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DEPLOYING PRESCRIPTION DRUG MONITORING TO ADDRESS THE OVERDOSE CRISIS: IDEOLOGY MEETS REALITY

LEO BELETSKY*

“The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding.” *Olmstead v. United States*, 277 U.S. 438, 479 (1928) (Brandeis, J., dissenting).

I. INTRODUCTION

The United States is in the midst of a historic drug overdose crisis. Each day, well over 100 Americans die of drug overdose, driven increasingly by street opioids.¹ Largely as a result of these deaths, overall life expectancy is steadily declining, and especially among certain groups of the American public—a trend seldom observed outside of conflict settings.² As deaths involving prescription painkillers have leveled off, the latest data on heroin and illicitly-manufactured

* Associate Professor at the School of Law & Bouvé College of Health Sciences, Northeastern University and Adjunct Professor at the University of California in San Diego School of Medicine. J.D., Temple University Beasley School of Law, 2008; M.P.H., Brown University, 2004; A.B., Vassar College, 2000. Financial assistance was provided by the Northeastern School of Law Research Stipend Program. A preliminary version of this article was presented at the *Indiana Health Law Review*'s Symposium Ideology Meets Reality, as well as faculty colloquia at Northeastern University School of Law, Suffolk University School of Law, The Data Privacy in the Digital Age Symposium at the US Department of Health and Human Services, and Oxford University Faculty of Law's Center for Socio-Legal Studies. Johnathon Card, Amanda Dolan, Daniel Espinoza, Mark Martinez, Sarah Scotland, Sarah Seymour and Zachary Siegel provided valuable research assistance.

1. Holly Hedegaard et al., *NCHS Data Brief No. 294: Drug Overdose Deaths in the United States, 1999–2016*, U.S. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION & NAT'L CTR. FOR HEALTH STATS. (Dec. 2017), <https://www.cdc.gov/nchs/data/databriefs/db294.pdf> [<https://perma.cc/9QRM-Z3K3>] (last accessed on December 22, 2017).

2. Kenneth D. Kochanek et al., *NCHS Data Brief No. 293, Mortality in the United States, 2016*, U.S. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL & PREVENTION & NAT'L CTR. FOR HEALTH STATS. (Dec. 2017), <https://www.cdc.gov/nchs/data/databriefs/db293.pdf> [<https://perma.cc/SC5W-Q46Y>] (last accessed on December 22, 2017).

fentanyl fatalities could not be more dire.³ These deaths have more than *quintupled* between 2010 and 2016,⁴ with the rate of fentanyl-attributable fatalities *doubling* in a single twelve-month period.⁵

As with past crises, what has been dubbed an “opioid epidemic”⁶ has invoked an expansion in the number and scope of public health surveillance efforts. Since the dominant narrative pins the root cause of this crisis on over-prescription and diversion of prescription drugs, the response has focused on tracking and suppression of medication prescription and dispensation.⁷ By collecting information on who is prescribing, dispensing, and receiving scheduled drugs, prescription drug monitoring systems (PDMPs) are intended to help identify problem patients, rogue prescribers, and pharmacists who may be diverting potentially addictive and otherwise risky drugs.⁸ By imposing this surveillance framework, programs are also thought to deter “aberrant” practices.⁹ The concept behind these systems is far from new,¹⁰ but the current crisis has spawned unprecedented extension in their number, scope, funding, and legal mandates. Every state and the District of Columbia has authorized a PDMP.¹¹ Much has

3. Hedegaard et al., *supra* note 1, at 4.

4. Josh Katz, *The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years*, N.Y. TIMES (Sept. 2, 2017), <https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html> [<http://perma.cc/B8BF-VHU3>]; CTRS. FOR DISEASE CONTROL & PREVENTION & U.S. DEP'T OF HEALTH & HUMAN SERVS., *Drug Overdose Deaths in the United States, 1999–2015*, NAT'L CTR. HEALTH STATS. (Feb. 2017), https://www.cdc.gov/nchs/data/databriefs/db273_table.pdf#5 [<http://perma.cc/RT2Q-4NXX>].

5. Hedegaard et al., *supra* note 1, at 4.

6. Nabarun Dasgupta, Leo Beletsky & Dan Ciccarone, *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. PUB. HEALTH 182 (2018) (arguing that the current framing of, and response to the crisis fails to address its social and economic drivers).

7. The regulatory framework for the collection of patient data on the prescription and dispensing of controlled substances is not new to the U.S., but the recent efforts mark a sharp scale-up in the scope and utilization of these mechanisms.

8. See e.g. *Prescription Drug Monitoring Programs: A Guide for Healthcare Providers*, 10 SAMHSA IN BRIEF 4 (2017), <https://store.samhsa.gov/shin/content/SMA16-4997/SMA16-4997.pdf> [<https://perma.cc/588S-VEPS>] (describing the concept of aberrant prescriber and patient behavior, and noting the difficulty in its precise definition).

9. *Id.* See also MICHEL FOUCAULT, *DISCIPLINE AND PUNISH: THE BIRTH OF THE PRISON* 195–201 (NY: Vintage Books 1995) (noting the introduction of “Panopticon” surveillance is to “induce ... a state of conscious and permanent visibility that assures the automatic functioning of power. So to arrange things that the surveillance is permanent in its effects, even if it is discontinuous in its action; that the perfection of power should tend to render its actual exercise unnecessary.”)

10. See *infra* notes 78–80, 87 and accompanying text.

11. *What States Need to Know about PDMPs*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 3, 2017), <http://www.cdc.gov/drugoverdose/pdmp/index.html> [<https://perma.cc/W2BJ-S6UN>] (last visited Dec. 5, 2017); see also *Prescription Drug Monitoring Programs*, NAT'L ALL. FOR MODEL STATE DRUG LAWS, <http://www.namsdl.org/prescription-monitoring-programs.cfm> [<https://perma.cc/4H84-N7F9>] (last visited Dec. 5, 2017).

been written to extol the potential of these programs—and their enabling legal instruments—to curb drug misuse and diversion.¹² But the discourse on PDMPs and their role in addressing the drug-related harms has been situated primarily in the province of criminal justice and criminal law,¹³ allowing these interventions to proliferate without sufficient scrutiny from ethical, sociolegal, and empirical public health perspectives.

In parallel with the rhetorical shift towards a “public health response” to the overdose crisis, the lens of health law and public health law research has begun to be trained on PDMPs.¹⁴ In addition, privacy concerns about PDMPs have spawned a number of important cases, including recent appellate decisions with wide-ranging implications.¹⁵ This article adds to this nascent discourse. I argue that the zeal with which we have traditionally pursued supply reduction measures to address drug-related harms¹⁶ reflects the legal and system design of PDMPs, as well as the implementation of these programs. In view of their law enforcement roots, PDMPs evolved primarily to track and restrict the supply of potentially addictive substances—the animating mission of U.S. drug policy.¹⁷ This is why the success of PDMPs has for too long been measured primarily by

12. Andrew Kolodny & Thomas Frieden, *Ten Steps the Federal Government Should Take Now to Reverse the Opioid Addiction Epidemic*, 318 JAMA 1537 (2017) (making the case for PDMPs, and other supply reduction strategies as an effective tool to reduce overdose deaths and prevent future cases of addiction); Nathan Trexler, *Developments in Delaware Health Law: Addressing Prescription Drug Abuse*, 14 DEL. L. REV. 29 (2013) (reviewing Delaware’s new prescription drug monitoring program, calling the new laws “safeguards in safely prescribing to a sensitive patient population”); Amy L. Cadwell, *In the War on Prescription Drug Abuse E-Pharmacies are making Doctor Shopping Irrelevant*, 7 HOUS. J. HEALTH L. & POL’Y 85 (2006) (arguing PDMPs reduce doctor shopping and diversion to illegal market).

13. Miles D. Schreiner, *A Deadly Combination: The Legal Response to America’s Prescription Drug Epidemic*, 33 J. LEGAL MED. 529 (2012) (arguing that doctors should be legally responsible for using PDMPs); Neha Casturi, *A Modern Day Apocalypse: The Pill Mill Epidemic, How It Took Texas by Storm, and How Texas Is Fighting Back*, 14 TEX. TECH. ADMIN. L. J. 445 (2012) (contending that the Texas PDMP law wiped out pill mills and doctor shopping in the state); Joanna Shepherd, *Combating the Prescription Painkiller Epidemic: A National Prescription Drug Reporting Program*, 40 AM. J. L. & MED. 85 (2014) (arguing against state PDMPs in favor of a national system); Ashley Dutko, *Florida’s Fight Against Prescription Drug Abuse: Prescription Drug Monitoring Program*, 34 NOVA L. REV. 739 (2010) (heralding the effectiveness of Florida’s PDMP as a response to doctor shopping and drug diversion).

14. See, e.g., D. B. Brushwood, *Maximizing the Value of Electronic Prescription Monitoring Programs*, 31 J. L., MED. & ETHICS 41 (2003); see also Rebecca 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 (2016); Devon T. Unger, *Minding Your Meds: Balancing the Needs for Patient Privacy and Law Enforcement in Prescription Drug Monitoring Programs*, 117 W. VA. L. REV. 345 (2014).

15. See *infra* notes 264-67 and accompanying text.

16. See *infra* notes 73-75 and accompanying text.

17. See *infra* notes 178, 182-83 and accompanying text.

their impact on suppressing medication supply, with too little regard for the more meaningful metrics anchored to reducing risky drug use and overdose.¹⁸

Government surveillance systems, including various electronic databases like PDMPs, are well-understood to have a sinister side.¹⁹ Monitoring mechanisms and the predictive technologies they deploy may perpetuate biases and disproportionate impact on underprivileged citizens, given their common roots with other kinds of surveillance of poor, immigrant, and stigmatized communities.²⁰ As an exercise of state “police power,” public health is never immune from operationalizing social control²¹ that responds to political and normative pressures.²² This implies the imperative to treat systems like PDMPs with caution and deliberate about their proper calibration that guards against unintended consequences. Such discourse is especially important at a time when the nation’s overdose crisis has spurred a rapid expansion in the number, scope, and legal authority of PDMPs.²³

Ultimately, PDMPs are here to stay. But deriving full value from effective public health surveillance without triggering unintended adverse consequences demands careful calibration. How do we decide what information must be collected? Who is able to access surveillance data? How are these data to be used? How must they be protected from undesired public and other disclosure? To answer these questions, the legal and bioethical canon is supposed to draw on a familiar balancing test: to weigh the state imperative to protect the public’s health against the patients’ individual privacy and confidentiality interests.²⁴

Supported by published and original empirical data, this article argues that surveillance efforts that fail to adequately safeguard patient data do much more than harm individual rights; by undermining patient trust and creating a system of perverse incentives, they can push patients away from seeking appropriate, timely help. At the population level, this hampers disease monitoring and control efforts, aggravating the very problems these policies and programs were intended to ameliorate. In other words, this policy heuristic fails to account for behavioral theory, sociolegal critique, and empirical evidence on the impact of public health

18. See *infra* notes 211-21 and accompanying text; See also Table 1 *infra*.

19. See *infra* notes 62-64 and accompanying text. Algorithms

20. See *infra* notes 206-08 and accompanying text. See also JOHN GILLIOM, *OVERSEERS OF THE POOR* (U. Chicago Press 2001).

21. WENDY E. PARMET, *POPULATIONS, PUBLIC HEALTH, AND THE LAW* 13, 117-19 (Geo. U. Press 2009).

22. *Id.* See also Foucault, *supra* note 9, at 195-99 (introducing the concept of Panopticon in the context of disease surveillance and quarantine).

23. The number of states with PDMPs grew rapidly from thirteen in 1999 to fifty states and Washington, D.C., in 2016. *PDMP Access and Registration*, THE POLICY SURVEILLANCE PROGRAM: A LAW ATLAS PROJECT (2016) <http://www.lawatlas.org/query?dataset=prescription-monitoring-program-laws-1408223332> [<http://perma.cc/QY9D-274F>]; see *infra* notes 177-80 and accompanying text.

24. Wendy K. Mariner, *Mission Creep: Public Health Surveillance and Medical Privacy*, 87 BOS. U. L. REV. 347 (2007).

surveillance programs.

The article unfolds as follows: Part II provides an overview of public health surveillance systems, the positioning of patient confidentiality as a countervailing consideration to balance individual rights with community interests, and the role of ideology in shaping the design, legal posture, and implementation of such systems. It then situates PDMPs and their early evolution within this larger public health surveillance story. Part III brings this historical discussion to the present day by focusing specifically on the role of PDMPs within the overdose crisis. It then reviews current programmatic and legal posture of PDMPs, with focus on law enforcement access, criminal justice data integration, and the continued struggle to harmonize the law enforcement-driven design of prescription drug monitoring with its supposed public health mandate. Part IV reviews the available empirical evidence on PDMP impact and adds original qualitative empirical data, supported by emerging jurisprudence elevating privacy concerns about these systems. Finally, in Part V, I synthesize the preceding analysis by proposing changes to PDMP policies and programs that are informed by evidence rather than ideology and are designed to maximize the utility of these programs while minimizing their risk of considerable unintended consequences.

II. PUBLIC HEALTH SURVEILLANCE AND THE HEALTH CARE ENCOUNTER

A. Patient Privacy and Public Health Surveillance

We trust the information we share with our health care providers to be received in confidence and without judgment.²⁵ This is why the patient's right to confidentiality is fundamental to the provision of medical care. At its core, this right protects the deeply private information gathered in the course of medical encounters from disclosure to third parties without the patient's express consent;²⁶ the very fact that a patient has sought medical assistance typically comes under the scope of restricted information.²⁷

From the normative perspective, such protections derive their justification in patients' expectation of privacy, agency, and control over information (including

25. Though the "do no harm" mantra is the most well-known element of the Hippocratic Oath, a less universally-known element of the declaration holds "sacred" any information learned in the course of medical practice. OXFORD TREASURY OF SAYINGS & QUOTATIONS 407 (Susan Ratcliffe ed., 4th ed. 2011) ("And whatsoever I shall see or hear in the course of my profession, as well as outside my profession . . . if it be what should not be published abroad, I will never divulge, holding such things to be holy secret."). Across the world, this normative and instrumental significance has overtime become codified by constitutional, statutory, and administrative protections, professional ethics rules, institutional policies, and an extensive canon from both domestic and international tribunals. For this international perspective, *see generally*, *Declaration of Geneva*, WORLD MED. ASSOC. (1948).

26. *See generally* H. TRISTRAM ENGELHARDT, JR., THE FOUNDATIONS OF BIOETHICS 337 (2nd ed. 1996).

27. *Id.* *See* 45 C.F.R. § 160.103 (2017).

possibly embarrassing, incriminating, or otherwise damaging facts) revealed during the health care encounter.²⁸ This right is central to a bioethical and medical providers' professional responsibility framework designed to recalibrate the balance of power within the inherently unequal provider-patient relationship.²⁹ As it has been enshrined in bioethical canon,³⁰ the rights-based framing of confidentiality empowers patients to avail themselves of the unique trust understood to be at the core of the provider-patient relationship since ancient times.³¹ Conversely, the absence of this trust—and the attendant sense of fear and pessimism³²—further exacerbates the fundamental vulnerability of patients at the hands of medical providers.

The right to privacy and confidentiality also has vital instrumental value. Perceived or real confidentiality breaches erode the trust necessary for the provision of effective medical care. First, without confidence that their physical and mental health concerns and conditions will be held in secret, patients may delay or forgo essential services, with detriment to their health.³³ Second, the lack

28. One example is in help-seeking during overdose events. Laws in most (32, 64%) states now provide good Samaritan protections for victims and witnesses of such events in order to dispel fears of legal consequences from calling emergency medical assistance. *State Legislation: Overdose Prevention*, DRUG POLICY ALL. (Jan. 2016), http://www.drugpolicy.org/sites/default/files/Fact%20Sheet_State%20based%20Overdose%20Prevention%20Legislation%20%28January%202016%29.pdf [<http://perma.cc/7NG3-EB92>].

29. See I. Kleinman et al., *Bioethics for clinicians: 8. Confidentiality*, 156 CANADIAN MED. ASS'N J. 521 (Feb. 15, 1997).

30. Bioethical pillars of beneficence, autonomy, and justice seek to address many of the types of patient abuses and human rights violations that may occur in healthcare settings. See generally ENGELHARDT, JR., *supra* note 26. Some commentators consider non-maleficence and human dignity as central facets of bioethics. See generally INTERNATIONAL DUAL LOYALTY WORKING GROUP & PHYSICIANS FOR HUMAN RIGHTS, DUAL LOYALTY AND HUMAN RIGHTS IN HEALTH PROFESSIONAL PRACTICE: PROPOSED GUIDELINES & INSTITUTIONAL MECHANISMS (2002), <http://physiciansforhumanrights.org/library/reports/dual-loyalty-and-human-rights-2003.html> [<https://perma.cc/6DTU-QFBR>] [hereinafter INTERNATIONAL DUAL LOYALTY WORKING GROUP].

31. There is some debate as to whether the concepts of trust and a "rights-based" framework are in opposition to one another, but I agree with Mark Hall's conceptualization of these frameworks as completely compatible. See generally Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463 (2002) (opposing the view of provider-patient trust as an inherently and unacceptably paternalistic concept, as framed by some scholars); see, e.g., Sheldon F. Kurtz, *The Law of Informed Consent: From "Doctor Is Right" to "Patient Has Rights"*, 50 SYRACUSE L. REV. 1243 (2000).

32. Hall, *supra* note 31, at 474 ("Trust consists of an optimistic attitude towards one's vulnerability, whereas distrust connotes an attitude of wariness or pessimism.").

