Dosing Discrimination: Regulating PDMP Risk Scores

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Prescription drug monitoring program (PDMP) predictive surveillance platforms were designed for—and funded by—law enforcement agencies. PDMPs use proprietary algorithms to determine a patient's risk for prescription drug misuse, diversion, and overdose. The proxies that PDMPs utilize to calculate patient risk scores likely produce artificially inflated scores for marginalized patients, including women and racial minorities with complex, pain-related conditions; poor, uninsured, under-insured, and rural individuals; and patients with co-morbid disabilities or diseases, including substance use disorder and mental health conditions.

Law enforcement conducts dragnet sweeps of PDMP data to target providers that the platform characterizes as "overprescribers" and patients that it deems as high risk of drug diversion, misuse, and overdose. Research demonstrates that PDMP risk scoring coerces clinicians to force medication tapering, discontinue prescriptions, and even abandon patients without regard for the catastrophic collateral consequences that attend to those treatment decisions. PDMPs, therefore, have the potential to exacerbate discrimination against patients with complex and stigmatized medical conditions by generating flawed, short-cut assessment tools that incentivize providers to deny these patients indicated treatment.

The Federal Food and Drug Administration (FDA) is authorized to regulate PDMP predictive diagnostic software platforms as medical devices, and the agency recently issued guidance that provides a framework for such oversight. Thus far, however, the FDA has failed to regulate PDMP platforms. This Article contends that the FDA should exercise its regulatory authority over PDMP risk scoring software to ensure that such predictive diagnostic tools are safe and effective for patients.

INTRODUCTION

Civilizations have long wrestled with problems linked to the use of alcohol and other psychoactive substances, and have made all manner of efforts to control and restrict use of these drugs. . . . Various forms of prohibition, punishment, and condemnation, including death by

stoning . . . have been tried throughout history. Most recently, we have witnessed a "war on drugs." Rarely have these efforts been informed by science or evaluated for efficacy.[1]

Over the last 50 years, we've unfortunately seen the "War on Drugs" be used as an excuse to declare war on people of color, on poor Americans and so many other marginalized groups.[2]

Imagine the following scenario. You are a thirty-year-old, Black, female Army veteran. While in the service, you were the victim of a horrific sexual assault and diagnosed with post-traumatic stress disorder (PTSD). Your military physician prescribes a low dose sedative "PRN" ("pro re nata" or take as needed) to mitigate your PTSD symptoms.

Several years later, you are diagnosed with a painful and debilitating inflammatory bowel disorder (IBD), which significantly diminishes your daily functioning without treatment. Your military physician prescribes you hydrocodone, which allows you to manage your IBD symptoms. As your condition deteriorates, you decide to retire from the military and seek treatment at a civilian clinic.

At first, your new physician continues your prescription drug treatment regimen. A few months later, however, that doctor informs you that (1) she is under U.S. Drug Enforcement Administration (DEA) investigation due to her state PDMP data, (2) you have been flagged by the PDMP as at risk for opioid misuse, and (3) she has no choice but to discontinue your medication. You try to no avail to find other prescribers, each of whom offers a different excuse for refusing to treat you. One insists that your pain is "all in your head" and recommends that you see a psychiatric specialist, while another contends that it is inappropriate to prescribe opioids to a patient "like you" who is susceptible to opioid misuse and diversion.

You lapse into opioid withdrawal and are riddled with severe IBD symptoms. Within a week of your medication discontinuation, you are bedridden, unable to work or take care of your family, severely depressed, and experiencing suicidal ideation. This Article exposes and critiques the laws and policies that collude to coerce this scenario; explains why they likely have a disparate impact on marginalized patient populations, including women, racial minorities, and socioeconomically deprived patients with complex, pain-related conditions; and identifies and examines a federal regulatory oversight framework that can mitigate such needless pain and suffering.

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1. Kathleen M. Carroll & William R. Miller, *Defining and Addressing the Problem*, *in* RETHINKING SUBSTANCE ABUSE: WHAT THE SCIENCE SHOWS, AND WHAT WE SHOULD DO ABOUT IT 3, 3 (William R. Miller & Kathleen M. Carroll eds., 2006).

2. Brian Mann, *After 50 Years of the War on Drugs, 'What Good Is It Doing for Us?,'* NPR (June 17, 2021), https://www.npr.org/2021/06/17/1006495476/after-50-years-of-the-war-on-drugs-what-good-is-it-doing-for-us [https://perma.cc/LEV8-8PWD] (quoting New York Attorney General Letitia James).

The American drug overdose crisis has instigated the rapid rise of patient, prescriber, and dispenser surveillance in the form of state PDMPs. They collect, maintain, and analyze troves of sensitive prescribing data. This Article is the second in a series that investigates PDMP health impacts on marginalized patient populations.[3] The first argued that the Fourth Amendment may limit the U.S. Drug Enforcement Administration's otherwise unfettered access to state PDMP data by requiring law enforcement to procure a warrant to obtain patient prescribing information.[4]

PDMP capabilities continue to evolve and threaten patient access to equitable, evidence-based treatment by exacerbating race, sex, socioeconomic, and health status discrimination, which are already pervasive in clinical decision-making. PDMPs are no longer passive collection systems that store voluminous amounts of sensitive and stigmatizing health care data. They are automated databases powered by robust data analytics software. PDMP software manufacturers identify specific prescription-related data points as proxies for drug misuse and overdose risk and deploy proprietary algorithms to generate patient drug misuse-related risk scores.

For example, the data analytics company Bamboo Health produces "NarxCare," the dominant algorithmic software platform driving PDMP evolution.[5] Bamboo concedes that it gathers information from patient electronic health records as well as court records, criminal and sexual trauma histories, and myriad other sources to hone its "black-box" PDMP predictive algorithms. "NarxCare" algorithms mine through this PDMP-plus data to assign patients multiple three-digit controlled substance "risk scores," including a composite overdose-risk score, collectively called "Narx Scores." PDMPs, therefore, continue to evolve in two ways: (1) by collecting and storing volumes of sensitive data from an expanding number of questionable sources and (2) by applying trade secret-protected algorithmic models to such data to assess and determine the risk of patient drug diversion, misuse, and overdose.

The little that can be gleaned about NarxCare's selection and valuation of patient "risk indicators" is troubling. The proxies that NarxCare algorithms

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3.   Marginalized patients are those who face significant barriers to accessing equitable healthcare treatment. They include, but are not limited to, patients who are members of groups that have experienced structural discrimination and health disparities due to their perceived sex, class, race, ethnicity, gender, sexual orientation, and health status. Foster Osei Baah, Anne M. Teitelman & Barbara Riegel, *Marginalization: Conceptualizing Patient Vulnerabilities in the Framework of Social Determinants of Health – An Integrative Review*, 26 NURSING INQUIRY 1, 2–3 (2019).

4.   Jennifer D. Oliva, *Prescription-Drug Policing: The Right to Health-Information Privacy Pre- and Post-*Carpenter, 69 DUKE L.J. 775, 833–34 (2020).

5.   NarxCare was initially developed and manufactured by Appriss Health, which recently rebranded itself "Bamboo Health." Press Release, Bamboo Health, Bamboo Health – Combination of Proven Care Collaboration Leaders – Unveiled to Enable Payer-Provider Collaboration for Whole Person Care (Aug. 31, 2021), https://bamboohealth.com/news/bamboo-health-unveiled/ [https://perma.cc/7AUQ-FW2R]. For clarity, this Article uses the new name for all references to the company formerly known as Appriss.

utilize as risk indicators—such as a patient's criminal and sexual trauma history, number of prescribers, prescription payment method, and distance traveled for treatment—are problematic on their face and likely discriminate against marginalized patient populations, including individuals with complex chronic pain and opioid use disorder who live in poverty. Patients who are low income are more likely to be underinsured or uninsured and more commonly reside in healthcare treatment deserts. As a result, they often have no choice but to resort to behaviors the PDMP algorithms deem as "high risk"—such as paying for prescriptions in cash and travelling long distances for prescribing and dispensing services—due to their socioeconomic status. PDMP risk proxies also appear to disparately impact racial minorities, who are more likely to have criminal histories and be uninsured than their White counterparts, and women, who are more likely to report and seek treatment for sexual trauma and live in poverty than male patients.

The NarxCare risk scoring platform neither measures patient outcomes nor has been externally validated. This is because PDMPs were not created by or for prescription drug prescribers or dispensers and were never intended to be used by clinicians to improve patient health. Instead, they were designed by and for law enforcement agencies—like the DEA—to enhance those agencies' ability to monitor and police the prescribing of certain classes of controlled substances.

PDMP predictive platforms deserve serious scrutiny because they are the only law enforcement-developed digital surveillance systems that health care providers have ever utilized to diagnose and treat patients. It is possible that providers rely on unvalidated PDMP risk scores to make prescribing decisions because they view those scores as clinically useful. That claim should be viewed with skepticism because there is no evidence that PDMP scores accurately ascertain patient drug misuse risk. It is also questionable whether clinical reliance on PDMP risk scores is truly voluntary, given that the regulatory environment leaves providers with little choice but to take seriously the information generated by proprietary PDMP algorithms.

Most states have enacted laws or regulations that require providers to review patient PDMP data before issuing prescriptions for PDMP-monitored drugs and mandate that dispensers report detailed prescribing data to PDMP prior to supplying those drugs to patients. In addition, law enforcement agencies like the DEA utilize PDMP data to surveil prescribers, dispensers, and patients and determine whether providers are prescribing or dispensing controlled substances to patients in a manner that warrants criminal investigation. Given the potential consequences of being deemed an overprescriber or overdispenser by the DEA, which range from criminal investigation to controlled substance licensure suspension and revocation to arrest and incarceration, it is fair to conclude that PDMP surveillance impacts prescribing and dispensing decisions.

This Article proceeds in six Parts. Part I chronicles the United States' turbulent history with opioids and pain management as well as its law

enforcement-driven, supply-side response to the nation's drug overdose crisis. Part II details the implementation of PDMPs across the country as law enforcement surveillance tools that aim to root out opioid pill mills, doctor shopping, prescription drug fraud, and the diversion of controlled substances.

Part III explains the nature and advent of PDMP risk scores and their use to diagnose and treat patients. Part IV subjects PDMP risk scoring platforms to a data science critique and evaluates their potential impact on various classes of patients. As the Section details, Narx Score algorithms likely produce artificially inflated risk scores for marginalized patients, including women and racial minorities with complex, pain-related conditions; poor, uninsured, under-insured, and rural individuals; and patients with co-morbid disabilities or diseases, including substance use disorder and mental health conditions. Narx Scores, therefore, may exacerbate discrimination against patients with complex medical conditions by generating flawed, short-cut assessment tools that incentivize providers to deny these individuals indicated treatment.

Part V argues that the U.S. Food and Drug Administration (FDA) has the legal authority to regulate PDMP risk scoring platforms as medical devices. The FDA has developed a framework for regulating software as a medical device (SaMD) but has failed to apply that framework to PDMP platforms. This Article concludes by arguing that the FDA should apply its SaMD framework to PDMP risk scoring platforms to determine their safety and effectiveness and, thereby, fulfill the agency's legal mandate to protect patients.

I.
A SHORT HISTORY OF AMERICAN OPIOID CRISES

A. *The Opening Steps of a Long Tarantella*

In 2020, the United States witnessed the highest number of drug overdose deaths ever recorded in a single calendar year and the largest annual percent increase in drug overdose fatalities in more than two decades.[6] Those ninety thousand-plus preventable deaths were predominantly driven by illicit substances, such as synthetic opioids like fentanyl, psychostimulants, methamphetamine, and cocaine.[7] Crises involving drug use, however, not only precede the current epidemic in America; they date back centuries.[8] As drug

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6. F.B. Ahmad, L.M. Rossen & P. Sutton, Nat'l Ctr. for Health Stat., *Provisional Drug Overdose Death Counts*, CTRS. FOR DISEASE CONTROL & PREVENTION (2021) [hereinafter *Drug Overdose Death Counts*], https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm [https://perma.cc/HU36-KUJE] (reporting 92,511 deaths for the 12-month period ending December 2020, a nearly 30 percent increase from the previous 12-month period).

7. *Id.*; *see* Alexandre Tanzi, *U.S. Had Most Drug Overdose Deaths on Record in 2020, CDC Says*, BLOOMBERG (July 14, 2021), https://www.bloomberg.com/news/articles/2021-07-14/u-s-had-most-drug-overdose-deaths-on-record-in-2020-cdc-says [https://perma.cc/K9FF-XYNT].

8. *See* Sarah Brady Siff, *Burn, Sell, or Drive: Forfeiture in the History of Drug Law Enforcement*, 80 OHIO ST. L.J. 859, 862 (2019) (explaining that "opium in various forms had been available in apothecaries' shops and among general merchandise since colonial times"); *see also* James

policy scholars have explained, Americans have engaged in a "long tarantella with opioids"[9] and other powerful drugs.[10]

Human use of opium and morphine has a long history,[11] and Americans widely used these substances—both medicinally and recreationally—throughout the nineteenth and early twentieth centuries.[12]

> In the 19th century, like today, . . . [d]octors did not fully appreciate the risks [opioids] posed. In the 1800s, many doctors viewed morphine as a wonder drug for pain, diarrhea, nerves and alcoholism. In addition to getting homemakers, Civil War veterans and others addicted, many doctors [developed opioid use disorder] themselves.[13]

Not only were morphine and opium cheap, easy to obtain, and sold over the counter at the time, opiates were so popular that contemporary cookbooks contained medical "recipes" that frequently featured the drugs as star

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Nevius, *The Strange History of Opiates in America: From Morphine for Kids to Heroin for Soldiers*, GUARDIAN (Mar. 15, 2016), https://www.theguardian.com/commentisfree/2016/mar/15/long-opiate-use-history-america-latest-epidemic [https://perma.cc/3WLC-W5DV] ("America's burgeoning opiate problem is a tragedy, but it shouldn't come as a surprise: it stretches back to the arrival of the Mayflower in 1620."); DAVID T. COURTWRIGHT, DARK PARADISE: A HISTORY OF OPIATE ADDICTION IN AMERICA 43 (2001) ("The therapeutic use of opium was common in colonial America . . . ."). *See generally* DAVID F. MUSTO, THE AMERICAN DISEASE: ORIGINS OF NARCOTIC CONTROL (1999) (discussing opium use in pre-1800s America).

9. Opiates are substances "naturally derived from the poppy plant, including raw opium, several psychoactive substances (thebaine, papaverine, and noscapine), morphine, codeine, and semisynthetic heroin . . . . [T]he term opioid is broad and includes everything from the naturally occurring opiates (e.g., opium, morphine, codeine, etc.) to the synthetic or semisynthetic opioids used medically for the treatment of pain (e.g., fentanyl, hydrocodone, hydromorphone, methadone, oxycodone, oxymorphone)." Timothy Atkinson, John J. Coleman & Jeffery Fudin, *Opioid Medications: Old Wine in New Bottles*, *in* PRESCRIPTION DRUG DIVERSION AND PAIN: HISTORY, POLICY, AND TREATMENT 1, 1 (John F. Peppin, John J. Coleman, Kelly K. Dineen & Adam J. Ruggles eds., 2018).

10. 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, 595 (2018) ("Epidemics of opioid use are old news in the United States.").

11. "There is general agreement that the Sumerians, who inhabited what is today Iraq, cultivated poppies and isolated opium from their seed capsules at the end of the third millennium B.C." Michael J. Brownstein, *A Brief History of Opiates, Opioid Peptides, and Opioid Receptors*, 90 PROC. NAT'L ACAD. SCIS. 5391, 5391 (1993). Opium was used medicinally as, among other things, a surgical anesthesia, as well as recreationally. *Id.* Morphine is the primary active ingredient or alkaloid in opium. *Id.* "After the invention of the hypordermic [sic] syringe and hollow needle in the 1850s, morphine began to be used for minor surgical procedures, for postoperative and chronic pain, and as an adjunct to general anesthetics." *Id.*

12. *See* COURTWRIGHT, *supra* note 8, at 43–53 (discussing use of opioids in early America); *see also* Erick Trickey, *Inside the Story of America's 19th-Century Opiate Addiction*, SMITHSONIAN MAG. (Jan. 4, 2018), https://www.smithsonianmag.com/history/inside-story-americas-19th-century-opiate-addiction-180967673/ [https://perma.cc/P2WA-EL6V]; Jonathan S. Jones, *Opium Slavery: Civil War Veterans and Opiate Addiction*, 10 J. CIV. WAR ERA 185, 188 (2020) ("Opiates were among nineteenth-century America's most commonly used medicines. . . . Hospital and pharmacy records indicate that opiates were present in the majority of physicians' prescriptions during the mid-nineteenth century.").

13. Editorial, *An Opioid Crisis Foretold*, N.Y. TIMES (Apr. 21, 2018), https://www.nytimes.com/2018/04/21/opinion/an-opioid-crisis-foretold.html [https://perma.cc/SLE4-KKPX].

ingredients.[14] The rampant inclusion of opiates in patent medicines to treat all manner of common ailments—an entirely unregulated practice until Congress enacted the Pure Food and Drug Act of 1906—also contributed to opioid consumption.[15] Embarking on what would become a recurrent practice, pharmaceutical companies started marketing certain opioids as "safer" (that is, less susceptible to misuse) than others in the late 1800s. Bayer Pharmaceuticals, for example, marketed heroin[16] as an analgesic and promoted the drug as less addictive than morphine beginning in 1898.[17]

By the turn of the twentieth century, approximately one in two hundred Americans had developed opioid use disorder (OUD) and the public tide began to turn against opioids.[18] Medical journals published articles warning doctors about the addictive properties of heroin. While serving as the Dean of Harvard Medical School, Oliver Wendell Holmes, Sr., expressly attributed the country's late nineteenth century OUD crisis to clinical overprescribing:

> [T]he constant prescription of opiates by certain physicians . . . has rendered the habitual use of that drug [in the western United States] very prevalent. . . . A frightful endemic demoralization betrays itself in the frequency with which the haggard features and drooping shoulders of the opium drunkards are met with in the street.[19]

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14. Nathan Connelly, Brian Balogh & Ed Ayers, *The Habit: Opioid Addiction in America*, BACKSTORY (Apr. 6, 2018), https://www.backstoryradio.org/shows/the-habit [https://perma.cc/4ELS-SD6Z].

15. *See* MUSTO, *supra* note 8, at 3 ("The manufacturers of [patent medicines containing opium] were remarkably effective during the nineteenth century in preventing any congressional action to require even the disclosure of dangerous drugs in commercial preparations."); *see also* Erik Grant Luna, *Our Vietnam: The Prohibition Apocalypse*, 46 DEPAUL L. REV. 483, 488 (1997) (describing the commonplace "[c]areless prescribing of physicians in the Reconstruction Era"). The Pure Food and Drug Act of 1906 required all drug packages "to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein." Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified as amended at 21 U.S.C. §§ 1–15).

16. "Heroin is [a] drug processed from morphine, a naturally occurring substance extracted from the seed pod of certain varieties of poppy plants. It is typically sold as a white or brownish powder that is 'cut' with sugars, starch, powdered milk, or quinine." NAT'L INST. ON DRUG ABUSE, HEROIN RESEARCH REPORT 2 (2021) https://www.drugabuse.gov/download/37596/heroin-research-report.pdf?v=51a4d835474c19d304997b55486a00ec [https://perma.cc/9TXS-84J8].

17. Laxmaiah Manchikanti, Jaya Sanapati, Ramsin M. Benyamin, Sairam Atluri, Alan D. Kaye & Joshua A. Hirsch, *Reframing the Prevention Strategies of the Opioid Crisis: Focusing on Prescription Opioids, Fentanyl, and Heroin Epidemic*, 21 PAIN PHYSICIAN 309, 312 (2018) (explaining that pharmaceutical companies made "similar claims about multiple other opioids as well as cocaine").

18. *See* COURTWRIGHT, *supra* note 8, at 9, 33 (estimating that 4.59 individuals per 1000 suffered OUD in the mid-1890s in the U.S.). *See generally* JOHN HARLEY WARNER, THE THERAPEUTIC PERSPECTIVE: MEDICAL PRACTICE, KNOWLEDGE, AND IDENTITY IN AMERICA, 1820–1885, at 98 (1986) ("Prescription books from such hospitals, requisition lists for medical supplies, and narrative accounts of medical treatment all testify to the fact that alcohol used as a stimulant and opiates as palliatives were the mainstays of military medical treatment during the war.").

19. MUSTO, *supra* note 8, at 4.

In addition, the use of opium and heroin became racialized and demonized, and both drugs were ultimately criminalized.[20] As sociologist Rebecca Tiger summarized, "[t]he first drug scares in the U.S., which were . . . about opiates, were reflections of thinly veiled anti-Chinese racism in the late 19th and early 20th centuries. Drug prohibition often relies on the image of a demonized racial other whose drug use threatens social stability."[21] This translates into the cultural conceptualization of certain drugs as "good" and "legal" and others as "bad" and "illicit" based on their racial and socioeconomic associations instead of their risk-benefit profile.

The prototypical opioid aficionado in the middle-to-late 1800s was a middle-class, middle-aged, white woman.[22] The men who tended to habitually indulge in opiates during that period were White physicians, dentists, pharmacists, and Civil War veterans.[23] These White Americans, who usually obtained their opioids from physicians or pharmacists, preferred specific opioid delivery systems: they ingested their opium, usually as an ingredient in a medicinal tincture, and injected their morphine with a hypodermic syringe.[24]

Middle-class White folks rarely procured opioids on the illicit market or smoked opium. Instead, it was working class "[s]hip passengers, particularly the Chinese immigrants who arrived to the [West Coast of the] United States beginning in the mid-19th century [who] brought along their opium smoking habit [and] continuously smuggled the compact and expensive article into the country."[25] As anti-Chinese sentiment exploded in the West, so did calls to exclude Chinese immigrants and outlaw opium smoking.[26]

Motivated by anti-Chinese hysteria, San Francisco passed the country's first anti-drug law, the Opium Den Ordinance, in 1875.[27] Numerous other Western states enacted laws in the late 1800s prohibiting the sale and distribution

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20. *See generally* COURTWRIGHT, *supra* note 8, at 49–53 (discussing medical use of opium); Trickey, *supra* note 12 ("Throughout the 1870s and 1880s, medical journals were filled with warnings about the danger of morphine addiction.").

21. Rebecca Tiger, *Race, Class, and the Framing of Drug Epidemics*, CONTEXTS, Fall 2017, at 46, 48.

22. CAROLINE JEAN ACKER, CREATING THE AMERICAN JUNKIE: ADDICTION RESEARCH IN THE CLASSIC ERA OF NARCOTIC CONTROL 1 (2002) (explaining that, in the 1800s, opiate "patients and customers were most typically middle-class, middle-aged women taking morphine to relive the pain of menstrual cramps or assuage domestic or social anxieties"); COURTWRIGHT, *supra* note 8, at 36–42.

23. COURTWRIGHT, *supra* note 8, at 39–42; Jones, *supra* note 12, at 186 ("'Slavery to opiates dominated many [Civil War] veterans' postwar lives.").

24. COURTWRIGHT, *supra* note 8, at 46–47.

25. Siff, *supra* note 8, at 863.

26. MUSTO, *supra* note 8, at 3 ("Weighing heavily against [opium smoking] was its symbolic association since mid-century with the Chinese, who were actively persecuted, especially on the West Coast. By then they were almost totally excluded from immigrating into the United States.").

27. *See* Roseann B. Termini & Rachel-Malloy Good, *50 Years Post-Controlled Substances Act: The War on Drugs Rages on with Opioids at the Forefront*, 46 OHIO N.U. L. REV. 1, 4 (2020) (discussing a San Francisco ordinance that criminalized maintaining or visiting opium dens, and positing that opium dens were a significant factor leading to the Chinese Exclusion Act).

of opium smoking.[28] This "virulent anti-Chinese movement" provoked Congress to pass the Chinese Exclusion Act of 1882, which barred Chinese laborers from entering the country.[29]

Federal government regulation of opioids swiftly followed. Congress outlawed the importation of non-medicinal opium in 1909.[30] Five years later, it passed the Harrison Narcotics Act, which taxed the legal possession, purchase, or sale of any form of opium or cocaine.[31]

The Harrison Narcotics Act specifically exempted from its purview the prescribing of opium and cocaine within the confines of legitimate doctor-patient relationships.[32] This limitation on the statute's reach was consistent with the long-standing view that the states have the authority to regulate the medical professions under their reserved police powers in the U.S. federalist system.[33] It also reflected the widely held belief that physicians were ethically obligated to ease the suffering of individuals with OUD by treating them with opioids.[34] It is uncontroversial today that opioid agonists, such as methadone and buprenorphine, are the gold standard of care treatments for OUD.[35]

Unfortunately, the Harrison Narcotics Act "was assigned, for enforcement, to the same righteous zealots who were undertaking another national mistake—

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28. *See, e.g.*, U.S. PUB. HEALTH SERV., STATE LAWS RELATING TO THE CONTROL OF NARCOTIC DRUGS AND THE TREATMENT OF DRUG ADDICTION 3–4 (1931).

29. Kitty Calavita, *The Paradoxes of Race, Class, Identity, and "Passing": Enforcing the Chinese Exclusion Acts, 1882–1910*, 25 LAW & SOC. INQUIRY 1, 4 (2000); Chinese Exclusion Act, Pub. L. 47-126, ch. 126, 22 Stat. 58 (1882).

30. Act of Feb. 9, 1909, Pub. L. No. 60-221, ch. 100, 60 Stat. 614.

31. Harrison Narcotics Tax Act, Pub. L. No. 63-223, ch. 1, 38 Stat. 785 (1914).

32. *Id.* at 786 ("Nothing contained in this section . . . shall apply . . . [t]o the dispensing or distribution of the aforesaid drugs to a patient by a physician, dentist, or veterinary surgeon . . . in the course of his professional practice only.").

33. *See, e.g.*, Linder v. United States, 268 U.S. 5, 18 (1925) ("[D]irect control of medical practice in the states is beyond the power of the federal government."); Barsky v. Bd. of Regents, 347 U.S. 442, 449 (1954) ("The state's [broad power to establish and enforce standards of conduct within its borders relative to health] extends naturally to the regulation of all professions concerned with health.").

34. Rufus G. King, *The Narcotics Bureau and the Harrison Act: Jailing the Healers and the Sick*, 62 YALE L.J. 736, 739–40 (1953).

