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Exploring Legal and Policy Responses to Opioids: America's Worst Public Health Emergency

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Exploring Legal and Policy Responses to Opioids: America's Worst Public Health Emergency

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**EXPLORING LEGAL AND POLICY RESPONSES TO OPIOIDS:
AMERICA’S WORST PUBLIC HEALTH EMERGENCY**

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I. INTRODUCTION

On October 26, 2017, the Department of Health and Human Services (HHS) formally declared a national state of public health emergency (PHE) in response to the opioid epidemic.¹ Urged by the White House's Opioid Commission,² HHS's declaration, since renewed multiple times,³ assimilates emergency declarations among a handful of state, tribal, and local governments.⁴ Countless public and private sector entities have engaged in additional opioid emergency response efforts across the United States.

These emergency declarations and measures collectively respond to the worst PHE confronting the country since the origination of this specific emergency classification in 2001.⁵ Americans across all socioeconomic groups are at risk of, or already addicted to, opioids in one form or another.⁶ Several hundred thousand Americans have lost their lives to prescription or illicit opioid misuse over the course of this epidemic.⁷ Nearly 130 more

1. See Lawrence O. Gostin et al., *Reframing the Opioid Epidemic as a National Emergency*, J. AM. MED. ASS'N, Aug. 23, 2017, at E1; Declaration by Alex M. Azar II, U.S. Dep't of Health & Human Servs., Renewal of Determination that a Public Health Emergency Exists (Oct. 18, 2018).

2. See generally THE PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS, INTERIM REPORT 2 (July 31, 2017), [hereinafter PRESIDENT'S COMMISSION INTERIM REPORT], <https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf> (acknowledging the severity of the opioid crisis and outlining actions for the President to take to combat the crisis).

3. See Press Release, The White House Office of the Press Sec'y, President Donald J. Trump Is Taking Action on Drug Addiction and the Opioid Crisis (Oct. 26, 2017), [hereinafter White House Press Release], <https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-drug-addiction-opioid-crisis/>. The PHE has been renewed for four 90-day periods. See Azar, *supra* note 1.

4. See James G. Hodge, Jr. & Chelsea Gulinson, Presentation at The Network for Public Health Law, Opioid-related Public Health Emergency Declarations 15 (July 31, 2018), https://www.networkforphl.org/_asset/9ymvp/Opioid-related-Public-Health-Emergency-Declarations---12-1-2018.pdf.

5. *The Ctr. for Law and the Pub.'s Health at Georgetown and Johns Hopkins University*, THE MODEL STATE EMERGENCY HEALTH ACT (2001), <https://www.aapsonline.org/legis/msehpa2.pdf>. Five years after the development of the Model Act, the federal Pandemic and All Hazards Preparedness Act authorized HHS to declare PHEs at the national level. Pandemic and All Hazards Preparedness Act, Pub. L. No. 109-417, § 2801(a), 120 Stat. 2831 (2006).

6. See generally Michael R. Joynt et al., *The Impact of Neighborhood Socioeconomic Status and Race on the Prescribing of Opioids in Emergency Departments Throughout the United States*, 28 J. GEN. INTERNAL MED. 1604 (2013) (illustrating the racial and ethnic disparities in opioid prescribing).

7. HOLLY HEDEGAARD ET AL., U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, NCHS DATA BRIEF, NO. 294, DRUG OVERDOSE DEATHS IN THE UNITED STATES, 1999–2016 (2017).

Americans die each day from opioid misuse.⁸ Millions are directly impacted by excess morbidity arising from opioid use disorders (OUDs).⁹ Most people know someone who is at risk of, or has succumbed to, opioid abuse.¹⁰ This epidemic is truly the *juggernaut of PHEs*.¹¹

While emergency responses to date are purposeful and often well-intentioned, for manifold reasons they have also proven inadequate in authorizing and funding sufficient, efficacious responses.¹² In many ways, the unique qualities of opioids as a class of drugs defy traditional public health and law enforcement interventions. At one end of the spectrum, prescription opioids like OxyContin[®]¹³ have revolutionized the treatment of chronic pain as the “fifth vital sign.”¹⁴ Over the years, massive distributions of these drugs¹⁵ has led to extensive, long-term addictions among millions of Americans. As a result, substantial prescription limitations are now in place¹⁶ and major litigation against opioid manufacturers and others is ongoing.¹⁷ At

8. Press Release, Health & Human Servs. Press Office, HHS Awards Over \$1 Billion to Combat the Opioid Crisis (Sept. 19, 2018), <https://www.hhs.gov/about/news/2018/09/19/hhs-awards-over-1-billion-combat-opioid-crisis.html>; see generally Keturah James & Ayana Jordan, *The Opioid Crisis in Black Communities*, 46 J.L. MED. & ETHICS 404 (2018) (examining the rate of opioid-related deaths in the African-American community).

9. Gostin et al., *supra* note 1, at E1.

10. Jennifer De Pinto et al., *Opioid Addiction in the U.S.: 7 in 10 Say It's a Very Serious Problem*, CBS NEWS (Oct. 24, 2018, 11:36 AM), <https://www.cbsnews.com/news/opioid-addiction-in-u-s-7-in-10-say-its-a-very-serious-problem-cbs-news-poll>.

11. See James G. Hodge, Jr. et al., *Redefining Public Health Emergencies: The Opioid Epidemic*, 58 JURIMETRICS 1, 10–11 (2017).

12. See Mattie Quinn, *6 Months Since Trump Declared an Opioid Emergency, What's Changed?*, GOVERNING STS. & LOCALITIES (Apr. 25, 2018, 3:00 AM), <http://www.governing.com/topics/health-human-services/gov-opioid-emergency-declaration-trump.html>.

13. See generally Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221 (2009) (providing an in-depth analysis of the promotion and marketing of Oxycontin and the associated issues surrounding the overpromotion of the drug).

14. Robert Heimer, Kathryn Hawk & Sten H. Vermund, *Countering the Prevailing Narrative About the Causes of the US Opioid Crisis*, 5 LANCET PSYCHIATRY 543, 543 (2018); D. Andrew Tompkins, J. Greg Hobelmann & Peggy Compton, *Providing Chronic Pain Management in the “Fifth Vital Sign” Era: Historical and Treatment Perspectives on a Modern-Day Medical Dilemma*, 173 DRUG & ALCOHOL DEPENDENCE S11, S13–S14 (Supp. 1 2017).

15. See, e.g., Keith Humphreys, *Avoiding Globalization of the Prescription Opioid Epidemic*, 390 LANCET 437, 437 (2017); Benjamin Levy et al., *Trends in Opioid Analgesic-Prescribing Rates by Specialty, U.S., 2007–2012*, 49 AM. J. PREVENTIVE MED. 409, 409 (2015).

16. Abby Goodnough, *As Opioid Prescriptions Fall, Prescriptions for Drugs to Treat Addiction Rise*, N.Y. TIMES (Apr. 19, 2018), <https://www.nytimes.com/2018/04/19/health/opioid-prescriptions-addiction.html>.

17. Rebecca L. Haffajee & Michelle M. Mello, *Drug Companies' Liability for the Opioid Epidemic*, 377 NEW ENG. J. MED. 2301, 2301 (2017).

the other end, highly addictive illicit opioids like carfentanyl¹⁸—arriving through the mail or across our borders—have instantly killed tens of thousands of users lacking rapid access to naloxone¹⁹ or other medical interventions.²⁰

Adding to the complexity is the interconnection of these two ends.²¹ Temporary access to prescription opioids for many patients is a gateway to illicit opioid use. Up to eighty percent of heroin users first got hooked on prescription opioids.²² Unsurprisingly, regulating this diverse class of drugs is legally convoluted. Simple solutions like total bans of prescription opioids for all patients are non-viable given their accepted role and efficacy in treating pain.²³ Vilifying illicit opioids users (akin to “crack addicts” historically subjected to heavy-handed law enforcement) is grossly unfair and serves no legitimate public health purpose.²⁴ Curtailing access to illicit opioids is

18. Carfentanil (also spelled Carfentanyl), an analogue of fentanyl designed for use in sedating large animals, is 10,000 times more potent than morphine and 100 times more potent than fentanyl. *Carfentanil*, PUBCHEM: OPEN CHEMISTRY DATABASE, <https://pubchem.ncbi.nlm.nih.gov/compound/carfentanil#section=Top> (last updated Dec. 22, 2018).

19. Press Release, U.S. Drug Enforcement Agency, DEA Issues Carfentanil Warning to Police and Public (Sept. 22, 2016), <https://www.dea.gov/press-releases/2016/09/22/dea-issues-carfentanil-warning-police-and-public>; Rachael Rzasa Lynn & J.L. Galinkin, *Naloxone Dosage for Opioid Reversal: Current Evidence and Clinical Implications*, 9 THERAPEUTIC ADVANCES DRUG SAFETY 63, 63 (2018).

20. Gostin et al., *supra* note 1, at E1–E2.

21. See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain—Misconceptions and Mitigation Strategies*, 374 NEW ENG. J. MED. 1253, 1253–55 (2016).

22. NAT’L INST. ON DRUG ABUSE, PRESCRIPTION OPIOIDS AND HEROIN 5 (2018), <https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/19774-prescription-opioids-and-heroin.pdf> (citing Christopher M. Jones, *Heroin Use and Heroin Use Risk Behaviors Among Nonmedical Users of Prescription Opioid Pain Relievers – United States, 2002–2004 and 2008–2010*, 132 DRUG & ALCOHOL DEPENDENCE 95, 95 (2013); Pradip K. Muhuri et al., *Association of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CTR FOR BEHAVIORAL HEALTH STATISTICS AND QUALITY: DATA REVIEW (Aug. 2013), <https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm> (examining the role of nonmedical prescription pain reliever use in the heroin trend among persons aged twelve to forty-nine)).

23. See Stephanie Armour, *Opioid Crackdown Has Patients Struggling to Get Their Meds*, WALL STREET J. (Apr. 26, 2018, 8:00 AM), <https://www.wsj.com/articles/opioid-crackdown-has-patients-struggling-to-get-their-meds-1524744001>.

24. See Phillip L. Marotta & Charlotte A. McCullagh, *A Cross-National Analysis of the Association Between Years of Implementation of Opioid Substitution Treatments and Drug-Related Deaths in Europe from 1995 to 2013*, 33 EUR. J. EPIDEMIOLOGY 679, 680, 684–85 (2018); 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, 664 (2016).

formidable given the free flow of these drugs.²⁵ Substituting other drugs in place of opioids, like marijuana, carries its own legal baggage and repercussions.²⁶ Developing new and non-addictive palliative drugs is promising, but likely years away. Rescinding the national PHE declaration only admits defeat.

While major legal and policy strides have been undertaken to curb the opioid epidemic,²⁷ more significant approaches and greater investments are needed to prevent excess mortality and morbidity.²⁸ Commencing with an assessment of the impacts of the opioid crisis, existing legal and policy responses, and related failures are explained. A series of interventions are proposed to (1) stymie opioid-related overdoses and deaths in real time and (2) obviate deleterious impacts for future generations.

II. AMERICA'S WORST PUBLIC HEALTH EMERGENCY

The evolving American opioid epidemic began with a shift in how health care providers treat pain.²⁹ Long-standing, widespread inattention to palliative care among millions of patients heightened ethical arguments and altered physician attitudes over prescribing narcotic pain medications in the 1990s.³⁰

25. See SEAN O'CONNOR, U.S.-CHINA ECON. & SEC. REVIEW COMM'N, FENTANYL: CHINA'S DEADLY EXPORT TO THE UNITED STATES 5–6 (2017).

26. See generally NAT'L ACADS. OF SCI., THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH 9–12 (2017) (examining cannabis or cannabinoid use as an effective or ineffective treatment of prioritized health endpoints of interest).

27. See generally NAT'L GOVERNORS ASS'N, FINDING SOLUTIONS TO THE PRESCRIPTION OPIOID AND HEROIN CRISIS: A ROAD MAP FOR STATES 17–27 (2016) (describing actions taken by Governors across the nation to implement public health and public safety strategies for prevention and early identification of opioid addiction).

28. See Rebecca L. Haffajee & Richard G. Frank, *Making the Opioid Public Health Emergency Effective*, 75 J. AM. MED. ASS'N: PSYCHIATRY 767, 767 (2018); Liz Schroyer, *We Can't Fight Our Opioid Crisis Alone. We Need Help from Countries Around the World*, USA TODAY (Aug. 2, 2018, 2:11 PM), <https://www.usatoday.com/story/opinion/2018/08/02/fighting-american-opioid-crisis-international-help-needed-column/850333002>.

29. COMM. ON PAIN MGMT. & REGULATORY STRATEGIES TO ADDRESS PRESCRIPTION OPIOID ABUSE, PAIN MANAGEMENT AND THE OPIOID EPIDEMIC: BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE 25–28 (Richard J. Bonnie et al. eds.) (2017); Marcia L. Meldrum, *The Ongoing Opioid Prescription Epidemic: Historical Context*, 106 AM. J. PUB. HEALTH 1365, 1365 (2016).

30. Jane C. Ballantyne & Lee A. Fleisher, *Ethical Issues in Opioid Prescribing for Chronic Pain*, 148 J. PAIN 365, 365–66 (2010). Limited scientific reports of low abuse potential in opioids bolstered this shift. See generally Pamela T.M. Leung et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 NEW ENG. J. MED. 2194, 2194 (2017). In 2011, the Institute of Medicine stated that “[e]ffective pain management is a moral imperative, a professional

Experts³¹ and advocates³² pushed for more lenient medical board oversight and expanded the prescribing of lawful narcotics to treat pain. In 1996, Purdue Pharma® released its opioid-based pain reliever, OxyContin®, allegedly assuring medical practitioners that it was non-addictive.³³ By 2000, the Department of Veterans Affairs (VA) and Joint Commission were promoting palliative care assessments for many patients.³⁴ The national push to treat pain was fueled by massive allocations of opioids. From 1997 to 2007, opioid prescriptions steadily rose seven-hundred percent (see **Figure 1**),³⁵ cresting in 2012 when nearly 260 million opioid prescriptions were written.³⁶

responsibility, and the duty of people in the healing professions.” COMM. ON ADVANCING PAIN RESEARCH, CARE AND ED., RELIEVING PAIN IN AMERICA: A BLUEPRINT FOR TRANSFORMING PREVENTION, CARE, EDUCATION, AND RESEARCH 3 (2011).

