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A New Prescription for the Opioid Epidemic: 360- Degree Accountability for Pharmaceutical Companies and Their Executives

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A New Prescription for the Opioid Epidemic: 360-Degree Accountability for Pharmaceutical Companies and Their Executives

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We can no longer ignore this—a national crisis resulting in almost one million American deaths, costing hundreds of millions of dollars, ravaging the health care system, and devastating state and local communities. This narrative describes the COVID-19 pandemic and something else: the epidemic of opioid addiction and abuse. In the last twenty years, the opioid epidemic claimed the lives of more than 700,000 people at the cost of more than 500 billion dollars to the economy. The COVID-19 pandemic has made the opioid epidemic worse, causing a staggering increase in opioid-related overdose deaths. Even now, on average, 140 people die every day from an opioid overdose, making it a leading cause of injury-related death in the United States. And 70% of those deaths involve a prescription opioid.

There is a growing sense that those responsible for the opioid epidemic, specifically drug companies and their executives, have escaped responsibility for their dangerous and deceptive practices in manufacturing and marketing opioids. Although they have confronted civil lawsuits, the pharmaceutical industry has faced virtually no criminal scrutiny; only a couple of companies and executives have ever been criminally charged for the devastation that opioids have caused. This raises questions: Given the increasing number of opioid overdose deaths nationally, why are charges and convictions of drug companies and their executives so rare? And why have existing legal mechanisms not worked to punish the improper manufacturing and marketing practices and curb the epidemic? Their misconduct continues because no single federal law exists to prosecute pharmaceutical companies and their executives for causing the epidemic. And existing laws are ineffective; they fail to criminalize the type of conduct that caused the epidemic, contain elements prohibitively difficult to prove, or impose minimal penalties that fail to deter bad actors. Thus, the drug industry has persisted in dubious practices unfettered by civil litigation, government enforcement actions, and fines. This Article seeks to examine these issues and others. It is the first in legal scholarship to offer a concrete and omnibus solution grounded in federal law to address the pharmaceutical industry's misconduct. The novel 360-degree solution proposed here—the "Controlled Substance Manufacturing and Marketing Accountability Act"—will deter and punish those pharmaceutical companies and their executives who provided misleading information to government regulators and used deceptive practices in marketing opioids to the public. It also recognizes that when properly prescribed, these drugs provide essential relief for pain and suffering. Thus, this Proposal seeks to address prior misconduct and point the way forward to avoid the next drug epidemic.

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TABLE OF CONTENTS

INTRODUCTION

At the dawn of the 2020s, the United States faces simultaneous crises—the global COVID-19 pandemic and the opioid epidemic. They share commonalities. Both crises have caused hundreds of thousands of deaths, destruction to the economy, and devastation to state and local communities. Both crises also bring together the same key actors: the American healthcare system, government policymakers and regulators, and the pharmaceutical industry. But the similarities end there. The country has marshalled the government, private sector, and medical and scientific communities en masse, in warp speed to combat the COVID-19 pandemic. The national reaction to the opioid epidemic is pale in comparison. Even though the COVID-19 pandemic's effects have exacerbated the opioid epidemic, our collective response is relatively anemic.[1] Why? If we can turn the tide on the pandemic and beat back a mutating virus, why have we been unable to alter the course of the opioid epidemic—a human-made crisis? The answer is not straightforward or simple; it requires a critical examination of the political economy, private business interests, and innate human desire to avoid pain.

Finding the answer requires an acknowledgment of a failure of accountability for the opioid epidemic. It is widely accepted that those responsible for instigating the opioid crisis—drug companies and doctors[2] who prescribe opioids—have not been held accountable.[3] Although some doctors and other prescribers have faced criminal exposure for contributing to the opioid epidemic,[4] pharmaceutical companies have encountered little criminal scrutiny, and drug company executives have experienced even less. Even though pharmaceutical companies and pharmacies have faced civil litigation[5] for their

1. *See* Megan Brooks, *US Drug Overdose Deaths Hit a Record High, CDC Reports*, MEDSCAPE MED. NEWS (Dec. 18, 2020), https://www.medscape.com/viewarticle/942917 (documenting that COVID-19 has resulted in an increase in opioid-related overdose deaths and addiction since early 2020). A national tracking system at the University of Baltimore has identified nearly an 18% increase in suspected drug overdoses from March through May 2020. *See* ALIESE ALTER & CHRISTOPHER YEAGER, OVERDOSE DETECTION MAPPING APPLICATION PROGRAM, COVID-19 IMPACT ON US NATIONAL OVERDOSE CRISIS (2020), http://www.odmap.org/Content/docs/news/2020/ODMAP-Report-June-2020.pdf.

2. *See* Rebecca A. Delfino, *The Prescription Abuse Prevention Act: A New Federal Statute to Criminalize Overprescribing Opioids*, 39 YALE L. & POL'Y REV. 347, 347 (2021) (addressing the role of doctors' opioid prescription practices in causing the opioid epidemic, chronicling the shortcomings in the law to hold overprescribing doctors criminally accountable and proposing to criminalize the conduct).

3. *See* House of Representatives, Committee on Oversight and Reform, Dec. 17, 2020, https://www.rev.com/transcript-editor/shared/Li70HMjsidbxdgdKMGt_KoYz5ThLh65uOETXJF0Ltez4OLcp5Q671xghqrTOkuwJK1psJgW3Y6LXUAt3JFf0eT7T-BA?. In the first ever appearance under oath by Sackler family members before Congress, Oversight and Reform Committee members expressed outrage at Purdue Pharma and members of the Sackler family in fueling the nationwide opioid epidemic by flooding the market with the highly addictive painkiller, OxyContin. *Id.*; *see also* Ronald Hirsch, *The Opioid Epidemic: It's Time to Place Blame Where It Belongs*, 114 MO. MED. 82, 82 (2017).

4. *See* Delfino, *supra* note 2 (describing the history of criminal cases against doctors who over prescribe opioids).

5. 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

opioid manufacturing and marketing practices, it is rare for them and their executives to face criminal charges[6] for the devastation that opioids have caused throughout the United States. Instead, the industry persisted in manufacturing and marketing practices undeterred by government warning letters, deferred prosecution agreements, civil fines, and criminal misdemeanor penalties.

One case is emblematic of these issues. In December 2019, a federal jury in Massachusetts returned guilty verdicts against the drug company, Insys Therapeutics, and several of its executives, including the company founder John Kapoor, for multiple violations of federal law for illegal drug distribution and marketing practices related to a conspiracy to distribute the company's fentanyl-based medication, Subsys.[7] The prosecutor showed that the company used improper marketing tactics, including bribing doctors to prescribe Subsys to patients who did not need it.[8] The convictions were unique, marking the first time in American history that prosecutors used federal racketeering laws to impose criminal liability for violations of the Controlled Substance Act ("CSA") on high-ranking individual corporate executives.[9] In light of the convictions, the individual defendants faced up to thirty-three years in prison.[10] However, the judge imposed sentences of three to five years and vacated several convictions, observing that, although fraudulent, the conduct did not violate federal drug laws.[11]

This situation raises several questions. First, given the increasing number of opioid overdose deaths, why are charges against and convictions of pharmaceutical companies and those who run them so uncommon? Second, what legal, ethical, and regulatory mechanisms exist to address the opioid crisis and, in particular, the manufacturing and marketing practices of companies like Insys Therapeutics and its executives? Why have the existing legal mechanisms not brought the industry wrongdoers to justice or deterred their deceptive

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manufacturers, distributors, and pharmacies across the United States into one suit in the Northern District of Ohio. *See* In re National Prescription Opiate Litigation, 290 F.Supp.3d. 1375 (US.Jud.Pan.Mult.Lit. 2017). 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, Ryan Lang, Sidney M. Wolfe & Michael Carome, *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.

6. *See, e.g.*, U.S. 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.

7. Memorandum and Order on Defendants' Motions for Judgment of Acquittal and for a New Trial at 19, U.S. v. Babich, No. 1:16-cr-10343-ADB (D. Mass. 2016) [hereinafter Memorandum and Order].

8. *Id.* at 5, 11.

9. Peter J. Henning, *RICO Offers a Powerful Tool to Punish Executives for the Opioid Crisi*s, N.Y. TIMES, (May 23, 2019), https://www.nytimes.com/2019/05/23/business/dealbook/rico-insys-opioid-executives.html.

10. *See* Memorandum and Order, *supra* note 7, at 19.

11. *Id.*; Chris Villani, *Insys Judge Wonders If Potential Punishment Is Too Harsh*, LAW360 (Jan. 13, 2020, 2:16 PM), https://www.law360.com/articles/1233650/insys-judge-wonders-if-potential-punishment-is-too-harsh.

practices? And more to the point, why did the judge decide she was required to vacate the convictions in the Insys Therapeutics case?

This Article seeks to examine these issues and others, and it is the *first* Article in legal scholarship to offer a concrete and omnibus solution grounded in federal law. This Article proposes a new 360-degree response: the "Controlled Substance Manufacturing and Marketing Accountability Act"[12] ("CS MAMA"), aimed directly at those pharmaceutical companies and their executives who provided fraudulent information when submitting their drugs for approval to the Food and Drug Administration ("FDA") and who employed deceptive practices in marketing their opioid drugs to prescribers and the public.

Part I of the Article describes the evolution of the human relationship to opium-based drugs and early legal efforts to regulate it. The root causes of the opioid epidemic are also described. The discussion focuses on the driving force—the pharmaceutical industry and its four-decade effect on research, the government, and the perception of pain. This Part explains how we got from the medically acceptable practice of prescribing opioids and other controlled substances for legitimate medical purposes such as acute pain and palliative care to where we are now: hundreds of thousands of drug overdose deaths resulting from addiction to prescription opioids.

Part II considers the current federal laws and ethical frameworks available to address pharmaceutical companies' dubious and fraudulent manufacturing and marketing practices. Even though no single federal law exists to prosecute pharmaceutical companies and their executives for their roles in causing the opioid epidemic, companies are regulated and occasionally prosecuted under the CSA,[13] Food, Drug, and Cosmetic Act,[14] and False Claims Act.[15] This Part examines the few cases, in addition to the Insys Therapeutics case, that have been brought against industry wrongdoers under these legal frameworks.[16] It explores the reality that even when prosecutors have brought charges under the existing law, the cases are hard to win because of challenges in proving the requisite intent. These statutes also fail to target misconduct specific to the pharmaceutical industry and its executives.

Further, the few convictions obtained for low-level offenses resulting in civil penalties have not proven to be an effective deterrent to future bad conduct, nor have they halted the opioid epidemic. Part II examines the shortcomings in the current approaches used to remedy the problem and asserts that responses under existing federal law are inadequate. Consideration is also given to the solutions proposed by other scholars and policymakers to impose criminal culpability on the pharmaceutical industry, such as the Racketeer Influenced and

12. The text of CS MAMA is set-forth in the Appendix to this Article.
13. 21 U.S.C. §§ 841(b)(1)(E)(i), (c)(2)(A).
14. *Id.* §§ 333(a)(1), (b)(1).
15. 31 U.S.C. § 3730(d).
16. *See* Almashat et al., *supra* note 5, at 10.

Corrupt Organizations Act ("RICO")[17] or new legislation such Opioid Crisis Accountability Act ("OCAA").[18] This Part concludes with a critique of the other solutions that have been offered thus far.

Part III proposes a 360-degree federal response as the right approach. The conduct of pharmaceutical companies in instigating the opioid epidemic is multi-faceted; it involved biasing the scientific research and clinical studies, influencing the government's drug approval process, manipulating prescribers, and misleading the public about the addictiveness of opioids. This conduct requires legislative action to address the full range of industry misconduct. The new law must punish the corporate entities and their executives' wrongdoing, and it must restore and repair the harm done to communities. The CS MAMA presented here achieves these objectives from every angle utilizing civil fines, criminal charges, and regulatory penalties. It embodies a comprehensive, omnibus proposal that draws upon current legal frameworks' most effective aspects and bolsters them with additional proposals.

Finally, this Article acknowledges that finding the best solution is both delicate and consequential. The legal framework offered here is not intended to end the availability of opioids or destroy the pharmaceutical industry. On the one hand, opioids are essential medication that can bring vital relief from acute pain in patients undergoing cancer treatment, recovering from surgery, and suffering from a terminal illness. Likewise, pharmaceutical companies are critical partners in our public health care system; they have been on the frontlines in developing vaccines for COVID-19. On the other hand, opium-based drugs are highly addictive and have been historically misused. Profit-driven pharmaceutical companies have a long practice of orchestrating schemes to manipulate government regulators and policymakers and deceive medical prescribers and the public. CS MAMA is calibrated to acknowledge this duality. It seeks to address prior misconduct and point the way forward to avoid the next drug epidemic.[19]

I. THE OPIOID EPIDEMIC AND THE PHARMACEUTICAL INDUSTRY

A. EVOLUTION OF THE OPIOID EPIDEMIC AND THE LAW

About 12,000 years ago, Neolithic humans began to cultivate crops and domesticate animals.[20] During this time, humans also figured out that the milky-

17. 18 U.S.C. §§ 1961–1968.

18. Rep. Tulsi Gabbard Re-introduces Opioid Crisis Accountability Act, Opioid Crisis Accountability Act, H.R. 2917, 116th Cong. (2019); 26 No. 4 FDA Advertising & Promotion Manual News. 7; H.R. 2917, 116th Cong. § Preamble (2019).

19. This proposal to pharmaceutical companies and their executives to account for their conduct is only a partial solution. Confronting and in the appropriate case criminalizing the prescribing practices of these drugs is also warranted. *See* Delfino, *supra* note 2, at 408 (proposing a new federal criminal framework—Prescription Abuse Prevention Act (PAPA) to address conduct of overprescribing healthcare professionals).

20. *Neolithic Revolution*, HIST., https://www.history.com/topics/pre-history/neolithic-revolution (last updated Aug. 23, 2019) (last visited Jan. 24, 2022).

white juice inside the bulbous head of a poppy plant could be dried, ground to powder, and smoked, the effects of which produced a euphoric relief from pain.[21] The "opium"[22] derived from the poppy was used for religious, cultural, and medicinal purposes in early cultures, spanning the Middle East, Asia, and Europe.[23]

In the last 300 years, the powerful effects produced by opium and its use in medicine and pain relief[24] have inspired commerce[25] and conflict. For example, to satisfy the domestic demand for Chinese-produced tea, the British, through their control of the East India Company, smuggled Indian opium to China.[26] As a result, the Chinese's addiction rate soared, instigating the Opium Wars of the mid-1800s.[27]

Simultaneously, because of its analgesic properties, opium became the main ingredient in several medicines during the Nineteenth Century including laudanum,[28] the alcohol-laced tincture[29] used to address surgical wounds and treat conditions such as cholera, yellow fever, menstrual cramps, headaches, and

21. BETH MACY, DOPESICK: DEALERS, DOCTORS, AND THE DRUG COMPANY THAT ADDICTED AMERICA 21 (2018). The human body produces its endorphins, which block pain signals by attaching to pain receptors in the brain. Like natural endorphins, opioids bind to the receptors and block pain signals. Although endorphins work for only a few minutes at a time, synthesized opioids work for many hours and bind more strongly to the receptors. Opioids also activate the reward areas of the brain by releasing the hormone dopamine, creating a feeling of euphoria or a "high." *Id.* The effect of opioids is profound and often addictive. *See* ANNA LEMBKE, DRUG DEALER M.D.: HOW DOCTORS WERE DUPED, PATIENTS GOT HOOKED, AND WHY IT'S SO HARD TO STOP 3 (2016).

22. The Sumerian, Babylonian, and Egyptian writings contain the first recorded references to the use of opium which cited the value of opium preparations for the relief of pain. The Sumerians referred to the poppy as Hul Gil, which means "The Joy Plant." In Asian cultures, the creation of the poppy and its hallucinogenic value was attributed to the Buddha, who was said to have cut off his eyelids to prevent sleep overtaking him, and where they fell, there grew a plant which bore a nodding violet flower which was to give sleep and dreams to all humans. *See Opium, Morphine and Heroin*, IMPERIAL COLL. LONDON, https://www.ch.ic.ac.uk/rzepa/mim/drugs/html/morphine_text.htm (last visited Jan. 24, 2022); UNITED NATIONS OFF. ON DRUGS AND CRIME, A CENTURY OF INTERNATIONAL DRUG CONTROL 15, 18–19 (2008), https://www.unodc.org/documents/data-and-analysis/Studies/100_Years_of_Drug_Control.pdf; *Heroin*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/drugs-abuse/heroin (last visited Jan. 24, 2022).

23. UNITED NATIONS OFF. ON DRUGS AND CRIME, *supra* note 22, at 15, 18–19.

24. The 17th-century pioneer of English medicine, Thomas Sydenham, described opium thusly: "Among the remedies which it has pleased Almighty God to give to man to relieve his sufferings, none is so universal and so efficacious as opium." Samuel Crumpe, *An Inquiry into the Nature and Properties of Opium* (1783), https://www.bl.uk/collection-items/an-inquiry-into-the-nature-and-properties-of-opium.

25. In the 1820's, a group of powerful Boston merchants organized opium-smuggling operations on the coast of China, which in turn funded the American industrial revolution and evolution of the United States railroads and factories. Martha Bebinger, *How Profits from Opium Shaped Nineteenth-Century Boston*, WBUR: LOC. COVERAGE (July 31, 2017), https://www.wbur.org/news/2017/07/31/opium-boston-history.

26. Takahiro Moritake, *The Opium War and Tea*, WORLD GREEN TEA ASS'N, http://www.o-cha.net/english/teacha/history/opiumwar.html (last visited Jan. 24, 2022).

27. UNITED NATIONS OFF. ON DRUGS AND CRIME, *supra* note 22, at 18–23.

28. Alexander Hamilton was treated with laudanum to treat a bout of yellow fever as well as the pain he suffered after his 1804 fatal duel with Aaron Burr. JOHN C. MILLER, ALEXANDER HAMILTON AND THE GROWTH OF A NEW NATION 380 (2004).

29. A tincture is typically an extract of active constituents of plant or animal material dissolved in ethyl alcohol. *See* NAT'L MED. CONVENTION AT WASH., D.C., THE PHARMACOPOEIA OF THE UNITED STATES 233 (Philadelphia, Lippincott, Grambo, & Co., 1850).

other non-specific pain.[30] One of the first modern opioids, morphine, was developed during this time. In 1806, a German apothecary, Friedrich Serturner, extracted an active ingredient in the poppy juice, which he named morphine.[31] He soon recognized that morphine was ten times more potent than opium and equally addictive, and he cautioned against its use.[32] Doctors, however, continued to prescribe it to treat many different ailments, such as anxiety and respiratory problems.[33] The first major opium-related addiction epidemic occurred during and after the American Civil War when morphine was used as a common form of palliative care to treat soldiers' pain.[34] Many soldiers and veterans became so dependent on the drug that morphine addiction became known as the "soldier's disease."[35]

In 1898, Henrich Dreser, a chemist working for the drug firm Bayer Co., developed Diacetylmorhine, or heroin, based on the work of another chemist researching non-addictive alternatives to morphine.[36] At the time, Dreser believed heroin was non-addictive and twice as powerful in its pain relief properties as morphine.[37] The Bayer Company pitched heroin as a non-addictive sedative to treat the symptoms of influenza and other respiratory ailments that were leading causes of death at the time, such as pneumonia and tuberculosis.[38] By 1899, Bayer began commercial production of heroin, selling it in twenty-three countries as a safe, pain-relieving, cure-all.[39] Heroin was soon realized to be more addictive than morphine.[40] As with most potent and addictive drugs, it started to be abused by drug users.[41]

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30. *See* MACY, *supra* note 21, at 21.

31. Michael J. Brownstein, *A Brief History of Opiates, Opioid Peptides, and Opioid Receptors*, 90 PROC. NAT'L ACAD. SCI. U.S. 5391, 5391 (1993).

32. MARTIN BOOTH, OPIUM: A HISTORY 69 (1996).

33. Renata Ferrari, Michela Capraro & Marco Visentin, *Risk Factors in Opioid Treatment of Chronic Non-Cancer Pain: A Multidisciplinary Assessment*, *in* PAIN MANAGEMENT-CURRENT ISSUES AND OPINIONS, 419–20 (2012). Other doctors, including Dr. Alexander Wood (who invented the hypodermic needle), promoted the use of liquid morphine, claiming that injecting morphine was less addictive than smoking, or swallowing opium or morphine. *See* MACY, *supra* note 21, at 22.

34. Sonia Moghe, *Opioid History: From 'Wonder Drug' to Abuse Epidemic*, CNN: HEALTH, https://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html (last updated Oct. 14, 2016).

35. *See* Amy Davidson, *The "Soldier's Disease"*, NEW YORKER (Nov. 11, 2010), http://www.newyorker.com/news/amy-davidson/the-soldiers-disease.

36. *See* Moghe, *supra* note 34.

37. *Id.*

38. *See* MACY, *supra* note 21, at 24; *see* Moghe, *supra* note 34.

39. Heroin was offered as treatment for many conditions from colic in infants to alcoholism to morphine addiction. ONE HUNDRED YEARS OF HEROIN 4 (David F. Musto, Thomas W. Mauluci & Pamela Korsmeyer eds., 2002).

40. *Heroin, Morphine and Opiates*, HIST. (June 10, 2019), https://www.history.com/topics/crime/history-of-heroin-morphine-and-opiates; *see also*, *Women Victims of Morphine: Physicians Discuss Danger in the Use of the Drug*, N.Y. TIMES (Oct. 25, 1895), https://www.nytimes.com/1895/10/25/archives/women-victims-of-morphine-physicians-discuss-the-danger-in-the-use.html.

41. *See* Moghe, *supra* note 34. Rather than it performing as non-addictive as advertised, however, heroin made addiction worse. *See* MACY, *supra* note 21, at 24.

As the effects of morphine and heroin addiction spread, the United States government started to monitor the distribution, use, and production of opioid-based drugs. The Opium Exclusion Act of 1909 was the first government regulation of opioids banning the smoking of opioids.[42] In 1914, the government enacted the Harrison Narcotics Tax Act (the "Harrison Act"), requiring physician and pharmacist approval to distribute opioids.[43] The Harrison Act also required manufacturers, distributors, and importers of narcotics to register with the Treasury Department and pay taxes on their products.[44]

Shortly after the Harrison Act became law, two German scientists at the University of Frankfurt reported that they had synthesized a new opioid, oxycodone, derived from thebaine.[45] The developers of oxycodone hoped it would provide the same pain-relieving benefits as morphine and heroin without the harm of addiction.[46] In early 1928, the German drug company Merck introduced a combination product containing oxycodone and ephedrine, which became known as the "Miracle Drug" in Continental Europe.[47] It was widely used in Europe in the 1930s and 1940s; Germans used it as a battlefield analgesic during the Second World War.[48]

In the years after the Harrison Act passage, the United States government's regulation of drugs increased as knowledge about the harms and addictive properties of opioids emerged. In 1924, the Heroin Act criminalized heroin, banning its manufacture, import, and possession.[49] In 1938, Congress created the Food and Drug Administration ("FDA") to monitor and regulate drugs and their safety before being sold in the United States.[50]

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42. 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.