33. For example, since medical and law enforcement emergency response is linked, many drug users and others who witness drug overdoses delay or forgo calling for professional help out of fear of adverse legal consequences. See, e.g., Leo Beletsky et al., *Prevention of Fatal Opioid Overdose*, 308 JAMA 1863, 1863-64 (2012) (providing a general discussion of this paradigm and the role of 9-1-1 Good Samaritan Laws); see also Caleb Banta-Green et al., *Police Officers' and*

of trust can produce dangerous gaps in patient-provider communication, whereby patients may misstate or omit important information. Such gaps can hamper appropriate diagnosis, treatment, and follow-up.³⁴

Third, the very presence or absence of trust in the patient-provider relationship has measurable therapeutic effects.³⁵ Likely related to the dynamics of the self-healing “placebo effect,” the extent to which a patient perceives her provider as trustworthy and dependable can enhance the health benefit of the patient’s treatment.³⁶ Conversely, unauthorized disclosure of sensitive patient information and associated stigmatization can cause a cascade of harm in physical and mental health, economic, family, social, and other dimensions.³⁷

Confidential medical care is not equally distributed. There is a growing, global body of empirical data documenting the disparities in systemic violations to confidentiality and other rights of patients belonging to marginalized groups. This includes ethnic minorities;³⁸ people living with HIV/AIDS;³⁹ people who use drugs;⁴⁰ and the poor.⁴¹ Reflecting the power imbalance that affects these groups in other domains, confidentiality violations disproportionately impact these patients because they are subject to increased state control, surveillance, and

Paramedics’ Experiences with Overdose and Their Knowledge and Opinions of Washington State’s Drug Overdose-Naloxone-Good Samaritan Law, 90 J. URB. HEALTH 1102, 1102-03 (2013).

34. Thomas A. LaVeist et al., *Mistrust of Health Care Organizations is Associated with Underutilization of Health Services*, 44 HEALTH SERVS. RES. 2093, 2093-3015 (2008) (finding that patient mistrust leads to underutilization of health care); Katrina Armstrong et al., *Distrust of the Health Care System and Self-Reported Health in the United States*, 21 J. GEN. INTERN. MED. 292, 292-97 (2006) (finding that patient distrust is associated with worse self-reported health).

35. See Hall, *supra* note 31, at 470 (“Trust is shown to be essential and unavoidable in medical relationships because patients need and want to trust, and without trust medical relationships never form or are entirely dysfunctional.”).

36. *Id.* at 479-80.

37. *Id.* at 473-88.

38. Alphia Abdikeeva, *Roma Health Rights in Macedonia, Romania, and Serbia: A Baseline for Legal Advocacy*, OPEN SOCIETY FOUNDS. (June 2013), <https://www.opensocietyfoundations.org/sites/default/files/roma-health-rights-macedonia-romania-serbia-20130628.pdf> [<https://perma.cc/V46D-AWBV>] (noting violations to right to privacy and confidentiality of Roma individuals).

39. Judith A. Schwartzbaum et al., *Physician Breach of Patient Confidentiality among Individuals with Human Immunodeficiency Virus (HIV) Infection: Patterns of Decision*, 80 AM. J. PUB. HEALTH 829 (1990) (outlining confidentiality breach in healthcare sector toward people living with HIV/AIDS).

40. Lianne L. Hu et al., *Privacy Protection for Patients with Substance Use Problems*, 2 SUBSTANCE ABUSE & REHAB. 227 (2011) (discussing privacy vulnerabilities in the substance use disorder field).

41. Amanda Dennis et al., *A Qualitative Exploration of Low-income Women’s Experiences Accessing Abortion in Massachusetts*, 25 WOMEN’S HEALTH ISSUES 463 (2015) (finding that low-income women reported fears of confidentiality violations while accessing abortion services).

stigmatization;⁴² they also often lack access to both formal and informal mechanisms to vindicate their individual rights and to address privacy violations.⁴³

Effective flows of accurate information play a vital role in informing decisions on both the individual and community health. Given accurate information about the patient's symptoms, risk factors, and medical history, providers can combine their clinical judgment with the latest available research to make diagnostic and treatment decisions.

Despite its critical importance and deep philosophical roots, the right to patient privacy and confidentiality is nowhere absolute, as it must be balanced with community interests.⁴⁴ Common law and statutory limitations of this right are acknowledged, for example to control emerging diseases and other public health and disease surveillance activities,⁴⁵ and to prevent clear and present danger to the patient or to third parties.⁴⁶

International, national and local laws around the world reflect the imperative to balance community interests in health and safety with the individual patient's right to privacy.⁴⁷ Many jurisdictions mandate provider disclosure of confidential patient information in certain cases, including virulent infections, child abuse, and domestic violence.⁴⁸ But normative and legal protections generally require such disclosure to be narrowly tailored and delineated by safeguards, for example in ways that facilitate testing and treatment.⁴⁹

Data gleaned in the course of health care encounters also holds enormous

42. See, e.g., Mariner, *supra* note 24, at 349 (noting the history of public health surveillance efforts in the U.S. as affecting economically marginalized communities and ethnic minorities).

43. DEBORAH L. RHODE, *ACCESS TO JUSTICE* (Oxford U. Press 2004) (outlining disparate access to justice system along social class lines); Michele Estrin Gilman, *The Class Differential in Privacy Law*, 77 BROOK. L. REV. 1389 (2012) (reviewing the methods of surveillance and privacy violations unique to lower class communities).

44. See ENGELHARDT, JR., *supra* note 26, at 337 (discussing the parallels between the exemptions in provider-patient privilege and that governing members of the clergy and attorneys), and at 338-39 (discussing the balancing of interests in allowing such exceptions to the confidentiality rule).

45. Chris Verity & Angus Nicoll, *Consent, confidentiality, and the threat to public health surveillance*, 324 BRIT. MED. J. 1210 (2002).

46. See, e.g., *Tarasoff v. Regents of Univ. of Cal.*, 17 Cal. 3d 425, 435-36 (Cal. 1976). This rule has been adopted widely by the courts throughout the United States. Many jurisdictions around the world follow similar principles.

47. See, e.g., Nino Kiknadze & Leo Beletsky, *Overview of the Gaps in the Health Care Legislation in Georgia: Short-, Medium-, and Long-term Priorities*, 15 HEALTH & HUMAN RIGHTS J. 32, 32-40 (2013); Gabriela Alcheva, Filip Gerovsky & Leo Beletsky, *Implementation of Patients' Rights Legislation in the Republic of Macedonia: Gaps and Disparities*, 15 HEALTH & HUMAN RIGHTS J. 20, 20-31 (2013).

48. See ENGELHARDT, JR., *supra* note 26, at 338-39.

49. See AMY L. FAIRCHILD ET AL., *SEARCHING EYES: PRIVACY, THE STATE, AND DISEASE SURVEILLANCE IN AMERICA* (U. California Press 2007).

value to the public. By tracking cases of emerging contagions, genetic problems among newborns,⁵⁰ clusters of poisonings, injuries, or cancer diagnoses, as well as antisocial behaviors like child abuse, surveillance data are essential to fully understanding community hazards.⁵¹ The aggregate sum of medical encounters forms a critical component of a society's public health defense—health care settings create a “sentinel surveillance” network to discern the prevalence of certain conditions and risk behaviors, track emerging health threats and offer a platform for prevention and intervention efforts. Only when armed with such information can governments mount timely and proportional responses to public health threats.⁵² Thus, up-to-date data on where and how diseases spread and how best to control them are critical to drive state efforts to protect the public. Generating the best available evidence for individuals and populations requires a number of elements, with patient confidentiality being one of the most fundamental.

Yet, as with other forms of government surveillance,⁵³ these systems are prone to abuse. In the face of emerging public health threats (be they real or perceived), policymakers often respond by mounting expansive, intrusive monitoring. These invasive initiatives certainly affect individuals; the failure of policymakers to adequately protect patients' rights and confidentiality can generate adverse impacts on a population level. With concrete and consistent safeguards, individuals are typically willing to cede some measure of confidentiality for the benefit of the community. Conversely, lack of trust in health providers and concern about legal, social, and other consequences of unauthorized disclosure push risky practices and stigmatized diseases underground. Fear of disclosure of confidential health information to employers, family members, mass media, and law enforcement can create dangerous barriers to preventative care, emergency services, and other domains of health care. A real or perceived risk that confidential medical information may be used to inflict psychological, social, economic, or other harm acts as a direct disincentive to patients seeking professional help or being completely forthright during their

50. *Newborn Screening Reports and Publications*, NAT'L NEWBORN SCREENING & GENETICS RES. CTR., http://genes-r-us.uthscsa.edu/newborn_reports [<https://perma.cc/BEG3-3HN5>] (last updated Nov. 3, 2014).

51. Over time, patient records can also help researchers glean lifesaving insights about factors shaping health and disease.

52. Flint represents a failure of such a system, as it took over a year to identify the lead poisoning trend. Much of the preliminary data that sounded the alarms was collected and identified within a patient care setting, highlighting the value of sentinel surveillance. *See Events that Led to Flint's Water Crisis*, N.Y. TIMES (Jan. 21, 2016), <https://www.nytimes.com/interactive/2016/01/21/us/flint-lead-water-timeline.html> [<https://perma.cc/A3EN-TMK7>].

53. *See* Barton Gellman, *NSA broke privacy rules thousands of times per year, audit finds*, WASH. POST (Aug. 25, 2013), https://www.washingtonpost.com/world/national-security/nsa-broke-privacy-rules-thousands-of-times-per-year-audit-finds/2013/08/15/3310e554-05ca-11e3-a07f-49ddc7417125_story.html?utm_term=.633543b25f3c [<https://perma.cc/9NWU-VSYV>]; *See generally* FAIRCHILD ET AL., *supra* note 49.

interactions with healthcare providers. Such risk may push patients to seek treatment outside of formal channels. This opens patients up to increased exposure to poor quality care and can potentially nudge them away from protective and towards risky health behaviors. When patients delay treatment, misrepresent their symptoms, and withhold information, public health authorities also lose their ability to contain and prevent emerging threats.⁵⁴ On the population level, these abuses can wreak havoc.⁵⁵

In special settings, such as schools, armed forces, or employer-sponsored health clinics, patients expect fewer privacy protections because of the intimate ties binding care providers with entities with an interest in private patient data.⁵⁶ Some of these settings are characterized by special links between health care providers and other third parties. Known as “dual loyalty,” health care providers’ split commitment or “simultaneous obligation to a patient and a third party” presents a number of challenges.⁵⁷ This includes obligations to third party payers, state actors, and other institutional parties. In most egregious cases, dual loyalty may lead to patient abuses and rights violations, such as coerced medical or mental health treatment.⁵⁸ Overall, balancing state, community, payer, and individual interests continues to be a hotly contested area,⁵⁹ and is highly dependent on a society’s cultural, economic, and legal contours.

The U.S. has a long and complicated history of public health surveillance. Dating back to the early days of the republic and substantially evolving during the late 19th and early 20th centuries, public health surveillance systems have typically emerged in response to real or perceived public health crises, such as yellow fever.⁶⁰ Typically intended to identify emergent threats, target interventions and inform policy responses, they are also often conceptualized as deterrents to undesirable behavior. By and large, these monitoring and surveillance systems

54. FAIRCHILD ET AL., *supra* note 49, at 510.

55. The recent Ebola crisis represents an example of how the lack of adequate protections for patient right for confidentiality can adversely impact public health. In many of the affected locales, cases of infection quickly became public knowledge, leading to devastating consequences to both individuals and their families and neighbors. In response, infected individuals were often hidden for the fear of being ostracized and did not seek help until it was too late and their caregivers had been put at an unnecessary risk of infection. *See, e.g., FEAR, POLITICS, AND EBOLA: HOW QUARANTINES HURT THE FIGHT AGAINST EBOLA AND VIOLATE THE CONSTITUTION*, AM. CIVIL LIBERTIES UNION & YALE GLOB. HEALTH J. P’SHIP (2015), https://law.yale.edu/system/files/documents/pdf/Intellectual_Life/aclu_yale_ghjp_-_fear_politics_and_ebola-december_2015.pdf [<https://perma.cc/DLG3-665T>].

56. *See* ENGELHARDT, JR., *supra* note 26, at 339-40.

57. *See* INTERNATIONAL DUAL LOYALTY WORKING GROUP, *supra* note 30, at 11.

58. *See, e.g., Policing Patient Privacy*, PROPUBLICA, <https://www.propublica.org/series/patient-privacy#> [<https://perma.cc/NPC3-F76B>].

59. *See generally* Mariner, *supra* note 24.

60. Stephen B. Thacker et al., *Public Health Surveillance in the United States: Evolution and Challenges*, CTRS. FOR DISEASE CONTROL & PREVENTION at 3-9 (2012), <https://www.cdc.gov/mmwr/pdf/other/su6103.pdf> [<https://perma.cc/D7DB-WLRH>].

have used health care encounters as their sentinel points of data collection, mandating providers to report confidential data without patient consent in instances of a whole range of instances ranging from suspected child abuse to gunshot wounds to sexually-transmitted diseases and, at one time, abortions.⁶¹

Just as with other forms of government surveillance, public health surveillance can be both “vital to the maintenance of our welfare” and “a policy of rounding undesirable” citizens.⁶² The history of mandated disclosure programs in the U.S. and elsewhere is marked by a steady march towards more comprehensive, systematic, and effective surveillance. The dual-edged view of surveillance also means that its development has been shaped by the parallel evolution of privacy as American “society’s limiting principle,”⁶³ especially its emergence as a normative consideration and legal construct in jurisprudence and political thought.⁶⁴

Throughout the decades, public health surveillance has periodically invoked privacy concerns, closely tied to the abuse, over-reach, and stigmatization it potentiated.⁶⁵ In instances exemplified by the vociferous advocacy of the Citizens’ Council on Health Care against birth defect registries, such concerns may have been principally theoretical.⁶⁶ They have been spurred by general distrust in government and libertarian sentiment.⁶⁷ Conversely, episodes like the Tuskegee syphilis study fueled well-founded suspicion of public health surveillance efforts in African Americans and other minority groups,⁶⁸ people living with HIV/AIDS,⁶⁹ gay men,⁷⁰ as well as undocumented immigrants.⁷¹

61. See *Whalen v. Roe*, 429 U.S. 589, 602 (1977); see also *Planned Parenthood of Cent. Missouri v. Danforth*, 428 U.S. 52, 79-81 (1976) (upholding the constitutionality of Missouri’s abortion registry).

62. James Scott, *SEEING LIKE A STATE: HOW CERTAIN SCHEMES TO IMPROVE THE HUMAN CONDITION HAVE FAILED* 4 (Yale U. Press 1998).

63. LAURENCE TRIBE, *AMERICAN CONSTITUTIONAL LAW* 1302 (Foundation Press, 2d ed. 1988).

64. FAIRCHILD ET AL., *supra* note 49, at 23-25.

65. *Id.*

66. *Id.* at 164-65 (noting that Minnesota Department of Public Health found themselves embroiled in an unanticipated political dispute concerning their prospective implementation of a birth defect registry in the 1990s. Though the surveillance system was introduced as a public health response to heightened pesticide exposure in children, political advocacy groups such as the Citizens’ Council on Health Care capitalized on social anxieties and historical concerns about patient privacy to launch a formidable counter-campaign against the measure. Consequently, public health officials eventually withdrew their proposal, despite the state’s rising rates in pesticide-related birth defects.).

67. *Id.*

68. *Id.* at 68-69.

69. *Id.* at 194-95 (describing a 1986 incident in Florida, where the HIV positive status of thousands of patients was widely disclosed).

70. *Id.* at 197-99.

71. *Id.*

These concerns included consideration of how class, social status, and racial characteristics of affected patients affected the implementation and “politics of surveillance.”⁷²

B. PDMPs as a Tool of Public Health Surveillance

The emergence of prescription drug monitoring programs reflects the evolution of disease-related surveillance in the US. In fact, efforts to track prescription of potentially-addictive medications date back to the early 1900s, including legislation like the Harrison Narcotics Act,⁷³ which set minimum standards for recording and reporting prescription of certain opioid medications. Steeped in drug panics of the era with roots in anti-immigrant sentiment,⁷⁴ this legislation cemented federal government jurisdiction of prescription and pharmacy practice in the space that would become known as “controlled substances.”⁷⁵ In the intervening years,⁷⁶ the tracking of prescription medications deemed at high risk of misuse was accomplished primarily through the requirement of a triplicate prescription form, with one form being given to the patient, another being retained on file with the pharmacy, and the third being sent to a relevant government agency.

The history of modern-day PDMPs dates back to the 1960s and 1970s. Renewed legislative interest in these programs reflected emerging concerns about substance misuse among soldiers returning from Vietnam⁷⁷ and changes wrought by the countercultural movement. During this era of panic over drug use, new legislation expanded both the scope and the tools of surveillance.⁷⁸ The simultaneous advent of computer-assisted PDMPs occurred just as public health surveillance⁷⁹ was making its transition into the digital age.⁸⁰

72. *Id.*

73. 38 U.S.C. § 785 (1914).

74. Deborah Ahrens, *Drug Panics in the Twenty-first Century: Ecstasy, Prescription Drugs, and the Reframing of the War on Drugs*, 6 ALB. GOV'T L. REV. 397 (2013).

75. Joe Spillane & William B. McAllister, *Keeping the lid on: a century of drug regulation and control*, 70 DRUG & ALCOHOL DEPENDENCE S5 (2003); DAVID F. MUSTO, *THE AMERICAN DISEASE: ORIGINS OF NARCOTIC CONTROL* (Yale U. Press 1973).

76. The first three states to pass PDMPs were California (1939), Hawaii (1943), and Illinois (1958).

77. Lee N. Robins et al., *Drug Use by U.S. Army Enlisted Men in Vietnam: A Follow-up on Their Return Home*, 99 AM. J. EPIDEMIOLOGY 235, 235-49 (1974).

78. FAIRCHILD ET AL., *supra* note 49, at 25-27.

79. William Phillips, Kurt Gorwitz, & Anita K. Bahn, *Electronic Maintenance of Case Registers*, 77 PUB. HEALTH REPS. 503, 503-04 (1962).

80. FAIRCHILD ET AL., *supra* note 49. States adopting PDMPs during this era also included Pennsylvania and New York (1972), and Rhode Island (1978). See KAREN BLUMENSCHEN ET AL., REVIEW OF PRESCRIPTION DRUG MONITORING PROGRAMS IN THE UNITED STATES (2010), <http://chfs.ky.gov/NR/rdonlyres/85989824-1030-4aa6-91e1-7f9e3ef68827/0/Kasperevaluationpdmstatusfinalreport624> [<https://perma.cc/V3Z6-4C85>].

