

## NOTES

### THE ROLE OF DIRECT-INJURY GOVERNMENT-ENTITY LAWSUITS IN THE OPIOID LITIGATION

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*The opioid epidemic has ravaged the United States, killing over 100 Americans every day and costing the nation upward of \$90 billion a year. All branches and levels of the government have pursued measures to combat the epidemic and reduce its societal costs. Perhaps the most interesting response is the emergence of direct-injury government-entity lawsuits, which seek to recover damages from opioid companies that facilitated prescription pill addictions. Cities, counties, and states across the country are suing opioid manufacturers and distributors in unprecedented numbers.*

*This Note explores the role of direct-injury government-entity claims as compared to other forms of civil litigation employed in the opioid crisis. It highlights the obstacles faced by parens patriae actions, individual lawsuits, class actions, and aggregate actions in general. This Note argues that direct-injury government claims have important advantages over other forms of civil litigation because they overcome certain defenses related to victim blameworthiness and because they function as inherently representative actions that bypass the certification requirements of traditional aggregate actions.*

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#### INTRODUCTION

Every day, 115 Americans die from opioid addiction.<sup>1</sup> Both former president Barack Obama<sup>2</sup> and current president Donald Trump<sup>3</sup> have labeled the opioid crisis a national emergency. More Americans today use

1. *Understanding the Epidemic*, CDC, <https://www.cdc.gov/drugoverdose/epidemic/index.html> [<https://perma.cc/B5KM-HH3N>] (last visited Nov. 15, 2018).

2. See Proclamation No. 9499, 3 C.F.R. 272, 273 (2016).

3. Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds*, N.Y. TIMES (Oct. 26, 2017), <https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html> [<https://perma.cc/492C-M3BY>].

prescription painkillers than tobacco,<sup>4</sup> and more people die from heroin than gun homicides.<sup>5</sup> Drug overdoses are the “leading cause of injury death in the United States”<sup>6</sup> and over 60 percent of those deaths involve an opioid.<sup>7</sup>

The term “opioid” is used to describe a family of drugs prescribed primarily for pain relief and derived either naturally from opium plants or artificially by transforming “the chemical structure of . . . naturally occurring opioids.”<sup>8</sup> When used recreationally, opioids produce a euphoric high that makes them “prone to abuse.”<sup>9</sup> While pleasing at first, continual opioid abuse raises an individual’s tolerance to the drug (requiring higher doses to “produce pleasure comparable to that provided in previous drug-taking episodes”), and eventually the individual becomes dependent on opioids to avoid extreme withdrawal symptoms.<sup>10</sup> There are various types of opioids and most correspond to a marketed pharmaceutical drug: oxycodone (OxyContin, Percodan, Percocet), hydrocodone (Vicodin, Lortab, Lorcet), diphenoxylate (Lomotil), codeine, fentanyl (Duragesic), propoxyphene (Darvon), hydromorphone (Dilaudid), meperidine (Demerol), methadone, and morphine (Kadian, Avniza, MS Contin).<sup>11</sup> Morphine, for example, is a natural chemical derived from the poppy plant and is used to create the illicit drug heroin,<sup>12</sup> a dangerous substance responsible for 13,000 overdose deaths in 2015.<sup>13</sup>

The road to heroin addiction today begins with legal prescription painkillers. Individuals first become addicted to prescription pills and “move on to heroin when it becomes too difficult or expensive to access prescription

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4. Christopher Ingraham, *Prescription Painkillers More Widely Used Than Tobacco, Federal Study Finds*, DENV. POST (Sept. 20, 2016, 8:14 PM), <http://www.denverpost.com/2016/09/20/prescription-painkillers-tobacco-study/> [<https://perma.cc/NEN7-J7U5>].

5. Christopher Ingraham, *Heroin Deaths Surpass Gun Homicides for the First Time, CDC Data Shows*, WASH. POST (Dec. 8, 2016), <https://www.washingtonpost.com/news/work/wp/2016/12/08/heroin-deaths-surpass-gun-homicides-for-the-first-time-cdc-data-show/> [<https://perma.cc/7ZPW-LAVG>].

6. This conclusion is based on statistics for 2014. DRUG ENF’T AGENCY, DEA-DCT-DIR-001-17, 2016 NATIONAL DRUG THREAT ASSESSMENT SUMMARY 25 (2016).

7. See Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010–2015*, 65 MORBIDITY & MORTALITY WKLY. REP. 1445, 1445 (2016), <https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm655051e1.pdf> [<https://perma.cc/3XNF-SECW>].

8. *Prescription Opioids*, CAMH, <https://www.camh.ca/en/health-info/mental-illness-and-addiction-index/prescription-opioids> [<https://perma.cc/YLA7-UQBS>] (last visited Nov. 15, 2018).

9. *Id.*

10. Thomas R. Kosten & Tony P. George, *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 SCI. & PRAC. PERSP., July 2002, at 13, 14–18.

11. Tony L. Yaksh & Mark S. Wallace, *Opioids, Analgesia, and Pain Management*, in GOODMAN & GILMAN’S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 481, 483–84 (Laurence L. Brunton ed., 12th ed. 2011); *List of Extended-Release and Long-Acting Opioid Products Required to Have an Opioid REMS*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm251735.htm> [<https://perma.cc/XY8V-U9X5>] (last updated Nov. 24, 2017).

12. See *Prescription Opioids*, *supra* note 8.

13. See Rudd et al., *supra* note 7, at 1450 tbl.2.

opioids.”<sup>14</sup> Whereas in the 1960s most opioid addicts began their addiction by injecting heroin, the average opioid addict today gets hooked by using prescription pills.<sup>15</sup> One study found that 75 percent of high school heroin users begin their opioid addiction with prescription medications.<sup>16</sup>

The opioid epidemic has created not only a health crisis, but also an economic burden on America. From 2011 to 2015, the United States realized a 1000 percent increase in “professional charges and allowed amounts for services for patients diagnosed with opioid abuse or dependence.”<sup>17</sup> In 2011, the societal cost of opioid abuse was an estimated \$55.7 billion: \$25 billion in health-care costs (primarily excess medical and drug costs), \$11.2 billion in lost earnings from premature death, \$7.9 billion in lost productivity, and \$5.1 billion in criminal justice expenditures.<sup>18</sup> In 2016, the “monetized burden” of prescription drug abuse rose to \$78.5 billion: \$28 billion in health-care costs, \$21.5 billion for overdose treatment, \$20 billion in lost productivity, and \$7.7 billion in criminal justice expenditures.<sup>19</sup> When converting the loss of life into monetary figures, the economic burden of the opioid epidemic is even higher. A health-care specialist from Harvard Medical School calculated “that loss of life alone costs the economy an additional sum of between a hundred and a hundred and fifty billion dollars a year.”<sup>20</sup>

One method that governments have used to recover the immense costs of the opioid crisis is to sue opioid companies for the economic harm that they have suffered as a result of opioid addiction. Quite recently, the popularity of these direct-injury claims has increased exponentially: cities, counties,

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14. Bridget M. Kuehn, *Driven by Prescription Drug Abuse, Heroin Use Increases Among Suburban and Rural Whites*, 312 JAMA 118, 119 (2014).