43. Michael Waldrop, *A Little Less Regulation: Why Federal Pain Management Laws Are Hurting State Efforts to Combat the Opioid*, 43 MITCHELL HAMLINE L. REV. 881, 890 (2017). The Harrison Act also required manufacturers, distributors, and importers of narcotics to register with the Treasury Department and pay taxes on their products. *See* Moghe, *supra* note 34.

44. *See* Moghe, *supra* note 34.

45. Martin Freund & Edmund Speyer, *Über die Umwandlung von Thebain in Oxycodeinon und dessen Derivate*, 94 J. FÜR PRAKTISCHE CHEMIE. 135–78 (1916); WALTER SNEADER, DRUG DISCOVERY: A HISTORY 119 (2005). Thebaine, a minor constituent of opium, is an opiate alkaloid chemically similar to both morphine and codeine but has stimulatory rather than depressant effects. *See* WHO Advisory Group, *The Dependence Potential of Thebaine*, UNITED NATIONS OFF. ON DRUG & CRIME (Jan. 1, 1980), https://www.unodc.org/unodc/en/data-and-analysis/bulletin/bulletin_1980-01-01_1_page006.html#n05; Mohammad Moradi, Sara Esmaeli, Saeed Shoar & Saeid Safari, *Use of OxyCodone in Pain Management*, 1 ANESTHESIOLOGY & PAIN MED. 262, 262 (2012).

46. Amanda Lautieri, *Oxycodone History and Statistics*, AM. ADDICTION CTRS. (Jan. 4, 2022) https://drugabuse.com/opioids/oxycodone/history-statistics.

47. Ray J. Deflaque & Amos J. Wright, *Scophedal (SEE) Was it a Fad or a Miracle Drug?*, 21 BULL. ANESTHESIA HIST. 12–14 (2003).

48. *Id.*

49. Richard D. deShazo, McKenzie Johnson, Ike Eriator & Kathryn Rodenmeyer, *Backstories on the US Opioid Epidemic. Good Intentions Gone Bad, an Industry Gone Rogue, and Watch Dogs Gone to Sleep*, 131 AM. J. MED. 595, 597 (2018).

50. Waldrop, *supra* note 43, at 890.

During the 1950s and 1960s, the prescription opioids and heroin use increased despite the known risks of addiction from opium-based drugs.[51] Oxycodone was introduced into the United States in the late 1930s but not widely prescribed until the 1950s when it was combined with aspirin and released under the brand name Percodan.[52] Like heroin, Percodan was touted as a non-addictive pain-relieving treatment.[53] In the second half of the 1960s, the public's perception of drugs began to evolve. Drugs, including opiates and opioids, became symbols of rebellion, social discord, and political dissent.[54] As a result, the government stopped funding scientific research to evaluate their medical safety and efficacy.[55] The 1970s ushered in the "War on Drugs" and with it a comprehensive regulation of illicit and prescription drugs.[56] In 1970, Congress enacted the CSA to criminalize importation, manufacture, distribution, possession, and use of controlled substances, finding those substances to have a substantial and detrimental effect on the American people's health and general welfare.[57]

The government's response to drug use in the 1970s affected prescribing practices and the perception of opioids in the medical community. The 1980s brought the first cases of "opiophobia"—a physician's fear that prescribing opioids would cause the patient to become addicted or fear being persecuted for prescribing the opioids.[58]

By the mid-1990s, however, the perception of pain and its treatment began to change. The medical community and patient rights advocates called for robust assessment and treatment of pain.[59] The primary medical report cited as supportive of this advocacy was a letter from Jane Porter and Dr. Hershel Jick, which appeared in a 1980 volume of the New England Journal of Medicine.[60]

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51. *Id.*

52. Kristin Compton, *Endo International and American Medical Systems*, DRUGWATCH, https://www.drugwatch.com/manufacturers/endo-american-medical-systems (last updated Mar. 17, 2021); Yael Waknine, *First-Time Generic Approvals: Xanax XR, Dostinex, Percocet*, MEDSCAPE (Feb. 3, 2006), https://www.medscape.com/viewarticle/522876.

53. Waldrop, *supra* note 43, at 890. The trend of increased use of prescription Oxycodone was immediately followed by an increase in the illegal heroin trade in the United States during this time, as those who became addicted to Oxycodone continued to chase the high and stave off the withdrawal symptoms—dopesickness—which resulted when they could no longer obtain their prescriptions of opioids. *Id.*

54. *A Brief History of the Drug War*, DRUG POL'Y ALL., http://www.drugpolicy.org/issues/brief-history-drug-war (last visited Jan. 24, 2022).

55. *Id.*

56. In 1971, President Richard Nixon declared a "war on drugs," and thus increased the size and presence of federal drug control agencies and pushed through measures such as mandatory sentencing for drug offenses. *Id.*

57. 21 U.S.C. §§ 801–971 (1970). The CSA makes it "unlawful for any person knowingly or intentionally (1) to manufacture, distribute, or 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." *Id.* § 841(a)(1)–(2).

58. Waldrop, *supra* note 43, at 891: M. Zenz & A. Willweber-Strumpf, *Opiophobia and Cancer Pain in Europe*, 341 THE LANCET 1075, 1075–76 (1993).

59. *See* Zenz & Willweber-Strumpf, *supra* note 58, at 1075–76.

60. *See* Moghe, *supra* note 34.

Porter and Jick reported that they had studied the medical records of 11,882 hospitalized patients who, while closely monitored by hospital staff, were treated with opioids.[61] The five-line, one-paragraph letter, which became known as "Porter and Jick," concluded that under the highly controlled environment in a hospital, the risk of addiction was less than one-half of one percent.[62] The letter was subsequently cited to support prescribing opioids regularly to outpatients to treat non-terminal, chronic pain; it was claimed that the report proved there was no risk of addiction with opioids prescribed for use in all settings.[63]

Porter and Jick created a domino effect. In reliance on the perceptions created by it, the DEA did not prosecute licensed medical professionals for prescribing opioids unless it appeared they were engaged in drug trafficking.[64] Additionally, institutions across the medical community, including the World Health Organization, advocated for increased opioid prescriptions and pain monitoring.[65]

Opioid prescribing skyrocketed. Between 1990 and 1995, prescriptions for opioids increased by two to three million per year.[66] The number of prescription opioids rose from 76 million annually in 1991 to a peak of 219 million prescriptions a year by 2013.[67] By 2016, nearly 62 million patients had at least one opioid prescription filled.[68] The number of opioid-related overdose deaths also increased.[69] As of 2017, forty-six people die every day because of

61. *Id.*

62. 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.

63. *Id.*; Sarah Zhang, *The One Paragraph Letter from 1980 That Fueled the Opioid Crisis*, THE ATLANTIC (June 2, 2017), https://www.theatlantic.com/health/archive/2017/06/nejm-letter-opioids/528840.

64. *See* Kathyrn Foxhall, *DEA Enforcement Verses Pain Practice*, 5 PPM J. (2016), https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/dea-enforcement-versus-pain-practice (highlighting that DEA enforcement efforts in early and mid-2000s focused on small number of doctors, who effectively acting as drug traffickers, running pill mills).

65. DAVID W. BAKER, THE JOINT COMMISSION'S PAIN STANDARDS: ORIGINS AND EVOLUTION 2–3 (2017); Mark R. Jones, Omar Viswanath, Jacquelin Peck, Alan D. Kaye, Jatinder S. Gill & Thomas T. Simopolous, *A Brief History of the Opioid Epidemic and Strategies for Pain Medicine*, 7 PAIN & THERAPY 13, 16 (2018).

66. Teresa A. Rummans, M. Caroline Burton & Nancy L. Dawson, *How Good Intentions Contributed to Bad Outcomes: The Opioid Crisis*, 93 MAYO CLIN. PROC. 344, 346 (2018); Gery P. Guy, Jr., Kun Zhang, Michele K. Mohn, Jan Losby, Brian Lewis, Randall Young, Louise B. Murphy & Deborah Dowell, *Vital Signs: Changes in Opioid Prescribing in the United States 2006-2015*, 66 MORBIDITY & MORTALITY WKLY REP. 697, 697 (2017).

67. *See* BAKER, *supra* note 65, at 5; *see also* AVALERE HEALTH, TRENDS IN OPIOID USE: HISTORY, BACKGROUND, AND ORIGINS OF THE EPIDEMIC 1 (2018), https://avalere.com/wp-content/uploads/2018/11/Avalere-20181030-Opioid-Trends-Brief-FINAL.pdf.

68. *See* Guy et al., *supra* note 66. During the first decade of the twenty-first century, prescription opioids increased rapidly. According to the CDC, "annual opioid prescribing rates increased from 72.4 to 81.2 prescriptions per 100 persons from 2006 to 2010, were constant from 2010 to 2012, and then decreased by 13.1% to 70.6 per 100 persons from 2012 to 2015." This 2015 number still remains three times higher than the 1999 prescription number when 180 MME per capita were sold in the United States. *See* BAKER, *supra* note 65, at 5.

69. *See* BAKER, *supra* note 65, at 5.

prescription opioid overdoses,[70] which is five times higher than in 1999.[71] And the arrival of the COVID-19 pandemic has provided an unanticipated and tragic boost to the opioid epidemic. Nationwide, authorities report a surge in fatal opioid overdoses since the spring of 2020.[72]

The human experience of using and abusing opiates and opioids is instructive. It reveals the cyclical nature of the human relationship to pain and our efforts to alleviate it. In the last 200 years, periods of hope following the development of new opioids that promised pain relief without adverse side effects are followed by periods of over-use and addiction. What are the driving forces behind these cycles? And why, given the government's War on Drugs and the enactment of the laws like the CSA, has the abuse and addiction evolved into the current epidemic? The answer requires identifying the constant presence and behind-the-scenes force in the evolution of the opioid epidemic—the pharmaceutical industry. The following Subpart explores the industry's areas of influence.

B. ROLE OF THE PHARMACEUTICAL INDUSTRY IN THE OPIOID EPIDEMIC

Pharmaceutical companies instigated the opioid epidemic in three interconnected ways: (1) private drug companies took the lead in funding the scientific research and studies of opioids and in changing the perception of pain; (2) they exerted political influence on the government's process of regulating drugs; and (3) they created a demand for opioids through their aggressive marketing to prescribers and consumers.

1. Influence of the Industry on Drug Research and the Perception of Pain

Industry-sponsored research into the efficacy and safety of opioids and funding of pain advocacy groups and organizations fueled the opioid epidemic. In the late 1940s, the federal government, primarily through the Veteran's Administration, sponsored research into various pain medications to treat those suffering the effects of injuries sustained in World War II.[73] However, the

70. *Prescription Opioid Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/data/prescribing.html (last updated Dec. 19, 2018).

71. *Id.* Opioid related deaths have continued to increase notwithstanding the decrease in prescriptions because users who are no longer able to obtain their prescriptions have to turn to other illegal, nonprescription narcotics available on the streets, such as heroin and fentanyl. *See* Guy et al., *supra* note 66. A study found that of those who began using opioids in the 2000s, 75% reported that their first opioid was a prescription drug. *Prescription Opioid Use is a Risk Factor for Heroin Use*, NAT'L INST. ON DRUG ABUSE (Jan. 2018), https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use.

72. *See* Brooks, *supra* note 1.

73. David F. Musto, *Drug Abuse Research in Historical Perspective*, *in* INSTITUTE OF MEDICINE (US) COMMITTEE ON OPPORTUNITIES IN DRUG ABUSE RESEARCH, PATHWAYS OF ADDICTION: OPPORTUNITIES IN DRUG ABUSE RESEARCH (1996); *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 was fueled by funding from the

government's sponsorship of research waned in the mid-1960s as the focus shifted to the enforcement of drug laws.[74] The decrease in funding in the last fifty years detrimentally affected programs that have relied on ongoing support to maintain research projects.[75] It left a void in the knowledge of the safety and efficacy of opioids that was ultimately filled by the private sector, specifically the research and studies funded by pharmaceutical companies and trade groups.[76] Without publicly funded research and independent studies, there was nothing to countervail the industry's misrepresentation of reports such as Porter and Jick, which the industry used to promote the marketing of opioids.

The pharmaceutical industry also promoted changing the perception of pain in the medical community during this time.[77] Although before the 1980s, these opium-based medications had been reserved for severe cancer pain, end-of-life care, and acute post-surgical pain, by the mid-1990s, pharmaceutical industry-funded groups began to raise awareness of the inadequate treatment of non-cancer pain and underutilization of pharmaceutical opioids. Part of the marketing strategy for drug companies was to instill a perceived need by making unsubstantiated claims about the existence of large numbers of people suffering from untreated chronic pain.[78]

Thus, the pharmaceutical companies promoted the adoption of pain as the "Fifth Vital Sign,"[79] meaning that the evaluation of pain became a requirement of proper patient care as important and essential as the assessment of temperature, blood pressure, respiratory rate, and heart rate.[80] The medical

United States government, with the National Institutes of Health seeing its federal funding rise to nearly $100 million by 1956. Brooks, *supra* note 1.

74. *See A Brief History of the Drug War*, *supra* note 54; *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].

75. *See* Musto, *supra* note 73; Michelle Llamas, *Big Pharma's Role in Clinical Trials*, DRUGWATCH, https://www.drugwatch.com/featured/clinical-trials-and-hidden-data (last updated Sept. 24, 2021).

76. *See* PHARMAPHORUM, *supra* note 73. The development of new drugs and the growth of the pharmaceutical industry was 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.*; *see also* Francie Diep, *Did Researchers Who Seek to Relieve Pain Contribute to the Opioid Epidemic?*, PAC. STANDARD (May 2, 2019), https://psmag.com/social-justice/did-researchers-who-seek-to-relieve-pain-contribute-to-the-opioid-epidemic (describing that history of pharmaceutical company funding for pain research organizations and their studies).

77. Waldrop, *supra* note 43, at 891.

78. Patrick O'Keefe, *The Family That Build an Empire of Pain*, NEW YORKER (Oct. 23, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

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

80. *Id.*

establishment[81] and lawmakers followed suit.[82] In the early 1990s, large drug manufacturers such as Purdue Pharma, Johnson & Johnson, and Endo Pharmaceuticals began funding nonprofit groups in pain management medicine, such as the American Pain Society.

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 non-cancer pain.[83] Furthermore, between 1996 and 2002, Purdue Pharma funded more than 20,000 pain-related educational programs to influence physician prescription habits.[84] Medical associations also lobbied the government to allow the use of opioids for all pain treatment, not just for chronic pain from a terminal illness.[85] In 2004, the Federation of State Medical Boards ("FSMB") [86] joined the movement by encouraging state medical boards to scrutinize and punish physicians for under-treatment of pain.[87]

2. Industry Influence on Federal Government Actors and Regulation

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. From "1999 to 2018, the pharmaceutical and health product industry recorded $4.7 billion—an average of $233 million per year—

81. In 1997, the Robert Wood Johnson Foundation, in collaboration with the University of Wisconsin-Madison School of Medicine, funded and establish 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 65, at 3.

82. BAKER, *supra* note 65, 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.'" In October of 2000, the United States Congress passed H.R. 3244, tit. VI § 1603 which contained similar provisions. *Id.* at 3.

83. Rummans et al., *supra* note 66, at 345; Jones et al., *supra* note 65, at 15.

84. Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221, 225 (2009).

85. *See* 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 65, at 3;

86. The FSMB is a national non-profit organization that represents the seventy-one state medical and osteopathic boards of the United States and co-sponsors the United States Medical Licensing Examination. *See About FSMB*, FED'N OF ST. MED. BDS., https://www.fsmb.org/about-fsmb (last visited Jan. 24, 2022). 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.* The FSMB published a book, subsidized by drug manufacturers that outlined polices designed to encourage the broad use of opioid for non-terminal patients. John Fauber, *Follow the Money: Pain, Policy, and Profit*, MEDPAGE TODAY (Feb. 19, 2012), https://www.medpagetoday.com/neurology/painmanagement/31256. The FSMB's policies were developed by several individuals with ties to narcotics manufacturers. *Id.*

87. *See generally* 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 L., MED. & ETHICS 21 (2003) (describing the Oregon Medical Board's 1999 discipline of physician for failure to prescribe adequate pain relief medication).

in lobbying expenditures" at the federal level.[88] As of 2020, the industry spent one billion dollars more than any other special interest group or industrial sector on lobbying and political contributions.[89]

The funding has directly influenced the approach of policymakers and regulators.[90] Before the 1980s, the FDA required drug manufacturers to demonstrate that their products were both safe and effective before they were marketed.[91] With the election of Ronald Reagan in 1980, however, the federal government deregulated many sectors of the economy, including the pharmaceutical industry.[92] The Reagan Administration cast the FDA regulatory process as hampering private markets, discouraging innovation, and inhibiting consumer choice.[93] The administration abandoned rules for tasks such as tracking adverse drug reactions and defective medical devices.[94] It also limited the authority of regulatory agencies and pushed for faster drug approval.[95] In the ten years that followed, pharmaceutical regulatory policies aimed to cut "bureaucratic red tape" in drug approvals, permit drug companies to market their

88. Olivier J. Wouters, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, 1999-2018*, 180 JAMA INTERN MED., 688, 688 (2020); After Purdue Pharma faced charges for its advertising its opioids in 2007, it hired lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly 900 million dollars on lobbying and political contributions—eight times what the gun lobby spent during the same time. O'Keefe, *supra* note 78.

89. *Top Industries: All Years (1998-2020)*, CTR. FOR RESPONSIVE POLS., https://www.opensecrets.org/federal-lobbying/industries?cycle=2020 (last visited Jan. 24, 2022).

90. *Id.*; Chris McGreal, *How Big Pharma's Money — And Its Politicians — Feed the US Opioid Crisis*, THE GUARDIAN (Oct. 19, 2017), https://www.theguardian.com/us-news/2017/oct/19/big-pharma-money-lobbying-us-opioid-crisis.

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

92. KEITH WAILOO, PAIN: A POLITICAL HISTORY 172–73 (2014).

93. *Id*. In his article, Eugene McCarthy describes the "long and arduous process" of obtaining FDA approval to bring a drug to market. *See* Eugene McCarthy, *The Pharma Barons: Corporate Law's Dangerous New Race to the Bottom in the Pharmaceutical Industry,* 8 MICH. BUS. & ENTREPRENEURIAL L. REV. 29, 47 (2018). This process requires first identifying a potential therapeutic use for the drug and then engaging in multiple clinical trials to test the drug's safety and effectiveness. *Id.* Taking a new drug from development to market could take up to ten years or longer, with the FDA approval process alone taking at least six to twelve months. *See* PHRMA, BIOPHARMACEUTICAL RESEARCH & DEVELOPMENT: THE PROCESS BEHIND NEW MEDICINES (2015), http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf. Drug development is also expensive, costing an estimated $2.6 billion per drug. *Id.* Clinical trials alone cost a median $19 million, with larger trials costing $135 million. Thomas Moore, Hanzhe Zhang, Gerard Anderson & G. Caleb Alexander, *Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016*, 178 JAMA INTERNAL MED. 1451, 1454 (2018).

94. WAILOO, *supra* note 92, at 172–73.

95. *Id.* at 173.

drugs direct-to-consumers ("DTC"),[96] and speed the flow of products from drug maker to consumer took hold.[97]

The pharmaceutical industry's deregulation 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.[98] 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 evidence.[99] Second, the FDA did not require sufficient and well-controlled clinical trials for opioids.[100] This contravened the FDA's general requirement of at least two randomized, controlled trials demonstrating clear efficacy for a drug's proposed indication.[101] Purdue and other opioid manufacturers lobbied for a new kind of clinical trial that utilized so-called "enriched enrollment" protocols that permitted opioid manufacturers to engage in clinical bias.[102] These protocols allowed researchers conducting the clinical trial to remove patients from the study who were not responding well to the opioid treatment.[103] As a result, if the drug was failing the clinical trial, the researchers would remove the subjects who showed that it was failing and continue the trial without them.[104] Ultimately the FDA approved Purdue's extended-release OxyContin in 1995 based on only one study, a two-

96. The Food and Drug Modernization Act of 1997 (FDAMA) ended the long-standing restriction on DTC prescription drug advertising. *See* Food and Drug Administration Modernization Act of 1997 § 421, 21 U.S.C. § 331(l); Draft Guidance for Industry, Consumer-Directed Broadcast Advertisements, Availability, 62 Fed. Reg. 43171, 43172 (Aug. 12, 1997). The United States is the only nation that affirmatively authorizes drug companies to advertise prescription drugs directly to the public. *See* Amanda L. Connors, Note, *Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics*, 73 ALB. L. REV. 243, 244, 267 (2009). New Zealand also allows drug companies to engage in DTC prescription drug advertising, but in New Zealand this legal outcome appears to be the result of a legislative oversight. *See* Susanna Every-Palmer, Rishi Duggal & David B. Menkes, *Direct-to-Consumer Advertising of Prescription Medication in New Zealand*, 127 N. Z. MED. J. 102, 103 (2014).

97. WAILOO, *supra* note 92, at 172–73.

98. Andrew Kolodny, *How FDA Failures Contributed to the Opioid Crisis*, 22 AM. MED. ASS'N J. ETHICS 743, 743 (2020). Kolodny maintains that drug companies have yet to conduct successful clinical trials that prove the safety and efficacy of their opioids for treating chronic pain. Andrew Kolodny, David T. Courtwright, Catherine S. Hwang, Peter Kreiner, John L. Eadie, Thomas W. Clark & G. Caleb Alexander, *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559, 562–63 (2015).

99. *How FDA Failures Contributed to the Opioid Crisis*, *supra* note 98, at 744–45.

100. *Id.* at 745.

101. Nicholas S. Downing, Jenerius A. Aminawung, Nilay D. Shah, Harlan M. Krumholz & Joseph S. Ross, *Clinical Trial Evidence Supporting FDA Approval of Novel Therapeutic Agents, 2005-2012*, 311 JAMA 368, 369 (2014).

102. Martha Rosenberg, *What Big Pharma Doesn't Want You to Know about the Opioid Epidemic*, SALON (June 3, 2016, 8:15 AM), https://www.salon.com/2016/06/03/what_big_pharma_doesnt_want_you_to_know_about_the_opioid_epidemic_partner.