31. Mitchell B. Max, *Improving Outcomes of Analgesic Treatment: Is Education Enough?*, 113 ANNALS INTERNAL MED. 885, 885 (1990).

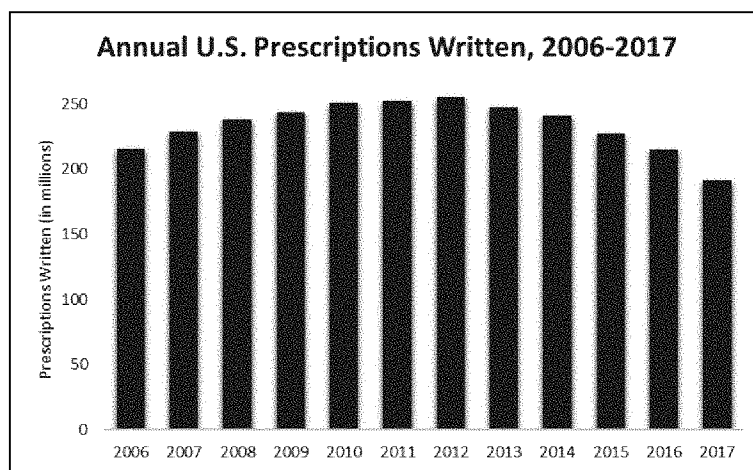
32. See Aaron M. Gilson & David E. Joranson, *Controlled Substances and Pain Management: Changes in Knowledge and Attitudes of State Medical Regulators*, 21 J. PAIN & SYMPTOM MGMT. 227, 236 (2001).

33. Van Zee, *supra* note 13, at 221–24 (noting the tactics used by Purdue Pharma® to downplay the risks of opioids). The company has since acknowledged the need to address opioid abuse and announced funding to increase access to naloxone. Purdue Pharma®, *We Manufacture Prescription Opioids, and We’ll Continue Our Work to Address the Opioid Crisis*, N.Y. TIMES, <https://www.nytimes.com/paidpost/purdue/we-manufacture-prescription-opioids-and-we-continue-our-work-to-address-the-opioid-crisis.html> (last visited Feb. 10, 2019) (“We are aware of the risks opioid pain medicines can create: even when taken as prescribed, they carry risks of addiction, abuse, and misuse that can lead to overdose and death.”); see also Purdue Pharma®, Advertisement, *We Want to Help People Understand the Risks of Misusing Prescription Medications*, N.Y. TIMES, <https://www.nytimes.com/paidpost/purdue/we-want-to-help-people-understand-the-risks-of-misusing-prescription-medications.html> (last visited Feb. 10, 2019) (“While no one intervention alone will solve this crisis, partnerships, determination, and innovative approaches are steps in the right direction.”).

34. U.S. DEP’T OF VETERANS AFF., PAIN AS THE 5TH VITAL SIGN TOOLKIT 1 (2000); Donald M. Phillips, *JCAHO Pain Management Standards Are Unveiled*, 284 J. AM. MED. ASS’N 428, 428 (2000).

35. Edward W. Boyer, *Management of Opioid Analgesic Overdose*, 367 NEW ENG. J. MED. 146, 146 (2012). Over this same period, non-opioid treatments in emergency rooms decreased. Hsien-Yen Chang et al., *Prevalence and Treatment of Pain in EDs in the United States, 2000 to 2010*, 32 AM. J. EMERGENCY MED. 421, 426 (2014).

36. U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, OPIOID PAINKILLER PRESCRIBING: WHERE YOU LIVE MAKES A DIFFERENCE 1 (2014), <https://www.cdc.gov/vitalsigns/pdf/2014-07-vitalsigns.pdf>. This figure exceeded the total number of adults in the U.S. population, although not every adult received a prescription. Patients receive varying dosages of therapeutic opioids with higher dosages linked more closely with increased overdose risk. U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, CALCULATING TOTAL DAILY DOSE OF OPIOIDS FOR SAFER DOSAGE 1 (2016), https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf. Of the 227 million opioid prescriptions written in 2015 (see **Figure 1**), nearly 92 million American adults were prescribed opioids therapeutically. Beth Han et al., *Prescription Opioid Use, Misuse, and Use Disorders in*

Figure 1. U.S. Opioid Prescriptions in Millions (2006–2017)³⁷

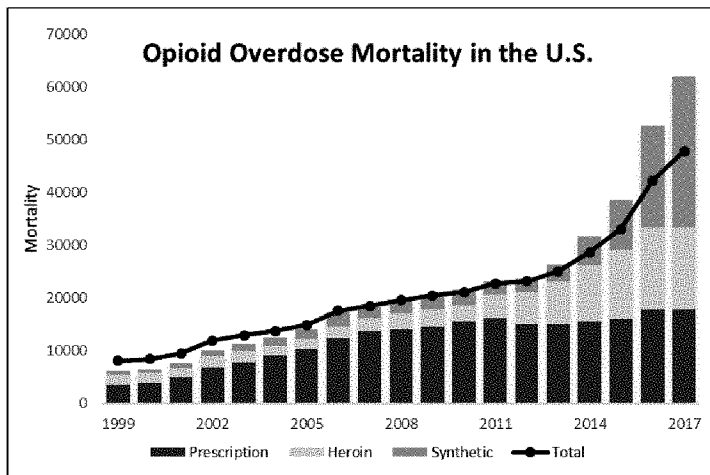
As prescription rates rose so did opioid overdose-related mortality.³⁸ Its addictive qualities entice patients to continuously ramp up their doses to dangerous levels. In most fatal overdoses, respiratory depression results in oxygen starvation that is sometimes coupled with cardiac arrest or arrhythmia and excess fluid in the lungs.³⁹ Overdose deaths increased by nearly six-hundred percent from 1999 to 2017 (see **Figure 2**).

U.S. Adults: 2015 National Survey on Drug Use and Health, 167 ANNALS INTERNAL MED. 293, 293 (2017).

37. *U.S. Opioid Prescribing Rate Maps*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html> (last updated Oct. 3, 2018).

38. Richard C. Dart et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 NEW ENG. J. MED. 241, 245 (2015). Some studies have found correlations between prescription rates and mortality in certain populations, including Medicare enrollees. Christos A. Grigoras et al., *Correlation of Opioid Mortality with Prescriptions and Social Determinants: A Cross-sectional Study of Medicare Enrollees*, 78 DRUGS 111, 119 (2018).

39. Jason M. White & Rodney J. Irvine, *Mechanisms of Fatal Opioid Overdose*, 94 ADDICTION 961, 962 (1999) (“[T]he primary mechanism responsible is opioid-induced depression of respiration with resulting hypoxia and death.”). Cardiac arrest or arrhythmia and excess fluid in the lungs likely contribute to the lethality of an overdose. Ankit Sakhuja et al., *National Trends and Outcomes of Cardiac Arrest In Opioid Overdose*, 121 RESUSCITATION 84, 84 (2017) (describing cardiac arrest); Roger Chou, Melissa B. Weimer & Tracy Dana, *Methadone Overdose and Cardiac Arrhythmia Potential: Findings from a Review of the Evidence for an American Pain Society and College on Problems of Drug Dependence Clinical Practice Guideline*, 15 J. PAIN 338, 338 (2014) (describing cardiac arrhythmia); Christopher

Figure 2. Opioid Overdose Mortality (1999–2017)⁴⁰

To date, opioids have caused nearly 400,000 confirmed American deaths; yet actual numbers may be considerably higher.⁴¹ While abuses of prescription opioids were at the source of many of these deaths initially, illicit

Sterrett et al., *Patterns of Presentation in Heroin Overdose Resulting in Pulmonary Edema*, 21 AM. J. EMERGENCY MED. 32, 32 (2003) (describing excess fluid in the lungs).

40. Data obtained from: HOLLY HEDEGAARD ET AL., U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, NCHS DATA BRIEF, NO. 294, DRUG OVERDOSE DEATHS IN THE UNITED STATES, 1999–2016, SUPPLEMENTAL DATA SPREADSHEET TBL.4 (2017), https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=4; *Vital Statistics Provisional Drug Overdose Death Counts*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> (last updated Feb. 13, 2019) [hereinafter *Vital Statistics*] (reporting CDC provisional estimates for 2018). For this figure, “prescription” opioids includes natural, semisynthetic, and methadone categories, pursuant to protocol in Puja Seth et al., *Quantifying the Epidemic of Prescription Opioid Overdose Deaths*, 108 AM. J. PUB. HEALTH 500, 501–02 (2018).

41. HEDEGAARD ET AL., *supra* note 40 (reporting 351,630 total opioid overdose fatalities from 1999 to 2016); *Vital Statistics*, *supra* note 40 (reporting 47,863 opioid overdose fatalities in 2017). Figures concerning opioid-related mortality are conservative estimates. For example, more than 110,000 mortalities from unspecified drugs have occurred since 1999. Hawre Jalal et al., *Changing Dynamics of the Drug Overdose Epidemic in the United States from 1979 Through 2016*, 361 SCI. 1218, 1219 (2018). Many of these unspecified drug deaths may be due to opioids since nearly two thirds of all drug overdose deaths since 1999 are attributable to opioids. *See id.* As well, state public health agencies may chronically underreport opioid fatalities by approximately 20%. Christopher J. Ruhm, *Geographic Variation in Opioid and Heroin Involved Drug Poisoning Mortality Rates*, 53 AM. J. PREVENTIVE MED. 745, 745 (2017).

drugs (e.g., heroin) and synthetic opioids⁴² (e.g., fentanyl) became primary causes of deaths in 2010 and 2013, respectively.⁴³ By 2016, American fatalities stemming from synthetic opioids exceeded those due to prescription opioids.⁴⁴ Absent greater interventions, one estimate suggests approximately 500,000 more deaths may occur between 2017 and 2027.⁴⁵

Additional negative impacts underlie multiple classes of opioids.⁴⁶ Neonatal abstinence syndrome, affecting newborns exposed to opioids in utero, nearly tripled from the late 1990s to the early 2010s.⁴⁷ Almost 22,000 newborns were diagnosed in 2012 alone.⁴⁸ From 2001 to 2011, the number of

42. Synthetic opioids including fentanyl and its analogues are stronger than prescription opioids, precipitating overdoses even in individuals experienced in using opioids non-therapeutically. U.S. DRUG ENF'T AGENCY, DEA-DCT-DIR-031-16, NATIONAL HEROIN THREAT ASSESSMENT SUMMARY – UPDATED 5 (2016); Donna A. Volpe et al., *Uniform Assessment and Ranking of Opioid Mu Receptor Binding Constants for Selected Opioid Drugs*, 59 REG. TOXICOLOGY & PHARMACOLOGY 385, 388 (2011). Fentanyl can be laced with heroin in unknown concentrations. See Jennifer J. Carroll et al., *Exposure to Fentanyl-Contaminated Heroin and Overdose Risk Among Illicit Opioid Users in Rhode Island: A Mixed Methods Study*, 46 INT'L J. DRUG POL'Y 136, 137 (2017); Lynn & Galinkin, *supra* note 19, at 64.

43. See Puja Seth et al., *Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants—United States, 2015–2016*, 67 MORBIDITY & MORTALITY WKLY. REP. 349, 349 (2018); Wilson M. Compton, Christopher M. Jones & Grant T. Baldwin, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin Use*, 374 NEW ENG. J. MED. 154, 154–55 (2016) (finding abuse of prescription drugs has led to increased uptake of heroin).

44. Christopher M. Jones, Emily B. Einstein & Wilson M. Compton, *Changes in Synthetic Opioid Involvement in Drug Overdose Deaths in the United States, 2010–2016*, 319 J. AM. MED. ASS'N 1819, 1819 (2018).

45. Max Blau, *STAT Forecast: Opioids Could Kill Nearly 500,000 Americans in Next Decade*, STAT NEWS (June 27, 2017), <https://www.statnews.com/2017/06/27/opioid-deaths-forecast>.

46. Prescription and illicit opioids can be administered via multiple routes, including oral tablets, intravenous and subcutaneous injection, nasal inhalation or vaporization, insufflation (snorting), transdermal patches, intrathecal, or rectal routes. See Henry J. Carson et al., *A Fatality Involving an Unusual Route of Fentanyl Delivery: Chewing and Aspirating the Transdermal Patch*, 12 LEGAL MED. 157, 157 (2010); Wojciech Leppert, Malgorzata Krajnik & Jerzy Wordliczek, *Delivery Systems of Opioid Analgesics for Pain Relief: A Review*, 19 CURRENT PHARMACEUTICAL DESIGN 7271, 7271 (2013).

47. See Stephen W. Patrick et al., *Neonatal Abstinence Syndrome and Associated Health Care Expenditures: United States, 2000–2009*, 307 J. AM. MED. ASS'N 1934, 1934 (2012) (1.20 per 1,000 in the year 2000 to 3.39 in the year 2009); Veeral N. Tolia et al., *Increasing Incidence of the Neonatal Abstinence Syndrome in U.S. Neonatal ICUs*, 372 NEW ENG. J. MED. 2118, 2118 (2015) (7 per 1,000 in the year 2004 to 27 per 1,000 in the year 2013); Jean Y. Ko et al., *Incidence of Neonatal Abstinence Syndrome—28 States, 1999–2013*, 65 MORBIDITY & MORTALITY WKLY. REP. 799, 799 (2016) (1.5 per 1,000 in the year 1999 to 6.0 per 1,000 in the year 2013).