15. *Id.* The demographic of drug users in the United States has also changed—opioid addicts in the 1960s were mostly young, uneducated boys, living in heavily populated cities. *Id.* at 118–19. The average addict today, however, is fairly well educated, not necessarily male, and becomes addicted in his or her midtwenties. *Id.* at 119.

16. CJ Arlotta, *More Than 75% of High School Heroin Users Started with Prescription Opioids*, FORBES (Dec. 7, 2015), <https://www.forbes.com/sites/cjarlotta/2015/12/07/more-than-75-of-high-school-heroin-users-started-with-prescription-opioids/> [https://perma.cc/LM H5-87T7].

17. *The Opioid Crisis: Impact on Healthcare Services and Costs*, FAIR HEALTH (2016), <https://s3.amazonaws.com/media2.fairhealth.org/infographic/asset/FH%20Infographic%20-%20The%20Opioid%20Crisis-59724533a5ac5.pdf> [https://perma.cc/Y9WK-3FVD] (“An allowed amount is the maximum amount an insurer will pay for a covered health service.”).

18. Howard G. Birnbaum et al., *Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States*, 12 PAIN MED. 657, 657–67 (2011).

19. Lippincott Williams & Wilkins, *Costs of US Prescription Opioid Epidemic Estimated at \$78.5 Billion*, SCIENCE DAILY (Sept. 14, 2016), <https://www.sciencedaily.com/releases/2016/09/160914105756.htm> [https://perma.cc/X7KK-XMFP]. It is important to note that the Lippincott study is a more conservative estimate than the Birnbaum study because it did not take into account the societal costs of lost earnings from premature death. *Id.*; see also Birnbaum et al., *supra* note 18, at 661.

20. These calculations take “a conservative estimate of twenty to thirty thousand opioid-related deaths a year” and multiplies that figure “by five million dollars—a figure commonly used by insurance companies to value a human life.” Sheelah Kolhatkar, *The Cost of the Opioid Crisis*, NEW YORKER (Sept. 18, 2017), <https://www.newyorker.com/magazine/2017/09/18/the-cost-of-the-opioid-crisis> [https://perma.cc/8PBV-9S4H].

and states ravaged by the opioid epidemic are filing civil complaints against opioid manufacturers and distributors in increasing numbers.<sup>21</sup> This Note explores the role of the direct-injury claim in the context of the opioid crisis, and why it is such a popular response. Part I of this Note discusses the variety of responses that the government has implemented to prevent opioid addiction, facilitate addiction treatment, and punish the parties responsible for the opioid epidemic. Part II focuses on direct-injury claims, a measure that seeks to punish the opioid manufacturers and distributors responsible for America's opioid crisis by recovering damages spent on infrastructure and health care in response to the crisis. Part II also explores the role of these direct-injury claims by noting the downfalls and challenges of other forms of civil litigation in the context of the opioid epidemic. Part III then explains how direct-injury government-entity claims circumvent the obstacles that have hindered individual, class action, and *parens patriae* actions against opioid companies.

### I. GOVERNMENT EFFORTS TO COMBAT THE OPIOID EPIDEMIC

Every branch and level of government has been involved in the fight against opioid addiction. To understand the distinct role played by direct-injury government claims, one must see these lawsuits in the context of the full panoply of government efforts to deal with the opioid crisis. These efforts can be split into two categories: proactive and reactive. Proactive measures aim to prevent American citizens from becoming addicted to prescription opioids in the first place. Reactive responses aim to treat opioid addicts and punish the parties responsible for facilitating opioid addiction. Part I.A discusses proactive measures that attempt to limit the market for illicit medications through regulation of the legal prescription drug industry. Although proactive measures are arguably superior because they address the issue of addiction before it proliferates, the opioid epidemic has grown far too serious to rely solely on proactive responses. Part I.B discusses reactive measures that aim to increase treatment options or penalize drug dealers, prescribers, and companies for facilitating opioid addiction.

#### A. Proactive Measures: Preventing Addiction

The prescription drug industry must be properly regulated to ensure that opioids are being used safely and only for medicinal purposes. Congress has placed much of the responsibility for regulating prescription opioids in the hands of executive agencies. Two agencies in particular, the Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA), are highly accountable for regulating the legal prescription drug industry. The FDA is responsible for regulating prescription painkillers prior to their

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21. See Scott Higham & Lenny Bernstein, *Drugmakers and Distributors Face Barrage of Lawsuits over Opioid Epidemic*, WASH. POST (July 4, 2017), [http://www.washingtonpost.com/investigations/drugmakers-and-distributors-face-barrage-of-lawsuits-over-opioid-epidemic/2017/07/04/3fc33c64-5794-11e7-b38e-35fd8e0c288f\\_story.html](http://www.washingtonpost.com/investigations/drugmakers-and-distributors-face-barrage-of-lawsuits-over-opioid-epidemic/2017/07/04/3fc33c64-5794-11e7-b38e-35fd8e0c288f_story.html) [https://perma.cc/5GLR-MK6F]; *infra* notes 101–04 and accompanying text.

entrance into the market, whereas the DEA regulates the manufacture, distribution, and possession of prescription medications once they are released to the public.

The FDA derives its authority to regulate drugs from the Federal Food, Drug, and Cosmetic Act (“FDCA”) of 1938.<sup>22</sup> The FDCA requires that the FDA approve every drug before it is manufactured or distributed in the United States.<sup>23</sup> The FDA’s task involves a tough balance between giving needy patients a valuable medication, reducing prices, and fostering innovation on one hand and, on the other hand, encouraging safety and efficacy for companies that are otherwise disincentivized to do so.<sup>24</sup> For example, when the FDA first approved OxyContin,<sup>25</sup> members of the medical community were convinced that it had approved a “gift from nature”: a medication that provides patients long-term pain relief “with few side effects.”<sup>26</sup> Once the agency understood the risk of opioid addiction and the misleading nature of Purdue Pharma’s advertisement scheme, its objective was to offset the danger by strengthening OxyContin’s warning label.<sup>27</sup> Since 2007, the FDA has erred on the side of safety and increased its regulation of prescription opioids by requiring prescription opioid manufacturers to undergo a three-tiered regulation process before releasing their drugs to the market.<sup>28</sup>

The DEA serves as the primary enforcer of the Controlled Substances Act (CSA).<sup>29</sup> The statute requires all distributors and manufacturers of prescription opioids to generate a “closed system” of distribution and keep adequate records on the quantity of drugs being produced, purchased, and

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22. 21 U.S.C. §§ 351–360ff-7 (2012).