The emergence of the early modern PDMP is also closely enmeshed with the passage of sweeping drug control reforms, especially federal Controlled Substances Act (CSA).⁸¹ This law would also become the model state-level drug control framework. In 1970, Congress adopted this legislation with the express purpose of “conquer[ing] drug abuse and . . . control[ing] the legitimate and illegitimate traffic in controlled substances.”⁸² This framework aimed to establish a “comprehensive” system to control the supply of drugs deemed potentially addictive or otherwise able to be abused.⁸³ Critical to this closed system is the articulation of a schedule, which categorizes drugs based on potential for abuse, accepted medical use, and likelihood of psychological or physical dependence.⁸⁴ Overtime, the scope of state PDMP laws adopted federal or state CSA scheduling frameworks by training their surveillance efforts on specific drug schedules (typically schedules II-V).

During this same era, the construct of patient privacy and autonomy saw substantial expansion. Emerging jurisprudence, epitomized in the progression from *Griswald v. Connecticut* in 1965 to *Roe v. Wade* in 1973, cemented the evolving understanding of privacy’s constitutional underpinnings.⁸⁵ Notably, both of these landmark privacy cases addressed disputes arising from highly-sensitive medical procedures, with *Griswald* specifically invoking the patient’s autonomy in controlling their prescription drug choices.⁸⁶

This jurisprudence set expanded PDMP laws and programs on a collision course with the emergent constitutional conceptualization—and public yearning for—privacy rights. Spurred by anxiety about novel electronic database systems, this tension would come to a head in the watershed PDMP case *Whalen v. Roe*.⁸⁷ At issue in *Whalen* was the 1972 passage of a New York State (NYS) provision directing the Department of Health to electronically document basic information for any patient prescribed a Schedule II medication.⁸⁸ In contrast to existing NYS paper-based prescription reporting, the new system would enable more practicable data management and streamlined analytical capability. This novel capability was aimed at identifying possible cases of drug diversion among patients and flagging patterns of potential inappropriate practices among prescribers.⁸⁹ Notably, this reform was part of a broad array of legislation buoyed by a wave of “get tough” ideology on drugs, exemplified by the highly-punitive Rockefeller Drug Laws.⁹⁰

A group of concerned citizens joined by health care providers challenged the

81. 21 U.S.C. § 801 *et seq.*

82. *Gonzales v. Raich*, 545 U.S. 1, 12 (2005).

83. 21 U.S.C. §§ 841(a)(1), 844(a) (1970).

84. 21 U.S.C. § 812 (1970).

85. *TRIBE*, *supra* note 63.

86. *Fairchild et al.*, *supra* note 49, at 22-23.

87. *Whalen v. Roe*, 429 U.S. 589 (1977).

88. *Id.*

89. *Id.*

90. *FAIRCHILD ET AL.*, *supra* note 49, at 25.

law. They sought to set minor constraints to state police power to store and collate data using new computerized tools. One plaintiff—a mother—claimed she had taken her child off Ritalin to avoid him being “branded for life.”⁹¹ Other adult plaintiffs recounted foregoing pain medication for the fear of being “labelled an addict,” especially disquieting at a time when Nixon’s “public enemy Number One” rhetoric was stoking the War on Drugs.⁹² After being initially upheld⁹³ the law was later struck down after the case was remanded on appeal.⁹⁴ Balancing low actual system utilization at the time of the trial with the law’s potential to violate “the most sensitive physical and psychological sensibilities” of patient privacy, the court struck down the new PDMP law.⁹⁵

Bucking its favorable disposition in privacy jurisprudence, the Burger Court reversed.⁹⁶ It deemed weighing program value against possible privacy violations a legislative, not a judicial matter. Brushing off these existential considerations, the Court opined that the state police power entitled New York State to rationally “experiment with new techniques of [drug] control.”⁹⁷ It further rationalized that the risk of harmful data disclosure through a subpoena was too “remote” to invalidate the entire state regulatory scheme—a scheme, it pointed out, analogous to two other states and any number of existing New York State patient reporting mechanisms.⁹⁸

By articulating that “privacy” has multiple meanings, and that case law relating to autonomy in decision making did not apply to all matters of confidentiality,⁹⁹ *Whalen* demarcated the limits of privacy-based objections to government surveillance in modern jurisprudence. Its broad recognition of state police power to collect and store large amounts of information formed the basis for controversial surveillance programs in the intervening decades.¹⁰⁰ In rejecting to implicate surveillance program utility and impact, the Court left the design and configuration of these surveillance programs generally (and PDMPs in particular) a difficult target for legal challenge. In the context of the ideological discourse that captivated legislatures during the dawn of the War on Drugs, this implicit endorsement set the stage for the later expansion and intensification of PDMPs in the context of the overdose crisis.

91. *Id.* at 26.

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.*

97. *Whalen v. Roe*, 429 U.S. 589, 598 (1977).

98. *Id.* at 601-02.

99. *Id.* at 599-602.

100. See FAIRCHILD ET AL., *supra* note 49 (describing the impact of *Whalen* and how upholding this public health surveillance as constitutional laid the groundwork for more extensive surveillance programs in later years), and at 246-50 (describing the social and political pressure following September 11, 2001 to increase national public health surveillance methods in order to prepare for bioterror attacks).

III. PDMPs IN THE AGE OF THE OVERDOSE CRISIS

Starting in around 2000, the US began to see steep increases in drug-related deaths, many involving opioid analgesics along with other depressants like benzodiazepines and alcohol.¹⁰¹ This has evolved into one of most devastating public health crises in its recent history. After rising at around 10% per year between 1999 and 2006, the overdose rate precipitously accelerated to 18% between 2014 and 2016. Over 64,000 Americans were killed by drug overdose in 2016—an unprecedented increase of more than 300% since the turn of the century.¹⁰² The death rate specifically attributable to synthetic drugs like fentanyl shockingly doubled just within a one-year period, from 2015 to 2016.

The grim toll of overdose-related death and disability is propelled primarily by opioids. A drug family that includes both prescription analgesics and street drugs like heroin, opioids contribute to an average of well over 100 Americans fatalities *every day*. The human toll of this crisis has impacted countless families,¹⁰³ communities, and businesses; its financial costs already number in tens—perhaps hundreds—of billions per year.¹⁰⁴ In order to understand this crisis, it is first useful to provide an overview of its key elements and evolution.

A. Opioid Overdose, Defined

Opioids kill by depressing the individual's central nervous system, which in turn slows respiration.¹⁰⁵ This process can take up to 90 minutes or longer.¹⁰⁶ In lay discourse, overdose is often conflated with opioid addiction. A small but significant (up to 8%)¹⁰⁷ prescription drug users develop substance use disorder

101. See Dasgupta et al., *supra* note 6.

102. Overdose Death Rates, NAT'L INST. ON DRUG ABUSE (Sept. 2017), <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> [<https://perma.cc/N7R3-FX95>].

103. In a recent poll, 56% of respondents, across all demographics, reported a personal connection to someone who has abused prescription painkillers. 63% of White-identifying respondents reported a personal connection, a rate higher than any other racial group. *Most Americans Report a Personal Connection to Those Who Have Abused Prescription Painkillers; Whites More Likely To Be Affected Than Blacks or Hispanics*, KAISER FAMILY FOUND. (Nov. 24, 2015), <https://www.kff.org/health-reform/press-release/most-americans-report-a-personal-connection-to-those-who-have-abused-prescription-painkillers-whites-more-likely-to-be-affected-than-blacks-or-hispanics/> [<http://perma.cc/M82E-85DC>].

104. Phillip O. Coffin & Sean D. Sullivan, *Cost-Effective of Distributing Naloxone to Heroin Users for Lay Overdose Reversal Variation in the Delivery of Health Care: The Stakes are High*, 158 ANNALS OF INTERNAL MED. 866 (2013).

105. Scott Burris, Leo Beletsky, Carolyn Castagna, Casey Coyle, Colin Crowe & Jennie McLaughlin, *Stopping an Invisible Epidemic: Legal Issues in the Provision of Naloxone to Prevent Opioid Overdose*, 1 DREXEL L. REV. 273, 274-76 (2009).

106. *Id.*

107. Mark J. Edlund et al., *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence among Individuals with Chronic Noncancer Pain: The Role of Opioid Prescription*,

(as “addiction” is referred to in clinical discourse),¹⁰⁸ translating to increasing prevalence of risky non-medical use, such as snorting or injecting crushed pills. Ultimately, it is not possible to ascertain what proportion of overdose victims would have met the diagnosis of severe substance use disorder. What we do know is that addiction is not the sole risk factor for a fatal overdose. Polydrug use, especially the kind of mixing of opioids with other depressants like benzodiazepines, vastly increases overdose risk; doubling with every illicit drug consumed in combination with opioids.¹⁰⁹

Another critical driver of risk for overdose is resuming drug use after periods of voluntary or forced abstinence.¹¹⁰ Such abstinence could result from drug “detoxification” or other treatment, incarceration, or other factors. Upon resuming drug use, individuals’ overdose risk skyrockets because of loss of tolerance to the drug; when an individual consumes a dose similar to what they had used prior to incarceration, the loss of tolerance can render that dose fatal.¹¹¹ In the case of incarceration, during the first month of re-entry, ex-prisoners’ risk of overdose is magnitudes higher than the background rate.¹¹² The opioid antidote naloxone reverses the respiratory depression, reviving the victims regardless of setting.¹¹³ Naloxone is a prescription medication, although states have adopted legal strategies to facilitate its lay distribution amidst calls to make this drug available over the counter.¹¹⁴

30 CLINICAL J. PAIN 557 (2014) (finding the rate of substance use disorder among pain patients on high dose opioids is roughly 6%); Nora D. Volkow & A. Thomas McLellan, 374 NEW ENG. J. MED. 1253 (2016) (underscoring the need for some patients to remain on opioids, citing fewer than 8% of pain patients develop substance use disorder).

108. See DIAGNOSTIC & STAT. MANUAL OF MENTAL DISORDERS (DSM-5) (2015).

109. WORLD HEALTH ORG., PREVENTION OF ACUTE DRUG-RELATED MORTALITY IN PRISON POPULATIONS DURING THE IMMEDIATE POST-RELEASE PERIOD 10 (2010).

110. Ingrid A. Binswanger et al., *Release From Prison—A High Risk of Death for Former Inmates*, 356 NEW ENG. J. MED. 157, 160-61 (2007). Among Washington State prisoners, overdose mortality risk was elevated twelve-fold compared to similar demographic groups within the general population; see also P.B. Christensen et al., *Mortality Among Danish Drug Users Released From Prison*, 2 INT’L J. PRISONER HEALTH 13, 13-19 (2006); Michael Farrell & John Marsden, *Acute Risk of Drug-Related Death Among Newly Released Prisoners in England and Wales*, 103 ADDICTION 251, 252-54 (2007).

111. Edle Ravndal & Ellen J. Amundsen, *Mortality among drug users after discharge from inpatient treatment: An 8-year prospective study*, 108 DRUG & ALCOHOL DEPENDENCE 65 (2010).

112. Binswanger et al., *supra* note 110, at 157, 160-61; See also MASS. DEP’T OF PUB. HEALTH, AN ASSESSMENT OF OPIOID-RELATED DEATHS IN MASSACHUSETTS (2013–2014) 38 (Sept. 2016), <http://www.mass.gov/eohhs/docs/dph/stop-addiction/dph-legislative-report-chapter-55-opioid-overdose-study-9-15-2016.pdf> [<https://perma.cc/96W3-NH3A>] (estimating post-incarceration risk at 650 times the background rate).

113. Leo Beletsky, Josiah D. Rich & Alex Y. Walley, *Prevention of Fatal Opioid Overdose*, 308 JAMA 1863 (2012).

114. *Id.* at Table 1. See also Leo Beletsky, *The Benefits and Potential Drawbacks in the Approval of EVZIO for Reversal of Opioid Overdose*, 48 AM. J. PREVENTATIVE MED. 357, 357-59

B. The Ideology of Opioid Response: Focus on the Drug Supply as the Vector

For decades, opioid overdose had been endemic in urban communities of color, pockets of deep poverty in Appalachia, and other limited settings.¹¹⁵ Aside from periodic celebrity deaths and occasional spikes in fatalities among heroin users related to fluctuations in drug purity, overall prevalence of opioid overdose remained relatively constant; so did public apathy.¹¹⁶ Stigma attached to illicit drug use and reinforced by criminal law—as well as class and racial prejudice—translated to the lack of any concerted public health response. This endemic phase of apathy would gradually come to an end as the sheer magnitude, geography and demographics—its “changing face”—would begin to attract the mainstream attention it now so consistently receives.¹¹⁷

The commonplace story about the current overdose crisis—both among professional and lay observers—is a narrative based on what in Public Health is referred to as the “vector model of disease.” Rooted in the customary public health concern with infection control, this theory frames opioid drugs as a contagion. As with a virus, exposure to the opioid supply carries a risk of disease and even death.¹¹⁸ Similarly, opioid fatalities have rapidly spread regionally and even internationally in a short period of time. This framing helps explain the wide popularity of the term “epidemic” to describe a crisis.

The vector model narrative proceeds as follows: towards the end of the Twentieth Century, American medicine was shocked by a series of epiphanies about the appalling societal levels of under-treated pain. This launched a well-intentioned drive to improve its management. Pain became the “fifth vital sign” and its self-assessment was introduced as a measure of consumer satisfaction, with implications for health care facilities’ ratings and accreditation.¹¹⁹ A movement towards “patient-centeredness” also catalyzed health care providers’ focus on patient comfort and satisfaction.

Sensing a business opportunity, several drug makers engaged in aggressive physician detailing and other marketing to assuage concerns about the risks of

(2015).

115. Theodore J. Cicero et al., *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, 71 JAMA PSYCHIATRY 821 (2014).

116. See Burris et al., *supra* note 105, at 273-75 (discussing the relative apathy of the general public towards opioid overdose, despite the relative frequency in deaths of celebrities struggling with heroin use).

117. 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); Theodore J. Cicero et al., *supra* note 115.

118. See generally Dasgupta et al., *supra* note 6 (interrogating the application of the vector model to the overdose crisis).

119. Jane C. Ballantyne & Mark D. Sullivan, *Intensity of Chronic Pain—The Wrong Metric?*, 373 NEW ENG. J. MED. 2098 (2015).

dependence, addiction, and overdose inherent to opioid therapy.¹²⁰ This included the creation of astro-turf “patient rights” groups that would use legitimate gaps in patient care to advance the agenda of the pharmaceutical industry. Some of these initiatives intentionally misled prescribers about risks by asserting, without much evidence, that new product formulations successfully minimized adverse side effects in treatment of chronic pain.¹²¹

These developments drove a rapid expansion in the availability of opioid analgesics. Prescribers readily relied on these medications to treat all kinds of pain, including acute, chronic, and palliative indications. Prescriptions were often made for medication courses that were substantially longer than necessary—epitomized in the narratives featuring high school athletes receiving a thirty-day OxyContin supply for a sprained ankle.¹²² In addition to those acting in good faith, a small proportion of providers established “pill mills,” which issued opioid prescriptions with inadequate regard for the patients’ actual medical need. As a result, the rate of opioid analgesic consumption more than tripled between 1999 and 2006¹²³ but leveled off and started to decline after 2011-2012.¹²⁴

With steep increases in exposure to these powerful depressants, the number of Americans experiencing accidental opioid poisonings began to grow.¹²⁵ This has been attributed to the inherent habit-forming properties of these drugs and to the poor understanding of how to properly balance appropriate pain care with the risk of addiction and overdose. Ultimately, the rising popularity of opioid analgesics was closely trailed by an upward curve in opioid overdose fatalities.¹²⁶

120. Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, FOOD & DRUG L. J. 423 (2002).

121. Ironically, the same pitch was used to market heroin when it was first formulated by Bayer Laboratories as a less addictive form of morphine.

122. L. Jon Wertheim & Ken Rodriguez, *How Painkillers Are Turning Young Athletes Into Heroin Addicts*, SPORTS ILLUSTRATED (June 18, 2015), <https://www.si.com/more-sports/2015/06/18/special-report-painkillers-young-athletes-heroin-addicts> [<http://perma.cc/BC4J-XB3W>]; Kenneth Craig & Polly Leider, *The surprising path from student athlete to heroin addict*, CBS NEWS (Mar. 2, 2016, 5:30 PM), <https://www.cbsnews.com/news/student-athletes-on-pain-killers-at-risk-for-heroin-addiction/> [<https://perma.cc/82EC-VSUK>].

123. Li-Hui Chen et al., *Rates of Deaths from Drug Poisoning* and Drug Poisoning Involving Opioid Analgesics*—United States, 1999–2013*, MORBIDITY & MORTALITY WEEKLY REPORT (Jan. 16, 2015), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a10.htm> [<https://perma.cc/3CCL-G9A5>].

124. *Id.* See also Gery P. Guy Jr. et al., *Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015*, MORBIDITY & MORTALITY WEEKLY REPORT (July 7, 2017),

<https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm> [<https://perma.cc/MM2W-SX2G>]; Edmund J. Pezalla, *Secular Trends in Opioid Prescribing in the USA*, 10 J. PAIN RES. 383 (2017).

125. Hedegaard et al., *supra* note 1.

126. Li-Hui Chen et al., *Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, NAT’L CTR. HEALTH STATS DATA BRIEF NO. 166 (Sept. 2014) <http://europepmc.org/abstract/med/25228059> [<https://perma.cc/56JG-2V4P>].