48. Stephen W. Patrick et al., *Increasing Incidence and Geographic Distribution of Neonatal Abstinence Syndrome: United States 2009 to 2012*, 35 J. PERINATOLOGY 650, 650 (2015).

patients admitted for OUD treatments at publicly-funded entities increased by 348%.⁴⁹ In 2016, the federal Substance Abuse and Mental Health Services Administration (SAMHSA) estimated that nearly twelve million individuals misused opioids and 2.1 million persons had an actual disorder.⁵⁰ Recent findings suggest that OUDs occur in eight to twelve percent of patients taking opioids therapeutically;⁵¹ consequently, hundreds of thousands of Americans are at heightened risk of opioid abuse.⁵²

Escalations of OUDs and related mortality are especially alarming when compared to similar data concerning other harmful substances like tobacco or alcohol. Opioids essentially cause death faster—and among a greater proportion of persons using them—than most other substances. While regular tobacco use can reduce total life expectancy by ten years,⁵³ opioid overdoses lead to sudden early loss of life in younger individuals.⁵⁴ One estimate suggests that twenty percent of all deaths of Americans aged twenty-five to

49. See generally U.S. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., TREATMENT EPISODE DATA SET (2013) (detailing discharge information from publicly-supported substance abuse treatment programs).

50. U.S. SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN., KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2016 NATIONAL SURVEY ON DRUG USE AND HEALTH 30 (2017) [hereinafter KEY SUBSTANCE USE & MENTAL HEALTH INDICATORS]. This figure may be underestimated due to the use of phone surveys and the stigma of reporting drug use. Margot Sanger-Katz, *Bleak New Estimates in Drug Epidemic: A Record 72,000 Overdose Deaths in 2017*, N.Y. TIMES (Aug. 15, 2018), <https://www.nytimes.com/2018/08/15/upshot/opioids-overdose-deaths-rising-fentanyl.html>.

51. Kevin E. Vowles et al., *Rates of Opioid Misuse, Abuse, and Addiction in Chronic Pain: A Systematic Review and Data Synthesis*, 156 PAIN 569, 573 (2015). The probability of dependence increases with duration of the opioid prescription regimen, particularly for the first month of treatment. Anuj Shah et al., *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use—United States, 2006–2015*, 66 MORBIDITY & MORTALITY WKLY. REP. 265, 265 (2017).

52. Higher risks of dependence arise among persons using illicit opioids. Olga J. Santiago Rivera et al., *Risk of Heroin Dependence in Newly Incident Heroin Users*, 75 J. AM. MED. ASS'N: PSYCHIATRY 863, 864 (2018) (reporting 23%–38% of new heroin users may develop a dependence).

53. Prabhat Jha et al., *21st-Century Hazards of Smoking and Benefits of Cessation in the United States*, 368 NEW ENG. J. MED. 341, 341 (2013).

54. See Tara Gomes et al., *The Burden of Opioid-Related Mortality in the United States*, J. AM. MED. ASS'N NETWORK OPEN, June 1, 2018, at 1, 2.

thirty-four in 2016 involved opioid misuse.⁵⁵ In contrast, tobacco use only minimally impacts survival rates for adults under age thirty five.⁵⁶

Excessive alcohol consumption and related injuries cause around 88,000 fatalities per year,⁵⁷ which actually exceeds reported opioid-related mortality. However, alcohol-related deaths arise from a considerably larger pool of prospective at-risk users. Nearly sixty-seven million persons in the United States reported monthly binge drinking in 2017.⁵⁸ Even if alcohol deaths were attributable solely to these users, still only about .001% of them die each year. By comparison, in 2017, overdose deaths (48,000) are 3.32 times more likely among the estimated eleven million Americans misusing opioids in 2017.⁵⁹

Public health impacts of opioid-related abuses also far outweigh morbidity and mortality data related to infectious disease outbreaks or natural disasters resulting in national or regional PHEs. The H1N1 outbreak claimed only 12,500 lives between 2009 and 2010,⁶⁰ which is actually considerably fewer than many annual flu seasons in the United States.⁶¹ Emerging infectious conditions, like Ebola virus disease⁶² and Zika virus,⁶³ caused a

55. *Id.* at 4; see also Jessica Y. Ho & Arun S. Hendi, *Recent Trends in Life Expectancy Across High Income Countries: Retrospective Observational Study*, 362 BRIT. MED. J. 1, 1 (2018) (stating that the declines in life expectancy in the United States are more concentrated at younger ages and are largely driven by increases in drug overdose mortality related to its ongoing opioid epidemic).

56. See Jha et al., *supra* note 53, at 347.

57. *Alcohol and Public Health: Alcohol-Related Disease Impact (ARDI)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, https://nccd.cdc.gov/DPH_ARDI/default/default.aspx (last visited Jan. 19, 2019) (reporting data from ICD codes reflecting alcohol related toxicity and alcohol associated injury).

58. KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS, *supra* note 50, at 11.

59. See *id.* at 18–19; HEDEGAARD ET AL., *supra* note 7, at 4.

60. Sundar S. Shrestha et al., *Estimating the Burden of 2009 Pandemic Influenza A (H1N1) in the United States (April 2009–April 2010)*, 52 CLINICAL INFECTIOUS DISEASE S75, S79 (2011) (reporting 12,469 deaths in the U.S.); see also U.S. DEP'T OF HEALTH & HUMAN SERVS., 2009 H1N1 FLU OUTBREAK: DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (2010).

61. *National Press Conference Kicks Off 2018-2019 Flu Vaccination Campaign, Influenza*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/flu/spotlights/press-conference-2018-19.htm#ref1> (last updated Sept. 27, 2018) (reporting 80,000 deaths from the flu in 2017–2018).

62. Beth P. Bell et al., *Overview, Control Strategies, and Lessons Learned in the CDC Response to the 2014–2016 Ebola Epidemic*, 65 MORBIDITY & MORTALITY WKLY. REP. S4, S4 (2016); see Letter from Dannel P. Malloy, Governor of Conn., to Denise Merrill, Sec'y of State of Conn., Declaration of Public Health Emergency (Oct. 7, 2014), http://governor.ct.gov/malloy/lib/malloy/2014.10.07_Declaration_of_Public_Health_Emergency.pdf.

63. Sankar Swaminathan et al., *Fatal Zika Virus Infection with Secondary Nonsexual Transmission*, 375 NEW ENG. J. MED. 1907, 1907 (2016) (reporting 1 death in the U.S.); see

mere handful of known deaths in the U.S. (although populations in other countries lacking public health resources were ravaged). Natural disasters, like Hurricanes Katrina (2005),⁶⁴ Maria (2017),⁶⁵ and Michael (2018),⁶⁶ have collectively caused several thousand instant or near-time fatalities. Still, the totality of deaths related to all of these PHEs (and many others) nationally over the last 20 years do not come close to the sheer numbers of deaths related to opioids.

III. THE SCOPE AND LIMITS OF LEGAL AND POLICY RESPONSES TO THE OPIOID CRISIS

Emergency public health powers and interventions in response to other PHEs, including disasters and infectious disease outbreaks, have helped to quell morbidity and mortality.⁶⁷ Consequently, effective legal and policy responses to the opioid crisis may greatly improve public health outcomes.⁶⁸ Public and private sector entities and actors are actively engaged in various legal response efforts to stymie opioid-related impacts supported by declared emergencies and other legal interventions. However, these responses comprise a patchwork of uncoordinated and sometimes specious efforts that collectively fail to sufficiently suppress opioid-related mortality and morbidity nationally.

SYLVIA M. BURWELL, DEP'T OF HEALTH & HUMAN SERVS., DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS IN PUERTO RICO AS A CONSEQUENCE OF THE ZIKA VIRUS OUTBREAK (Aug. 12, 2016).

64. John L. Beven II et al., *Atlantic Hurricane Season of 2005*, 136 MONTHLY WEATHER REV. 1109, 1140 (2008) (reporting 1,833 fatalities); see *Public Health Emergency Declarations*, U.S. OFF. ASSISTANT SECRETARY FOR PREPAREDNESS & RESPONSE, <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx> (last updated Jan. 31, 2019).

65. Nishant Kishore et al., *Mortality in Puerto Rico After Hurricane Maria*, 379 NEW ENG. J. MED. 162, 162 (2018) (estimating 4,645 fatalities).

66. See Alan Blinder, *'No Word From My Son': Dozens Still Missing as Hurricane Michael Death Toll Rises*, N.Y. TIMES (Oct. 16, 2018), <https://www.nytimes.com/2018/10/16/us/hurricane-michael-death-toll-missing.html>.

67. See Thea L. James et al., *Response to Hepatitis A Epidemic: Emergency Department Collaboration with Public Health Commission*, 36 J. EMERGENCY MED. 412, 413 (2009).

68. See generally Dale A. Rose et al., *The Evolution of Public Health Emergency Management as a Field of Practice*, 107 AM. J. PUB. HEALTH S126 (2017) (examining policy and regulatory responses to public health emergencies).

A. Federal, State, Tribal, and Local Responses

Federal responses to the opioid crisis tend to center on large scale efforts and funding, leaving frontline responses up to state, tribal, and local governments. HHS's declaration of a national PHE in October 2017 raised national awareness and stimulated a series of key interventions.⁶⁹ The Centers for Disease Control and Prevention (CDC) tightened its opioid prescribing guidelines.⁷⁰ The Centers for Medicare and Medicaid Services (CMS) required increased communication between pharmacies and opioid prescribers.⁷¹

On March 23, 2018, President Trump signed legislation⁷² allocating \$2.3 billion for federally-based efforts, such as CDC's prescription monitoring activities,⁷³ opioid research at the National Institutes of Health (NIH), and response efforts at the VA, Department of Justice (DOJ)⁷⁴ and Food and Drug Administration (FDA).⁷⁵ An additional \$1 billion was set aside for state grants funded through SAMHSA.⁷⁶ Additional federal assistance has focused on helping children of opioid misusers and promoting anti-addiction efforts in

69. See generally White House Press Release, *supra* note 3. Federal executive authorities have considerable, additional powers that could be applied to stymie the epidemic, but the Trump Administration has yet to declare a national emergency (other than a PHE) nor classified opioid importation as a national security threat.

70. See *Guideline for Prescribing Opioids for Chronic Pain*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/prescribing/guideline.html> (last updated Aug. 29, 2018).

71. *CMS Finalizes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS-4182-F)*, CTRS. FOR MEDICAID & MEDICARE SERVS. (Apr. 02, 2018), <https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-policy-changes-and-updates-medicare-advantage-and-prescription-drug-benefit-program>.

72. Consolidated Appropriations Act of 2018, Pub. L. No. 115-141, 132 Stat. 348 (2018).

73. One month earlier, then Attorney General Jeff Sessions announced a plan to use PDMP data to target over-prescribing doctors and pharmacies. Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, No. 18-242, Attorney General Sessions Announces New Prescription Interdiction & Litigation Task Force (Feb. 27, 2018).

74. DOJ funding followed enactment of the INTERDICT Act, signed on January 10, 2018, giving federal agents tools to detect synthetic opioids at U.S. borders. International Narcotics Trafficking Emergency Response by Detecting Incoming Contraband with Technology (INTERDICT) Act, Pub. L. No. 115-112, 131 Stat. 2274. Later Congress created a complementary program to monitor and predict opioid misuse in the military. John S. McCain National Defense Authorization Act for Fiscal Year 2019, Pub. L. No. 115-232, 132 Stat. 1636.

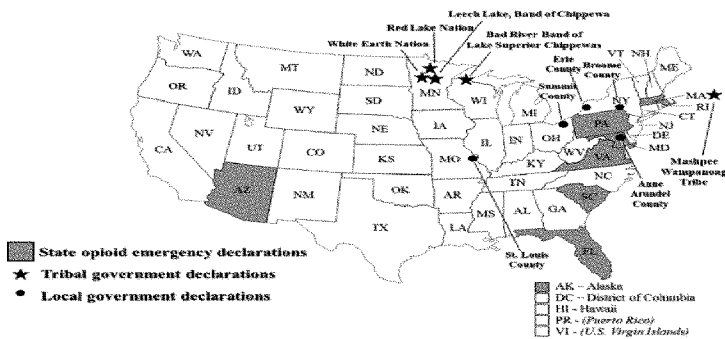
75. FDA is "committed to addressing the epidemic on all fronts." Press Release, U.S. Food & Drug Admin., Statement by FDA Commissioner Scott Gottlieb, M.D., on the FDA's New Resource Guide to Support Responsible Opioid Prescribing for Pain Management in Animals (Aug. 15, 2018).

76. 132 Stat. at 724.

rural and underserved areas.⁷⁷ On October 24, 2018, President Trump signed the bipartisan SUPPORT for Patients and Communities Act (SUPPORT Act),⁷⁸ which aims to curb drug imports, increase access to addiction treatments, and promote development of new non-addictive pain relievers.

As per **Figure 3**, eight states and multiple tribal and local governments have declared their own opioid-related emergencies.⁷⁹ Tribal authorities, including the White Earth Nation and the Leech Lake Band of Chippewa Indians, were the first jurisdictions to declare opioid-related emergencies in 2011.⁸⁰ Massachusetts was the first state to declare an emergency in 2014.⁸¹ States like Arizona and South Carolina have classified their epidemic as public health emergencies.⁸² Other states, like Alaska and Pennsylvania, have legally declared states of disaster.⁸³ Local public health and law enforcement officials in Snohomish County, Washington are responding to its opioid crisis as if it were a natural disaster.⁸⁴

Figure 3. Subnational Opioid-Related Emergency Declarations⁸⁵



77. *Id.* at 724–25.

78. SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, 132 Stat. 3894 (2018).

79. In fact, most tribal and state PHE declarations preceded the federal PHE declaration. See Hodge & Gulinson, *supra* note 4, at 14, 25.

80. *Id.* at 25.

81. *Id.* at 14.

82. *Id.* at 22–23.

83. *Id.* at 19, 24.

84. Anna Boiko-Weyrauch, *A Rural Community Decided to Treat Its Opioid Problem Like a Natural Disaster*, NPR (Oct. 28, 2018, 8:17 AM), <https://www.npr.org/sections/health-shots/2018/10/28/658476111/a-rural-community-decided-to-treat-its-opioid-problem-like-a-natural-disaster>.

85. Hodge & Gulinson, *supra* note 4, at 14 (data current as of Oct. 15, 2018).

Collectively, these legal declarations supplement an array of existing public health law and policies to limit the flow of opioids through (1) enhanced prescription monitoring, (2) coordinated public communications, and (3) increased funding for efficacious medically-assisted treatment (MAT) and other preventive measures.⁸⁶ Multiple states allow first responders to carry and distribute naloxone via their emergency declarations (Arizona, Alaska, Massachusetts, Florida, and Pennsylvania).⁸⁷ Standing orders provide an effective route to save lives in real time by authorizing pharmacists to dispense naloxone to law enforcement officials and others without a prescription.⁸⁸

Uptake and implementation of Good Samaritan Acts (GSAs) increase access to medical aid for overdosers.⁸⁹ Under these laws, bystanders seeking assistance for individuals experiencing opioid overdoses are protected from criminal prosecution for possession of a controlled substance or drug paraphernalia.⁹⁰ While their efficacy is not fully proven, researchers in a 2011 study found that opiate users were eighty-eight percent more likely to call 9-1-1 during an overdose if they were knowledgeable of GSA protections.⁹¹

States are also increasing the tracking and limitation of opioid prescriptions. Developed initially over a century ago to combat abuses of then-legal heroin and cocaine,⁹² prescription drug monitoring programs (PDMPs) comprise of electronic databases allowing health care providers to (1) better track whether a patient has received a controlled substance from

86. *See id.* at 16.

87. *Id.* In addition, SAMSHA reports that 49 states (all but Nebraska) allow for “some model of non-patient specific prescription.” U.S. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., PREVENTING THE CONSEQUENCES OF OPIOID OVERDOSE: UNDERSTANDING NALOXONE ACCESS LAWS 6 (2018).

88. Corey Davis & Derek Carr, *State Legal Innovations to Encourage Naloxone Dispensing*, 57 J. AM. PHARMACISTS ASS’N S180, S181 (2017).

89. *See Drug Overdose Immunity & Good Samaritan Laws*, NAT’L CONF. OF ST. LEGISLATURES (June 5, 2017), <http://www.ncsl.org/research/civil-and-criminal-justice/drug-overdose-immunity-good-samaritan-laws.aspx>. Arizona and Iowa passed GSAs in 2018. Press Release, Office of the Governor of Ariz., Arizona Joins Together to Pass Opioid Legislation (Jan. 26, 2018); Press Release, Office of the Governor of Iowa, Gov. Reynolds Signs Bipartisan Opioid Bill Into Law (2018).

90. COREY DAVIS, NETWORK FOR PUB. HEALTH LAW LEGAL INTERVENTIONS TO REDUCE OVERDOSE MORTALITY: NALOXONE ACCESS AND OVERDOSE GOOD SAMARITAN LAWS 1 (2017).

91. ALCOHOL & DRUG ABUSE INST., UNIV. OF WASH., INFO BRIEF: WASHINGTON’S 911 GOOD SAMARITAN DRUG OVERDOSE LAW: INITIAL EVALUATION RESULTS 1 (2011).

92. PRESCRIPTION DRUG MONITORING PROGRAM TRAINING & TECHNICAL ASSISTANCE CTR., TECHNICAL ASSISTANCE GUIDE: HISTORY OF PRESCRIPTION DRUG MONITORING PROGRAMS 2 (2018).

other providers and (2) the patient's daily prescribed dosage.⁹³ All states utilize PDMPs, but at least three states (Arizona, Massachusetts, and Pennsylvania)⁹⁴ employ enhanced surveillance through their emergency declarations.⁹⁵ As of April 2018, twenty-eight states have also implemented laws restricting the number of days or dosage of opioids that a patient may receive,⁹⁶ with exceptions for those most in need of palliative care. South Carolina has legislatively restricted opioid prescribing to minors and required licensing among addiction counselors.⁹⁷

B. Liability and Accountability

Pharmaceutical companies are increasingly being held accountable for their roles underlying the crisis. From January to September 2018, national prescription opiate litigation reportedly jumped from 229 to 1,250 pending actions.⁹⁸ Among these cases, twenty-seven states and the District of Columbia have sued Purdue Pharma® for “deceptively marketing” OxyContin®.⁹⁹ In response, Purdue “restructured and significantly reduced

93. U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, PRESCRIPTION DRUG MONITORING PROGRAMS.

94. Hodge & Gulinson, *supra* note 4, at 16.

95. *Pennsylvania Launches New Interactive Database for Drug Prescribing and Overdose Information*, PA. PRESSROOM (Jan. 23, 2018), <https://www.media.pa.gov/Pages/Health-Details.aspx?newsid=468>. Additionally, in January 2018, Pennsylvania announced a new interactive data reporting system to identify overdose spikes by collecting data in the PDMP from prescribers and emergency departments. *Id.*

96. *Prescribing Policies: States Confront Opioid Overdose Epidemic*, NAT'L CONF. OF ST. LEGISLATURES (Oct. 31, 2018), <http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx>. For example, under Maryland's Prescriber Limits Act of 2017, health care providers are required to prescribe the lowest effective dose in the lowest quantity needed. H.B. 1432, 2017, Reg. Sess. (Md. 2017). Other states limit prescriptions more strictly. In Arizona, patients who have not received an opioid prescription in the preceding sixty days are limited to a five-day supply. S.B. 1001, 53d Leg., 1st Spec. Sess. (Ariz. 2018).

97. Madeline Montgomery, *'I Think This Is Huge:' Nine Bills Passed in SC to Fight Opioid Epidemic*, WPDE (June 5, 2018), <http://wpde.com/news/local/i-think-this-is-huge-nine-bills-passed-in-sc-to-fight-opioid-epidemic>.

98. *Compare* U.S. JUDICIAL PANEL ON MULTIDISTRICT LITIG., DISTRIBUTION OF PENDING MDL DOCKETS BY ACTIONS PENDING (Jan. 2018), *with* U.S. JUDICIAL PANEL ON MULTIDISTRICT LITIG., DISTRIBUTION OF PENDING MDL DOCKETS BY ACTIONS PENDING (Sept. 2018).

99. *See* Tina Bellon, *U.S. State Lawsuits Against Purdue Pharma Over Opioid Epidemic Mount*, REUTERS (May 15, 2018, 2:29 PM), <https://www.reuters.com/article/us-usa-opioids-litigation/u-s-state-lawsuits-against-purdue-pharma-over-opioid-epidemic-mount-idUSKCN1I1G2WU>; *State of Indiana Sues Purdue Pharma Over Misleading Opioid Claims, Opioid Abuse Epidemic*, FOX59 (Nov. 14, 2018, 10:39 AM), <https://fox59.com/2018/11/14/state-of-indiana>

[its] commercial operation and will no longer [promote] opioids to prescribers.”¹⁰⁰ Liability claims have also been brought against other drug companies, distributors, retailers, rehabilitation centers,¹⁰¹ and the Joint Commission.¹⁰² In August 2018, President Trump asked then-Attorney General Jeff Sessions to file a separate federal lawsuit against opioid manufacturers.¹⁰³

Federal authorities have also cracked down on unscrupulous opioid prescribing and distribution. In 2017, the DOJ tripled its prosecutions for distributing illicit fentanyl,¹⁰⁴ including indictments against foreign manufacturers and distributors.¹⁰⁵ In April 2018, federal agents arrested a couple behind the largest dark web fentanyl conspiracy in the United States.¹⁰⁶ Later that same year, then-Attorney General Sessions announced charges against two Chinese citizens for “operating a conspiracy that manufactured and shipped deadly fentanyl analogues” to the U.S., causing at least two overdose-related deaths.¹⁰⁷ In June 2018, the DOJ publicly announced charges

sues-purdue-pharma-over-misleading-opioid-claims-opioid-abuse-epidemic. States are also starting to hold pharmacies accountable for their role in the opioid crisis. *Florida Sues Walgreens, CVS Over Opioid Sales*, CNBC (Nov. 19, 2018, 6:25 AM), <https://www.cnbc.com/2018/11/19/florida-sues-walgreens-cvs-over-opioid-sales.html>.

100. Gigen Mammoser, *Is OxyContin Losing Its Luster?*, HEALTHLINE (Feb. 21, 2018), <https://www.healthline.com/health-news/oxycontin-losing-its-luster#1>.

101. Ken Alltucker, *Arizona Lawsuit Opens Window into Lucrative Drug Rehab Business—And Allegations of Fraud*, AZCENTRAL (Dec. 4, 2017, 2:57 PM), <https://www.azcentral.com/story/money/business/health/2017/12/04/arizona-lawsuit-health-net-drug-rehab-business-fraud/907734001>.

102. Brian Ward, *West Virginia Cities Sue Joint Commission Over Alleged Role in Opioid Crisis*, HCPRO BLOG (Nov. 9, 2017), <http://blogs.hcpro.com/acc/2017/11/west-virginia-cities-sue-joint-commission-over-alleged-role-in-opioid-crisis>.

103. Rebecca Ballhaus, *Trump Calls on Justice Department to Sue Opioid Companies*, WALL STREET J. (Aug. 16, 2018, 8:29 PM), <https://www.wsj.com/articles/trump-encourages-justice-department-to-sue-opioid-companies-1534438160>.

104. Katie Zezima & Sari Horwitz, *Federal, State Authorities Step Up Fentanyl Prosecutions as Drug Drives Spike in Overdoses*, WASH. POST (June 7, 2018), https://www.washingtonpost.com/national/federal-state-authorities-step-up-fentanyl-prosecutions-as-drug-drives-spike-in-overdoses/2018/06/07/5631edd0-69c0-11e8-bf8c-f9ed2e672adf_story.html?noredirect=on&utm_term=.3cba699b42d4.

105. Gregg Re, *Trump Declares Opioids from Mexico, China ‘Almost a Form of Warfare,’ Tells Sessions to Sue Drug Makers*, FOX NEWS (Aug. 16, 2018), <https://www.foxnews.com/politics/trump-declares-opioids-from-mexico-china-almost-a-form-of-warfare-tells-sessions-to-sue-drug-makers>.

106. Press Release, U.S. Dep’t of Justice, Operation Darkness Falls Results in Arrest of One of the Most Prolific Dark Net Fentanyl Vendors in the World (Aug. 22, 2018).

107. Press Release, U.S. Dep’t of Justice, Two Chinese Nationals Charged with Operating Global Opioid and Drug Manufacturing Conspiracy Resulting in Deaths (Aug. 22, 2018).

against hundreds of health care providers for fraudulent opioid prescriptions.¹⁰⁸

C. *Systemic Failures to Curb the Crisis*

When HHS's Secretary Alex Azar announced on October 23, 2018, that opioid overdose deaths may have begun to "plateau," he conceded that the nation is still "far from the end of the epidemic."¹⁰⁹ In reality, the crisis may merely be shifting gears. Opioid overdose deaths from prescription opioids are declining in some places,¹¹⁰ but deaths from illicit opioids are rising elsewhere.¹¹¹ Federal authorities have been criticized for failing to act swiftly and fully in exerting the gamut of their emergency powers and efforts.¹¹² In

108. Lev Facher, *Justice Department Announces Crackdown on Fraudulent Opioid Prescriptions*, STAT NEWS (June 28, 2018), <https://www.statnews.com/2018/06/28/justice-department-crackdown-on-fraudulent-opioid-prescriptions>; Sarah Gray, *Justice Department Charges 601 Defendants for Health Care Fraud and Opioid Epidemic-Related Schemes*, FORTUNE (June 29, 2018), <http://fortune.com/2018/06/29/justice-department-charges-fraud-opioid-epidemic>. One Delaware physician allegedly wrote more than 25,000 prescriptions for over 2 million doses of oxycodone products in 18 months from July 2012 to December 2014. See Indictment at 7, *United States v. Titus*, No. 1:18-cr-00045-UNA (D. Del. filed June 14, 2018).

109. Ricardo Alonso-Zaldivar & Carla K. Johnson, *U.S. Health Chief Says Overdose Deaths Beginning to Level Off*, AP NEWS (Oct. 23, 2018), <https://www.apnews.com/2bf839f545ca4ed98637c1a44ef854ec>.

110. Between 2016 and 2017, Massachusetts witnessed its first decline in seven years in opioid overdose deaths, a drop of 8.3%. *Massachusetts Sees Encouraging Decline in Overdose Deaths*, ASS'N OF STATE & TERRITORIAL HEALTH OFFICIALS: ASTHO EXPERTS BLOG (Apr. 5, 2018, 10:25 AM), <http://www.astho.org/StatePublicHealth/MA-Sees-Encouraging-Decline-in-Overdose-Deaths/04-05-18>.