23. *Id.* § 355(a).

24. Mark A. Ford, Note, *Another Use of OxyContin: The Case for Enhancing Liability for Off-Label Marketing*, 83 B.U.L. REV. 429, 430–36 (2001). Despite their complexity, these regulatory efforts are “inherently superior to tort liability because [they are] proactive rather than reactive.” *Id.* at 436.

25. The FDA first approved OxyContin, a controlled-release formula for oxycodone that “allowed dosing every 12 hours instead of every 4 to 6 hours” in 1995. *Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse*, U.S. FOOD & DRUG ADMIN. [hereinafter *FDA Opioid Timeline*], <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm> [<https://perma.cc/T2AJ-RQBY>] (last visited Nov. 15, 2018).

26. Patrick R. Keefe, *The Family That Built an Empire of Pain*, NEW YORKER (Oct. 30, 2017), <https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain> [<https://perma.cc/S83V-VSHV>] (quoting Dr. Russell Portenoy, a pain specialist, in 1993).

27. See *FDA Opioid Timeline*, *supra* note 25.

28. This three-tiered system is known as the Risk Evaluation and Mitigation Strategy. Hilary Homenko, Note, *Rehabilitating Opioid Regulation: A Prescription for the FDA’s Next Proposal of an Opioid Risk Evaluation and Mitigation Strategy (REMS)*, 22 HEALTH MATRIX 273, 275 (2012).

29. Reorganization Plan No. 2 of 1973, 5 U.S.C. app. § 1 (2012); U.S. DEP’T OF JUSTICE, PRACTITIONER’S MANUAL: AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT 4 (2006), [https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract\\_manual012508.pdf](https://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf) [<https://perma.cc/BF9C-VK4Q>].

sold in the United States.<sup>30</sup> Under authority from the CSA, the DEA promulgated Rule 1301.74, which requires all distributors to “design and operate a system to disclose . . . suspicious orders of controlled substances.”<sup>31</sup> In addition to reporting these suspicious orders, distributors must prevent diversion to illegitimate outlets by “conduct[ing] an independent analysis of suspicious orders *prior* to completing a sale.”<sup>32</sup> The DEA administers, enforces, and sets detailed regulations in line with the CSA. It has the ability, for example, to set “quantity and production” quotas for drug manufacturers and penalize any distributors that fail to adhere to Rule 1301.74.<sup>33</sup>

Opioid manufacturers and distributors are just one part of the distribution chain. In addition to regulating their conduct, the government must also regulate the parties that provide medications directly to patients: the opioid prescribers. A subset of the Department of Health and Human Services, the Centers for Disease Control and Prevention, is responsible for setting federal guidelines aimed specifically at opioid prescription.<sup>34</sup> Each state also has its own statutory structure for monitoring prescription medications and separate licensing requirements for physicians, hospitals, and pharmacies.<sup>35</sup> Some states particularly afflicted by the opioid epidemic have added restrictions on a physician or pharmacy’s ability to dispense prescription medication. Florida, for example, has completely banned doctors from prescribing oxycodone on-site.<sup>36</sup> This measure has decreased the number of oxycodone doses purchased in the state by 97 percent.<sup>37</sup>

By regulating the legal prescription drug industry, the government effectively limits the market for illicit prescription opioids. However, as the illicit market for opioids kept growing despite regulatory efforts, state

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30. U.S. DEP’T OF JUSTICE, *supra* note 29, at 4; *see also* 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 32 (Richard J. Bonnie et al. eds., 2017), [https://www.ncbi.nlm.nih.gov/books/NBK458660/pdf/Bookshelf\\_NBK458660.pdf](https://www.ncbi.nlm.nih.gov/books/NBK458660/pdf/Bookshelf_NBK458660.pdf) [<https://perma.cc/4KLA-PFPD>].

31. 21 C.F.R. § 1301.74(b) (2018). Suspicious orders are characterized by unusual size, frequency, or significant deviations from “normal pattern.” *Id.*

32. Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, to Cardinal Health (Dec. 27, 2007) (emphasis added). This letter was filed as an attachment to the government’s motion papers in *Cardinal Health, Inc. v. Holder*. *See* Attachment 5 to Defendant’s Opposition to Plaintiff’s Motion for Preliminary Injunction, *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012), ECF No. 14-8.

33. Melissa Ferrara, Comment, *The Disparate Treatment of Addiction-Assistance Medications and Opiate Pain Medications Under the Law: Permitting the Proliferation of Opiates and Limiting Access to Treatment*, 42 SETON HALL L. REV. 741, 746 (2012).

34. *See, e.g.*, *CDC Guidelines for Prescribing Opioids for Chronic Pain*, CDC, [https://www.cdc.gov/drugoverdose/pdf/guidelines\\_at-a-glance-a.pdf](https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf) [<https://perma.cc/MLW2-7USK>] (last visited Nov. 15, 2018).

35. *See* Aaron Gilson & David E. Joranson, *Controlled Substances, Medical Practice, and the Law*, in *PSYCHIATRIC PRACTICE UNDER FIRE: THE INFLUENCE OF GOVERNMENT, THE MEDIA, AND SPECIAL INTERESTS ON SOMATIC THERAPIES* 173, 181–82 (Harold I. Schwartz ed., 1994).

36. Lizette Alvarez, *Florida Shutting ‘Pill Mill’ Clinics*, N.Y. TIMES (Aug. 31, 2011), <http://www.nytimes.com/2011/09/01/us/01drugs.html> [<https://perma.cc/F4BH-VHAB>].

37. *Id.*

legislatures began taking a more targeted approach by focusing on the methods that opioid addicts frequently use to obtain illicit medications. The two most prominent methods are “doctor shopping” and “pill mills.” Doctor shopping occurs when a single patient seeks multiple treatment providers to illicitly procure prescription medications.<sup>38</sup> The objective behind doctor shopping is “to obtain the maximum amount of pills without the medical community becoming wise to the scheme.”<sup>39</sup> Drug abusers also commonly obtain large amounts of prescription pills through so-called pill mills: doctors, clinics, or pharmacies that inappropriately prescribe or dispense prescription medications, often in large quantities.<sup>40</sup> The most popular state solution to address both these issues has been the creation of prescription monitoring programs (PMPs): systems that track every prescription medication being dispensed throughout the state and “make it easier for law enforcement agencies to identify pill mills [and doctor-shopping activity] without adversely affecting legitimate pain clinics that properly prescribe controlled medications.”<sup>41</sup> Every state aside from Missouri has enacted a PMP program, and these have “proven effective in helping reduce [the] availability, abuse, and diversion of illicitly obtained prescription drugs.”<sup>42</sup> Unfortunately, PMPs and other reactive measures are insufficient to prevent American citizens from becoming addicted to prescription opioids. Therefore, it is necessary for the government to pursue reactive measures that accept opioid addiction as a reality of American culture and aim to lower the societal cost of the crisis.