103. LEMBKE, *supra* note 21, at 68–69.

104. *How FDA Failures Contributed to the Opioid Crisis*, *supra* note 98, at 745.

week clinical trial.[105] When the FDA approved OxyContin for treating moderate to severe pain, Purdue had conducted no clinical studies on its addictive potential.[106] The FDA also approved a package insert for OxyContin that claimed the drug was safer than rival painkillers.[107]

Finally, the FDA has not managed conflicts of interest between agency staff and the industry. A revolving door has existed between the FDA and pharmaceutical manufacturers for the last twenty years. Agency officials and staffers responsible for drug approvals, opioid oversight, and opioid manufacturing routinely leave the FDA to work for opioid makers or private industry consultants.[108] In 2020, more than sixty-three percent (955 of 1,502) of registered pharmaceutical industry lobbyists disclosed that they were once federal officials.[109] Senior FDA officials are typically industry insiders or have strong financial ties to drug companies.[110] It appears that many government regulators bide their time before departing for more lucrative opportunities in the pharmaceutical industry, which experts agree compromises their regulatory decisions.[111] For example, the FDA examiner who oversaw OxyContin's approval process left the agency shortly after the drug was approved.[112] Within two years, he had taken a job at Purdue Pharma.[113]

3. Industry's Influence on the Prescribers and the Public Through Marketing and Advertising

Simultaneous with the pharmaceutical industry's efforts to control drug research, influence governmental actors, and encourage a new approach to the treatment of pain, pharmaceutical companies also engaged in aggressive marketing to prescribers and the public, which affected prescribing practices and laid the groundwork for the opioid epidemic that followed. Purdue Pharma and

105. *Id.*; *see also* CTR. FOR DRUG EVAL. & RSCH., APPROVAL PACKAGE FOR OXYCODONE HYDROCHLORIDE CONTROLLED RELEASE TABLETS (July 8, 1996), https://www.accessdata.fda.gov/drugsatfda_docs/nda/96/020553s002.pdf (describing the clinical trial conducted for the 80 mg. OxyContin time-released tablet).

106. O'Keefe, *supra* note 78.

107. *Id.*

108. *How FDA Failures Contributed to the Opioid Crisis*, *supra* note 98, at 746; *see* Charles Pillar, *FDA's Revolving Door: Companies Often Hire Agency Staffers Who Managed Their Successful Drug Reviews*, SCI. MAG. (July 5, 2018), https://www.sciencemag.org/news/2018/07/fda-s-revolving-door-companies-often-hire-agency-staffers-who-managed-their-successful (describing how FDA staffers who review applications for drug approvals, and present evidence to the agency's advisory panels are free to move to jobs in pharma or consulting with drug companies, and documenting that many former FDA staffers transition to the industry less than a year after working on a company's application).

109. *Industry Profile: Pharmaceuticals/Health Products, 2020*, OPENSECRETS, https://www.opensecrets.org/federal-lobbying/industries/lobbyists?cycle=2020&id=h04 (last visited Jan. 24, 2022).

110. McCarthy, *supra* note 93, at 59.

111. FRAN HAWTHORNE, INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT 150 (2005).

112. O'Keefe, *supra* note 78.

113. *Id.*

its owners, the Sackler family, laid the cornerstone for that the marketing structure.

In the early 1950s, Arthur Sackler, a psychiatrist by training, was employed by a small medical advertising firm in New York.[114] Working with the drug maker Pfizer, Sackler developed a novel advertising method to market a Pfizer antibiotic directly to doctors by purchasing multiple advertisements in medical journals, direct-mail marketing, and sending Pfizer sales representatives to visit doctors' offices.[115] This advertising blitz resulted in record-breaking sales of Pfizer's antibiotic.[116] Through his efforts, Sackler invented modern pharmaceutical marketing, a field of advertising which did not previously exist.[117] Sackler ultimately bought the advertising firm that had employed him, and a few years later, he and his brothers bought an unknown drug company, Purdue Fredrick.[118]

In the early 1960s, Sackler's advertising firm partnered with the drug firm Hoffman-La Roche to sell a new tranquilizer, Valium.[119] Sackler turned the successful marketing strategies that he had developed on the Pfizer campaign to the promotion of Valium. He promoted it to doctors, who at the time viewed the drug with suspicion because of its potential for addiction.[120] But Sackler's relentless marketing techniques based on building personal connections between salespeople and doctors helped to reframe the narrative of Valium as a safe and legitimate remedy for stress and anxiety.[121] By the end of the 1960s, as the result of Sackler's advertising approach, Valium became the pharmaceutical industry's first billion-dollar drug.[122] He also used his influence with other drug companies to fund and sponsor continuing education programs for the medical community, as well as publish an industry-friendly biweekly newspaper for doctors.[123]

In the early 1980s, the Sacklers' drug firm, by then renamed Purdue Pharma, developed a pain management drug, which they marketed as MS Contin—a new formulation of oxycodone that featured a timed-release formula to send high doses of morphine directly into a patient's bloodstream continuously over several hours.[124] At the time it was released, Purdue marketed MS Contin only for cancer patients, post-surgical hospital patients, and end-of-life palliative care.[125] In the mid-1990s, Purdue repackaged MS Contin into

114. SAM QUINONES, DREAMLAND 28–30 (2015).
115. *Id.*
116. *Id.*
117. O'Keefe, *supra*, note 78.
118. Warren & Rogers, *supra* note 118.
119. O'Keefe, *supra* note 78.
120. *Id.*; QUINONES, *supra* note 114, at 30.
121. QUINONES, *supra* note 114, at 30.
122. *Id.*
123. *Id.*; O'Keefe, *supra* note 78.
124. O'Keefe, *supra* note 78.
125. *Id.*

OxyContin, which featured a reformulated time-released coating.[126] In the decade between the release of MS Contin and OxyContin, as discussed in Part I.B.1. and I.B.2., the drug regulatory environment, the political climate, and the medical communities' perception of pain—had changed dramatically. By the 1990s, OxyContin could be directly marketed to doctors and the public.[127] The Sacklers' aggressive marketing and advertising efforts for the drug arrived in a marketplace of doctors and consumers eager to deploy OxyContin to treat all forms of pain. A tsunami of opioid prescriptions followed. From 1997 to 2002, the annual number of prescriptions for OxyContin alone increased from 670,000 to 6.2 million, reaching a total number of prescriptions of 45 million.[128]

To be sure, Purdue did not act alone in causing the opioid epidemic. Other pharmaceutical companies also contributed through similar advertising practices, such as advocating to medical professionals and direct-to-consumer (DTC) marketing efforts about the beneficial use of their drugs as safe palliative care for chronic pain.[129] Although pharmaceutical companies have asserted that DTC drug advertising is designed to inform and educate the public, "the primary purpose of DTC advertising is not to educate consumers, but instead is to encourage them to actively seek out medication that their physician would not otherwise prescribe."[130] DTC marketing has proven profitable because studies show that doctors prescribe the drugs that patients request approximately 75% of the time.[131] Consequently, DTC advertisements have earned drug companies more than four dollars in profit for every one dollar they invest in DTC prescription drug advertising.[132] As a result, drug companies have consistently spent twice as much money on marketing than research and development.[133]

The Food and Drug Modernization Act of 1997 ("FDAMA") also instituted changes that permitted drug company representatives to influence doctor's prescribing practices in other ways. The FDAMA allows companies to engage in off-label "detailing" to doctors,[134] which is the practice of persuading doctors

126. *Id.* OxyContin differed from MS Contin only to the extent that OxyContin featured as new slow-release delivery mechanism in the form of a digestible coating which purportedly slowed the absorption of the drug over the course of several hours and thus allowed for steady pain and long-lasting pain relief. Thus, Purdue touted it as having less potential for addiction and abuse than other formulations of opioids because of its coating. MACY, *supra* note 21, at 315 (2018).

127. O'Keefe, *supra* note 78.

128. Jones et al., *supra* note 65, at 16.

129. David C. Vladeck, *The Difficult Case of Direct-To-Consumer Drug Advertising*, 41 LOY. L.A. L. REV. 259, 286 (2007).

130. *Id.*

131. *Id.* at 270.

132. *See* Hannah Brennan, *The Cost of Confusion: The Paradox of Trademarked Pharmaceuticals*, 22 MICH. TELECOMM. TECH. L. REV. 1, 27 (2015).

133. Stephanie M. Greene, *After Caronia: First Amendment Concerns in Off Label Promotion*, 51 SAN DIEGO L. REV. 645, 696 (2014) (discussing various concerns about off-label prescription drug use including undisclosed side effects).

134. *See* U.S. Food & Drug Admin., Draft Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 73 Fed. Reg. 9342, 9342 (Feb. 20, 2008).

to prescribe drugs to patients for uses that the FDA has not approved.[135] To persuade doctors to overlook the lack of FDA approval, sales representatives presented doctors with journal articles—which the drug company paid for—about a drug's effectiveness to treat a particular ailment for which the drug has not been approved.[136] Detailing has also proven an effective marketing tactic, as 20% of all prescriptions that doctors write are for off-label uses.[137]

Beyond detailing, it is estimated that pharmaceutical companies spend five billion dollars annually on gifts to physicians and medical students to promote their products.[138] 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.[139] 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.[140]

Pharmaceutical companies' gifts noticeably impact doctors' prescribing practices. One study found that physicians prescribe drugs in which they attended paid conferences 4.5 to 10 times more often than other drugs.[141] Another study, which combined data from 538 similar studies, concluded that the current "extent of physician-industry interactions appears to affect the prescribing and professional behavior" of physicians.[142] For example, it found that the recipient physician of free drug samples was associated with "preference and rapid prescription of a new drug and a positive attitude towards the

135. Puneet Manchanda & Elisabeth Honka, *Pharmaceutical Innovation and Cost: An American Dilemma: The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 YALE J. HEALTH POL'Y L. & ETHICS 785, 785 (2005). Doctors may prescribe any drug they deem medically necessary, even if the FDA has not approved that drug to treat a particular condition. Marc A. Rodwin, *Rooting Out Institutional Corruption to Manage Inappropriate Off-Label Drug Use*, 41 J. L. MED. & ETHICS 654, 654 (2013).

136. Rodwin, *supra* note 135, at 657.

137. Stephanie M. Greene & Lars Noah, Debate, *Off-Label Drug Promotion and the First Amendment*, 162 U. PA. L. REV. 239, 241 (2014). In fact, in many patient populations, off-label prescriptions constitute the bulk of treatment. Rodwin, *supra* note 135, at 656. Up to 75% of cancer drugs, 80% of pediatric drugs, and 90% of prescription drugs for rare diseases are off label. *Id.* As a result, drug companies earn billions of dollars each year from the sale of off-label prescription drugs. This calculation is based on the estimate that 2017 global pharmaceutical sales are expected to top $1.2 trillion. *See* Craig W. Lindsley, *New 2016 Data and Statistics for Global Pharmaceutical Products and Projections through 2017*, 8 ACS CHEM. NEUROSCI. 1635, 1635 (2017). Twenty percent—the percentage of off-label prescription sales—would amount to $240 billion. *See id.* These numbers are alarming given that "more than 70 percent of off-label uses lack significant scientific support." Rodwin, *supra* note 135, at 658.

138. Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373, 373 (2009).

139. 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).

140. Sheena T. Wheeler, Note, *Under the Influence: An Examination of the Tactics Pharmaceutical Companies Use to Manipulate Physicians*, 7 IND. HEALTH L. REV. 89, 90 (2010).

141. *Id.* at 105.

142. Wazana, *supra* note 138, at 373.

pharmaceutical representative."[143] From these studies, it is clear that physicians prescribing practices have attributed to the opioid epidemic, albeit subconsciously. Throughout the 1990s and 2000s, medical professionals deferred to the messaging of pharmaceutical representatives on the efficacy and safety of opioids. Prescribers did not question the lack of evidence, including the mischaracterization of Porter and Jick, because they lacked training and medical education in pain management sufficient to critique the evidence.[144]

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 resulted in a lack of meaningful critique of the evidence the pharmaceutical industry presented to demonstrate the efficacy and safety of the opioids developed during this time. As a result, the aggressive marketing to doctors and consumers remained effective in boosting drug sales well into the 2000s.[145]

Insys Therapeutics' marketing of Subsys to doctors is illustrative of the typical sales practices prevalent in the industry. Insys Therapeutics' sales representatives, among other things, targeted doctors who prescribed at higher rates.[146] They also encouraged doctors to give patients free Subsys while awaiting approval from their insurance companies.[147] The Insys former head of sales admitted that when deciding which doctors to work with, he "[assessed] whether they had a killer instinct, almost no conscience"[148] and if they were willing to prescribe Subsys at unnecessarily high doses—"label, off-label,

143. *Id.* Pharmaceutical representatives are trained to make physicians feel obligated to prescribe their brand's product. They will strengthen their relationship with medical professionals through passive tactics by inciting feelings of social tension between themselves and the physician. For example, in one case a pharmaceutical representative would bring coffee to the office every Tuesday without being asked. She would then insist that if the physician did not write two prescriptions for her brand that day, she would no longer bring coffee to the office. *See* Conners, *supra* note 139, at 263. The physician testified that this made his office feel pressure to prescribe her brand's product, despite not ever having asked for the coffee. He claimed the representative had access to the physician's prescribing patterns and therefore could see how many written prescriptions were for her brand or for the competitor. *Id.* A study done by the University of Washington in 2000 examined the effect of free drug samples on physician prescribing practices. The study found that when there is a presence of free drug samples, physicians were influenced to prescribe drugs that differ from their preferred drug choice. *See* Wheeler, *supra* note 140, at 110.

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

145. U.S. GEN. ACCT. OFF., GAO-04-110, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM (2003). Purdue's sales of OxyContin escalated from $44 million (316,000 prescriptions dispensed) in 1996 to a 2001 and 2002 combined sales of nearly $3 billion (over 14 million prescriptions). *Id.* at 31.

146. *See* Memorandum and Order on Defendants' Motions for Judgment of Acquittal and for a New Trial at 1, U.S. v. Babich, No. 1:16-cr-10343-ADB (D. Mass. 2016).

147. *Id.* at 5.

148. Hannah Kuchler, Nicky Verbitsky, Tom Jennings & Shaunagh Connaire, *Insys Executives Are Sentenced to Prison Time, Putting Opioid Makers on Notice*, PBS: FRONTLINE (Jan. 23, 2020), https://www.pbs.org/wgbh/frontline/article/opioid-maker-insys-executives-sentenced-prison-subsys.

nobody cares." [149] One sales representative also testified that she and her boss performed lap dances for a doctor to encourage him to prescribe Subsys.[150] Other sales representatives reported that their bonuses increased if they could convince doctors to prescribe higher doses of Subsys, and executives encouraged knowing that addicted patients refilled their prescriptions more often.[151]

A straight line can be drawn from the sales techniques Insys Therapeutics employed to Purdue Pharma's practices in marketing OxyContin. The convergence of pharmaceutical companies like Purdue and Insys Therapeutics' aggressive marketing practices, their dominance of opioid research, influence on the perception of pain, and their efforts to manipulate government actors account for the explosive increase of opioid prescriptions and abuse in the last three decades. These factors may also help explain why, at least in part, the government has failed to prosecute individual drug company executives after it uncovers their fraud. However, the question remains: why has the crisis occurred despite the CSA and other laws implemented to prevent its existence? Finding the answer to this question begins with a closer examination of the current law and the existing ethical framework governing the pharmaceutical industry.

II. THE STATE OF THE LAW AND ITS LIMITATIONS

No single federal law exists to prosecute pharmaceutical companies and their executives for causing the opioid epidemic. Although most of the statutes used to regulate pharmaceutical companies allow some form of criminal liability, historically, it has been rare for the government to prosecute pharmaceutical companies and corporate executives.[152] Even when prosecutors have brought charges, those cases have not proven to be an effective deterrent for future bad conduct, nor have they halted the opioid epidemic. Therefore, scholars and policymakers have offered other solutions to impose criminal culpability on the pharmaceutical industry and corporate actors, such as using the Racketeer Influenced and Corrupt Organizations Act (RICO)[153] or new legislation such OCAA.[154] This Part discusses the current state of the law, analyzes its shortcomings, and critiques the other solutions that have been offered thus far.

A. THE CURRENT LEGAL FRAMEWORKS AND ETHICAL NORMS APPLIED TO

149. *Id.*

150. Gabrielle Emanuel & Katie Thomas, *Opioid Company Executives Convicted of Racketeering*, N.Y. TIMES, May 3, 2019, at B1.

151. *Id.*

152. Almashat et al., *supra* note 5, at 24.

153. 18 U.S.C. §§ 1961–1968.

154. Opioid Crisis Accountability Act of 2019, H.R. 2917 116th Cong. Preamble, § 1 (2019).

THE PHARMACEUTICAL INDUSTRY

This Subpart describes current federal[155] laws that govern the industry, and notable prosecutions of pharmaceutical companies and executives for misconduct in manufacturing, marketing, and distributing opioids are reviewed. Ethical standards designed to shape industry behavior are also considered.

1. Federal Laws and Regulatory Mechanisms

Pharmaceutical companies are currently regulated piecemeal under several federal laws that target specific industry practices. The most common of these laws are (1) FDCA, (2) FCA, and (3) CSA.[156] The application of these laws and notable pharmaceutical industry cases are discussed in turn.

a. Food, Drug, and Cosmetic Act (FDCA)

The FDCA, originally enacted in 1938, empowers the FDA to regulate the safety of food, drugs, and cosmetics.[157] The FDCA and its regulations contain pharmaceutical companies' requirements to test, produce, and market their drugs.[158] It specifically prohibits the manufacture and introduction into interstate commerce of a drug that is "adulterated or misbranded."[159] A drug is "misbranded" under the FDCA if a false or misleading representation is made about some aspect of the drug's nature.[160]

A violation of the FDCA may be charged as a misdemeanor, subject to strict liability, resulting in a fine of $1,000, one year of imprisonment, or both.[161] Those that violate the act knowingly or repeatedly are subject to felony prosecution under the act and face a term of imprisonment of ten years, a fine of $250,000, or both.[162] Further, dissemination of "direct-to-consumer

155. This Article focuses on prosecuting pharmaceutical companies and their executives under federal law. Most pharmaceutical companies manufacture and distribute opioids on national rather than state or local level. As described in note 5, *infra*, nearly every state has filed litigation against pharmaceutical companies based on their false marketing and labeling practices under states' False Claim Acts, common law fraud or unfair trade laws and many have joined the MDL. *See* Almashat et al., *supra* note 5, at 56. *See* State v. Abbott Labs, Inc., 208 So. 3d 384 (La. App. 1 Cir. 2016), writ denied, 216 So. 3d 802, and writ denied, 216 So. 3d 808, and overruled by State, by & through Caldwell v. Astra Zeneca AB, 249 So. 3d 38 (La. App. 1 Cir. 2018) (alleging fraud, negligent misrepresentation, and unlawful marketing practices); Com. v. TAP Pharm. Prod., Inc., 626 Pa. 1 (94 A.3d 350 2014) (alleging unfair trade practices, fraud, civil conspiracy, negligent misrepresentation); Watts v. Medicis Pharm. Corp., 239 Ariz. 19, 23 (2016) (alleging tort and product liability); *see also* MDL 2804, National Prescription Opiate Litigation, United States District Court, Northern District of Ohio, https://www.ohnd.uscourts.gov/mdl-2804. A thorough review of the MDL and other state civil and criminal ligation against pharmaceutical companies is beyond the scope of this Article.

156. 21 U.S.C. §§ 801–803.

157. 21 C.F.R. § 1.1 (2010).

158. Eugene McCarthy, *A Call to Prosecute Drug Company Fraud as Organized Crime*, 69 SYRACUSE L. REV. 439, 444 (2019).

159. 21 U.S.C. § 331(a); 21 U.S.C. § 331(g).

160. United States v. Torigian Labs, Inc., 577 F. Supp. 1514, 1525 (E.D.N.Y.), aff'd sub nom. United States v. Torigian Labs., 751 F.2d 373 (2d Cir. 1984).

161. 21 U.S.C. § 333(a)(1).

162. *Id.* § 333(b)(1).

advertisement that is false or misleading may result in a civil penalty of $250,000 for the first such violation in any 3-year period."[163]

Because the intent of individual actors in a corporation is difficult to prove, a violation of the FDCA is not frequently charged as a felony.[164] Corporate officers may, however, face misdemeanor prosecution under the strict liability portions of the FDCA under the "responsible corporate officer doctrine." In *United States v. Dotterweich*, the Supreme Court recognized that a corporate officer might be held individually liable for violating the FDCA.[165] The Supreme Court explained that the strict liability scheme of the FDCA is justified because individual consumers are not well-situated to protect themselves from adulterated or misbranded food and drugs while businesses are.[166] Thus, businesses may be held liable for any risks they create by choosing to operate in those fields.[167] After that, in *United States v. Park*, the Supreme Court held that a corporate officer could be held liable for a company's violation of the FDCA without any personal "awareness of some wrongdoing" if the officer had the authority to prevent a violation and failed to do so.[168]

Despite the availability of the responsible corporate officer doctrine, prosecutors have not frequently prosecuted corporate officers unless there is at least evidence of the officer's negligence.[169] For example, in 2007, in a case brought by federal prosecutors in Virginia, Purdue Pharma and three executives were convicted of FDCA misbranding violations.[170] The defendants acknowledged that Purdue had marketed OxyContin with the intent to defraud or mislead.[171] Purdue pleaded guilty to felony charges and paid more than $600 million in fines.[172] Michael Friedman, the executive vice-president, along with Howard Udell and Purdue Pharma's chief medical officer Paul Goldenheim,

163. *Id.* § 333(g)(1).

164. Ty McCoy, *The Need for Higher Punishment: Lock Up the Real Drug Dealer*s, 54 GONZ. L. REV. 47, 69 (2019).

165. *See* United States v. Dotterweich, 320 U.S. 277, 279 (1943).

166. *Id.*

167. *Id.*

168. United States v. Park, 421 U.S. 658, 672 (1975).

169. Marc A. Rodwin, *Do We Need Stronger Sanctions to Ensure Legal Compliance by Pharmaceutical Firms?*, 70 FOOD & DRUG L.J. 435, 440 (2015). The majority opinion in *Park* did not specifically establish a standard of negligence, other than to state that "the [FDCA] punishes neglect where the law requires care." *Park*, 421 U.S. at 658–59. The *Park* dissent, however, specified a negligence standard more specifically. *Park*, 421 U.S. at 679 (Stewart, J., dissenting). Since then, many courts have followed the dissent's interpretation and have required cases brought pursuant to Park to establish negligence on the part of the corporate officer. *See* United States v. DeCoster, 828 F.3d 626, 633 (8th Cir. 2016), *aff'd*, 137 S. Ct. 2160 (2017); United States v. New England Grocers Supply Co., 488 F. Supp. 230, 233 (D. Mass. 1980); United States v. Ayo-Gonzalez, 536 F.2d 652, 661–62 (5th Cir. 1976).

170. United States v. Purdue Frederick Co., 495 F. Supp. 2d 569, 572 (W.D. Va. 2007); Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. TIMES, May 10, 2007, at A1.