35. *See, e.g.*, Alison Knopf, *The Stigma of MAT: Can You Protect Patients from Discrimination?*, ALCOHOLISM & DRUG ABUSE WKLY., July 15, 2019, at 1, 2 ("In 2014, [the U.S. Substance Abuse and Mental Health Services Administration] called methadone and buprenorphine 'the gold standard of addiction care,' and the medical literature has supported this."); NAT'L ACADS. OF SCIS. ENG'G & MED., MEDICATIONS FOR OPIOID USE DISORDER SAVES LIVES 18 (Alan I. Leshner & Michelle Mancher eds., 2019) ("Large systematic reviews and randomized controlled trials have demonstrated that treatment with either methadone or buprenorphine is associated with an array of positive outcomes, including fewer fatal overdose deaths, better treatment retention rates, lower rates of other opioid use, decreased mortality, less injection drug use, reduced transmission of HIV infections, improved social functioning, decreased engagement in criminal activity, and lower rates of neonatal abstinence syndrome. Expanding access to these medications reduces the number of deaths due to opioid overdose." (internal citations omitted)); *see also* Aubrey Whelan, *Using Opioids to Treat Addiction Is Considered the Gold Standard. So Why Aren't More Doctors Prescribing Them?*, PHILA. INQUIRER (Feb. 11, 2019), https://www.inquirer.com/health/opioid-addiction-treatment-methadone-buprenorphine-prescriptions-20190211.html [https://perma.cc/VNP9-3Y73] (discussing the regulations and required training to administer methadone and prescribe and dispense buprenorphine).

enforcement of our then-new Prohibition laws[,] . . . a great public hullabaloo about the 'dope menace' swept the country[, and t]he narcotics-user suddenly became a 'dope fiend.'"[36] Those "righteous zealots" were the federal Treasury Department's Narcotics Division led by Commissioner Harry J. Anslinger, whose core tenets were that people who use drugs "are bad characters and . . . addiction essentially is a police problem."[37] Anslinger and his allies not only convinced the public that individuals with substance use disorder were criminals who deserved punishment, they broadly construed the Harrison Act as vesting the Narcotics Division with the authority to prohibit physicians from prescribing opioids to treat and manage OUD.[38]

In 1919, the United States Supreme Court endorsed the federal government's position that the Harrison Act prohibited doctors from prescribing opioids to individuals with OUD,[39] and thus ingrained into federal law a science-denying and health-harming premise that persists to date: that is, that individuals with OUD are morally depraved and are not entitled to evidence-based therapeutic treatment. That principle is currently enshrined in Title II of the Comprehensive Drug Abuse and Prevention Control Act of 1970,[40] better known as the Controlled Substances Act (CSA).[41]

Heroin developed an underground market following distinct from morphine. As noted above, Bayer began to market heroin in the late 1800s as a less addictive analgesic alternative to morphine. Likely due to the widespread availability of morphine and the introduction of aspirin in 1899, that effort was unsuccessful. As a result, heroin was primarily prescribed as an antitussive—and not an analgesic—during the first decade of the twentieth century.[42]

By 1910, however, heroin had found its way to the illicit market. Working class individuals who had smoked opium—a form of opioid use that was difficult to maintain due to the 1909 import ban—and the children of urban immigrants

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36. King, *supra* note 34, at 737; *see* TROY DUSTER, THE LEGISLATION OF MORALITY: LAW, DRUGS, AND MORAL JUDGMENT 22 (1970) (arguing that the Harrison Act "brought about the conditions that were conducive to a reinterpretation of narcotics usage into almost purely moral terms").

37. EDWIN M. SCHUR, NARCOTIC ADDICTION IN BRITAIN AND AMERICA: THE IMPACT OF PUBLIC POLICY 192 (1968).

38. King, *supra* note 34, at 740 ("The [Narcotics Division] aimed for a construction which would exclude from the Harrison Act exemption a doctor's dispensation of narcotics to ease an addict's craving.").

39. Webb v. United States, 249 U.S. 96, 99–100 (1919); Richard C. Boldt, *Drug Policy in Context: Rhetoric and Practice in the United States and the United Kingdom*, 62 S.C. L. REV. 261, 262–63 (2010).

40. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended in scattered sections of 21 U.S.C.).

41. Controlled Substances Act, Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242–84 (1970) (codified as amended at 21 U.S.C. §§ 801–971). The CSA is discussed in more detail *infra* Part I.B.

42. *See* David T. Courtwright, *The Roads to H: The Emergence of the American Heroin Complex, 1898–1956*, *in* ONE HUNDRED YEARS OF HEROIN 3, 4–5 (David F. Musto ed., 2002) ("Advertising stressed heroin as a specific for respiratory symptoms.").

used heroin recreationally.[43] Whereas morphine had been the province of "respectable" middle-aged, middle-class Whites, heroin became associated with working-class "ruffians" and the underground vices of inner-city America.[44]

Consequently, the move to outlaw heroin was swift and akin to the crusade to criminalize opium.[45] In 1920, the American Medical Association House of Delegates passed a resolution advocating for a heroin ban in the United States.[46] Congress answered that call in 1924 by amending the Harrison Act to prohibit the importation and manufacture of the drug.[47] Heroin remained a mainstay of the illicit urban drug market until the onset of the Second World War.[48] During the 1940s, however, the youth went off to fight for Uncle Sam, the American economy boomed, folks were gainfully employed, the flow of illicit drugs was disrupted, and "[h]eroin receded from the national consciousness."[49]

B.   The Controlled Substances Act and War on Drugs

Heroin's World War II-era impasse was short-lived. As the Cold War set in, the drug returned to illicit urban markets and its consumers were predominantly Black and Latinx Americans.[50] The federal government responded by enacting legislation that imposed mandatory minimum sentences for nonmedical heroin use[51] and authorized the death penalty for drug sales to minors.[52] Illicit heroin use in U.S. cities continued to escalate throughout the 1960s,[53] "feeding a prejudice lingering to this day that regards African Americans as more prone to drug addiction."[54]

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43.   *Id.* at 7, 11; *see also* Jill Jonnes, *Hip to Be High: Heroin and Popular Culture in the Twentieth Century*, *in* ONE HUNDRED YEARS OF HEROIN 227, 227–28 (David F. Musto ed., 2002) ("[H]eroin also served . . . as the rebel hipster's drug of choice.").

44.   Courtwright, *supra* note 42, at 8.

45.   *See generally* Taleed El-Sabawi, *What Motivates Legislators to Act: Problem Definition & the Opioid Epidemic, A Case Study*, 15 IND. HEALTH L. REV. 189, 211–12 (2018) (explaining that public discourse regarding drug epidemics is more punitive when drug users are poor).

46.   Courtwright, *supra* note 42, at 10.

47.   An Act Prohibiting the Importation of Crude Opium for the Purpose of Manufacturing Heroin, Pub. L. 68-274, 43 Stat. 657 (1924) (repealed 1970).

48.   *See* Bruce D. Johnson & Andrew Golub, *Generational Trends in Heroin Use and Injection in New York City*, *in* ONE HUNDRED YEARS OF HEROIN 91, 94, 107 (David F. Musto ed., 2002) (describing use of heroin in the pre-war years).

49.   Courtwright, *supra* note 42, at 12; Johnson & Golub, *supra* note 48, at 107.

50.   Courtwright, *supra* note 42, at 12–13 ("Latino and, especially, black narcotic use was up sharply in the late 1940s and 1950s."); Johnson & Golub, *supra* note 48, at 107 ("The second epidemic of heroin use and sales had a particularly strong impact on blacks and other ethnic minorities who had recently migrated to New York.").

51.   Boggs Act of 1951, Pub. L. No. 82-255, 65 Stat. 767 (repealed 1970).

52.   Narcotics Control Act of 1956, Pub. L. No. 84-728, § 107, 70 Stat. 567, 571 (repealed 1970).

53.   Johnson & Golub, *supra* note 48, at 94 ("[T]wo major 'heroin eras' occurred in America in general, and New York City specifically, having their peaks . . . from about 1900 to 1920 and 1965 to 1974.").

54.   CHRIS MCGREAL, AMERICAN OVERDOSE: THE OPIOID TRAGEDY IN THREE ACTS 20 (2018).

The racialization of heroin also triggered the 1970s War on Drugs, which spawned our current drug control regulatory system—the CSA—and its law enforcement oversight authority, the DEA.[55] The CSA's regulatory structure "vastly exceeded any previous [American drug] control measures in scope" and, in the process, the DEA "emerged as a powerful administrative agency."[56] The CSA created a closed chain for controlled-substance distribution designed to facilitate the DEA's surveillance and monitoring of licit drugs as they make their way through the legal drug supply chain to prevent their diversion into the illicit market.[57]

The historical record makes clear that the CSA was rooted in political and racial animus at inception. As Watergate co-conspirator and senior Nixon administration advisor John Ehrlichman famously conceded:

> The Nixon campaign in 1968, and the Nixon White House after that, had two enemies: the antiwar left and black people. . . . We knew we couldn't make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did.[58]

Like the early twentieth century and 1950s drug crackdown laws, the CSA advances a myopic, law enforcement-centric, supply-side scheme.[59] In addition

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55. *See* Courtwright, *supra* note 42, at 14.

56. Joseph F. Spillane, *Debating the Controlled Substances Act*, 76 DRUG & ALCOHOL DEPENDENCE 17, 25 (2004).

57. *See* Gonzales v. Raich, 545 U.S. 1, 12–13 (2005) ("The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels.").

58. Dan Baum, *Legalize It All: How to Win the War on Drugs*, HARPER'S MAG., Apr. 2016, at 22, 22.

59. In this Article, a "supply-side" approach is used to describe drug laws and policies that attempt to reduce U.S. drug consumption with criminal justice–led approaches such as drug eradication, interdiction, production controls, surveillance, and enforcement, including arrests and incarceration. Demand-side approaches, on the other hand, recognize drug use as a public health issue and seek to reduce the harms associated with problematic drug use through legalization, education, harm reduction strategies, and enhanced access to evidence-based treatment. *See* Abby Alpert, David Powell & Rosalie Liccardo Pacula, *Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids*, 10 AM. ECON. J. 1, 2 (2018), https://pubs.aeaweb.org/doi/pdfplus/10.1257/pol.20170082 [https://perma.cc/KV95-UQL2] ("[T]he federal government and states have implemented a vast array of policies aimed at curbing prescription opioid abuse. These policies have disproportionately targeted the supply-side of the market by limiting access to opioids, including Prescription Drug Monitoring Programs (PDMPs), Medicaid Lock-In Programs, pain clinic laws, diversion control, black box warnings, and abuse-deterrent drug formulations. Less attention and funding have been directed to demand-side interventions, such as prevention and substance abuse treatment, which aim to reduce the prevalence of addiction.").

to implementing a strictly regulated methadone OUD treatment system,[60] the CSA established a powerful drug control, surveillance, and enforcement regime that preferred policing drugs over public health approaches that reduce the harms associated with their misuse.[61] Congress has hardened the CSA over time through punitive amendments in response to drug scares ranging from the 1980s cocaine crisis to the 2000s methamphetamine surge to more recent upticks in the use of club drugs like MDMA (ecstasy).[62]

And just like the opioid criminalization campaigns that preceded it, the CSA's ongoing drug war has been costly, racist, ineffective, and counterproductive. Since 1971, the price of the drug war at just the federal level has cost taxpayers over $1 trillion.[63] The drug war also has cemented the United States as the highest per capita incarcerator in the world.[64] American police arrest someone for drug possession every twenty-five seconds and are four times more likely to arrest a Black person for such an offense.[65]

Criminalizing drug use has not only resulted in mass incarceration and significant justice- and health-related racial disparities, it is also ineffective. Locking up individuals who use drugs correlates with increased drug use mortality and morbidity and thus enhances substance use disorder (SUD)-related harms.[66] Perhaps counterintuitively, criminalizing drug use also appears to have a negative, rather than positive, impact on crime: "Half of the serious crime in

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60. *See, e.g.*, Jennifer D. Oliva, *Policing Opioid Use Disorder in a Pandemic*, U. CHI. L. REV. ONLINE (Nov. 16, 2020), https://lawreviewblog.uchicago.edu/2020/11/16/covid-oliva/ [https://perma.cc/TKJ2-8B6B] (discussing regulations that limit access to methadone to treat OUD).

61. *See generally* David T. Courtwright, *The Controlled Substances Act: How a "Big Tent" Reform Became a Punitive Drug Law*, 76 DRUG & ALCOHOL DEPENDENCE 9, 13 (2004) (discussing Nixon administration policies).

62. *See* PRESIDENT'S COMM'N ON ORGANIZED CRIME, AMERICA'S HABIT: DRUG ABUSE, DRUG TRAFFICKING, AND ORGANIZED CRIME 187 (1986) ("The history of Federal drug policy . . . demonstrates that approaches to reduce supply have been the preferred and dominant Federal response over the last 75 years."); *see also* Courtwright, *supra* note 61, at 11 ("Nixon stressed the supply side of the problem. . . . His deepest instincts on the issue were prohibitionist, as he later showed when he rejected marijuana decriminalization and heroin maintenance.").

63. Betsy Pearl, *Ending the War on Drugs: By the Numbers*, CTR. FOR AM. PROGRESS (June 27, 2018), https://www.americanprogress.org/issues/criminal-justice/reports/2018/06/27/452819 /ending-war-drugs-numbers/ [https://perma.cc/BC93-REYW].

64. Michelle Ye Hee Lee, *Yes, U.S. Locks People Up at a Higher Rate than Any Other Country*, WASH. POST (July 7, 2015), https://www.washingtonpost.com/news/fact-checker/wp/2015/07/07/yes-u-s-locks-people-up-at-a-higher-rate-than-any-other-country/ [https://perma.cc/P92Z-8GG9].

65. Pearl, *supra* note 63.

66. *See* Vedan Anthony-North & Leah Pope, *The State of Opioids*, VERA INST. OF JUST. (2018), https://www.vera.org/state-of-justice-reform/2017/the-state-of-opioids [https://perma.cc/9TMN-SCGV] (finding that more than 64,000 Americans died of drug overdose in 2016 and that drug overdose death rates have increased significantly since the 1980s); *see also* Ingrid A. Binswanger, Marc F. Stern, Richard A. Deyo, Patrick J. Heagerty, Allen Cheadle, Joann G. Elmore & Thomas D. Koepsell, *Release from Prison—A High Risk of Death for Former Inmates*, 356 NEW ENG. J. MED. 157, 157 (2007) (finding that formerly incarcerated people are 3.5 times more likely to die than other state residents after their release from custody).

America is a result of drug prohibition (not drug use), and two-thirds of all homicides in major cities are connected to the drug trade (again, not drug use)."[67]

Heroin serves as a case study regarding the futility of the drug war. While crack cocaine "eclipsed heroin as drug enemy number one in the late 1980s," heroin made a formidable comeback in the 1990s.[68] In fact, heroin plays a central role in our current drug overdose crisis, which is the subject of the following Section of this Article.

C.   The Evolution of the Current Crisis

Americans have increasingly consumed dangerous drugs, overdosed on those substances, and died of those overdoses over the last three decades. At the same time, American drug control law and policy make it difficult for most individuals who live with either debilitating chronic pain or opioid use disorder to access efficacious treatment. The country's failed approach has ensured that our jails and prisons are overrun.[69] Meanwhile, "[t]he drug war has produced profoundly unequal outcomes across racial groups, manifested through racial discrimination by law enforcement and disproportionate drug war-related misery suffered by communities of color."[70]

Our current drug crisis is often characterized as a *prescription opioid* epidemic.[71] This depiction is primarily attributed to pharmaceutical manufacturers' aggressive and misleading marketing of licit opioids to treat pain, which in turn instigated analgesic overprescribing.[72] It is more accurate to describe the status quo, however, as an illicit, polysubstance drug crisis that has

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67.   Luna, *supra* note 15, at 552.

68.   Courtwright, *supra* note 42, at 14; *see* Shane Darke & Wayne Hall, *Heroin Overdose: Research and Evidence-Based Intervention*, 80 J. URB. HEALTH 189, 189 (2003) (documenting the dramatic increase in fatal and nonfatal heroin overdose between the 1960s and 1990s); Scott Burris, Joanna Norland & Brian Edlin, *Legal Aspects of Providing Naloxone to Heroin Users in the United States*, 12 INT'L J. DRUG POL'Y 237, 237 (2001) (emphasizing that heroin overdose deaths had increased dramatically from 1980–2000).

69.   *See* Jay Stanley, *The War on Drugs and the Surveillance Society*, ACLU (June 6, 2011), https://www.aclu.org/blog/smart-justice/sentencing-reform/war-drugs-and-surveillance-society [https://perma.cc/92XF-JYGP] (explaining how the War on Drugs made America the world's biggest incarcerator).

70.   *Race and the Drug War*, DRUG POL'Y ALL., https://drugpolicy.org/issues/race-and-drug-war [https://perma.cc/78GC-CTYM].

71.   *See, e.g.*, Thomas C. Buchmueller & Colleen Carey, *The Effect of Prescription Drug Monitoring Programs on Opioid Utilization in Medicare*, 10 AM. ECON. J. 77, 77 (2018) ("The *misuse of prescription opioids* has become a serious epidemic in the United States." (emphasis added)); Sarah Vander Schaaff, *Amid the Opioid Crisis, Some Seriously Ill People Risk Losing Drugs They Depend On*, WASH. POST (July 14, 2018), https://www.washingtonpost.com/national/health-science/amid-the-opioid-crisis-some-seriously-ill-people-risk-losing-drugs-they-depend-on/2018/07/13/65850640-730d-11e8-805c-4b67019fcfe4_story.html [https://perma.cc/4GAG-N6NT] (reporting that "the nation [is] now fighting to reverse a drug epidemic fed *by prescription opioids*" (emphasis added)).

72.   *See, e.g.*, Aaron Kessler, Elizabeth Cohen & Katherine Grise, *CNN Exclusive: The More Opioids Doctors Prescribe, the More Money They Make*, CNN (Mar. 12, 2018), https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html [https://perma.cc/D7YV-SEUS].

evolved over "three phases of an intertwined epidemic."[73] Unfortunately, the misguided, supply-side national response to each phase of the epidemic greased the skids for the next. The following Sections of this Article provide an overview of the three phases of the U.S. drug overdose epidemic and a summary of the federal regulatory response that exacerbated the evolving health crisis.

1. *Phase One: Prescription Opioids*

The country's above-detailed tarantella with opioids helps us understand how the first phase of the current crisis, which dates from the 1990s until around 2010, came to pass. Twentieth century racialization and criminalization of opiates cast a sharp stigma over individuals with opioid use disorder. Doctors excluded individuals with OUD "from their practices and reserved opioid prescriptions for the comfort of patients with terminal illnesses or for the short-term relief of patients experiencing postinjury or postoperative pain."[74] Anti-opioid sentiment coupled with long-standing medical myths concerning pain also incentivized health care providers to undertreat individuals with chronic pain conditions. "[T]he U.S. medical establishment increasingly regarded [chronic pain patients] as malingerers and not in any particular need of relief."[75]

A confluence of events in the 1970s and 1980s, including the creation of the field of pain management, inspired a backlash against the medical profession's underassessment and undertreatment of pain.[76] During the 1980s, the *New England Journal of Medicine* printed a letter to the editor,[77] and the journal *Pain* published a small study,[78] indicating that iatrogenic opioid use disorder was rare in particular groups of patients.[79] Both publications—now recognized as flawed—were widely cited, and the prescription of opioid analgesics to treat pain soon became *de rigueur* in the practice of medicine.[80]

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73.   Nabarun Dasgupta, Leo Beletsky & Daniel Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182, 182 (2018)*; see* Steven Rich, Meryl Kornfield, Brittany Renee Mayes & Aaron Williams, *How the Opioid Epidemic Evolved*, WASH. POST (Dec. 23, 2019), https://www.washingtonpost.com/graphics/2019/investigations/opioid-pills-overdose-analysis/ [https://perma.cc/52C4-HJ26] (describing multiple causes of opioid overdose deaths).

74.   Marcia Meldrum, *Opioids' Long Shadow*, 22 AMA J. ETHICS 729, 731 (2020).

75.   MCGREAL, *supra* note 54, at 19.

76*.   See* Meldrum, *supra* note 74, at 731 (discussing formation of pain management field focused on undertreatment of chronic pain); *see also* Stephen A. Bernard, Paul R. Chelminski, Timothy J. Ives & Shabbar I. Ranapurwala, *Management of Pain in the United States—A Brief History and Implications for the Opioid Epidemic*, 11 HEALTH SERVS. INSIGHTS 1, 2 (2018) (discussing impact of political changes on attitudes towards opioids).

77.   Jane Porter & Hershel Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123 (1980).

78.   Russell K. Portenoy & Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-malignant Pain: Report of 38 Cases*, 25 PAIN 171 (1986).

79.   deShazo et al., *supra* note 10, at 596.

80.   MCGREAL, *supra* note 54, at 23 ("The *Pain* paper marked the start of a revolution that turned attitudes to opioids on their head and brought about a fundamental shift in medical culture."); *see id.* at 25 (reporting that the *New England Journal of Medicine* letter was "misrepresented . . . as 'an extensive study,' called a 'landmark report' [and] cited hundreds of times in scholarly papers").

Between 1990 and 1995, opioid prescribing increased by two to three million prescriptions annually in the United States.[81]

In the mid-1990s, the American Pain Society, which was propped up and funded by prescription opioid manufacturers, embarked on its highly successful "pain as the fifth vital sign" campaign.[82] This campaign encouraged clinicians to evaluate and manage patients' pain.[83] "By the late 1990s, it was generally accepted that all patients [we]re entitled to the assessment and treatment of pain."[84] The DEA and Federation of State Medical Boards even promised to ease surveillance of opioid prescribing, "thereby assuaging physician reluctance to prescribe more liberal amounts of opioid analgesics."[85]

Prescription opioid manufacturers took advantage of medicine's new fervor for pain management by manufacturing analgesics that they marketed as abuse-deterrent. In 1995, the FDA approved Purdue Pharma's twelve-hour extended release oxycodone medication, OxyContin, to treat moderate to severe pain.[86] The drug's label read: "delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."[87] Consistent with that claim, Purdue began to assertively market OxyContin to prescribers by overstating its benefits while downplaying its risk of misuse.[88] Individuals who sought a fast high, however, quickly learned how to crush and snort or dissolve and inject the pills to rapidly release their potent content.[89] Opioid prescribing continued to

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81.   Bernard et al., *supra* note 76, at 2.

82.   Greg H. Jones, Eduardo Bruera, Salahadin Abdi & Hagop M. Kantarjian, *The Opioid Epidemic in the United States—Overview, Origins, and Potential Solutions*, 124 CANCER 4279, 4279–80 (2018).

83.   D. Andrew Tompkins, J. Greg Hobelmann & Peggy Compton, *Providing Chronic Pain Management in the "Fifth Vital Sign" Era: Historical and Treatment Perspectives on a Modern-Day Medical Dilemma*, 173 DRUG & ALCOHOL DEPENDENCE S11, S13 (Supp. 1 2017).

84.   *Id.*

85.   Mark R. Jones, Omar Viswanath, Jacqueline Peck, Alan D. Kaye, Jatinder S. Gill & Thomas T. Simopoulos, *A Brief History of the Opioid Epidemic and Strategies of Pain Medicine*, 7 PAIN & THERAPY 13, 16 (2018).

86.   U.S. GEN. ACCT. OFF., GAO-04-110, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM 1 (2003) [hereinafter OXYCONTIN ABUSE], https://www.gao.gov/new.items/d04110.pdf [https://perma.cc/29AS-62PJ].

87.   Andrew Joseph & Shraddha Chakradhar, *Faced with Prescriber Fears of OxyContin Misuse, Purdue Sales Reps Misleadingly Played Up Drug's Safety, Documents Show*, STAT (Jan. 9, 2020), https://www.statnews.com/2020/01/09/prescriber-fears-oxycontin-misuse-purdue-pharma-sales-reps-misleadingly-played-up-safety/ [https://perma.cc/SQN6-3VMJ].

88.   Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, N.Y. TIMES (May 29, 2018), https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html [https://perma.cc/VR5C-FRDR].

89.   *See* Sujata S. Jayawant & Rajesh Balkrishnan, *The Controversy Surrounding OxyContin Abuse: Issues and Solutions*, 1 THERAPEUTICS & CLINICAL RISK MGMT. 77, 77 (2005); *see also* OXYCONTIN ABUSE, *supra* note 86, at 29 (hypothesizing that "the original label's safety warning advising patients not to crush the tablets because of the possible rapid release of a potentially toxic amount of oxycodone may have inadvertently alerted abusers to methods for abuse").

skyrocket during the first decade of the twenty-first century and prescription opioid-related overdose deaths increased fourfold from 1999 to 2011.[90]

2. *Federal Regulatory Response*

Federal and state regulators blamed the rising opioid crisis on prescription opioid manufacturers, like Purdue Pharma, and opioid prescribers, distributors, and dispensers.[91] There is no question that certain opioid manufacturers engaged in egregious and unlawful market behavior that exploited the legitimate clinical concern that pain was underassessed and undertreated.[92] And there is little debate that providers prescribed—and pharmacists dispensed—volumes of opioids, which created a lucrative market for the diversion and nonmedical use of prescription pills.[93]

Far less attention, however, has been directed at the significant role federal and state regulators played in the overdose crisis, including the FDA, DEA, Centers for Disease Control and Prevention (CDC), Office of National Drug Control Policy (ONDCP), and state medical and pharmacy licensing boards.[94] Detailing these agencies' collective contributions to our ever-worsening drug overdose epidemic, however, would fill the pages of a hefty text and exceed the concerns of this Article. Specifically, this Article will address the impact of prescription drug monitoring program (PDMP) surveillance and the lack of

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90. Sally Satel, *The Truth About Painkiller Addiction*, ATLANTIC (Aug. 4, 2019), https://www.theatlantic.com/ideas/archive/2019/08/what-america-got-wrong-about-opioidcrisis/595090 [https://perma.cc/4TUR-D3EM].

91. *See, e.g.*, U.S. DEP'T OF JUST. OFF. OF THE INSPECTOR GEN., AUDIT OF THE DRUG ENFORCEMENT ADMINISTRATION'S COMMUNITY-BASED EFFORTS TO COMBAT THE OPIOID CRISIS 1 (2020), https://oig.justice.gov/sites/default/files/reports/a20-102.pdf [https://perma.cc/R72C-3PDQ] ("The Department of Health and Human Services (HHS) traces the opioid epidemic to the late 1990s, as pharmaceutical companies assured doctors that patients would not become addicted to opioid pain relievers, resulting in healthcare providers prescribing these drugs at greater rates."); Rebecca L. Haffajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301, 2301–05 (2017) (describing and enumerating the numerous civil and criminal actions that federal and state governments have brought against physicians, pharmacies, opioid manufacturers, and opioid distributors); Barbara Fedders, *Opioid Policing*, 94 IND. L.J. 389, 393 (2019) ("Elected officials stress the culpability of pharmaceutical companies for aggressive marketing, and physicians for profligate prescribing.").

92. *See, e.g.*, Press Release, U.S. 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 [https://perma.cc/6EET-APCN] (describing Purdue's guilty plea after admitting it knew its products were being diverted).

93. *See U.S. Opioid Dispensing Rate Maps*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/rxrate-maps/index.html [https://perma.cc/M533-XT8Q]; Shann Hulme, David Bright & Suzanne Nielsen, *The Source and Diversion of Pharmaceutical Drugs for Non-Medical Use: A Systematic Review and Meta-Analysis*, 186 DRUG & ALCOHOL DEPENDENCE 242, 242–43 (2018) ("In the US, the [non-medical use] of pharmaceutical opioids has been estimated to cost over $70 billion annually.").