### B. Reactive Measures: Treatment, Punishment, and Retribution

There are a variety of reactive measures that American government entities have pursued to address opioid addiction after it afflicts individuals. In line with the perspective that opioid addiction is a medical problem rather than a crime,<sup>43</sup> many reactive measures seek to increase opioid-addiction treatment options for addicted individuals.<sup>44</sup> The alternative is a penal approach, which

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38. Randy A. Sansone & Lori A. Sansone, *Doctor Shopping: A Phenomenon of Many Themes*, 9 INNOVATIONS CLINICAL NEUROSCIENCE 42, 42–43 (2012).

39. Amy L. Cadwell, *In the War on Prescription Drug Abuse, E-Pharmacies Are Making Doctor Shopping Irrelevant*, 7 HOUS. J. HEALTH L. & POL’Y 85, 90 (2007).

40. Pia Malbran, *What’s a Pill Mill?*, CBS NEWS (May 31, 2007), <https://www.cbsnews.com/news/whats-a-pill-mill/> [<https://perma.cc/6S29-P34S>].

41. Ed Woodworth, Note, *Pharmageddon: A Statutory Solution to Curb Ohio’s Prescription Abuse Problem*, 26 J.L. & HEALTH 103, 121 (2013) (discussing Ohio’s implementation of prescription monitoring).

42. See DRUG ENF’T AGENCY, *supra* note 6, at 26. Thirty-three of the forty-nine states that utilize PMPs share prescription data among themselves using an InterConnect system created by the National Association of Boards of Pharmacy. *Id.*

43. *Treating Opioid Addiction as a Chronic Illness*, AM. SOC’Y ADDICTION MED., <https://www.asam.org/docs/default-source/advocacy/emm-fact-sheet---11-07-14.pdf> [<https://perma.cc/B2XZ-7355>] (last visited Nov. 15, 2018).

44. Some commentators have argued that, unlike other forms of drug addiction, opioid addiction is more likely to be viewed as a medical problem rather than a crime because it afflicts mostly white individuals. See German Lopez, *When a Drug Epidemic’s Victims Are White*, VOX (Apr. 4, 2017), <https://www.vox.com/identities/2017/4/4/15098746/opioid->

addresses on the criminal and tortious conduct by parties that facilitate opioid addiction through criminal prosecutions and civil litigation, respectively.

### 1. Increase of Treatment Options

Congress and various bureaucratic agencies have worked to facilitate the treatment of opioid use disorder (OUD)<sup>45</sup> and addiction. Well before the opioid epidemic, Congress passed the Narcotic Addiction Treatment Act of 1974 (NATA)<sup>46</sup> and the Drug Addiction Treatment Act of 2000 (DATA)<sup>47</sup> to increase addiction and overdose treatment options for opioid users.<sup>48</sup> Congress has also provided huge grants to state governments for substance abuse treatment.<sup>49</sup> Around 32 percent of all state funding for substance abuse problems comes from a 1992 block grant from the federal government.<sup>50</sup> In 2016, the federal government set aside an extra \$1 billion for states to administer and create treatment and recovery programs for opioid users.<sup>51</sup>

State legislatures have also done their part by increasing access to overdose or addiction treatments,<sup>52</sup> decreasing liability for physicians prescribing

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heroin-epidemic-race [<https://perma.cc/VR6P-NJDE>]; Jesse Mechanic, *When a Drug Epidemic Hit White America, Addiction Became a Disease*, HUFFINGTON POST (July 10, 2017), [https://www.huffingtonpost.com/entry/when-a-drug-epidemic-hit-white-america-addiction-became\\_us\\_5963a588e4b08f5c97d06b9a](https://www.huffingtonpost.com/entry/when-a-drug-epidemic-hit-white-america-addiction-became_us_5963a588e4b08f5c97d06b9a) [<https://perma.cc/3F3K-28AJ>].

45. The CDC defines opioid use disorder as “[a] problematic pattern of opioid use that causes significant impairment or distress” characterized by “unsuccessful efforts to cut down or control use, or use resulting in social problems and a failure to fulfill obligations at work, school, or home.” *Commonly Used Terms*, CDC, <https://www.cdc.gov/drugoverdose/opioids/terms.html> [<https://perma.cc/K3CW-YLMJ>] (last visited Nov. 15, 2018).

46. Narcotics Addiction Treatment Act of 1974, Pub. L. No. 93-281, 88 Stat. 124 (codified at 21 U.S.C. §§ 802, 823, 827 (2012)). The Narcotic Addiction Treatment Act formally recognized “the practice of using opioids to treat opioid addiction.” Corey S. Davis & Derek H. Carr, *The Law and Policy of Opioids for Pain Management, Addiction Treatment, and Overdose Reversal*, 14 IND. HEALTH L. REV. 1, 17 (2017). For almost fifty years prior to the enactment of NATA, it was illegal to prescribe methadone or other opioids as a treatment for drug-dependent individuals. *Id.*

47. DATA enabled physicians to prescribe narcotics for opioid addiction treatment, which opened up a broader range of treatment options for opioid users alienated by the idea of attending drug treatment clinics. *See* Drug Addiction Treatment Act of 2000, Pub. L. No. 106-310, § 3502(a)(5), 114 Stat. 1222, 1223–27 (codified at 21 U.S.C. § 823(g) (2012)).

48. The main issue with DATA was its limitation on the number of patients a practice can treat simultaneously: thirty. *Id.* § 3502(a)(5), 114 Stat. at 1223. Even large clinics with plenty of physicians were restricted by DATA’s thirty-patient limitation. *Id.* Over time, the Department of Health and Human Services fixed this problem by promulgating rules that expanded the number of persons a single practice could treat simultaneously, raising the limit in 2016 to 275. 42 C.F.R. § 8.1 (2017).