171. Meier, *supra* note 170, at A1.

172. *Id.*

pleaded guilty to misdemeanors and were sentenced to fines, probation, and community service.[173]

However, the 2007 FDCA convictions of Purdue Pharma and its executives did not serve to deter the company's misconduct. They continued to aggressively market opioids, and prescriptions increased.[174] In 2020, Purdue Pharma once again pled guilty to violating the FDCA.[175] As part of the guilty plea, Purdue admitted that from May 2007 through at least March 2017, it conspired to defraud the United States by impeding the lawful function of the DEA, including representing that Purdue maintained an effective anti-diversion program when, in fact, Purdue continued to market its opioid products to health care providers whom the company had good reason to believe were diverting opioids.[176] Purdue also reported misleading information to the DEA to boost its manufacturing quotas.[177] The conspiracy also involved aiding and abetting violations of the FDCA by facilitating the dispensing of its opioid products, including OxyContin, without a legitimate medical purpose.[178] Under the terms of the plea agreement, Purdue agreed to the imposition of the largest penalties ever levied against a pharmaceutical manufacturer, including a fine of $3.544 billion and an additional $2 billion in criminal forfeiture.[179] However, no individual corporate owner or executive was charged in connection with the case.[180]

b. False Claims Act (FCA)

A False Claims Act violation can be charged as a criminal or civil offense. The criminal violation, codified in 18 U.S.C. § 287, criminalizes the intentional presentation of a false claim to a government actor knowing such claim to be false, and it imposes a five-year prison term and a fine.[181] The civil FCA, codified in 31 U.S.C. §§ 3729–3733 is likewise not specific to the regulation of the pharmaceutical industry.[182] However, claims against pharmaceutical companies are often brought under the civil FCA for "misbranding and mislabeling products, promoting products for off-label or non-FDA approved uses, misrepresenting or adulterating data and clinical trial results, and failing to

173. *See Purdue Frederick Co.*, 495 F. Supp. 2d at 570.

174. Guy et al., *supra* note 66, at 698–99. 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.*

175. Press Release, Dep't of Just., Opioid Manufacturer Purdue Pharma Pleads Guilty to Fraud and Kickback Conspiracies (Nov. 24, 2020), https://www.justice.gov/opa/pr/opioid-manufacturer-purdue-pharma-pleads-guilty-fraud-and-kickback-conspiracies.

176. *Id.*

177. *Id.*

178. *Id.*

179. *Id.*

180. *Id.*

181. 18 U.S.C. § 287.

182. 31 U.S.C. §§ 3729–3733.

disclose or adequately warn consumers of potential risks and side effects."[183] The FCA provides that any person who knowingly presents false claims to the government is liable for a civil penalty of $5,000 to $10,000 and three times the amount of damages sustained by the government.[184]

In a civil FCA action, the named plaintiff is the United States government.[185] The FCA also contains a *qui tam* provision, awarding 15–25% of the proceeds of the action to a whistleblower who brings a violation to the government's attention.[186] An analysis of pharmaceutical civil penalties from 1991 to 2017 found that *qui tam* actions represented most claims against pharmaceutical companies.[187]

The criminal FCA provision, Section 287, has not been used to prosecute pharmaceutical companies. However, the government has brought charges against drug companies under the civil FCA, Section 3729.[188]. Although both sections require proof of the defendant's "knowledge," Section 287 has been interpreted to require actual knowledge of wrongdoing,[189] while Section 3729 provides that knowledge can be shown through proof of "actual knowledge of the information, deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information."[190]

Notably, in late 2020, in addition to the criminal charges brought against it under the FDCA, Purdue Pharma settled FCA civil claims against it for $3 billion based on its marketing and selling of opioids purchased by Medicare and other federal health care providers.[191] Although the deal also required the Sacklers to pay $225 million, none of the corporate executives faced criminal liability under the FCA.[192]

183. Annastasia Moriarty, *Avoiding Accountability: The Insulation of Pharmaceutical Companies from Criminal Liability*, SUFFOLK J. OF HEALTH & BIOMED. L. BLOG (Feb. 26, 2020), https://sites.suffolk.edu/jhbl/2020/02/26/avoiding-accountability-the-insulation-of-pharmaceutical-companies-from-criminal-liability.

184. 31 U.S.C. § 3729(a).

185. Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 PENN ST. L. REV. 41, 54 (2005).

186. 31 U.S.C. § 3730(d). A qui tam is a provision which allows a private individual, or "whistleblower" (or relator), with knowledge of past or present fraud committed against the federal government to bring suit on its behalf. *Qui Tam Action*, LEGAL INFO. INST.: CORNELL L. SCH., https://www.law.cornell.edu/wex/qui_tam_action (last visited Jan. 24, 2022); Greene, *supra* note 185, at 54–55.

187. Almashat et al., *supra* note 5, at 10.

188. 31 U.S.C. § 3729.

189. Under the criminal FCA, 18 U.S.C. § 287, to be false, the claim must not only be inaccurate but consciously so. United States v. Barker, 967 F.2d 1275, 1279 (9th Cir. 1991). *See* United States. v. Coop. Grain & Supply Co., 476 F.2d 47, 59 (8th Cir. 1973) (comparing the intent elements of civil FCA and criminal FCA violations, recognizing the heightened scienter requirement in section 287, and suggesting that "knowing" under section 287 implied actual guilty knowledge rather than a "guilty avoidance of knowledge").

190. 31 U.S.C. § 3729(b)(1).

191. Dep't of Just., *supra* note 175.

192. *Id.*

c. Controlled Substances Act (CSA)

The CSA provides the Attorney General, FDA, and DEA with broad authority to regulate various drugs.[193] As the primary federal law regulating controlled substances, the CSA categorizes drugs, including 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.[194] 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.[195] The drugs in Schedules II-V also have the potential for abuse but have medical uses in treatment in the United States or a currently accepted medical use with severe restrictions.[196] The class of drugs listed in Schedule II includes commonly prescribed opioid drugs such as morphine, methadone, oxycodone, and injectable forms of methamphetamine that have been used to treat chronic and acute pain.[197] Schedule II drugs have been most closely associated with abuse in the opioid epidemic.[198] The fact that prescription opioids have been placed on Schedule II reflects a finding that they have an accepted medical use but pose a high potential for abuse, and such abuse may lead to severe psychological or physical dependence.[199]

Because some controlled substances, such as opioids, have legitimate medical uses, the CSA creates two overlapping legal schemes: "(1) a registration system to monitor and control the flow of controlled substances dispensed under legitimate prescriptions, and (2) a set of penalties for illegitimate trafficking and possession of controlled substances."[200] To legally sell opioids, drug manufacturers and distributors must register annually with the Attorney

193. Mariano-Florentino Cuéllar & Keith Humphreys, *The Political Economy of the Opioid Epidemic*, 38 YALE L. & POL'Y REV. 1, 20 (2019); 21 U.S.C. § 811(a).

194. *Controlled Substance Schedules*, DRUG ENF'T AGENCY, https://www.dea.gov/drug-information/drug-scheduling.

195. Waldrop, *supra* note 43, 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-methylenedioxypyrovalerone or MDPV). *See* , DRUG ENF'T AGENCY, CONTROLLED SUBSTANCES BY CSA SCHEDULE (2021), https://www.deadiversion.usdoj.gov/schedules/orangebook/e_cs_sched.pdf; *Controlled Substance Schedules*, *supra* note 194.

196. *Controlled Substance Schedules*, *supra* note 194.

197. *Id.*

198. *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 194.

199. *Controlled Substance Schedules*, *supra* note 194.

200. JOANNA R. LAMPE, CONG. RSCH. SERV., LSB10307, CORPORATE DRUG TRAFFICKING LIABILITY—A NEW LEGAL FRONT IN THE OPIOID CRISIS (2019).

General.[201] Registrants must adhere to the CSA's requirements regarding, among other things, distribution, labeling, and warning of opioids.[202] Violations of the registration requirements are not generally considered criminal offenses unless they were committed knowingly, in which case, a registrant could be subject to a fine or imprisonment for up to one year.[203] However, a violation of the general drug trafficking provision is subject to stricter penalties, such as a $2.5 million fine and up to fifteen years imprisonment for violations related to Schedule II drugs.[204] Finally, the CSA's registration system and its trafficking regime are not mutually exclusive, and participation in the registration system does not insulate registrants from the statute's trafficking penalties.[205]

In April 2019, the DOJ indicted Rochester Drug Cooperative, Inc. (RDC), the sixth largest drug distributor in the United States, and two of its executives for CSA violations based on the company's distribution of oxycodone and fentanyl to pharmacies.[206] The RDC indictments represent the first time the government brought felony charges against any company in the pharmaceutical industry under the general drug trafficking provisions of the CSA.[207] Previously when the DOJ brought criminal trafficking charges against CSA registrants, it targeted individual doctors and pharmacies that improperly prescribed or dispensed opioids directly to patients. By contrast, prior DEA enforcement actions against pharmaceutical companies have generally proceeded under the CSA's registration provisions, rather than the trafficking provisions, and have involved only civil and administrative penalties, such as suspension of registration and fines.[208]

RDC, however, was charged with felony conspiracy to distribute opioids, failure to report suspicious drug orders, and conspiracy to defraud the United States.[209] The complaint alleged that between 2012 and 2017, RDC supplied large quantities of opioids to pharmacies that it knew did not have a legitimate medical need for the amount supplied.[210] The company's compliance

201. 21 U.S.C. § 822(a).

202. *Id.* § 825.

203. *Id.* § 842(c)(2)(A).

204. *Id.* § 841(E)(i)(b).

205. United States v. Moore, 423 U.S. 122, 124 (1975) (holding that physicians registered under the CSA can be prosecuted under the general drug trafficking provision "when their activities fall outside the usual course of professional practice").

206. Press Release, Dep't of Just., Manhattan U.S. Attorney and DEA Announce Charges Against Rochester Drug Co-Operative and Two Executives for Unlawfully Distributing Controlled Substances (Apr. 23, 2019), https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-and-dea-announce-charges-against-rochester-drug-co-operative-and.

207. *Id.* Richard Gonzales, *Drug Distributor and Former Execs Face First Criminal Charges in Opioid Crisis*, NAT'L. PUB. RADIO (Apr. 23, 2019, 9:43 PM), https://www.npr.org/2019/04/23/716571375/drug-distributor-and-former-execs-face-first-criminal-charges-in-opioid-crisis.

208. *See* LAMPE, *supra* note 200.

209. Gonzales, *supra* note 207.

210. *See id.*; Trial Pleading, United States v. Rochester Drug Co-op., Inc., No. 19 CRIM 290, (S.D.N.Y. Apr. 23, 2019), WL 7667033.

department repeatedly warned executives that the pharmacies in question displayed "red flags" such as purchasing only controlled substances and accepting a high amount of cash from customers.[211] Despite the warnings, senior management allegedly continued to instruct sales personnel to supply the controlled substances to the pharmacies.[212] Another allegation stated that executives pushed employees to open new pharmacy customer accounts without conducting due diligence as required by the CSA.[213] In 2019, RDC entered into a five-year Deferred Prosecution Agreement under which it agreed to pay $20 million as forfeiture, report suspicious orders to DEA moving forward, and acknowledge responsibility for its conduct.[214] In exchange, prosecutors agreed to seek dismissal of the charges against the company after the five-year term expired.[215] The agreement specifically states that it does not apply to "any individual or entity other than [RDC],"[216] meaning that the two executives who were also charged will still be prosecuted, and if convicted, could face ten years to life in prison for violations of the CSA's drug trafficking provisions.[217] Since the charges, the company has also announced it will no longer distribute opioid medications.[218]

2. Pharmaceutical Industry Ethics

In addition to complying with the patchwork of federal statutes and regulations, pharmaceutical companies are also guided by industry ethics. The industry has two primary sources for ethical guidelines. The FDA provides one source,[219] and the second set of guidelines are provided by the Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group that represents pharmaceutical company interests.[220]

211. *See id.*

212. *See id.*

213. Gonzales, *supra* note 207; Notably, out of 2,000 suspicious orders received, the company reported only four to the DEA. *Id.*

214. Gonzales, *supra* note 207.

215. Deferred Prosecution Agreement Between U.S. Dep't of Just., U.S. Attorney S.D.N.Y. and Rochester Drug Co-Operative, Inc., 4 (Apr. 22, 2019), https://www.justice.gov/usao-sdny/press-release/file/1156381/download.

216. *Id.*

217. Gonzales, *supra* note 207.

218. Sonia Mogre, *Pharmaceutical Distributor Embroiled in Criminal Charges Ceases Opioid Sales*, CNN (Jan. 14, 2020, 7:23 PM), https://www.cnn.com/2020/01/14/us/pharmaceutical-company-stops-selling-opioid-medications/index.html.

219. *Guidance (Drugs)*, FOOD & DRUG ADMIN. (July 13, 2020), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.

220. *Codes & Guidelines*, PHARM. RES. & MFRS. OF AM., https://www.phrma.org/about/codes-and-guidelines (last visited Jan. 24, 2022).

a. FDA Guidelines

The FDA's website provides guidelines for the industries that it regulates, including the pharmaceutical industry.[221] Guidelines found on the FDA's website include, for example, guidance on product labeling and product descriptions on social media platforms.[222] Although the guidelines are comprehensive and specific, the document states they are expressly voluntary.[223]

b. PhRMA Guidelines

PhRMA represents the interests of the pharmaceutical industry; its members include many large pharmaceutical companies.[224] Its priorities are "explaining the increased complexity and risk of the research and development process; reinforcing the need for investment in R&D; ensuring broad access to and appropriate use of medicines, and emphasizing the importance of strong intellectual property incentives for new medicines."[225] In addition to advocacy on behalf of the pharmaceutical industry, PhRMA publishes various best practices for its members,[226] including topics related to advertising, interaction with medical professionals, and principles of conducting clinical trials.[227] For example, the "Code of Interaction with Health Care Professionals" advises that pharmaceutical representatives "should not provide any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment . . . ."[228] If a company adopts the guidelines, the company executives must certify the commitment.[229] No penalties exist for the failure to comply with PhRMA's guidelines.[230]

B. CRITIQUE OF LAW AND RECENT PROPOSALS

As described in Part II.A, prosecutors have federal laws at their disposal to bring cases against pharmaceutical companies and their executives for their

221. *Search for FDA Guidance Documents*, FED. DRUG AGENCY, https://www.fda.gov/regulatory-information/search-fda-guidance-documents (last updated Jan. 3, 2022); *Guidances (Drugs)*, FED. DRUG AGENCY, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs (last visited Jan. 24, 2022).

222. FED. DRUG AGENCY, *supra* note 221.

223. FED. DRUG AGENCY, PRODUCT NAME PLACEMENT, SIZE, AND PROMINENCE IN PROMOTIONAL LABELING AND ADVERTISEMENTS 1 (2017), https://www.fda.gov/media/87202/download.

224. *About*, PHARM. RES. & MFRS. OF AM., https://www.phrma.org/en/About (last visited Jan. 24, 2022); *Members*, PHARM. RES. & MFRS. OF AM., https://www.phrma.org/en/About/Members (last visited Jan. 24, 2022).

225. *About*, PHARM. RES. & MFRS. OF AM., *supra* note 224.

226. PHARM. RES. & MFRS. OF AM., *supra* note 221.

227. *Id.*

228. PHARM. RES. & MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS 5 (2019), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Code-of-Interaction_FINAL21.pdf.

229. *Id.* at 14.

230. *Id.* at 3.

conduct in connection with the opioid epidemic. But even when these laws have been deployed, they have done little to deter the improper industry wrongdoing that contributed to millions of opioid addictions and hundreds of thousands of opioid overdose deaths. This Subpart explores the reasons criminal liability against a pharmaceutical company and its executives has rarely been imposed.[231] It critiques the current laws and explains how the lack of personal liability for pharmaceutical executives has created a climate in which it is more profitable for a pharmaceutical company to pay monetary penalties than to stop engaging in illegal and unethical activity.[232] Although suggestions on the appropriate solution differ, there is a growing chorus of scholars and policymakers that have called for criminal penalties to hold pharmaceutical companies and their top executives accountable.[233] This Subpart also explores solutions that have been suggested by others, including the use of federal criminal racketeering laws. Recent legislative initiatives, such as OCAA, are critiqued here as well.

1. Existing Legal Approaches Have Proven Ineffective

The laws that govern pharmaceutical companies' conduct have failed to end the opioid crisis for several reasons that relate to the statutes' scope and purpose and the challenges in proving the elements, especially intent.

a. Problems with Purpose and Scope

Existing laws do not target criminal misconduct specific to the pharmaceutical industry and its executives. These statutes—FDCA, FCA, and CSA—were implemented to regulate a broad range of corporate and individual conduct outside the pharmaceutical industry. Consequently, because these laws were not specifically designed or directed towards the pharmaceutical industry, their application to industry practices is subject to challenge. In defending the industry, company lawyers have argued that these statutes do not criminalize the company's practices and corporate executives' behavior. For example, in July 2019, a federal grand jury charged an Ohio-based pharmaceutical distributor, Miami-Luken, Inc., and two of the company's former officials, with conspiring to distribute controlled substances in violation of the drug trafficking provisions of the CSA.[234] According to the indictment, company executives and Miami-Luken sought to enrich themselves by distributing millions of painkillers to doctors and pharmacies in rural Appalachia.[235] The distributor and its officials

231. Brian Mann, *As Drugmakers Face Opioid Lawsuits, Some Ask: Why Not Criminal Charges Too?*, NPR (Sept. 19, 2019, 6:37 PM), https://www.npr.org/2019/09/19/762455218/as-drugmakers-face-opioid-lawsuits-some-ask-why-not-criminal-charges-too.

232. Reuben Guttman, *Effective Compliance Means Imposing Individual Liability*, 5 EMORY CORP. GOV. & ACCOUNTABILITY REV. 77, 84 (2019); McCarthy, *supra* note 158, at 442.

233. Guttman, *supra* note 232, at 84; McCarthy, *supra* note 158, at 442; McCoy, *supra* note 164, at 48.

234. United States v. Rattini, No. 1:19-cr-81, 2021 U.S. Dist. LEXIS 41872, at *3 (S.D. Ohio Mar. 5, 2021) (indictment returned July 17, 2019).

235. *Id.*

allegedly continued distributing the drugs to pharmacies even after being advised by the DEA of their responsibilities as a wholesaler to ensure that drugs were not being diverted and to report suspicious orders.[236] It was further alleged that Miami-Luken filled suspicious orders.[237] Each of the defendants, including Miami-Luken, was charged with conspiring to illegally distribute controlled substances, a crime punishable by up to twenty years in prison.[238] In April 2020, Miami-Luken, and the individual defendants filed motions to dismiss the case, asserting that their conduct did not violate the CSA.[239] The motion accused the government of seeking to punish behavior that is not prohibited by federal law.[240] According to the motion, "[t]he government's action here violates the constitutional bedrock of separation of powers," and the indictment also violates due process limits on regulatory authority and the DOJ's prosecution policies.[241]

Even those statutes that are designed to regulate the industry directly do not fully respond to the industry's practices. The FDCA, for instance, prohibits the introduction into interstate commerce of misbranded and adulterated drugs and regulates the marketing and safety of drugs.[242] Nevertheless, the statute is not broad enough to address the range of pharmaceutical company misconduct. For example, the FDCA does not address the problem of selling unnecessarily large quantities of drugs. Thus, the FDCA cannot alone deter and punish pharmaceutical companies and executives from engaging in bad behavior.

b. Problems with Proving Scienter

These statutes—in particular, the criminal FCA, CSA, and the felony FDCA—have high burdens of proof on the element of intent. Under the FCA, prosecutors must show that the defendant intentionally presented a false claim to the government "knowing"[243] the claim to be false.[244] These elements of intent are challenging to prove, especially against corporate executives. Prosecutors rarely attempt to bring such charges and instead opt to assess civil penalties under the FCA's civil provisions.[245] Similarly, the major challenge in prosecuting pharmaceutical companies and their executives under the CSA is proving the requisite intent. A violation of the CSA's drug trafficking provision must be committed "knowingly or intentionally."[246] Prosecutors routinely use

236. *Id.*
237. *Id.*
238. *Id.*; 21 U.S.C. § 841(g).
239. Defs.' Mot. to Dismiss 32–37, United States v. Rattini, 1:19-cr-81-MWM (S.D. Ohio Apr. 30, 2020).
240. *Id.*
241. *Id.*
242. 21 U.S.C. §§ 331(a),(g).
243. 18 U.S.C. § 287; *see Cooperative Grain*, 476 F.2d at 59.
244. *See* 18 U.S.C. § 287.
245. Moriarty, *supra* note 183.
246. 21 U.S.C. § 841(a).

the CSA to target street drug dealers who distribute controlled substances because the distribution by a non-registrant of the substance is illegal.[247]

In contrast, because drug manufacturers are registrants under the CSA, they are authorized to distribute controlled substances.[248] Thus, to prosecute an authorized registrant under the trafficking provisions of the CSA, prosecutors must prove that pharmaceutical executives intended to illicitly distribute controlled substances.[249] This is difficult to accomplish because drug companies have historically shielded their executives from liability by creating an army of lower-level employees that act as a buffer between the illegal conduct and the executives.[250]

In the recent case against drug distributor RDC, prosecutors charged several executives with the CSA felony trafficking violations.[251] The CSA charges require proof that the executives knew or reasonably should have known that opioids the corporation distributed were dispensed outside the usual course of professional practice.[252] One of the RDC executives, the former chief compliance officer, pled guilty to charges and agreed to cooperate with the prosecution, but the other high-ranking executive, the former CEO, vowed to fight the charges.[253] His lawyer told the press that his client "is being framed," adding that "the government has it all wrong and is being used by others to cover up their wrongdoing."[254] The CEO's case has not yet been set for a hearing.[255] Given the difficulty in establishing a corporate executive's intent in a CSA drug trafficking case, the likelihood of a conviction on the charges is uncertain.

Prosecuting pharmaceutical executives and companies under the FDCA has proved equally challenging to demonstrate the required scienter. As discussed above, most violations of the FDCA are strict liability offenses, requiring no proof of culpable intent or even knowledge of an offense.[256] The strict liability provisions of FDCA apply to minor violations of the FDCA.[257]

247. *See, e.g.*, Press Release, U.S. Dep't of Just., Federal Authorities Announce 11 Cases Charging Alleged Drug Dealers with Providing Opioids that Led to Fatal Overdoses (May 13, 2021), https://www.justice.gov/usao-cdca/pr/federal-authorities-announce-11-cases-charging-alleged-drug-dealers-providing-opioids (describing cases brought against non-registrants charged with CSA drug trafficking offenses).

248. 21 U.S.C. § 822(a).

249. *Id.*

250. McCarthy, *supra* note 158, at 441.

251. U.S. Dep't of Just., *supra* note 207.

252. 21 U.S.C. § 822(a).

253. Gary Craig, *Case Against Rochester Drug Cooperative Could Provide New Way to Fight Opioid Epidemic*, DEMOCRAT & CHRON. (Apr. 30, 2019), https://www.democratandchronicle.com/story/news/2019/04/25/opioid-crisis-rochester-drug-cooperative-lawsuit-opioids/3549315002.

254. William K. Rashbaum, *For First Time, Pharmaceutical Distributor Faces Federal Criminal Charges Over Opioid Crisis*, N.Y. TIMES (Apr. 23, 2019), https://www.nytimes.com/2019/04/23/nyregion/opioid-crisis-drug-trafficking-rochester.html.

255. Stewart Bishop, *Ex-Drug Distributor CEO Slated For January Opioid Trial*, LAW360 (Sept. 1, 2021), https://www-law360-com.etron.lls.edu/articles/1418083/print?section=compliance.

256. *See* 21 U.S.C. § 333(a)(1).