Around 2010, the second phase of the crisis began to take shape. After remaining stable for years, overdose deaths involving heroin spiked rapidly, tripling between 2010 and 2015.¹²⁷ The “vector model” associates this shift with rising rates of addiction among those taking opioid medications; once the users were exposed and seeking an ever-elusive high, prescription opioids would then act as a “gateway” to black market drugs, based on their ubiquitous availability and lower price relative to diverted prescription medications. This narrative is encapsulated in the often-cited statistic that “4 out of 5 new heroin users started with prescription drugs.”¹²⁸

Starting in 2014, the crisis spiraled into its third phase. Black market drugs—including heroin and counterfeit pills—became increasingly adulterated with illicitly-manufactured synthetic opioids, mainly fentanyl analogues.¹²⁹ These substances can be clandestinely synthesized cheaply and with relative ease by anyone with the requisite knowledge of—and access to—chemical laboratory equipment. In the span of a single year, from 2014 to 2015, U.S. deaths attributed to fentanyl analogues spiked by over 72% to almost 10,000.¹³⁰ In an increasing number of locales, these clandestinely-manufactured synthetics now constitute the primary drivers of fatal opioid poisoning.¹³¹

Under the vector model, the fault for this uncontained crisis falls principally—and almost exclusively—on the substances and their distributors. Were it not for the unenlightened or unscrupulous behavior by health care providers and drug companies, this line of logic suggests we would not be in the situation we are in today. This logic certainly applies to contaminated food products.¹³² However, aside from their habit-forming properties, opioids provide, powerful relief to sufferers of physical and emotional pain—which is the reason they have remained a critical healing tool for centuries.¹³³ Even a cursory

127. Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, MORBIDITY & MORTALITY WEEKLY REPORT (Dec 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm?mbid=synd_yahoohealth&s_cid=mm655051e1_w [<https://perma.cc/AQ4T-YAAT>].

128. *Heroin*, NAT’L INST. ON DRUG ABUSE (July 2017), <https://www.drugabuse.gov/publications/drugfacts/heroin> [<https://perma.cc/5JMF-AZWC>].

129. Sheila Kaplan, *C.D.C. Reports a Record Jump in Drug Overdose Deaths Last Year*, N.Y. TIMES (Nov. 3, 2017) https://www.nytimes.com/2017/11/03/health/deaths-drug-overdose-cdc.html?_r=0 [<https://perma.cc/GJW2-37JR>].

130. Rudd, *supra* note 127. Some of this increase may have been caused by broader awareness and better surveillance of the problem.

131. MASS. DEP’T OF PUB. HEALTH, *supra* note 112. See also DENISE PAONE, UNINTENTIONAL DRUG POISONING (OVERDOSE) DEATHS INVOLVING HEROIN AND/OR FENTANYL IN NEW YORK CITY, 2000–2015 (2016).

132. *Multistate Outbreak of Listeriosis Linked to Soft Raw Milk Cheese Made by Vulto Creamery (Final Update)*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 3, 2017, 1:30 PM), <https://www.cdc.gov/listeria/outbreaks/soft-cheese-03-17/index.html> [<https://perma.cc/H7D4-QHTN>].

133. *Id.*

examination of the demographic, epidemiological and economic evidence limits the explanatory power of the vector model as it applies to the overdose crisis.

C. The Social Determinants Critique

Although it is a common refrain to say that the overdose crisis cuts across geographic and demographic fault lines, not all racial and economic groups have been uniformly affected. Areas and groups characterized by poverty, concentrated disadvantage, and poor economic opportunity have been noted to be at much higher risk.¹³⁴ These statistics readily point to more fundamental underlying causes of the crisis.

Modern Public Health embraces economic, social, and other “structural” factors as “social determinants” of health.¹³⁵ Central to the social determinants framework is the recognition of wide disparities in health.¹³⁶ Although some differences in health outcomes may be due to biological factors (for example, life expectancy differences between the sexes), observed differences in disease prevalence and life expectancy based on racial, class, geographical and other arbitrary characteristics vividly demonstrate the influence of structural factors.¹³⁷ In addition to clear links between poor health and low economic attainment, inequality in-and-of-itself appears to play a role in generating stress, substance misuse, and other disease-causing processes.¹³⁸

A deeper exploration of the relationship between structural determinants, pain, addiction, and overdose has been covered elsewhere¹³⁹ and is beyond the scope of this paper. What is critical to the discussion of the role of PDMPs in the response to the current crisis is that there is ample evidence pointing to the importance of social, economic, health care systems, and other factors as the drivers of drug use and overdose crisis.¹⁴⁰ So, while the expansion in the availability of prescription analgesics certainly played a role in facilitating this crisis, an exclusive focus on that expansion misses its underlying root causes.

An emerging domain of demographic research into “diseases of despair” helps to better understand the broader phenomena that precipitated the current overdose emergency. Coined by Princeton economists Anne Case and Angus Deaton, this term refers to the interconnected trends in fatal drug overdose, alcohol-related disease, and suicide. Since 1999, age-specific mortality attributed

134. See *infra* notes 139-40 and accompanying text.

135. See PARMET, *supra* note 21.

136. *Id.* at 53-54; see also Katherine Unger Davis, *Racial Disparities in Childhood Obesity: Causes, Consequences, and Solutions*, 14 U. PA. J. L. & SOC. CHANGE 313, 333 (2011).

137. David S. Jones et al., *The Burden of Disease and the Changing Task of Medicine*, 366 NEW ENG. J. MED. 2336 (2012).

138. Rick Mayes & Thomas R. Oliver, *Chronic Disease and the Shifting Focus of Public Health: Is Prevention Still a Political Lightweight?*, 37 J. HEALTH POL., POL'Y, & LAW 181 (2012).

139. JOHANN HARI, CHASING THE SCREAM: THE FIRST AND LAST DAYS OF THE WAR ON DRUGS (Bloomsbury 2015).

140. See Dasgupta et al., *supra* note 6.

to “diseases of despair” has seen an “extraordinary” and “unanticipated” rise previously rarely seen in times of peace.¹⁴¹ Based substantially on these three causes of death, middle-aged white Americans without a bachelor’s degree now have a lower life expectancy than their parents.¹⁴² The “reversal of fortunes”¹⁴³ in life expectancy originally identified in underserved counties of Appalachia and the Southwest in the first decade of the 21st Century now characterizes the overall demographic trend for the United States.¹⁴⁴

Alcohol-related liver disease and—to a substantial degree—suicide are not directly attributable to the risks posed by opioid medications. Alarming upward trends in those realms challenge the centrality of opioid supply as the root cause of the overdose crisis.¹⁴⁵ Case and Deaton attribute these unprecedented demographic shifts to deterioration in economic and social factors, linked primarily to the stagnation in real wages, decline in economic opportunity, and the economic shocks following the 2008 financial crisis.¹⁴⁶ Ultimately, they argue, these drastic demographic shifts are linked to cumulative deprivation following a long-term process of decline. This has culminated in the loss of hope for a better future that has hit white working-class Americans especially hard.

Austerity politics have accelerated these trends.¹⁴⁷ In a wave of political

141. Anne Case & Angus Deaton, *Mortality and morbidity in the 21st century*, BROOKINGS PANEL ON ECON. ACTIVITY CONFERENCE 8 (Mar. 17, 2017), https://www.brookings.edu/wp-content/uploads/2017/03/6_casedeaton.pdf [<https://perma.cc/Z3F4-XRQA>].

142. *Id.* See also Majid Ezzati et al., *The Reversal of Fortunes: Trends in County Mortality and Cross-County Mortality Disparities in the United States*, PLOSMEDICINE (April 22, 2008) <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050066> [<https://perma.cc/V8WK-93WB>] (noting that mortality rates of whites with no more than a high school degree, which were around 30% lower than mortality rates of blacks in 1999, grew to be 30% higher than blacks by 2015).

143. Ezzati et al., *supra* note 142 (stating that ultimately, disparities are responsible for reversing overall life expectancy gains made in the last century).

144. Case & Deaton, *supra* note 141, at 12 (“The epidemic spread from the southwest, where it was centered in 2000, first to Appalachia, Florida and the west coast by the mid-2000s, and is now country-wide.”).

145. Anne Case & Angus Deaton, *Rising morbidity and mortality in midlife among white non-Hispanic Americans in the 21st century*, 112 PROC. NAT’L ACAD. OF SCI. OF THE U.S. 15078 (2015), <http://www.pnas.org/content/112/49/15078.full> [<https://perma.cc/8P2X-88RE>].

146. See *id.* This paper has not been peer reviewed, but it fits with a broader literature on “reversal of fortunes” for large swaths of US population in terms of health outcomes tied to economic and other factors.

147. Arne Ruckert & Ronald Labonté, *Health inequalities in the age of austerity: The need for social protections policies*, 187 SOC. SCI. & MED. 306 (Aug. 2017) (arguing that paradoxically, divestment and dismantling of the social safety net has rendered governments on all levels ill-equipped to provide meaningful and effective protection from major community threats. Regulated industries have seized on this opportunity to advance policies based on laissez-faire economic principles. Ironically, the downward spiral in investment and regulation has fueled libertarian movements like the Tea Party. In the U.S., this has culminated with the surprise victory of Trump

pressure to cut costs, governments on all levels of the U.S. federalist structure have failed to invest in prevention, basic services, and economic resilience.¹⁴⁸ They have also failed to address deep structural issues that have fueled the crisis, eroding perceived utility of collective responses to societal challenges. Paradoxically, this frustration propelled to victory politicians espousing increasingly more austere policies.¹⁴⁹ In view of the broader uncertainty, declining opportunity, and other societal stressors, opioids are singular in their ability to provide fast, effective, and relatively cheap analgesia, be it from physical and psychological trauma. If we recast “pain” as inclusive of economic stress, social isolation, and other structural trends, the role of opioids as symptomatic of neglected societal problems begins to come into focus.¹⁵⁰

Other, more proximal structural contributors to the opioid crisis are also clearly important. This includes the architecture and function of the health care system. Far beyond merely acting as a potential source of harmful exposure to opioid drugs, health care can have a protective effect against precursors to opioid misuse and overdose; this includes provision of effective and accessible pain care, mental health care, and risk-reduction interventions for individuals with substance use disorder.¹⁵¹

Yet, the U.S. health care system and its providers are unprepared to meet many of these challenges. Utilization of psychoactive medications other than opioids—including benzodiazepines—has literally skyrocketed in the last two decades, underscoring over-reliance on risky pharmacotherapy to address complex psychosocial challenges.¹⁵² Limited physician understanding of substance use disorder is well-documented: very few providers receive adequate training in this realm (although this may be changing).¹⁵³ Substance use screening and other risk reduction interventions are not systematic and may be disincentivized by insurance architecture, lack of enforcement of legal mandates such as mental health and substance use coverage parity, and other financial

and handing Republican control of all three branches of the federal government, along with the overwhelming majority of governorships and state legislatures).

148. *Id.* See also DAVID STUCKLER & SANJAY BASU, *THE BODY ECONOMIC: WHY AUSTERITY KILLS* (Basic Books 2013).

149. *Id.*

150. See Dasgupta et al., *supra* note 6, at 184-85.

151. Sarah Bowman et al., *Reducing the Health Consequences of Opioid Addiction in Primary Care*, 126 AM. J. MED. 565 (2013).

152. Maia Szalavitz, *The Mystery of the Terrifying Xanax Resurgence in America*, VICE NEWS (Mar. 28, 2018), https://www.vice.com/en_us/article/paxg39/the-mystery-of-the-terrifying-xanax-resurgence-in-america [<https://perma.cc/9RQ4-Y72K>] (noting the eight-fold rise in benzodiazepine-related overdose since the start of the 21st Century and the relationship to deaths of despair structural cause framework).

153. COLUM. U. NAT'L CTR. ON ADDICTION & SUBSTANCE ABUSE, *MISSSED OPPORTUNITY: NATIONAL SURVEY OF PRIMARY CARE PHYSICIANS AND PATIENTS ON SUBSTANCE ABUSE* (Apr. 2000), <http://files.eric.ed.gov/fulltext/ED452442.pdf> [<https://perma.cc/FW86-CAC9>].

pressures.¹⁵⁴ More generally, providers share general societal attitudes towards substance users as a difficult population not amenable to intervention.¹⁵⁵

In addition, geographical barriers, inadequate health insurance coverage, and uneven distribution of medical resources may influence access to pain management services, preventative care, and substance use treatment.¹⁵⁶ Technical features like insurance pre-authorization requirements, coverage limitations, and provider compensation rates can substantially shape what care is provided, and to whom.¹⁵⁷ Gaps in care can induce self-medication (for pain, as well as for drug withdrawal symptoms) and contribute to overdose risk. For instance, nationwide, access to evidence-based substance use treatment—a critical tool in the fight against opioid overdose—is available only to an estimated one-in-ten patients who require it.¹⁵⁸ In about one third of US states, including some of the hardest-hit jurisdictions, state Medicaid policies prohibit coverage of methadone—a lifesaving maintenance medication that can cut overdose risk by over 50%.¹⁵⁹ The extent to which these and other protective functions of health care are accessible, appropriate, affordable, and of high quality are critical determinants of opioid overdose risk.

Finally, the demand for pain relief is often a function of the individual's overall health. Consider the example of obesity. Individuals who meet the definition of obesity are much more likely to suffer from other chronic health

154. UNCOVERING COVERAGE GAPS: A REVIEW OF ADDICTION BENEFITS IN ACA PLANS, NAT'L CTR ON ADDICTION & SUBSTANCE ABUSE (June 2016), <https://www.centeronaddiction.org/download/file/fid/1678> [<https://perma.cc/3Y28-GXQR>].

155. Lin Ding et al., *Predictors and Consequences of Negative Physician Attitudes Toward HIV-Infected Injection Drug Users*, 165 ARCH. INTERN. MED. 618, 618-23 (Mar. 28, 2005); see also Leo Beletsky et. al., *Physicians' Knowledge of and Willingness to Prescribe Naloxone to Reverse Accidental Opiate Overdose: Challenges and Opportunities*, 84 J. URB. HEALTH 126-37 (2007).

156. Colleen Galambos, *Health Care: Overview*, ENCYC. OF SOC. WORK (2014) <http://socialwork.oxfordre.com/view/10.1093/acrefore/9780199975839.001.0001/acrefore-9780199975839-e-549> [<https://perma.cc/33MX-FHF4>].

157. Zachary Siegel, *We Know How to Treat Opioid Addiction*, SLATE (Nov. 30, 2016, 9:17 AM), http://www.slate.com/articles/health_and_science/medical_examiner/2016/11/we_do_not_use_an_evidence_backed_method_for_treating_heroin_addiction.html [<https://perma.cc/BZ2J-KZTC>] (arguing that pre-authorization and other bureaucratic obstacles causes a lack of access to lifesaving drugs like methadone and buprenorphine).

158. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF THE SURGEON GENERAL, FACING ADDICTION IN AMERICA: THE SURGEON GENERAL'S REPORT ON ALCOHOL, DRUGS, AND HEALTH 1-3 to 1-25 (2016).

159. Christine Vestal, *Still Not Enough Treatment in the Heart of the Opioid Crisis*, PEW CHARITABLE TRUSTS (Sept. 26, 2016), <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/09/26/still-not-enough-treatment-in-the-heart-of-the-opioid-crisis> [<https://perma.cc/D8CF-8G45>] (noting that "West Virginia is one of the 17 states where Medicaid does not pay for methadone, and it has had an adversarial relationship with methadone clinics for decades. Methadone clinics weren't allowed in the state until 2001, and after nine for-profit clinics set up shop in West Virginia, the Legislature in 2007 placed a moratorium on opening any more.").

problems, including chronic pain.¹⁶⁰ Rates of “overweight” and obesity have skyrocketed among Americans in the last four decades.¹⁶¹ Today, two thirds of American adults are overweight or obese.¹⁶² Among well-documented “obesogenic” factors are the individual’s nutritional, informational, and built environment.¹⁶³ To the extent that being overweight elevates one’s vulnerability to acute and chronic pain, the numerous environmental elements operative in obesity may factor into the structural equation for the overdose crisis.

Although far from exhaustive, this overview of the “structural determinants” framework helps illuminate the reality that the conditions for the overdose crisis have deep, tangled roots. Only in embracing this complexity can we hope to craft appropriate, multi-pronged responses. To date, this conceptualization has seldom reflected the solutions and interventions that have been advanced to curb the crisis.

D. The Role of PDMPs in Overdose Crisis Response

Broadly speaking, the opioid crisis illustrates the folly of employing simple solutions to address complex problems. The crisis’ origins implicate health care providers’ over-reliance on opioid therapy for a broad set of health problems. In many cases, especially those involving patients with complex interactions of physical and mental health needs, opioids became an attractive go-to response to a range of physical and mental health complaints, including many cases where a highly-personalized and resource-intensive course of treatment would have been more appropriate.¹⁶⁴ This resulted in temporarily assuaging patient symptoms and claiming success in metrics such as patient satisfaction surveys. Over time, however, it became clear that the failure to apply more intensive and case-appropriate care up front caused considerable downstream complications.¹⁶⁵

On the policy level, reducing the supply of prescription medications to solve the overdose crisis offers an analogous mirage of a simple solution to a complex challenge. This parallel appears to be lost on key decision-makers tasked with addressing the crisis. As deaths involving prescription painkillers have leveled off, the latest data on opioid-related fatalities could not be more dire. These

160. Aiko Okifuji & Bradford D. Hare, *The Association Between Chronic Pain and Obesity*, 8 J. PAIN RES. 399 (2015).

161. INST. OF MED., ACCELERATING PROGRESS IN OBESITY PREVENTION 2 (2012); *See also* Cynthia L. Ogden et al., *Prevalence of Childhood and Adult Obesity in the United States, 2011-2012*, 311 JAMA 806, 806-07 (2014).

162. *See* INST. OF MED., ACCELERATING PROGRESS IN OBESITY PREVENTION, *supra* note 161.

163. James O. Hill et al., *Obesity and the Environment: Where Do We Go from Here?*, 299 SCI. 853 (2003). Over the last several decades, the nutritional value of food and beverages has shifted to higher simple sugar content. Portions in retail and restaurant offerings have grown considerably. Another notable aspect of the food environment is food and beverage advertising, which is pervasive and highly-targeted.

164. *See* Dasgupta et al., *supra* note 6, at 184-85.