49. *Addressing the Opioid Crisis in America: Prevention, Treatment and Recovery: Hearing Before the S. Subcomm. on Labor, Health & Human Servs., Educ. & Related Agencies of the S. Comm. on Appropriations*, 115th Cong. 7–10 (2017) (written testimony of Francis Collins, Elinore McCance-Katz & Debra Houry, Dep’t of Health & Human Servs.) (discussing the Substance Abuse Prevention and Treatment block grants of 1992).

50. *Id.* at 8.

51. The 21st Century Cures Act set aside \$1 billion “in funding over 2 years for grants to states targeting opioid prevention and treatment activities.” COMM. ON PAIN MGMT. & REGULATORY STRATEGIES TO ADDRESS PRESCRIPTION OPIOID ABUSE, *supra* note 30, at 29.

52. In the past, states imposed barriers that prevented laypersons from accessing overdose-reversing drugs, by, for example, restricting doctors from prescribing naloxone “for

overdose-treatment drugs,<sup>53</sup> and providing legal immunity to bystanders who assist during overdoses.<sup>54</sup> By 2016, forty-seven states had passed legislation that does one or more of the following: (1) provides immunity to prescribers of overdose treatments such as naloxone;<sup>55</sup> (2) permits doctors to make third-party prescriptions of overdose treatments to friends, family, or acquaintances of an overdosing patient;<sup>56</sup> or (3) authorizes trained responders to administer naloxone “if they believe[] someone [i]s experiencing a drug overdose.”<sup>57</sup> Furthermore, all of these forty-seven states have passed some form of a Good Samaritan law that grants either reduced liability or complete “immunity to individuals who summon emergency aid in the event of an overdose.”<sup>58</sup>

The FDA has employed its regulatory authority to authorize abuse-deterrent opioids,<sup>59</sup> medications that prevent OUD,<sup>60</sup> and drugs that reverse overdoses.<sup>61</sup> Furthermore, the FDA has had an important role (either on its own or with other agencies) researching the effects of opioid use and educating the public about substance abuse problems.<sup>62</sup> These treatment measures are complemented by reactive measures that focus on penalizing wrongful actions rather than assisting addicted persons.

## 2. Criminal Prosecutions

State and federal governments criminally prosecute any party responsible for facilitating the opioid epidemic—whether it be street dealers, doctors, or huge pharmaceutical companies.<sup>63</sup> Although the federal government and most states have chosen to view opioid addiction as an illness by focusing more on addiction treatment, some states are reinvigorating a “tough on crime” approach to deter drug dealers. Kentucky, for example, has recently increased penalties for heroin trafficking,<sup>64</sup> and Florida has enacted a law that

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persons other than the person to whom they are to be administered (a process referred to as third-party prescription) or to a person the physician has not personally examined.” Davis & Carr, *supra* note 46, at 29. By 2016, however, almost all states had modified their laws to “improve layperson naloxone access.” *Id.* at 30.

53. *Id.* at 30–32.

54. *Id.* at 33.

55. *Id.* at 30–32.

56. *Id.* at 31.

57. Daniel Rees et al., *With a Little Help from My Friends: The Effects of Naloxone Access and Good Samaritan Laws on Opioid-Related Deaths*, 78 RES. BRIEFS ECON. POL’Y, June 2017, at 1, 1.

58. Davis & Carr, *supra* note 46, at 33.

59. See *FDA Opioid Timeline*, *supra* note 25 (noting that on July 23, 2014, the FDA approved Targiniq ER, an abuse-deterrent, extended-release pain reliever). In 2013, the FDA went beyond its role of authorization and actually assisted the opioid industry in creating new abuse-deterrent opioids. *Id.*

60. The FDA “has approved three medications for the treatment of OUD: methadone, buprenorphine, and naltrexone.” Davis & Carr, *supra* note 46, at 13.

61. *Id.* at 28.

62. See *FDA Opioid Timeline*, *supra* note 25.

63. See DRUG ENF’T AGENCY, *supra* note 6, at 28–40.

64. KY. REV. STAT. ch. 218A (2018).

charges drug dealers with murder if their customers overdose on opioids.<sup>65</sup> The DEA takes a similar “tough on crime” approach. In 2001, it initiated a plan to “investigate and prosecute doctors for improper prescribing of OxyContin.”<sup>66</sup> Federal prosecutors have used a variety of liability theories to sue physicians, ranging from unlawful distribution of controlled substances resulting in death<sup>67</sup> to money laundering.<sup>68</sup> From 1998 to 2006, there were a total of 986 lawsuits against physicians “involving the prescribing of opioid analgesics.”<sup>69</sup> About 80 percent of the physicians “pled guilty or no contest to at least one of the criminal charges brought against them.”<sup>70</sup>

Prosecutors also target pharmacists who illegally distribute prescription opioids. Of particular interest are internet “e-pharmacies” that have the ability to dispense millions of prescription pills and evade regulatory mechanisms implemented by states.<sup>71</sup> *United States v. Tobin*<sup>72</sup> featured an attack on one such internet pharmacy, Jive Network, which connected consumers to doctors who spent under ten seconds reviewing orders and filled thousands of prescriptions without hesitation.<sup>73</sup> The DEA also collaborates with federal prosecutors to bring cases against opioid manufacturers and distributors. In 2002, the U.S. Attorney for the Western District of Virginia began a criminal investigation focused on Purdue’s misbranding of OxyContin.<sup>74</sup> The investigation culminated in a guilty plea by Purdue Frederick Company, Inc., the manufacturer of OxyContin at the time. Purdue and three of its top executives were forced to pay “more than \$600 million to federal and state agencies.”<sup>75</sup> Civil lawsuits filed by

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65. FLA. STAT. § 782.04(1)(a)(3) (2018).

66. Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L. REV. 1117, 1157–58 (2014).

67. See, e.g., *United States v. Ignasiak*, 667 F.3d 1217, 1228–29 (11th Cir. 2012); *United States v. McIver*, 470 F.3d 550, 556 (4th Cir. 2006); *United States v. Hurwitz*, 459 F.3d 463, 475 (4th Cir. 2006); *United States v. Williams*, 445 F.3d 1302, 1308 (11th Cir. 2006).

68. See, e.g., *United States v. Alerre*, 430 F.3d 681, 688 (4th Cir. 2005); *United States v. Valdivieso Rodriguez*, 532 F. Supp. 2d 316, 321–22 (D.P.R. 2007).

69. Donald M. Goldenbaum et al., *Physicians Charged with Opioid Analgesic-Prescribing Offenses*, 9 PAIN MED. 737, 741–43 (2008).

70. *Id.*

71. Some critics argue that “e-pharmacies” render doctor shopping irrelevant by giving opioid addicts a quick and easy method to obtain illicit prescription medications. See Cadwell, *supra* note 39, at 107–16.

72. 676 F.3d 1264 (11th Cir. 2012).