257. *Id.* Some have suggested expanding the strict liability portions of the FDCA statutes so that it is not necessary to prove intent to convict for a felony violation. McCoy, *supra* note 164, at 72. Removing the

However, to secure a felony conviction under the FDCA, a prosecutor must demonstrate that either the defendant knowingly violated the act or has violated the act repeatedly.[258] Although the FDCA contains provisions for imprisonment, the provisions are not often used against opioid manufacturers. Prosecutors instead tend to opt for civil or criminal financial penalties when bringing charges under the FDCA.[259] Even when charges are particularly egregious, imprisonment is challenging to secure. For example, Purdue's conduct in the 2007 misbranding case[260] was egregious—the company's sales representatives falsely described the risk of addiction and OxyContin's dangers to healthcare providers.[261] Nevertheless, prosecutors were unable to establish sufficient proof of knowledge of wrongdoing, and misdemeanors, fines, and civil penalties were imposed on them instead of jail time.[262]

c. Deferred Prosecutions Agreements are No Remedy

Rather than charging individual executives with a crime, the government usually enters into deferred-prosecution agreements ("DPA") or non-prosecution agreements ("NPA") with the corporate entity.[263] Under a DPA, the prosecutor and the corporation agree that although the prosecutor will charge the corporation in federal court, the prosecutor will defer the continued prosecution of the charges until the end of a certain period of time agreed upon by both parties.[264] If the corporation has followed through on its obligations at the end of the term of the agreement, the prosecutor will dismiss the charges.[265] As part

knowledge element will undoubtedly make it easier for prosecutors to secure convictions, as knowledge is notoriously difficult to prove in the corporate crime context. *Id.* at 68–69. However, strict liability offenses tend to also carry lighter penalties because courts are reluctant to punish those that are convicted of offenses without a mental state element. *Id.* at 70. Thus, it is highly unlikely that courts will sentence executives to long prison terms for strict liability violations of the FDCA.

258. 21 U.S.C. § 333(b)(1); McCoy, *supra* note 164, at 72.

259. *See e.g.*, McCoy, *supra* note 164, at 65 (providing examples and stating that "In 2008, Cephalon pleaded guilty to a misdemeanor criminal violation of the FDCA for its misleading promotion of three drugs, Actiq (aka fentanyl), Gabitril, and Provigil, and agreed to pay $425 million and entered into a five-year Corporation Integrity Agreement (CIA). In 2009, Pfizer agreed to pay $2.3 billion for misbranding the painkiller Bextra. In 2007, Merck paid $4.85 billion to settle for over-promoting the painkiller, Vioxx. In 2011, Merck agreed to pay $950 million for illegally promoting Vioxx, and plead guilty to illegal marketing charges. In 2011, Johnson & Johnson agreed to pay $70 million to settle DOJ charges related to foreign bribery. Johnson & Johnson was again fined $2.2 billion in 2013, for promoting drugs not approved as safe by the FDA").

260. United States v. Purdue Frederick Co., 495 F. Supp. 2d 569, 571–72 (W.D. Va. 2007); McCoy, *supra* note 164, at 63; Katie Warren & Taylor Nicole Rogers, *The Family Behind OxyContin Pocketed $10.7 Billion from Purdue Pharma. Meet the Sacklers, Who Built Their $13 Billion Fortune Off the Controversial Opioid*, BUS. INSIDER (Mar. 23, 2020, 11:05 AM), https://www.businessinsider.com/who-are-the-sacklers-wealth-philanthropy-oxycontin-photos-2019-1; Van Zee, *supra* note 84, at 223.

261. *Purdue Frederick Co.*, 495 F. Supp. 2d at 571.

262. *Id.* at 576.

263. *See* Cindy R. Alexander & Mark A. Cohen, *The Evolution of Corporate Criminal Settlements: An Empirical Perspective on Non-Prosecution, Deferred Prosecution, and Plea Agreements*, 52 AM. CRIM. L. REV. 537, 537(2015).

264. *Id.*

265. *Id.* at 545. An NPA functions in a similar manner, only the government does not even take the step of filing charges in federal court so as to defer them to a later date. *Id.*

of the DPA or NPA, a drug company will typically pay a criminal fine out of the corporate treasury and agree to implement internal reforms to prevent future criminal fraud.[266] One scholar has suggested that the government resorts to DPAs rather than individual criminal prosecutions of executives because proving intentional fraud is difficult given the organizational complexity and diffused corporate decision-making responsibility.[267] As such, the scholar suggests the government conducts a cost-benefit analysis and determines that the DPA is the safer bet for ensuring at least some corporate accountability.[268]

The 2007 case against Purdue Pharma is a textbook example of the ineffective use of DPA to combat the crisis. The financial penalties assessed against Purdue, even when married with misdemeanor criminal convictions, did not alter pharmaceutical company conduct. Misconduct is profitable. Ultimately, pharmaceutical companies make more money from engaging in misconduct and paying penalties than they would if they did not engage in misconduct in the first instance.[269] Thus, for many pharmaceutical companies, "committing criminal and civil violations have become part of their business model."[270] Decades of civil and monetary penalties have not been enough to deter pharmaceutical companies from their bad conduct.[271]

2. Current Proposed Solutions Fall Short

Neither legal scholars nor policymakers have developed an adequate legal framework to address the opioid epidemic and hold pharmaceutical companies and industry executives accountable for their role in the crisis. Most legal scholarship and commentary on the opioid crisis focuses on distinct issues, including the burdens to the legal system and health care system or the decimation of communities because of opioid misuse and addiction.[272] Few discuss the interaction of civil litigation, criminal enforcement, and regulatory tools that comprise the national response to the opioid crisis.[273]

For instance, scholars have reviewed strategies the federal government has recently employed against the opioid crisis, such as (1) coordinated Law Enforcement actions against drug cartels and traffickers in specific communities; (2) Diversion Control actions against DEA registrants operating outside the law and long-term engagement with pharmaceutical drug

266. *See* Brandon L. Garrett, *The Corporate Criminal as Scapegoat*, 101 VA. L. REV. 1789, 1848 (2015).

267. *Id.* at 1825–26, 1836.

268. *Id.* at 1835.

269. McCoy, *supra* note 164, at 66.

270. *Id.* at 65.

271. Guttman, *supra* note 232, at 84; McCarthy, *supra* note 158, at 441; McCoy, *supra* note 164, at 66.

272. *See* Cuéllar & Humphreys, *supra* note 193, at 29 (exploring the political economy of the public health law and regulation in relation to the opioid crisis).

273. *See, e.g.*, Andrew M. Parker, Daniel Strunk & David A. Fiellin, *State Responses to the Opioid Crisis*, 46 J.L. MED. & ETHICS 367 (2018); Rachel L. Rothberg & Kate Stith, *The Opioid Crisis and Federal Criminal Prosecution*, 46 J.L. MED. & ETHICS 292 (2018); Alex Wang & Aaron S. Kesselheim, *Government Patent Use to Address the Rising Cost of Naloxone: 28 U.S.C. § 1498 and Evzio*, 46 J.L. MED. & ETHICS 472 (2018).

manufacturers, wholesalers, pharmacies, and practitioners; and, (3) Community Outreach through local partnerships that empower communities to take back affected neighborhoods.[274] Commentators have also examined the DOJ's enforcement strategies, like prescription-drug monitoring programs,[275] forensic analysis of drug ledgers,[276] and enhanced sentencing requirements for drug trafficking that results in death.[277]

Some commentators have called upon the Supreme Court to address the problem by expanding the application of the *Park* Doctrine to allow for pharmaceutical company executives to be held strictly liable for FDCS felony violations.[278] Others have argued that policymakers should probe the root cause of the opioids epidemic by focusing on regulatory solutions like having the federal government challenge patents, requiring sample sharing for bioequivalence studies, and promoting cost-effectiveness research and dissemination.[279] Timothy S. Coyne has noted that in stark contrast to the crack-cocaine epidemic, the legislative reaction to the current opioid epidemic "has generally been far more treatment-oriented, with some exceptions."[280]

Eugene McCarthy's proposal suggests that charging criminal RICO will resolve the challenge of holding high-level pharmaceutical executives criminally accountable for the opioid epidemic.[281] In theory, McCarthy's suggestion offers a possible means to impose criminal liability with the potential for lengthy prison sentences upon individual corporate executives. The application of RICO is therefore examined here.

a. Criminal RICO

In 1970, Congress enacted RICO to reign in criminal mafia activity.[282] RICO makes it "unlawful for any person [to receive] any income derived, directly or indirectly, from a pattern of racketeering activity."[283] Racketeering is defined as "any act or threat involving murder, kidnapping, gambling, arson,

274. Mike Gill, Gary Owen & Sean Fearns, *DEA's 360 Strategy: Attacking the Opioid Crisis on Three Fronts*, 64 U.S. ATT'YS BULL. 55, 55 (2016).

275. *See* Tara Kunkel, *Data-Driven Approaches to Responding to the Opioid Epidemic*, 64 U.S. ATT'YS BULL. 79, 79–82 (2016).

276. *See* Jessica L. Affeldt, *Drug Ledge Analysis Capabilities of the FBI's Cryptanalysis and Racketeering Records Unit*, 64 U.S. ATT'YS BULL. 83, 83–86 (2016).

277. William J. Ihlenfeld II, *"Death Results" Prosecutions Remain Effective Tool Post-Burrage*, 64 U.S. ATT'YS BULL. 45, 45–52 (2016).

278. McCoy, *supra* note 164, at 67–79.

279. Ameet Sarpatwari, Michael S. Sinha & Aaron S. Kesselheim, *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market*, 11 HARV. L. & POL'Y REV. 463, 481–84 (2017).

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

281. Marie Bussey-Garza, *Say Hello to My Little Friend Civil Rico: The Third Circuit Green Lights Insurance Shakedown of Big Pharma with in Re Avandia*, 61 VILL. L. REV. 625 (2016) (explaining that "Congress's expressed purpose in enacting RICO was to keep organized crime from infiltrating legitimate businesses").

282. McCarthy, *supra* note 158, at 461.

283. 18 U.S.C. § 1962(a).

robbery, bribery, extortion, dealing in obscene matter, or dealing in a controlled substance."[284] RICO allows the government to prosecute an entire criminal enterprise and its constituent members at once, "[painting] with a broad brush" to unite individual criminal acts into an organized pattern of crime.[285] RICO holds each criminal enterprise member—whether the CEO or the salesperson—accountable for conduct of the other members of the crime syndicate.[286] It thus prevents those at the highest level of the enterprise from escaping legal liability for the conduct of others who carry out the aims of the enterprise. RICO aggregates all enterprise members' crimes into the single offense of *participating* in the criminal enterprise and imposes the same punishment on all participants regardless of their rank in—or illegal contribution to—the organization.[287] The enterprise element also allows prosecutors to introduce previously inadmissible evidence about the crime syndicate's history, structure, and operations.[288] Thus, RICO has been an attractive tool to address corporate fraud.[289] RICO includes both criminal and civil[290] violation provisions. Those convicted under RICO face criminal fines, forfeiture of interests obtained through prohibited racketeering activity, and imprisonment for up to twenty years "or for life, if related to racketeering activity for which the maximum sentence includes life imprisonment."[291]

In the context of pharmaceutical company fraud, RICO permits charging pharmaceutical company executives, sales representatives, doctors, and lawyers at once for participating in the "association-in-fact criminal enterprise."[292] In proposing RICO as a promising solution to criminalize pharmaceutical executive misconduct, Eugene McCarthy likened pharmaceutical companies' structure to organized crime syndicates. He called for criminal prosecution of executives using RICO.[293] Professor McCarthy asserts that, like the Mafia, pharmaceutical companies routinely engage in illegal practices, but companies shield executives from prosecution "simply by delegating crimes to underlings who would take the fall for the larger organization."[294] He argues that RICO

284. *Id.* § 1961(a)(A).

285. Peter J. Henning, *RICO Charge in Pharmaceutical Case May Signal Tougher Tactics*, N.Y. TIMES (Dec. 12, 2016), https://www.nytimes.com/2016/12/12/business/dealbook/rico- charge-in-pharmaceutical-case-may-signal-tougher-tactics.html.

286. *Id.*

287. *See* 18 U.S.C. § 1962(c); Brian Goodwin, *Civil Versus Criminal RICO and the "Eradication" of La Cosa Nostra*, 28 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 279, 287 (2002).

288. James B. Jacobs & Lauryn P. Gouldin, *Cosa Nostra: The Final Chapter?*, 25 CRIME & JUST. 129, 170 (1999).

289. McCarthy, *supra* note 158, at 442.

290. RICO's civil provisions allow those harmed by prohibited RICO activity to sue for triple damages, litigation costs, and attorney's fees. 18 U.S.C. § 1964(c).

291. *Id.* § 1963(a).

292. McCarthy, *supra* note 158, at 463.

293. McCarthy, *supra* note 158, at 441.

294. *Id.*

would allow the government to prosecute high-ranking members of an organization through their connection to the organization in general.[295]

The idea of using RICO to impose criminal liability on pharmaceutical executives is appealing, but using RICO to prosecute pharmaceutical company executives includes the hurdles of establishing intent and causation for the predicate RICO offense.[296]

The Insys Therapeutics prosecution illustrates the limitations of using RICO to hold pharmaceutical executives criminally accountable. There, prosecutors brought multiple charges at once, including for predicate act criminal violations of the CSA for drug distribution, wire fraud, and conspiracy to illegally distribute Subsys.[297] The jury returned guilty verdicts against the company and the individual defendants, but the court partially vacated the verdicts questioning the prosecutor's use of a CSA violation as the predicate offense for RICO.[298] The judge stated that the prosecutors failed to demonstrate "that Defendants agreed and intended that healthcare practitioners would illicitly distribute Subsys to patients that did not need it at an unnecessarily high dose . . . ."[299] The judge found that the corporate executives' conduct constituted "garden variety" fraud, not a CSA violation.[300] The court was "very reluctant [to] disturb[] a jury verdict" but found that "even though the evidence could be readily understood as proving that defendants did not care whether patients needed the drug, that still is not enough to prove the requisite intent.'"[301] Although the individual defendant executives faced up to thirty-three years in prison and more than $300 million in restitution, the court sentenced the founder to five and a half years imprisonment, while six other executives received between one to three years imprisonment.[302] Insys Therapeutics also agreed to a $255 million settlement.[303] The Insys case demonstrates that although RICO offers some benefits in terms of admissibility of evidence and the possibility of bringing an array of charges against multiple corporate actors, the problem of proving the predicate offense remains challenging because such offenses, like

295. *Id.*

296. Bussey-Garza, *supra* note 281, at 626–27; *Judge Vacates Criminal Convictions Against Pharma Execs in First-of-its-Kind Opioid Case*, ADVISORY BD. (Dec. 2, 2019), https://www.advisory.com/daily-briefing/2019/12/02/opioid-cases; 18 U.S.C. § 1961(1) (containing list of predicate offenses applicable to RICO violations, as RICO requires first establishing the presence of a predicate offense).

297. Henning, *supra* note 9.

298. Memorandum and Order on Defendants' Motions for Judgment of Acquittal and for a New Trial at 11, U.S. v. Babich, No. 1:16-cr-10343-ADB (D. Mass. 2016).

299. *Id.*

300. Villani, *supra* note 11.

301. ADVISORY BD., *supra* note 296.

302. *United States v. Michael Babich, Alec Burlakoff, Richard Simon, Sunrise Lee, Joseph Rowan, and Michael Gurry, John Kapoor*, U.S. DEP'T OF JUST. (May 7, 2020), https://www.justice.gov/usao-ma/victim-and-witness-assistance-program/united-states-v-michael-babich-alec-burlakoff-richard-simon-sunrise-lee-joseph-rowan-and.

303. Chris Villani, *Insys Founder John Kapoor Gets 5½ Years*, LAW360 (Jan. 23, 2020, 4:23 PM), https://www.law360.com/articles/1237076/insys-founder-john-kapoor-gets-5-years.

CSA violations, contain elements that are difficult to prove. RICO, therefore, is no panacea.

b. Recent Legislation

Policymakers have proposed legislative fixes that are either tangential or problematic. As discussed, the stringent scienter requirements that apply to the CSA criminal trafficking, the FCDA felony misbranding, and FCA criminal false claims violations make it difficult to secure convictions, particularly for pharmaceutical industry actors who are not directly involved in day-to-day drug distribution decisions. Likewise, filing criminal RICO charges requires proof of a predicate offense like a CSA, FDCA, or FCA violation that will have a specific intent element that may be hard to prove.

In the last several years, , however, momentum and bipartisan political will have coalesced in the legislative branch to address the opioid epidemic. A few laws have been enacted which address some aspects of the epidemic. For example, H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment ("SUPPORT") for Patients and Communities Act,[304] passed with overwhelming bipartisan support and was signed into law in 2018.[305] The 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.[306] Other legislative initiatives also sought to address the problem of the over-prescription of opioids. The Using Data to Prevent Opioid Diversion Act, signed into law in 2019, aims to reduce the diversion of opioids by requiring more frequent reporting of suspiciously large opioid orders and providing additional transparency in opioid distribution reporting.[307] Although the legislative initiatives that have been introduced and gained the most traction are important, they are tangential, existing around the margins of the larger problem—how to hold the pharmaceutical industry and its executives criminally accountable for their conduct creating the opioid epidemic. An effort to address that problem in 2018 directly took the form of the OCAA of 2018.

304. Support for Patients and Communities Act of 2018, H.R. 6, 115th Cong. (2d Sess. 2018).

305. Cameron Fox, *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Public Law 115-271)*, SCIPOL (Jan. 24, 2019), [https://perma.cc/WUM9-3J8W].

306. *Id.*

307. 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. Using Data to Prevent Opioid Diversion Act of 2018, H.R. 6491, 115th Cong. (2d Sess. 2018). Manufacturers and distributors are required to review this information and detect suspicious orders (for example, orders of abnormal size, orders that differ substantially from a normal arrangement, or orders of unusual frequency) or unusual patterns of distribution.

c. Opioid Crisis Accountability Act ("OCAA")

The OCAA, introduced by Bernie Sanders and Michael Bennet in the Senate, and then re-introduced in 2019 by former congress member Tulsi Gabbard and Ro Khanna in the House of Representatives,[308] was designed to target pharmaceutical company marketing practices that led to "creating and exacerbating the opioid epidemic in the United States."[309] If enacted, the OCAA would have provided that it is "unlawful for any person involved in the manufacture or distribution of an opioid to engage in dubious marketing or distribution practice with respect to an opioid."[310] The bill broadly defined "dubious marketing" to include making false representations about an opioid's addictiveness, supplying to states a medically unreasonable quantity of opioids, and failing to report orders for opioids "that the person knows are not being dispensed in a medically reasonable manner."[311]

The bill called for both direct and vicarious liability for corporate actors. All individuals who directly violated the statute by engaging in dubious marketing or distribution practices would be fined the amount of their salaries plus the increased value of their company assets for every year of violation.[312] They would also be subject to imprisonment of up to ten years for CSA Schedule II drugs or up to five years for Schedule III drugs.[313] The OCAA would have subjected corporate entities to a civil penalty equal to 75% of the total profit of opioid sales for which it engaged in dubious marketing and distribution practices.[314]

As for vicarious liability, the bill provided that if a company violates the statute, certain executives would be subject to civil financial penalties "without regard to the participation of such individuals in, or knowledge of such individuals of, the violation."[315] The CEO would incur a civil penalty in the amount of their salary for the period of the violation and the increase in the value of the ownership interest held in the company during the period of violation.[316] In addition, other executives who led finance, research, marketing, or sales departments would be fined 25% of their salaries and the increased value of their company assets for every year of violation.[317]

The bill also, among other things, would have provided for assessment of fees against each company that manufactured or distributed any opioid between 1993 and the date of enactment.[318] Companies that fail to pay the fee would lose

308. Opioid Crisis Accountability Act of 2019, H.R. 2917, 116th Cong. (1st Sess. 2019).
309. H.R. 2917, 116th Cong. Preamble (2019).
310. H.R. 2917 § 2(b).
311. *Id.* § 2(a)(1)(C).
312. *Id.* § 2(c)(1).
313. *Id.* § 2(c)(1)(A).
314. *Id.* § 2(c)(1)(B).
315. *Id.* § 2(c)(2).
316. *Id.* § 2(c)(2)(A).
317. *Id.* § 2(c)(2)(B).
318. *Id.* § 2(e)(1) (2019).

FDA approval to market the opioid.[319] This assessment fee and any other financial penalties imposed for violating the act would be collected in an "Opioid Reimbursement Fund" intended to "combat the misuse and abuse of opioids in the United States."[320] In addition, the bill would have terminated or reduced the period of market exclusivity that the company held for the opioid that had been marketed in violation of the proposed statute. [321]

The OCAA failed to advance out of committee and expired at the end of the 116th Congress, [322] but it contained some provisions which, if enacted, would have been helpful in holding the pharmaceutical industry and their executives criminally liable for their roles in the opioid epidemic. Although aspects of the bill were legally problematic, it offers a good place to start. To develop a workable solution, discussed in Part III, the OCAA's positive attributes and shortcomings are considered.

(i) The Positives of the OCAA

First, the OCAA appropriately focused on the pharmaceutical industry. It targeted marketing practices specific to pharmaceutical companies for a single class of drugs—opioids.[323] The OCAA was promising because it provided prosecutors with an act designed explicitly for pharmaceutical companies, which would prevent exclusively relying on existing laws like the CSA, the FCA, and the FCDA that do not directly apply to the conduct at issue in these cases.

Second, violations of the OCAA's provisions imposed personal financial liability and prison time for executives.[324] The financial liability provision targeted executives' personal wealth and not only the large coffers of their companies. More importantly, the potential for imprisonment is a consequence that few pharmaceutical executives want to endure.[325] The prospect of a criminal sentence serves to deter others in the future.[326]

Third, the OCAA's requirement to establish the Opioids Reimbursement Fund derived from appropriations from the United States Treasury and monies

319. *Id.* § 2(e)(4) (2019).

320. *Id.* § 2(e)(5) (2019).

321. *Id.* § 3(a) (2019).

322. *See* All Actions, Opioid Crisis Accountability Act of 2019, H.R. 2917, 116th Cong. (2019), https://www.congress.gov/bill/116th-congress/house-bill/2917/all-actions?q=%7B%22search%22%3A%5B%22opioid+and+distribution%22%5D%7D&r=1&overview=closed&s=1#tabs; Media coverage on the OCAA is scarce, and the bill was not often discussed—not even by the Representatives and Senators that proposed it. Notably, Senator Bernie Sanders and Representative Tulsi Gabbard, who proposed a version of the bill in 2018 and 2019 respectively, both announced their bids for the 2020 presidential election soon after proposing the OCAA.

323. H.R. 2917, Preamble.

324. *Id.* § 2(c)(2).