165. *Id.*

deaths have *quadrupled* between 2000 and 2013,¹⁶⁶ *doubling* just between 2010 and 2012.¹⁶⁷ They have experienced another, even more shocking recent spike, largely related to fatalities caused by illicitly-manufactured fentanyl.¹⁶⁸ This is because the trends in prescription painkiller and heroin use are linked. There is substantial evidence¹⁶⁹ to suggest that the crisis is being fueled by the crackdown on painkillers like OxyContin and Vicodin. Shuttering pill-mills, tightening restrictions on certain analgesics, and making products harder to snort and inject seem to be curbing prescription drug use.¹⁷⁰

But addiction does not simply go away when the pills do, which is why people dependent on prescription opioids have been switching to heroin in record numbers.¹⁷¹ From a chemical standpoint, heroin is very similar to its prescription drug cousins. Its uncontained black market availability, increasing adulteration with the potent synthetics, and association with injection drug use make heroin a much more risky substance of choice.¹⁷² Troubling emerging data indicate that an increasing proportion of users are now initiating opioid use with heroin, not with particular prescription drugs.¹⁷³ These data underscore the fundamental reality that slashing opioid prescribing is unlikely to result in marked reductions

166. Hedegaard et al., *supra* note 1.

167. Matt Sledge, *Heroin-Linked Deaths Surge 39 Percent, CDC Finds*, HUFFPOST (Jan. 12, 2015, 7:14 PM), http://www.huffingtonpost.com/2015/01/12/heroin-deaths-cdc_n_6459130.html [<https://perma.cc/3CSF-KV7K>].

168. Katz, *supra* note 4.

169. See Olga Khazan, *The New Heroin Epidemic*, THE ATLANTIC (Oct. 30, 2014), <http://www.theatlantic.com/features/archive/2014/10/the-new-heroin-epidemic/382020> [<https://perma.cc/X6SW-X4EJ>].

170. Gregory D. Curfman, Leo Beletsky & Ameet Sarpatwari, *Benefits, Limitations, and Value of Abuse-Deterrent Opioids*, 178 JAMA INTERNAL MED. 131 (2018). See also Mark R. Larochelle et al., *Rates of Opioid Dispensing and Overdose After Introduction of Abuse-Deterrent Extended-Release Oxycodone and Withdrawal of Propoxyphene*, 175 JAMA INTERNAL MED. 1978 (2015); Abby Alpert et al., *Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids* (Nat'l Bureau of Econ. Research, Working Paper No. 23031, 2017), <http://www.nber.org/papers/w23031.pdf> [<https://perma.cc/E7LV-YJAR>].

171. Cicero et al., *supra* note 115.

172. Nora D. Volkow, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing before S. Caucus on International Narcotics Control*, NAT'L INSTITUTE ON DRUG ABUSE (May 14, 2014), <http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2014/americas-addiction-to-opioids-heroin-prescription-drug-abuse> [<https://perma.cc/2VV5-YEPT>].

173. Theodore J. Cicero et al., *Increased Use of Heroin as an Initiating Opioid of Abuse*, 74 ADDICTIVE BEHAV. 63 (2017) ("In 2005, only 8.7% of opioid initiators started with heroin, but this sharply increased to 33.3% ($p < 0.001$) in 2015, with no evidence of stabilization. The use of commonly prescribed opioids, oxycodone and hydrocodone, dropped from 42.4% and 42.3% of opioid initiators, respectively, to 24.1% and 27.8% in 2015, such that heroin as an initiating opioid was now more frequently endorsed than prescription opioid analgesics.").

in overdose morbidity and mortality;¹⁷⁴ unless we address the underlying health and structural factors driving demand, efforts to curb supply will simply result in an increasingly morbid game of whack-a-mole.

Nevertheless, to date, much of the discourse on the crisis continues to emphasize opioid supply. The zeal for supply reduction policies and programs has withstood a growing body of empirical and theoretical critique, much of which suggests that the application of these interventions was doing more harm than good.¹⁷⁵

From the very early days of the overdose crisis, PDMPs have served as the central feature in this ideologically-driven supply reduction paradigm. PDMPs are now prominently featured¹⁷⁶ by government agencies on all levels as a key weapon in the fight against the mounting overdose toll. If only we could get more prescribers and pharmacists to use these databases—the accepted wisdom goes—the overdose crisis could subside.¹⁷⁷

This logic has spurred broad exuberance about the potential role of PDMPs as a near-panacea in US response to the crisis, leading to the rapid expansion in the number, scope, and intensity of these programs. As of 2018, all fifty states and the District of Columbia have authorized PDMPs, up from only fourteen in 2000.¹⁷⁸ These fifty-one systems are increasingly interoperable, thanks in part to federal grants authorized through the National All Schedules Prescription Electronic Reporting Act (NASPER), as well as other sources.¹⁷⁹ Interoperability is moving the patchwork system ever-closer to a national PDMP infrastructure conceptualized by NASPER's architects (but never funded by Congress).¹⁸⁰

174. See Sally Satel & Stefan Kertesz, *Pill Limits Are Not a Smart Way to Fight the Opioid Crisis*, SLATE (Mar. 30, 2018, 1:53 PM), <https://slate.com/technology/2018/03/pill-limits-are-not-a-smart-way-to-fight-the-opioid-crisis.html> [<https://perma.cc/6NTD-G39S>] (describing the evidence that opioid prescribing reductions, including the 48% drop in high-dose prescriptions, has not resulted in significant changes in overdose deaths, including those from prescription medications).

175. *Id.* (describing the likely harm that will result from Trump Administration's proposals to slash opioid prescribing by 30% to address the overdose crisis). See, e.g., Dan Werb et al., *The temporal relationship between drug supply indicators: an audit of international government surveillance systems*, 3 BMJ OPEN e003077 (2013) (noting that heroin's price has declined by 80% over the last three decades, while purity has increased more than two-fold).

176. *Opioid Painkiller Prescribing*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vitalsigns/opioid-prescribing/> [<https://perma.cc/ZNG4-M2T5>].

177. Jeanmarie Perrone et al., *Medication Reconciliation for Controlled Substances—An “Ideal” Prescription-Drug Monitoring Program*, 366 NEW ENG. J. MED. 2341 (2012).

178. See Figure 1.

179. National All Schedules Prescription Electronic Reporting Act (NASPER), Pub. L. No. 109-60, 119 Stat. 1979 (2005); see also BUREAU OF JUSTICE ASSISTANCE, INTERIM POLICY: ALLOWABLE USES FOR HAROLD ROGERS PRESCRIPTION DRUG MONITORING PROGRAM GRANT FUNDS (Mar. 21, 2012), <https://www.bja.gov/Programs/PDMPInterimPolicy.pdf> [<https://perma.cc/N9RE-2WLJ>].

180. National All Schedules Prescription Electronic Reporting Reauthorization Act of 2016, S. 480, 114th Cong. (2016).

Theoretically, the creation of uniform and interoperable systems tracking prescription drug use creates the potential of benefit on a number of levels. Such systems could play an important patient care function, including preventing dangerous drug interactions, monitoring medication adherence, streamlining care coordination among various providers, and identifying patients in need of additional care or services. In terms of their public health surveillance function, PDMPs can help understand the prevalence and incidence of use of certain drugs, track unexpected or adverse events, and target resources and interventions to patients and geographical areas most in need.

The Centers of Disease Control lists many of these ideal functions and uses in its public guidance for the utilization of PDMPs.¹⁸¹ But what is the actual express purpose stated by the programs themselves? Reflecting the fact that these systems have roots as tools of law enforcement, many continue to characterize their principal function as to identify possible prescription drug misuse and diversion;¹⁸² this primarily addresses “doctor shopping” whereby a patient receives prescriptions from a number of different doctors for the exact same condition. In a systematic national analysis of language PDMPs use to describe their own goals and functions, this “Supply Reduction-Punitive” orientation was near-universal, with 83% of the forty-one analyzed programs.¹⁸³ Depending on a jurisdiction, additional goals such as balancing medication access, improving access to drug treatment, and supporting clinical decision making are also featured among the stated aims.¹⁸⁴ Demand reduction, mostly related to using PDMP data to facilitate patient access to substance use treatment was invoked by 51% of the programs.¹⁸⁵ Less than half (49%) mentioned public health functionality and goals.¹⁸⁶ Remarkably, 62% of the PDMP in this study did not so much mention overdose prevention in their public-facing materials.¹⁸⁷

In terms of their legal and institutional structure, the national PDMP landscape is heterogeneous along a number of parameters. Many PDMPs (20, 39%) now reside in Departments of Health, though a significant minority (6, 12%) continue to be operated by law enforcement or justice agencies.¹⁸⁸ Since none of the programs reside within healthcare institutions, they are not covered

181. *What States Need to Know About PDMPs*, *supra* note 11.

182. Traci C. Green et al., *Discrepancies in addressing overdose prevention through prescription monitoring programs*, 153 *DRUG & ALCOHOL DEPENDENCE* 355, 356-57 (2015) (illustrating the thematic orientation of the program language (*see* Figure 1)).

183. *Id.*

184. *Id.*

185. *Id.* at 356

186. *Id.*

187. *Id.*

188. *See* Figure 1. *Cf.* NAT’L ALL. FOR MODEL STATE DRUG LAWS, PRESCRIPTION DRUG MONITORING PROGRAM (PMP) ADMINISTERING AGENCY (June 30, 2017), <http://www.namsdl.org/library/4421DC96-D2C0-7410-FA15C9C4E6C3BF56/> [<https://perma.cc/BP7V-NSQC>] (noting discrepancies in data, with NAMS DL reporting only (3, 6%) programs are housed in law enforcement agencies and (36, 70%) reside in DPH or Board of Pharmacies).

by HIPAA and other federal and state provisions that protect personal health information.¹⁸⁹

Programs vary in the scope of controlled substances coverage. Most (36, 70%) track all five schedules.¹⁹⁰ Although it is not a controlled substance under the federal schedule, proposals have been made to integrate naloxone--the opioid antidote--among tracked medications.¹⁹¹ Other drugs increasingly implicated in polysubstance use with opioids are being advanced as candidate for PDMP tracking.¹⁹² It is important to underscore that this record-keeping constitutes much more than just highly-dangerous narcotic or amphetamine drugs. Schedules within the federal and state CSAs are expansive, which means that PDMPs engage in sweeping data collection sometimes seemingly disconnected from their stated purpose. For instance, this surveillance includes prescription hormonal therapy used in gender transition therapy (classified under Schedule III).¹⁹³

To improve system utilization, states have also adopted a number of mandates that prescribe the situations when providers must register for and access the PDMP.¹⁹⁴ For instance, Massachusetts mandates all newly-licensed prescribers to be registered in the system, and has instituted an effort to register existing

189. NAT'L ALL. FOR MODEL STATE DRUG LAWS, PRESCRIPTION DRUG MONITORING PROGRAMS (PMPs) AND THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPPA): BRIEF OVERVIEW (2017), <http://www.namsdl.org/library/ED56718E-A683-22AA-FDEE3CD77BE925DE/> [<https://perma.cc/H4R2-LDYF>]. The Privacy Rule of HIPPA (45 C.F.R. §164.502) only protects the confidentiality of health information when used and disclosed by a statute-defined "covered entity" or "business associate". Under HIPPA, a covered entity is defined as a "health plan, a health care clearinghouse, or a health care provider". A business associate is defined as a person "providing certain services to or for a covered entity" or "creating, receiving, maintaining, or transmitting [public health information], on behalf of a covered entity". Because PDMPs fail to align with either definition, they are not subject to the Privacy Rule or other standards of HIPPA.

190. NAT'L ALL. FOR MODEL STATE DRUG LAWS, SUBSTANCES MONITORED BY PMP (May 2016), <http://www.namsdl.org/library/8D7261F8-E47D-B6A5-DD0CAFA98FEA4846/> [<https://perma.cc/N327-TCPA>].

191. *Naloxone Data*, PREVENT OVERDOSE RI (2017), <http://preventoverdoseri.org/naloxone-data/> [<https://perma.cc/X4SE-KKYB>] (showing that Rhode Island is already tracking naloxone prescriptions).

192. KY. REV. STAT. ANN. § 218A.202 (2017).

193. *AndroGel® (testosterone gel) 1%*, UNIMED PHARMACEUTICALS, INC. (2004), https://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21015s0121b1.pdf [<https://perma.cc/4PHP-8SNX>].

194. Sixteen states require prescribers to access the PDMP. While all these states require a PDMP check before prescribing to a new patient, other mandates are also in place, varying by state: every time a prescription is started for longer than seven days, every six months that a patient is on a continuous opioid prescription, anytime a provider prescribes a Schedule II or III drug, or anytime a provider prescribes an opioid or benzodiazepine. *PDMP Reporting and Authorized Use Map*, LAW ATLAS: THE POLICY SURVEILLANCE PORTAL (2016) <http://legacy.lawatlas.org/query?dataset=prescription-monitoring-program-laws-1408223416> [<https://perma.cc/J29F-NKK6>].

providers as part of their continuing medical education.¹⁹⁵ It also requires health care providers to consult its MassPat system each time they prescribe any Schedule II substance.¹⁹⁶ Every new patient presenting to a Massachusetts prescriber triggers a mandatory PDMP assessment.¹⁹⁷ Nationally, an increasing number of states are adopting similar provisions.¹⁹⁸

States legislatures have recognized patient privacy concerns by erecting a variety of protections to safeguard highly-personal data collected by prescription surveillance systems. These PDMP privacy protections vary widely, but often include a definition of the circumstances and authorization required for each querying party. For instance, a substantial number (15, 29%) require in-state law enforcement to present a warrant, (25, 49%) require a certification of an active investigation, and (45, 88%) require a subpoena to access PDMP data.¹⁹⁹ For out-of-state law enforcement, a substantial number (13, 25%) require a warrant or a judicially-approved show of probable cause.²⁰⁰ Conversely, the overwhelming majority of programs (39, 76%) either compel or permit PDMPs to transmit data on suspicious activity to law enforcement.²⁰¹

This context has a number of implications for the public health value and potential unintended impact of PDMPs. First, though heterogeneous in their precise design and legal posture, the majority of PDMPs currently allow warrantless law enforcement access.²⁰² In states where access is contingent upon the presence of an “active investigation” or “probable cause,” PDMPs systems may run searches and deploy “predictive” algorithms that trigger investigations, functionally circumventing these access requirements.²⁰³

Broad law enforcement access to some of the most private health information creates a number of problems, including blurring the line between healthcare and law enforcement.²⁰⁴ It risks further stigmatization, deterring patients from

195. 105 MASS. CODE REGS. 700.004(A)(1) (2017).

196. 105 MASS. CODE REGS. 700.012(G) (2017).

197. *Id.*

198. NAT'L ALL. FOR MODEL STATE DRUG LAWS, MANDATED USE OF PRESCRIPTION DRUG MONITORING PROGRAMS (PMPs)—MAP (June 30, 2017), <http://www.namsdl.org/library/FE179822-E782-AA56-9E97D5E5D9F19D7B/> [<https://perma.cc/K6HB-6Q9Q>] (noting that as of 2017, thirty-six states have adopted legislation which under specific circumstances requires prescribers to access the PMP).

199. *See* Figure 1.

200. *Id.*

201. *Id.*

202. NAT'L ALL. FOR MODEL STATE DRUG LAWS, TYPES OF AUTHORIZED RECIPIENTS—LAW ENFORCEMENT OFFICIALS (Dec. 2014), <http://www.namsdl.org/library/BCEA5CFB-E29A-B561-3B62960EF453D9B3/> [<https://perma.cc/NN92-797U>].

203. *Id.*

204. *See, e.g.*, Joannah Shepherd, *Combating the Prescription Painkiller Epidemic: A National Prescription Drug Reporting Program*, 40 AM. J. L. & MED. 85 (2014) (calling for a federal PDMP to replace state systems, no mention of possible unintended consequence is made); *see also* Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L.

accessing appropriate medications or seeking help for problematic substance use. This disproportionately impacts those groups with a history of discrimination and exclusion in healthcare settings, including people who inject drugs, racial minorities, trans and sexual minority patients.²⁰⁵

These concerns are not unique to the deployment of PDMPs. Even elsewhere in the health care arena, observers have critiqued the advent of algorithms, artificial intelligence analytical tools and other “big data” techniques whose cavalier adoption did not adequately consider the data quality, practical, or ethical implications of these systems.²⁰⁶ More in line with the law enforcement roots of PDMPs however are the growing concerns about “predictive policing,” “gang database” and other algorithmic systems increasingly used by security agencies.²⁰⁷ These critiques have focused on assumptions of questionable empirical, ethical, or legal value that, when codified into algorithms, perpetuate injustice and misapplication of resources.²⁰⁸

REV. 1117, 1164 (2014) (asserting that PDMPs are a key response in the overdose crisis; once again, no mention of possible unintended consequence is made).

205. FAIRCHILD, ET AL., *supra* note 49. *See also* Or. Prescription Drug Monitoring Program v. U.S. Drug Enf’t Admin., 860 F.3d 1228 (9th Cir. 2017).

206. Bonnie Kaplan, *How Should Health Data Be Used? Privacy, Secondary Use, And Big Data Sales*, 25 CAMBRIDGE Q. HEALTHCARE ETHICS 312 (2016) (presenting an ethical analysis on the commodification of health data, and the questions of privacy versus public interest and considering the impact of two court decisions involving the sale of prescription drug data, *Sorrell v. U.S.* and *Source v. U.K.*, and their influence on both public trust and future policy). *See also* Aris Gkoulalas-Divanis et al., *Publishing data from electronic health records while preserving privacy: A survey of algorithms*, 50 J. BIOMED. INFORMATICS 4 (2014) (reviewing forty-five algorithms for protecting patient privacy when publishing electronic health record data and establishing the importance of designing data sharing around patient privacy protections).

207. WALTER L. PERRY ET AL., *PREDICTIVE POLICING: THE ROLE OF CRIME FORECASTING IN LAW ENFORCEMENT OPERATIONS* (RAND CORP. 2013) (investigating law enforcements’ increasing utilization of quantitative analytical techniques to predict crime, determine future offenders and anticipate locations for police intervention); Uzodima F. Aba-Onu, *Evaluation of gang databases in Minnesota and recommendations for change*, 19 INFO. & COMM. TECH. L. 223 (2010) (establishing the impact of Minnesota’s gang database on communities of color, and highlights its failure to protect privacy or eliminate racial bias within its design).