94. *But see, e.g.*, Zachary Siegel, *The Opioid Crisis Is About More Than Corporate Greed*, NEW REPUBLIC (July 30, 2019), https://newrepublic.com/article/154560/opioid-crisis-corporate-greed [https://perma.cc/KL2V-N2RN] ("While politicians are making hay out of Big Pharma's wanton greed and recklessness, far less attention has been paid to the DEA.").

regulation of PDMP platforms on opioid patient health and safety. It is therefore necessary to scrutinize the federal agencies vested with significant authority over controlled substance surveillance and PDMP software platform regulation: the DEA and the FDA.[95]

Under the Controlled Substance Act, the DEA is charged with preventing the diversion of legal drugs into the illicit market by maintaining strict control over the availability of controlled substances. This extends to CSA-regulated prescription opioids, which are monitored "through quotas, registration, recordkeeping, reporting, and security requirements."[96] The CSA also vests the DEA—a law enforcement agency located in the United States Department of Justice (and not a public health agency located in the Department of Health and Human Services, like the FDA)—with the authority to categorize drugs into five schedules (I-V) based on their medicinal value and abuse potential.[97] The DEA has classified most prescription opioids as Schedule II substances on the theory that those drugs have both a medically accepted use and a high potential for abuse.[98]

Federal law delegates to the DEA the duty to set specific limits on the volume of CSA Schedule II opioids that pharmaceutical manufacturers are permitted to manufacture and distribute each year.[99] The DEA then publishes those aggregate production quotas annually in the Federal Register.[100] This warrants emphasis because the prevailing drug overdose crisis causal narrative

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95. *See, e.g.*, Lars Noah, *Federal Regulatory Responses to the Prescription Opioid Crisis: Too Little, Too Late?*, 2019 UTAH L. REV. 757, 760 ("Drug manufacturers . . . saw [the condemnation of the undertreatment of pain] as an emerging business opportunity, and an ineffectual FDA quickly lost control of the situation."); Leo Beletsky & Jeremiah Goulka, *The Opioid Crisis: A Failure of Regulatory Design and Action*, A.B.A. CRIM. JUST. MAG., Summer 2019, at 35, 35–36 (opining that while the FDA and other "federal institutions involved in shaping drug policy . . . share some blame" for the opioid crisis, "the two most influential and problematic structures regulating opioids in both the health care and the black-market spheres have been the Controlled Substances Act and its implementing agency, the DEA").

96. John A. Gilbert & Barbara Rowland, *Practicing Medicine in a Drug Enforcement World*, *in* 27 HEALTH L. HANDBOOK 391, 394 (Alice G. Gosfield ed., 2015).

97. 21 U.S.C. §§ 811, 812(b); *see* 28 C.F.R. § 0.100 (2021) (delegating the Attorney General's authority to the DEA).

98. 21 C.F.R. § 1308.12(b)–(c) (2021) (listing all Schedule II opium and opiate substances); *see, e.g.*, *Drug Scheduling*, U.S. DRUG ENF'T ADMIN., https://www.dea.gov/drug-scheduling [https://perma.cc/E69P-ZUMY] (explaining that "Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence," opining that "[t]hese drugs are also considered dangerous," and enumerating the following opioids as Schedule II drugs: "[c]ombination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), . . . methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), [and] fentanyl"). A small group of narcotic controlled substances, including the opioid agonist buprenorphine, which is used to treat opioid use disorder, and drugs that contain relatively low milligrams per dosage units of codeine, are classified as Schedule III substances. *See* 21 C.F.R. § 1308.13(e) (2021).

99. 21 U.S.C. § 826.

100. *See, e.g.*, Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2021, 85 Fed. Reg. 76604 (Nov. 30, 2020).

misleads the public to believe that profit-driven Big Pharma flooded the market with opioids for years independent of any federal oversight. In fact, the DEA has exclusive control over the precise number of pills that are distributed through the supply chain each year. The DEA further insists that it "does not take into account business or other circumstantial considerations" in setting the annual opioid production quotas.[101]

As a result, to the extent that the U.S. market was overexposed to prescription opioids, the DEA is at least partially to blame.[102] "[T]he agency allowed aggregate production quotas for oxycodone to increase thirty-nine-fold between 1993 and 2015, and quotas for fentanyl to increase twenty-five-fold."[103] The DEA also failed to reduce the annual opioid production supply until 2017, more than five years after prescription opioid prescribing peaked in the United States.[104]

The CSA also requires prescription drug manufacturers and distributors to submit controlled substance drug transaction reports to the DEA detailing every sale, delivery, or other disposal of Schedule II opioids.[105] The DEA stores those transactions in its Automation of Reports and Consolidated Orders System (ARCOS) database, which the agency uses to identify suspicious orders and the potential diversion of controlled substances.[106] According to the DEA,

> ARCOS is an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level . . . . Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV

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101. *See* Lev Facher, *Pressure Builds on DEA to Stem Supply of Controlled Substances, but at What Cost?*, Bos. Globe (Dec. 24, 2017), https://www.bostonglobe.com/business/2017/12/24/pressure-builds-dea-stem-supply-controlled-substances-but-what-cost/0RJFpYimkOrUUiXf0jySeP/story.html [https://perma.cc/CU7Z-4VTW] ("To set the quotas, the DEA says it relies on estimates of legitimate medical need from the Food and Drug Administration, prescription levels from the previous year, manufacturers' forecasts, and other data.").

102. *See, e.g.*, Jacey Fortin, *D.E.A. Let Opioid Production Soar as Crisis Grew, Justice Dept. Says*, N.Y. Times (Oct. 1, 2019), https://www.nytimes.com/2019/10/01/us/dea-opioid-crisis.html [https://perma.cc/5RBP-J7DS].

103. Facher, *supra* note 101.

104. *Id.*

105. 21 U.S.C. § 827(d)(1).

106. *Id.* § 827(f); 21 C.F.R. § 1304.33 (2021); *see also* Declaration of John J. Martin in Support of the United States of America's Brief Posing Objections to Disclosure of ARCOS Data at 2, *In re* Nat'l Prescription Opiate Litig., No. 17-md-2804 (N.D. Ohio June 25, 2018). ARCOS includes the following information for each CSA-regulated drug transaction: supplier's name, DEA registration number, address and business activity, buyer's name, DEA registration number and address, prescription-drug code, transaction date, total dosage units, and total grams. *Id.* The CSA also imposes specific duties upon wholesale distributors to monitor, identify, halt, and report "suspicious orders" of prescription opioids. 21 C.F.R. § 1301.74(b) (2021).

psychotropic drugs (manufacturers only). ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States . . . by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts.[107]

Until recently, little was known about DEA ARCOS opioid transaction information. In late 2017, however, a group of Ohio opioid litigation plaintiffs, whose cases were later transferred to the federal opioid multidistrict litigation (MDL) docket, subpoenaed the DEA to obtain access to the opioid transaction data stored in the ARCOS database.[108] That request was met with forceful opposition by the United States Department of Justice (DOJ), which was not a party to the litigation but intervened on behalf of the DEA to resist disclosure of any ARCOS data.[109] The DEA argued that production of its ARCOS opioid data "would reveal investigatory records compiled for law enforcement purposes, and would interfere with [Controlled Substances Act] enforcement proceedings."[110] Further, it claimed that such disclosure would make public confidential business information, and thus cause opioid manufacturer and distributor defendants competitive harm.[111] In sum, "the DEA—a federal agency created by Congress to monitor and improve controlled substance-related public health outcomes—injected itself into the [federal] opioid [MDL] litigation not to assist the public entity plaintiffs but to advance the alleged privacy interests of *the defendant pharmaceutical corporations that it is charged with regulating*."[112]

Media organizations sought access to ARCOS data that was released to the plaintiffs under seal and appealed the district court's denial of their request for those materials to the United States Court of Appeals for the Sixth Circuit.[113] The opioid MDL district court ordered the DEA to produce a historical subset of ARCOS transaction records.[114] It became immediately apparent why the DEA had fought so hard to keep that information secret from the public. The *Washington Post* obtained the data and released a report revealing that opioid manufacturers and distributors had flooded the country with more than seventy-

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107. *Automation of Reports and Consolidated Orders Systems (ARCOS)*, DRUG ENF'T ADMIN. DIVERSION CONTROL DIV., https://www.deadiversion.usdoj.gov/arcos/index.html [https://perma.cc/M5RK-QBNJ].

108. Jennifer D. Oliva, *Opioid Multidistrict Litigation Secrecy*, 80 OHIO ST. L.J. 663, 666 (2019).

109. Objections of the United States Department of Justice, Drug Enforcement Administration to Plaintiff's Subpoena at 3–9, City of Cincinnati v. AmerisourceBergen Drug Corp., No. 2:17-cv-713 (S.D. Ohio Nov. 27, 2017), ECF No. 101.

110. *Id.* at 5.

111. *Id.* at 5–6.

112. Oliva, *supra* note 108, at 666–67.

113. *In re* Nat'l Prescription Opiate Litig., 927 F.3d 919 (6th Cir. 2019).

114. Order Regarding ARCOS Data Protective Order at 1–2, *In re* Nat'l Prescription Opiate Litig., No. 17-md-2804 (N.D. Ohio July 15, 2019), ECF No. 1845.

six billion prescription opioid pills from 2006-2012 on the DEA's watch.[115] In 2019, in response to the release of the ARCOS data and other information, the U.S. DOJ Office of the Inspector General issued a harsh rebuke of the DEA's opioid-related regulatory and enforcement efforts. The DOJ concluded that the DEA "was slow to respond to the significant increase in the use and diversion of opioids since 2000," "did not use its available resources, including its data systems and strongest administrative enforcement tools, to detect and regulate diversion effectively," and "did not adequately hold registrants accountable or prevent the diversion of pharmaceutical opioids."[116]

In addition to abdicating its obligation to control the supply of prescription opioids though quota setting and to deter diversion with its considerable ARCOS intelligence, the DEA continues to double down on failed, supply-side surveil-and-prosecute tactics.[117] Determined to "get tough on drugs," the agency broadcasted that it would root out and prosecute rogue opioid prescribers, pill mills, and doctor shoppers.[118] In order to facilitate its law and order crackdown, the DEA expended considerable financial and political resources assisting states to create law enforcement surveillance tools in the form of state PDMPs. For reasons explained later in this Article, these programs may well be exacerbating the drug overdose crisis and other health-harming outcomes by motivating the undertreatment of marginalized patients with chronic pain conditions and OUD, whose health is improved by prescription opioid treatment.[119] In sum, the record

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115.   Scott Higham, Sari Horwitz & Steven Rich, *76 Billion Opioid Pills: Newly Released Federal Data Unmasks the Epidemic*, WASH. POST (July 16, 2019), https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-theepidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html?utm_term=.8e8c6785485f [https://perma.cc/FSP7-WHQU].

116.   OFF. OF THE INSPECTOR GEN., U.S. DEP'T OF JUST., REVIEW OF THE DRUG ENFORCEMENT ADMINISTRATION'S REGULATORY AND ENFORCEMENT EFFORTS TO CONTROL THE DIVERSION OF OPIOIDS, at ii (2019), https://www.oversight.gov/sites/default/files/oig-reports/e1905.pdf [https://perma.cc/D3FM-22XF].

117.   *See, e.g.*, David Herzberg, Honoria Guarino, Pedro Mateu-Gelabert & Alex S. Bennett, *Recurring Epidemics of Pharmaceutical Drug Abuse in America: Time for an All-Drug Strategy*, 106 AM. J. PUB. HEALTH 408, 408–09 (2016) (explaining that, while "[s]upply-side and criminal justice approaches" dominate U.S. drug policy, "history offers little evidence that primary reliance on such strategies can genuinely reduce problematic drug use").

118.   *See, e.g.*, Jan Hoffman, *Medicare Is Cracking Down on Opioids. Doctors Fear Pain Patients Will Suffer.*, N.Y. TIMES (Mar. 27, 2018), https://www.nytimes.com/2018/03/27/health/opioids-medicare-limits.html [https://perma.cc/9UPF-BD75]; Barry Meier, *A New Painkiller Crackdown Targets Drug Distributors*, N.Y. TIMES (Oct. 17, 2012), https://www.nytimes.com/2012/10/18/business/to-fight-prescription-painkiller-abuse-dea-targets-distributors.html [https://perma.cc/QZ86-AZQM]. Pill mills are characterized as places "where doctors indiscriminately prescribe opioid medications for cash" and doctor shopping involves patients "vist[ing] multiple doctors to get prescriptions for opioid painkillers" and other drugs. Christine Vestal, *States Require Opioid Prescribers to Check for 'Doctor Shopping,'* PEW CHARITABLE TRS. (May 9, 2016), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/05/09/states-require-opioid-prescribers-to-check-for-doctor-shopping [https://perma.cc/R8MK-4PUY].

119.   *See* PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECH. ASSISTANCE CTR., TECHNICAL ASSISTANCE GUIDE: HISTORY OF PRESCRIPTION DRUG MONITORING PROGRAMS (2018),

strongly suggests that the DEA continues to exacerbate an epidemic that it was complicit in creating.

The DEA's counterproductive criminal justice-driven response was aided and abetted by the FDA's apparent disinterest in the collateral consequences of its opioid-related drug approval decisions. In 2010—a year during which 38,329 Americans died of drug overdose[120]—Purdue developed a new tamper-resistant, abuse-deterrent formulation of OxyContin on the theory that this version of the oxycodone tablet was more difficult to crush and dissolve.[121] In other words, "after years of ignoring reports of people misusing their painkillers by crushing them, thus giving plenty of time for misuse to become rampant," the FDA approved the pharmaceutical companies' formula changes "to make their painkillers harder to crush—an additional nudge for some people to switch to heroin for ease of use."[122] The FDA also has aided and abetted the DEA's misguided prescription opioid deprescribing crusade. Specifically, the FDA has failed to exercise its authority to regulate prescription drug monitoring program software platforms as medical devices and, thereby, ensure their safety and effectiveness in the clinical setting.

Psychiatrist Sally Satel summed up the harm-enhancing federal regulatory response to the initial wave of the drug overdose crisis as follows:

> Starting around 2010 or 2011, events converged in ways that made prescription pills less widely available. Law enforcement cracked down on pill mills, the maker of Oxycontin made the pill harder to crush, physicians tightened their prescribing practices, and more states created prescription registries to help identify people who were obtaining prescriptions by "doctor shopping"—that is, by seeking prescriptions from multiple physicians at the same time.[123]

Simply stated, the federal regulators that were complicit in the over-supply and diversion of prescription opioids for nonmedical use in the first instance responded to the first wave of the drug overdose crisis with tactics aimed at quickly limiting the supply of then-available, FDA-approved prescription opioids. These strategies included, but were not limited to, law enforcement crackdowns on prescribers and dispensers, unregulated and ubiquitous state prescription drug surveillance, and approval of an abuse-resistant opioid pill formulation that made things worse by paving the way for a more deadly second wave dominated by illicit heroin.

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https://www.pdmpassist.org/pdf/PDMP_admin/TAG_History_PDMPs_final_20180314.pdf [https://perma.cc/4G9A-5G4Y]; Buchmueller & Carey, *supra* note 71.

120.   *Overdose Death Rates 1999-2018*, NAT'L INST. ON DRUG ABUSE (Jan. 29, 2021), https://www.drugabuse.gov/drug-topics/trends-statistics/overdose-death-rates [https://perma.cc/2WJ4-EWB2].

121.   Gary M. Reisfield, *OxyContin, the FDA, and Drug Control*, 16 VIRTUAL MENTOR 279, 281 (2014).

122.   Beletsky & Goulka, *supra* note 95.

123.   Satel, *supra* note 90.

3. *Phase Two: Heroin*

In the face of sweeping surveillance, the rate of opioid prescribing in the United States peaked and plateaued between 2010-2012 and heroin took up the slack.[124] Heroin drug overdose deaths more than doubled between 2011 and 2014.[125] One study found that 77 percent of individuals who used both heroin and nonmedical pain relievers during this period had initiated their drug use with the nonmedical use of prescription opioids.[126] Individuals who had used diverted prescription opioids likely turned to heroin because it was "five to eight times cheaper than a black-market OxyContin tablet" and easier to obtain.[127]

4. *Phase Three: Fentanyl*

The heroin crisis quickly transitioned to an illicit fentanyl crisis.[128] Fentanyl is a powerful synthetic opioid that is thirty to fifty times as potent as heroin and fifty to one hundred times as potent as morphine.[129] While fentanyl is an FDA-approved Schedule II drug utilized in the practice of medicine as an analgesic and surgical anesthetic, the third and current wave of our overdose crisis is driven by illicit, underground fentanyl and fentanyl analogs "synthesized

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124.   *Prescribing Practices: Changes in Opioid Prescribing Practices*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/data/prescribing/prescribing-practices.html [https://perma.cc/8V8T-MKCU] ("The overall opioid prescribing rate in the United States peaked and leveled off from 2010–2012 and has been declining since 2012.").

125.   Rich et al., *supra* note 73.

126.   Pradip K. Muhuri, Joseph C. Gfroerer & M. Christine Davies, *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CTR. FOR BEHAV. HEALTH STAT. & QUALITY DATA REV., Aug. 2013, https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm [https://perma.cc/L5BX-YD3Z].

127.   *See* Beletsky & Goulka, *supra* note 95; Satel, *supra* note 90; Sari Horwitz & Scott Higham, *The Flow of Fentanyl: In the Mail, Over the Border*, WASH. POST (Aug. 23, 2019), https://www.washingtonpost.com/investigations/2019/08/23/fentanyl-flowed-through-us-postal-service-vehicles-crossing-southern-border/?itid=lk_inline_manual_10 [https://perma.cc/JFE5-YTDP] ("Fentanyl is the third wave of the opioid epidemic, which began with prescription pills, migrated to heroin and then morphed into the current crisis.").

128.   *See* Pedro Mateu-Gelabert & Honoria Guarino, *The Opioid Epidemic and Injection Drug Use: MIPIE and Health Harms Related to the Injection of Prescription Opioids*, 57 INT'L J. DRUG POL'Y 130, 130 (2018); *see also* Nadia Kounang, *Fentanyl Is the Deadliest Drug in the US, but in Some Places, Meth Kills More*, CNN (Oct. 25, 2019), https://www.cnn.com/2019/10/25/health/fentanyl-deadliest-drug/index.html [https://perma.cc/JF99-2MDJ] (describing the deadliness of the fentanyl epidemic).

129.   Ying Han, Wei Yan, Yongbo Zheng, Muhammad Zahid Khan, Kai Yuan & Lin Lu, *The Rising Crisis of Illicit Fentanyl Use, Overdose, and Potential Therapeutic Strategies*, 9 TRANSLATIONAL PSYCHIATRY 1, 1–2 (2019); *Fentanyl*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/drug-topics/fentanyl [https://perma.cc/PG46-U67F] ("Fentanyl is a powerful synthetic opioid analgesic that is similar to morphine but is 50 to 100 times more potent."); Vanila M. Singh, Thom Browne & Joshua Montgomery, *The Emerging Role of Toxic Adulterants in Street Drugs in the US Illicit Opioid Crisis*, 135 PUB. HEALTH REPS. 6, 6 (2020) (explaining that "the number of overdose deaths involving illicitly manufactured opioids ("eg, [sic] fentanyl and fentanyl analogues) is increasing" raising the concern that "illicitly manufactured opioids have become the main drivers of the nation's opioid crisis").

in laboratories and sold as heroin substitutes or mixed with other illicitly sourced drugs."[130] Illicit fentanyl and fentanyl-laced drugs present a significant risk of overdose death due to the very small margin between an effective and fatal dose and, equally terrifying, the fact that many individuals "who have survived fentanyl overdose appear to be unaware that they ever took the drug."[131]

"Between 2013 and 2016, fentanyl overdoses increased 540% and surpassed common opioid and heroin overdoses."[132] During that time, initial opioid prescriptions dropped 54 percent[133] yet "annual drug overdose deaths rose more than 22%, from 52,000 to 64,000 . . . killing Americans at a rate faster than the peak fatality rates of car crashes, the human immunodeficiency virus (HIV) epidemic, or gunshot wounds."[134] As investigative journalist Ben Westhoff observed,

> [W]hile civil leaders, law enforcement, and politicians struggled to find answers [to the prescription opioid and heroin crises,] fentanyl was quietly creating a brand-new drug epidemic, one that quickly outstripped the previous one[s] and has become more destructive than any drug crisis in American history: worse than crack in the 1980s, worse than meth in the first decade of the 2000s, worse than heroin and prescription pills in the 2010s.[135]

America's illicit fentanyl-fueled drug overdose crisis continues to worsen. After a 5 percent decline in overdose deaths in 2018 due to a decrease in prescription drug overdoses, the United States relapsed.[136] According to the CDC data, over 70,000 individuals died of drug overdose in 2019.[137] The overwhelming majority of those deaths involved the use of multiple substances, and 73 percent of the fatal opioid-related overdoses involved synthetic opioids

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130.   Han et al., *supra* note 129, at 1–2.

131.   *Id.* at 2.

132.   Jones et al., *supra* note 82, at 4281.

133.   Wenjia Zhu, Michael E. Chernew, Tisamarie B. Sherry & Nicole Maestas, *Initial Opioid Prescriptions Among U.S. Commercially Insured Patients, 2012–2017*, 380 NEW ENG. J. MED. 1043, 1043 (2019) ("The monthly incidence of initial opioid prescriptions among enrollees who had not used opioids declined by 54%, from 1.63% in July 2012 to 0.75% in December 2017. This decline was accompanied by a decreasing number of providers (from 114,043 in July 2012 to 80,462 in December 2017) who initiated opioid therapy in any patient who had not used opioids.").

134.   Jones et al., *supra* note 82, at 4281.

135.   Ben Westhoff, FENTANYL, INC.: HOW ROGUE CHEMISTS ARE CREATING THE DEADLIEST WAVE OF THE OPIOID EPIDEMIC 3 (2019).

136.   Josh Katz, Abby Goodnough & Margot Sanger-Katz, *In Shadow of Pandemic, U.S. Drug Overdose Deaths Resurge to Record*, N.Y. Times (July 15, 2020), https://www.nytimes.com/interactive/2020/07/15/upshot/drug-overdose-deaths.html [https://perma.cc/BKE2-3Q6G].

137.   *Drug Overdose Death Counts*, *supra* note 6; Carla K. Johnson, *New Peak of 71K US Overdose Deaths in 2019 Dashes Hopes*, WASH. POST (July 15, 2020), https://www.washingtonpost.com/health/new-peak-of-71k-us-overdose-deaths-in-2019-dashes-hopes/2020/07/15/5bdffc2c-c6cf-11ea-a825-8722004e4150_story.html [https://perma.cc/S3M7-R7VJ].

like illicit fentanyl.[138] Natural and semisynthetic prescription opioids, such as morphine, codeine, oxycodone, hydrocodone, hydromorphone, and oxymorphone, on the other hand, were present in only 24 percent of 2019 opioid overdose deaths.[139] Deaths involving methamphetamines, cocaine, and heroin respectively exceeded the number of overdoses involving any prescription opioid.[140]

According to the provisional CDC data, a record 92,511 individuals died of drug overdose in 2020 and illicit fentanyl was, yet again, the dominant culprit.[141] However, overdose deaths alone only paint a partial picture of the current crisis. If, as studies indicate, there are approximately thirty nonfatal overdoses for every one fatality, the United States racked up nearly 3 million nonfatal overdoses in 2020.[142]

In addition, and although the opioid crisis is frequently framed as a white suburban and rural problem, the largest increases in fentanyl-related overdose deaths were among racial minorities.[143] As the Substance Abuse and Mental Health Services Administration explained in a report entitled *The Opioid Crisis and the Black/African American Population: An Urgent Issue*:

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138. *Drug Overdose Death Counts*, *supra* note 6; *see* U.S. Drug Enf't Admin., DEA Issues Carfentanil Warning to Police and Public (Sept. 22, 2016), https://www.dea.gov/press-releases/2016/09/22/dea-issues-carfentanil-warning-police-and-public [https://perma.cc/T4NB-W92R].

139. *Drug Overdose Death Counts*, *supra* note 6; *see* Betsy McKay, *U.S. Drug-Overdose Deaths Soared Nearly 30% in 2020, Driven by Synthetic Opioids; Fentanyl, Along with Isolation and Stress from Covid-19 Pandemic, Propelled Surge, Experts Say*, WALL ST. J. (July 14, 2021), https://www.wsj.com/articles/u-s-drug-overdose-deaths-soared-nearly-30-in-2020-11626271200 [https://perma.cc/P2KJ-5JSM] ("[T]he 2020 data show [that the drug overdose surge] was driven largely by a proliferation of fentanyl, a powerful synthetic opioid whose use has spread across the nation."); *id.* ("Definitely fentanyl is the driving factor." (quoting CDC mortality statistics branch chief Robert Anderson)).

140. *Drug Overdose Death Counts*, *supra* note 6.

141. *Id.*; Press Release, Ctrs. for Disease Control & Prevention, Overdose Deaths Accelerating During COVID-19 (Dec. 17, 2020), https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html [https://perma.cc/F9NX-EQ7W] ("Synthetic opioids (primarily illicitly manufactured fentanyl) appear to be the primary driver of the increases in overdose deaths, increasing 38.4 percent from the 12-month period leading up to June 2019 compared with the 12-month period leading up to May 2020.").

142. *See, e.g.*, Andrea Hsu, *Hospitals Could Do More for Survivors of Opioid Overdoses, Study Suggests*, NPR (Aug. 22, 2017), https://www.npr.org/sections/health-shots/2017/08/22/545115225/hospitals-could-do-more-forsurvivors-of-opioid-overdoses-study-suggests [https://perma.cc/VQ33-ULFP]; Shane Darke, Richard P. Mattick & Louisa Degenhardt, *The Ratio of Non-fatal to Fatal Heroin Overdose*, 98 ADDICTION 1169, 1170 (2003).

143. Substance Abuse & Mental Health Servs. Admin. Off. of Behav. Health Equity, *The Opioid Crisis and the Black/African American Population: An Urgent Issue* 3–4 (2020) [hereinafter The Opioid Crisis and the Black/African American Population], https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-05-02-001_508%20Final.pdf [https://perma.cc/7JSP-8WDS] ("Synthetic opioids are affecting opioid death rates among non-Hispanic Blacks more severely than other populations."); *id.* at 3 ("Attention to this epidemic has focused primarily on White suburban and rural communities. Less attention has focused on Black/African American communities which are similarly experiencing dramatic increases in opioid misuse and overdose deaths.").