325. Kuchler et al., *supra* note 148. In a video interview with PBS, Insys executive Alex Burloff, who was sentenced to twenty-six months imprisonment for illegally marketing the opioid Subsys, describes how he knew that it was likely Insys could face financial penalties, but that he never expected to face prison time for his illegal behavior and reflecting on how he did not want to go to prison for his conduct. *Id.*

326. Guttman, *supra* note 232, at 84; McCarthy, *supra* note 158, at 442.

generated from penalties imposed for violations of the law was commendable because it would provide much-needed financial resources to address the opioid epidemic. More funding is needed for evidence-based addiction treatment, drug research, and other programs to address the financial burden imposed by the crisis on states and local communities directly affected by the epidemic.[327]

Finally, the OCAA's provision providing the revocation of market exclusivity for the covered opioid was an apt punishment.[328] During the drug exclusivity period, the opioid manufacturer enjoys a monopoly on the drug and can profit from its sale without significant competition.[329] Opioids are often high-grossing products for pharmaceutical companies.[330] Eliminating exclusivity means that competitors can release generic versions of the drug, taking the offending drug's market share. This consequence will result in a significant financial loss for companies that invest millions into research and development. The OCAA's loss of market exclusivity provision also properly precluded an offending company from avoiding the financial losses by engaging in "product hopping," which is the practice of reformulating a previously approved drug to obtain a new drug application under the FDCA.[331] Thus, the potential for loss of exclusivity and prohibition on product hopping may create a strong deterrent from engaging in misconduct.

(ii) Limitations of the OCAA

Although the OCAA contains some promising elements to target and eradicate pharmaceutical companies and their executives' wrongdoing, other aspects of the bill are problematic and raise legal questions.

First, the OCAA employed specific terms that it failed to define adequately. For example, although the OCAA applied to "opioids" and defined "covered opioid" as "a prescription opioid drug,"[332] the term "opioid" was not otherwise defined. Given the wide variety of opiate substances and their derivatives that exist, and the high potential for abuse and addiction, a comprehensive and precise definition of the substances subject to the statute would lend clarity to the law and assist those—companies, regulators, and the public—in understanding and complying with the law. Likewise, even though the bill criminalized the supplying quantities of opioids that are not "medically reasonable,"[333] it provides the Secretary of Health and Human Services and

327. Christine Vestal, *Opioid Money Has Helped, But States Want More*, PEW CHARITABLE TRS.: STATELINE (Jan. 30, 2019), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/01/30/opioid-money-has-helped-but-states-want-more.

328. H.R. 2917 § 3(a)(1).

329. *Exclusivity and Generic Drugs: What Does It Mean?*, FOOD & DRUG ADMIN., https://www.fda.gov/files/drugs/published/Exclusivity-and-Generic-Drugs-What-Does-It-Mean-.pdf.

330. Notably, during his PBS interview, Insys executive Alex Burloff stated that Subsys accounted for such a large portion of Insys' revenue that the public would never have even heard of Insys if it did not sell Subsys.

331. H.R. 2917 § 3(a)(3).

332. H.R. 2917 § 3(b).

333. *Id.* § 2(d)(1)(A).

Attorney General with broad discretion to "establish a formula for determining the quantity of opioids that is not medically reasonable with respect to a community or State."[334] The bill suggested that the Secretary and Attorney General should "as appropriate, [work with] provider groups" and patient advocacy groups to develop the formula.[335] It is important to define the terms of art such as "medically reasonable" to provide guidance to the industry and notice to the world as to prohibited conduct. It is likewise appropriate to give regulators the express authority to draft regulations that define statutory terms. However, in using language like "as appropriate" and failing to describe the formula that should apply, the OCAA gave policymakers and regulators unfettered discretion to determine the quantity of opioids a pharmaceutical company can reasonably sell. Likewise, the list of stakeholders with whom the regulators should consult to define these terms should have been more specifically defined to include independent experts and health professionals. Developing guidelines should not open the door for the industry and its lobbyists to exert undue influence in this process.

Second, the OCAA provisions describing the required intent were overly complicated and would have created challenges of proof. Indeed, the OCAA "dubious marketing" provisions mandated proof of knowledge—that the defendant knew the marketing representations were false or knew that they supplied opioids knowing that that the quantities distributed were not medically reasonable or failed to report orders for distribution that they knew were not being dispensed in a medically reasonable manner.[336] Requiring proof that executives have knowledge of this conduct would prove difficult for prosecutors.

In an apparent effort to address the problem of proving knowledge, the OCAA provisions that govern the distribution of opioids (and the failure to report such distributions) contain a rebuttable presumption of knowledge that the distributor was aware that the quantity of opioids distributed was not medically reasonable.[337] This presumption shifts the burden of proving the lack of intent to the defendants. However, such a presumption would not satisfy due process unless the presumed facts are rationally related to the established facts.[338] To pass constitutional muster, a sufficient logical link must exist

334. *Id.* § 2(d)(1)(A).

335. *Id.*

336. *See id.* § 2(a)(1).

337. *Id.* § 2(d)(1)(B).

338. Although the legislature, by statute, may create inferences and presumptions, the facts proved must bear a rational relationship to the fact to be inferred. If they do not, the statutory inference or presumption cannot stand. With respect to the validity of statutory presumptions, the United States Supreme Court has observed: "[A] statutory presumption cannot be sustained if there be no rational connection between the fact proved and the ultimate fact presumed, if the inference of the one from proof of the other is arbitrary because of lack of connection between the two in common experience. This is not to say that a valid presumption may not be created upon a view of relation broader than that a jury might take in a specific case. But where the inference is so strained as not to have a reasonable relation to the circumstances of life as we know them, it is not competent

between the fact—that they distributed the drug—and the inference—that they knew the drug was distributed in a medically unreasonable quantity under the formula established by the Secretary of Health and Human Services and Attorney General.[339]

Questions of legal viability also arise in connection with the vicarious liability provisions in the OCAA, which imposed high financial penalties upon corporate executives for the corporate entity's conduct. For example, the Constitution may limit the penalties that the law can impose based on strict liability. Imposing strict liability for vicarious offenses would expand the holding in *Park* and expose pharmaceutical executives to sanctions regardless of their knowledge, intent, or ability to prevent a violation. The Supreme Court has not directly addressed whether the Fifth Amendment's Due Process Clause limits the penalties imposed under the *Park* Doctrine. Federal appellate courts have also wrestled with this issue and are not all in accord.[340] In *Staples v. United States*, the Court noted that for most strict liability offenses, "penalties commonly are relatively small" and that "imposing severe punishments for offenses that require no [culpable mental state] would seem incongruous."[341] Moreover, although the Court in *Park* upheld the imposition of strict liability on the facts before it, it rejected the proposition that "a finding of guilt could be predicated solely on respondent's corporate position," instead of requiring a finding that the executive had the "authority and responsibility" to address his company's violation.[342] Thus, the strict liability provisions of the OCAA may be infirm.

Third, the size of the penalties and fees in the OCAA raises separate questions, including whether such penalties would qualify as excessive fines

for the legislature to create it as a rule governing the procedure of courts." *Tot v. United States*, 319 U.S. 463, 467–68 (1943) (footnotes omitted); *see also Leary v. United States*, 395 U.S. 6, 34–36 (1969) (a criminal statutory presumption regarding the knowledge element of a crime is unconstitutional "unless it can at least be said with substantial assurance that the presumed fact is more likely than not to flow from the proved fact on which it is made to depend") (footnote omitted).

339. H.R. 2917 § 2(d)(1)(B).

340. *See, e.g.*, *DeCoster*, 828 F.3d at 635 (upholding three month prison sentences as not grossly disproportionate to the gravity of their misdemeanor offenses and rejecting a claim that due process concerns prevent individual corporate officers from being sentenced to prison for a crime involving no mens rea on their part because it is based solely on vicarious liability) cert denied, 137 S. Ct. 2160 (2017). *But see* Lady J. Lingerie, Inc. v. City of Jacksonville, 176 F.3d 1358, 1367–68 (11th Cir. 1999) (rejecting the application of Park where the sentence includes period of incarceration and holding that due process prohibits the state from imprisoning a person without proof of some form of personal blameworthiness more than a "responsible relation"). This unease with the idea of strict liability in the criminal context is reflected in *DeCoster*. In that case, Judge Murphy, writing for the majority, found both that the responsible corporate officer doctrine implies an aspect of blameworthiness, but also that the record showed that the defendants in that case were "liable for negligently failing to prevent the salmonella outbreak" at issue in the case. *Id.* at 633. Judge Gruender concurred but wrote "separately in order to make clear [his] view that Park requires a finding of negligence in order to convict a responsible corporate officer" and joined Judge Murphy only because he and the district court found the defendants negligent. *Id.* at 637 (Gruender, J., concurring). Finally, Judge Beam dissented based on his belief that Due Process requires mens rea for a criminal conviction. *Id.* at 640 (Beam, J., dissenting).

341. Staples v. United States, 511 U.S. 600, 616–17 (1994).

342. *See Park,* 421 U.S. at 674.

barred by the Eighth Amendment. In considering a constitutional challenge to the imposition of such a penalty, a reviewing court would determine if the payment, whether styled as a "fee" or "civil penalty," constitutes a punishment that is "grossly disproportional" to the gravity of the offense.

Moreover, the aspect of the OCAA, which imposes a fee upon all entities that manufactured or distributed opioids after January 1993, and that punishes those that fail to timely pay the assessed fee, may implicate the Ex Post Facto Clause of the Constitution. Although the ban on ex post facto laws generally applies only to penal laws and thus may not implicate the OCAA, the Supreme Court has held that "the ex post facto effect of a law cannot be evaded by giving a civil form to that which is essentially criminal."[343] The fees could be considered punitive measures subject to the Ex Post Facto Clause if they were "so punitive either in purpose or effect" that they could not be deemed civil in nature.[344]

Finally, the OCAA is backward facing. Although the OCAA garnered virtually no media attention, one commentator critiqued the bill as "too little, too late," observing that limiting the quantity of opioids sold "would have been very helpful fifteen years ago" at the beginning of the opioid crisis, but is not likely to help now.[345] The OCAA focuses almost exclusively on the conduct well after it occurred and provides little guidance for the industry going forward to avoid the next prescription drug epidemic that may be on the horizon.

III. THE 360-DEGREE SOLUTION: THE CONTROLLED SUBSTANCE MANUFACTURER AND MARKETING ACCOUNTABILITY ACT (THE "CS MAMA")

For more than one hundred years, the federal government has been applying criminal law solutions to the abuse of substances derived from opium.[346] The government has also sought to regulate those involved in the distribution of those substances in society.[347] However, none of those efforts have proved successful.[348] The opioid epidemic—boosted by the COVID-19 pandemic—shows no sign of ending. As discussed in Part II, although some proposals to address the opioid epidemic argue for employing existing statutes

343. Burgess v. Salmon, 97 U.S. 381, 385 (1878).

344. To determine whether a fee is punitive, courts use an "intent-effects test." Under the test, the fee is punitive if the legislature intended the statute to be punitive. Moyer v. Alameida, 184 F. App'x 633, 636 (9th Cir. 2006). For example, the Ninth Circuit found that an imposition of a retroactive 10% fee on a prisoner's wages to pay off restitution fines was punitive and therefore gave rise to an ex post facto claim. *Id.* at 637. There, the fee was punitive because the legislature had enacted the statute to increase funds available for restitution. The OCAA's fee is similarly intended to raise funds for restitution and to punish pharmaceutical companies for their role in the opioid epidemic. Therefore, it is unlikely to pass muster under intent-effects test.

345. Lawrence Greenblatt, *Sanders's Proposed Opioid Legislation Is Too Focused on The Past,* THE HILL (Apr. 18, 2018), https://thehill.com/opinion/healthcare/383819-sanders-proposed-opioid-legislation-is-too-focused-on-the-past.

346. *See supra* Part I and II.

347. *See supra* Part I and II.

348. *See supra* Part II.

or offer narrow remedies focused on discrete aspects of the problem, all of those methods and proposals have significant drawbacks, and none of those currently in place have been effective in altering the behavior of the pharmaceutical industry.

This Article offers something new—the Controlled Substance Manufacturer and Marketing Accountability Act ("CS MAMA"). This comprehensive, omnibus proposal blends the most useful aspects of the OCAA with other existing legal frameworks.[349] It also incorporates new ideas, recognizing the political and economic forces that shape the epidemic. The CS MAMA is a holistic, end-to-end approach designed to align private incentives with public interests. This Part explains CS MAMA's three pillars aimed at (1) ending the drug development to drug addiction cycle by creating new norms for the industry actors, (2) inspiring responsible corporate conduct by reinvigorating the regulatory environment, and (3) remedying prior harms by creating a fund of financial resources that can be called upon to address the epidemic going forward. Finally, the feasibility of the proposal is considered.

A. THE OBJECTIVES OF CS MAMA

Policymakers and the public have consistently expressed outrage that few if any pharmaceutical companies or their executives have been criminally punished for their conduct in bringing about the opioid epidemic.[350] Acknowledging this reality, the legislative response to the pharmaceutical industry's role in causing the crisis must be evaluated and observed through the lens of the criminal justice system's penological objectives.

The U.S. Supreme Court has recognized legitimate penological schemes to enforce criminal punishment based on retribution,[351] deterrence,[352] incapacitation,[353] and rehabilitation.[354] The criminal justice system in the United

349. *See infra* Appendix.

350. Chris McGreal, "*Your Actions are Sickening": Sackler Hearing Inspires Rare Bipartisan Disgust,* THE GUARDIAN (Dec. 18, 2020), https://www.theguardian.com/us-news/2020/dec/18/sackler-congress-opioid-purdue-hearing; Brian Mann, *Critics Want Sacklers to Face Criminal Charges for Role in Opioid Crisis*, NPR (Nov. 25, 2020), https://www.npr.org/2020/11/25/938801514/critics-want-sacklers-to-face-criminal-charges-for-role-in-opioid-crisis.

351. *Retribution*, BLACK'S LAW DICTIONARY (8th ed., 2004) ("Punishment imposed as a repayment or revenge for the offense committed; requital.").

352. *Deterrence*, BLACK'S LAW DICTIONARY (8th ed., 2004) ("The act or process of discouraging certain behavior, particularly by fear; [especially], as a goal of criminal law, the prevention of criminal behavior by fear of punishment."). HERBERT L. PACKER, THE LIMITS OF THE CRIMINAL SANCTION 39 (1968) (describing deterrence as "the inhibiting effect that punishment, either actual or threatened, will have on the actions of those who are otherwise disposed to commit crimes").

353. *Incapacitation*, BLACK'S LAW DICTIONARY (8th ed., 2004) ("The action of disabling or depriving of legal capacity.").

354. Harmelin v. Michigan*,* 501 U.S. 957, 959, 999 (1991); *Rehabilitation*, BLACK'S LAW DICTIONARY (8th ed., 2004) ("The process of seeking to improve a criminal's character and outlook so that he or she can function in society without committing other crimes.").

States has placed different emphasis on these four goals over time.[355] These goals are the result of a mixture of the two theories of punishment—utilitarianism and retributivism.[356] Utilitarians are primarily concerned with the future of society.[357] They believe that a person balances the expected benefits of the criminal conduct with its risks, such as detection and punishment, and will avoid criminal activity if the perceived potential pain outweighs the expected potential pleasure stemming from the rewards of committing the criminal conduct.[358] On the other hand, retributivists focus on punishing the past acts of wrongdoers who perform criminal acts based on the belief that punishment is deserved when the wrongdoer freely chooses to violate rules enacted by society.[359] Although the utilitarian theory has dominated the American system of criminal justice,[360] the retributivist concept of moral blameworthiness, as a justification for punishment, has also influenced the theory of punishment.[361]

More recently, the concepts of restoration and reparation have also gained recognition as legitimate objectives of criminal punishment.[362] Restorative justice does not fit neatly into either the utilitarian or the retributivist camp. The theory focuses on the harm done to the victim by healing the wounds and restoring the offender to the community.[363] The components of CS MAMA are organized and evaluated according to these penological objectives.

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355. *See Harmelin*, 501 U.S. at 999. Prior to 1970, the American criminal justice system considered the principal goals of punishment to be rehabilitation and incapacitation; *See* James Q. Whitman, *Equality in Criminal Law: The Two Divergent Western Roads*, 1 J. LEG. ANALYSIS, 119, 127 (2009). However, beginning in the early 1970s, there was a dramatic shift toward determinative sentencing guidelines, which resulted in the restriction of judicial discretion. *See id.* at 127–28. Today, retribution seems to be the principal focus of the criminal justice system. *See id.* at 128.

356. *See* JOSHUA DRESSLER, UNDERSTANDING CRIMINAL LAW 22 (3d ed., 2001) (arguing that the criminal law system that has developed in the United States is not philosophically consistent, as "some rules of criminal responsibility are primarily retributive in nature, whereas others are utilitarian in character"); Caprice L. Roberts, *Ratios, (Ir)rationality & Civil Rights Punitive Awards*, 39 AKRON L. REV. 1019, 1033 (2006).

357. *See* DRESSLER, *supra* note 356, at 14–15.

358. *See id.*

359. *See id.* at 16. "Just desert" stems from retributive theory, and refers to the mandatory punishment of a morally culpable wrongdoer; *see* Joshua Dressler, *Hating Criminals: How Can Something That Feels So Good Be Wrong?*, 88 MICH. L. REV. 1448, 1451 (1990). Retributivists believe that it is morally wrong to punish an innocent person even if society might benefit from the action, and would rather have a guilty person go unpunished than an innocent person pay their "just deserts" for a crime that they did not commit. *See id.*

360. Stephen F. Smith, *Proportional Mens Rea*, 46 AM. CRIM. L. REV. 127, 146–47 (2009); William L. Barnes, Jr., *Revenge on Utilitarianism: Renouncing a Comprehensive Economic Theory of Crime and Punishment*, 74 IND. L.J. 627, 629–30 (1999).

361. *See* Smith, *supra* note 360, at 146.

362. Donald H. J. Hermann, *Restorative Justice and Retributive Justice: An Opportunity for Cooperation or an Occasion for Conflict in the Search for Justice*, 16 SEATTLE J. FOR SOC. JUST. 71, 94 (2017); Mark Umbreit, *Crime Victims Seeking Fairness, Not Revenge: Toward Restorative Justice*, 53 FED. PROBATION 52, 52 (1989).

363. "The new paradigm of 'restorative justice' defines crime as a violation of one person, by another, not a violation of the state. Dialogue and negotiations are normative, with a focus upon problem-solving for the future rather than establishing blame for past behavior. Rather than the imposition of severe punishment, restorative justice emphasizes restitution as a means of restoring both parties; reconciliation and restoration of the parties is the goal. Instead of ignoring the victims and placing offenders in a passive role, the new paradigm of restorative justice places both victim and offender in active and interpersonal problem-solving roles." Umbreit, *supra* note 362, at 52.

1. Retribution Deterrence and Incapacitation

Pharmaceutical companies and their executives who engaged in misconduct contributing to the opioid epidemic should be punished and deterred from future wrongdoing. The sanction imposed should be calibrated to end the conduct and serve as a warning to others. To meet these objectives, the CS MAMA includes elements that clearly define the drugs to which it applies and precisely identifies prohibited behavior. It also includes an intent requirement that is reasonably calibrated to how the pharmaceutical industry operates and contains penalties designed to punish, deter, and incapacitate.

a. Coherent Elements

The OCAA inspires the CS MAMA. Building upon the best elements of the OCAA, the CS MAMA contains provisions that clarify the scope of the drugs subject to the bill and clearly identifies the prohibited conduct and required intent to violate the law.

(i) Regulated Substances

As proposed, the OCAA would have regulated the marketing and distribution practices of only an unspecified class of "opioids."[364] Curbing the opioid epidemic is an important goal. As the history described in Part I teaches, however, without applying the law to other opiates and other highly addictive natural and engineered substances, the cycle of drug development, marketing, and addiction will repeat. If the past is any guide, it is only a matter of time before pharmaceutical companies develop and market derivatives of other controlled substances such as MDMA and ketamine.[365] Thus, to address the current opioid epidemic and anticipate the next, the CS MAMA includes a definition of "Regulated Substance," which expressly applies not only to the opioids which gave rise to the current epidemic but to all Schedule II and III controlled substances.[366]

364. *See generally* Opioid Crisis Accountability Act of 2019, H.R. 2917, 116th Cong. (2019*).*

365. Ryan Troup, *These Two Companies Could Be Turning LSD, Magic Mushrooms, Ketamine and MDMA Into the Next Blockbuster Drugs*, CANNABIS INV. (May 22, 2020), https://www.thecannabisinvestor.ca/these-2-companies-are-turning-lsd-magic-mushrooms-ketamine-and-mdma-into-the-next-blockbuster-drugs (describing how there are already several companies looking to create the next "blockbuster drug" from several controlled substances).

366. *See infra* Appendix, CS MAMA § 2 Definitions, (a) "Regulated Substance." Although beyond the scope of this Article, the DOJ should also re-evaluate how drugs are classified under the CSA Schedules in light of recent legal and scientific developments. For example, marijuana is currently classified as a Schedule I drug, along with heroin and other dangerous substances, despite the various accepted medicinal uses for marijuana in recent years. German Lopez, *The Federal Drug Scheduling System, Explained*, VOX (Aug. 11, 2016, 9:05 AM), https://www.vox.com/2014/9/25/6842187/drug-schedule-list-marijuana.

(ii) Prohibited Behavior

Like the OCAA,[367] the CS MAMA would amend FDCA to render it "unlawful for any person who manufactures or distributes a regulated substance to engage in a dubious marketing or distribution practice with respect to a regulated substance."[368] The bill defines "dubious marketing" to include making false representations about a regulated substance's addictiveness, supplying to states a medically unreasonable quantity of the regulated substance, and failing to report such orders.[369] The CS MAMA would also afford the Secretary of Health and Human Services and the Attorney General the discretion to develop a formula that defines "medically reasonable" and requires that regulators consult with independent experts in doing so.[370]

Although dubious marketing practices have been a hallmark of the campaign to sell opioids, the industry's harmful behavior is not solely related to marketing or distribution practices. As the Insys Therapeutics case illustrates, the pharmaceutical industry also has a history of bribing and buying prescribers.[371] Also, like Purdue Pharma, drug firms have routinely submitted false and misleading studies to regulators when seeking drug approvals.[372] Thus, the CS MAMA expands the prohibited activities to include providing financial payments and incentives to prescribers and misrepresenting results of scientific studies to regulators.[373] Bringing these behaviors into this statute's scope will deter pharmaceutical companies and their executives from these common wrongful practices and bring the prohibitions in line with the conditions on the ground in the industry.

(iii) Rational Scienter Requirement

Unlike the OCAA's scienter requirements which are undefined and raise constitutional concerns,[374] the CS MAMA expressly prescribes the required intent to violate the statute. A conviction of the statute as a felony demands proof of "knowledge."[375] In contrast to the CSA, felony FDCA violations and criminal FCA violations which contain unspecified knowledge requirements that prosecutors have struggled to prove, knowledge under the CS MAMA expressly includes actual knowledge, acts in deliberate ignorance of the truth or falsity of the matter, or acts in reckless disregard of the truth or falsity of the information.[376] Defining knowledge to incorporate willful blindness and

367. H.R. 2917 § 2(a)(1).
368. *See infra* Appendix, CS MAMA § 3 "Prohibited Activities."
369. *See infra* Appendix, CS MAMA § 3 "Prohibited Activities."
370. *See infra* Appendix, CS MAMA § 2.
371. *See* Wheeler, *supra* note 140.
372. *See* Downing et al., *supra* note 101.
373. *See infra* Appendix, CS MAMA § 3 (a)(2)–(3).
374. *See* Limitations of the OCAA, *supra* Part II B(2)(c)(i).
375. *See infra* Appendix, CS MAMA § 3.
376. *See infra* Appendix, CS MAMA § 3.

recklessness reflects the range of culpable mental states of the corporate actors who engaged in the prohibited conduct. It also gives prosecutors additional evidentiary tools to prove intent and thus a greater opportunity to hold corporate wrongdoers to account. The expanded definition of intent will translate into just punishment for wrongdoers, including those in executive positions within pharmaceutical companies. It is also a disincentive to other corporate actors, discouraging them from closing their eyes to what would otherwise be apparent.