208. Kristian Lum & William Isaac, *To predict and serve?*, 13 SIGNIFICANCE 14 (2016) (demonstrating that current models of predictive policing can reinforce racial bias and lead to disparate policing practices on communities already confronted with over-policing); ANDREW GUTHRIE FERGUSON, *THE RISE OF BIG DATA POLICING: SURVEILLANCE, RACE, AND THE FUTURE OF LAW ENFORCEMENT* (NYU Press 2017) (examining what Ferguson defines as the “black data” of big data policing: data buried within complicated algorithms, disproportionately affecting people of color, passed along as trendy and “futuristic,” and resting in the legal shadows, and claiming that big data is revolutionizing policing, with serious implications for already vulnerable populations); CHRISTIAN SANDVIG ET AL., *AUDITING ALGORITHMS: RESEARCH METHODS FOR DETECTING DISCRIMINATION ON INTERNET PLATFORMS, DATA AND DISCRIMINATION: CONVERTING CRITICAL CONCERNS INTO PRODUCTIVE INQUIRY* (2014) (highlighting the need for both increased public

An emerging trend in PDMP design and authority underscores more overt stigmatizing potential of these systems. It involves PDMP provision of criminal justice information, specifically drug conviction or charge data, to prescribers and dispensers. The State of Wisconsin requires law enforcement agencies to report drug-related violations, opioid overdoses or deaths, and prescription drug diversion incidents to the PDMP, integrating those data with the patient's prescription information. Similarly, Kentucky requires the Administrative Office of the Courts (AOC) to communicate drug conviction data to its PDMP.²⁰⁹ The stand-alone Diversion Alert program in Maine provides data on drug-related criminal charges to health care providers.²¹⁰ Now that we understand the landscape, what is the evidence on the impact of these programs? The next section addresses this.

IV. PDMPs IMPACT ON THE OVERDOSE CRISIS

A. Review of the Available Evidence

What is known about the impact of PDMPs on the overdose crisis? When it comes to tracking diversion of medications, curbing their misuse, and reducing “doctor shopping,” the evidence on PDMPs has been characterized as “mixed and inconclusive.”²¹¹

More fundamentally, however, determining “success” of PDMPs is predicated first and foremost on how success is defined and measured. When PDMPs are assessed, the outcomes of interest tend to closely reflect the “epidemic” framing of the overdose crisis as a vector-driven problem, with “over-prescription” at its root and supply reduction its most promising remedy. This framing helps explain why most of the research published this decade focuses narrowly on the relationship between PDMP policies or programs and indicators closely aligned with opioid supply (see Table 1). When assessing the thirty-four peer-reviewed empirical studies of PDMP impact from 2010 onwards, most (71%, twenty-one of thirty-four studies; see Table 1) focused on outcomes such as the frequency, volume and durations of prescriptions.²¹²

interest scrutiny and systematic analyses of algorithms. Sandvig adapts the social scientific audit study to offer potential research methodologies for an “algorithm audit”, intended to provide researchers with the tools to identify, analyze and hold accountable discriminatory and problematic algorithms).

209. KY. REV. STAT. ANN. § 218A.202.

210. DIVERSION ALERT: A SPOTLIGHT ON PRESCRIPTION DRUG ABUSE, <http://www.diversionalert.org> [<https://perma.cc/3ZWP-8ZTB>].

211. See DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF THE SURGEON GENERAL, *supra* note 158; Tamara M. Haegerich et al., *What We Know, and Don't Know, About the Impact of State Policy and Systems-Level Interventions on Prescription Drug Overdose*, 145 DRUG & ALCOHOL DEPENDENCE 34 (2014).

212. David Baehren et al., *A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors*, 56 ANNALS OF EMERGENCY MED. 19 (2010) (showing decrease

in prescribing among physicians after access to PDMP data); Leonard J. Paulozzi et al., *Prescription Drug Monitoring Programs and Death Rates from Drug Overdose*, 12 PAIN MED. 747 (2011) (showing increase in prescribing of Schedule III opioids after PDMP and no impact on Schedule II prescribing and overdose deaths); Joanne E. Brady et al., *Prescription Drug Monitoring and Dispensing of Prescription Opioids*, 129 PUB. HEALTH REPS. 139 (2014) (finding that implementation of PDMPs did not show a significant impact on per-capita opioids dispensed); Hal Johnson et al., *Decline in Drug Overdose Deaths After State Policy Changes — Florida, 2010–2012*, 63 MORBIDITY & MORTALITY WEEKLY REPORT 569 (July 4, 2014) (noting a CDC report finding state policies in Florida, including PDMP implementation, were associated with a reduction in fatal overdoses); PATRICIA R. FREEMAN ET AL., INST. FOR PHARMACEUTICAL OUTCOMES & POL., KENTUCKY HOUSE BILL 1 IMPACT EVALUATION (2015) (explaining that impact evaluation for state of Kentucky found a relationship between mandating the PDMP system and reducing doctor shopping in the state, and displaying relationship between PDMP mandate and increased heroin overdoses); Lainie Rutkow et al., *Most Primary Care Physicians Are Aware of Prescription Drug Monitoring Programs, but Many Find the Data Difficult to Access*, 34 HEALTH AFF. 484 (2015); Yuhua Bao et al., *Prescription Drug Monitoring Programs are Associated with Sustained Reductions in Opioid Prescribing by Physicians*, 35 HEALTH AFF. 1045 (2016) (finding implementation of PDMP had limited effect on opioid prescribing); Linda Simoni Wastila & Jingjing Qian, *Influence of Prescription Monitoring Programs on Analgesic Utilization by an Insured Retiree Population*, 21 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 1261 (2012) (according to this study, PDMPs were associated with reduction in Schedule II prescription opioids and increases in lower scheduled analgesics); Sarah E. Wixson et al., *Impact Of South Carolina's Prescription Drug Monitoring Program On The Use Of Benzodiazepines In A Commercially Insured Population*, 16 VALUE IN HEALTH A248 (2013) (finding a relationship between PDMP implementation in South Carolina and an increase in the prescribing of benzodiazepines); Hsien-Chang Lin et al., *Associations between statewide prescription drug monitoring program (PDMP) requirement and physician patterns of prescribing opioid analgesics for patients with non-cancer chronic pain*, 76 ADDICTIVE BEHAVIORS 348 (2018) (finding no significant relationship between the implementation of prescription monitoring systems and rates of opioid prescribing for chronic pain management); Brian Suffoletto et al., *The Impact of a Statewide Mandatory Prescription Drug Monitoring Program on Opioid Prescribing by Emergency Medicine Providers Across 15 Hospitals in a Single Health System*, AM. PAIN SOCIETY (2017) (in press with the Journal of Pain) (finding that a state-mandated PDMP reduced prescribing of opioids among emergency medicine providers in PA); Hsien-Yen Chang et al., *Impact Of Prescription Drug Monitoring Systems And Pill Mill Laws On High-risk Opioid Prescribers: A Comparative Interrupted Time-series Analysis*, 165 DRUG & ALCOHOL DEPENDENCE 1 (2016) (finding a significant reduction in opioid prescribing by “high-risk” prescribers in Florida); Eric Wright, *The Early Impact Of The Indiana Scheduled Prescription Electronic Collection And Tracking (“Inspect”) Program: A Potentially Effective Policy Tool For Reducing Prescription Drug Abuse*, 14 INDIANA HEALTH L. REV. 112 (2017) (finding reduction in overall opioid prescribing within the state after Indiana’s implementation of a prescription monitoring system); Matthew McAllister et al., *Impact of prescription drug-monitoring program on controlled substance prescribing in the ED*, 33 AM. J. EMERGENCY MED. 781 (2015) (finding that although a majority of prescribers perceived their prescribing practices had changed in response to prescription monitoring, there was no change in the average number of prescribed controlled substances when presented with PDMP data); Patience Moyo et al., *Impact of*

Prescription Drug Monitoring Programs (PDMPs) on Opioid Utilization Among Medicare Beneficiaries in 10 US States, 112 ADDICTION 1784 (2017) (finding the use of PDMPs resulted in a reduction of prescription duration); Courtney R. Yarbrough, *Prescription Drug Monitoring Programs Produce a Limited Impact on Painkiller Prescribing in Medicare Part D*, HEALTH SERVS. RES. (2017) (finding PDMPs were not associated with changes for prescription of nonopioid analgesics or other opioids in Schedules II and III and a modest effect on oxycodone); Linda Rasubala et al., *Impact of a Mandatory Prescription Drug Monitoring Program on Prescription of Opioid Analgesics by Dentists*, 10 PLOS ONE (2015) (finding significant reduction in the number of opioid prescriptions after implementation of the mandatory PDMP); Richard Brown et al., *Impact of New York prescription drug monitoring program, I-STOP, on statewide overdose morbidity*, 178 DRUG & ALCOHOL DEPENDENCE 348 (2017) (finding an insignificant leveling off prescription overdose mortality levels after PDMP but increase in heroin overdose); Deborah Dowell et al., *Mandatory Provider Review and Pain Clinic Laws Reduce the Amounts of Opioids Prescribed and Overdose Death Rates*, 35 HEALTH AFF. 1876 (2016) (finding PDMP implementation associated with reduction in both prescription and illicit opioid overdose deaths); Ellen Meara et al., *State Legal Restrictions and Prescription-opioid Use among Disabled Adults*, 375 NEW ENG. J. MED. 44 (2016) (finding controlled-substance laws, including PDMP implementation, was not associated with reductions in potentially hazardous use of opioids or overdose); Hefei Wen et al., *States with Prescription Drug Monitoring Mandates saw a Reduction in Opioids Prescribed to Medicaid Enrollees*, 36 HEALTH AFF. 733 (2017) (finding PDMP utilization mandates were associated with a reduction in Schedule II opioid prescriptions); Dhaval M. Dave et al., *Mandatory Access Prescription Drug Monitoring Programs and Prescription Drug Abuse* (Nat'l Bureau of Econ. Research, Working Paper No. 23537, 2017) (finding mandatory PDMP access was significantly associated with a reduction in prescription drug abuse); Liza M. Reifler et al., *Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse?*, 13 PAIN MED. 434 (2012) (finding reduction in opioid-related treatment admissions following PDMP implementation); Marcus Bachhuber et al., *Prescription monitoring programs and emergency department visits involving benzodiazepine misuse: Early evidence from 11 United States metropolitan areas*, 28 INTERN. J. DRUG POL. 120 (2016) (finding PDMP implementation did not affect rates of emergency department visits related to the misuse of benzodiazepines); Brandon Maughan et al., *Prescription monitoring programs and emergency department visits involving opioids, 2004-2011*, 156 DRUG & ALCOHOL DEPENDENCE 282 (2015) (finding no significant effect on the misuse of prescription drugs); Hilary L. Surratt et al., *Reductions in Prescription Opioid Diversion Following Recent Legislative Interventions in Florida*, 23 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 314 (2014) (finding significant declines in diversion rates for opioids in Florida after PDMP implementation); CJ Hayes, *Impact Of State Mandated Queries Of The Prescription Drug Monitoring Programs On Opioid And Non-opioid Drug Related Adverse Effects: A Difference In Difference Approach*, 19 HEALTH IN VALUE A347 (2016) (finding no association between adverse events related to prescription use and PDMP mandates); Douglas Keith Branham et al., *Time-Series Analysis of the Impact of Prescription Drug Monitoring Programs on Heroin Treatment Admissions*, SUBSTANCE USE & MISUSE 1 (2017) (finding an increase in heroin treatment admissions after PDMP implementation); Bryce Pardo, *Do more robust prescription drug monitoring systems reduce prescription opioid overdose?*, 112 ADDICTION 1773 (2017) (finding increase in PMP strength associated with decrease in prescription overdose deaths); Guohua Li et al., *Prescription Drug Monitoring and Drug Overdose Mortality*, 1 INJURY EPIDEMIOLOGY 9 (2014) (finding that

Given the central role of drug control and other law enforcement in the design, utilization, and continued principal resourcing²¹³ of PDMPs, evaluators have also focused closely on how PDMP deployment may impact instances of (notably arbitrarily-defined) “aberrant behavior,” including “doctor shopping”²¹⁴ (12%, four of thirty-four studies), diversion, and drug misuse²¹⁵ (32%, eleven of thirty-four studies).

Even using these supply-oriented metrics, PDMP evaluations have continued to bear mixed results. In a ten-state study, Moyo²¹⁶ observed an overall decrease in the monthly opioid volume being dispensed across PDMP states. However, the presence of monitoring programs was not associated with changes in number of prescriptions or the mean morphine milligram equivalent per prescription.²¹⁷ Similarly, a recent analysis of a new policy in Massachusetts aimed at reducing opioid prescribing (in a state that ranked seventh in the nation for opioid overdose deaths in 2015), found no evidence of impact.²¹⁸ The policy entailed the state’s Department of Public Health emailing all prescribers information on the number of opioid prescriptions they and their peers wrote, along with the total volume of opioids they had prescribed in the previous year. Not only was there no evidence of fewer prescriptions, but there was also no reduction in opioid prescribing

implementation of PDMPs did not reduce drug overdose mortality rates in most states); Chris Delcher et al., *Abrupt Decline In Oxycodone-caused Mortality After Implementation Of Florida’s Prescription Drug Monitoring System*, 150 *DRUG & ALCOHOL DEPENDENCE* 68 (2015) (finding a significant relationship between PDMP implementation and a decrease in oxycodone-caused mortality in Florida).; Stephen W Patrick et al., *Implementation Of Prescription Drug Monitoring Programs Associated With Reductions In Opioid-Related Death Rates*, 35 *HEALTH AFF.* 1324, 1324-32 (2016), <https://www.ncbi.nlm.nih.gov/pubmed/27335101> [<https://perma.cc/U474-BQW5>].

213. Principal funding of PDMPs comes through grants to the states from the Hal Rogers Program at the Bureau of Justice Assistance, U.S. Department of Justice. *Technical Assistance Guide No. 04-13: Funding Options for Prescription Drug Monitoring Programs*, PRESCRIPTION DRUG MONITORING PROGRAM TRAINING AND TECHNICAL ASSISTANCE CENTER (2013).

214. See Freeman et al., *supra* note 212; Meara et al., *supra* note 212; Ali et al., *supra* note 212; See Buchmueller et al., *supra* note 212; Carey Colleen, *The Effect of Prescription Drug Monitoring Programs on Opioid Utilization in Medicare* (Nat’l Bureau of Econ. Research, Working Paper No. w23148, 2017) (finding mandatory use of PMDPs was associated with fewer patients receiving prescriptions from multiple doctors).

215. See Johnson et al., *supra* note 212; Brown et al., *supra* note 212; Meara et al., *supra* note 212; Ali *supra* note 212; Dave et al., *supra* note 212; Reifler et al., *supra* note 212; Bachhuber et al., *supra* note 212; Maughan et al., *supra* note 212; Surratt et al., *supra* note 212; Hayes, *supra* note 212; Branham et al., *supra* note 212.

216. See Moyo et al., *supra* note 212.

217. *Id.* (finding strong variability across states and subcategories of Medicare beneficiaries).

218. Michael L. Barnett et al., *Coupling Policymaking with Evaluation—The Case of the Opioid Crisis*, 377 *NEW ENG. J. MED.* 2306, 2306-09 (2017) (examining the effect of a recent policy aimed at reducing opioid prescribing in Massachusetts found no evidence that prescribing rates dropped).

among the highest-volume opioid prescribers.²¹⁹ Substantially fewer evaluations have focused in the public health realm, with (6%, two of thirty-four studies) opioid-related treatment admissions²²⁰ and opioid overdose mortality²²¹ (32%, eleven of thirty-four studies).

In addressing the current crisis, measuring PDMP success primarily through study endpoints like reductions in prescribing volume²²² and suppression of multiple-prescriber episodes (“doctor shopping” in colloquial parlance) is problematic. Such narrow definitions of effectiveness mask the complexities of addressing overdose and addiction on the systems level.²²³ It is not clear to what extent outcomes such as prescribing volume²²⁴ can serve as an appropriate “surrogate” endpoint for research in the realm of PDMP public health impact.²²⁵

Ongoing debate about the appropriate use of surrogate endpoints in clinical trials²²⁶ helps to inform this debate. Just like it may be inappropriate to use an intermediate biological marker as evidence that a drug may improve cancer survivorship,²²⁷ it may not in fact be appropriate to use declines in opioid prescribing rates as a metric of progress in the effort to address population-level overdose morbidity and mortality. This is especially true because nationally, as well as on a more granular jurisdictional level, reductions in prescribing have not systematically resulted in statistically significant drops in overdose rates.²²⁸ For example, after the implementation of West Virginia’s PDMP, a significant drop

219. *Id.*

220. See Reifler et al., *supra* note 212; Branham et al., *supra* note 212.

221. See Johnson, *supra* note 212; Paulozzi, *supra* note 212; Hayes, *supra* note 212; Brown et al., *supra* note 212; Dowell et al., *supra* note 212; Freeman, *supra* note 212; Meara et al., *supra* note 212; Pardo, *supra* note 212; Li et al., *supra* note 212; Delcher et al., *supra* note 212.

222. See Wen et al., *supra* note 212; Brady et al., *supra* note 212.

223. Robert G. Newman, *The Epidemiological Approach to Drug Abuse: Its Relevance to the Teaching of Future Professionals*, 3 AM. J. DRUG & ALCOHOL ABUSE 439, 439-46 (1976) (making the case that dogma and simplistic solutions toward substance use have historically led to inadequate public health policy).

224. See Rasubala et al., *supra* note 212.

225. Janet Weiner et al., *Prescription Drug Monitoring Programs Evolution and Evidence*, LEONARD DAVIS INST. OF HEALTH ECON. ISSUE BRIEF 6 (2017) (finding that PDMPs were not associated with reductions in drug overdose mortality rates, and may be related to increased mortality from illicit drugs).

226. David A. Grimes & Kenneth F. Schulz, *Surrogate End Points in Clinical Research: Hazardous to Your Health*, 105 OBSTETRICS & GYNECOLOGY 1114 (2005); Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858 (2016).