The rate of increase of Black/African American drug overdose deaths between 2015-2016 was 40 percent compared to the overall population increase at 21 percent. This exceeded all other racial and ethnic population groups in the U.S. From 2011-2016, compared to all other populations, Black/African Americans had the highest increase in overdose death rate for opioid deaths involving synthetic opioids like fentanyl and fentanyl analogs.[144]

Racial minorities in urban areas have been particularly hard hit by the fentanyl wave of the overdose crisis. While White overdose deaths decreased in Philadelphia by 3 percent in 2019, for example, Black American and Latinx deaths increased by 14 percent and 24 percent, respectively.[145] St. Louis County experienced a similar trend. There, although opioid overdose deaths decreased by 8 percent among all populations in 2019, such deaths increased by 17 percent among Black men.[146] Because Black Americans misuse opioids at the same rate as their White counterparts, these trends demonstrate the heightened lethality of illicit fentanyl relative to other opioids.[147]

Harrowing statistics and the history of American opioid wars inform several of the themes that run through this Article and its critiques of law enforcement-driven prescription drug surveillance tools. While U.S. policymakers have softened their drug war rhetoric over the last two decades—a tactic that many experts chalk up to the perceived whiteness of the epidemic[148]—little else has changed. The small steps that policymakers have taken toward a public health approach are a sideshow in the ongoing drug control circus. At each stage of our current crisis, the United States has responded with a law enforcement-led, sanction-imposing, supply-side-dominated strategy that has, just like previous drug wars, not only failed to stem the epidemic but made it worse.[149]

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144.   *Id.* at 3.

145.   Katz et al., *supra* note 136.

146.   *Id.*

147.   The Opioid Crisis and the Black/African American Population, *supra* note 143, at 4; Simona Pichini, Renata Solimini, Paolo Berretta, Roberta Pacifici & Francesco Paolo Busardò, *Acute Intoxications and Fatalities from Illicit Fentanyl and Analogues: An Update*, 40 THERAPEUTIC DRUG MONITORING 38, 38 (2018) ("Illicit fentanyl and its analogues are very dangerous synthetic opioids, with high abuse potential and severe adverse effects including coma and death. They are used as adulterants in street heroin, cocaine, and methamphetamine, or as heroin substitutes sold to unaware users with a high risk of overdoses.").

148.   *See, e.g.*, Julie Netherland & Helena B. Hansen, *The War on Drugs that Wasn't: Wasted Whiteness, "Dirty Doctors," and Race in Media Coverage of Prescription Opioid Misuse*, 40 CULTURE MED. & PSYCHIATRY 664 (2016) (contrasting representation of white opioid users with that of Black and Brown heroin users and explaining how representation impacts public and policy responses); Deborah Raji, *How Our Data Encodes Systemic Racism*, MIT TECH. REV. (Dec. 10, 2020), https://www.technologyreview.com/2020/12/10/1013617/racism-data-science-artificial-intelligence-ai-opinion/ [https://perma.cc/5A92-UQM9] (noting the discrimination embedded in the characterization of drug-related topics as a "war on drugs" versus an "opioid epidemic").

149.   EVA BERTRAM, MORRIS BLACHMAN, KENNETH SHARPE & PETER ANDREAS, DRUG WAR POLITICS: THE PRICE OF DENIAL 3 (1996) ("[A] singular goal lies behind decades of American drug wars: stopping all drug use through a strategy of tough enforcement. The strategy['s] . . . primary aim is

Law enforcement has responded to the drug crisis with a variety of drug control tools that bear some responsibility for the crisis' terrible trajectory.[150] The DEA's funding and utilization of a national surveil-and-sanction system in the form of state prescription drug monitoring programs (PDMPs) is one such tool. The implementation and evolution of an artificial intelligence-enhanced network of state PDMP databases to facilitate the surveillance of prescribers, dispensers, and patients is the subject of the following Section of this Article.

II.
THE RISE OF PDMPS

> Law enforcement officials appear to believe that patients complaining of pain who need large volumes of medication often are either addicts or diverters and, therefore, prescribing to them is not a legitimate medical purpose.[151]

As it became obvious that prescription opioid diversion and misuse was on the rise in the late 1990s, the DEA initiated a well-funded campaign to incentivize states to implement, operate, and enhance PDMPs.[152] A handful of states had PDMPs in place prior to this effort. Those PDMPs' relatively limited size, scope, and capabilities markedly distinguish them from today's robust, integrated, and algorithm-driven monitoring systems. Early PDMPs were created, however, for the same purpose as their modern surveillance progeny: to assist law enforcement to use punitive sanctions to control the prescription of certain drugs. As the Prescription Drug Monitoring Program Training and Technical Assistance Center (TTAC) concedes, "[t]he earliest PDMPs were established primarily as enforcement and regulatory tools providing data to officials responsible for enforcing drug laws and overseeing the prescribing and dispensing of these drugs by health care professionals."[153]

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to prohibit supply, so that Americans cannot find or cannot afford drugs to use; its secondary aim is to discourage those who do consume drugs, mainly by penalizing them.").

150.   Beletsky & Goulka, *supra* note 95.

151.   Diane E. Hoffmann, *Treating Pain v. Reducing Drug Diversion and Abuse: Recalibrating the Balance in Our Drug Control Laws and Policies*, 1 ST. LOUIS U. J. HEALTH L. & POL'Y 231, 271 (2008).

152.   *See* Prescription Drug Monitoring Program Training & Tech. Assistance Ctr., *History of Prescription Drug Monitoring Programs* 2 (2018) [hereinafter History of PDMPs], https://www.pdmpassist.org/pdf/PDMP_admin/TAG_History_PDMPs_final_20180314.pdf [https://perma.cc/X3KX-GE4F] ("In 2003, DOJ began the Harold Rogers Prescription Drug Monitoring Grant Program (HRPDMP). DOJ, through its Bureau of Justice Assistance (BJA), made funding available to states that were interested in establishing, implementing, and enhancing PDMPs. The availability of federal funds through the HRPDMP played an integral role in the proliferation of PDMPs.").

153.   *Id.* at 1; *see* Oliva, *supra* note 4, at 793, (explaining that the purpose of modern PDMPs is "to help enforcement agencies 'identify problem patients, rogue prescribers, and pharmacists who may be diverting potentially addictive and otherwise risky drugs' and, thereby, 'deter "aberrant" practices' 'in an effort to reduce prescription drug abuse'" (internal citations omitted)).

The state of New York enacted legislation to create the country's first PDMP under the Boylan Act in 1914 in the midst of the Harrison Act crackdown on opioid and cocaine use.[154] New York's PDMP law required pharmacists who dispensed prescription cocaine, heroin, morphine, opium, or codeine, to send a record of those prescriptions to the New York State Department of Health.[155] New York lessened its regulations after just three years "because of concerns that supply-side restrictions were fueling the illicit opioid market," but other states began to implement similar programs to control the drug supply.[156] In 1939, California implemented a prescription drug monitoring system, the California Triplicate Prescription Program, now recognized as "the oldest continuously operated PDMP program in the country," under the authority of its Bureau of Narcotic Enforcement.[157]

Eight additional states created drug monitoring programs between 1943 and 1988.[158] Quite unlike the modern PDMP regime, these nascent surveillance programs all had the same basic characteristics.[159] They collected and stored limited information on only Schedule II controlled substances, and did so via a rudimentary, carbon paper-based record keeping system.[160] The programs required prescribers to fill out a duplicate or triplicate state-issued form to issue to patients to whom they prescribed Schedule II drugs.[161] Patients then provided those forms to pharmacists at the point of dispensing, and pharmacists, in turn, submitted a copy of the form to the state.[162]

Once the DOJ and DEA began to fund and advocate for the creation—and expansion—of PDMPs to enhance prescription opioid surveillance in the early 2000s, states began to implement more sophisticated drug monitoring systems at a dizzying clip.[163] Twenty-seven states adopted PDMPs between 2000 and 2010 alone, and today, all fifty states have authorized PDMPs.[164]

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154.   A. Jay Holmgren, Alyssa Botelho & Allan M. Brandt, *A History of Prescription Drug Monitoring Programs in the United States: Political Appeal and Public Health Efficacy*, 110 AM. J. PUB. HEALTH 1191, 1192 (2020).

155.   History of PDMPs, *supra* note 152, at 2.

156.   Holmgren et al., *supra* note 154, at 1192.

157.   History of PDMPs, *supra* note 152, at 2.

158.   *Id.* at 2–3.

159.   *Id.* at 3.

160.   *See id.*

161.   *Id.* at 2–3.

162.   *Id.* at 3–4; LISA N. SACCO, JOHNATHAN H. DUFF & AMANDA K. SARATA, CONG. RSCH. SERV., R42593, PRESCRIPTION DRUG MONITORING PROGRAMS 2 (2018), https://fas.org/sgp/crs/misc/R42593.pdf [https://perma.cc/HBY2-LCNE] ("For over a decade, the federal government has provided financial support for state-level PDMPs. In 2002, Congress established the Harold Rogers PDMP grant, administered by the Department of Justice (DOJ), to help law enforcement, regulatory entities, and public health officials analyze data on prescriptions for controlled substances.").

163.   *Id.* at 5–6.

164.   *Id.* at 1, 2–3, 5–6; Beletsky & Goulka, *supra* note 95 ("DEA and DOJ invested ramping up the investment of funding and law enforcement expertise in state-based prescription drug monitoring programs, 27 of which were established in the first decade of this century."); *see* Cameron Gerber,

Modern prescription drug surveillance platforms vary considerably from their modest, paper-based predecessors. Today's PDMPs are state-administered electronic databases that collect, store, and analyze voluminous information concerning prescribed and dispensed controlled substances as well as any number of other prescribed drugs.[165] Unlike their predecessors, modern PDMPs are no longer passive data collection and storage programs.[166] Instead, they are electronic databases that use algorithm-powered models to score patient risk and to counsel diagnosis and treatment decisions.[167] In addition, and also unlike their predecessors, modern PDMPs are heterogeneous across states on a number of characteristics.[168] Those characteristics include, but are not limited to: which state entity has operational responsibility for and regulatory authority over the database; which entities and individuals are authorized to access the database; and which drugs the system monitors.[169] In addition, certain program requirements are inconsistent between states, including whether prescribers and dispensers are mandated to utilize the database, which criteria triggers mandatory utilization where applicable, and the extent of and sources from which PDMP data can be collected and analyzed.[170]

States delegate day-to-day PDMP operation to a variety of state actors and regulatory entities—from state departments of health to state pharmacy boards to law enforcement agencies.[171] The drugs monitored by state programs are similarly disparate. In addition, state PDMPs cover an increasingly expansive list of drugs that are less "dangerous" on the CSA Schedule. A minority of states

Missouri Legislature Gives Final Approval to Statewide PDMP Bill, MO. TIMES (May 11, 2021), https://themissouritimes.com/missouri-legislature-gives-final-approval-to-statewide-pdmp-bill [https://perma.cc/7LNK-Z5WD] ("Missouri [was] the only state not to have a statewide PDMP.").

165. *See* Substance Abuse & Mental Health Servs. Admin., *Prescription Drug Monitoring Programs: A Guide for Healthcare Providers*, IN BRIEF, Winter 2017, at 1, 1–3.

166. *Id.* at 1 ("The first PDMPs, which were paper based, did not provide reports to healthcare providers for use during individual patient care; however, today's electronic databases have a variety of features that make them practical for such care."); *see* Oliva, *supra* note 4, at 847–48.

167. Oliva, *supra* note 4, at 847–48; *see NarxCare*, BAMBOO HEALTH, https://bamboohealth.com/solutions/narxcare/ [https://perma.cc/Q9B3-E7DS] ("NarxCare is an analytics and clinical decision support tool that helps prescribers and dispensers evaluate controlled substance data from Prescription Drug Monitoring Programs (PDMPs) and help prevent substance use disorder and misuse. NarxCare analyzes a patient's PDMP data and provides substance risk scores, an overall overdose risk score, and an interactive visualization of usage patterns.").

168. A. Travis Manasco, Christopher Griggs, Rebecca Leeds, Breanne K. Langlois, Alan H. Breaud, Patricia M. Mitchell & Scott G. Weiner, *Characteristics of State Prescription Drug Monitoring Programs: A State-by-State Survey*, 25 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 847, 847 (2016).

169. Marilyn Bulloch, *The Evolution of the PDMP*, PHARMACY TIMES (July 25, 2018), https://www.pharmacytimes.com/contributor/marilyn-bulloch-pharmd-bcps/2018/07/the-evolution-of-the-pdmp [https://perma.cc/663D-BMB3].

170. *Id.*

171. *See* Prescription Drug Monitoring Program Training & Tech. Assistance Ctr., PDMP By Operating State Agency Type (2019), https://perma.cc/KUP5-85E8 (showing the state agencies used to operate PDMP programs); *see also* Bulloch, *supra* note 169 (explaining that a variety of different entities administered state monitoring programs, including "boards of pharmacy, consumer protection agencies, departments of health, law enforcement, professional licensing groups, and substance abuse organizations").

and territories—just nine—track only Schedule II-IV drugs while the vast majority—thirty-nine—monitor either all CSA Schedule II-V controlled substances or all of those controlled substances in addition to other non-scheduled "drugs of concern."[172] One state, Nebraska, surveils every single prescription drug dispensed.[173] While the list of drugs that PDMPs track vary across jurisdictions, all states collect the following information from dispensers with regard to every prescription drug that they monitor: "[t]ype of drug dispensed"; "[q]uantity of drug dispensed"; "[n]umber of days a given quantity is supposed to last"; "[d]ate dispensed"; "[p]rescriber and pharmacy identifiers"; and "[p]atient identifiers," such as "name, address, zip code, and date of birth."[174]

A majority of states require prescribers, dispensers and other "authorizer users," such as law enforcement agents, to register to access the PDMP.[175] Bolstering the argument that PDMPs serve primarily as law enforcement—and not public health—tools is the fact that almost half of the states do not require prescribers to consult the PDMP under any circumstances.[176] In fact, no state required prescribers to review PDMP data prior to prescribing a controlled substance until 2007.[177] And even in jurisdictions that demand that providers query the database, the criteria that trigger those use mandates varies considerably. Some states, for example, require their prescribers and dispensers to check the PDMP if they either suspect drug misuse or intend to prescribe or dispense specific controlled substances—like opioids or benzodiazepines—or certain dosages of designated drugs.[178]

History makes clear that PDMPs are—and have always been—funded by and created for law enforcement for the purpose of surveilling controlled

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172. *See* Prescription Drug Monitoring Program Training & Tech. Assistance Ctr., Drugs Monitored by PDMP (2019), https://perma.cc/9B6M-VZ44 (showing drugs monitored by PDMP by state).

173. *Id.*

174. EDUC. DEV. CTR., USING PRESCRIPTION DRUG MONITORING PROGRAM DATA TO SUPPORT PREVENTION PLANNING—AT-A-GLANCE! 1, 1–2, 2 n.3, https://preventionsolutions.edc.org/sites/default/files/attachments/Using-Prescription-Drug-Monitoring-Program-Data-to-Support-Prevention-Planning_0.pdf [https://perma.cc/22BX-8FRW].

175. Prescription Drug Monitoring Program Training & Tech. Assistance Ctr., PDMP Mandatory Enrollment of Prescribers and Dispensers (2019), https://perma.cc/VS7C-ETBB (showing that thirty-three states require both prescribers and dispensers to register, eleven require only prescribers to register, one only requires dispensers to register, and eight do not require any registration).

176. *See* Prescription Drug Monitoring Program Training & Tech. Assistance Ctr., PDMP Mandatory Query by Prescribers and Dispensers (2019), https://perma.cc/NZ5H-9H39 (showing that only twenty-seven states required prescribers to query the PDMP and only nineteen require both prescribers and dispensers to query the program).

177. Prescription Drug Monitoring Program Training & Tech. Assistance Ctr., Mandatory Enrollment and Use of PDMPs 3 (2020), https://www.pdmpassist.org/pdf/TAG_Mandatory_Enrollment_Use_20200710.pdf [https://perma.cc/BS62-JV43].

178. *Id.* at 5.

substances and criminally investigating their misuse and diversion.[179] PDMPs were neither created by clinicians nor designed primarily to diagnose and treat health care conditions.[180] The view that PDMPs are potentially useful public health tools has nonetheless become increasingly prevalent as more and more states have mandated their clinical use and transferred their administration from law enforcement to health agencies.[181]

This shift is troubling because there is scant evidence that PDMPs either improve patient care or enhance access to evidence-based treatment for individuals with SUD, chronic pain, or other complex conditions for which monitored controlled substances are indicated.[182] Moreover, "[a]lthough [PDMPs] are not meant to deter opioid prescribing per se, resistant clinicians may simply decline to prescribe opioids, raise prescribing thresholds, refer patients elsewhere, or substitute to nonmonitored drugs—all of which could compromise appropriate symptom management."[183] In practice, PDMPs "pressure[] doctors to cut back on prescribing, and then their legitimately suffering patients are driven to the illegal market where they get laced opioids, or they go to cheaper heroin and, of course, that is where the overdoses occur."[184]

PDMP effectiveness research indicates that prescription-drug surveillance is neither associated with decreases in the nonmedical use of controlled substances nor reductions in drug-overdose mortality rates.[185] One study concluded that "implementation of PDMPs was associated with an 11% *increase* in drug overdose mortality."[186] "Rising overdose mortality[,] despite decreasing opioid prescribing[,] suggests that merely reducing the prescription-opioid supply will have little positive short-term impact. Reducing prescribing could

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179. History of PDMPs, *supra* note 152, at 1; *see* Oliva, *supra* note 4, at 793.

180. *See* History of PDMPs, *supra* note 152, at 1.

181. Holmgren et al., *supra* note 154, at 1193–94.

182. *See, e.g.*, *id.* at 1194 (pointing out that "[a] 2011 study found that although states with PDMPs had lower opioid-prescribing rates than those without, they did not have lower rates of opioid overdose deaths" and "[a] 2018 study found that although supply-side restrictions such as PDMPs decrease overdose deaths from prescription pill use, they may actually increase heroin-related deaths, as individuals who are denied medical prescriptions turn to riskier, illicit sources of nonprescription opioids"); Rebecca L. Haffajee, *Preventing Opioid Misuse with Prescription Drug Monitoring Programs: A Framework for Evaluating the Success of State Public Health Laws*, 67 HASTINGS L.J. 1621, 1621 (2016) ("PDMP policies are widespread . . . [and] largely uninformed by robust evidence or a systematic assessment of best practices. Whether [PDMPs] successfully reduce opioid misuse and overdoses remains unclear.").

183. *See, e.g.*, Rebecca L. Haffajee, Anupam B. Jena & Scott G. Weiner, *Mandatory Use of Prescription Drug Monitoring Programs*, 313 JAMA 891, 891–92 (2015).

184. *The Myth of an Opioid Prescription Crisis*, CATO POL'Y REP., Sept.–Oct. 2017, at 9, 11, https://www.cato.org/sites/cato.org/files/serials/files/policy-report/2017/9/cpr-v39n5-4.pdf [https://perma.cc/5895-ADBT].

185. *See* Janet Weiner, Yuhua Bao & Zachary Meisel, Leonard Davis Inst. of Health Econ., *Prescription Drug Monitoring Programs: Evolution and Evidence* 5 (2017).

186. Guohua Li, Joanne E. Brady, Barbara H. Lang, James Giglio, Hannah Wunsch & Charles DiMaggio, *Prescription Drug Monitoring and Drug Overdose Mortality*, INJURY EPIDEMIOLOGY, 2014, at 1, 3 (emphasis added).

even increase the death toll as people with opioid use disorder or untreated pain shift into the unstable, illicit drug market."[187]

Research also indicates that PDMPs influence clinical behavior, thereby reducing the prescription of opioids, even when that treatment decision is unwarranted.[188] PDMP surveillance provokes prescribers to cut loose chronic pain patients and other complex patients for whom opioids and other suspect controlled substances are indicated.[189] Prescribers engage in such behavior to avoid criminal investigation and professional licensing board scrutiny.[190] As one journalist recently reported, "[f]or over a decade, the DEA and attorneys general have ramped up investigations of practitioners, pharmacists and distributors" and, as a result, "[t]he fear of law enforcement in chilling prescriptions cannot be overstated."[191] A 2020 study confirmed that the DEA's favorite target for opioid prescribing-related criminal prosecution are pain medicine specialists.[192]

Prescription drug surveillance also has created tremendous suffering. Prescription drug monitoring and the threat of criminal investigation, arrest, and prosecution have been so successful at curtailing opioid prescribing that even individuals with metastatic cancer and patients in hospice have been left to live with their terminal illnesses in excruciating pain.[193] "As medical professionals and lawmakers tighten controls on prescription opioids, people with chronic pain who have genuinely benefitted from them have been not just neglected, but stigmatized and systematically deprived."[194] Practitioners who force taper or

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187. Sarah E. Wakeman & Michael L. Barnett, *Primary Care and the Opioid-Overdose Crisis: Buprenorphine Myths and Realities*, 397 NEW ENG. J. MED. 1, 3 (2018); *The Myth of an Opioid Prescription Crisis*, *supra* note 184, at 11.

188. *See, e.g.*, Yuhua Bao, Yijun Pan, Aryn Taylor, Sharmini Radakrishnan, Feijun Luo, Harold Alan Pincus & Bruce R. Schackman, *Prescription Drug Monitoring Programs Are Associated with Sustained Reductions in Opioid Prescribing by Physicians*, 35 HEALTH AFFS. 1045 (2016).

189. *The Myth of an Opioid Prescription Crisis*, *supra* note 184, at 11.

190. *See, e.g.*, Kelly K. Dineen & James M. Dubois, *Between a Rock and a Hard Place: Can Physicians Prescribe Opioids to Treat Pain Adequately While Avoiding Legal Sanction?*, 42 AM. J. L. & MED. 7, 8–9 (2016); *id.* at 24 ("A substantial number of [state medical board] actions involve misuse and misprescribing of controlled substances, including opioid misprescribing."); *id.* at 22 ("An investigation alone can be devastating and a finding of liability can trigger a cascade of consequences that make it impossible to practice medicine."); Sessi Kuwabara Blanchard, *How Fear, Misinformation, Stigma Have Devastated US Pain Patients*, FILTER (Apr. 28, 2021), https://filtermag.org/pain-patients-opioids-fear [https://perma.cc/64HY-RREL].

191. Blanchard, *supra* note 190.

192. David Daewhan Kim & Nabil Sibai, *The Current State of Opioid Prescribing and Drug Enforcement Agency (DEA) Action Against Physicians: An Analysis of DEA Database 2004-2017*, 23 PAIN PHYSICIAN E297, E299 (2020).

193. Sara Ray & Kathleen Hoffman, *Opioid Stigma Is Keeping Many Cancer Patients from Getting the Pain Control They Need*, STAT (July 6, 2018), https://www.statnews.com/2018/07/06/cancer-patients-pain-opioid-stigma [https://perma.cc/6DQ7-JJGD] ("Two-thirds of individuals with metastatic cancer and more than half of those being treated for cancer report experiencing chronic pain, and 1 in 3 cancer patients do not receive medication appropriate for the intensity of their pain.").

194. Andrew Pulrang, *People with Chronic Pain Are Claiming a Voice in the Opioid Crisis*, FORBES (Mar. 17, 2021), https://www.forbes.com/sites/andrewpulrang/2021/03/17/people-with-

refuse to prescribe opioids to opioid-dependent patients also put lives at risk by incentivizing those patients to opt out of the healthcare delivery system and, therefore, become more susceptible to illicit overdose and suicide.[195] These serious collateral consequences of prescription opioid surveillance, however, have failed to stymie PDMP enforcement zeal.[196]

As already noted, the country's drug crisis has been driven primarily by illicit opioids and polysubstance drug use since at least 2012. The Federation of State Medical Boards (FSMB) nonetheless argued in an August 2018 policy statement that "[the] escalating [prescription opioid] public health epidemic has led to a wave of implementations and upgrades to states' prescription drug monitoring programs over the past decade in an effort to curb substance use disorder."[197] There is no indication that substance use disorder has been "curbed" by prescription drug surveillance, but the FSMB was spot on about prescription drug surveillance. State PDMPs are no longer passive collectors of voluminous prescription drug-related data—they are an integrated system of AI-driven databases that incorporate data from numerous non-prescribing sources and use black-box, proprietary algorithms to assess patient risk. The following Section details the algorithmic evolution of PDMPs.

III.
THE ADVENT OF PDMP RISK SCORES

The NarxCare [PDMP] platform is used to inform providers millions of times a month across the nation. It has been integrated into workflow and used as the default portal platform at the state PDMP level.[198]

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chronic-pain-are-claiming-a-voice-in-the-opioids-crisis/?sh=331c9906c274 [https://perma.cc/NRS5-S9PD].

195. Nat'l Council on Independent Living, *Chronic Pain Congressional Letter*, ADVOC. MONITOR (Mar. 1, 2021), https://advocacymonitor.com/chronic-pain-sign-on-letter/ [https://perma.cc/6ZJ3-3NEG] ("[P]atients are being forcibly or abruptly tapered off of their medications in dangerous ways—often with devastating results, such as increased suffering, loss of function, drug overdose and suicide."); German Lopez, *Solving America's Painkiller Paradox*, VOX (Sept. 26, 2018), https://www.vox.com/science-and-health/2018/9/25/17327976/opioid-epidemic-painkiller-prescriptions [https://perma.cc/BZ5T-R26E] (noting expert opposition to abrupt tapers because they "could lead some to suffer unnecessary pain or withdrawal or, perhaps worse, push patients toward dangerous illicit drugs—even if they're not technically addicted to opioids").

196. Holmgren et al., *supra* note 154, at 1191 ("Although the empirical evidence on the efficacy of PDMPs is mixed, they have garnered widespread support from policymakers and the popular press over the past decade.").

197. FED. OF STATE MED. BDS., PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): REPORT AND RECOMMENDATIONS OF THE WORKGROUP ON PDMPs 2 (2018) [hereinafter Report and Recommendations from the Workgroup on PDMPs], https://web.archive.org/web/20200925235207/https://www.fsmb.org/siteassets/advocacy/policies/prescription-drug-monitoring-programs---adopted.pdf.

198. APPRISS HEALTH, UP FRONT, EVERY PATIENT, EVERY TIME: A MODEL FOR MAXIMUM PDMP EFFECTIVENESS 10 (2018) [hereinafter Up Front, Every Patient, Every Time], https://www.pmp.pharmacy.state.mn.us/assets/files/Resource%20Pages/HLTH_Max%20PDMP%20Effectiveness%20WP_FINAL.pdf [https://perma.cc/K2S4-Z88Z].

As enforcement demand for PDMP capability has evolved, software development companies have incorporated algorithmic logic and machine learning into their prescription monitoring platforms.[199] Bamboo Health (formerly Appriss Health), which manufactures NarxCare, is the largest PDMP platform provider in the United States, serving "43 of the nation's 54 prescription drug monitoring programs."[200] Bamboo's technology not only allows for in-state prescription data management, it enables interstate sharing and accessibility of PDMP information, integration of that data into patients' electronic health records (EHRs), and patient-specific calculation of opioid prescribing "risk scores."[201]

For the majority of their existences, state PDMPs operated in isolation from one another.[202] However, as more states passed laws mandating PDMP utilization over the last two decades,[203] various entities have intensified efforts to standardize and streamline access to drug monitoring information across state lines.[204] In the early 2010s, the Office of the National Coordinator for Health IT (ONC), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the MITRE Corporation began to conduct research to improve access to PDMP information and incorporate its use across a variety of clinical settings.[205]

Standardization efforts accelerated in 2012 when the National Association of Boards of Pharmacy (NABP) launched its PMP InterConnect program, allowing virtually instantaneous access to multistate controlled substance

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199.   *A Balanced Approach to Opioids and Chronic Pain: Part X - Machine Learning*, APPRISS HEALTH (Sept. 19, 2018) [hereinafter *A Balanced Approach to Opioids and Chronic Pain*], https://web.archive.org/web/20210409004410/https://apprisshealth.com/blog/machine-learning/; Press Release, NIC, NIC Launches RxGov, a Best-in-Class Technology Choice for Government to Combat the Opioid Epidemic (Aug. 1, 2018), https://www.businesswire.com/news/home/20180801005187/en/NIC-Launches-RxGov-Best-in-Class-Technology-Choice-Government [https://perma.cc/6GJX-5J53].

