MacKay* demonstrate, the interpretation of death “resulting from” enhancement in the CSA makes it extremely difficult to convict opioid prescribers. Many overdose victims have multiple drugs, including the prescribed opioid, in their systems that contributed to the cause of death.²⁸⁷ The new implied malice standard proposed in the PAPA, however, shifts the focus away from the “but-for” causation requirement, redirecting the causation analysis to a proximate cause inquiry. The implied malice/proximate cause standards in the PAPA would apply to those over-prescribers of opioids who, despite their specialized knowledge of the dangerousness of opioids, prescribe these addictive medications without the proper care and risk assessment. Charged under the PAPA, it is more likely than not that “pill mill” doctors like MacKay, Baldi, and Klein would have been convicted.

C. *The Feasibility of the Proposed Statute*

As discussed above, because the PAPA is specifically designed as a focused and measured response to the problem of overprescribing doctors, it will punish those outlier doctors who have stepped outside the bounds of legitimate medical treatment, deter others from joining them by incentivizing cautious prescribing practices, and it will create space for other doctors with legitimate justifications for continuing to use opioids to treat patients. However, a question that remains centers on the workability of the measure—that is, whether passing a statute like the one proposed here is politically feasible.

Recent developments at the federal congressional level suggest that the PAPA is politically feasible. In the last two years, momentum and bipartisan political will has coalesced in the legislative branch to address the opioid crisis, and it has resulted in many legislative proposals. More than 300 bills related to opioids were introduced in the 115th Congress alone. These proposals represent a renewed determination to address the opioid crisis

286. See Freeman, *supra* note 144; Hastings, *supra* note 152; United States v. MacKay 20 F. Supp. 3d 1287, 1295 (D. Utah 2014).

287. See United States v. MacKay 20 F. Supp. 3d 1287, 1295 (D. Utah 2014).

from various angles including improving education for doctors and the public, bolstering treatment options and resources for individuals with opioid use disorder, and regulating the dispersion of opioids.²⁸⁸ For example, H.R. 6, the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act,²⁸⁹ passed with overwhelming bipartisan support and was signed into law in 2018.²⁹⁰ The new act appropriates funds and amends current federal law governing welfare programs, law enforcement, licit and illicit drug use, and public health, among other measures, to increase resources for treating those with opioid use disorder and reduce the use of opioids in healthcare settings.²⁹¹

In 2019, other legislative initiatives took additional steps to address the problem of the overprescription of opioids. The Using Data to Prevent Opioid Diversion Act, signed into law in 2019, is aimed at reducing the diversion of opioids by requiring more frequent reporting of suspiciously large opioid orders and providing additional transparency in opioid distribution reporting.²⁹² The work in this space continued into the 116th Congress. In November 2020, a follow-on bill was introduced to modify

288. *Using Data to Prevent Opioid Diversion Act of 2018 (HR 6491 / S 2838, 115th Congress)*, SCI POL, <https://scipol.org/track/hr-6491-using-data-prevent-opioid-diversion-act-2018/using-data-prevent-opioid-diversion-act> [https://perma.cc/XNB2-Q3WS].

289. H.R. 6, 115th Cong. (2d Sess. 2018).

290. *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Public Law 115-271)*, SCI POL, <https://scipol.org/track/hr-6-substance-use-disorder-prevention-promotes-opioid-recovery-and-treatment-patients-and-0> [https://perma.cc/WUM9-3J8W].