111. For example, opioid overdose deaths rose 20% in Arizona despite drops in the number of opioid pills dispensed. Jason Pohl, *Deaths from Heroin, Painkiller Abuse Surge in Arizona*, AZCENTRAL (Aug. 20, 2018, 10:37 AM), <https://www.azcentral.com/story/news/local/arizona-health/2018/08/13/opioid-heroin-deaths-continue-climb-arizona-despite-state-efforts/979180002>; *Deaths Involving Heroin and Fentanyl Spike as Prescription Opioid Deaths Decline*, PARTNERSHIP FOR DRUG-FREE KIDS (Apr. 12, 2018), <https://drugfree.org/learn/drug-and-alcohol-news/deaths-involving-heroin-fentanyl-spike-prescription-opioid-deaths-decline>. One source suggests that opioid deaths spiked in the East and Midwest although impacts in many Western states were more stable. This may be attributable to fentanyl saturating East Coast markets, but not Western states. Pauline Bartolone, *Opioid Deaths Surge in Midwest and East, While West Sees Declines*, SEATTLE TIMES (Jan. 10, 2018, 8:02 PM), <https://www.seattletimes.com/seattle-news/opioid-deaths-surge-in-midwest-and-east-while-west-sees-declines/>.

112. See, e.g., David Von Drehle, *The Opioid Crisis is a Government Failure of Epic Proportions*, WASH. POST (Mar. 2, 2018), https://www.washingtonpost.com/opinions/the-opioid-crisis-is-a-government-failure-of-epic-proportions/2018/03/02/5c1dcecf6-1e4f-11e8-b2d9-08e748f892c0_story.html?utm_term=.2b8cb77ca3d3; Brianna Ehley, *Trump Declared an*

October 2018, the General Accounting Office reported that the federal government has not utilized the dozen legal powers or authorities to respond under its PHE declaration.¹¹³ Though urged by his own White House Commission, President Trump has never declared an additional national state of emergency to supplement HHS's PHE and free up millions more in response dollars.¹¹⁴

While the epidemic raged on, initial Congressional legislative proposals languished for months, lacked sufficient funds,¹¹⁵ denied increased access to life-saving medications,¹¹⁶ and ignored multiple recommendations of the White House Commission.¹¹⁷ Aware of China's role in fueling the opioid crisis based on an international report released in early 2017,¹¹⁸ Congress initially did little to address the importation of toxic synthetic opioids, often laced with other illicit drugs.¹¹⁹ For months opioid packages from Chinese laboratories went largely undetected through the United States Postal Service

Opioids Emergency. Then Nothing Changed, POLITICO (Jan. 11, 2018, 10:31 AM), <https://www.politico.com/story/2018/01/11/opioids-epidemic-trump-addiction-emergency-or-der-335848>. The PHE declaration does not appear to have quelled national concerns either, with one survey finding public concern about opioid use disorder increased from thirty-three percent in 2016 to forty-three percent in 2018. ASSOCIATED PRESS-NORC CTR. FOR PUB. AFFAIRS RESEARCH, AMERICANS RECOGNIZE THE GROWING PROBLEM OF OPIOID ADDICTION 1 (2018). The poll also found increased concern about heroin use in 2018 (37%) versus 2016 (32%). *Id.*

113. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-18-685R, OPIOID CRISIS: STATUS OF PUBLIC HEALTH EMERGENCY AUTHORITIES 12–17 (2018). The government has exercised only three available authorities: (1) “[w]aiver of Paperwork Reduction Act requirements,” (2) “[w]aiver of public notice procedures for section 1115 Medicaid demonstrations,” and (3) “[e]xpedited support for research.” *Id.* at 5–6.

114. PRESIDENT'S COMMISSION INTERIM REPORT, *supra* note 2, at 2.

115. *See generally* CONGRESSIONAL BUDGET OFFICE, COST ESTIMATE: S. 2680, OPIOID CRISIS RESPONSE ACT OF 2018 (2018) (estimating the program would cost \$7.1 billion); THE COUNCIL OF ECON. ADVISORS, THE UNDERESTIMATED COST OF THE OPIOID CRISIS (2017) (noting the 2015 estimated cost of the epidemic was six times larger than the most recent estimate).

116. James Hodge, Chelsea Gulinson & Drew Hensley, *The Opioid Crisis Response Act: Looking Ahead, Ignoring the Present*, JURIST (Sept. 22, 2018, 3:15:36 PM), <https://www.jurist.org/commentary/2018/09/james-hodge-opioid-responseact>.

117. *See generally* THE PRESIDENT'S COMM'N ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS, SUMMARY OF RECOMMENDATIONS 12–18 (Nov. 1, 2017) (listing all recommendations from the Commission).

118. O'CONNOR, *supra* note 25, at 3.

119. Sanger-Katz, *supra* note 50 (explaining that “drug distributors are finding ways to mix fentanyl with black tar heroin,” a type of heroin common in Western states thought difficult to alter). In August 2018, more than seventy people overdosed on K2—a synthetic marijuana—over several days in New Haven, Connecticut. Eric Levenson & Evan Simko-Bednarski, *More Than 90 People Overdosed on K2 in One New Haven Park*, CNN (Aug. 16, 2018, 10:41 PM), <https://www.cnn.com/2018/08/15/health/new-haven-overdoses/index.html>.

(USPS) due in part to a lack of advanced technology.¹²⁰ The afore-mentioned federal SUPPORT Act finally requires USPS to share electronic data with Customs and Border Protection on “at least 70 percent of international mail.”¹²¹

Many have called for greater public health legal efforts coordinated by states and localities across the frontlines of the epidemic.¹²² Every state is negatively impacted in varying degrees,¹²³ but only eight have declared opioid-related emergencies (see **Figure 3**),¹²⁴ authorizing a divergent series of emergency responses (see **Figure 4**).¹²⁵ Other states aspire to do more but face funding shortages or legal limitations. West Virginia suffers the highest opioid-related death rate per capita nationally but received no additional federal funding from HHS’s original PHE declaration.¹²⁶ Consequently, like

120. See Anthony Zurcher, *Opioid Addiction and Death Mail-Ordered to Your Door*, BBC (Feb. 22, 2018), <https://www.bbc.com/news/world-us-canada-43146286>.

121. Jody Lutz, *Sweeping Opioid Legislation Passed by Senate: What You Need to Know About STOP & OCRA*, AFFIRMHEALTH (Sept. 25, 2018 11:00 AM), <https://www.affirmhealth.com/blog/sweeping-opioid-legislation-passed-by-senate.-what-you-need-to-know-about-stop-ocra>.

122. See, e.g., Haffajee & Frank, *supra* note 28, at 768; Schrayner, *supra* note 28.

123. See generally HEDEGAARD ET AL., *supra* note 40 (examining drug overdose deaths within the fifty states).

124. *Emergency Declarations in Eight States to Address the Opioid Epidemic*, ASS’N OF ST. & TERRITORIAL HEALTH OFFICIALS: ASTHO EXPERTS BLOG (Jan. 11, 2018, 3:55 PM), <http://www.astho.org/StatePublicHealth/Emergency-Declarations-in-Eight-States-to-Address-the-Opioid-Epidemic/01-11-18>; LAUREN DEDON, NAT’L GOVERNORS ASS’N, USING EMERGENCY DECLARATIONS TO ADDRESS THE OPIOID EPIDEMIC: LESSONS LEARNED FROM STATES 3 (2018).

125. See Lainie Rutkow, *An Analysis of State Public Health Emergency Declarations*, 104 AM. J. PUB. HEALTH 1601, 1603 (2014). Four of those states provide naloxone standing orders. MARISSA J. LEVINE, VA. ST. HEALTH COMM’R, DECLARATION OF PUBLIC HEALTH EMERGENCY (2016); RICK SCOTT, GOVERNOR OF FLA., EXECUTIVE ORDER NO. 17-146 § 6 (2017); DOUGLAS A. DUCEY, GOVERNOR OF ARIZ., DECLARATION OF EMERGENCY AND NOTIFICATION OF ENHANCED SURVEILLANCE ADVISORY: OPIOID OVERDOSE EPIDEMIC (2017); BILL WALKER, GOVERNOR OF ALASKA, DECLARATION OF DISASTER EMERGENCY (2017). Three orders enhanced PDMP surveillance. Press Release, Executive Office of Health & Human Servs., Mass. Dep’t of Pub. Health, Massachusetts Health Officials Issue Advisory to the Public and Health Care Providers on Opiate Overdose (Mar. 28, 2014); DUCEY, *supra*; TOM WOLF, GOVERNOR OF PA., PROCLAMATION OF DISASTER EMERGENCY (2018). South Carolina successfully restricts opioid prescribing. HENRY MCMASTER, GOVERNOR OF S.C., NO. 2018-19, CONFORMING EXECUTIVE ORDER 2017-43’S OPIOID PRESCRIPTION LIMITATION WITH ACT 201 OF 2018 (2017). Two increased treatment funding. LAWRENCE J. HOGAN, GOVERNOR OF MD., NO. 01.01.2017.02, EXECUTIVE ORDER REGARDING THE HEROIN, OPIOID, AND FENTANYL OVERDOSE CRISIS DECLARATION OF EMERGENCY (2017); SCOTT, *supra*.

126. Eric Eyre & Erin Beck, *WV Needs Money for Fight Against Opioid Emergency*, *Health Experts Say*, CHARLESTON GAZETTE-MAIL (Oct. 26, 2017),

many states, it developed its own PHE response plan¹²⁷ in lieu of declaring a state of emergency.

Figure 4. State Opioid Emergency Declaration Legal Responses¹²⁸

Responses	MA	VA	AK	MD	FL	AZ	SC	PA
Naloxone Standing Order		X	X		X	X		
First Responders Carry/Distribute Naloxone	X		X		X	X		X
Enhanced PDMP Surveillance	X					X		X
Opioid Prescribing Restrictions	X						X	
Increased Funding for Treatment				X	X			
Interagency Coordination				X		X	X	X

States not declaring PHEs have implemented a scattered series of harm reduction measures instead.¹²⁹ Stigmas surrounding opioid addiction curtail some effective measures including syringe services programs (SSPs).¹³⁰ Supported by the federal Consolidated Appropriations Act of 2016 and HHS guidance, SSPs help prevent the spread of blood-borne infections by offering clean needles and used needle disposal along with prevention and education

https://www.wvgazettemail.com/news/politics/wv-needs-money-for-fight-against-opioid-emergency-health-experts/article_8b8fb4ec-878f-5b3d-8e3b-712741403bfb.html.

127. W. VA. DEP'T HEALTH & HUMAN RESOURCES, OPIOID RESPONSE PLAN FOR THE STATE OF WEST VIRGINIA (2018).

128. Hodge & Gulinson, *supra* note 4, at 16 (data current as of Oct. 15, 2018).

129. See Emma E. McGinty et al., *Public Support for Safe Consumption Sites and Syringe Services Programs to Combat the Opioid Epidemic*, 111 PREVENTATIVE MED. 73, 73 (2018).

130. *Id.* at 75. Conversely, addiction stigma played less of a role in naloxone access debates. *Id.*

materials.¹³¹ Despite their efficacy,¹³² many states are slow to implement SSPs,¹³³ fail to legalize them,¹³⁴ or rescind support.¹³⁵ As a result, access to clean needles varies extensively across the United States.¹³⁶

Other legal responses to the epidemic are antiquated or off-target, assimilating failed efforts from the regrettable “War on Drugs” campaign in the 1980s.¹³⁷ In 2014, Tennessee authorized prosecution of pregnant women with assault for the illegal use of narcotics.¹³⁸ In 2017, an Ohio municipality proposed a “three strikes and you’re dead” law that would allow emergency medical providers to refuse to dispatch antidotes to multiple “repeat” overdose victims.¹³⁹ On August 23, 2018, President Trump suggested imposing the death penalty for fentanyl dealers.¹⁴⁰

131. *Syringe Services Programs*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/hiv/risk/ssps.html> (last updated Dec. 13, 2018).

132. See, e.g., David Vlahov & Benjamin Junge, *The Role of Needle Exchange Programs in HIV Prevention*, 113 PUB. HEALTH REP. 75, 75 (1998); ALEX WODAK & ANNIE COONEY, WORLD HEALTH ORG., EFFECTIVENESS OF STERILE NEEDLE AND SYRINGE PROGRAMMING IN REDUCING HIV/AIDS AMONG INJECTING DRUG USERS 28–29 (2004); *Access to Clean Syringes*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/policy/hst/hi5/cleansyringes/index.html> (last updated Aug. 5, 2016) (citing Abu S. Abdul-Quader et al., *Effectiveness of Structural-Level Needle/Syringe Programs to Reduce HCV and HIV Infection Among People Who Inject Drugs: A Systematic Review*, 17 AIDS & BEHAVIOR 2878, 2878 (2013)).

133. Former Governor Mike Pence issued an executive order permitting syringe distribution nearly two months after an HIV outbreak in Indiana. Megan Twohey, *Pence on HIV Crisis: Prayer and Pragmatism*, STAR ADVERTISER (Oct. 18, 2018, 9:43 AM), <https://www.staradvertiser.com/2016/08/08/news/pence-on-hiv-crisis-prayer-and-pragmatism>.

134. As of November 20, 2018, eleven states do not authorize SSPs. *Syringe Exchange Programs*, AMFAR: OPIOID & HEALTH INDICATORS DATABASE, http://opioid.amfar.org/indicator/num_SSPs (last visited Feb. 9, 2019).

135. See Maggie Fox, *Indiana County Stops Needle Program Meant to Halt HIV*, NBC NEWS (Oct. 18, 2017, 6:41 PM), <https://www.nbcnews.com/storyline/americas-heroin-epidemic/indiana-county-stops-needle-program-meant-stop-hiv-n811741>.

136. See AMFAR: OPIOID & HEALTH INDICATORS DATABASE, *supra* note 134 (California offers 43 SSPs while 30 states and the District of Columbia offer less than 10. Nine states offer only one SSP).