Moreover, the CS MAMA allows for misdemeanor penalties for those who negligently[377] engage in the prohibited conduct. It is rational to adopt a criminal negligence standard for conduct below the standard established to protect others against unreasonable risk of harm. It allows those with a less culpable mindset to be punished while avoiding the constitutional concerns that have arisen with the FDCA penalties imposed based on strict liability under the *Park* Doctrine.

b. Rational Penalties

The penalties in the CS MAMA are designed to target and punish the wrongful manufacturing, marketing, and distribution practices of pharmaceutical companies and the individual corporate executives who participated, encouraged, and ultimately benefited from the behavior.

(i) Individual Financial Liability for Executives

Under the existing legal frameworks, financial penalties under the FDCA, FCA, and CSA have been factored into the cost of doing business in the pharmaceutical industry.[378] As discussed in Part II, they have created an environment where it has been more profitable for pharmaceutical companies to engage in misconduct and pay fees than it is to not engage in misconduct in the first place. The CS MAMA will change that calculus. The CS MAMA subjects a corporation found to violate the statute to a civil penalty in the amount equal to 75% of the total profit such corporate entity made on lawful sales of regulated substances in the United States during the period in which the corporate entity engaged in dubious marketing or distribution practices.[379] In addition, like the OCAA, the proposed statute contains provisions that would impose personal financial liability and prison time for executives who act with the requisite knowledge.[380] Prison time and financial fines for pharmaceutical company executives will punish them and discourage other executives from engaging in aggressive, unethical, or illegal drug marketing practices.

377. *See infra* Appendix, CS MAMA § 3(b)(2).
378. *See* sources cited *supra* note 232.
379. *See infra* Appendix, CS MAMA § 3(b)(1)(B).
380. *See infra* Appendix, CS MAMA § 3(b)(1)(A).

(ii) Maximum and Minimum Prison Terms

The CS MAMA includes a maximum of "not more than 15 years" for Schedule II drugs and "not more than 10 years" for Schedule III drugs if the defendant is convicted of a felony violation of the statute.[381] It also provides for a maximum sentence of one year in prison for a misdemeanor conviction.[382] The statute also includes mandatory minimums of five years for a Schedule II felony, three years for a Schedule III conviction, and six months for misdemeanor convictions.[383]

Mandatory minimum sentences have been justly criticized in other sentencing contexts because they have increased racial disparities in sentencing and cause harm to lower-income communities and communities of color, who are disproportionally targeted by these laws.[384] Mandatory minimum sentences for pharmaceutical executives, however, are different. They do not raise similar concerns as nearly all pharmaceutical executives are affluent and have significant legal and financial resources at their disposal to defend themselves; they are not among those whom criminal laws have disproportionally impacted.[385] A minimum prison term is required so that powerful pharmaceutical executives do not negotiate generous plea deals to avoid prison time.

Mandatory minimum sentencing for white-collar pharmaceutical defendants would respond to the complaint that "district court judges[] refus[e] to impose harsh sentences on serious white-collar violators."[386] They would also, among other things, provide a deterrent from engaging in misconduct.[387]

(iii) Revocation of Drug Exclusivity

Research and development for drugs require significant time and millions of dollars in investment from pharmaceutical companies.[388] Obtaining an exclusive market for a drug allows those drug developers to recoup their development expenses and generate profits from their monopoly in the

381. *See infra* Appendix, CS MAMA § 3(b)(1)(A).

382. *See infra* Appendix, CS MAMA § 3(b)(1)–(2).

383. *See infra* Appendix, CS MAMA § 3(b)(2).

384. Darren Lenard Hutchinson, *Who Locked Us Up? Examining the Social Meaning of Black Punitiveness*, 127 YALE L.J. 2388, 2391–92 (2018).

385. Cynthia A. Challener, *Is the Pharma Industry Developing Cultural Intelligence?*, PHARMA'S ALMANAC (Mar. 19, 2020), https://www.pharmasalmanac.com/articles/is-the-pharma-industry-developing-cultural-intelligence; Waseem Noor & Saule Serikova, *Diversity and Inclusion: A Pharma 50 Perspective*, PHARMA. EXEC. (June 22, 2016), https://www.pharmexec.com/view/diversity-and-inclusion-pharma-50-perspective.

386. John D. Esterhay, *"Street Justice" for Corporate Fraud-Mandatory Minimums for Major White-Collar Crime*, 22 REGENT U. L. REV. 135, 164–65 (2010) (demonstrating that white collar crimes receive lower sentences than non-white collar crimes for the same guideline range).

387. *Id.*

388. PHRMA, BIOPHARMACEUTICAL RESEARCH & DEVELOPMENT (2015), http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf.

market.[389] Similar to the OCAA, the CS MAMA revokes drug exclusivity for statutory violations.[390] If a company loses market exclusivity because of a violation of the CS MAMA, other companies may sell generic versions of the drug, taking market share from the company that developed it. Revocation of exclusivity thus provides an incentive to ensure compliance with the proposed statute.

(iv) Five-Year Revocation of Right to Engage in Direct-to-Consumer Advertising

In addition to revoking market exclusivity, the CS MAMA would also punish drug companies by revoking the offender's right under the FDAMA[391] to engage in DTC marketing for the violating drug for five years.[392] DTC has resulted in enormous profits for the industry.[393]

The five-year prohibition would also withstand constitutional scrutiny. Although DTC marketing is commercial speech entitled to constitutional protection,[394] that protection is not absolute.[395] The restriction proposed in the CS MAMA is a valid restriction on commercial speech because "experience has proved that in fact, such advertising is subject to abuse."[396] The ban on DTC marketing in CS MAMA applies to a specific product once a pharmaceutical company violated the law as to that product. Violating the law demonstrates that the offending company is likely to abuse the privilege to advertise to consumers directly. In addition, a restriction on DTC marketing may be justified based on the government's substantial interest in protecting consumers and ending the

389. Aaron S. Kesselheim, Michael S. Sinha & Jerry Avorn, *Determinants of Market Exclusivity for Prescription Drugs in the United States*, 177 JAMA INTERN MED., 1685, 1658–64 (2017).

390. H.R. 2917 § 3(a); *see also infra* Appendix, CS MAMA § 5.

391. *See* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105–115, § 421, 111 Stat. 2296, 2380 (codified at 21 U.S.C. § 331(l) (2012)).

392. *See infra* Appendix, CS MAMA § 6.

393. Deweerdt, *supra* note 144, at S11. Another aspect of the American healthcare system that encourages opioid prescriptions is that insurance plans tend to cover medications more frequently than they cover "pain management approaches such as physical therapy." *Id.*

394. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 557 (1980) (explaining "[a]lthough the Constitution accords a lesser protection to commercial speech than to other constitutionally guaranteed expression, nevertheless the First Amendment protects commercial speech from unwarranted governmental regulation").

395. In *Central Hudson*, the Supreme Court established a test to determine the constitutionality of government regulation of commercial speech. *Id.* Under *Central Hudson*, government restrictions on commercial speech are valid if the speech is unlawful or misleading and regulation of the speech is justified by a substantial government interest, if the regulation advances that interest and is no more extensive than necessary to achieve the government's interest. *Id.* Rocket Learning, Inc. v. Rivera-Sanchez, 715 F.3d 1, 13–14 (1st Cir. 2013) ("For commercial speech to come within [First Amendment protection] it at least must concern lawful activity and not be misleading."). Turtle Island Foods SPC v. Soman, 424 F. Supp. 3d 552, 572 (E.D. Ark. 2019) (explaining "'[i]f the communication is neither misleading nor related to unlawful activity, the government's power is more circumscribed,' and courts proceed with the remainder of the Central Hudson analysis") (citations omitted).

396. *See* In re R. M. J., 455 U.S. 191, 203 (1982); Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 639 (6th Cir. 2010).

opioid epidemic.[397] The five-year restriction on DTC in CS MAMA directly advances the government's interest because it disrupts the flow of false information to consumers.

Further, the ban is no more extensive than necessary to promote the government's interest. The ban does not prohibit all advertising.[398] It applies narrowly to companies that have already violated the law and only for a limited period. Pharmaceutical companies have consistently shown that lesser measures such as fines are ineffective deterrents for their highly profitable misconduct. Thus, the time-limited ban on DTC advertising for violating the statute is constitutionally proportionate punishment for conduct.

c. Predicate Act Under RICO

CS MAMA also expressly provides that a violation of the act constitutes a predicate act under RICO.[399] As discussed in Part II, because RICO permits the admission of otherwise inadmissible evidence of an individual's association with an organization, RICO is an attractive tool to address corporate fraud.[400] RICO appears well suited to target pharmaceutical company executives, who have learned to shield themselves from accountability for corporate misdeeds. Adding a violation of the CS MAMA as a predicate act under RICO means that pharmaceutical executives could be held liable for the misconduct of lower-level corporate employees if prosecutors can demonstrate that the executive "either gave a directive to engage in fraud, followed by a directive to do so, or extended some sort of influence or control over the enterprise in its pursuit of profit from the sale of prescription drugs through fraud."[401] Thus, prosecutors could prosecute pharmaceutical executives for creating unlawful and unethical corporate strategies, "[putting] the entire criminal enterprise on trial at once."[402]

CS MAMA will succeed in RICO cases where other legal frameworks like the CSA and FCDA have failed. As discussed in Part II, in Insys Therapeutics, prosecutors have alleged CSA violations as predicate offenses only to vacate the convictions for failure to prove intent. Indeed, the Insys case illustrated the difficulty of using a CSA violation as a predicate act for RICO.[403] As the court observed in vacating the verdicts against the company founder John Kapoor, the prosecutors failed to prove the requisite intent for a CSA violation.[404] The CS

397. *Opioid Overdose Crisis*, NAT'L INST. HEALTH (Oct. 4, 2021), https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis.

398. Blanket prohibitions on potentially misleading advertisements are generally disfavored. *See, e.g.*, *In re R. M. J.*, 455 U.S. at 203; Loughlin v. Tweed, 310 F.R.D. 323, 335 (E.D. La. 2015).

399. *See infra* Appendix, CS MAMA § 7.

400. McCarthy, *supra* note 158, at 441.

401. *Id.* at 476.

402. *Id.* at 460 (explaining that RICO's enterprise element will allow prosecutors to charge any individual who commits two predicate acts that contributes to a pattern of fraud as a part of an organization).

403. Memorandum and Order on Defendants' Motions for Judgment of Acquittal and for a New Trial at 19, U.S. v. Babich, No. 1:16-cr-10343-ADB (D. Mass. 2016).

404. *Id.*

MAMA avoids the problem that arose in Insys because the *mens rea* requirement of CS MAMA is broader than the intent required in the CSA. Thus, the proposed statute will be a viable tool for prosecutors to secure RICO convictions against pharmaceutical executives that will survive judicial review, unlike those in Insys Therapeutics.

2. Rehabilitation

In addition to punishing and deterring the pharmaceutical industry's marketing and distribution practices which paved the way for the opioid epidemic, the CS MAMA contains provisions aimed at the penological goal of rehabilitating, rebuilding, and improving the character of the industry. The proposal includes provisions to mandate ethical and best practice standards for the industry, re-invigorate the regulatory requirements governing drug research and clinical trials, and prevent the conflicts of interest that have dominated the sector.

A prerequisite to rehabilitation is a full accounting and review of which industry prior practices exerted undue influence on government regulators. Thus, the CS MAMA calls for a 9/11-style Blue Ribbon Commission to review the prior practices of all government entities involved with the industry.[405] The CS MAMA requires the Commission to direct the Office of Inspector General at the Department of Health and Human Services to examine the rules, practices, and procedures of the FDA, DEA, and DOJ in regulating the industry concerning opioids and to shine a light on how the government has failed to protect the public. The Commission should recommend changes that executive branch agencies can implement to protect the public and strike a better balance between private sector interests and public health concerns.

To that end, the CS MAMA also tasks the FDA with forming a working group charged with writing regulations that impose mandatory ethical and research standards on pharmaceutical companies.

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405. The federal government has previously established commissions to study the issue of opioid abuse and addiction, including one established but later abandoned by President Trump. *See* Emily Dufton, *Richard Nixon Went to War on Marijuana. Donald Trump Is Making the Same Mistake with Opioids*, WASH. POST (Apr. 20, 2018), https://www.washingtonpost.com/news/made-by-history/wp/2018/04/20/richard-nixon-went-to-war-on-marijuana-donald-trump-is-making-the-same-mistake-with-opioids. Various states and local communities have also formed their own commissions to consider the issue. *See, e.g.*, Press Release, Kansas Off. Dep't of Health & Environ., Strategic Plan Outlines Efforts to Address Opioid Crisis (Aug. 17, 2018), https://khap2.kdhe.state.ks.us/NewsRelease/PDFs/08-17-2018%20Strategic%20Plan%20Outlines%20Efforts%20to%20Address%20Opioid%20Crisis.pdf (describing the state of Kansas' formation of a commission to study and make recommendation to end the state's opioid addiction crisis); *The Mayors' Blue Ribbon Commission on Addiction*, IFARGO (City of Fargo, N.D.), Spring 2017, https://download.fargond.gov/0/ifargo_spring_2017_final.pdf (documenting the efforts of city of Fargo North Dakota to address the drug abuse crisis in its city). Although designed to study the root causes of the epidemic, the entities constituted to investigate these issues thus far have not focused on the pharmaceutical industry's relationship with and influence on the government. Russell J. Chibe & David B. Sudzus, *America's Opioid Crisis: Potential Increased Regulation of Marketing*, PHARMEXEC (Dec. 17, 2017), https://www.pharmexec.com/view/america-s-opioid-crisis-potential-increased-regulation-marketing.

a. Mandatory Ethical Standards

As discussed in Part II, the FDA[406] and the private industry trade association PhRMA have developed ethical norms to guide pharmaceutical companies and corporate actors. Although these guidelines provide comprehensive direction on many ethical issues, compliance is voluntary.[407]

Given the state of the opioid epidemic, it appears that the FDA's and PhRMA's ethical prescriptions have proven ineffective in altering behavior. The CS MAMA will change that; the statute establishes an FDA committee and working group to review existing voluntary ethical standards and develop ethical standards that will be made mandatory as a condition of the drug approval process.[408]

b. Updated Research and Clinical Trial Requirements.

As described in Part I, in the last fifty years, drug companies have taken the lead in drug research and have exerted tremendous pressure on the FDA and policymakers to water down the requirements for drug approvals. Much of the effort has been directed at the rules governing clinical trials. Pharmaceutical companies exercise "complete control over the design and execution of their clinical trials."[409] Drug companies have used biased clinical trials and company-funded, ghostwritten medical journal articles to create the dangerous misimpression that their drugs are effective and safe.[410] Companies have the ability to report biased data in their favor by refusing to disclose all clinical data from a study.[411] Current rules also allow companies to ignore ineffective clinical trials and only submit successful trials for consideration when seeking drug approval.[412] As discussed in Part I, some opioid manufacturers, including Purdue Pharma, have used "enriched enrollment" protocols that allowed

406. *Search for FDA Guidance Documents*, FOOD & DRUG ADMIN., https://www.fda.gov/regulatory-information/search-fda-guidance-documents (last visited Jan. 24, 2022).

407. FOOD & DRUG ADMIN, PRODUCT NAME PLACEMENT, SIZE, AND PROMINENCE IN PROMOTIONAL LABELING AND ADVERTISEMENTS 1 (2017), https://www.fda.gov/media/87202/download; PHARM. RSCH. & MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS 5 (2019), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Code-of-Interaction_FINAL21.pdf.

408. Although the scope and substance of the guidelines is a topic for another day, it is recommended that ethical guidelines address the problems that led to the epidemic, including practices in marketing and distribution of pharmaceutical products and conflicts of interest that arise when industry executives move back and forth between careers in the private sector and the government.

409. McCarthy, *supra* note 93, at 48.

410. *See supra* Part I.B.2.; *see also* Elise Langdon-Neuner, *Medical Ghost-Writing*, 6 MENS SANA MONOGRAPH 257, 259–60 (2008) (describing the history of ghost-written articles in the promotion of various drugs); Natalie McGauran, Beate Wieseler, Julia Kreis, Yvonne-Beatrice Schüler, Heike Kölsch & Thomas Kaiser, *Reporting Bias in Medical Research - A Narrative Review*, 11 TRIALS, no. 37, 2010, at 3 (reviewing the history of reporting bias in clinical trials of drug interventions).

411. *See* Deanna Minasi, Note, *Confronting the Ghost: Legal Strategies to Oust Medical Ghostwriters*, 86 FORDHAM L. REV. 299, 306–07 (2017) (describing drug companies' failure to disclose all data from clinical trials even when required by a court order).

412. McCarthy, *supra* note 93, at 48.

researchers to manipulate the outcome of clinical trials.[413] These practices must end.

The FDA guidelines and rules governing the clinical trial process must be revised to eliminate the bias that has infected the drug approval process. The FDA should develop and enforce regulations that require drug makers to disclose all of the clinical trial data, not only cherry-picked data, for drugs in the approval process. In addition, the FDA should disavow and disallow the use of enriched enrollment protocols by the industry.

Moreover, the current system in which drug companies fund and control all drug research is dangerous and irresponsible. Independent research is crucial to ensuring that safe and effective drug therapies are developed and that transparent drug trials are free from the influence and control of pharmaceutical companies. The federal government must re-invest and re-engage in this arena. And the industry should provide most of the funding for the work. Because the federal government cannot fund and conduct independent drug trials for every new drug, the CS MAMA creates a "Regulated Substance Rehabilitation Fund" that drug companies must contribute to test and market their drugs.[414]

c. Slowing the Revolving Door Between Industry and The Government

Another component to rehabilitate the industry and the government would be to slow the revolving door between the pharmaceutical industry and its regulators. Regulators and pharmaceutical executives can move freely and quickly between jobs in the industry and the government. Although there has been some legislative interest in curbing these practices,[415] nothing specific has been directed to ending these pharmaceutical industry practices. To address these conflict of interest issues, the CS MAMA directs the federal employees previously employed by drug makers to recuse themselves from any official action that would provide a direct and substantial financial benefit for a recent former employer, prohibits a federal employee from participating in matters that involve an individual or entity with whom the employee is negotiating future employment, and establishes a mandatory cooling-off period of least two years during which federal employees must wait before accepting a role within the pharmaceutical industry. Establishing these ethical rules will slow the movement of personnel between the pharmaceutical industry and the FDA, which invariably will help rid the government decision-making process of undue

413. Rosenberg, *supra* note 102.

414. *See infra* Appendix, CS MAMA § 3(e).

415. *See* S. 156, Executive Branch Conflict of Interest Act, 116th Cong. (2020), https://www.congress.gov/bill/116th-congress/senate-bill/156/actions. The "Executive Branch Conflict of Interest Act" (H.R. 599/S. 156) would curb many of these abuses by mandating recusal periods, prohibiting employer bonuses to those leaving to take government positions, tightening lobbying rules and lengthening "cooling off" periods. The bill did not advance out of the committee and expired at the end of December 2020.

influence and bias. It will also help the regulators refocus on their public role and build back confidence in the government.

3. Restoration and Reparation

In addressing the opioid epidemic, the CS MAMA omnibus charge justifies including measures intended to restore and repair the damage done by the industry's conduct. Harmed communities and individuals have brought thousands of civil cases in the federal and state courts against industry actors that manufactured and marketed opioids.[416] However, in addition to civil liability for prior wrongdoing, the law needs to address the epidemic's effects going forward. As described in Part II, OCAA called for the creation of a fund to pay those costs.[417] CS MAMA improves upon that idea through the "Regulated Substance Rehabilitation Fund."[418] In addition to funding derived from an appropriation from the U.S. Treasury, the fund would collect all civil penalties from violations of the law. It would also assess a fee to go into effect after the enactment of the law in an amount established by the Secretary of Health and Human Services from each entity seeking to market, manufacture, or distribute any Regulated Substance covered by a federal health program.[419] And it would impose civil penalties for nonpayment of the fee.[420] This funding could be used, among other things, to pay for programs, projects, and activities to combat the misuse and abuse of drugs, and to provide services to individuals directly affected by the misuse and abuse of opioids. The fund would also be used to pay for independent drug research and testing of new drugs.[421]

B. FEASIBILITY OF THE CS MAMA

The CS MAMA is a reimagining of the current approach to regulating the pharmaceutical industry. As an omnibus legislative proposal, it reaches further than any other prior proposal to address the broad range of pharmaceutical company misconduct, targeting companies and executives and imposing both criminal and monetary penalties for violation. As discussed, it is also designed to look forward by establishing new guardrails and norms of conduct for the industry and reconstituting and energizing the government's regulatory role. However, a question remains as to the measure's workability—that is, whether passing a statute like the CS MAMA is politically feasible.

416. *See supra* notes 5, 155 (describing the landscape of state and MDL civil cases pending against industry actors).

417. H.R. 2917, 116th Cong. § 2(f) (2019).

418. *See infra* Appendix, CS MAMA § 3(e).

419. *See infra* Appendix, CS MAMA § 3(d).

420. *See infra* Appendix, CS MAMA § 3(d)(2).

421. *See infra* Appendix, CS MAMA § 3(e)(3).

To be sure, the pharmaceutical industry retains its strong influence in the political sphere through political contributions and lobbying efforts.[422] In addition, the COVID-19 pandemic has shifted society's perception of the pharmaceutical industry. In 2019, a Gallup poll found that 58% of Americans viewed the pharmaceutical industry negatively, mainly because of the opioid epidemic and high drug prices.[423] One year later, at the height of the COVID-19 pandemic, the same poll found that only 49% of respondents expressed a negative view of the pharmaceutical industry.[424] Given the pharmaceutical industry's efforts to bring life-saving COVID-19 vaccines to Americans, the shift in public opinion is not surprising.[425] The pharmaceutical industry's positive response to the COVID-19 pandemic should not, however, dissuade lawmakers from passing comprehensive legislation that holds the industry accountable for the decades of devastation caused by the opioid epidemic. Even as the pharmaceutical industry received praise for creating the vaccines, the opioid epidemic has raged on, and overdose deaths have increased.[426] Tremendous political will and energy will be required to take on the industry. But its influence must find counterweight from activists, public health advocates, healthcare practitioners, and academics who must continue to shed light and attention on these issues and put pressure on policymakers and elected officials.

Currently, developments in the executive and legislative branches suggest that the CS MAMA is feasible. The election of Joe Biden as president and the Democratic control of Congress make CS MAMA's passage possible in the near term. The Democratic Party's expansive view of the government's role in healthcare and the private sector[427] and its positive view of government oversight[428] mean that the changes proposed by CS MAMA may be viable.