200.   *Appriss Health & State Governments*, APPRISS HEALTH, https://apprisshealth.com/who-we-help/state-governments/ [https://perma.cc/VVV2-73LP] (self-identifying Appriss as "[t]he national leader in PDMP solutions" and contending that "[o]ur platform connects most U.S. PDMPs, close to 1 million prescribers and half a million care team members, more than 30,000 pharmacies, and thousands of hospitals, managing more than 400 million monthly transactions").

201.   *Id.*

202.   *Id.*

203.   *See, e.g.*, Report and Recommendations from the Workgroup on PDMPs, *supra* note 197, at 3; *see also* History of PDMPs, *supra* note 152, at 7. The availability of federal funding drove state adoption of laws requiring PDMP queries prior to prescribing or dispensing. Bulloch, *supra* note 169 ("PDMPs continued to grow through the 1990s and early 2000s, with 70% of program establishments occurring in the first 15 years of the 21st century. This growth was mainly a result of the Harold Rogers Prescription Drug Monitoring Grant in 2003, which provided federal funding to states to implement and enhance PDMPs.").

204.   Karen Blum, *IT Upgrades Bolster PDMP in Fight Against Opioid Misuse*, PAIN MED. NEWS (Feb. 27, 2014), https://www.painmedicinenews.com/Clinical-Pain-Medicine/Article/03-14/IT-Upgrades-Bolster-PDMP-In-Fight-Against-Opioid-Misuse/26026/ses=ogst [https://perma.cc/S3QH-TWB3].

205.   *Id.*

prescribing information.[206] States rapidly adopted PMP InterConnect and the NABP turned its efforts to development of its NARxCHECK software.[207] NARxCHECK was the NABP's "automatic prescription drug abuse assessment and management tool," which provided prescribers and dispensers with an individual score and report for each patient based on aggregated PDMP data.[208] The NABP aimed to increase the clinical use of PDMPs by providing "access to analytical tools to automate analysis of PMP reports," and NARxCHECK was intended to provide fully integrated clinical decision support within the PDMP platform.[209] NARxCHECK, therefore, constituted the first effort to develop computer-generated drug use "risk scores," a component of PDMP software that has developed at a rapid pace in the ensuing years.

PDMP risk scores calculate a patient-specific, numerical value that purports to represent the overall level of risk associated with prescribing the patient a controlled substance.[210] In this context, "risk" includes the patient's potential for drug misuse, abuse, diversion, addiction, and overdose.[211] The NARxCHECK-generated risk scores allegedly relied on "nationally recognized, research-proven factors indicative of risk," including the number of providers a patient consulted, the number of dispensing pharmacies a patient utilized, the amount of drug equivalent units per days of supply prescribed, the amount of drug overlap in the patient's prescribing history, and the number of active prescriptions the patient had on file at the time of prescribing.[212] Bamboo Health acquired NARxCHECK from the NABP in 2014 and expanded the type and scope of data utilized to calculate patient risk scores.[213]

Bamboo branded its PDMP risk scoring platform "NarxCare." Bamboo claims that it continues to "improve" the calculation of PDMP risk scores, which the company refers to as "Narx Scores."[214] Bamboo's Narx Scores provide

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206. Malcolm J. Broussard, 2012–2013 Chairperson, Nat'l Ass'n of Bds. of Pharmacy, Report of the Executive Committee 3 (May 18, 2013), https://perma.cc/C25R-YM2L.

207. *Id.* at 4.

208. Marty Allain, NARxCHECK Senior Manager, The Current State of Prescription Drug Monitoring Programs: Presentation at the National Association of Boards of Pharmacy Annual Conference 14 (Sept. 30, 2013), https://injurycenter.web.itd.umich.edu/sites/default/files/presentation-pdfs/Link%20to%20Marty%20Allain%27s%20Presentation.pdf [https://perma.cc/DDX4-273T].

209. *Id.* at 12–13.

210. J.E. Huizenga, B.C. Breneman, V.R. Patel, A. Raz & D.B. Speights, Appriss Health, NARxCHECK Score as a Predictor of Unintentional Overdose Death 1 (2016), https://apprisshealth.com/wp-content/uploads/sites/2/2017/02/NARxCHECK-Score-as-a-Predictor.pdf [https://perma.cc/UL8W-NH3Z].

211. *See id.* at 2, 7; Broussard, *supra* note 206, at 4–5.

212. Allain, *supra* note 208, at 15.

213. Press Release, Appriss Health, Appriss Acquires NARxCHECK from the National Association Boards of Pharmacy Foundation (Nov. 11, 2014), https://apprisshealth.com/press-release/appriss-acquires-narxcheck-from-the-national-association-boards-of-pharmacy-foundation/ [https://perma.cc/C5VG-2MXC].

214. *Our Partners*, APPRISS HEALTH (2021), https://apprisshealth.com/about/partners/ [https://perma.cc/Z9HZ-RXE4]; Appriss Health, *supra* note 213; Huizenga et al., *supra* note 210, at 3.

PDMP users as three-digit values ranging from 000 to 999.[215] According to Bamboo, a higher risk score correlates with an increased probability that the prescribing or dispensing of a particular drug to a particular patient will result in negative consequences.[216]

Bamboo's NarxCare platform deploys algorithms to calculate at least four separate Narx Scores in each patient's PDMP report.[217] Three of those scores provide a predictive analysis for "a host of outcomes" across three prescribing areas: narcotics (including opioids), sedatives (including benzodiazepines), and stimulants.[218] The system also calculates a composite "overdose risk" score as well as configurable "red flag" alerts to draw attention to specific data points captured by the Narx Score algorithms.[219] While NarxCare's algorithmic calculation of risk scores is proprietary, and therefore remains enigmatic, Bamboo acknowledges that the platform assigns various data points collected from PDMP information a "scaled value between 0 and 99" and the last digit of the predictive scores always represents the number of active prescriptions on record for the patient.[220]

Bamboo has publicly announced that, at a minimum, its Narx Scores algorithms measure and score the original NARxCHECK system risk indicators. These indicators include (1) the number of prescribers a patient has, (2) the number of pharmacies at which a patient fills medications, (3) the amount or strength of medications prescribed, (4) the presence or amount of potentiating medications, and (5) the number of overlapping prescriptions.[221] Bamboo further concedes that its algorithms also incorporate and evaluate myriad other "PDMP and non-PDMP" information to improve the "accuracy" of their numerical risk reporting system.[222]

PDMP data may include, among other things, the patient's name, age, gender, address, prescription history, method of payment,[223] distance travelled

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215. Up Front, Every Patient, Every Time, *supra* note 198, at 5.

216. *See, e.g.*, *id.* at 5–6; Broussard, *supra* note 206, at 5; Huizenga et al., *supra* note 210, at 3.

217. Up Front, Every Patient, Every Time, *supra* note 198, at 5–6.

218. Appriss Health, Virginia NarxCare Product Sheet 1 [hereinafter Virginia NarxCare Product Sheet], https://cdn2.hubspot.net/hubfs/2881008/PDFDocuments/NarxCare%20Product%20Sheet%20V2_VA. pdf [https://perma.cc/CSX9-NTGQ].

219. *Id.*; *see* Appriss Health, Addressing Substance Use Disorder Through Analytics and Technology 10 (2018) [hereinafter Addressing Substance Use Disorder Through Analytics and Technology], https://knowledgecenter.csg.org/kc/system/files/Cohen.Appriss.pdf [https://perma.cc/D726-3QQE].

220. Up Front, Every Patient, Every Time, *supra* note 198, at 7.

221. Appriss Health, About NarxCare: For Patients and Their Families 2, https://apprisshealth.com/wp-content/uploads/sites/2/2019/03/HLTH_Patient-Information-Sheet_FINAL.pdf [https://perma.cc/44QG-37CL]; *see* Allain, *supra* note 208, at 15.

222. Virginia NarxCare Product Sheet, *supra* note 218, at 1.

223. ERICA SPIES, ALEXIS PETERSON, AMANDA GARCIA-WILLIAMS, JOHN HALPIN, MATT GLADDEN, JON ZIBBELL & CAROLYN LULLO MCCARTY, CTRS. FOR DISEASE CONTROL & PREVENTION, UNDETERMINED RISK FACTORS FOR FENTANYL-RELATED OVERDOSE DEATHS 52–53 (2015), https://odh.ohio.gov/wps/wcm/connect/gov/1e032637-7f3d-4039-8f72-

to provider and dispenser, drug-related arrests and convictions, child welfare case information, criminal case information, drug court case information, medical marijuana dispensings, naloxone administrations and dispensings, overdose-related information, pharmaceutical manufacturer and distributor information, ARCOS data,[224] medical claims data, electronic health records, and EMS information.[225] Bamboo also has added messaging and communication features to its platform, including integration with hc1 Opioid Advisor software,[226] to enable data collection from additional sources.[227] The company has shown a clear desire to incorporate additional data sets,[228] and industry has suggested the inclusion of "contributory databases," including CLUE (auto industry), SIRIS (banking), MIDEX (real estate), and information provided from other businesses.[229]

In sum, Bamboo's PDMP platform collects a wealth of highly sensitive patient information, much of which appears to have little or questionable relevance to prescription opioid-related adverse event risk calculation. Given the American health care delivery system's emphasis on treatment "efficiency" and law enforcement scrutiny of PDMP data, it comes as little surprise that Narx Scores feature prominently in clinical decision-making.[230] Clinical reliance on

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c0c6f994a24e/CDC_EpiAid_Ohio.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ROOT WORKSPACE.Z18_M1HGGIK0N0JO00QO9DDDDM3000-1e032637-7f3d-4039-8f72-
c0c6f994a24e-mrAGSKH [https://perma.cc/M4T2-RCW9]; *see* CHAD GARNER, JIM HUIZENGA & DAVID SPEIGHTS, HOW TO PREDICT OVERDOSE DEATH WITH PDMP DATA AND ADVANCED ANALYTICS: PRESENTATION AT NATIONAL DRUG ABUSE & HEROIN SUMMIT 17 (Mar. 16, 2017), https://docplayer.net/50204352-How-to-predict-overdose-death-with-pdmp-data-and-advanced-analytics-live-webinar.html [https://perma.cc/RU7X-ZRX8] (pointing out that Appriss's PDMP risk score algorithms escalate if a patient pays with cash and that cash payment is one of the four risk factors strongly associated with overdose death).

224. *Prescription Drug Monitoring Program: Louisiana State Profile*, OFF. OF JUST. PROGRAMS (Aug. 2018), https://www.ojp.gov/ncjrs/virtual-library/abstracts/prescription-drug-monitoring-program-louisiana-state-profile [https://perma.cc/23SN-KY6Z] (acknowledging that the Louisiana PDMP "also has the authority to monitor other substances, including marijuana data, ARCOS data, and drug manufacturers or distribution data"). ARCOS refers to the Automation of Reports and Consolidated Orders System, a national drug tracking system operated by the Department of Justice. *See supra* notes 106–107 and accompanying text.

225. Virginia NarxCare Product Sheet, *supra* note 218, at 1.

226. *hc1 Opioid Advisor*, hc1, https://www.hc1.com/solutions/opioid-advisor/ [https://perma.cc/4TX5-UFNC] (explaining that the "hc1 Opioid Advisor, delivered via a strategic partnership with Appriss Health . . . automatically compares toxicology results with PDMP data" by "connect[ing] with the laboratory information system to perform an intelligent consistency analysis of toxicology results compared to the PDMP in real-time").

227. Addressing Substance Use Disorder Through Analytics and Technology, *supra* note 219, at 12–13, 16.

228. *Id.* at 6.

229. TONY SCHUETH, THOMAS BIZZARO, BRIAN EIDEX & ROB COHEN, PDMP ALERTS, ANALYTICS AND THE PHARMACY WORKFLOW: PRESENTATION AT NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS CONFERENCE 2 (May 9, 2017), https://pocp.com/wp-content/uploads/PDMP_FinalNCPDP_2017AC.pdf [https://perma.cc/Z49D-ACRQ].

230. Huizenga et al., *supra* note 210, at 7 (explaining that "prescribers and pharmacists are increasing their use of PDMP data as a tool for clinical decision support" sometimes due to "self-motivation" and sometimes driven by "regulatory compliance").

Narx Scores is the focus of the next Section of this Article, which also explores the significant accuracy problems that attend to Narx Scores and their potential disparate impacts on marginalized populations.

IV.

A DATA SCIENCE CRITIQUE OF PDMP RISK SCORES

> [Automated decision] opacity, combined with the risk of bias and injustice resulting from decisions taken at the design stage, and in relation to the data used to train automated systems, means that these systems can reproduce or intensify inequalities already existing in society.[231]

The adoption of a privately manufactured, proprietary digital risk scoring platform by state PDMP agencies may seem unsurprising given America's ubiquitous reliance on automated decision-making.[232] Mathematical models generate rules that determine who is entitled to employment,[233] higher education,[234] housing,[235] and various types of public benefits.[236] They also discern, among other things, who deserves reasonably priced credit[237] and which of us will receive triage treatment priority during a critical care capacity crisis.[238] As has been widely reported, U.S. law enforcement agencies rely on predictive algorithms to police and profile the public,[239] and courts use digital technology

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231. Alison Powell, *Understanding Automated Decisions: Reaching the Limits of Explainability?*, MEDIA@LSE (Nov. 26, 2019), https://blogs.lse.ac.uk/medialse/2019/11/26/understanding-automated-decisions-reaching-the-limits-of-explainability/ [https://perma.cc/JA8A-44FN].

232. *See, e.g.*, Hannah Bloch-Wehba, *Access to Algorithms*, 88 FORDHAM L. REV. 1265 (2020); Danielle Keats Citron, *Technological Due Process*, 85 WASH. U. L. REV. 1249 (2008).

233. Miranda Bogen, *All the Ways Hiring Algorithms Can Introduce Bias*, HARV. BUS. REV. (May 6, 2019), https://hbr.org/2019/05/all-the-ways-hiring-algorithms-can-introduce-bias [https://perma.cc/6VSL-TUYM].

234. DJ Pangburn, *Schools Are Using Software to Help Pick Who Gets In. What Could Go Wrong?*, FAST CO. (May 17, 2019), https://www.fastcompany.com/90342596/schools-are-quietly-turning-to-ai-to-help-pick-who-gets-in-what-could-go-wrong [https://perma.cc/A2S8-BWYV].

235. Patrick Sisson, *Housing Discrimination Goes High Tech*, CURBED (Dec. 17, 2019), https://archive.curbed.com/2019/12/17/21026311/mortgage-apartment-housing-algorithm-discrimination [https://perma.cc/9KFS-CG4D].

236. Michele Gilman, *Poverty Lawgorithms* 5 (2020), https://datasociety.net/wp-content/uploads/2020/09/Poverty-Lawgorithms-20200915.pdf [https://perma.cc/KX5U-2ARC] (pointing out that "[m]illions of Americans have lost access to desperately needed public benefits as a result of coding errors" and other automated decision-making errors).

237. Talia Gillis, *Discriminating Credit Algorithms*, OXFORD BUS. L. BLOG (June 18, 2020), https://www.law.ox.ac.uk/business-law-blog/blog/2020/06/discriminating-credit-algorithms [https://perma.cc/7JX8-4GYF].

238. Colin K. Grissom, Samuel M. Brown, Kathryn G. Kuttler, Jonathan P. Boltax, Jason Jones, Al R. Jephson & James F. Orme, Jr., *A Modified Sequential Organ Failure Assessment (MSOFA) Score for Critical Care Triage*, 4 DISASTER MED. & PUB. HEALTH PREPAREDNESS 1, 1 (2010).

239. *See, e.g.*, ANDREW GUTHRIE FERGUSON, THE RISE OF BIG DATA POLICING: SURVEILLANCE, RACE, AND THE FUTURE OF LAW ENFORCEMENT (2017); SARA ESTHER LAGESON, DIGITAL PUNISHMENT: PRIVACY, STIGMA, AND THE HARMS OF DATA-DRIVEN CRIMINAL JUSTICE (2020).

to forecast recidivism risk and make pre-trial release and sentencing determinations.[240]

The pervasiveness of algorithmic governance in modern life has motivated a robust literature that exposes government surveillance and predictive risk scoring as controlling, manipulative, and discriminatory.[241] Experts also query whether the inherent opaqueness of algorithm-driven models is intentional insofar as their obscurity renders them difficult to regulate.[242] Such critiques stem from several inextricably intertwined issues that pertain to predictive scoring models, each of which is explained and applied to PDMP risk scoring in the following Sections.

A.   Defining and Evaluating Risk Model Success

A model's blind spots reflect the judgments and priorities of its creators.[243]

A bedrock principle of data science is that the designer of a predictive algorithmic model should define and routinely evaluate the model's success. As mathematician Cathy O'Neil pointed out, "a key component of every [predictive] model . . . is its definition of success" and, as such, "we must ask not only who designed the model but also what that person or company is trying to accomplish."[244] This is because the model's objectives necessarily drive its design, implementation, and evaluative metrics.[245]

Dr. O'Neil's well-informed perspective prompts at least three questions concerning PDMP risk assessment models. First, what purpose does the PDMP NarxCare platform serve? Second, how does NarxCare define success? Finally, what metrics do Bamboo and state PDMP agencies use to measure and assess the platform's performance?

Bamboo characterizes NarxCare as "[a] substance use disorder platform" that "empowers prescribers and dispensers to identify patients that may be at risk

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240.   *See, e.g.*, Erin Collins, *Punishing Risk*, 107 GEO. L.J. 57 (2018).

241.   *See, e.g.*, RUHA BENJAMIN, RACE AFTER TECHNOLOGY: ABOLITIONIST TOOLS FOR THE NEW JIM CODE (2019); VIRGINIA EUBANKS, AUTOMATING INEQUALITY: HOW HIGH-TECH TOOLS PROFILE, POLICE, AND PUNISH THE POOR (2018); SAFIYA UMOJA NOBLE, ALGORITHMS OF OPPRESSION: HOW SEARCH ENGINES REINFORCE RACISM (2018); CATHY O'NEIL, WEAPONS OF MATH DESTRUCTION: HOW BIG DATA INCREASES INEQUALITY AND THREATENS DEMOCRACY (2016); FRANK PASQUALE, THE BLACK BOX SOCIETY: THE SECRET ALGORITHMS THAT CONTROL MONEY AND INFORMATION (2015); DOROTHY ROBERTS, FATAL INVENTION: HOW SCIENCE, POLITICS, AND BIG BUSINESS RE-CREATE RACE IN THE TWENTY-FIRST CENTURY (2011).

242.   *See* Pasquale, *supra* note 241, at 4.

243.   O'Neil, *supra* note 241, at 21.

244.   *Id.*

245.   *See id.* at 1–31; *see also* Karel G.M. Moons, Douglas G. Altman, Johannes B. Reitsma, John P.A. Ioannidis, Petra Macaskill, Ewout W. Steyerberg, Andrew J. Vickers, David F. Ransohoff & Gary S. Collins, *Transparent Reporting of Multivariate Prediction Model for Individual Prognosis or Diagnosis (TRIPOD): Explanation and Elaboration*, 162 ANNALS INTERNAL MED. W1 (2015).

for prescription drug addiction, overdose and death."[246] It contends that the platform "aggregates and analyzes prescription information from providers and pharmacies and presents interactive, visual representations of that information, as well as advanced analytic insights, complex risk scores and more to help physicians, pharmacists and care teams to *provide better patient safety and better patient outcomes*."[247] Ohio claims that its NarxCare PDMP platform[248] "is designed to monitor . . . for suspected abuse or diversion (i.e., channeling drugs into illegal use)" and that such information "can help prescribers and pharmacists *identify high-risk patients who would benefit from early interventions*."[249] North Carolina maintains that its NarxCare-powered PDMP[250] "*is used as a clinical tool to improve patient care and safety* while avoiding potential drug interactions and identifying individuals that may be in need of referral to substance use disorder services."[251] The ONDCP contends that PDMPs "serve multiple functions, including: patient care tool; drug epidemic early warning system; and drug diversion and insurance fraud investigative tool."[252]

To the extent that PDMP risk scoring platforms aim to modify clinical behavior, thereby reducing the sheer amount opioids that providers prescribe without concern for collateral consequences, they appear to be a success. Opioid prescriptions decreased by 60 percent between 2012 and 2019 alone.[253] If, however, the purpose of PDMP risk scoring software is to reduce drug misuse or overdose deaths, the platforms appear to perform poorly. While results are

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246. Appriss Health, NarxCare 1–2, https://mha.org/Portals/0/Documents/News%20Room/appriss-health-narxcare.pdf [https://perma.cc/Y2AU-JRYL].

247. *Id.* at 1 (emphasis added); *see* Appriss Health, Yale New Haven Health Case Study 4, https://info.apprisshealth.com/hubfs/HLTH%20-%20Case%20Studies/HLTH-CS-YaleNewHaven_FINAL.pdf [https://perma.cc/X6CT-7F47].

248. Press Release, Appriss Health, Appriss Health to Provide NarxCare Platform to Ohio Prescribers and Pharmacists to Assist in Clinical Decision-Making and Promote Patient Safety (Nov. 2, 2017), https://apprisshealth.com/press-release/appriss-health-provide-narxcare-platform-ohio-prescribers-pharmacists-assist-clinical-decision-making-promote-patient-safety/ [https://perma.cc/8QB5-ZQGL].

249. *Welcome to OARRS*, OHIO AUTOMATED RX REPORTING SYS. (emphasis added), https://www.ohiopmp.gov/ [https://perma.cc/5FGG-HSLG].

250. Press Release, Appriss Health, N.C. Department of Health and Human Services Partners with Appriss Health to Provide Access to NarxCare Platform and Controlled Substances Reporting System Information Directly Within Electronic Health Record and Pharmacy Management Systems (Nov. 26, 2018), https://apprisshealth.com/press-release/n-c-department-of-health-and-human-services-partners-with-appriss-health-to-provide-access-to-narxcare-platform-and-controlled-substances-reporting-system-information-directly-within-electronic-healt/ [https://perma.cc/4AZW-UX4Z].

251. *NC Controlled Substances Reporting System*, N.C. DEP'T OF HEALTH & HUM. SERVS. (emphasis added), https://www.ncdhhs.gov/divisions/mental-health-developmental-disabilities-and-substance-abuse/north-carolina-drug-control-unit/nc-controlled-substances-reporting-system [https://perma.cc/3PT8-CK5D].

252. OFF. OF NAT'L DRUG CONTROL POL'Y, FACT SHEET: PRESCRIPTION DRUG MONITORING PROGRAMS 1 (2011), https://www.ncjrs.gov/pdffiles1/ondcp/pdmp.pdf [https://perma.cc/NB58-TY2T].

253. IQVIA INST. FOR HUM. DATA SCI., PRESCRIPTION OPIOID TRENDS IN THE UNITED STATES 3 (2020); *see U.S. Opioid Dispensing Rate Maps*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html [https://perma.cc/HR7J-BQX7].

mixed, research rarely associates PDMPs with reduced overdose mortality rates.[254] In fact, several studies associate PDMPs with *increased illicit drug overdose mortality*,[255] and the national drug overdose statistics bolster those results.[256]

Worse yet, drug overdoses have increased exponentially as PDMP platforms have enhanced their predictive surveillance capabilities. As previously noted, the CDC recently released a provisional report announcing record high national overdose deaths during 2020.[257] As has been the trend over the prior several years, those deaths were overwhelmingly driven by illicitly manufactured fentanyl and psychostimulants, such as methamphetamine. Those deaths were not overwhelmingly driven by prescription drugs, raising the concern that individuals with OUD are switching from regulated and safer drugs to a much more dangerous illicit supply.[258]

Bamboo and various state PDMP agencies expressly contend that risk scoring aims to enhance patient safety and health outcomes.[259] The goal of improved patient health outcomes ought to be inherent to digital tools used to diagnose and treat patients. It also should be a primary objective of PDMP risk assessment platforms given the well-documented collateral consequences of non-individualized and, therefore, arbitrary opioid deprescribing. As experts have pointed out, there is "widespread recognition that reductions in [opioid] prescribing [were] not implemented in ways that consistently protected patients. Patients, media, government agencies, and professional literature acknowledged instances of worsening pain, loss of access to care, and death by suicide. . . ."[260]

NarxCare, however, neither tracks nor assesses patient health outcomes related to opioid deprescribing and tapering. As previously explained, NarxCare generates patient risk scores by scouring through the troves of information that PDMP databases collect to identify and weigh various data points that the company's software designers have designated as "proxies" for drug diversion, misuse, and overdose. NarxCare does not evaluate whether clinical deprescribing decisions improve or worsen patients' pain, mental health, daily functioning, or quality of life. NarxCare neither "flags" prescribers nor sends

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254.   *See* Young Hee Nam, Dennis G. Shea, Yunfeng Shi & John R. Moran, *State Prescription Drug Monitoring Programs and Fatal Drug Overdose*, 23 AM. J. MANAGED CARE 297, 298 (2017).

255.   *Id.* at 300; *see also* Li et al., *supra* note 186, at 3; *The Myth of an Opioid Prescription Crisis*, *supra* note 184, at 11.

256.   *See Drug Overdose Death Counts*, *supra* note 6.

257.   *Id.*; *see* HEALTH ADVISORY, CTRS. FOR DISEASE CONTROL & PREVENTION, INCREASE IN FATAL DRUG OVERDOSES ACROSS THE UNITED STATES DRIVEN BY SYNTHETIC OPIOIDS BEFORE AND DURING THE COVID-19 PANDEMIC (Dec. 17, 2020), https://emergency.cdc.gov/han/2020/pdf/CDC-HAN-00438.pdf [https://perma.cc/B5KF-TKQA].

258.   *See* sources cited *supra* note 257.

259.   Appriss Health, *supra* note 246.

260.   Stefan G. Kertesz, Megan B. McCullough, Beth D. Darnall & Allyson L. Varley, *Promoting Patient-Centeredness in Opioid Deprescribing: A Blueprint for De-implementation Science*, 35 J. GEN. INTERNAL MED. S972, S972 (2020).

clinicians an alert when a medication-discontinued or force-tapered patient dies by suicide or is admitted to the emergency room with debilitating pain or depression.