227. *Id.*

228. See Li et al., *supra* note 212; Meara et al., *supra* note 212; Young Hee Nam et al., *State Prescription Drug Monitoring Programs and Fatal Drug Overdoses*, 23 AM. J. MANAGED CARE 297 (2017) (finding the PDMPs were not associated with reductions in drug overdose mortality rates, and may be related to increased mortality from illicit drugs).

in opioids dispensed was found from 2008 to 2015.²²⁹ During that same time window, the study also documented a 200% spike in unintentional poisonings involving heroin.²³⁰

If the ultimate goal is to curb overdose, then PDMPs' utility is far from clear.²³¹ Our review found that only 32% (eleven of thirty-four)²³² of the relevant empirical studies even included overdose morbidity or mortality as a metric of PDMP impact, despite this outcome clearly being the policy goal of primary—if not sole—importance. Of those studies that assessed PDMP impact in this vital arena, all eleven considered prescription drug related overdoses as a metric of interest. Among these studies, six found PDMP deployment to be associated with lower prescription drug overdose rates,²³³ and five reported a null result.²³⁴

More recent research continues to bear characteristically mixed results. In an analysis of programs nationwide, Patrick et al.²³⁵ found an average reduction of 1.12 prescription opioid-related overdose deaths per 100,000 population in the year after a state's implementation of a prescription monitoring program. But this analysis did not control for key confounders, like state medical marijuana policies.²³⁶ Pardo, for example,²³⁷ found that states with more intensive PDMP programs saw a reduction in prescription drug overdoses; however, when controlling for covariates, they found that states with medical marijuana dispensaries reported a 16% reduction in in prescription drug overdose deaths.

Ultimately, PDMP evaluation research should not be limited to measuring only overdose morbidity and mortality linked only to prescription drugs. Given

229. Sarah Warfield et al., Address at American Public Health Association Annual Meeting & Expo: Heroin and Prescription Opioid Poisonings in West Virginia, 2008-2015—The Potential Impact of Legislative Interventions (2017) (evaluating changes in opioid poisoning hospitalization rates after implementation of West Virginia's Prescription Drug Monitoring Program).

230. *Id.*

231. See Paulozzi et al., *supra* note 212 (noting that in 2011, the CDC reviewed the evidence on links between PDMPs and overdose, finding no evidence of impact).

232. See Johnson et al., *supra* note 212; Freeman et al., *supra* note 212; Delcher et al., *supra* note 212; Dowell et al., *supra* note 212; Patrick et al., *supra* note 212; Pardo, *supra* note 212; Paulozzi et al., *supra* note 212; Li et al., *supra* note 212; Brown et al., *supra* note 212; Hayes et al., *supra* note 212; Meara et al., *supra* note 212.

233. See Johnson et al., *supra* note 212; Freeman et al., *supra* note 212; Delcher et al., *supra* note 212; Dowell et al., *supra* note 212; Patrick et al., *supra* note 212; Pardo, *supra* note 212.

234. See Paulozzi et al., *supra* note 212; Li et al., *supra* note 212; Brown et al., *supra* note 212; Hayes et al., *supra* note 212; Meara et al., *supra* note 212.

235. See Patrick et al., *supra* note 212.

236. There have been a number of studies identifying an independent relationship between marijuana regulation and opioid overdose rates. For instance, a time-series analysis of medical cannabis laws and state-level cause of death data revealed a 24.8% lower mean annual opioid overdose mortality compared to states which prohibit medical cannabis. See Bachhuber et al., *supra* note 212; see also Elyse Phillips & Julie Gazmararian, *Implications of prescription drug monitoring and medical cannabis legislation on opioid overdose mortality*, 13 J. OPIOID MGMT. (2017).

237. See Pardo, *supra* note 212.

widespread misclassification of opioid overdose deaths,²³⁸ as well as the fungibility of the opioid use and documented transition from prescription to black market drugs, the most appropriate metric of success would be to consider PDMP impact on all opioid-involved overdoses, including prescription *and* nonprescription sources. In this review, only one in five published peer-reviewed studies (21%; see Table 1) included an overdose morbidity or mortality-related research endpoint that was not specific to prescription drugs.²³⁹ Of those, three found PDMP deployment to be associated with lower overall overdose rates,²⁴⁰ while four reported a null result.²⁴¹ Notably, three studies reported PDMP program or policy elements to be associated with a *rise* in non-prescription overdose rates.²⁴² These decidedly equivocal findings stand to challenge the kind of unbridled enthusiasm, generous investment, and cavalier policy emphasis that has buoyed PMDPs since the onset of the overdose crisis.

Insofar as the PDMP tracks reductions in doctor shopping or other drug user behavior deemed “problematic,” those observations may reflect health care providers’ and drug users’ defensive practices, rather than real improvements. Providers may rebuke, abandon, and “fire” patients with suspicious or in some way aberrant histories or behaviors, as a defensive tactic to reduce their exposure to potential professional and criminal liability.²⁴³ An evolving trend in high-profile cases where prescribers are being held criminally responsible for the overdose deaths of their patients²⁴⁴ underscores the real and perceived risk of

238. See Rudd et al. *supra* note 127 (noting that “heroin and morphine are metabolized similarly, [opioid overdose deaths may be] misclassified,” and citing Gregory G. Davis & National Association of Medical Examiners and American College of Medical Toxicology Expert Panel on Evaluating and Reporting Opioid Deaths, *National Association of Medical Examiners Position Paper: Recommendations for the Investigation, Diagnosis, and Certification of Deaths Related to Opioid Drugs*, 10 J. MED. TOXICOLOGY 100 (2014)).

239. See Paulozzi et al., *supra* note 212; Li et al., *supra* note 212; Brown et al., *supra* note 212; Hayes et al. *supra* note 212; Johnson et al., *supra* note 212; Freeman et al., *supra* note 212; Patrick et al., *supra* note 212.

240. See Paulozzi et al., *supra* note 212; Li et al., *supra* note 212; Brown et al. *supra* note 212; Hayes et al., *supra* note 212.

241. See Johnson et al., *supra* note 212; Freeman et al., *supra* note 212; Patrick et al., *supra* note 212.

242. See Brown et al., *supra* note 212; Freeman et al., *supra* note 212; Johnson et al., *supra* note 212.

243. M. Demidenko et al., *Suicidal ideation and suicidal self-directed violence following clinician-initiated prescription opioid discontinuation among long-term opioid users*, 47 GEN. HOSP. PSYCHIATRY 29 (2017) at 29-32 (noting the tragic consequences of opioid tapering and patient abandonment in response to policies and programs that emphasize dose reduction).

244. See Michael Nedelman, *Doctors Increasingly Face Charges for Patient Overdose*, CNN (July 31, 2017, 5:19 AM), <http://www.cnn.com/2017/07/31/health/opioid-doctors-responsible-overdose> [<https://perma.cc/7P48-GAPP>] (outlining a trend in doctors being charged with the death of their patients); Marisa Gerber et al., *California Doctor Convicted of Murder in Overdose Deaths of Patients*, L.A. TIMES (Oct. 30, 2015, 3:46 PM), <http://www.latimes.com/local/lanow/la-me-ln->

criminal, civil, and professional censure. Defensive practices spurred by these regulatory forces are chilling opioid prescribing even when medically necessary.²⁴⁵

Patients may also respond to both PDMP and provider-initiated signals by shifting their behavior to avoid detection. In that context, a patient with a severe substance use disorder who had previously engaged in doctor shopping (and therefore be at a high risk of future overdose)²⁴⁶ may respond to perceived or real monitoring by moving their activity outside of the surveillance realm. Without concerted efforts to retain that patient in care, such a move would entail being relegated to the black market. The result: The PDMP may reflect fewer “drug seeking” incidents or multiple prescriber episodes, but at a cost of increased risk to the individual and to the public’s health.

Methodological challenges will continue to muddy the picture on PDMP impact.²⁴⁷ Given the number of different policy and programmatic elements of PDMPs, as well as the historical reality that these elements have often changed contemporaneously with implementation of other policy and programmatic interventions, it may not be ultimately possible to isolate their impact. In the words of the Surgeon General’s seminal report on the opioid crisis: “Multiple efforts to address prescription drug misuse within states occurring in concert with mandatory PDMP legislation may limit the ability to draw causal conclusions about the effectiveness of mandatory use of PDMPs.”²⁴⁸

What is behind the mismatch between the confidence and resources invested in PDMPs and their real-world impact? The problem is not, as some have argued, just that many healthcare providers are reluctant²⁴⁹ to use these (sometimes clunky) databases, that states fail to share data²⁵⁰ or that mandates requiring their

doctor-prescription-drugs-murder-overdose-verdict-20151030-story.html [https://perma.cc/2694-9MNR] (describing story of high-profile doctor charged with the death of his patient who overdosed); Robert Siegel, *DOJ Stepping Up Prosecutions Of Medical Providers Who Abuse Prescribing Authority*, NPR (Dec. 11, 2017, 4:38 PM), <https://www.npr.org/2017/12/11/569983638/doj-stepping-up-prosecutions-of-medical-providers-who-abuse-prescribing-authority> [https://perma.cc/ET5C-XLTC] (describing how the Department of Justice is ramping up prosecutions of providers who overprescribe opioids).

245. Stefan G. Kertesz, *Turning the tide or riptide? The changing opioid epidemic*, 38 SUBSTANCE ABUSE 3 (2017).

246. Meghan Fibbi et al., *Denial of Prescription Opioids Among Young Adults with Histories of Opioid Misuse*, 13 PAIN MED. 1040, 1040-48 (2012).

247. See Corey S. Davis, *Commentary on Pardo (2017) and Moyo et al. (2017): Much Still Unknown About Prescription Drug Monitoring Programs*, 112 ADDICTION 1797, 1797-98 (2017).

248. DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF THE SURGEON GENERAL, *supra* note 158, at 3-26.

249. See Rutkow et al., *supra* note 212.

250. DEP’T OF HEALTH & HUMAN SERVS., PRESCRIPTION DRUG MONITORING PROGRAMS INTEROPERABILITY STANDARDS: REPORT TO COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS AND COMMITTEE ON ENERGY AND COMMERCE, 112th Cong. (2013).

use are insufficiently strict.²⁵¹ The problem isn't even that over-reliance on PDMPs may, at times, paradoxically increase prescription²⁵² of painkillers. The key issue is that PDMPs are designed only to generate information. What ultimately matters is how that information is used, and by whom.

Without adequate context and transparency between patients and providers about their own information stored on PDMPs, patients stabilized on high doses of opioids are increasingly concerned about the future their pain management care.²⁵³ Currently, such patients have no right to review their own PDMP data, thus having no recourse to challenge or correct discrepancies in their prescription history that may be misconstrued as substance misuse or "drug-seeking behavior."²⁵⁴ This imbalance of power is especially concerning in the context of law enforcement accessing sensitive medical records: what criteria are based to distinguish between substance misuse emblematic of addiction, *bona fide* pain care, and venal diversion? The lack of agency for patients to review—and correct—their own records may sow distrust among the patient community.

Withholding prescriptions and abandoning or "firing" complex or suspicious patients appear to be actions that may result from finding of unexpected information in PDMPs. These actions may push patients away from the health care system, precipitating stigmatization and multiple cascading health harms. If "problem" patients are rebuked and turned away, they will likely seek out black-market alternatives—typically heroin, and increasingly, illicit fentanyl. Even when practitioners do refer patients to treatment, many of the affordable, evidence-based programs have waitlists that are weeks—or months—long,²⁵⁵ leaving patients with few options in the meantime. In other words, without health

251. Rebecca L. Haffajee et al., *Mandatory Use of Prescription Drug Monitoring Programs*, 313 JAMA 891, 891-92 (2015).

252. Scott G. Weiner et al., *Clinician Impression Versus Prescription Drug Monitoring Program Criteria in the Assessment of Drug-Seeking Behavior in the Emergency Department*, 62 ANNALS EMERGENCY MED. 281, 284-89 (2013) (describing an assessment of emergency room physicians prescribing behaviors before and after accessing PDMP data reflected a small increase in their likelihood to prescribe opioid medication at discharge, and noting access to this PDMP data may have given providers greater confidence in prescribing to patients previously assumed to be at risk for prescription drug misuse).

253. See Dan Verango, *He Took Opioids To Manage His Chronic Pain. When His Doctors Took Them Away, He Didn't Want To Live Anymore*, BUZZFEED (Nov. 30, 2017, 10:47 AM), https://www.buzzfeed.com/danvergano/chronic-pain-debate-opioid-painkillers?utm_term=.tk6EZddRY#.tx50P88n2 [<https://perma.cc/TUP9-KMZU>] (discussing pain patients losing access to opioids); Robert Langreth, *Millions of Patients Face Pain and Withdrawal as Opioid Prescriptions Plummet*, BLOOMBERG (Nov. 21, 2017, 11:26 AM), <https://www.bloomberg.com/news/articles/2017-11-21/millions-of-patients-face-pain-and-withdrawal-as-opioid-prescriptions-plummet> [<https://perma.cc/YC52-A84M>] (discussing pain patients being abandoned due to prescribers abruptly ending pain management).

254. See generally Weiner et al, *supra* note 252.

255. Jason Cherkis, *Dying To Be Free*, HUFFPOST (Jan. 28, 2015), <http://projects.huffingtonpost.com/dying-to-be-free-heroin-treatment#chapter-one> [<https://perma.cc/4FFY-YB6J>].

care providers adequately understanding how to use information gleaned from PDMPs to simultaneously reduce prescription drug misuse *and* keep patients engaged in care, the increased use of PDMPs can cause more harm than good.

Public health surveillance can act as an intervention, changing behavior of those affected as well as other members of the community. In the case of PDMPs, these programs engage in disseminating information and providing training to a variety of stakeholders, including law enforcement and health care providers. Empirical analysis found little evidence that PDMPs were using their online channels to educate its users and members of the public that were likely to reduce overdose or advance other public health goals. Most programs provide didactic aides but do not provide substantive training.²⁵⁶

Evaluation of the Diversion Alert program in Maine underscores this point. This program provides health care practitioners with access to a database and alert system that contains criminal justice information about their patients.²⁵⁷ Its evaluation found that system access was associated with increased deployment of patient surveillance methods, including urine drug screens, random pill counts, and utilization of prescription drug monitoring program.²⁵⁸

The broader context for this empirical overview is that there is little evidence that interventions to reduce drug supply have any lasting positive impact on substance misuse or overdose.²⁵⁹ As has been the case with the vast majority of “supply-reduction” efforts mounted by the criminal justice system, the development of PDMPs occurred largely without regard for empirical insights into how regulated entities may alter their behavior in response. The engineers of PDMP interventions did not appear to contemplate how patients would react to the real or perceived risk of breach of their confidential prescription information, or to being rebuked by a provider in response to information gleaned from the PDMP. Much was assumed about how providers’ access and interpretation of prescription drug information can reduce inappropriate prescribing and diversion of drugs; doing so without unnecessarily restricting access to medication for *bona fide* patients received little consideration.

B. Original Data

Original data collected as part of a larger project helps to contextualize these findings. We conducted twenty-three interviews with key stakeholders in Massachusetts regarding their perspectives and experiences with the prescription

256. Green et al., *supra* note 182.

257. Sarah Levin Martin & Clare Derosiers, *Diversion Alert: 1-Year Evaluation Across Northern New England, 2013-2014*, PREVENTING CHRONIC DISEASE, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 23, 2016), https://www.cdc.gov/pcd/issues/2016/16_0229.htm [<https://perma.cc/9XNE-AA53>].

258. *Id.*

259. See Leo Beletsky & Corey Davis, *Today's fentanyl crisis: Prohibition's Iron Law, revisited*, 46 INT'L J. OF DRUG POL'Y (2017). See also Werb et al., *supra* note 175.

drug program.²⁶⁰ The full description of the study is beyond the scope of this paper, but several data points help to underscore a number of the shortcomings in PDMP design and implementation.

Two of the stakeholder groups interviewed during the project included healthcare providers and advocates for the substance user community. Interviewees from both stakeholder groups expressed overlapping concerns regarding the PDMPs effect on patient-physician relationships, the unintended harms of surveillance on prescribing practices and the failure of the PDMP design to provide support for patients with addiction. An advocate from a community organization for substance users suggested the PDMP does not play a major role in “curbing the epidemic” and may be responsible for increasing the use of illicit drug use:

I really don't see it playing much a role. I think it may have played an unintended role of more people accessing what substances they choose to use illegally. I think there are a lot of folks out there who are in legitimate pain and because they aren't being treated properly for that pain, they have been accessing the medications and chemicals they need to make themselves feel better in an illicit and illegal way now, because of the PDMP.

Drug user group representative²⁶¹

As this stakeholder suggested, the PDMPs “supply-reduction” design offers little opportunity for patients and providers to reduce the “demand” for pain medication, potentially diverting patients towards illicit drug use through limitations on prescription medication.

Another dominant theme in these narratives was the role of PDMPs as potentially furthering existing stigmatization of drug users in health care and pharmacy settings.

A lot of people stay away from certain healthcare facilities or companies or whatever and because, they, of the way, the way they've begun targeting us and treating us in terms of, as using the PMP as a tool of oppression.

Drug user group representative²⁶²

This perspective highlights the potential of PDMPs as a real or perceived barrier to help-seeking. Such adverse impact could disproportionately impact individuals whose mistrust of government surveillance is based on personal or social group experiences warranting such caution.

260. Leo Beletsky, Presentation at the 40th Annual Meeting of the College on Problems of Drug Dependence: Prescription Drug Monitoring: Of Law Enforcement, or Public Health? Montreal, Canada (June 19, 2017).

261. *Id.*

262. *Id.*

The dominant narrative from physicians was somewhat parallel to the community groups' perspective, in the sense that prescribers critiqued the effect of the PMDP on patient-physician relationships and their ability as providers to effectively treat pain and addiction, the root causes of opioid "demand", with one prescribing physician stating:

I think physicians currently believe that their prescribing practices are now vulnerable to being monitored and unlike other aspects of their care and their treatment, how they prescribe to a given patient is there for everybody to see, however the reasons that they prescribed it, the carefulness with which they're monitoring, the effectiveness that it may have for the patient, that's not there.

Prescribing physician²⁶³

C. Concerns Emerging from Litigation

Another important source of information about the real-world impact of PDMPs comes from emerging litigation, based specifically on privacy concerns. The recently-decided Oregon Prescription Drug Monitoring Program and the ACLU Foundation of *Oregon v. United States Drug Enforcement Administration*²⁶⁴ case is especially illustrative of the privacy issues raised by the new or newly expanded PDMPs, as they have emerged to combat the overdose crisis.