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422. *Pharmaceuticals / Health Products*, OPENSECRETS (Oct. 6, 2021), https://www.opensecrets.org/industries/summary.php?ind=H04 (details statistics on financial contributions to elected officials by the pharmaceutical industry); Elizabeth Lucas & Sydney Lupkin, *Pharma Cash to Congress*, KHN (May 22, 2020), https://khn.org/news/campaign.

423. Annalisa Merelli, *The Only Cure Strong Enough for Big Pharma's Bad Reputation is a Covid-19 Vaccine*, QUARTZ (Dec. 7, 2020), https://qz.com/1940201/pharma-companies-biggest-covid-19-profits-may-be-in-reputation.

424. *Id.*

425. Robert Blum, *Our Covid-19 Vaccine Hopes Hang on Drug Companies/ It's time to Stop Demonizing Them*, NBC (Oct. 22, 2020, 8:34 AM), https://www.nbcnews.com/think/opinion/our-covid-19-vaccine-hopes-hang-drug-companies-it-s-ncna1244191.

426. Joan Stephenson, *CDC Warns of Surge in Drug Overdose Deaths During COVID-19*, JAMA (Jan. 5, 2021), https://jamanetwork.com/channels/health-forum/fullarticle/2774898; *Overdose Deaths Accelerating During COVID-19*, CDC (Dec. 17, 2020), https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html.

427. *See Views of Government, Constitution, American Exceptionalism*, PEW RSCH. CTR. (May 4, 2011), https://www.pewresearch.org/politics/2011/05/04/section-5-views-of-government-constitution-american-exceptionalism.

428. *See Views of Government Regulation*, PEW RSCH. CTR. (Feb. 23, 2012), https://www.pewresearch.org/politics/2012/02/23/section-2-views-of-government-regulation.

1. President Biden's Campaign Initiatives

On his campaign website, President Biden promised to "[h]old accountable big pharma[ceutical] companies, executives, and others responsible for their role in triggering the opioid crisis," and impose "[criminal liability] where appropriate."[429] Specifically, President Biden proposes directing the DOJ to bring criminal enforcement actions where needed, directing the DEA to "step up its efforts to identify suspicious shipments," and banning drug makers from providing financial payments and incentives to healthcare providers.[430] These declarations offer promise for the CS MAMA.

However, because of the industry's high-profile role in producing vaccines for COVID-19, President Biden is unlikely to punish the pharmaceutical industry for causing the opioid epidemic in the short term. President Biden has been criticized for failing to act on the epidemic quickly enough.[431] However, once the pandemic abates, the country will be forced to reckon with its major effects—one of which is the increased intensity of the opioid epidemic. The CS MAMA provides provisions to address President Biden's concerns raised during his campaign. President Biden's resolve, combined with a politically allied Congress, could make passing and enacting comprehensive opioid legislation a reality.

2. Developments in the Legislative Branch

In the last three years, hundreds of legislative proposals—more than 300 bills related to opioids in the 115th Congress alone[432]—were introduced. These proposals represent a renewed determination to address the opioid crisis 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 distribution of opioids.[433]

Some new acts signed into law in 2018, like the SUPPORT Act[434] and the Using Data to Prevent Opioid Diversion Act,[435] have been passed with bi-

429. *The Biden Plan to End the Opioid Crisis*, JOEBIDEN, https://joebiden.com/opioidcrisis (last visited Jan. 24, 2022).

430. *Id.*

431. The Biden Administration cancelled former President Trump's plan to allow physicians to more easily prescribe the opioid-treatment drug buprenorphine over "legal concerns over how it was implemented." Brian Mann, *Biden Administration Criticized for Delay in Tackling Opioid Crisis*, NPR (Jan. 26, 2021), https://www.npr.org/2021/01/26/960860326/biden-administration-criticized-for-delay-in-tackling-opioid-crisis.

432. Keegan Williams & Jennifer Tribble, *Using Data to Prevent Opioid Diversion Act of 2018 (HR 6491 / S 2838, 115th Congress)*, SCI. POL. (Feb. 1, 2019), https://scipol.org/track/hr-6491-using-data-prevent-opioid-diversion-act-2018/using-data-prevent-opioid-diversion-act [https://perma.cc/XNB2-Q3WS].

433. *Id.*

434. Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Public Law 115-271), Pub. L. No. 115-271, 132 Stat. 3894 (2018).

435. 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. (2018). Manufacturers and distributors are required to review this information and detect

partisan support.[436] In November 2020, a follow-on bill was introduced to modify reporting requirements under the CSA.[437] If enacted, the bill, entitled Preventing Pill Mills Through Data Sharing Act (S 3070/HR 8732), would have required drug manufacturers and distributors to report the sale, delivery, and disposal of all controlled substances to the DEA every month, rather than quarterly as is currently required.[438] The legislation also extends the penalties and reporting requirements that currently apply to drug manufacturers and distributors.[439] Even within the first two months of the 117th Congress, a bill has already been introduced to combat the opioid crisis.[440] The bill, introduced by Representative Greg Stanton, seeks to amend the CSA to require dispensers of opioids to include a warning that the drug can cause addiction.[441]

These new bills have garnered bipartisan support, demonstrating that Congress is motivated to find solutions to combat the opioid epidemic. The 360-degree approach of the CS MAMA provides benefits to all stakeholders and constituencies, and it addresses the broad range of conduct that brought about the opioid epidemic. Enacting the CS MAMA and similar statutes like the PAPA[442] will communicate that fighting the opioid epidemic is a top priority. Democratic control of the federal government's executive and legislative branches offers the opportunity to convert that priority into reality.

CONCLUSION

Humans have been using and abusing opium for thousands of years, and for more than one hundred years, healthcare professionals have prescribed drugs derived from opium. Access to these highly addictive drugs has increased in the last three decades, leading to an epidemic of opioid addictions. The scope of the opioid epidemic in terms of lives lost and economic cost is staggering. It has brought havoc and hardship to those addicted and their families and communities[443]and has resulted in a cost to the national economy of hundreds

suspicious orders (for example, orders of abnormal size, orders that differ substantially from a normal arrangement, or orders of unusual frequency) or unusual patterns of distribution.

436. Fox, *supra* note 305. Democratic Senator Elizabeth Warren said that the bill "makes common sense changes that will help us in [the fight against the opioid epidemic]," while Republican Senator Greg Waldon said that the legislation will "save lives." Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Public Law 115-271). *Id.*

437. Preventing Pill Mills Through Data Sharing Act, S. 3070, H.R. 8732, 116th Cong. (2020).

438. *Id.*

439. *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. (2019).

440. H.R. 1026, 117th Cong. (2021).

441. *Id.*

442. *See* Delfino, *supra* note 2 (The PAPA is aimed at criminalizing the conduct of over-prescribing doctors. The PAPA will punish outlier prescribers who have stepped outside the bounds of legitimate medical treatment, deter others from joining them by incentivizing appropriate prescribing practices, and will create space for other healthcare professionals with legitimate medical justifications to prescribe opioids to treat patients.)

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

of billions of dollars.[444] Although some responsibility for the epidemic lay with healthcare professionals who prescribe the drugs and pharmacies that dispense them, the lion's share of the blame falls on the pharmaceutical industry. Pharmaceutical companies paid for the scientific research on opioids, infiltrated government spaces where drug laws and policies were enacted, and exploited loopholes in the regulations. These companies pushed a false narrative about the safety, efficacy, and lack of addictiveness of their drugs and unleashed schemes to bribe and mislead prescribers. The industry deployed manipulative advertising strategies to create a market for their drugs. Pharmaceutical companies and their executives have carried out these schemes without regard to their illegality. Although the federal government has regulated controlled substances under laws such as the FDCA and CSA for more than half a century, the laws and regulations have not proven effective in stopping these companies' conduct. The few convictions obtained resulted in minor penalties that the companies characterized as "the cost of doing business." The companies paid the fines and fees, resumed their behavior, and the epidemic has continued.

The 2020s, however, are an inflection point in the opioid epidemic. Inspired by the urgency of the COVID-19 pandemic, a unique opportunity has arisen to change the course of the opioid epidemic by enacting new laws like the CS MAMA to hold the pharmaceutical industry accountable. The impact of the COVID-19 pandemic on the opioid epidemic cannot be overstated. In addition to dramatically increasing the rate of opioid addictions and death, the COVID-19 pandemic has brought something else that will inadvertently assist in bringing about changes in the law presented here. Like no other issue in the last fifty years, the COVID-19 pandemic has singularly focused public awareness on the healthcare system, including how the government collaborates with the pharmaceutical industry. The operation of clinical trials and the minutia of the drug approval process has captured the public's attention. They have also witnessed the inequities in healthcare delivery systems and the disparity in access to medical treatment. Throughout the pandemic, the public has also experienced the benefits and limitations of pharmacological responses to disease. The attention, momentum, and clear-eyed determination arising from these events, should not be permitted to dissipate. We must direct it to transforming our response to the opioid epidemic and ending it. The CS MAMA represents a significant step in that direction.

444. *See* Curtis S. Florence, Chao Zhou, Feijun Luo & Likang Xu, *The Economic Burden of Prescription Opioid Overdose, Abuse and Dependence in the United States, 2013*, 54 MED. CARE 901, 901 (2016) (citing estimates that the misuse of prescription opioids alone costs the United States $78.5 billion per year); *see also* COUNCIL OF ECON. ADVISORS, THE UNDERESTIMATED COST OF THE OPIOID CRISIS 2 (2017) (concluding that the economic cost of the opioid crisis reached $504 billion in 2015, representing 2.8% of the nation's GDP).

APPENDIX

A. THE CONTROLLED SUBSTANCE MANUFACTURER AND MARKETING ACCOUNTABILITY ACT (THE "CS MAMA")

PURPOSE: To hold pharmaceutical companies and their executives accountable for their role in creating and exacerbating the opioid epidemic in the United States and to deter companies from future misconduct in the distribution and marketing of Schedule II and Schedule III controlled substances as defined by the Controlled Substances Act, 21 U.S.C. § 801, *et seq*.

1. SECTION 1. SHORT TITLE

This Act may be cited as THE CONTROLLED SUBSTANCE MANUFACTURER AND MARKETING ACCOUNTABILITY ACT (THE "CS MAMA")

2. SECTION 2. DEFINITIONS

"Regulated Substance" as used in this statute means a prescription Schedule II, or Schedule III controlled substance as defined by the Controlled Substances Act, 21 U.S.C. § 801, et seq., the sales of which in the United States, beginning on the date on which the drug was first eligible to be marketed in the United States and ending on the date on which the manufacturer was found to violate Section 2(b), has generated at least $1.

"medically reasonable" as used in this statute means a quantity of Regulated substances as determined pursuant to Section 3, subdivision (c).

"know," "knowing," and "knowingly" as used in this statute means that a person, with respect to information—

has actual knowledge of the information;

acts in deliberate ignorance of the truth or falsity of the information; or

acts in reckless disregard of the truth or falsity of the information.

"negligent," "negligence," or "negligently" as used in this statute means the failure to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation.

"person" as used in this statute includes a natural person and a corporate entity.

3. SECTION 3. PROHIBITED ACTIVITIES AND PENALTIES

(a) Prohibited Activities: It shall be unlawful for any person involved in the manufacture or distribution of a Regulated Substance to engage in any and all activities described in this Section 3 with respect to a regulated substance.

1. DUBIOUS MARKETING OR DISTRIBUTION PRACTICE WITH RESPECT TO A REGULATED SUBSTANCE.—In this Section, the term "dubious marketing or distribution practice with respect to a regulated substance" means—

(A) including in any advertisement, promotion, direct-to-consumer marketing materials, or other marketing material a representation that a Regulated Substance has no addiction-forming or addiction-sustaining liability or has less of an addiction-forming or addiction-sustaining liability than one or more other Regulated Substance, knowing the representation to be false as determined by the Secretary of Health and Human Services (referred to in this Section as the "Secretary"), in consultation with the Commissioner of Food and Drugs (referred to in this Section as the "Commissioner"), based on research, testimonials, and other evidence;

(B) knowingly supplying States or communities with a quantity of regulated substances that the person knows is not medically reasonable; or

(C) failing to report to the Secretary any order or pattern of orders for the distribution of regulated substances in a State or community that the person knows are not being dispensed in a medically reasonable manner.

1.1 LIMITATION.—An act does not constitute a "dubious marketing or distribution" practice with respect to a Regulated Substance, with respect to a natural person—

(A) within the meaning of paragraph (1)(B), if such natural person can demonstrate that they were not involved in the decision making regarding the quantity of regulated substances to supply; or

(B) within the meaning of paragraph (1)(C) if such natural person knows that the Secretary should reasonably be aware of the relevant order or pattern of orders for the distribution of regulated substances.

2. PROVIDING FINANCIAL PAYMENTS OR INCENTIVES TO PRESCRIBERS FOR PRESCRIPTION OF REGULATED SUBSTANCES.—It shall be unlawful for a manufacturer of pharmaceuticals or any person acting on its behalf to provide any doctor, nurse, health care provider, or prescriber of medication any monetary incentive or gift in exchange for prescribing a drug.

3. MISREPRESENTATION OF SCIENTIFIC RESULTS.—It shall constitute a violation of this statute for any drug manufacturer or any person acting on its behalf to misrepresent research and studies in connection with the drug approval process required under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)

(b) Penalties.—

1. FELONY.—any person who violates Section 3 of this statute—

(A) if a natural person employed by a manufacturer or distributor of a Regulated Substance, shall be—

(i) subject to a civil penalty in an amount equal to the sum of—

(I) such person's full amount of salary for each year during which such person engaged in dubious marketing or distribution practices with respect to a product containing a regulated substance; and

(II) the amount by which the stock or other certificates of ownership interest of the person that is owned by the individual has increased in value during the period during which such person engaged in dubious marketing or

distribution practices of a product containing a regulated substance, without regard to whether the individual has sold any of the stock or certificates from such manufacturer or distributor of a regulated substance; and

(ii) is guilty of a felony and is subject to a term of imprisonment—

(I) with respect to a violation involving a drug in Schedule II of Section 202 of the Controlled Substances Act (21 U.S.C. 812), of not less than 5 years but not more than 15 years; or

(II) with respect to a violation involving a drug in Schedule III of Section 202 of the Controlled Substances Act (21 U.S.C. 812), of not less than 3 years but not more than 10 years; or

(B) if a corporate entity shall be subject to a civil penalty in the amount equal to 75 percent of the total profit such corporate entity made on lawful sales of regulated substances in the United States during the period in which the corporate entity engaged in dubious marketing or distribution practices.

2. MISDEMEANOR.—Any person who: (1) engages in the conduct prohibited in Section 3 negligently, or (2) violates Section 4 of this statute, is guilty of a misdemeanor. If a natural person employed by a manufacturer or distributor of a regulated substance, the penalty shall be—

(A) a civil penalty in an amount equal to the sum of—

(i) 50 percent of the salary of the individual during the period that the corporate entity engaged in dubious marketing or distribution practices and such individual served as such an executive; and

(ii) 50 percent of the amount by which the stock or other certificates of ownership interest of the corporate entity that is owned by the individual has increased in value during the period that the corporate entity engaged in dubious marketing or distribution practices and such individual served as such an executive, without regard to whether the individual has sold any of the stock or certificates; and

(B) is subject to a term of imprisonment—with respect to a violation involving a drug in Schedule II or III of Section 202 of the Controlled Substances Act (21 U.S.C. 812), of not less than 6 months but not more than 1 year.

(c) Rules for Application.—

1. QUANTITY OF REGULATED SUBSTANCES COVERED. FORMULA.—For purposes of subparagraphs (B) and (C) of Section 3(a)(1), the Secretary, in consultation with the Attorney General, and health care groups, patient advocacy groups, and independent health care professionals (unaffiliated with pharmaceutical companies, or trade groups or associations) using, if applicable, data from the Automated Reports and Consolidated Ordering System of the Department of Justice, shall establish a formula for determining the quantity of regulated substances that is not "medically reasonable" with respect to a community or State.

2. MEDICALLY REASONABLE QUANTITIES IN AN ORDER. GUIDANCE.—For purposes of Section 3(a)(1)(C), the Secretary shall issue guidance setting forth a procedure that manufacturers and distributors of

regulated substances shall follow to recognize orders or patterns of orders for the distribution of regulated substances that are not medically reasonable.

(d) Fees Applicable To All Opioid Manufacturers and Distributors.—

1. IN GENERAL.—As of the date of enactment of this statute, the Secretary shall assess a fee against each corporate entity that manufactures or distributes or seeks approval under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for any Schedule II or III drug covered by a Federal health program in amounts, for each such manufacturer or distributor, determined by the Secretary through rulemaking.

2. WITHDRAWAL OF APPROVAL IN THE CASE OF NONPAYMENT BY MANUFACTURER.—If a manufacturer assessed a fee under this subsection fails to pay the full fee as required under paragraph (1), the Secretary shall withdraw approval of the application under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or deny any appending application for approval under the FDCA, for the drug until the fee is paid in full.

3. INVESTIGATION.—Immediately after the date of enactment of this Act, the Secretary, acting through the Commissioner and in consultation with the Attorney General, acting through the Administrator of the Drug Enforcement Administration, shall begin an assessment to set fees under this subsection.

(e) Reimbursement of Economic Impact.—

1. ESTABLISHMENT OF FUND.—There is established in the Treasury of the United States a fund, to be known as the "Regulated Substance Rehabilitation" (referred to in this subsection as the "Fund"), to be administered by the Secretary, in consultation with the Commissioner.

2. APPROPRIATIONS; TRANSFERS TO THE FUND.—

(A) APPROPRIATION.—There is appropriated, out of any monies in the Treasury not otherwise appropriated, $20,000,000,000 to the Fund.

(B) TRANSFERS.—In a manner consistent with Section 3302(b) of title 31, United States Code, there shall be transferred to the Fund from the General Fund of the Treasury an amount equal to—

(i) the amount of the civil penalties collected under subsection (c).

(C) AVAILABILITY.—Funds appropriated under paragraph (1) and transferred under subparagraph (B) shall remain available until expended.

3. USE OF FUNDS.—

(A) IN GENERAL.—The Secretary, in consultation with the Commissioner, may, without further appropriation, use amounts in the Fund to combat the misuse and abuse of Regulated Substances, which may include transferring amounts from the Fund to other agencies to carry out programs, projects, and activities of the agencies to combat the misuse and abuse of Regulated Substances in the United States. The Fund will also be used to support independent research on the efficacy and safety of drugs in the FDA drug approval process.

(B) AVAILABILITY.—Amounts transferred to an agency under subparagraph (A) shall remain available until expended.

(C) SUPPLEMENT NOT SUPPLANT.—Amounts transferred to an agency under subparagraph (A) to carry out programs, projects, and activities of the agency shall supplement, and not supplant, amounts otherwise available for such purpose.

4. SECTION 4. FDA STANDARDS COMMITTEE, MANDATORY ETHICAL AND RESEARCH STANDARDS

FDA STANDARDS COMMITTEE.—The Secretary shall direct the FDA to create a committee ("Committee") tasked with developing

ETHICAL STANDARDS–mandatory ethical standards for the pharmaceutical industry. The Committee shall create mandatory ethical standards related to the marketing and distribution of pharmaceutical products. The Committee shall review and update the standards annually. As a condition of any drug approval pursuant to Section 505 of the FDCA (21 U.S.C. 355) issued on or after the date of the enactment of this statute, the Secretary shall require the applicant to agree to adhere to the mandatory ethical standards.

RESEARCH REQUIREMENTS.—Safety and efficacy criteria that each drug must meet to qualify for approval by the Food and Drug Administration. Such criteria will include a requirement that drugs containing a Regulated Substance be evaluated by at least one independent research and study paid for from the Fund provided in Section 3(e)(3)(A). "Independent" as used in this Section means that the research and study do not receive funding from the pharmaceutical industry or industry-related trade groups or associations.

CONFLICTS OF INTEREST.—No employee of the Food and Drug Administration shall accept employment with or provide private consulting services to any manufacturer or distributor of pharmaceutical products for 2 years after terminating employment with the FDA.

VIOLATION.—of this Section by any person shall be punished as a misdemeanor pursuant to Section 3(b)(2).

5. SECTION 5. REDUCED EXCLUSIVITY

(a) In General.—If a drug manufacturer violates Section 3 with respect to a Regulated Substance, effective on the date on which such manufacturer is found to have so violated such Section—

1. REVOCATION.—Any remaining period of market exclusivity with respect to such covered Regulated Substance shall be revoked;

2. REDUCTION.—The period of market exclusivity for any other Regulated Substance for which such manufacturer is the holder of an approved application under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a license under Section 351 of the Public Health Service Act (42

U.S.C. 262) shall be reduced to one half of the remaining period of market exclusivity; and

3. PRODUCT HOPPING.—No new or additional exclusivity shall be awarded to any regulated substance for which such manufacturer submits an application for approval under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or under Section 351 of the Public Health Service Act (42 U.S.C. 262) or marketed as a result of product hopping.

(b) Definitions.—For purposes of this Section:

1. PERIOD OF MARKET EXCLUSIVITY.—The term "period of market exclusivity" with respect to a drug means the total period of market exclusivity granted under clause (ii), (iii), or (iv) of Section 505(c)(3)(E) of the FDCA (21 U.S.C. 355(c)(3)(E)), Section 505(j)(5)(B)(iv) of such Act, clause (ii), (iii), or (iv) of Section 505(j)(5)(F) of such Act, Section 527 of such Act (21 U.S.C. 360cc), or paragraph (6) or (7) of Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), and any extension of such a period granted under Section 505A or 505E of the FDCA (21 U.S.C. 355a, 355f).

2. PRODUCT HOPPING.—The term "product hopping" means a reformulation of an approved drug or biological product that allows a manufacturer to submit a new drug application under Section 505(b) of the FDCA (21 U.S.C. 355(b)) or a new application for a license under Section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) and that—

(A) is intended for the treatment of the same medical condition as the drug or biological product that was originally so approved; and

(B) is undertaken in conjunction with the sponsor's actions to reduce or eliminate the demand for the drug's original formulation or biological product.

6. SECTION 6. REVOKE RIGHT TO ENGAGE IN DIRECT TO CONSUMER MARKETING

(a) In General.—If a drug manufacturer violates Section 3 with respect to a Regulated Substance, effective on the date on which such manufacturer is found to have so violated such Section, the right to engage in direct to consumer advertising of the Regulated Substance shall be revoked for a period of 5 years from the date of the judgment;

(b) Definitions.—For purposes of this Section:

(1) DIRECT TO CONSUMER MARKETING.—"Direct to consumer marketing" refers to any and all marketing and advertising of a covered regulated substance in any magazine, newspaper, newsletter, radio station, television station, or internet website that reaches an audience of non-healthcare professionals.

7. SECTION 7. VIOLATION OF THIS STATUTE SHALL CONSTITUTE A PREDICATE ACT PERSUANT TO THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C.

§ 1961 ET AL.

Any violation of any provision of this Act shall constitute "racketeering activity" pursuant to 18 U.S.C. § 1961(1).

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