73. *Id.* at 1271.

74. Purdue had engaged in deceptive sales techniques: training their sales representatives “to make false representations to health care providers” and claiming that OxyContin was difficult to abuse, less addictive and less euphoric than other opioids, lacked withdrawal symptoms, and provided “fewer peaks and valleys” than other opioids. Paul D. Frederickson, *Criminal Marketing: Corporate and Managerial Liability in the Prescription Drug Industry*, 22 MIDWEST L.J. 115, 137 (2008). All these assertions were false. *Id.*

75. *Id.* at 115. “After their pleas, the Department of Health and Human Services barred the three [Purdue executives] for 20 years from doing business with Medicare or other taxpayer-financed health care program[s].” Barry Meier, *Ruling Is Upheld Against Executives Tied to Oxycontin*, N.Y. TIMES (Dec. 15, 2010), <http://www.nytimes.com/2010/12/16/business/16purdue.html> [<https://perma.cc/BN8R-2BMM>].

individuals and class actions were a great help to DEA officials; information gathered during those early lawsuits was utilized to convict the opioid companies.<sup>76</sup>

Whereas criminal actions against opioid *manufacturers* are focused on alleged misrepresentations and deceptive marketing, criminal actions against opioid *distributors* are focused on a lack of oversight and violations of the Controlled Substances Act. The DEA penalizes those distributors that fail to adhere to the regulations set forth in the CSA.<sup>77</sup> For example, in 2007, the DEA issued an immediate suspension order (ISO) and fined Cardinal Health \$34 million for failing to prevent (or notify the DEA) of its hydrocodone distribution to illegitimate internet pharmacies.<sup>78</sup>

### 3. Civil Lawsuits

In addition to criminal prosecutions, there have been many civil lawsuits filed against opioid companies by governments seeking to recover damages resulting from the opioid epidemic. Although the viability of the tort theories has not been tested in court, the rise in settlement figures over the years indicates the growing success of such lawsuits.<sup>79</sup> In 2004, Purdue settled with West Virginia for a small sum of \$10 million.<sup>80</sup> West Virginia was required to use the proceeds from settlement to fund programs that further educate doctors, encourage drug prevention, or facilitate drug rehabilitation.<sup>81</sup>

This settlement motivated twenty-six other states to bring suit in 2007, which culminated with a \$19.5 million settlement in the states' favor.<sup>82</sup> In addition, the settlement required Purdue to (1) "market and promote

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76. "Then, as Hanly [a prominent lawyer that lead civil trials against Purdue Pharma] tells it, the Justice Department caught wind of the civil litigation and asked if he would help with a budding criminal investigation into Purdue. Hanly was happy to assist." Andrew Joseph, *A Veteran New York Litigator Is Taking on Opioid Makers: They Have a History*, STAT NEWS (Oct. 10, 2017), <https://www.statnews.com/2017/10/10/opioid-lawsuits-paul-hanly/> [<https://perma.cc/TA35-BA8L>].

77. See *supra* notes 30–33 and accompanying text.

78. "In December 2007, DEA issued an ISO at the location as a result of its distribution of hydrocodone to 'rogue' internet pharmacies. That action, and similar actions at other Cardinal Health facilities across the United States, resulted in a \$34 million fine." Press Release, Drug Enf't Admin., DEA Suspends for Two Years Pharmaceutical Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility (May 15, 2012), <https://www.dea.gov/pubs/pressrel/pr051512.html> [<https://perma.cc/ANE3-5VN2>].

79. See Ausness, *supra* note 66, at 1149.

80. Christopher R. Page, Comment, *These Statements Have Not Been Approved by the FDA: Improving the Postapproval Regulation of Prescription Drugs*, 88 OR. L. REV. 1189, 1205 (2009).

81. See Frederickson, *supra* note 74, at 134.

82. The states were permitted to allocate their share of the \$19.5 million as they each saw fit. John O'Brien, *Purdue Pharma Settles Multi-State Marketing Claim*, LEGAL NEWS LINE (May 8, 2007), <http://legalnewsline.com/stories/510518258-purdue-pharma-settles-multi-state-marketing-claim> [<https://perma.cc/HVZ7-7GAC>]; see Press Release, Wash. State Office of the Att'y Gen., Washington to Receive Share of \$19.5 Million Settlement with OxyContin Maker (May 8, 2007), <http://www.atg.wa.gov/news/news-releases/washington-receive-share-195-million-settlement-oxycontin-maker> [<https://perma.cc/ZYQ6-CQ8W>].

OxyContin in a manner consistent with its package insert and not in a manner that minimizes the approved uses for the drug”; (2) refrain from “market[ing] or promot[ing OxyContin] for off-label uses”;<sup>83</sup> (3) ensure that any person or entity receiving funding from Purdue disclose the source of that funding; (4) refrain from “sponsoring or funding any educational events” if the speaker recommends off-label uses of OxyContin; (5) refrain from paying bonuses to salespersons that are contingent upon the volume of OxyContin sold; and (6) “make sure that prescriber education about OxyContin and its potential for abuse and diversion is a component of the evaluations of Purdue sales representatives.”<sup>84</sup>

Also in 2007, the state of Kentucky and the government of Pike County, Kentucky, sued Purdue Pharma for alleged misrepresentations regarding the highly addictive nature of OxyContin.<sup>85</sup> Pike County alone settled with Purdue for \$4 million in 2013.<sup>86</sup> The state of Kentucky settled with Purdue for \$24 million in 2015—\$13.5 million more than Purdue’s offer to the state in 2007.<sup>87</sup> Around the time that Pike County settled with the opioid manufacturer, California began its litigation against Purdue Pharma. California joined other manufacturers of prescription opioids besides Purdue and alleged damages resulting from negligent and deceptive marketing in the form of downplaying the risks of opioid painkillers.<sup>88</sup> One of the named defendants in the lawsuit, Teva Pharmaceutical Industries,<sup>89</sup> settled its claims in 2017 by agreeing to pay \$1.6 million.<sup>90</sup>

Government entities have also targeted distributors of prescription opioids. In 2012, West Virginia’s Attorney General (AG) sued Cardinal Health and AmerisourceBergen (two of the three leading distributors of prescription opioids in America)<sup>91</sup> for their failure to monitor suspicious orders, which

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83. Off-label uses are “those purposes beyond the FDA-approved indications and uses of the drug.” Press Release, Ill. Att’y Gen., Attorney General Madigan Reaches Agreement with Pharmaceutical Company over Its Promotion of Pain Reliever OxyContin (May 8, 2007), [http://www.illinoisattorneygeneral.gov/pressroom/2007\\_05/20070508.html](http://www.illinoisattorneygeneral.gov/pressroom/2007_05/20070508.html) [<http://perma.cc/D52A-RVBH>].