At issue in this case is the Oregon PDMP law, which requires law enforcement to obtain a warrant supported by probable cause to access prescription data. The DEA routinely seeks data from state PDMPs using only an administrative subpoena. Oregon challenged this practice. Joining the lawsuit were ACLU of Oregon and five individuals, including four patients and one prescribing physician. Two of the John Doe interveners were transgender men, whose hormone transition therapy was documented in the PDMP. In their declarations, these five individuals communicated their misgivings about the nearly unfettered availability of deeply-private PDMP data to federal agents, and the effect that is likely to have on their physical and mental health and prescribing behavior.²⁶⁵ They objected to the law on Fourth Amendment grounds.

After prevailing below, the challenge to warrantless access advanced to the 9th Circuit. On appeal, Oregon lost. The Court reasoned that the Oregon law was in positive conflict with the federal CSA, and was therefore preempted: it also reasoned that the intervenors lacked standing because "threatened injury must be certainly impending to constitute injury in fact, and . . . [a]llegations of possible

263. *Id.*

264. *Or. Prescription Drug Monitoring Program v. U.S. Drug Enf't Admin.*, 860 F.3d 1228 (9th Cir. 2016).

265. *Id.*

future injury are not sufficient.”²⁶⁶ The state elected not to appeal the case further. The parallel case *DOJ v. Utah Department of Commerce* reached a similar conclusion, though that opinion did reach—and rejected—the Fourth Amendment question on the expectation of privacy, based on third party doctrine.²⁶⁷ Notably, the decision states “Physicians and patients have no reasonable expectation of privacy in the highly-regulated prescription drug industry.”²⁶⁸ This decision was similarly not appealed.

Although these decisions technically constitute the law only in the 9th and 10th Circuits, they are certain to have national impact. Across the country, PDMP legislation includes a warrant requirement for law enforcement in 27 states.²⁶⁹ The broad subpoena power granted to the Department of Justice through the CSA essentially means that federal law enforcement is able to obtain PDMP information without judicial review, extinguishing state-level protections as they apply to DEA and other federal agents. Moreover, there is nothing stopping federal agents from subsequently transferring data gleaned from warrantless PDMP searches to state or local law enforcement. This would certainly be in line with routine coordination and data sharing between federal, state, and local law enforcement in all aspects of drug law enforcement. This mechanism is in addition to the other “back door” which is the proactive PDMP reporting of “outlier” information authorized or mandated in thirty-nine states.²⁷⁰

V. HARNESSING PDMPs TO ADDRESS THE OVERDOSE CRISIS

The preceding analysis carries key lessons for ways in which PDMP policies and programs can move towards evidence and away from ideology. As they now exist, and especially in view of the recent jurisprudence, the privacy issues may have a disproportionate impact on marginalized patients. It is not that the data are being collected, it is how these data are being used and who has access. In this, emerging concerns echo not just the past objections to public health surveillance but also current debates about dragnet government surveillance and “big data” techniques increasingly used for marketing and surveillance purposes.²⁷¹

Historical experience should prompt us to think critically about PDMPs and proceed with caution. Spurred by the opioid crisis, the evolution of PDMPs has

266. *Id.* at 1235 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)).

267. *U.S. Dep’t of Justice v. Utah Dep’t of Commerce*, Case No. 2:16-CV-611-DN-DBP, 2017 WL 3189868 (D. Utah, July 27, 2017); see also *Smith v. Maryland*, 442 U.S. 735 (1979) (articulating the “third party doctrine” that challenges an individual’s reasonable expectation of privacy when dialing phone numbers, because those numbers are transmitted to the telephone company).

268. *Id.*

269. See LAW ATLAS, *supra* note 194 and accompanying text.

270. *Id.* See also JUSTICE SYSTEM USE OF PRESCRIPTION DRUG MONITORING PROGRAMS, BUREAU OF JUSTICE ASSIST. 11-13 (2015), <https://www.bja.gov/Publications/Global-JusticeSystemUsePDMPs.pdf> [<https://perma.cc/WN3Z-7W56>].

271. See Bonnie Kaplan, *supra* note 206.

occurred without adequate attention to informed, user-driven design to maximize PDMPs' clinical and public health benefits, while minimizing their potential harms. As currently configured, there is little reason to believe that PDMPs increase the use of proven overdose prevention measures; there is even some evidence they may drive patients away from engagement with the health care system.²⁷² People with history of criminal justice involvement may be especially reticent to seek help if they perceive risk of law enforcement involvement. Many of the same individuals may also face much higher risk of overdose.²⁷³

As the overdose crisis is driving the expansion of their operational and legal scope, these systems are being deployed with without adequate consideration of patient privacy and confidentiality. While their deterrence impact has not been adequately assessed, the potential for—and troubling signs of—unintended public health harms add urgency to a better calibration of the design and implementation of these programs.²⁷⁴

There are clear opportunities for improvement, along several fronts. First and foremost, PDMPs can and should be functionally reconfigured away from their current orientation on arbitrary metrics of “aberrant” practices to instead focus on health promotion as their express policy and evaluation guidepost. The conceptual, normative, and operational goal of PDMPs must be to advance patient well-being. This implies the imperative to improve their ability to support sound clinical decision-making,²⁷⁵ including through common-sense choice architecture elements protective against opioid-benzodiazepine and other risky drug interactions within a patient’s pharmacotherapy regimen. Algorithms can be deployed to assist providers in identifying patients who are especially vulnerable to overdose risk. Instead of facilitating isolation and abandonment of at-risk individuals, these systems have the potential to facilitate engagement with improved physical and mental health care, including substance use treatment and other risk reduction modalities, such as naloxone access and syringe access services.

Simple design modifications can turn, PDMP into tools of patient care coordination, for example by integrating internal messaging platforms that could

272. Richard M. Reisman, *Prescription Opioid Usage and Abuse Relationships: An Evaluation of State Prescription Drug Monitoring Program Efficacy*, 3 SUBSTANCE ABUSE 41 (2009). See also *supra* note 212.

273. Leo Beletsky, et al., *Fatal Re-Entry: Legal and Programmatic Opportunities to Curb Opioid Overdose among Individuals Newly Released from Incarceration*, 7 NE. U. L.J. 155 (2015).

274. See, e.g. Or. Prescription Drug Monitoring Program v. U.S. Drug Enf’t Admin., 860 F.3d 1228, http://aclu-or.org/sites/default/files/PDMP_Motion_to_Intervene.pdf [<https://perma.cc/VZK2-XXQE>] (challenging the administration of the Oregon PDMP vis a vis the Fourth Amendment).

275. Erin P. Finley et al., *Implementing prescription drug monitoring and other clinical decision support for opioid risk mitigation in a military health care setting: a qualitative feasibility study*, J. AM. MED. INFORMATICS ASS’N (2017), <http://academic.oup.com/jamia/advance-article/doi/10.1093/jamia/ocx075/4086553> [<https://perma.cc/9URA-CQA5>] (discussing the opportunities of utilizing PDMPs as a clinical decision support tool).

allow prescribers and pharmacists to communicate about a patient's particular health needs. In terms of their public health surveillance function, PDMPs can help understand the prevalence and incidence of use of certain drugs, track unexpected or adverse events, and target resources and interventions to patients and geographical areas most in need.

As matters stand, PDMPs exist largely outside of the health care information infrastructure and legal architecture. This means that, when looking up a patient on a typical PDMP database, a provider has no way of knowing anything about the patient beyond their basic demographic characteristics and prescription drug history within the particular state. This limits the utility of the data to inform provider, regulator, and public health researcher conclusions about appropriate regimens and dosage.²⁷⁶ Inability to view PDMP data in context can lead to false positive and false negative conclusions about risky or problematic patterns and thus hampers efficacious policy or regulatory responses. Therefore, PDMPs should be integrated into other electronic medical records and treated in the same manner—from the perspective of clinical care. Just like with any health information technology tool, providers need training to help them understand how and when they can fit these new sources of information into their practice.²⁷⁷ In similar vein, patients' and potential patients' knowledge and attitudes about PDMPs are important considerations in efforts to encourage help-seeking and reduce stigmatization of drug use—whether licit or illicit. Public health and law enforcement are beginning to work collaboratively to address the overdose crisis,²⁷⁸ including on the utilization of data. But there are very few examples of its uses to reduce patient risk at the point of care. The emerging reality that law enforcement in many jurisdictions can obtain largely unfettered access to PDMPs through the legal back door mechanisms deserves further scrutiny.

In this context, curtailment of federal regulations protecting drug treatment-related data being proposed in various forums²⁷⁹ would facilitate the integration of SUD treatment data into PDMPs, where the *Oregon* and *Utah* court decisions discussed above²⁸⁰ would expose highly-private information to warrantless Drug Enforcement Administration searches. Such access could discourage help- and healthcare-seeking, especially among the most vulnerable SUD patients. Instead, we should advocate that privacy protections be *expanded* to shield PDMP data from unfettered law enforcement access at state and federal levels. On the other hand, inclusion of an ever-broader set of information elements under the scope

276. Joshua W. Elder, Garret DePalma, and Jesse Pines, *Optimal Implementation of Prescription Drug Monitoring Programs in the Emergency Department*, 19 WEST. J. EMER. MED. 387, 387-391 (2018).

277. *Id.*

278. See Leo Beletsky, *Law Enforcement, Drugs and the 'Public Health' Approach*, THE CRIME REPORT (Apr. 19, 2016), <https://thecrimereport.org/2016/04/19/law-enforcement-drugs-and-the-public-health-approach/> [<https://perma.cc/7LVP-A34X>]; see also JUSTICE SYSTEM USE OF PRESCRIPTION DRUG MONITORING PROGRAMS, *supra* note 270.

279. See, e.g. Kolodny and Frieden, *supra* note 12, at 1537-38.

280. See *supra* notes 264-267 and accompanying text.

of PDMPs, such as the criminal justice data now being made available to providers in Maine, Kentucky and Wisconsin, raise questions about further expansion of these systems into potentially stigmatizing domains of questionable clinical value.

Ultimately, deriving full value from effective public health surveillance without triggering unintended adverse consequences demands careful calibration. To accomplish this, legal and ethical canon draws on a familiar balancing test: to weigh the state imperative to protect the public's health against the patients' individual confidentiality and privacy rights.²⁸¹

This framework, though rhetorically straightforward, is fundamentally flawed because more robust privacy protections catalyze effective surveillance and other essential public health functions. As illustrated above, surveillance efforts that fail to adequately safeguard patient data do much more than harm individual rights: by undermining patient trust and creating a system of perverse incentives, they can push patients away from seeking appropriate, timely help. At the population level, this hampers disease surveillance and control efforts, aggravating the very problems these policies and programs were intended to ameliorate.²⁸² In other words, this policy heuristic fails to account for behavioral theory and empirical evidence on the impact of public health surveillance programs, sometimes backfiring a classic case of a "cobra effect."²⁸³ This is an example of a situation where interests of individuals and populations are complimentary.²⁸⁴

American history is replete with episodes when confidentiality interests proved a weak counterweight to what in retrospect proved to be abusive or otherwise inappropriate public health surveillance efforts.²⁸⁵ This record is especially dismal when it comes to discriminatory and draconian monitoring of racial minorities or other groups deemed dangerous—the very same groups that face the most formidable hurdles in mounting legal or political challenges to such abuse.²⁸⁶

In place of this balancing test, I advocate for an approach that infuses formal legal norms and their implementation mechanisms with the precautionary

281. Mariner, *supra* note 24, at 381.

282. *Id.* at 375.

283. *Id.* at 394.

284. See PARMET *supra* note 21, at 273.

285. See Mariner, *supra* note 24, at 388.

286. See *id.* (showing this balancing test is of further diminished utility in the many jurisdictions around the world where confidentiality rights hold less normative weight, and where substantive and procedural safeguards from undue government intrusion are poorly developed); Stuart Rennie et al., *Conducting Unlinked Anonymous HIV Surveillance in Developing Countries: Ethical, Epidemiological, and Public Health Concerns*, PLOS MEDICINE (2009) (exploring the ethical implications of HIV surveillance programs in developing nations and the potential for vulnerable populations to be exploited or unjustly treated); Anil Kalhan, *Immigration Surveillance*, 74 MD. L. REV. 1 (2014) (describing surveillance programs unique to the immigrant and refugee populations, and identifies national public health surveillance tools that have been used to track the health data of noncitizens).

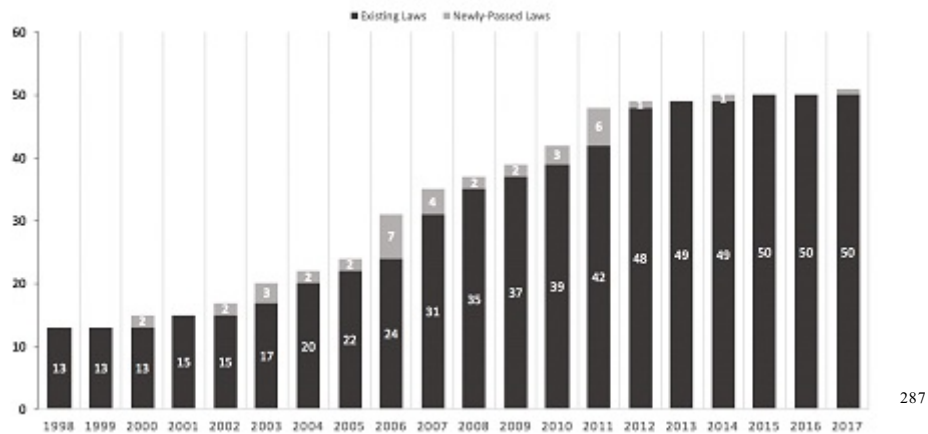
principle to “do no harm.” To calibrate policy and programmatic elements of public health surveillance initiatives, policymakers should be expected to balance potential public benefits against foreseeable harms, be they rooted in the normative and ethical concerns about individual rights or patterns of perverse incentives predicted by behavioral theory and documented by empirical research. Anchoring this balancing test in the precautionary principle requires decision-makers to more actively engage the public health evidence base to overcome the presumption against interventions that trigger unintended consequences. This balancing test favors surveillance policies and program designs that are narrowly tailored in scope, access privileges, and data use only so far as to serve their express public health purpose.

VI. CONCLUSION

Patient confidentiality is a matter of normative importance, especially when it comes to protecting the most vulnerable patients. On the population level, stigmatization, ideology and violations of patient confidentiality can create a deadly mix. Guided by the precautionary principle, we must design surveillance systems like PDMPs in ways that avoid doing more harm than good. Deploying these programs in ways that facilitate patient abandonment and criminalization must give way to a reorientation towards engaging patients and improving care coordination. Without doing the hard work to actually help those who need it—and when they need it—most, prescription drug monitoring programs and policies threaten to continue fuel America’s overdose crisis.

APPENDIX I:

Figure 1. The Diffusion of Prescription Drug Monitoring Legislation in United States 1999-2017



287. See *supra* note 23.

Table 1. Narrative Summary of Peer-Reviewed Studies Assessing PDMP Impact (2010-2018)

Article	System Utilization	Rx rate / volume	Dr. Shopping / # prescribers	Diversio n / Misuse	Rx Overdose	Non-Rx Overdose	
David F. Baehren et al. (2010)	NA	↓	NA	NA	NA	NA	Increase effect noted: ↑
Leonard J. Paulozzi (2011)	NA	↑	NA	NA	0	0	Decrease effect noted: ↓
Lisa Reifler et al. (2012)	NA	NA	NA	↓	NA	NA	Examined, but no effect noted: 0
Linda Simoni-Wastila, Jingjing Qian (2012)	NA	↓	NA	NA	NA	NA	Not examined: N/A
Wixson et al (2013)	NA	↑	NA	NA	NA	NA	
Jeanne E. Brady et al. (2014)	NA	0	NA	NA	NA	NA	
Hal Johnson et al. (2014)	↑	↓	NA	↓	↓	↑	
Guohua Li et al. (2014)	NA	NA	NA	NA	0	0	
Hilary L. Surratt et al. (2014)	↑	NA	NA	↓	NA	NA	
Chris Delcher et al. (2015)	NA	NA	NA	NA	↓	NA	
Freeman et al. (2015)	↑	↓	↓	NA	↓	↑	
Matthew McAllister et al. (2015)	NA	0	NA	NA	NA	NA	
Brandon Maughan et al (2015)	NA	NA	NA	0	NA	NA	
Laine Ruskow et al. (2015)	NA	↓	NA	NA	NA	NA	
Linda Rusubala et al. (2015)	↑	↓	NA	NA	NA	NA	
Wright et al (2015)	NA	↓	NA	NA	NA	NA	
Yuhua Bao et al. (2016)	NA	↓	NA	NA	NA	NA	
Marcus Bachhuber et al (2016)	NA	NA	NA	0	NA	NA	
Brown et al. (2016)	NA	0	NA	0	0	↑	
Hsien Yen Chang et al (2016)	NA	↓	NA	NA	NA	NA	
Deborah Dowell et al. (2016)	↑	↓	NA	NA	↓	NA	
CJ Hayes et al (2016)	NA	NA	NA	0	0	0	
Ellen Moura et al. (2016)	NA	0	0	0	0	NA	
Bryce Pardo (2017)	NA	NA	NA	NA	↓	NA	
Stephen Patrick et al. (2016)	NA	NA	NA	NA	↓	↓	
Ali et al. (2017)	NA	NA	↓	0	NA	NA	
Douglas Keith Brunham et al. (2017)	NA	NA	NA	↑	NA	NA	
Thomas C. Buchmueller & Colleen Carey (2017)	↑	NA	↓	↓	NA	NA	
Dhaval M. Dave et al. (2017)	↑	NA	NA	↓	NA	NA	
Patience Moyo et al. (2017)	NA	↓	NA	NA	NA	NA	
Brian Suffoletto et al (in press)	NA	↓	NA	NA	NA	NA	
Hefei Wen et al. (2017)	↑	↓	NA	NA	NA	NA	
Courtney R. Yarbrough (2017)	NA	↓	NA	NA	NA	NA	
Hsien Chang Lin et al. (2018)	NA	0	NA	NA	NA	NA	