137. Miriam Aroni Krinsky & Dan Satterberg, *Don’t Jail Addicts. Overdose Prevention Sites Work, and the US Needs to Get On Board*, USA TODAY (Nov. 1, 2018, 2:01 AM), <https://www.usatoday.com/story/opinion/policing/2018/11/01/drugs-opioids-policing-usa/1821797002>.

138. S.B. 1391, 108th Gen. Assemb., Reg. Sess. (Tenn. 2014).

139. Ritchie Farrell, *Heroin: Three Strikes and You Die*, HUFFINGTON POST (July 6, 2017, 6:07 PM), https://www.huffingtonpost.com/entry/heroin-three-strikes-and-you-die_us_595e9517e4b085e766b5113e.

140. Jennifer Jacobs & Steven T. Dennis, *Trump Tells Sessions He Favors Death Penalty for Fentanyl Dealers*, BLOOMBERG (Aug. 23, 2018, 6:41 PM), <https://www.bloomberg.com/news/articles/2018-08-23/trump-is-said-to-propose-death-penalty-for-fentanyl-dealers>; see also

Some legal approaches run counter to modern techniques to curb opioid-related deaths. Quitting opioids “cold turkey” is unsafe and often ineffective.¹⁴¹ Medicated assisted treatment (MAT) is considerably more efficacious, but many recovery centers have not adopted it¹⁴² due in part to legal prescribing impediments.¹⁴³ Supervised injection facilities (SIFs) offering protected havens for drug users are globally proven to reduce overdose deaths.¹⁴⁴ However, United States Deputy Attorney General Rod Rosenstein opined in August 2018 that SIFs are unlawful, promising “swift and aggressive [DOJ] action” against their known operation.¹⁴⁵

Some responses may prove misguided. The FDA recently approved DSUVIA,¹⁴⁶ a new, sublingual (under-the-tongue) opioid more potent than

Federal Death Penalty Act, 18 U.S.C. § 3591(b) (2012) (a defendant found guilty of possessing a large quantity of heroin under certain circumstances can be sentenced to death).

141. *The Dangers of Quitting Cold-Turkey*, CRC HEALTH, <https://www.crchealth.com/find-a-treatment-center/opiate-addiction-treatment-centers/additional-resources/dangers-quit-cold-turkey> (last visited Feb. 9, 2019). Rather, MAT and tapering-off programs are strongly suggested. See, e.g., Hilary Smith Connery, *Medication-Assisted Treatment of Opioid Use Disorder: Review of the Evidence and Future Directions*, 23 HARV. REV. PSYCHIATRY 63, 63 (2015); Chantal Berna, Ronald J. Kulich & James P. Rathmell, *Tapering Long-Term Opioid Therapy in Chronic Noncancer Pain: Evidence and Recommendations for Everyday Practice*, 90 MAYO CLINIC PROC. 828, 833 (2015).

142. Nina Feldman, *Many ‘Recovery Houses’ Won’t Let Residents Use Medicine to Quit Opioids*, NPR (Sept. 12, 2018, 5:11 AM), <https://www.npr.org/sections/health-shots/2018/09/12/644685850/many-recovery-houses-wont-let-residents-use-medicine-to-quit-opioids>; MAT Overview: *Medication Assisted Treatment (MAT)*, SAMHSA-HRSA CTR. FOR INTEGRATED HEALTH SOLUTIONS, <https://www.integration.samhsa.gov/clinical-practice/mat/mat-overview> (last visited Feb. 9, 2019).

143. Physicians must obtain a waiver to prescribe MAT and can only prescribe MAT for up to 275 patients. SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, § 3201(a), 132 Stat. 3894, 3943 (2018).

144. SHARON LARSON ET AL., MAIN LINE HEALTH CENTER FOR POPULATION HEALTH RESEARCH, SUPERVISED CONSUMPTION FACILITIES – REVIEW OF THE EVIDENCE 6 (2017), https://dbhids.org/wp-content/uploads/2018/01/OTF_LarsonS_PHLReportOnSCF_Dec2017.pdf. The American Medical Association released its support for SIFs before the PHE declaration. Press Release, Am. Med. Ass’n, AMA Wants New Approaches to Combat Synthetic and Injectable Drugs (June 12, 2017), <https://www.ama-assn.org/ama-wants-new-approaches-combat-synthetic-and-injectable-drugs>.

145. Rod J. Rosenstein, *Fight Drug Abuse, Don’t Subsidize It*, N.Y. TIMES (Aug. 27, 2018), <https://www.nytimes.com/2018/08/27/opinion/opioids-heroin-injection-sites.html>.

146. Press Release, AcelRx Pharmaceuticals, Inc, AcelRx announces FDA approval of DSUVIA™ (Nov. 2, 2018). Despite FDA’s Opioid Policy Steering Committee 10-3 vote in favor of DSUVIA, the Committee’s chair publicly opposed approval. Lenny Bernstein, *FDA Approves Powerful Opioid Despite Fears of More Overdose Deaths*, WASH. POST (Nov. 2, 2018), https://www.washingtonpost.com/national/health-science/fda-approves-a-powerful-new-opioid/2018/11/02/88cd27e6-deaf-11e8-85df7a6b4d25cfbbstory.html?utm_term=.1d2d67ff60eb.

fentanyl,¹⁴⁷ developed with support from the United States Department of Defense.¹⁴⁸ While the drug can only be dispersed in health care settings, former FDA Commissioner Scott Gottlieb expressed concerns over the risk of diversion.¹⁴⁹ Even within controlled health care uses, DSUVIA's potency may exacerbate potential patient abuse.¹⁵⁰

Conflicts of interest have also plagued response efforts. Multiple United States Senators have received campaign funding from pro-opioid interest groups.¹⁵¹ Owners of Purdue Pharma® not only sell OxyContin® but also its generic equivalents.¹⁵² When FDA entrusted pharmaceutical companies and drug distributors to help manage opioid safety programs, it essentially allowed “the fox [to guard] the henhouse.”¹⁵³ Drug distributor McKesson®,¹⁵⁴ for example, was entrusted to run its own “risk evaluation and mitigation strategy” safety program¹⁵⁵ overseeing potential misuses of transmucosal immediate-release fentanyl.¹⁵⁶

147. Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on Agency's Approval of Dsuvia and the FDA's Future Consideration of New Opioids (Nov. 2, 2018) [hereinafter Statement from FDA Commissioner Scott Gottlieb, M.D.].

148. Press Release, AcelRx Pharmaceuticals, Inc., AcelRx Provides Updated Comments Following Positive FDA Advisory Committee Meeting (Oct. 19, 2018). FDA Commissioner Scott Gottlieb noted DSUVIA is ideal in military battlefield situations. Statement from FDA Commissioner Scott Gottlieb, M.D., *supra* note 147.

149. Statement from FDA Commissioner Scott Gottlieb, M.D., *supra* note 147.

150. DSUVIA (sufentanil) misuse will likely depend on dosage and duration of prescribed use. Anuj Shah et al., *Factors Influencing Long-Term Opioid Use Among Opioid Naïve Patients: An Examination of Initial Prescription Characteristics and Pain Etiologies*, 18 J. PAIN 1374, 1374 (2017); Gabriel A. Brat et al., *Postsurgical Prescriptions for Opioid Naïve Patients and Association with Overdose and Misuse: Retrospective Cohort Study*, 360 BMJ 1, 1 (2018), <https://www.bmj.com/content/bmj/360/bmj.j5790.full.pdf>.

151. Matthew S. McCoy & Genevieve P. Kanter, *Campaign Contributions from Political Action Committees to Members of Congressional Committees Responding to the Opioid Crisis*, 320 J. AM. MED ASS'N 1489, 1489 (2018).

152. Natalie O'Neill, *OxyContin Makers Secretly Ran Massive Knockoff Opioid Firm*, N.Y. POST (Sept. 11, 2018, 7:49 PM), <https://nypost.com/2018/09/11/oxycontin-makers-secretly-ran-massive-knockoff-opioid-firm>.

153. Emily Baumgaertner, *F.D.A. Did Not Intervene to Curb Risky Fentanyl Prescriptions*, N.Y. TIMES (Aug. 2, 2018), <https://www.nytimes.com/2018/08/02/health/fda-fentanyl-opioid-epidemic-overdose-cancer.html> (FDA previously “tasked Purdue Pharma in the early 2000s with leading a risk management program for OxyContin, its own product.”).

154. *Id.*

155. *Questions and Answers: FDA Approves a Class Risk Evaluation and Mitigation Strategy (REMS) for Transmucosal Immediate-Release Fentanyl (TIRF) Medicines*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm284717.htm> (last updated July 7, 2015).

156. Transmucosal immediate-release fentanyl is medication for cancer patients delivered by tablet, nasal spray, or film. *Id.*

IV. ENHANCED LAW AND POLICY RESPONSES TO CURB OPIOID-RELATED MORTALITY AND MORBIDITY

Existing limits in reigning in the opioid crisis via emergency or other public health legal powers¹⁵⁷ have not only failed to curb the epidemic but may be essentially fueling it. More aggressive and expansive approaches are needed to reduce real-time morbidity and mortality. Innovations under consideration or in early phases of implementation nationally or regionally have strong potential for positive impacts. In 2018, for example, multiple digital platforms broadcasted opioid prevention messages, including the White House's "The Truth About Opioids" campaign importing voice-controlled artificial intelligence devices to respond to opioid-related inquiries.¹⁵⁸ To address worker productivity losses,¹⁵⁹ the Ohio Bureau of Workers' Compensation developed a pilot program for employers to better understand employees' addiction and recovery facets.¹⁶⁰

Innovative training, testing, treatment, and notification options for at-risk persons or their providers are emerging.¹⁶¹ Boston University is integrating addiction training into its medical school curriculum, providing a national

157. See Robert Pear, *Senate Poised to Pass Bill to Stop Flow of Opioids Through the Mail*, N.Y. TIMES (Sept. 10, 2018), <https://www.nytimes.com/2018/09/10/us/politics/opioids-fentanyl-postal-service-senate.html> (acknowledging a bill passed to close loopholes allowing illicit drugs to enter the U.S. through mail); see also Katie Benner, *Snaring Doctors and Drug Dealers, Justice Dept. Intensifies Opioid Fight*, N.Y. TIMES (Aug. 22, 2018), (announcing the DOJ's crackdown on opioid traffickers, including physicians).

158. See, e.g., *Kyle's Story*, TRUTH, <https://opioids.thetruth.com/o/articles/kyle> (last visited Nov. 1, 2018); Adam K. Raymond, *The First White House Anti-Opioid PSA Shows a Guy Smashing His Hand with Hammer*, INTELLIGENCER (June 7, 2018), <http://nymag.com/intelligencer/2018/06/wh-anti-opioid-psa-shows-guy-smashing-his-hand-with-hammer.html>. Purdue Pharma® recently announced support for another education program focused on high school populations, the Prescription Drug Safety Network, in a full-page advertisement. Purdue Pharma®, Advertisement, *We Want to Help People Understand the Risks of Misusing Prescription Medications, Including Opioids*, N.Y. TIMES, <https://www.nytimes.com/paidpost/purdue/we-want-to-help-people-understand-the-risks-of-misusing-prescription-medications.html> (last visited Feb. 9, 2019).

159. Tara O'Neill Hayes & Ryan Manos, *The Opioid Epidemic: Costs, Causes, and Efforts to Fight It*, AM. ACTION FORUM (Jan. 30, 2018), <https://www.americanactionforum.org/research/opioidepidemic>.

160. Holly Zachariah, *Ohio Pilot Program to Enlist Businesses in Anti-Addiction Effort*, COLUMBUS DISPATCH (Sept. 24, 2018, 8:19 AM), <http://www.dispatch.com/news/20180924/ohio-pilot-program-to-enlist-businesses-in-anti-addiction-effort>.

161. For example, one police chief in Massachusetts invites opioid addicts to the city police station to help with finding treatment centers. *Four Innovative Ideas for Fixing the Opioid Crisis*, BOS. GLOBE (May 11, 2016), <https://www.bostonglobe.com/magazine/2016/05/11/four-innovative-ideas-for-fixing-opioid-crisis/nx1YSjMzo0UMPEI9NBpBVl/story.html>.

model for other programs.¹⁶² Government-sponsored communications in New York and other jurisdictions notify physicians when one of their patients dies by overdosing on opioids they prescribed. These efforts have led to a nearly ten-percent reduction in physician prescribing practices.¹⁶³ Drug checking services¹⁶⁴ offer fentanyl testing strips to help ascertain dangerous drugs prior to their use.¹⁶⁵ Some health insurance companies will stop covering OxyContin® in 2019.¹⁶⁶ Huntington, West Virginia employs mental health professionals within its emergency response departments.¹⁶⁷ Vermont integrates a successful hub-and-spoke system for expanding OUD treatment (see **Figure 5**).¹⁶⁸

162. See Jan Hoffman, *Most Doctors Are Ill-Equipped to Deal With the Opioid Epidemic. Few Medical Schools Teach Addiction*, N.Y. TIMES (Sept. 10, 2018), <https://www.nytimes.com/2018/09/10/health/addiction-medical-schools-treatment.html>.

163. Jason N. Doctor et al., *Opioid Prescribing Decreases After Learning of a Patient's Fatal Overdose*, 361 SCI. 588, 588 (2018); Margot Sanger-Katz, *Here's a Cheap Way to Fight Drug Misuse: Send Doctors a Sharp Letter*, N.Y. TIMES (Sept. 5, 2018), <https://www.nytimes.com/2018/09/05/upshot/letters-to-doctors-opioid-research.html>.