NarxCare does not track and assess patient health outcomes because the platform's success is not measured by those results. This ought to worry clinicians, state health agencies, and state health care professional licensing boards. Best practices demand that opioid deprescribing "be undertaken with care, so as to alleviate adverse outcomes and avoid exacerbating health care inequities."[261] As a result and to the extent that state law and policy mandate the clinical use of PDMP risk scoring for the purpose of improving patient outcomes, state PDMP agencies should require NarxCare to track and assess patient outcomes and utilize those outcomes to measure NarxCare's success.[262]

B. *Clinical Bias in NarxCare Utilization*

Predictive algorithmic models can be corrupted by human error or bias at numerous stages of the model's life cycle because humans design the model, determine its goals, write the code, choose the model's data sources, and implement the model.[263] Due to its alluring appearance of objectivity, machine-generated decision-making is dangerous. It is indisputable, however, that digital risk scoring platforms encode social and economic biases that reproduce and exacerbate existing inequities.[264] As a result, predictive technology often has a disparate impact on marginalized populations, including women, racial and ethnic minorities, and individuals who live in poverty.[265] Dr. Ruha Benjamin characterizes "the employment of new technologies that reflect and reproduce existing inequalities but that are promoted and perceived as more objective and progressive than the discriminatory systems of a previous era" as "the New Jim Code."[266] In this connection, the following Sections chronicle the likely disparate impacts that PDMPs risk scoring will visit on several categories of marginalized patients, including complex chronic pain patients, individuals with OUD, individuals who live in poverty, and patients who are perceived as Black, female, or both.

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261. *Id.* at S973.

262. *Id.* at S975 ("Health systems must measure outcomes of their de-implementation efforts to ensure that their actions are advancing patient health.").

263. Wenlong Sun, Olfa Nasraoui & Patrick Shafto, *Evolution and Impact of Bias in Human and Machine Learning Algorithm Interaction*, 15 PLOS ONE 1, 1 (2020).

264. *See, e.g.*, Ed Pilkington, *Digital Dystopia: How Algorithms Punish the Poor*, GUARDIAN (Oct. 14, 2019), https://www.theguardian.com/technology/2019/oct/14/automating-poverty-algorithms-punish-poor [https://perma.cc/Y25Q-2WHZ]; Navneet Alang, *Turns Out Algorithms Are Racist*, NEW REPUBLIC (Aug. 31, 2017), https://newrepublic.com/article/144644/turns-algorithms-racist [https://perma.cc/9NCH-X9RW]; Tom Simonite, *Machines Taught by Photos Learn a Sexist View of Women*, WIRED (Aug. 21, 2017), https://www.wired.com/story/machines-taught-by-photos-learn-a-sexist-view-of-women/ [https://perma.cc/S3NM-2SAC].

265. *See* sources cited *supra* note 264.

266. Benjamin, *supra* note 241, at 5–6.

1. Opioid Prescribing Discrimination and Complex Chronic Pain Patients

[F]or over a 1000 years [sic], pain stigma has been an enduring feature of the experience in the West.[267]

Medicine has a long history of discriminating against patients with complex, chronic pain across racial, ethnic, and gender lines.[268] Much of this disparate treatment has been chalked up to western medicine's disdain for—and discrediting of—disorders that clinicians cannot "see" and do not understand.[269] Such beliefs date back to the Cartesian dualist notion that our minds are disconnected from our bodies and that, therefore, invisible injuries and their concomitant pain and suffering are simply psychogenetic.[270] Primary care physicians not only acknowledge that they are insufficiently trained in pain management, but they "rate their satisfaction with treating chronic pain lower than treating acute, cancer, or terminal illness pain."[271]

Clinical reliance on PDMP risk scores reinforces the widespread stigma and distrust that attend to chronic pain patients.[272] Scoring pain patients as risky for nefarious behavior is congruent with providers' unwillingness to put stock in the self-reports of patients they deem suspicious and "untrustworthy."[273] "Physician worries about iatrogenic addiction and whether patients are 'drug seeking', 'abusing' and 'diverting' prescription opioids exist against a backdrop of professional and legal consequences of prescribing [surveillance] that have created a climate of distrust in chronic pain management."[274] Distrust between providers and patients is problematic in the clinical setting because it can

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267. Daniel S. Goldberg, *Pain, Objectivity and History: Understanding Pain Stigma*, 43 MED. HUMANS. 238, 238 (2017).

268. *Id.*

269. Milton Cohen, John Quintner, David Buchanan, Mandy Neilsen & Lynette Guy, *Stigmatization of Patients with Chronic Pain: The Extinction of Empathy*, 12 PAIN MED. 1637, 1637–39 (2011); *see also* Lorna J. Simon, Aurelia N. Bizamcer, Charles W. Lidz, Susan Stefan & Mark J. Pletcher, *Disparities in Opioid Prescribing for Patients with Psychiatric Diagnoses Presenting with Pain to the Emergency Department*, 29 EMERGENCY MED. J. 201, 202 (2012) ("Pain levels for pain-related visits of patients with psychiatric diagnosis were less likely to be evaluated by the clinician as 'severe', and more likely to be evaluated as 'no pain' . . . . [O]nly 18% . . . of pain-related visits by patients with psychiatric diagnoses resulted in either an opioid prescription at discharge or the administration of an opioid during the visit, whereas 33% . . . of visits by other patients did.").

270. Cohen et al., *supra* note 269, at 1638.

271. Carole C. Upshur, Gonzalo Bacigalupe & Roger Luckmann, *"They Don't Want Anything to Do with You"; Patient Views of Primary Care Management of Chronic Pain*, 11 PAIN MED. 1791, 1791 (2010).

272. Goldberg, *supra* note 267, at 238 ("While there are no good estimates of the prevalence of pain stigma, extensive qualitative evidence across a wide variety of settings documents that such stigma is an altogether typical experience. . . . there is no serious dispute that [pain] stigma, and especially chronic pain stigma, is part and parcel of the illness experience for far too many.").

273. Daniel Z. Buchman, Anita Ho & Judy Illes, *You Present Like a Drug Addict: Patient and Clinician Perspectives on Trust and Trustworthiness in Chronic Pain Management*, 17 PAIN MED. 1394, 1398 (2016).

274. Daniel Z. Buchman & Anita Ho, *What's Trust Got to Do with It? Revisiting Opioid Contracts*, 40 J. MED. ETHICS 673, 673 (2014).

provoke a provider to make poor treatment decisions or even miss a serious illness that warrants immediate attention.[275] In addition, patients who sense provider distrust are less likely to be forthcoming about their symptoms and struggles and may even forgo treatment.[276]

Further evidencing a culture of stigma and distrust in chronic pain care settings is the prevalent imposition of behavioral controls on pain patients as a prerequisite to treatment.[277] Clinicians frequently require chronic pain patients to execute "opioid treatment contracts" that require patients to comply with a panoply of rules in exchange for opioid therapeutics.[278] These rules include mandates to submit to random, in-person urine drug tests (UDTs), unannounced pill counts, and PDMP surveillance.[279] Opioid treatment contracts also make it clear that violations of their behavioral edicts can trigger forced tapers and treatment termination—either of which can be dangerous and even deadly for opioid patients due to the severity of opioid withdrawal.[280]

Chronic pain patients are well aware of the health-harming and stigma-enhancing "climate of distrust" in the treatment setting. A group of qualitative researchers conducted focus group interviews with seventeen sets of chronic pain patients and found that "across all . . . gender, ethnicity, and age groups, most patients reported suboptimal interactions with their providers when seeking care for chronic pain. Subjects acknowledged feeling disrespected and distrusted, suspected of drug-seeking, and having their symptoms dismissed . . . and/or not warranting medical care."[281]

Recent research concerning opioid patient experiences with PDMP surveillance reinforce these findings. In response to a Health in Justice Action Lab survey, "more than half of [opioid patients] described an experience with the PDMP system which left them feeling criminalized, stigmatized, and/or humiliated" and "over 50% of patients reported that a negative interaction with the PDMP system resulted in detrimental change to their medical care and/or

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275. Deborah Hellman, *Prosecuting Doctors for Trusting Patients*, 16 GEO. MASON L. REV. 701, 735–77 (2009).

276. Leonieke C. van Boekel, Evelien P.M. Brouwers, Japp van Weeghel & Henk F.L. Garretsen, *Stigma Among Health Professionals Towards Patients with Substance Use Disorders and Its Consequences for Healthcare Delivery: Systematic Review*, 131 DRUG & ALCOHOL DEPENDENCE 23, 24 (2013).

277. Buchman & Ho, *supra* note 274, at 674.

278. *See, e.g.*, AM. ACAD. OF PAIN MED., AGREEMENT ON CONTROLLED SUBSTANCES THERAPY FOR CHRONIC PAIN TREATMENT (2013), https://www.cmezone.com/Content/pdf/APS_Controlled_Substances_Agreement.pdf [https://perma.cc/M9YK-KENG].

279. Scott M. Fishman, Rollin M. Gallagher & Bill H. McCarberg, *The Opioid Treatment Agreement: A Real-World Perspective*, 10 AM. J. BIOETHICS 14, 14 (2010) (concluding that "opioid treatment agreements are a standard of care when prescribing chronic opioid therapy").

280. Travis N. Rieder, *Is Nonconsensual Tapering of High-Dose Opioid Therapy Justifiable?*, 22 AMA J. ETHICS 651, 654–55 (2020).

281. Upshur et al., *supra* note 271, at 1791.

abandonment by their provider."[282] 43 percent of patients further reported that they experienced increased pain and a decreased quality of life as a result of their interaction with a PDMP.[283] As the study concluded, "[g]iven mixed evidence of [PDMP] impact, the unintended harms of these systems warrant urgent examination. This includes deterring proper prescribing practices; chilling help-seeking among patients, especially those made vulnerable by a history of trauma in healthcare settings and criminal justice involvement; and further fraying the fabric of provider-patient trust."[284]

2. *Opioid Prescription Discrimination and Black Patients*

> Addiction is viewed as an evil to be avoided even when its likelihood is low, leaving patients to a stoic absorption of pain that most cannot achieve.[285]

Due to the complex ways in which ableism, racism, and sexism interact, patients with chronic pain or OUD who take opioids and are perceived as Black or female are subjected to multidimensional, intersectional discrimination and subordination by health care providers.[286] In 2019, the HBO comedy show, *Last Week Tonight with John Oliver*, aired an episode centered around gender and racial bias in medicine.[287] During the show, Mr. Oliver plays a clip of Black comedian Wanda Sykes commenting as follows:

> "Because of racism, Black people, we don't even get our hands on opioids. They don't even give them to us. White people get opioids like they tic tacs. . . . I had a double mastectomy. You know what they sent my Black ass home with? Ibu-[expletive]-pro-fen."[288]

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282. *Prescription Drug Monitoring Programs*, Health in JUST. ACTION LAB, https://www.healthinjustice.org/prescription-drug-monitoring [https://perma.cc/J8CH-MTG9].

283. *Id.*

284*. Id.*

285. Barry R. Furrow, *Pain Management and Provider Liability: No More Excuses*, 29 J.L. MED. & ETHICS 28, 29 (2001).

286. *See, e.g.*, Kimberlé Crenshaw, *Demarginalizing the Intersection of Race and Sex: A Black Feminist Critique of Antidiscrimination Doctrine, Feminist Theory and Antiracist Politics*, 1989 U. CHI. LEGAL F. 139, 140 ("Because the intersectional experience is greater than the sum of racism and sexism, any analysis that does not take intersectionality into account cannot sufficiently address the particular manner in which Black women are subordinated."); Angela P. Harris, *Race and Essentialism in Feminist Legal Theory*, 42 STAN. L. REV. 581, 588–89 (1990) ("The result of essentialism is to reduce the lives of people who experience multiple forms of oppression to addition problems. . . . Thus, in an essentialist world, black women's experience will always be forcibly fragmented before being subjected to analysis, as those who are 'only interested in race' and those who are 'only interested in gender' take their separate slices of our lives."); Pulrang, *supra* note 194 ("As a Black woman with a physical disability who lives with chronic pain . . . I have encountered multiple barriers to accessing opioids for chronic pain management. I suspect that ableism, racism, and sexism interact in complex ways that lead to me being treated in this way, as well as class as I was on Medicaid and/or Medicare at the time of each incident." (quoting Dr. Angel Miles)).

287. *Last Week Tonight with John Oliver: Bias in Medicine* (HBO broadcast Aug. 18, 2019), available at https://www.youtube.com/watch?v=TATSAHJKRd8 [https://perma.cc/5G2H-RG3S].

288*. Id.* at 12:02–12:32.

Like the overwhelming majority of Ms. Sykes' material, these observations landed with the audience because they are true. Research demonstrates long-standing and persistent implicit biases against Black Americans across the spectrum of medical practice, including in pain assessment and treatment.[289] Black people are systematically underassessed and undertreated for pain.[290] They are less likely to be prescribed analgesics to treat moderate to severe pain than White patients and, even when Black patients are prescribed opioids, they receive lower doses than white patients with identical medical conditions.[291] The disparities between Black and White patients in opioid analgesia prescribing are so widespread they even extend to young Black children with severe injuries.[292]

A recent study examining this phenomenon found that "a substantial number of white laypeople and *medical students and residents* hold false beliefs about biological differences between blacks and whites and . . . these beliefs predict racial bias in pain perception and treatment recommendation accuracy."[293] The biases that undermine appropriate pain management and analgesia prescribing for Black people are incredible. Among other things, the researchers concluded that approximately 73 percent of non-medically trained White people endorsed at least one known false belief about the biological differences between Black people and White people that would result in lower

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289. *See, e.g.*, Kelly M. Hoffman, Sophie Trawalter, Jordan R. Axt & M. Norman Oliver, *Racial Bias in Pain Assessment and Treatment Recommendations, and False Beliefs About Biological Differences Between Blacks and Whites*, 113 PROC. NAT'L ACAD. SCIS. 4296 (2016); Diana J. Burgess, David B. Nelson, Amy A. Gravely, Matthew J. Bair, Robert D. Kerns, Diana M. Higgins, Michelle van Ryn, Melissa Farmer & Melissa R. Partin, *Racial Differences in Prescription of Opioid Analgesics for Chronic Noncancer Pain in a National Sample of Veterans*, 15 J. PAIN 447 (2014); UNEQUAL TREATMENT: CONFRONTING RACE AND ETHNIC DISPARITIES IN HEALTH CARE (Brian D. Smedley, Adrienne Y. Stith & Alan R. Nelson eds., 2013), https://www.ncbi.nlm.nih.gov/books/NBK220358/pdf/Bookshelf_NBK220358.pdf [https://perma.cc/AV5G-9283]; Ronald Wyatt, *Pain and Ethnicity*, 15 AMA J. ETHICS 449 (2013); Vickie L. Shavers, Alexis Bakos & Vanessa B. Sheppard, *Race, Ethnicity, and Pain Among the U.S. Adult Population*, 21 J. HEALTH CARE FOR POOR & UNDERSERVED 177 (2010); Karen O. Anderson, Carmen R. Green & Richard Payne, *Racial and Ethnic Disparities in Pain: Causes and Consequences of Unequal Care*, 10 J. PAIN 1187 (2009); Knox H. Todd, Christi Deaton, Anne P. D'Amado & Leon Goe, *Ethnicity and Analgesic Practice*, 35 ANNALS EMERGENCY MED. 11 (2000).

290. Hoffman et al., *supra* note 289, at 4296 ("Extant research has shown that, relative to white patients, black patients are less likely to be given pain medications and, if given pain medications, they receive lower quantities.").

291. *See, e.g.*, Todd et al., *supra* note 289, at 11 ("White patients were significantly more likely than black patients to receive ED analgesics (74% versus 57% . . .) despite similar records of pain complaints in the medical record. The risk of receiving no analgesic while in the ED was 66% greater for black patients than for white patients . . . ."); Charles S. Cleeland, René Gonin, Luis Baez, Patrick Loehrer & Kishan J. Pandya, *Pain and Treatment of Pain in Minority Patients with Cancer*, 127 ANNALS INTERNAL MED. 813, 815 (1997) (finding that only 35 percent of racial minorities with metastatic or recurrent cancer received appropriate analgesia prescriptions compared with 50 percent for non-minority patients).

292. Monika K. Goyal, Nathan Kuppermann, Sean D. Cleary, Stephen J. Teach & James M. Chamberlain, *Racial Disparities in Pain Management of Children with Appendicitis in Emergency Departments*, 169 JAMA PEDIATRICS 996, 999 (2015) ("Black children with appendicitis were less likely to receive opioid analgesia than white children (12.2% . . . vs. 33.9% . . . , respectively . . .).").

293. Hoffman et al., *supra* note 289, at 4296 (emphasis added).

pain ratings for Black people.[294] Worse yet, *50 percent of medical students and residents polled endorsed at least one of those same false beliefs*.[295] Such fictions, which reflect fantastical notions rooted in slave breeding that Black people are immune to pain and physically superior to White people, include the following:

- Black people's nerve endings are less sensitive than White people's;

- Black people's skin is thicker than White people's;

- Black people's blood coagulates more quickly than White people's; and

- Black people have a stronger immune system than White people.[296]

The overwhelming evidence demonstrates that racism is deeply embedded in medicine and clinicians routinely refuse to prescribe opioid analgesics to Black people with debilitating and life-threatening conditions. Yet, the response to that uncontested information has not been outrage. Instead, the *New York Times* published an article written by two White men in 2019 entitled *A 'Rare Case' Where Racial Biases' Protected African-Americans*.[297] As its title makes obvious, the article contends that racism benefitted Black Americans because it spared them exposure to prescription opioids and potential drug use disorder.[298] These authors, of course, were not alone in expressing such sentiments. In an interview with NPR, Dr. Andrew Kolodny, who serves as executive director of Physicians for Responsible Opioid Prescribing (PROP), stated:

> Something that we do know is that doctors prescribe narcotics more cautiously to their non-white patients. It would seem that if the patient is black, the doctor is more concerned about the patient becoming addicted, or maybe they're more concerned about the patient selling their pills, or maybe they are less concerned about pain in that population. But the black patient is less likely to be prescribed narcotics, and therefore less likely to wind up becoming addicted to the medication. So what I believe is happening is that *racial stereotyping is having a protective effect on non-white populations*.[299]

Dr. Kolodny's argument that the undertreatment of Black pain and suffering benefits Black people is both audaciously racist and entirely undermined by the actual facts. "The American health care system is beset with

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294. *Id.* at 4297.

295. *Id.* at 4298.

296. *Id.*

297. Austin Frakt & Toni Monkovic, *A 'Rare Case Where Racial Biases' Protected African-Americans*, N.Y. TIMES (Nov. 25, 2019), https://www.nytimes.com/2019/11/25/upshot/opioid-epidemic-blacks.html [https://perma.cc/EX4C-SEES].

298. *Id.*

299. All Things Considered, *Why Is The Opioid Epidemic Overwhelmingly White?*, NPR (Nov. 4, 2017), https://www.npr.org/2017/11/04/562137082/why-is-the-opioid-epidemic-overwhelmingly-white [https://perma.cc/4VWC-MCPQ].

inequalities that have a disproportionate impact on people of color and other marginalized groups" and exactly none of those inequalities benefit Black people who continue to face significant obstacles to treatment, receive lower quality care, and experience far worse health outcomes than their White counterparts.[300] Moreover, not only have Black Americans not benefitted from inequitable treatment during the U.S. drug overdose crisis, they have experienced the highest increase in overdose deaths involving illicit synthetic opioids of any racial group in the nation since 2011.[301] Worse yet, the tragic impacts of the drug overdose crisis on Black communities gets more harrowing each year. "Black men in Missouri are now four times more likely than a white person to die of an overdose" and "[i]n Massachusetts, health officials announced that overdose deaths among Black men soared in 2020 by nearly 70%."[302] Moreover, "[i]n 2020, drug overdose death rates among Black Americans overtook those of white Americans for the first time since the 1990s," constituting "a sharp reversal from 2010, when white Americans were over twice as likely to die of overdose."[303]

3. Opioid Prescription Discrimination and Women Patients

Woman is a pain that never goes away.[304]

Women's pain and suffering also has been discounted, underassessed, and undertreated by clinicians.[305] As two legal scholars observed, providers resort to a number of misogynistic excuses to ignore women's pain: "[w]omen complain more than men; women are not accurate reporters of their pain; men are more

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300. Jamila Taylor, *Racism, Inequality, and Health Care for African Americans*, CENTURY FOUND. (Dec. 19, 2019), https://tcf.org/content/report/racism-inequality-health-care-african-americans/?agreed=1 [https://perma.cc/Q7R7-7BRQ] ("[T]he disparities in health outcomes between African Americans and whites are stark.").

301. THE OPIOID CRISIS AND THE BLACK/AFRICAN AMERICAN POPULATION, *supra* note 143, at 4.

302. Claire Galofaro, *In Pandemic, Drug Overdoses Soar Among Black Americans*, ABC NEWS (June 24, 2021), https://abcnews.go.com/Lifestyle/wireStory/pandemic-drug-overdose-deaths-soar-black-americans-78459019 [https://perma.cc/66EF-H79T].

303. Joseph Friedman & Helena Hansen, Opinion, *Surging Overdose Deaths Are a Tragic Racial Justice Issue*, L.A. TIMES (Nov. 23, 2021), https://www.latimes.com/opinion/story/2021-11-23/overdoses-u-s-black-white-native-americans [https://perma.cc/DKR4-JY7Z].

304. Leslie Jamison, *Grand Unified Theory of Female Pain*, VA. Q. REV. ONLINE (Apr. 2, 2014), https://www.vqronline.org/essays-articles/2014/04/grand-unified-theory-female-pain [https://perma.cc/VAB8-P4WB] (quoting the ancient Greek comic playwright Menander).

305. *See, e.g.*, Andis Robeznieks, *Women Bear Greater Burden of Opioid Epidemic*, AMA (June 27, 2017), https://www.ama-assn.org/delivering-care/opioids/women-bear-greater-burden-opioid-epidemic [https://perma.cc/9C56-C3DF]; Jennifer Billock, *Pain Bias: The Health Inequality Rarely Discussed*, BBC (May 22, 2018), https://www.bbc.com/future/article/20180518-the-inequality-in-how-women-are-treated-for-pain [https://perma.cc/34FQ-FCKL]; Carolyn M. Mazure & David A. Fiellin, *Women and Opioids: Something Different Is Happening Here*, 392 LANCET 9 (2018); Laura Kiesel, *Women and Pain: Disparities in Experience and Treatment*, HARV. HEALTH BLOG (Oct. 9, 2017), https://www.health.harvard.edu/blog/women-and-pain-disparities-in-experience-and-treatment-2017100912562 [https://perma.cc/BVH4-Z2MA]; Joe Fassler, *How Doctors Take Women's Pain Less Seriously*, ATLANTIC (Oct. 15, 2015), https://www.theatlantic.com/health/archive/2015/10/emergency-room-wait-times-sexism/410515/ [https://perma.cc/SME8-9L52].

stoic so that when they do complain of pain, 'it's real'; and women are better able to tolerate pain or have better coping skills than men."[306] Epidemiological and clinical studies demonstrate, however, that significant sex differences attend to pain across a number of evaluative criteria. Women, for example, are at greater risk for pain conditions and experience both heightened pain sensitivity and diminished relief from opioid analgesics.[307] This latter dynamic may cause women to need higher doses of opioids than men with similar pain conditions to experience analgesia efficacy.[308]

Women are nonetheless "more likely to receive psychotropic medication for pain, less likely to receive opioid analgesia, and more likely to have pain attributed to emotional or psychological factors when compared to men."[309] Because the majority of clinical research regarding pain management has centered on male research subjects, there remains a huge gap in clinical understanding of the sex differences that pertain to these conditions.[310] This is particularly problematic given that (1) pain is the prevailing cause of disability and the primary reason that individuals seek medical attention in the United States;[311] (2) clinicians generally lack the training and competency to assess

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306. Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29 J.L. MED. & ETHICS 13 (2001).

307. Evan F. Fullerton, Hillary H. Doyle & Anne Z. Murphy, *Impact of Sex on Pain and Opioid Analgesia: A Review*, 23 CURRENT OP. BEHAV. SCIS. 183, 183–84 (2018) ("Epidemiological studies report that women suffer from chronic pain more frequently than men. Women also experience higher rates of chronic pain conditions such as fibromyalgia, migraine, and osteoarthritis . . . . [O]ther studies report that opioids exhibit decreased analgesic efficacy in women."); E.J. Bartley & R.B. Fillingim, *Sex Differences in Pain: A Brief Review of Clinical and Experimental Findings*, 111 BRIT. J. ANAESTHESIA 52, 53, 56 (2013) ("[T]he findings from epidemiological and clinical studies demonstrate convincingly that women are at substantially higher risk for many common pain conditions. . . . Studies of experimentally induced pain have produced a very consistent pattern of results, with women exhibiting greater pain sensitivity, enhanced pain facilitation and reduced pain inhibition compared with men . . . .").

308. *See, e.g.*, Fullerton et al., *supra* note 307, at 184–85.

309. Jaylyn Clark & Michael E. Robinson, *The Influence of Patient Race, Sex, Pain-Related Body Postures, and Anxiety Status on Pain Management: A Virtual Human Technology Investigation*, 12 J. PAIN RSCH. 2637, 2638 (2019). "The phrase 'psychotropic drugs' is a technical term for psychiatric medicines that alter chemical levels in the brain which impact mood and behavior." Enjoli Francis, *What You Need to Know About Psychotropic Drugs*, ABC NEWS (Dec. 2, 2011), https://abcnews.go.com/blogs/health/2011/12/02/what-you-need-to-know-about-psychotropic-drugs [https://perma.cc/E2SQ-2VBM].

310. Andrew L. Koons, Marna Rayl Greenberg, Robert D. Cannon & Gillian A. Beauchamp, *Women and the Experience of Pain and Opioid Use Disorder: A Literature-Based Commentary*, 40 CLINICAL THERAPEUTICS 190, 190 (2018) (observing that "pain experience and opioid abuse have relied on male-dominated models"); Hoffmann & Tarzian, *supra* note 306, at 13 ("The question of whether men and women experience pain differently is a relatively recent one. Until about a decade ago, many clinical research studies excluded women, resulting in a lack of information about gender differences in disease prevalence, progression, and response to treatment.").

311. *Symptoms Matter—Leading Causes of Disability*, NAT'L CTR. FOR COMPLEMENTARY & INTEGRATIVE HEALTH (2021), https://www.nccih.nih.gov/about/symptoms-matterleading-causes-of-disability [https://perma.cc/FU6U-M8ET]; U.S. Burden of Disease Collaborators, *The State of US Health, 1990-2016: Burden of Disease, Injuries, and Risk Factors Among US States*, 319 JAMA 1444, 1447–49 (2018).

pain;[312] and (3) clinicians use race and sex to make clinical pain assessment and treatment decisions generally to the detriment of racial minorities and women.[313]

C. *NarxCare Design Exacerbates Existing Inequities*

NarxCare risk scoring likely exacerbates existing disparities in chronic pain treatment for Black patients, women, individuals who are socioeconomically marginalized, rural individuals, and patients with complex, co-morbid disabilities and OUD. NarxCare algorithms weigh and score several "risk" factors, including (1) the number of a patient's prescribers and dispensers, (2) the method by which the patient pays for their prescription drugs, (3) the distance a patient travels from their home for treatment and medication, and (4) the patient's criminal and sexual trauma history. The following Sections examine each of these risk factors and explain how they potentially discriminate against marginalized patients.