84. *Id.*

85. Ausness, *supra* note 66, at 1149–50.

86. *Id.* at 1156.

87. Verdict and Settlement Summary, *Commonwealth v. Purdue Pharma*, No. 07-CI-01303 (Ky. Cir. Ct. Dec. 22, 2015), 2015 WL 10458550; *see also Kentucky Settles Lawsuit with OxyContin Maker for \$24 Million*, CBS NEWS (Dec. 23, 2015, 5:11 PM), <https://www.cbsnews.com/news/kentucky-settles-lawsuit-with-oxycontin-maker-for-24-million/> [<https://perma.cc/MDR4-3PS2>].

88. *See* Complaint for Violations of California False Advertising Law, California Unfair Competition Law, and Public Nuisance, Seeking Restitution, Civil Penalties, Abatement, and Injunctive Relief, *California v. Purdue Pharma L.P.*, No. 8:14-CV-1080-JLS DFM, 2014 WL 6065907 (C.D. Cal. Nov. 12, 2014), ECF No. 1-1.

89. Teva manufactures, sells, and distributes the prescription opioids Actiq and Fentora. *Id.* at 8.

90. Nate Raymond, *Teva to Pay \$1.6 Million to Resolve California Counties’ Opioid Case*, REUTERS (May 25, 2017, 5:09 PM), <https://www.reuters.com/article/health-teva/teva-to-pay-1-6-million-to-resolve-california-counties-opioid-case-idUSL1N1R1W3> [<https://perma.cc/U72S-GFJV>].

91. McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Drug Corporation are considered the “Big 3” of opioid distribution, “dominat[ing] 85 percent of the

facilitated the operation of pill mills throughout the state.<sup>92</sup> West Virginia sued for violations of the West Virginia Uniform Controlled Substances Act, the West Virginia Consumer Credit and Protection Act, and the West Virginia Antitrust Act; the state also asserted public nuisance and negligence claims.<sup>93</sup> In 2016, both Cardinal Health and AmerisourceBergen settled with West Virginia for \$36 million.<sup>94</sup>

That same year, Cardinal Health entered into yet another huge settlement. This time Cardinal settled to “resolv[e] the outstanding civil penalty portion of the company’s 2012 administrative settlement with the U.S. Drug Enforcement Agency.”<sup>95</sup> The \$44 million settlement was made with the federal prosecutors in the Middle District of Florida, the Southern District of New York, the District of Maryland, and the Western District of Washington.<sup>96</sup> Cardinal’s New York distribution center, for example, failed to report more than twenty highly suspicious orders to the DEA.<sup>97</sup> The next year, another distributor of opioid analgesics, Mallinckrodt Pharmaceuticals, entered into a similar settlement for its failure to report suspicious orders of oxycodone products. Mallinckrodt reached a \$35 million settlement with the DEA, the Eastern District of Michigan, and the Northern District of New

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market share for the distribution of prescription opioids.” Complaint at 5, *City of Birmingham v. AmerisourceBergen Drug Corp.*, No. 2:17-CV-01360-JEO (N.D. Ala. Aug. 14, 2017), ECF No. 1; *see also* Adam J. Fein, *2016 MDM Market Leaders: Top Pharmaceutical Distributors*, MDM, <http://www.mdm.com/2016-top-pharmaceuticals-distributors> [<http://perma.cc/CV2B-PT4W>] (last visited Nov. 15, 2018) (“Three companies account for about 85 percent to 90 percent of all revenues from drug distribution in the United States: AmerisourceBergen Corporation (NYSE:ABC), Cardinal Health, Inc. (NYSE:CAH) and McKesson Corporation (NYSE:MCK).”).

92. *See* Complaint at 7–8, *West Virginia ex rel. Morrissey v. Cardinal Health, Inc.*, No. A212-CV-3836, 2013 WL 1305647 (S.D.W. Va. Mar. 27, 2013), ECF No. 1-1.

93. *See id.* at 8–22.

94. *See* Charles Ornstein, *Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic*, NPR (Jan. 27, 2017, 5:00 AM), <http://www.npr.org/sections/health-shots/2017/01/27/511858862/drug-distributors-penalized-for-turning-blind-eye-in-opioid-epidemic> [<https://perma.cc/QD2U-NLGR>] (“That’s on top of another \$20 million that Cardinal Health agreed this month to pay the state of West Virginia, which has been among the hardest hit by opioid overdoses. Other distributors have also agreed to pay smaller amounts to West Virginia within the past few months. AmerisourceBergen, for instance, will pay \$16 million.”); Press Release, Cardinal Health, *Cardinal Health Reaches Settlement with West Virginia* (Jan. 9, 2017), <http://ir.cardinalhealth.com/news/press-release-details/2017/Cardinal-Health-Reaches-Settlement-With-West-Virginia/default.aspx> [<https://perma.cc/R4Y6-DFYH>] (“Under the terms of the settlement, Cardinal Health has agreed to pay \$20 million to the State of West Virginia to resolve these issues, and the State has released the company from any further actions.”).

95. Press Release, Cardinal Health, *Cardinal Health Announces Civil Settlement with DOJ* (Dec. 23, 2016), <http://ir.cardinalhealth.com/news/press-release-details/2016/CARDINAL-HEALTH-ANNOUNCES-CIVIL-SETTLEMENT-WITH-DOJ/default.aspx> [<https://perma.cc/25QP-3DZW>].

96. *Id.*

97. Press Release, U.S. Dep’t of Justice, *Manhattan U.S. Attorney Announces \$10 Million Civil Penalty Recovery Against New York Pharmaceutical Distributor Kinray, Llc.* (Dec. 23, 2016), <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-10-million-civil-penalty-recovery-against-new-york> [<https://perma.cc/4TDJ-Y23F>].

York.<sup>98</sup> The “groundbreaking” aspect of this settlement was that it prospectively required Mallinckrodt to utilize its discounting system<sup>99</sup> as a monitoring device for suspicious orders.<sup>100</sup>

Recently, there has been an explosion of lawsuits by government entities targeting opioid companies for their role in the opioid epidemic.<sup>101</sup> In Kentucky alone, twenty-four counties have sued opioid-industry defendants, alleging harms caused by the three major opioid distributors in the country: Amerisource, Cardinal Health, and McKesson.<sup>102</sup> The sheer number of claims prompted calls for multidistrict litigation,<sup>103</sup> which led to a consolidation of over one hundred opioid lawsuits.<sup>104</sup> These civil actions target a broad range of parties: opioid distributors,<sup>105</sup> opioid manufacturers,<sup>106</sup> pharmacies,<sup>107</sup> state pharmacy boards,<sup>108</sup> and physicians.<sup>109</sup> Overall, however, the focus seems to be on the companies that

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98. Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders> [https://perma.cc/VK6L-HWZU].