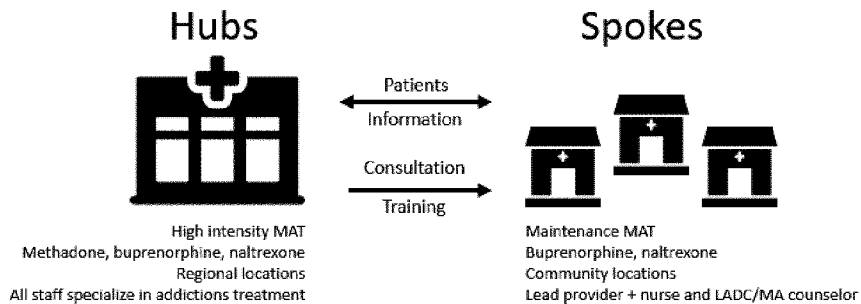
164. Josh Katz, *How a Police Chief, a Governor and a Sociologist Would Spend \$100 Billion to Solve the Opioid Crisis*, N.Y. TIMES (Feb. 14, 2018), <https://www.nytimes.com/interactive/2018/02/14/upshot/opioid-crisis-solutions.html>.

165. SUSAN G. SHERMAN ET AL., JOHNS HOPKINS BLOOMBERG SCH. OF PUB. HEALTH, FENTANYL OVERDOSE REDUCTION CHECKING ANALYSIS STUDY 2 (2018), https://americanhealth.jhu.edu/sites/default/files/inline-files/Fentanyl_Executive_Summary_032018.pdf.

166. Brett Kelman, *Blue Cross Will Stop Covering OxyContin in Tennessee Next Year*, TENNESSEAN (Sept. 6, 2018, 2:45 PM), <https://www.tennessean.com/story/news/health/2018/09/06/blue-cross-stop-covering-oxycontin-tennessee-opioid-epidemic/1109915002>.

167. *2018 Champion City Ideas*, BLOOMBERG PHILANTHROPIES: MAYORS CHALLENGE, <https://mayorschallenge.bloomberg.org/2018-champion-city-ideas> (last visited Feb. 9, 2019).

168. See RICHARD A. RAWSON, VT. CTR. ON BEHAVIOR & HEALTH, VERMONT HUB-AND-SPOKE MODEL OF CARE FOR OPIOID USE DISORDERS: AN EVALUATION 10 (2017) (participants show a 96% decrease in opioid use when compared to those outside the treatment regimen).

Figure 5. Vermont Hub & Spoke System¹⁶⁹

More progressive responses may reduce opioid-related mortality and morbidity over the short- and long-terms. Some common-sense approaches entail minimal expenditures to execute. Public health authorities may recommend that patients store their prescription opioids (like guns) in secure containers at home to deter nonintentional or intentional misuse by others. Any health care provider treating patients for pain should (1) implement more substantial informed consent processes (e.g., mandatory videos, risk/benefit information) designed to effectively communicate potential harms and (2) closely look for signs of addiction among at-risk patients.

Other efforts require greater funding commitments nationally. Reaching patients in rural settings, where per capita death rates can exceed urban areas, may be facilitated through student loan forgiveness mechanisms for health care providers practicing in these settings, whether directly or remotely via telemedicine.¹⁷⁰ National models for greater oversight and regulation of drug rehabilitation centers could deter devious practices subjecting patients to cyclical misuse. Prisoners, often at heightened risk of opioid misuse, need access to enhanced mental health and substance abuse treatment options while incarcerated and social work assistance to avoid opioid behaviors when released.¹⁷¹

169. *Id.* at 22.

170. See U.S. HEALTH RES. & SERVS. ADMIN., RURAL GUIDE TO HEALTH PROFESSIONS FUNDING 8 (2012); Press Release, U.S. Health Res. & Servs. Admin., Affordable Care Act Helps National Health Service Corps Increase Access to Primary Care (Nov. 26, 2013).

171. The Arizona Health Care Cost Containment System (AHCCCS), Arizona's Medicaid system, provides an "enrollment suspension & reinstatement" program to suspend, rather than terminate, care to AHCCCS members who become incarcerated. *Support for Individuals Transitioning out of the Criminal Justice System*, ARIZ. HEALTH CARE COST CONTAINMENT SYS., <https://www.azahcccs.gov/AHCCCS/Initiatives/CareCoordination/justiceinitiatives.html> (last visited Feb. 9, 2019) (internal quotations omitted). Upon release, the correctional facility

Select proposed interventions may be efficacious but are not presently legally viable. SIFs save lives, but their domestic operation is subject to federal prosecution via the DOJ or the Drug Enforcement Agency (DEA).¹⁷² Opening free-standing SIFs and later expanding their operations to include select emergency rooms across the United States could significantly reduce opioid-related mortality. Other approaches, discussed below, carry their own legal, political, or fiscal repercussions, but also present real opportunities to dramatically slow or reverse opioid-related morbidity and mortality.

A. Incentives for Preventive Measures

In many emergencies caused by infectious or chronic conditions, terrorism, environmental hazards, or natural disasters, public health interventions are either freely distributed or incentivized. For example, communities are provided no-cost vaccinations. Guns are bought back by law enforcement authorities. These emergency victims are compensated for their losses. These handouts and incentives are provided in emergencies for a simple reason: *they work to improve the public's health*. Similar approaches may be taken in response to the opioid epidemic.

Public and private sector entities crafting pathways to charge and pay for expensive OUD treatments and rehabilitation services should look as well to creating incentives for persons to engage in preventive measures. Patients with temporary pain who opt out of opioid prescriptions should get a rebate from their health insurer. Excess prescription opioid collection drives could include cash buybacks or distributions of gift cards. Opioid abusers should be offered direct financial benefits (or at least free options) to undertake approved treatments. Prisoners undergoing treatment while incarcerated may garner their own benefits in the warden's discretion. Coupled with each of these incentives are effective risk communications centered on targeted public health messaging about the risks of opioid use in any form. To the extent these initiatives intercede to prevent persons from becoming addicted to or dying from opioids, they more than sustain their costs.

can coordinate care. *Id.* The Arizona Department of Corrections works with AHCCCS to share data to simplify the discharge transition process. *Id.* AHCCCS health plans must also have a "justice systems contact" that "ensure[s] a connection to needed physical and behavioral health services." *Id.*

172. See Lawrence O. Gostin et al., *Supervised Injection Facilities: Legal and Policy Reforms*, 321 JAMA 745 (2019) (presenting several legal routes for future implementation of SIFs nationally against the backdrop of DOJ threats to prosecute states or localities that operate them). Disestablishment of DEA altogether has been raised given its archaic approach to opioids. Leo Beletsky & Jeremiah Goulka, *The Federal Agency That Fuels the Opioid Crisis*, N.Y. TIMES (Sept. 17, 2018), <https://www.nytimes.com/2018/09/17/opinion/drugs-dea-defund-heroin.html>.

B. Limited Access and Uses for Minors

Mitigating response efforts must increasingly focus on underage opioid use. Prescription and illicit opioid misuse are highly prevalent in young adolescents.¹⁷³ Adolescent opioid prescribing rates almost doubled from 1994–2007.¹⁷⁴ In 2015, an estimated 122,000 minors (ages twelve to seventeen) were addicted to prescription pain relievers.¹⁷⁵ Overdose death rates for minors (ages fifteen to nineteen) more than nearly tripled from 1999–2007.¹⁷⁶ After a slight decline until 2014, rates increased again in 2015 when opioids were at the source of more than half of adolescent drug overdose deaths.¹⁷⁷ For every adolescent prescription opioid overdose, there were 119 emergency room visits and twenty-two treatment admissions.¹⁷⁸

Just like other legal restrictions governing minors' access or use of multiple products (see **Figure 6**), stringent opioid prescription limits could decrease opioid misuse and overdose death rates among these vulnerable persons. Persons under age seventeen should be prohibited from receiving an opioid prescription subject to narrow exceptions involving minors with painful, terminal conditions or long-term, irreversible pain. For excepted patients, greater access to preventive measures (including treatment or recovery plans) is essential.

173. *Abuse of Prescription (Rx) Drugs Affects Young Adults Most*, NAT'L INST. DRUG ABUSE, <https://www.drugabuse.gov/related-topics/trends-statistics/infographics/abuse-prescription-rx-drugs-affects-young-adults-most> (last updated Feb. 2019) [hereinafter *Abuse of Prescription (Rx) Drugs*].

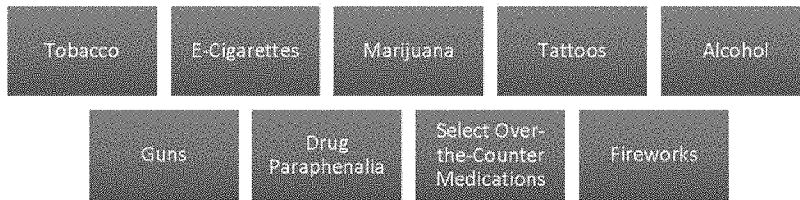
174. AM. SOC'Y OF ADDICTION MED., OPIOID ADDICTION 2016 FACTS & FIGURES 2 (2016) (citing R.J. Fortuna et al., *Prescribing of Controlled Medications to Adolescents and Young Adults in the United States*, 126 PEDIATRICS 1108 (2010)).

175. *Id.* (citing CTR. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, NO. SMA 16-4984, KEY SUBSTANCE USE AND MENTAL HEALTH INDICATORS IN THE UNITED STATES: RESULTS FROM THE 2015 NATIONAL SURVEY ON DRUG USE AND HEALTH (2015)) ("In 2015, 276,000 adolescents were current nonmedical users of pain reliever . . .").

176. SALLY C. CURTIN, BETZAIDA TEJADA-VERA & MARGARET WARNER, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, NCHS DATA BRIEF NO. 282, DRUG OVERDOSE DEATHS AMONG ADOLESCENTS AGED 15–19 IN THE U.S.: 1999–2015 1, 3 (2017).

177. *Id.* at 3. Of the 5,376 drug overdose deaths for persons ages fifteen to twenty-four in 2016, 3,151 were due to illicit opioids. *Drug Overdoses in Youth*, NAT'L INST. ON DRUG ABUSE FOR TEENS, <https://teens.drugabuse.gov/drug-facts/drug-overdoses-youth> (last updated Nov. 2018).

178. *Abuse of Prescription (Rx) Drugs*, *supra* note 173.

Figure 6. Legal Product Restrictions Concerning Minors¹⁷⁹

C. Secondary Prescription Restrictions

Current legal trends limiting the potency and dosage of opioid prescriptions are promising, but patients are still gaining access to far too many pills nationally. Access to a steady stream of opioids puts patients on the fast-track to addiction.¹⁸⁰ Greater limits on the dispensing of opioids can save lives. Like persons who must pass an examination before receiving a driver's license, patients should be required to complete risk aversion educational training and testing prior to receiving an opioid prescription.

Those with acute pain (e.g., post-surgery recovery patients) may be treated responsibly with opioids in health care settings. Outside closely

179. 21 U.S.C. § 387f(d)(3)(A)(ii) (2012) (tobacco); Ryan Martin, *Vaping Laws For All 50 States*, SIGNS.COM (Feb. 13, 2017), <https://www.signs.com/blog/vaping-laws-for-all-50-states-e-cigarettes/>; *What Is the Age Limit of Medical Cannabis in California?*, AM. CANNABIS CO. (Sept. 18, 2018), <https://americancannabisconsulting.com/2018/09/18/california-medical-cannabis-age-limit/> (marijuana); *Tattooing and Body Piercing | State Law, Statutes and Regulations*, NAT'L CONF. ST. LEGISLATURES (Aug. 31, 2018), <http://www.ncsl.org/research/health/tattooing-and-body-piercing.aspx> (tattoos); *Social Host Liability for Underage Drinking Statutes*, NAT'L CONF. ST. LEGISLATURES (Mar. 27, 2014), <http://www.ncsl.org/research/financial-services-and-commerce/social-host-liability-for-underage-drinking-statutes.aspx> (alcohol); *Minimum Age to Purchase & Possess*, GIFFORDS L. CTR. TO PREVENT GUN VIOLENCE, <https://lawcenter.giffords.org/gun-laws/policy-areas/who-can-have-a-gun/minimum-age/#federal> (last visited Nov. 13, 2018) (guns); CAL. DEP'T. OF PUB. HEALTH, CALIFORNIA TOBACCO RETAILERS FREQUENTLY ASKED QUESTIONS (FAQ) ABOUT JUNE 2016 STATE TOBACCO LAWS FAQ #2 1-6 (2016), <http://www.lapublichealth.org/tob/pdf/CA%20Retailer%20Tobacco%20Laws%20FAQ%20-%20June%202016.pdf> (drug paraphernalia); NAT'L ALL. FOR MODEL STATE DRUG LAWS, MINIMUM AGE FOR OVER-THE-COUNTER PURCHASES OF EPHEDRINE AND PSEUDOEPHEDRINE (2013), <http://www.namsdl.org/library/80BD2CD6-1C23-D4F9-746BA81987602693> (select over-the-counter medications); Miriam Rosen, *Are Fireworks Legal in Your State?*, WEATHER CHANNEL (June 24, 2014, 10:06 PM), <https://weather.com/holiday/july-fourth/news/are-fireworks-legal-your-state-20140619> (fireworks).

180. See *Prescription Opioids: Addiction & Overdose*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/opioids/prescribed.html> (last updated Aug. 29, 2017).

monitored settings, patients with chronic or significant pain should be allowed access to opioids only where alternative palliative care or other methods (e.g., OTC drugs, physical therapy) are proven ineffective. Significant investments in opioid prevention research would help identify instances where less risky alternatives to opioids for palliative care were as or more effective.

Tamping down opioid prescriptions is a two-way street.¹⁸¹ Providers authorized to prescribe opioids should also be required to complete MAT training as a condition to obtaining and renewing licensure. Increased knowledge and testing among patients and providers contribute to more informed decision making about pain management. Requiring non-opioid pain management alternatives prior to opioid prescriptions may diminish rates of opioid misuse.