1. *Number of Prescribers and Dispensers*

NarxCare algorithms factor the number of an individual patient's prescribers and dispensers into that patient's risk scores because the model views evidence that a patient has multiple prescribers and dispensers as a proxy for doctor and pharmacy shopping. The model, however, does not appear to take into consideration the myriad reasons why a patient might have multiple prescribers or dispensers that are unrelated to drug misuse. NarxCare certainly does not account for the role that the surveillance platform itself plays in contributing to the number of prescribers and dispensers that opioid patients accrue.

Patients have been forced, for example, to find new prescribers to avoid inevitable opioid withdrawal because the DEA has suspended their clinician's right to prescribe based on PDMP data.[314] Patients are similarly obligated to find

312. NAT'L ACADS. OF SCIS. ENG'G & MED., PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 3 (Richard J. Bonnie, Morgan A. Ford & Jonathan K. Phillips eds., 2017) ("The complexity of pain is matched by the complexity of achieving appropriate use of opioids in the context of the often suboptimal clinical management of pain within the fragmented U.S. health care delivery system.").

313. *See, e.g.*, Laura D. Wandner, Lauren A. Stutts, Ashraf F. Alqudah, Jason G. Craggs, Cindy D. Scipio, Adam T. Hirsh & Michael E. Robinson, *Virtual Human Technology: Patient Demographics and Healthcare Training Factors in Pain Observation and Treatment Recommendations*, 3 J. PAIN RSCH. 241 (2010); Adam T. Hirsh, Ashraf F. Alqudah, Lauren A. Stutts & Michael E. Robinson, *Virtual Human Technology: Capturing Sex, Race, and Age Influences in Individual Pain Decision Policies*, 140 PAIN 231 (2009).

314. *See, e.g.*, Taylor Knopf, *A Doctor's Tweet, a Mother's Complaint, a Loss for Chronic Pain Patients.*, N.C. HEALTH NEWS (Mar. 10, 2020), https://www.northcarolinahealthnews.org/2020/03/10/chronic-pain-doc-suspended-after-tweets/ [https://perma.cc/9ADH-X2BR]; Gail Levy, *Patients Shocked About FBI and DEA Raid at Local Clinic*, WJHG (Feb. 20, 2020), https://www.wjhg.com/content/news/Patients-shocked-about-local-clinic-FBI-and-DEA-raid-568056881.html [https://perma.cc/8NRF-DVRQ]; Pat Anson, *Lawyer Calls for DOJ to End 'Indiscriminate Raids' on Doctors*, PAIN NEWS NETWORK (July 25, 2019),

new prescribers and dispensers when they are abandoned by a treatment provider or pharmacist who is concerned about those patients' PDMP risk scores.[315] The NarxCare platform increases a patient's risk score even when the patient seeks new prescribing and dispensing services for entirely benign reasons, such as when a patient relocates to start a new job, or for reasons beyond the patient's control, such as when their provider retires from the practice of medicine or their community pharmacy shutters its doors. Such practice has obviously disparate impacts on patients who must move frequently due to work, such as individuals in the Armed Forces.

A platform that enhances patient risk scores based on the sheer number of a patient's prescribers and dispensers also over-targets patients who unavoidably see multiple providers simply due to the nature of their health care condition. For example, a recent study found that 20 percent of the patients that PDMPs are most like to flag as "doctor shoppers" are cancer patients, who routinely have multiple specialists because that is the nature of oncology practice.[316] Risk-scoring platforms that penalize patients due to their number of prescribers and dispensers are also likely to discriminate against patients that providers deem "untrustworthy" and are most likely to stop treating: Black patients, women, individuals with complex, chronic co-morbidities, and individuals with OUD.[317]

2. *Payment Method*

NarxCare algorithms enhance a patient's risk score when a patient pays for their prescriptions in cash or uses multiple forms of payment (e.g., Medicaid, credit card, and cash) over time.[318] This is because the platform views cash and mixed payment behavior as indicative of surreptitious drug seeking to avoid prior authorizations or surveillance tracking. Unfortunately, individuals who are uninsured or underinsured are often compelled to pay for their prescriptions out-

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https://www.painnewsnetwork.org/stories/2019/7/25/lawyer-calls-for-doj-to-end-indiscriminate-raids-on-doctors [https://perma.cc/GUG5-HJY8].

315.   Elizabeth Brico, *How Stigma Against Addiction Devastates Pain Patients*, FILTER (Feb. 11, 2019),   https://filtermag.org/how-stigma-against-addiction-devastates-pain-patients/ [https://perma.cc/6BB3-7HP4]; Anne Fuqua, *The Other Opioid Crisis: Pain Patients Who Can't Access the Medicine We Need*, WASH. POST (Mar. 9, 2018), https://www.washingtonpost.com/outlook/the-other-opioid-crisis-pain-patients-who-cant-access-the-medicine-they-need/2018/03/09/5ad83b24-2301-11e8-badd-7c9f29a55815_story.html [https://perma.cc/2AX7-9DZA]; Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 LAW & PSYCH. REV. 1, 4 (2016) ("Some providers and policymakers seem invested in the wholesale rejection of not only opioids, but also of patients themselves."); Lynn R. Webster, *Pain and Suicide: The Other Side of the Opioid Story*, 15 PAIN MED. 345 (2014).

316.   Maia Szalavitz, *The Pain Was Unbearable. So Why Did Doctors Turn Her Away?*, WIRED (Aug. 11, 2021), https://www.wired.com/story/opioid-drug-addiction-algorithm-chronic-pain/ [https://perma.cc/9TKW-EJZR].

317.   *See* discussion *supra* Part IV.B.

318.   *See, e.g.*, UP FRONT, EVERY PATIENT, EVERY TIME, *supra* note 198, at 5; Garner et al., *supra* note 223, at 17; INSPECT: INDIANA'S PRESCRIPTION DRUG MONITORING PROGRAM 30, https://web.archive.org/web/20161221053014/https://www.in.gov/ipac/files/Brady.pdf.

of-pocket with cash or credit because they simply do not have a third-party payor to foot the bill.[319] The method of payment risk factor, therefore, discriminates on its face against underinsured and uninsured patients, who are more likely to be people of color and women who live in poverty.[320]

The method of payment risk factor also has the potential to impute to a patient a third-party payor's decision to not cover certain controlled substances—or certain dosages of specific drugs. Numerous payors, including Medicare, Medicaid, and private insurers, for example, refuse to fill opioid prescriptions above 90 morphine milligram equivalents (MMEs) per day either as a blanket prohibition or without prior authorization.[321]

The method of payment risk factor may also disparately impact individuals who are prescribed opioid therapeutics to treat opioid use disorder. West Virginia has the highest per capita number of residents on Medicaid[322] and the highest per capita rate of drug poisoning deaths in the country.[323] West Virginia Medicaid, however, refused to cover methadone treatment for its beneficiaries with OUD until 2018.[324] Those Medicaid patients, therefore, were forced to pay for their prescriptions with cash, check, or credit. According to a recent report by the Kaiser Family Foundation, nine state Medicaid plans continue to refuse to pay

319.   *See generally* Rachel Garfield, Kendal Orgera & Anthony Damico, *The Uninsured and the ACA: A Primer - Key Facts About Health Insurance and the Uninsured Amidst Changes to the Affordable Care Act*, KAISER FAM. FOUND. (Jan. 25, 2019), https://www.kff.org/report-section/the-uninsured-and-the-aca-a-primer-key-facts-about-health-insurance-and-the-uninsured-amidst-changes-to-the-affordable-care-act-what-are-the-financial-implications-of-lacking-insu/ [https://perma.cc/B8P4-9CU7].

320.   Samantha Artiga, Latoya Hill, Kendal Orgera & Anthony Damico, *Health Coverage by Race and Ethnicity, 2010-2019*, KAISER FAM. FOUND. (July 16, 2021), https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/ [https://perma.cc/3JK5-44GR] ("As of 2019, nonelderly AIAN, Hispanic, NHOPI, and Black people remained more likely to lack health insurance than their White counterparts."); *Women's Health Insurance Coverage*, KAISER FAM. FOUND. (Nov. 8, 2021), https://www.kff.org/womens-health-policy/fact-sheet/womens-health-insurance-coverage/ [https://perma.cc/VW3L-E68R] (explaining that "[o]n average, women have lower incomes and have been more likely to qualify for Medicaid than men" and "[l]ow-income women, women of color, and non-citizen women are at greater risk of being uninsured").

321.   Stefan G. Kertesz, Ajay Manhapra & Adam J. Gordon, *Nonconsensual Dose Reduction Mandates Are Not Justified Clinically or Ethically: An Analysis*, 48 J.L. MED. & ETHICS 259, 260 (2020).

322.   *Medicaid's Role in West Virginia*, KAISER FAM. FOUND. (July 21, 2017), https://www.kff.org/medicaid/fact-sheet/medicaids-role-in-west-virginia/#:~:text=Over%20564%2C000%20people%20in%20West,its%20population%20enrolled%20in%20Medicaid [https://perma.cc/M2EJ-XT3F] ("Over 564,000 people in West Virginia are covered by Medicaid (29% of the population), making West Virginia the state with the highest share of its population enrolled in Medicaid.").

323.   *2018 Drug Overdose Death Rates*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/data/statedeaths/drug-overdose-death-2018.html [https://perma.cc/ZJ6D-Q2PC].

324.   *Substance Use Disorder (SUD) Waiver*, W. VA. BUREAU FOR MED. SERVS., https://dhhr.wv.gov/bms/Programs/WaiverPrograms/Pages/Substance-Use-Disorder-(SUD)-Waiver-.aspx [https://perma.cc/9M55-JNVV].

for methadone maintenance treatment for individuals with OUD.[325] This disparately impacts the risk scores of poor people of color with OUD in those jurisdictions because racial minorities are significantly more likely to use methadone to treat OUD than other indicated therapeutics.[326]

3. Distance Travelled

NarxCare also factors into its risk score calculations the distance that a patient travels from their home to their prescriber(s) and dispenser(s).[327] This factor is included in the risk scoring algorithm based on the assumption that the further a patient travels from their home to their provider or pharmacist, the more likely it is that the patient is engaging in suspicious drug-seeking activity. But how, exactly, do the NarxCare algorithms generate a "score" for distance travelled and what do those scores actually prove?

Bamboo does not publicize information concerning its algorithmic use of distance travelled to calculate patient risk scores. It is, however, entirely foreseeable that certain patients—including individuals who live in rural communities that lack a pain treatment provider or other opioid treatment deserts—may be unjustly punished by distance-travelled scores. Distance-travelled scores also disadvantage patients who are compelled to travel increasingly farther from their home to "shop" for a prescriber and dispenser that will see them because of their PDMP risk scores.

Individuals with OUD who live in states that have a limited number of opioid treatment programs (methadone clinics) due to either state policies or run-of-the-mill NIMBYism might also receive enhanced risk scores due to the inclusion of the distance-travelled factor.[328] West Virginia, for example, only has nine methadone clinics in the entire state because it has had a moratorium on new OTPs in place since 2007.[329] Wyoming, on the other hand, which is a large,

325.   *Medicaid's Role in Addressing the Opioid Epidemic*, KAISER FAM. FOUND. (June 3, 2019), https://www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/ [https://perma.cc/7MJM-K9YJ].

326.   *See, e.g.*, Jose A. Del Real, *Opioid Addiction Knows No Color but Its Treatment Does*, N.Y. TIMES (Jan. 12, 2018), https://www.nytimes.com/2018/01/12/nyregion/opioid-addiction-knows-no-color-but-its-treatment-does.html [https://perma.cc/9DEC-CMVN] (observing that "[m]ore affluent patients can avoid the methadone clinic entirely, receiving a new treatment directly from a doctor's office" while "[m]any poorer Hispanic and black individuals struggling with drug addiction must rely on these highly regulated [methadone] clinics, which they must visit daily to receive their plastic cup of methadone"); Helena B. Hansen, Carole E. Siegel, Brady G. Case, David N. Bertollo, Danae DiRocco & Marc Galanter, *Variation in Use of Buprenorphine and Methadone Treatment by Racial, Ethnic, and Income Characteristics of Residential Social Areas in New York City*, 40 J. BEHAV. HEALTH SERVS. & RSCH. 367, 371 (2013).

327.   *A Balanced Approach to Opioids and Chronic Pain*, *supra* note 199.

328.   NIMBY is an acronym for "Not In My Back Yard," which is used to describe resistance to the establishment of social services facilities, low income housing, group homes, and other land uses in neighborhoods or communities. Michael B. Gerrar, *The Victims of NIMBY*, 21 FORDHAM URB. L.J. 495, 495, 499–502 (1994).

329.   Erin L. Winstanley, Laura R. Lander, James H. Berry, James J. Mahoney III, Wanhong Zheng, Jeremy Herschler, Patrick Marshalek, Sheena Sayres, Jay Mason & Marc W. Haut, *West*

rural state with the second lowest population density in the nation,[330] is home to exactly zero methadone clinics.[331] This means that individuals who live in the more rural counties in West Virginia are forced to travel considerable distances to access methadone treatment and all Wyoming residents are required to literally leave their home state to have the medication administered. Methadone patients who reside in these states, of course, are not to blame for these egregious travel obligations.

4. *Criminal and Sexual Trauma Histories*

[D]ata is not neutral. Data sets reflect structural inequities, which in turn can result in digital discrimination against marginalized groups.[332]

NarxCare incorporates patient criminal and sexual trauma history into the risk scores that it generates for several state PDMPs.[333] It is unknown exactly how NarxCare uses or weighs such information in its risk score calculation, but to the extent that the mere existence of criminal or sexual trauma history in a patient's record increases a patient's risk score, these factors are likely to have a disparate impact on Black and women patients. As a 2018 report to the United Nations on racial disparities in the U.S. criminal justice system explains:

> African Americans are more likely than white Americans to be arrested; once arrested, they are more likely to be convicted; and once convicted, and they are more likely to experience lengthy prison sentences. African-American adults are 5.9 times as likely to be incarcerated than whites. . . . As of 2001, one of every three black boys born in that year could expect to go to prison in his lifetime . . . compared to one of every seventeen white boys. Racial and ethnic disparities among women are less substantial than among men but remain prevalent.[334]

Virginia's Model of Buprenorphine Expansion: Preliminary Results, 108 J. SUBSTANCE ABUSE TREATMENT 40, 41 (2020).

330.   *Wyoming: Population,   Area,   and   Density*,   STATES101, https://www.states101.com/populations/wyoming#:~:text=The%20total%20area%20in%20Wyoming, (55th%20out%20of%2056) [https://perma.cc/6TFT-W4QV].

331.   Linda Keslar, *The Methadone Blind Spot*, PROTO (Apr. 26, 2018), http://protomag.com/articles/methadone-blind-spot [https://perma.cc/2JLL-FTBB].

332.   GILMAN, *supra* note 236, at 6.

333.   Leo Beletsky, *Deploying Prescription Drug Monitoring to Address the Overdose Crisis: Ideology Meets Reality*, 15 IND. HEALTH L. REV. 139, 169 (2018) (describing "[a]n emerging trend in PDMP design and authority" that "involves PDMP provision of criminal justice information" in several states); *see* REG'L JUD. OPIOID INITIATIVE, LEVERAGING SOCIAL, BEHAVIORAL, AND HEALTH DATA: PRESENTATION AT HAROLD ROGERS PDMP NATIONAL MEETING 9 (June 26, 2019), https://www.pdmpassist.org/pdf/26E1_Bryant.pdf [https://perma.cc/29QV-VK3F] (demonstrating that the states of Kentucky, Indiana, Michigan, Ohio, Tennessee, West Virginia and North Carolina incorporate criminal justice and "child welfare/family services" history into their PDMPs).

334.   SENTENCING PROJECT, REPORT OF THE SENTENCING PROJECT TO THE UNITED NATIONS SPECIAL RAPPORTEUR ON CONTEMPORARY FORMS OF RACIAL DISCRIMINATION, XENOPHOBIA, AND RELATED INTOLERANCE REGARDING RACIAL DISPARITIES IN THE UNITED STATES CRIMINAL JUSTICE SYSTEM 1 (2018).

Risk scoring inclusive of criminal justice history, therefore, is highly likely to exacerbate the health inequities already experienced by Black opioid patients in the health care delivery system.

PDMP algorithms that weigh sexual abuse and trauma history as a proxy for increased risk of opioid misuse, on the other hand, are likely to disparately impact women and exponentially discriminate against women of color. This is because "[w]omen have a higher prevalence of gender-based violence and sexual abuse, as well as the subsequent psychological effects, such as post-traumatic stress disorder, anxiety, and depression."[335] Women are also twice as likely as men to be diagnosed with trauma-based psychological conditions, such as post-traumatic stress disorder (PTSD), notwithstanding the fact that men are exposed to more traumatic events due to implicit gender bias in the Diagnostic and Statistical Manual criteria for PTSD.[336]

D. Model Validation

Bad algorithmic inputs and proxies generate bad or inaccurate outputs, a phenomenon that is commonly referred as "garbage in, garbage out" by data scientists.[337] This persistent issue is exacerbated by models that create self-perpetuating feedback loops of faulty data, and thereby train the platform to generate increasingly biased and inaccurate results.[338] Predictive platform designers also have little motivation to fix faulty feedback loops because their models are "black boxes": unregulated, proprietary, and therefore protected from external review.[339] As privacy expert Frank Pasquale explained, predictive models "take in data about us and convert it into scores, rankings, risk calculations, and watch lists with vitally important consequences. But the proprietary algorithms by which they do so are immune from scrutiny, except on the rare occasions when a whistleblower litigates or leaks."[340]

As explained above, law enforcement and regulatory PDMP surveillance create considerable incentives for prescribers and dispensers to rely on PDMP risk scores to make clinical decisions that may adversely impact patients.[341]

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335.   Koons et al., *supra* note 310, at 192.

336.   Alexandra H. Cowden Hindash, Callan Lujan, Meghan Howard, Aoife O'Donovan, Anne Richards, Thomas C. Neylan & Sabra S. Inslicht, *Gender Differences in Threat Biases: Trauma Type Matters in Posttraumatic Stress Disorder*, 32 J. TRAUMATIC STRESS 701, 701–03 (2019).

337.   Jeff Gorke, *AI and Machine Learning in Healthcare: Garbage In, Garbage Out*, FORBES (June 18, 2020), https://www.forbes.com/sites/jeffgorke/2020/06/18/ai-and-machine-learning-in-healthcare-garbage-in-garbage-out/?sh=5a1b3a2d50a7 [https://perma.cc/W4JC-MFJH].

338.   O'NEIL, *supra* note 241, at 3–7.

339.   PASQUALE, *supra* note 241, at 6.

340.   *Id.* at 4.

341.   M. Mofizul Islam & Ian S. McRae, *An Inevitable Wave of Prescription Drug Monitoring Programs in the Context of Prescription Opioids: Pros, Cons and Tensions*, 15 BIOMED. CENT. PHARMACOLOGY & TOXICOLOGY 46, 48 (2015) ("[S]urveys indicate that some prescribers underutilise controlled substances due to fear of legal repercussions. There is greater perceived legal risk for prescribing/dispensing too much pain medication than for prescribing/dispensing too little pain medication.").

Clinicians whose prescribing practices raise "red flags" in the platform risk losing their licenses, livelihoods, and freedom. It is therefore imperative that the data points selected, scored, and weighed by the NarxCare algorithms are excellent proxies for patient OUD and diversion risk. It is equally imperative that the method used by Bamboo to train its software to continuously identify and incorporate more—and more refined—risk proxies into its model is accurate.

Bamboo's risk scoring model, however, is not available for objective, external validation. The company contends that its patented algorithms are proprietary and therefore protected from third-party disclosure and evaluation by trade secret laws.[342] The proprietary or "black-box" nature of Bamboo's risk assessment methodologies raise serious questions about clinical reliance on Narx Scores to diagnose and treat patients.

Bamboo, of course, contends that its internal studies "validate the NarxCare scores."[343] But such self-serving assertions hardly quell the concerns identified. As one legal scholar has aptly observed, "[t]he initial innovator [of a black-box software platform] faces strong financial incentives not to disprove its own algorithm once marketed and retains whatever biases or errors may have created problems in the first place."[344] It is also difficult to scrutinize Bamboo's contentions about its own studies because they are not available for public review and the company's marketing documents that cite those internal studies are bereft of critical details. As it turns out, Bamboo's publicized information about Narx Score accuracy raises more questions than it provides answers.

In one marketing report, for example, Bamboo characterizes an internal "survey" of "223 users" as evidence that PDMP users gave its risk assessment platform "high value responses on usability and *accuracy*."[345] The company goes on to admit, however, that the response rate to that survey was only 21 percent—

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342. HUIZENGA ET AL., *supra* note 210, at 3 ("NARxCHECK is a patented algorithm that analyzes controlled substance data from PDMPs and provides easy-to-use insights into a patient's controlled substance use.").

343. UP FRONT, EVERY PATIENT, EVERY TIME, *supra* note 198, at 8. Bamboo also misleadingly contends that its NarxCare risk scores have been subjected to a single external validation study. *See* Gerald Cochran, Jennifer Brown Ziji Yu, Stacey Frede, M. Aryana Bryan, Andrew Ferguson, Nadia Bayyari, Brooke Taylor, Margie E. Snyder, Elizabeth Charron, Omolola A. Adeoye-Olatunde, Udi E. Ghitza & T. Winhusen, *Validation and Threshold Identification of a Prescription Drug Monitoring Program Clinical Opioid Risk Metric with the WHO Alcohol, Smoking, and Substance Involvement Screening Test*, 228 DRUG & ALCOHOL DEPENDENCE 1 (2021). That study, however, only assesses *one of the four risk scores* that NarxCare generates: the narcotics score (NS). It neither evaluated the composite overdose risk score nor the other categorical risk scores (sedatives and stimulants). The study also excluded important groups of patients, including those who take buprenorphine, are under eighteen, and do not speak English and was limited to patients of "average health" and whose pain was controlled or "average," thereby entirely excluding individuals with complex, chronic pain. It also failed entirely to either address or incorporate patient outcomes because, of course, NarxCare neither collects nor measures patient outcomes. Yet, even this non-representative, questionable, and entirely incomplete study concluded that the NarxCare NS generates concerning numbers of false negatives and false positives. *See id.*

344. W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 441 (2015).

345. UP FRONT, EVERY PATIENT, EVERY TIME, *supra* note 198, at 8 (emphasis added).

or forty-seven total users.[346] The report also fails to disclose the identity, profession, or training of the "users" polled; the nature of the questions asked; or the response options provided to the respondents. It certainly does not explain what Bamboo means by "high value responses." Such anecdotal internal surveys that poll unidentified users for their opinions, of course, do not answer the important question presented, which is whether the NarxCare scoring algorithms accurately assess patient risk of OUD, diversion, and overdose.

Meta-analyses evaluating the accuracy of publicly available automated algorithms that purport to detect and identify prescription opioid misuse raise additional issues. A group of researchers conducted a systemic review of fifteen such risk assessment algorithms.[347] They observed that many of those algorithms "lacked a true reference standard . . . against which to evaluate automated algorithm performance."[348] The absence of such a standard was "not surprising," given that most clinicians struggle to assess the risk of a patient's potential non-medical use of opioids.[349] This issue, however, undermined model accuracy because the absence of a standard required the algorithmic designers to make "far from precise" assumptions about non-medical opioid use that were likely to generate a high number of false negatives and false positives.[350] As a result of these flaws, the researchers concluded that:

> [i]f the algorithm is relied upon for definite diagnosis, patient trust could be irreparably broken or a provider could lose his/her license to practice. Similar to a tuberculous sensitivity test, administered quickly and cheaply for tuberculous, initial screening must be followed by additional testing, as the consequences of being falsely diagnosed are not trivial.[351]

A recent study by Northeastern University health economist Angela E. Kilby is even more damning.[352] Dr. Kilby created a machine learning algorithm to predict OUD risk "using commercially available claims data similar to those utilized in the development of proprietary [OUD] prediction algorithms."[353] By evaluating the risk predictions generated by her NarxCare-like model in a "quasi-experimental setting where opioid prescribing was reduced across-the-board," Dr. Kilby found that "the magnitude of the estimated treatment effect of reducing opioid prescribing on [OUD was] *uncorrelated with the risk score generated by*

346.   *Id.*

347.   Chelsea Canan, Jennifer M. Polinski, G. Caleb Alexander, Mary K. Kowal, Troyen A. Brennan & William H. Shrank, *Automatable Algorithms to Identify Nonmedical Opioid Use Using Electronic Data: A Systematic Review*, 24 J. AM. MED. INFORMATICS ASS'N 1204, 1209 (2017).

348.   *Id.*

349.   *Id.*

350.   *Id.*

351.   *Id.*

352.   Angela E. Kilby, Algorithmic Fairness in Predicting Opioid Use Disorder Using Machine Learning, Proceeding of the 2021 ACM Conference on Fairness, Accountability, and Transparency (FAccT '21) (March 3, 2021).

353.   *Id.* at 1.

the machine."[354] "In other words, models [like those used by state PDMPs] trained with the typical risk-prediction objective function *do not produce a valid proxy for the object of interest*": individual patient health outcomes.[355] As Dr. Kilby explained:

> We find that the machine identifies high risk for [OUD] based on a few key demographic characteristics, as well as flagging complex chronic pain patients with a number of comorbidities as high risk, but these patients do not on average benefit from a reduction in prescribing more than any other group. In fact, results suggest that reallocating prescribing according to machine recommendation, in a quantity-neutral manner, away from groups with high risk scores and towards groups with low risk scores, might paradoxically *increase* the prevalence of [OUD].[356]

Dr. Kilby's research findings are sobering. They suggest that Bamboo's model generates risk scores that are likely to increase harmful health outcomes for patients. As she explained, there are potentially dire consequences of clinical reliance on a model like NarxCare that generates a high rate of false positives by consistently mislabeling low risk, complex, chronic pain patients as high risk for OUD.

Chronic pain patients, who have been prescribed opioids to function without issue for long periods of time but nonetheless generate high risk scores (e.g., "legacy patients"), risk forced tapering and medicated discontinuation.[357] The DEA and other regulators incentivize this behavior by routinely sweeping PDMPs for "red flag" prescribers—those providers that the system deems "overprescribers"—to suspend, investigate, and prosecute.[358] As one Oregon physician recently testified, "[e]ven in situations where patients are experiencing dire and debilitating pain, I have seen . . . many physicians become unwilling to

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354. *Id.* at 4, 6 (emphasis added).

355. *Id.* at 4 (emphasis added).

356. *Id.*

357. Hector R. Perez, Michele Buonora, Chinazo O. Cunningham, Moonseong Heo & Joanna L. Starrels, *Opioid Taper Is Associated with Subsequent Termination of Care: A Retrospective Cohort Study*, 35 J. Gen. Internal Med. 36, 36 (2019); Rieder, *supra* note 280, at 654–55.