291. *Id.*

292. Specifically, the Using Data to Prevent Opioid Diversion Act amends the CSA to require the attorney general to provide information to drug manufacturers and distributors regarding opioid sales and distribution. H.R. 6491, 115th Cong. (2d Sess. 2018). Manufacturers and distributors are required to review this information and detect suspicious orders (e.g., orders of abnormal size, orders that differ substantially from a normal arrangement, or orders of unusual frequency) or unusual patterns of distribution. *Id.*

reporting requirements under the Controlled Substances Act.²⁹³ If enacted, the bill, entitled Preventing Pill Mills Through Data Sharing Act (S 3070/HR 8732), would require drug manufacturers and distributors to report the sale and delivery, or disposal, of all controlled substances to the DEA every month, rather than quarterly as is currently required. The legislation also extends the penalties and reporting requirement that currently apply to drug manufacturers and distributors.²⁹⁴

These new initiatives and laws are a starting point, and the fact that they have been passed with bipartisan support indicates that the momentum has shifted among the political class into the problem-solving mode. Increasing resources and access for treating those with opioid use disorder, reducing the use of opioids in healthcare settings with additional reporting, and transparency in tracking drug diversion are all good starts, but until those who write the prescriptions are deterred, and if necessary punished, over-prescribing will continue. The PAPA complements and builds upon these current proposals by removing the licensed prescriber, or the head of the pill mill. Enacting the PAPA addresses this problem directly and is the next logical step along the legislative path to address the opioid crisis.

To be sure, promulgating a new criminal statute may not prove easier than amending the CSA. However, at least in terms of optics and symbolism, a federal criminal statute focused expressly and exclusively on opioid prescribers signals to the public that the opioid crisis is being specifically addressed at the highest levels of government. It is a recognition that the opioid crisis is of such monumental significance that it deserves unique treatment. Moreover, under the current circumstances, including an escalation of the opioid crisis brought on by the COVID-19 pandemic, in which the political will of elected leaders appears to align with the public's perception of the crisis, the PAPA's enactment may be possible despite the strength of the healthcare industry and pharmaceutical lobbies who may oppose it.²⁹⁵

293. Preventing Pill Mills Through Data Sharing Act, S.B. 3070 / H.R. 8732, 116th Cong. (2d Sess. 2020).

294. *Id.* Companion legislation was previously introduced in the Senate in 2019 by Sens. Dianne Feinstein (D-CA), Chuck Grassley (R-IA), Shelly Moore Capito (R-WV), and Dick Durbin (D-IL). S.B. 3070, 116th Cong. (1st Sess. 2019).

295. Liz Essely Whyte, Geoff Mulvihill, & Ben Wieder, *Politics of Pain: Drugmakers Fought State Opioid Limits Amid Crisis*, CTR. FOR PUB. INTEGRITY (Sept. 16, 2018), <https://publicintegrity.org/politics/state-politics/politics-of-pain->

Passage of the PAPA, however, is not guaranteed. Strong political divisions among the parties, their leaders, and the electorate remain even after the 2020 election cycle. The Biden Administration will appoint new leaders to the DEA, the FDA, and the DOJ. New leadership may take a different approach to the enforcement of the CSA and a more active regulatory stance with respect to opioids, potentially making implementation of the PAPA easier. Still, challenges will remain because of the strength of forces that may oppose its passage.²⁹⁶ The legislative bodies are closely divided and thus challenges to passing legislation will persist.²⁹⁷ The possibility of enactment of a statute that criminalizes the actions of some healthcare providers is also affected by the public's evolving perception of the medical profession, especially in light of the ongoing COVID-19 pandemic in which medical professionals are lauded and lionized as frontline, first responders, and pharmaceutical companies are attempting to rehabilitate their images via the development of a COVID-19 vaccine.²⁹⁸ But because the opioid epidemic has not abated on its own and has even been exacerbated by the COVID-19 pandemic,²⁹⁹ we must continue to engage with a variety of solutions.

drugmakers-fought-state-opioid-limits-amid-crisis [https://perma.cc/K8Y4-7FMP].

296. Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, 1999-2018*, 180 JAMA INTERNAL MED. 688-697 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7054854/> [https://perma.cc/6ACS-ZXGU] (concluding that from 1999 to 2018, the pharmaceutical and health product industry recorded \$4.7 billion—an average of \$233 million per year—in lobbying expenditures at the federal level, more than any other industry).
297. Derek Willis & Paul Kane, *How Congress Stopped Working*, PROPUBLICA, (Nov. 5, 2018) <https://www.propublica.org/article/how-congress-stopped-working> [https://perma.cc/2LF3-V8SA].
298. Jay Hancock, *Drug Makers Tout COVID-19 Vaccines to Refurbish Their Public Image*, KAISER HEALTH NEWS (May 20, 2020), <https://khn.org/news/drugmakers-tout-covid-19-vaccines-to-refurbish-their-public-image> [https://perma.cc/DDT2-YAA8].
299. Peter Grinspoon, *A Tale of Two Epidemics: When COVID-19 and Opioid Addiction Collide*, HARVARD HEALTH PUBL'G. (Apr. 20, 2020), <https://www.health.harvard.edu/blog/a-tale-of-two-epidemics-when-covid-19-and-opioid-addiction-collide-2020042019569> [https://perma.cc/64T4-8K7D]; David Wedge, *Epidemics at Odds: Preventing the Next Wave of the*

The proposal here is intended to highlight the complexity of the problem and move the conversation forward by offering one solution. An example of recently enacted federal criminal legislation that achieved bipartisan support presents a possible roadmap for the PAPA to follow. In December of 2018, President Trump signed into law the Formerly Incarcerated Reenter Society Transformed Safely Transitioning Every Person Act (known as the First Step Act).³⁰⁰ The Act was the culmination of a bipartisan effort to improve criminal justice outcomes, as well as to reduce the size of the federal prison population.³⁰¹ It includes new laws aimed at reassessing the recidivism risk of certain incarcerated individuals, laws changing the incarceration conditions for others, and laws altering the way sentences are calculated and imposed.³⁰² The Act was not without its opponents and detractors, but its passage was achieved because its proponents successfully reframed the issue in a non-ideological manner, coupled it with other legal reforms designed to maintain public safety, and personalized the harms of lengthy prison sentences dictated by the federal sentencing guidelines.³⁰³

The PAPA could use the same playbook. First, in terms of reframing, the description of the effects of the opioid crisis should be expanded beyond the public health impacts to include the devastation to the economy as a whole. Furthermore, more should be done to point out that the effects of the opioid

Opioid Crisis During COVID-19, BOS. MEDICAL CTR. HEALTH CITY (Mar. 23, 2020), <https://www.bmc.org/healthcity/population-health/preventing-next-wave-opioid-crisis-during-covid-19> [<https://perma.cc/LNU8-879H>].

300. First Step Act of 2018, Pub. L. No. 115- 391.

301. *Id.*

302. Ames Grawert & Tim Lau, *How the First Step Act Became Law — and What Happens Next*, BRENNAN CTR. (Jan. 4, 2019), <https://www.brennancenter.org/our-work/analysis-opinion/how-first-step-act-became-law-and-what-happens-next> [<https://perma.cc/C8AV-E9NG>].

303. Alan Blinder & Shaila Dewan, *The Real People Who Lobbied for Justice Reform: A Son, a Widow, an Expectant Mother*, N.Y. TIMES (Dec. 12, 2018), <https://www.nytimes.com/2018/12/12/us/criminal-justice-reform-lobbying-family.html> [<https://perma.cc/5M3A-6CWC>]; Jeremy Diamond & Alex Rodgers, *How Jared Kushner, Kim Kardashian West, and Congress Drove the Criminal Justice Overhaul*, CNN (Dec. 21, 2018), <https://www.cnn.com/2018/12/18/politics/criminal-justice-overhaul/index.html> [<https://perma.cc/EJ7W-NWAE>].

epidemic touch every ethnic, social, religious, and political group equally, and thus the problem of over-prescribing doctors is not an ideological or regional issue. Second, to gain support from a cross-section of divergent constituencies, the PAPA could be coupled with other legal reforms, such as increasing funding for opioid addiction treatment, researching and regulating the practices of pharmaceutical industry, and other drug-sentencing laws more generally. Third, proponents would be well advised to humanize the crisis and to promote the stories of sympathetic, individual victims of opioid addiction. With these steps, passage of the PAPA is not beyond the realm possibility.