D. Naloxone Access

Despite arguments for making naloxone available over the counter (OTC) to at risk persons or caretakers, widespread access remains inhibited for illegitimate reasons. Naloxone is not a controlled substance, has little to no side effects,¹⁸² and has no significant abuse potential.¹⁸³ Although forty-five states have issued standing orders allowing wider distribution of the drug,¹⁸⁴ access remains problematic due to a lack of consumer awareness¹⁸⁵ and prohibitive naloxone pricing.¹⁸⁶ The FDA is considering whether to (1)

181. See, e.g., Will Humble, *2018 Child Fatality Review Report Published*, ARIZ. PUB. HEALTH ASS'N: PUB. HEALTH TODAY (Nov. 20, 2018), <http://www.azpha.org/wills-blog>.

182. NALOXONEINFO.ORG, NALOXONE: FREQUENTLY ASKED QUESTIONS 2, http://naloxoneinfo.org/sites/default/files/Frequently%20Asked%20Questions-Naloxone_EN.pdf. The most substantial side effect of naloxone may be that improper use could trigger treatable allergic reactions. *Naloxone: Frequently Asked Questions*, ANNE ARUNDEL CTY. DEP'T HEALTH, <https://www.aahealth.org/naloxone-frequently-asked-questions> (last updated Sept. 19, 2018).

183. Megan McLemore & Corey Davis, *A Simple Move to Save Thousands of Lives From Overdose*, N.Y. TIMES (Aug. 18, 2017), <https://www.nytimes.com/2017/08/18/opinion/overdose-naloxone-opioids-trump.html>; U.S. FOOD & DRUG ADMIN., NALOXONE FOR TREATMENT OF OPIOID OVERDOSE 3 (2016). In April 2018, U.S. Surgeon General Jerome Adams issued an advisory recommending that more Americans learn how to use naloxone and to keep the drug within reach. Press Release, U.S. Dept. of Health & Human Servs., Surgeon General Releases Advisory on Naloxone, an Opioid Overdose-Reversing Drug (Apr. 5, 2018).

184. See DAVIS, *supra* note 90, at 3–6.

185. *Surgeon General's Advisory on Naloxone and Opioid Overdose*, U.S. DEPT. HEALTH & HUMAN SERVS., <https://www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html> (last visited Feb. 10, 2019).

186. Narcan costs \$150 but was available for \$1 ten years ago. Michael Hufford & Donald S. Burke, *The Costs of Heroin and Naloxone: A Tragic Snapshot of the Opioid Crisis*, STAT (Nov. 8, 2018), <https://www.statnews.com/2018/11/08/costs-heroin-naloxone-tragic-snapshot->

mandate co-prescribing naloxone with opioid prescriptions and (2) allow naloxone to be sold OTC.¹⁸⁷ These initiatives will cut overdose fatalities by proactively placing naloxone with people who can rapidly administer it.

Strategic public placement of naloxone is also essential. Multiple lawmakers support adding opioid antidotes to automated external defibrillator (AED) cabinets.¹⁸⁸ The University of Rochester already includes naloxone in its cabinets.¹⁸⁹ VA hospitals nationally are preparing to follow suit.¹⁹⁰ Given its availability in nasal mist form (i.e., Narcan®), even bystanders can follow basic instructions on naloxone administration (see **Figure 7**). National commitments to assisting persons at risk of death or serious morbidity due to opioids can improve survivability of victims so long as naloxone is available in places people can readily identify.

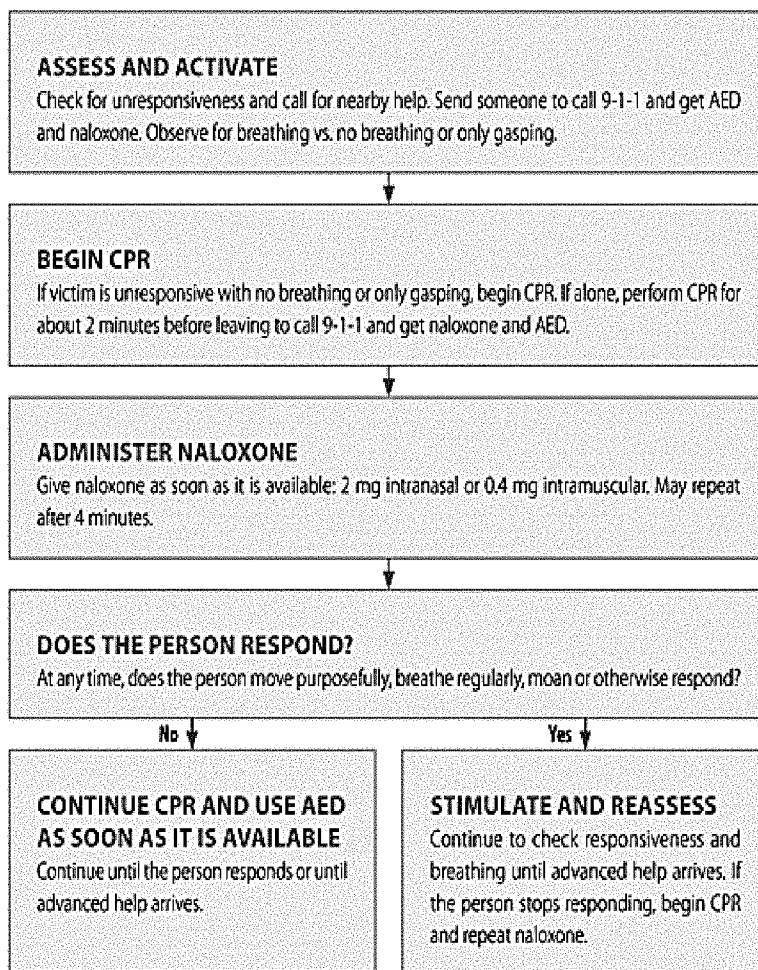
opioid-crisis (citing Ravi Gupta et al., *The Rising Price of Naloxone—Risks to Efforts to Stem Overdose Deaths*, 375 NEW ENG. J. MED. 2213, 2214 (2016)).

187. Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., On Agency's Efforts to Advance New Ways to Increase the Availability of Naloxone as One Means for Reducing Opioid Overdose Deaths (Oct. 23, 2018).

188. Matt Steecker, *Naloxone Program Gains Approval in Tompkins County*, ITHACA J. (Apr. 19, 2018, 12:58 PM), <https://www.ithacajournal.com/story/news/2018/04/18/naloxone-program-gains-approval-tompkins-county/528123002>; Geoffrey A. Capraro & Claudia B. Rebola, *The NaloxBox Program in Rhode Island: A Model for Community-Access Naloxone*, 108 AM. J. PUB. HEALTH 1649, 1649 (2018) (NaloxBox provides naloxone and barrier masks to the public in a Plexiglas unit similar to an AED that electronically alerts facility staff when a box is opened to indicate a potential emergency and need for replacement).

189. Martha Bebinger, *VA Adding Opioid Antidote to Defibrillator Cabinets for Quicker Overdose Response*, NPR (Sept. 27, 2018, 7:44 AM), <https://www.npr.org/sections/health-shots/2018/09/27/650639122/va-adding-opioid-antidote-to-defibrillator-cabinets-for-quicker-overdose-response>.

190. Martha Bebinger, *Boston's VA Adds Overdose-Reversing Naloxone to AED Cabinets*, WBUR (Sept. 19, 2018), <http://www.wbur.org/commonhealth/2018/09/19/boston-v-a-narcan-aed-boxes>.

Figure 7. Opioid-Related Emergency Instructions¹⁹¹

191. Ian R. Drennan & Aaron M. Orkin, *Prehospital Naloxone Administration for Opioid-Related Emergencies*, J. EMERGENCY MED. SERVS. (Mar. 2, 2016), <https://www.jems.com/articles/print/volume-41/issue-3/special-focus-resuscitation-recommendations/prehospital-naloxone-administration-for-opioid-related-emergencies.html>.

E. Enhanced Surveillance

Fighting a multi-dimensional epidemic is not easy when data about its reach and impacts are largely retrospective. Current public health surveillance methods concentrate on prescription drug monitoring and overdoses reported in emergency departments or by paramedics.¹⁹² Existing data are purposeful but also under-funded, incomplete, and insufficient in determining specific emerging risks among affected populations.

As the crisis shifts, so must commitments to generating and responding to accurate, timely data sources. Renewed investments and data (see **Figure 8**) may identify high-risk communities, improve treatment and other resource allocations, and assess the effectiveness of innovative responses.¹⁹³

Figure 8. Enhanced Data Methods and Surveillance Tools



Encouraging medical examiners to better specify what kind of opioid precipitated a fatality may illuminate the impacts of prescription versus illicit

192. *Enhanced State Opioid Overdose Surveillance*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/foa/state-opioid-mm.html> (last updated Oct. 3, 2017).

193. This may include efforts to notify affected persons when individuals are at risk of opioid misuse similar to anonymized partner notification commonly used with infectious conditions like tuberculosis, syphilis, and HIV. See Chad H. Hochberg, Kathryn Berringer & John A. Schneider, *Next-Generation Methods for HIV Partner Services: A Systematic Review*, 42 SEXUALLY TRANSMITTED DISEASES 533, 533 (2015).

opioids.¹⁹⁴ Conducting syndromic surveillance on anonymous purchases of the OTC medication loperamide (Imodium®) may reveal sub-populations attempting to mitigate opioid withdrawal symptoms.¹⁹⁵ Close monitoring of purchases of prescribed naloxone and non-prescribed sterile syringes enhances community risk assessments.¹⁹⁶ To support community public health surveillance, the Biodesign Institute at Arizona State University monitors geo-localized levels of pharmaceutical and illicit drug consumption by analyzing metabolites in wastewater.¹⁹⁷ Untapped data streams, including internet search history and social media posts, offer new surveillance techniques,¹⁹⁸ notwithstanding privacy repercussions.

Uniform data reporting through existing and emerging sources nationally may obviate impacts of the epidemic through better informed responses. Methods that leverage data to map local jurisdictions can highlight high-risk areas and enable targeted interventions.¹⁹⁹ New developments enable better

194. See Svetla Slavova et al., *Drug Overdose Deaths: Let's Get Specific*, 130 PUB. HEALTH REP. 339, 340 (2015).

195. Loperamide is a medication for controlling diarrhea, which may be used extensively by people using opioids. Press Release, U.S. Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Help Prevent New Addiction, Curb Abuse & Overdose Related to Opioid Products (Jan. 30, 2018).

196. Thomas J. Stopka et al., *Nonprescription Naloxone and Syringe Sales in the Midst of Opioid Overdose and Hepatitis C Virus Epidemics: Massachusetts, 2015*, 57 J. AM. PHARMACISTS ASS'N. S34, S34 (2017). Over half of the states have enacted legislation permitting the sale of sterile syringes without a prescription in some contexts. See *Laws Related to the Sale of Syringes/Needles*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/hepatitis/policy/RetailSaleOfSyringes.html> (last updated Sept. 27, 2017).

197. By tracking drug consumption, governments can implement proactive interventions and strategically concentrate law enforcement and health resources. See The Biodesign Institute, *Urban Metabolism Metrology and Sewage Epidemiology Panel*, ARIZ. ST. U., <https://biodesign.asu.edu/news/urban-metabolism-metrology-and-sewage-epidemiology-panel> (last visited Feb. 10, 2019) (monitoring wastewater for chemical indicators of illicit drug use); see also David Common, *Sewer Robots Sampling Human Waste May Track Drugs, Disease Through Cities*, CBC NEWS (May 27, 2016), <http://www.cbc.ca/news/technology/sewer-robots-disease-tracking-1.3601525>; Keridwen Cornelius, *Sewage Is Helping Cities Flush Out the Opioid Crisis*, SCI. AM. (May 25, 2018), <https://www.scientificamerican.com/article/sewage-is-helping-cities-flush-out-the-opioid-crisis>.

198. See generally Sudhakar V. Nuti et al., *The Use of Google Trends in Health Care Research: A Systematic Review*, PLOS ONE, Oct. 2014, at 1 (examining data obtained through Google Trends to understand patterns of disease); Ovidiu Șerban et al., *Real-Time Processing of Social Media with SENTINEL: A Syndromic Surveillance System Incorporating Deep Learning for Health Classification*, INFO. PROCESSING & MGMT. (June 1, 2018), <https://doi.org/10.1016/j.ipm.2018.04.011> (using social media data to detect outbreaks of disease).

199. Tamara Dubowitz et al., *Using Geographic Information Systems to Match Local Health Needs with Public Health Services and Programs*, 101 AM. J. PUB. HEALTH 1664, 1664 (2011).

distribution of naloxone to communities in need through analysis of the locations of overdose events against pharmacies carrying naloxone.²⁰⁰ Access to enhanced and new data—combined with support and incentives for state and local public health officials—will bolster responses and adaptability to the opioid crisis.

V. CONCLUSION

The opioid epidemic began with the notion that patients deserved greater access to palliative care. Decades later, the known consequences of America's worst PHE are appalling. Hundreds of thousands are dead prematurely due to opioid addiction escalating to overdose. Millions are at heightened risk. Tens of thousands of youth are exposed to these drugs in prescription and illicit forms. Responding to lingering emergencies at this level requires prevention innovations. Efforts focused on (1) substantial incentives to engage at-risk persons, (2) minors' limited access to opioids, (3) restrictions on secondary prescriptions, (4) strategic placement of naloxone, and (5) advanced surveillance techniques represent more than cost-saving investments in the public's health: they could be life savers for thousands of Americans facing a scourge they cannot defeat alone.

200. See Zan M. Dodson et al., *Spatial Methods to Enhance Public Health Surveillance and Resource Deployment in the Opioid Epidemic*, 108 AM. J. PUB. HEALTH 1191, 1195–96 (2018).