358. Oliva, *supra* note 4, at 787, 795 n.101; Beth Schwartzapfel, *Guess Who's Tracking Your Prescription Drugs?*, Marshall Project (Aug. 2, 2017), https://www.themarshallproject.org/2017/08/02/guess-whos-tracking-your-prescription-drugs [https://perma.cc/4TFZ-TLTA] ("[I]n 21 states and the District of Columbia, police can also access the databases as a matter of course; some have their own log-ins to use at their discretion."); Mark Greenblatt & Angela M. Hill, *Exclusive Investigation: Your Prescriptions Aren't Private*, Scripps Loc. Media (Aug. 30, 2016), https://www.wcpo.com/longform/so-you-think-prescriptions-are-private [https://perma.cc/YM5U-SH3H] (pointing out that "[t]hirty-one states grant law enforcement warrantless access to databases containing drug histories, and the U.S. Drug Enforcement Administration is pushing hard to search records even in states that have privacy safeguards" and "law enforcement tapped into at least 344,921 prescription histories of Americans between 2014–2015 in the states that don't require a warrant or other form of court authorization" to access their PDMP); *Criminal Cases Against Doctors*, Drug Enf't Admin. Diversion Control Div. https://www.deadiversion.usdoj.gov/crim_admin_actions/index.html [https://perma.cc/P2EG-2QNQ].

issue prescriptions for medically necessary narcotic painkillers because they fear scrutiny by law enforcement."[359] Medicaid, Medicare, and other insurers further compound this dynamic by refusing to pay for opioid prescriptions above an arbitrary dose based on 2016 CDC guidelines, which the CDC has acknowledged were misapplied and caused patients harm.[360] Even quality metric agencies and pharmacies have gotten into the business of policing opioid prescribers and chilling doctor-patient relationships.[361]

Law enforcement organizations, regulators, quality control entities, and insurers also have developed mandates and other policies that aim to reduce the number of patients on "high doses" (as a general rule, greater than 90 morphine milligram equivalents (MMEs)) of prescription opioids.[362] "Such policy initiatives incentivize taper and discontinuation, with or without the patient's consent,"[363] and notwithstanding that the evidence in support of those practices is, at best, mixed.[364]

The significant risks associated with rapid, aggressive taper and discontinuation of patients on "high doses" of opioids, on the other hand, are well documented. Potential adverse events range from debilitating pain and suffering to severe depression and suicidal ideation to hospitalization and death.[365] In a published letter to their colleagues, an international coalition of researchers that self-identified as "deeply concerned about forced opioid tapering in patients receiving long-term prescription therapy for chronic pain," warned that the suffering and functional impairment inflicted on patients by opioid deprescribing and tapering was likely to cause them to "seek relief from illicit (and inherently more dangerous) sources of opioids, whereas others may become acutely suicidal."[366] Nonetheless, "[c]linicians across specialties reported

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359.   Schwartzapfel, *supra* note 358.

360.   *See* Press Release, Ctrs. for Disease Control & Prevention, CDC Advises Against Misapplication of the Guideline for Prescribing Opioids for Chronic Pain (Apr. 24, 2019), https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html [https://perma.cc/XZ54-7P5P]; Deborah Dowell, Tamara Haegerich & Roger Chou, *No Shortcuts to Safer Opioid Prescribing*, 380 NEW ENG. J. MED. 2285, 2285 (2019); Hoffman, *supra* note 118.

361.   Kertesz et al., *supra* note 321, at 260, 264; Elizabeth Chiarello, *The War on Drugs Comes to the Pharmacy Counter: Frontline Work in the Shadow of Discrepant Institutional Logics*, 40 L. & SOC. INQUIRY 86, 88 (2015).

362.   Kertesz et al., *supra* note 321, at 262 (concluding that high dose "reduction alone permits institutions to document good faith in confronting a societal crisis, and also to contain political and legal vulnerability").

363.   *Id.* at 264.

364.   *See, e.g.*, Marianne S. Matthias, *Opioid Tapering and the Patient-Provider Relationship*, 35 J. GEN. INTERNAL MED. 8, 8 (2020) ("[T]here is insufficient evidence to support any particular tapering approach, and, more concerning, there is a dearth of information on patient outcomes during and after tapering.").

365.   Travis N. Rieder, *In Opioid Withdrawal, with No Help in Sight*, 36 HEALTH AFFS. 182, 183 (2017).

366.   *International Stakeholder Community of Pain Experts and Leaders Call for an Urgent Action on Forced Tapering*, 20 PAIN MED. 429, 429–30 (2019); *see* Perez et al., *supra* note 357, at 36.

declining to prescribe opioids to new patients with worrisome PDMP profiles, except in the case of acute, verifiable conditions (e.g., broken bone, herniated disc)" and even long-term providers reported discontinuing stable, legacy patients due to "perceived patient dishonesty, previous worrisome [PDMP] profiles, and high scores on . . . opioid risk screening."[367]

V.
PDMP RISK SCORE REGULATION

Widespread and coerced clinical reliance on potentially inaccurate and discriminatory PDMP risk score algorithms to diagnose and treat patients raises a litany of legal issues. Risk scoring software manufacturers, like Bamboo, could be subject to contractual breach of warranty challenges.[368] Manufacturers could also face product liability claims on the theory that they create, sell, and distribute a defective product that causes harm to patients.[369]

Hospitals, physician practice groups, and pharmacies that adopt blanket policies to arbitrarily deny opioid treatment to patients with "flagged" PDMP risk scores may face corporate negligence causes of action.[370] They could also be held liable under several federal anti-discrimination statutes, including the Americans with Disabilities Act (ADA),[371] Section 504 of the Rehabilitation Act of 1973,[372] and Section 1557 of the Patient Protection and Affordable Care Act.[373] In January 2019, the U.S. Department of Justice entered into a settlement agreement with a medical facility after investigating a complaint alleging that the private provider discriminated against patients treated with opioids in violation of Title III of the ADA.[374] As one legal commentator noted, that settlement made clear that "providing the full range of care and services to [prescription opioid] patients is required under the ADA—and that any failure to do so can lead to litigation, costly settlements and adverse publicity."[375]

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367.   Gillian J. Leichtling, Jessica M. Irvine, Christi Hildebran, Deborah J. Cohen, Sara E. Hallvik & Richard A. Deyo, *Clinicians' Use of Prescription Drug Monitoring Programs in Clinical Practice and Decision-Making*, 18 PAIN MED. 1063, 1065–66 (2017).

368.   Michael D. Scott, *Tort Liability for Vendors of Insecure Software: Has the Time Finally Come?*, 67 MD. L. REV. 425, 435 (2008).

369.   *Id.* at 457–72.

370.   Sharona Hoffman & Andy Podgurski, *E-Health Hazards: Provider Liability and Electronic Health Record Systems*, 24 BERKELEY TECH. L.J. 1523, 1528 (2009).

371.   42 U.S.C. §§ 12101–12213.

372.   29 U.S.C. § 794.

373.   42 U.S.C. § 18116.

374.   SETTLEMENT AGREEMENT BETWEEN THE UNITED STATES OF AMERICA AND SELMA MEDICAL ASSOCIATES, INC. UNDER THE AMERICANS WITH DISABILITIES ACT (2019), https://www.ada.gov/selma_medical_sa.html [https://perma.cc/K6NT-4QKT]; *see* Press Release, U.S. Dep't of Just., Justice Department Reaches Settlement with Selma Medical Associates, Inc. to Resolve ADA Violations (Jan. 31, 2019), https://www.justice.gov/opa/pr/justice-department-reaches-settlement-selma-medical-associates-inc-resolve-ada-violations [https://perma.cc/XV24-247U].

375.   Frank C. Morris, Jr., *DOJ Considers Opioid Use Disorder an ADA Covered Disability and Pursues Claims Against a Provider for Refusing Medical Services to Opioid Users*, EPSTEIN BECKER & GREEN, P.C.: HEALTH EMP. & LAB. (Feb. 5, 2019),

Prescribers and dispensers who rely too heavily on PDMP risk scores to force taper and abandon opioid patients could also be subject to tort liability and professional licensing disciplinary actions.[376] National opioid prescribing guidelines emphasize patient-centered care and prohibit the forced taper or discontinuation of opioids for legacy patients due to the risks of several withdrawal symptoms, debilitating pain, depression, psychological agony, suicidal ideation, and drug switching to more dangerous, illicit substances.[377] In addition, every state has enacted laws and regulations that require professional medical licensees, including prescribers and dispensers, to deliver individualized patient treatment consistent with their obligations under the applicable standards of professional care.[378]

The breadth and scope of these potential legal challenges deserve scrutiny, and the author intends to explore these issues in future articles. The current legal regime, however, has placed prescribers and dispensers in a precarious vice. This is because two competing sets of laws motivate opposing clinical behavior in this context. On the one hand, anti-discrimination law and tort liability encourage clinicians to treat patients equitably and individually—consistent with the applicable standards of care. On the other, law enforcement surveillance and its attendant threat of criminal investigation and prosecution incentivize patient abandonment, forced taper, and involuntary medication discontinuation. Worse yet, while prescribers and dispensers face a lose-lose legal environment, the FDA, which is the federal agency responsible for regulating predictive clinical diagnostic tools, has received little scrutiny in this context. In addition, a solution

https://www.healthemploymentandlabor.com/2019/02/05/doj-considers-opioid-use-disorder-an-ada-covered-disability-and-pursues-claims-against-a-provider-for-refusing-medical-services-to-opioid-users/ [https://perma.cc/AD2W-VEMX].

376. *See, e.g.*, Robyn S. Shapiro, *Health Care Providers' Liability Exposure for Inappropriate Pain Management*, 24 J.L. MED. & ETHICS 360, 361 (1996) (explaining that courts have held that palliative care providers have a duty to treat pain and that "pain management is an integral component of appropriate medical care"); Landeros v. Flood, 551 P.2d 389, 392–93 (Cal. 1976) (explaining that, under the modern law of torts, professional reasonableness is measured by the "degree of knowledge and skill which is ordinarily possessed and exercised by other members of [the] profession in similar circumstances").

377. *See, e.g.*, U.S. DEP'T OF HEALTH & HUM. SERVS., HHS GUIDE FOR CLINICIANS ON THE APPROPRIATE DOSAGE REDUCTION OR DISCONTINUATION OF LONG-TERM OPIOID ANALGESICS 1 (2019), https://www.hhs.gov/opioids/sites/default/files/2019-10/8-Page%20version__HHS%20Guidance%20for%20Dosage%20Reduction%20or%20Discontinuation%20of%20Opioids.pdf [https://perma.cc/4M8T-E7C8] (explaining that "[o]pioids should not be tapered rapidly or discontinued suddenly" and that the risks of such practice "include acute withdrawal symptoms, exacerbation of pain, serious psychological distress, and thoughts of suicide" and may cause patients to "seek other sources of opioids, including illicit opioids, as a way to treat their pain and withdrawal symptoms").

378. *See, e.g.*, Demint v. State Med. Bd. of Ohio, 70 N.E.3d 21, 43 (Ohio Ct. App. 2016) (affirming board revocation of a medical doctor's professional license for breaching the state standard of care with regarded to his controlled substance prescribing); Jarrott v. La. State Bd. of Med. Exam'rs, 19 So. 3d 526, 553 (La. Ct. App. 2009) (affirming a board suspension of a medical doctor's professional license for breaching the state standard of care and the board's Pain Management Rules with regarded to his treatment of individual prescribed controlled substances).

at the FDA level has the benefit of being systematic, unlike a piecemeal, private litigation approach. The remainder of this Article, therefore, is devoted to critiquing the FDA's abdication of its duty to the public to ensure that predictive assessment tools that are used to treat and diagnose patients, like PDMP risk scoring platforms, are safe and effective for patients.

As has been contended throughout this Article, PDMPs were developed as law enforcement surveillance systems designed to control the supply of prescription drugs that the DEA characterizes as high risk for misuse and diversion. PDMPs were not created to assist clinicians in the diagnosis, treatment, and management of chronic pain, OUD, or other complex health care conditions. Due to state PDMP use mandates and law enforcement surveillance, clinicians nonetheless increasingly rely on PDMP risk scores to diagnose and treat patients. And there is little doubt that such clinical reliance will become even more pervasive. States continue to adopt and expand PDMP use mandates, and a recently enacted provision of the federal SUPPORT Act requires all Medicaid providers to query the PDMP prior to prescribing controlled substances beginning October 1, 2021.[379]

There are no other examples of automated predictive risk scoring models created primarily for law enforcement surveillance that are used in clinical practice. This is likely because such cross-over use of risk assessment tools is ill advised. That stated, to the extent that clinicians do use PDMP risk scores to inform or determine patient treatment, PDMP software platforms ought to be subject to the same regulatory oversight as other health care predictive analytic tools used for similar purposes. The significant questions raised about PDMP risk score accuracy and such risk scores' potential to disparately impact the health and well-being of marginalized patients demand immediate regulatory attention.

Scholars have spilled considerable ink expounding on the FDA's failure to regulate clinical decision support (CDS) tools,[380] like PDMP risk scoring platforms, under the agency's existing medical device regulatory scheme.[381] Recognizing the challenge of situating predictive analytic models into dated

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379. Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (the SUPPORT Act), Pub. L. 115-271, § 5042, 132 Stat. 3894, 3966 (codified as amended in scattered sections of 42 U.S.C.).

380. Efthimios Parasidis, *Clinical Decision Support: Elements of a Sensible Legal Framework*, 20 J. HEALTH CARE L. & POL'Y 183, 186 (2018) ("CDS encompasses any computer program that is designed to help patients and health care professionals make a clinical decision.").

381. *See, e.g.*, *id.* at 189–91 ("Important questions remain unanswered, such as which CDS programs come within the purview of the FDA, and how FDA oversight should be structured for those that do."); Nathan G. Cortez, I. Glenn Cohen & Aaron S. Kesselheim, *FDA Regulation of Mobile Health Technologies*, 371 NEW ENG. J. MED. 372, 376 (2014) ("[W]e think the FDA should regulate . . . products that incorporate clinical-decision support."); Aaron S. Kesselheim, Kathrin Cresswell, Shobha Phansalkar, David W. Bates & Aziz Sheikh, *Clinical Decision Support Systems Could Be Modified to Reduce 'Alert Fatigue' While Still Minimizing the Risk of Litigation*, 30 HEALTH AFFS. 2310, 2314 (2011).

legal and regulatory frameworks for which they were not designed, experts have advocated for Congress to authorize—and for the FDA to implement—a new and more appropriate framework to regulate CDS.[382] These propositions are well taken. It is beyond time to enact a legal and regulatory regime that ensures that predictive diagnostic software is safe and effective for patients. In the context of PDMP risk scoring, however, there is no need to wait for a perfected regulatory scheme because the current framework is sufficient under the circumstances.

The FDA's medical device regulatory regime is complex. Prior to the mid-1970s, the agency's Food, Drug, and Cosmetics Act (FDCA) oversight of medical devices was limited to the post-market policing of adulterated and misbranded devices.[383] In response to considerable concern regarding the safety and effectiveness of medical devices,[384] Congress enacted the Medical Device Amendments to the FDCA in 1976.[385] Those Amendments created a three-tiered, risk-based medical device classification system.[386] The FDA thus has both pre-market approval authority and expanded post-market regulatory powers over medical devices under the current regime.

The FDCA defines a "medical device" broadly as "an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for the use in the diagnosis of disease and other conditions, or in the cure, mitigation, treatment or prevention of disease . . . ."[387] As early as 1987, the FDA acknowledged that CDS software could qualify as a medical device and thereby trigger agency oversight.[388] Two years later, the agency issued nonbinding guidance announcing that it would exercise its enforcement discretion and forego regulation of CDS "intended to involve competent human intervention before any impact on human health occurs (e.g., where clinical judgment and experience can be used to check and interpret a system's output)."[389]

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382.   Nathan Cortez, *Substantiating Big Data in Health Care*, 14 I/S: J.L. & POL'Y FOR INFO. SOC'Y 61, 82–85 (2017).

383.   Robert B. Leflar, *Public Accountability and Medical Device Regulation*, 2 HARV. J.L. & TECH. 1, 6 (1989).

384.   STUDY GRP. ON MED. DEVICES, U.S. DEP'T OF HEALTH, EDUC. & WELFARE, MEDICAL DEVICES: A LEGISLATIVE PLAN 7–8 (1970).

385.   Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

386.   *Id.* at 540–46.

387.   21 U.S.C. § 321(h).

388.   Draft Policy Guidance for Regulation of Computer Products; Availability, 52 Fed. Reg. 36,104 (Sept. 21, 1987) ("Computer products which are medical devices . . . are regulated with the least degree of control necessary to provide reasonable assurance of safety and effectiveness.").

389.   U.S. FOOD & DRUG ADMIN., FDA POLICY FOR THE REGULATION OF COMPUTER PRODUCTS (DRAFT) 3 (1989).

Due to the fast-paced growth and ever-increasing complexity of CDS, the FDA rescinded its 1989 guidance in 2005.[390] Over the ensuing eleven years, the agency grappled with—but failed to develop—a viable regulatory framework for CDS.[391] The FDA did, however, repeatedly emphasize that CDS was a top priority, worked with its international counterparts to define SaMD,[392] and indicated its desire to institute a risk-based rubric to regulate SaMD.[393]

"Alarmed that FDA might be embarking on a broad program to regulate stand-alone medical software, the software industry pressed Congress for clarification" and Congress answered that call with the 21st Century Cures Act in 2016.[394] Section 3060 of the Cures Act, which is titled "Clarifying Medical Software Regulations," exempts five categories of CDS from the FDCA's definition of medical device.[395] Congress, thereby, permits those products to be manufactured and distributed in interstate commerce without FDA oversight. The first four of those exclusions, none of which implicate PDMP risk scoring platforms, include: (1) health care facility administrative support software;[396] (2) wellness software "unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition";[397] (3) electronic health records (EHRs) "not intended to interpret or analyze patient records . . . for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition";[398] and (4) software that transfers, stores, converts, or displays laboratory test or other medical device data so long as it does not interpret or analyze that information.[399]

The Cares Act's fifth exclusion, which harkens back to the FDA's 1989 "human intervention" exception, exempts a broad subset of CDS. It deregulates medical software that aggregates patient-specific data to "support[] or provide[] recommendations to a health care professional [HCP] about prevention, diagnosis, or treatment of a disease or condition" so long as the HCP is able to "independently review the basis for such recommendations that such software presents" and, therefore, does not primarily rely on the software to diagnose and

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390.   U.S. FOOD & DRUG ADMIN., POLICY FOR DEVICE SOFTWARE FUNCTIONS AND MOBILE MEDICAL APPLICATIONS 3 (2019).

391.   Parasidis, *supra* note 380, at 195–98.

392.   *See* INT'L MED. DEVICE REGULS. F., SOFTWARE AS A MEDICAL DEVICE (SAMD): KEY DEFINITIONS 4 (2013), http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf [https://perma.cc/PV7R-JBUM]; *Software as a Medical Device (SaMD)*, U.S. FOOD & DRUG ADMIN. (Dec. 4, 2018), https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd [https://perma.cc/YJ2T-K9TT].

393.   *Id.*

394.   Barbara Evans & Pilar Ossorio, *The Challenge of Regulating Clinical Decision Support Software After 21st Century Cures*, 44 AM. J.L. & MED. 237, 238 (2018).

395.   21 U.S.C. § 360j(o).

396.   *Id.* § 360j(o)(1)(A).

397.   *Id.* § 360j(o)(1)(B).

398.   *Id.* § 360j(o)(1)(C).

399.   *Id.* § 360j(o)(1)(D).

treat the patient.[400] In other words, "[t]o escape FDA regulation, the software vendor/manufacturer must intend for the software to make it possible for health care professionals to override its recommendations by explaining its rationale in terms that a clinician could understand, interrogate, and possibly reject."[401]

As scholars were quick to point out, the Cures Act "independent review" exclusion potentially permitted CDS software manufacturers to escape oversight simply by declaring that their products were intended only to assist clinicians to make independent diagnosis or treatment determinations rather than provide the primary basis for such decisions.[402] This concern stemmed from the FDA's long-standing practice of relying almost exclusively on manufacturer statements to ascertain a product's intended use.[403]

The independent review exclusion also raised other confounding questions.[404] How, for example, would the FDA evaluate whether a clinician could independently review the basis for a model's diagnosis and treatment recommendation? And would a platform driven by proprietary machine learning algorithms, like NarxCare, ever be capable of independent clinical review?

The FDA issued guidance in September 2019 that provided important clarification.[405] First, that guidance explained that a software product does not satisfy the Cures Act independent review exception unless the software manufacturer describes that product "in plain language" to the clinician, including: (1) "the purpose or intended use of the software function"; (2) "the intended user"; (3) "the inputs used to generate the recommendation"; and (4) "the basis for rendering a recommendation."[406] The FDA went on to say that, "regardless of the complexity of the software and whether or not it is proprietary," the software manufacturer is required to describe to the clinician the data points and underlying algorithmic logic or rationale used to render its recommendation.[407] The manufacturer must also identify and make available to clinicians the sources supporting and underlying the basis of the recommendation, such as "clinical practice guidelines with the date or version, published literature, or information that has been communicated to the CDS developer to the intended user."[408] The FDA retained regulatory jurisdiction over software manufacturers that do not—or cannot—share this information with clinicians.

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400.   *Id.* § 360j(o)(1)(E).

401.   Evans & Ossorio, *supra* note 394, at 240.

402.   *Id.*

403.   *Id.*; 21 C.F.R. § 801.4 (2021).

404.   Parasidis, *supra* note 380, at 204.

405.   U.S. FOOD & DRUG ADMIN., CLINICAL DECISION SUPPORT SOFTWARE: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2019), https://www.fda.gov/media/109618/download [https://perma.cc/64H5-6LWB].

406.   *Id.* at 12.

407.   *Id.*

408.   *Id.*

Second, the FDA adopted a risk-based regulatory rubric for CDS software functions using factors from the International Medical Device Regulators Forum (IMDRF) Framework.[409] The IMDRF determines the risk level of SaMD based on two factors: "(A) the significance of the information provided by the SaMD to a health care decision: to treat or diagnose, to drive clinical management, or to inform clinical management; and (B) the state of the patient's health care situation or condition: critical, serious, or non-serious."[410] The FDA provided the following table to summarize the SaMD categories established by the IMDRF Framework.[411]

State of health care situation or condition	Significance of information provided by SaMD to health care decision		
	Treat or Diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

The FDA explicitly situates nontransparent, proprietary OUD risk scoring software, like NarxCare, as a "II" (inform clinical management and critical situation or condition) on this rubric. The agency further explained that it intends to focus regulatory oversight on

> [s]oftware, for which the inputs are not explained, that identifies patients who may exhibit signs of opioid addiction based on patient-specific data, family history, electronic health records data, prescription patterns, and geographical data. This software is a Device CDS function, because the HCP is not expected to be able to independently evaluate the basis for the software's recommendations. *FDA intends to focus its regulatory oversight on this software, because it is intended to inform clinical management for a critical situation or condition.*[412]

The FDA's determination that OUD risk scoring software is "intended to inform clinical management for a critical situation or condition" has significant implications due to a separate Cares Act safety valve. The statute expressly authorizes the FDA to assert jurisdiction over *otherwise exempt* medical software if it is "reasonably likely to have serious adverse health consequences."[413] As a result, the FDA retains the statutory authority to regulate NarxCare even if Bamboo is willing and able to provide clinicians with the information demanded by the independent review exemption.[414]

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409. *Id.* at 7–8.
410. *Id.* at 7.
411. *Id.* at 13.
412. *Id.* at 23 (emphasis added).
413. 21 U.S.C. § 360j(o)(3)(A)(i).
414. *Id.* § 360j(o)(3)(B).

As already mentioned, experts have voiced concern that the FDA's current framework for evaluating the safety and effectiveness of medical devices is a poor model for regulating clinical predictive analytics.[415] The FDA, however, issued guidance in 2017 that adopted the IMDRF principles and provided updated regulatory framework for regulating Software as a Medical Device.[416] That framework enumerated robust standards for clinical, analytic, and technical validity, as well as clinical performance for digital diagnostic tools.[417]

As the IMDRF guidance explained, "regulators expect that performance metrics for [SaMD] have a scientific level of rigor that is commensurate with the risk and impact of the SaMD to demonstrate safety, effectiveness, and performance."[418] The IMDRF guidance followed a three-step inquiry:

- Is there a valid clinical association between your SaMD output and your SaMD's targeted clinical condition?

- Does your SaMD correctly process input data to generate accurate, reliable, and precise output data?

- Does use of your SaMD's accurate, reliable, and precise output data achieve your intended purpose in your target population in the context of clinical care?[419]

Bamboo's PDMP risk scoring platform is likely to fail each of these SaMD safety and effectiveness evaluative criteria. As previously explained, there is no scientific indication that PDMPs either reduce overdose death or improve patient outcomes.[420] Certain studies, in fact, associate PDMPs with increased drug overdose mortality.[421] Equally concerning, recent research explicitly modeled on NarxCare found that "the estimated treatment effect of reducing opioid prescribing on [OUD was] *uncorrelated with the risk score generated by*" the model and that PDMP risk scoring platforms "*do not produce a valid proxy for the object of interest*": patient-level health outcomes.[422]

Considerable evidence also demonstrates that PDMP risk scores disparately impact specific patient groups experiencing "a critical situation or condition."[423] These populations include women, ethnic and racial minorities, rural individuals, and socioeconomically disadvantaged patients with complex, chronic pain, OUD, and other stigmatized conditions. The FDA already has determined that PDMP scoring models pose significant risks to vulnerable patients, and therefore

415.   *See, e.g.*, Cortez, *supra* note 382, at 77.
416.   U.S. FOOD & DRUG ADMIN., SOFTWARE AS A MEDICAL DEVICE (SAMD): CLINICAL EVALUATION—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 2 (2017), https://www.fda.gov/media/100714/download [https://perma.cc/TU6K-NRA7].
417.   *Id.* at 4.
418.   *Id.* at 7.
419.   *Id.*
420.   *See* discussion *supra* Part V.
421.   Li et al., *supra* note 186, at 3; *The Myth of an Opioid Prescription Crisis*, *supra* note 184, at 11.
422.   Kilby, *supra* note 352, at 4 (emphasis added).
423.   U.S. FOOD & DRUG ADMIN., *supra* note 405, at 23.

deserve regulatory scrutiny. As a result, the agency is obligated to subject PDMP risk scoring platforms to external, peer-reviewed, clinical evaluation utilizing the validation criteria outlined in the agency's 2017 SaMD guidance.

CONCLUSION

The United States is currently embroiled in an exponentially expanding illicit drug overdose crisis. Substantial evidence indicates that proprietary PDMP risk scoring software has exacerbated the crisis and disparately impacted the treatment and health outcomes of various classes of marginalized patients. Research also raises serious questions regarding the validity of propriety PDMP risk scoring platforms.

Congress has vested the FDA with the legal duty to regulate proprietary PDMP risk scoring software and the agency concedes that such oversight is a priority. The FDA also has adopted a framework to evaluate the safety and effectiveness of predictive diagnostic software. There is, therefore, no excuse for the agency to continue to sit on its hands and permit clinical reliance on unregulated and unverified PDMP risk scores to the potential detriment and needless suffering of countless marginalized patients.