IV. CONCLUSION

The scope of the opioid epidemic in terms of lives lost and economic cost is immense. It has brought hardship to those addicted, their families and communities,³⁰⁴ and has resulted in a cost of hundreds of billions of dollars to the national economy.³⁰⁵ The root causes of the current epidemic, the ineffectiveness of the existing criminal law, and the biases baked into the legal system, all give rise to nuanced issues that defy a one-size-fits-all answer. To be sure, the solution to this crisis has to be holistic, acknowledging the complex issues involved. Consequently, the remedy requires a multi-faceted approach that consists of addressing more than the criminal conduct of doctors who over-prescribe opioids. In addition to providing prosecutors with a new tool to punish doctors who over-prescribe opioids, efforts should also be directed at the medical community in several areas such as education, licensing, and treatment. Medical education needs to improve and medical students need more robust training about opioid prescribing practices and addiction.³⁰⁶ Moreover,

304. *Prescription Opioid Data*, CDC (Dec. 19, 2018), <https://www.cdc.gov/drugoverdose/data/prescribing.html> [<https://perma.cc/ZMT6-Q9RD>].

305. See Curtis S. Florence et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013*, 54 *MED. CARE* 901 (2016) (citing estimates that the misuse of prescription opioids alone costs the United States \$78.5 billion per year); see also *The Underestimated Costs of the Opioid Crisis*, COUNCIL OF ECON. ADVISORS (2017) (concluding that the economic cost of the opioid crisis reached \$504 billion in 2015, representing 2.8% of the nation's GDP).

306. See Rohanit Singh & Gary W. Pushkin, *How Should Medical Education Better Prepare Physicians for Opioid Prescribing?*, 21 *AMA J. OF ETHICS* 636-41 (2019)

state medical licensing boards need more resources to police the field,³⁰⁷ and the medical community as a whole needs to put more resources and advocacy into effective and humane drug treatment programs.³⁰⁸ We must also reinvest in our understanding of opioids by addressing the dearth of peer-reviewed replicable scientific research and clinical studies on the efficacious applications of opioids by applying public funding to contextualize prior “studies” such as the Porter and Jick letter.³⁰⁹ Additionally, we must address the pharmaceutical industry’s undue influence on prescribers and hold them accountable for their conduct that has contributed to the opioid epidemic.³¹⁰ We must also amend current

(recognizing that medical education about the ethical dimensions of opioid prescribing lacks clarity, consistency, and structure, and that opioid-related education in many medical schools is impeded by a lack of experienced faculty and good strategies for assessing students’ learning).

307. Diane E. Hoffmann, *Can State Medical Boards Adequately Respond to Reports that Physicians Are Inappropriately Prescribing Opioids?*, 81 *CLINICAL PHARMACOLOGY & THERAPEUTICS* 799, 800 (2007) (discussing the option of having state medical boards handle these cases instead of prosecutors).
308. See Christopher M. Jones et al., *National and State Treatment Need and Capacity for Opioid Agonist Medication-Assisted Treatment*, 105 *AM. J. PUB. HEALTH* e55-63 (June 11, 2015), <http://www.ncbi.nlm.nih.gov/pubmed/26066931> [<https://perma.cc/JNZ6-CUVF>]; Devesh Vashishtha, Maria Luisa Mittal, & Daniel Werb, *The North American Opioid Epidemic: Current Challenges and a Call for Treatment as Prevention*, 14 *HARM REDUCTION J.* 7 (May 12, 2017), <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-017-0135-4> [<https://perma.cc/U68A-DQST>].
309. See Hawkins *supra* note 45.
310. Efforts by state attorneys general, the federal government, and private plaintiffs over the last several years have begun to do this by holding pharmaceutical companies and their leaders criminally and civilly liable. See Colin Dwyer, *Your Guide To The Massive (And Massively Complex) Opioid Litigation*, *NAT. PUB. RADIO* (Oct. 15, 2019), <https://www.npr.org/sections/health-shots/2019/10/15/761537367/your-guide-to-the-massive-and-massively-complex-opioid-litigation> [<https://perma.cc/DP6V-88WZ>]. The federal government has also begun to prosecute pharmaceutical company executives for their actions in connection with the sale of opioids. For example, in May of 2019, five executives with Insys Therapeutics were found guilty of federal racketeering and conspiracy charges. See Gabrielle Emanuel & Katie Thomas, *Top Executives of Insys, an Opioid Company, Are Found Guilty of Racketeering*, *N.Y. TIMES* (May 2, 2019),

drug sentencing laws and enforcement mechanisms that are discriminatorily applied to the poor and people of color.³¹¹ Finally, we must reframe the public and political narrative around this crisis, as well as drug abuse in general, by emphasizing that this epidemic is not simply a criminal law issue, but rather a widespread public health emergency.³¹² Admittedly, therefore, adding to the canon of criminal law with a statute to prosecute overprescribing doctors for murder is not the only, most obvious, or least controversial response to this crisis. It is, however, a place to start and a step in the right direction.

Although the opioid crisis has gained national attention, and major pharmaceutical companies are increasingly found liable for their role in creating the crisis, the problem of overprescribing opioids persists because the current law criminalizing this conduct is unclear and lacks national uniformity. It is also important to differentiate the criminality of the act of prescribing from the other actions that the CSA is intended to regulate, not only because of the direction of decriminalization of most drug charges but also because the CSA was not crafted with the current state of the American opioid crisis in mind. Therefore, the creation of a new federal statute aimed specifically at doctors, rather than an approach aimed at amending the problematic provisions in the CSA, is the appropriate response to the opioid epidemic. Enacting a new federal criminal statute, divorced from the CSA statutory framework and embedded in the Federal Criminal Code, which specifically targets scenarios that have defined the opioid crisis, is a

<https://www.nytimes.com/2019/05/02/health/insys-trial-verdict-kapoor.html> [<https://perma.cc/69HK-RREU>]. They were sentenced to multi-year terms in prison in January of 2020. See Tim McLaughlin, *Insys Founder Kapoor Sentenced to 66 Months in Prison for Opioid Scheme*, REUTERS BUS. NEWS (Jan. 23, 2020), <https://www.reuters.com/article/us-insys-opioids/insys-founder-kapoor-sentenced-to-66-months-in-prison-for-opioid-scheme-idUSKBN1ZM1QB> [<https://perma.cc/TJF2-59F8>]; see also, Rebecca A. Delfino, *A New Prescription for the Opioid Epidemic: 360-Degree Accountability for Pharmaceutical Companies and Their Executives*, 73 *Hastings L.J.* (forthcoming) (exploring the role of the pharmaceutical companies and their executives in causing the opioid crisis and proposing new federal legislation to hold the industry and its leader's criminally accountable).

311. Netherland & Hansen, *supra* note 269.

312. The question of how to achieve and deploy these remedies (changing the public and political discourse around opioids, engaging in more scientific research, countering the pharmaceutical industry, and amending the federal drug law and enforcement mechanisms in general) is beyond the scope of this Article.

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significantly more effective strategy than attempting to amend a statute that was not enacted with these scenarios in mind. Charges under the proposed federal homicide law will not only provide space for healthcare professionals engaged in legitimate and medically necessary pain management practices to continue using these drugs to relieve their patients' suffering, but they will also act as an appropriate punishment and effective deterrent for physicians whose prescription practices cause their patients' deaths.