99. Many manufacturers, including Mallinckrodt, offer discounts or “chargebacks” to their downstream consumers who purchase the most oxycodone. *Id.* As part of Mallinckrodt’s settlement, the company was required to use its existing chargeback system “to monitor and report to DEA suspicious sales of oxycodone.” *Id.*

100. *Id.*

101. *See, e.g.*, Complaint, Fiscal Court v. AmerisourceBergen Drug Corp., No. 4:17-CV-00120-JMH-HBB (W.D. Ky. Sept. 13, 2017), ECF No. 1 [hereinafter Union County Complaint]; Complaint, Illinois v. AmerisourceBergen Drug Corp., No. 3:17-cv-00876 (S.D. Ill. Aug. 17, 2017), ECF No. 1 [hereinafter Illinois Complaint]; Complaint, City of Birmingham v. AmerisourceBergen Drug Corp., No. 2:17-CV-01360-JEO (N.D. Ala. Aug. 14, 2017), ECF No. 1; Complaint, County of San Joaquin v. Purdue Pharma, L.P., No. 2:17-CV-01485-MCE-GGH (E.D. Cal. July 17, 2017), ECF No. 1 [hereinafter San Joaquin Complaint]; Complaint, Kanawha Cty. Comm’n v. Rite Aid of Md., Inc., No. 2:17-CV-01666 (S.D.W. Va. Mar. 9, 2017), ECF No. 1 [hereinafter Kanawha County Complaint]; Complaint, City of Everett v. Purdue Pharma, L.P., No. 2:17-CV-00209-RSM (W.D. Wash. Feb. 10, 2017), ECF No. 1-1 [Everett Complaint].

102. *See* Brief in Support of Plaintiffs’ Motion for Transfer of Actions Pursuant to 28 U.S.C. § 1407 for Coordinated or Consolidated Pretrial Proceedings at 20, *In re Nat’l Prescription Opiate Litig.*, 290 F. Supp. 3d 1375 (J.P.M.L. 2017), ECF No. 1-1 [hereinafter MDL Brief]; Complaint, Fiscal Court v. AmerisourceBergen Drug Corp., No. 1:17-OP-45031-DAP (E.D. Ky. Sep. 20, 2017), ECF No. 1; Complaint, Fiscal Court v. AmerisourceBergen Drug Corp., No. 3:17-CV-557-TBR (W.D. Ky. Sept. 13, 2017), ECF No. 1; Union County Complaint, *supra* note 101.

103. MDL Brief, *supra* note 102, at 20; Sara Randazzo, *Washington State Joins Legal Challenges over Opioids*, WALL ST. J. (Sept. 28, 2017, 2:40 PM), <https://www.wsj.com/articles/washington-state-joins-legal-challenges-over-opioids-1506624009> [https://perma.cc/4GU4-5D9M].

104. *See infra* note 323 and accompanying text.

105. *See infra* note 323 and accompanying text.

106. *See* Complaint, City of Parma v. Purdue Pharma L.P., No. 1:17-CV-1872 (N.D. Ohio Aug. 9, 2017), ECF No. 1 [hereinafter Parma Complaint].

107. *See* Kanawha County Complaint, *supra* note 101.

108. *See* Complaint, Cty. Comm’n v. W. Va. Bd. of Pharmacy, No. 2:17-CV-3366 (S.D.W. Va. June 22, 2017), ECF No. 1-1.

109. *See* Parma Complaint, *supra* note 106.

are profiting the most from opioid addiction—the manufacturers and distributors of prescription opioids.

State AGs have sued firearm, lead paint, automobile, and tobacco companies in the past using similar tactics. The lawsuits against the tobacco industry led to the “largest legal settlement in United States history”<sup>110</sup>—a settlement with an actual value of over \$210 billion between forty-six states and six tobacco manufacturers (known as the “Master Settlement Agreement”).<sup>111</sup> But even compared to the tobacco litigation, the current opioid litigation is unparalleled. Whereas in the tobacco litigation only states and a few government subdivisions sued tobacco companies,<sup>112</sup> in the opioid litigation, there is a “profusion of county and municipal plaintiffs.”<sup>113</sup> There is also a larger and more diverse group of defendants in the current opioid litigation than in the tobacco litigation. The tobacco litigation involved only six major manufacturers whereas the opioid litigation involves “at least 20 opioid manufacturers and 13 distributors” as well as local pharmacies, physicians, and pharmacy boards.<sup>114</sup> Perhaps the most interesting aspect of the opioid litigation, however, is the fact that so many claims are focused on direct injury to the government’s interests rather than the interests of citizens or consumers.

## II. DIRECT-INJURY GOVERNMENT-ENTITY LAWSUITS IN THE CONTEXT OF THE OPIOID EPIDEMIC

Government-entity lawsuits against opioid companies are reactive responses that seek to recover damages incurred from the opioid epidemic. These lawsuits employ a wide variety of liability theories that take the form of either *parens patriae* claims on behalf of the citizenry or direct-injury claims on behalf of the government itself. The lawsuits generally target opioid manufacturers for alleged misrepresentations during advertisement<sup>115</sup> or opioid distributors for an alleged failure to monitor illicit distribution.<sup>116</sup> Most importantly, these lawsuits have the potential to avoid the pitfalls of other forms of civil litigation.

### A. *What Is a Direct-Injury Claim?*

When initiated by a party other than the government, a direct-injury claim is simple: a plaintiff’s personal interests (e.g., health or property) have been

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110. Ryan D. Dreveskracht, *Forfeiting Federalism: The Faustian Pact with Big Tobacco*, 18 RICH. J.L. & PUB. INT. 291, 292 (2015).

111. Gregory W. Traylor, Note, *Big Tobacco, Medicaid-Covered Smokers, and the Substance of the Master Settlement Agreement*, 63 VAND. L. REV. 1081, 1085 (2010).

112. There were “only a few governmental subdivisions [that] sued [tobacco companies] when their state attorneys general refused to join the litigation.” Richard Scruggs, *Are Opioids the New Tobacco?*, LAW360 (Sept. 15, 2017, 11:04 AM), <https://www.law360.com/articles/962715> [<https://perma.cc/7JSX-WCRT>].

113. *Id.*

114. *Id.*

115. See *infra* notes 132–33 and accompanying text.

116. See *infra* notes 133–36 and accompanying text.

injured by a third party and the plaintiff seeks to recover damages flowing from that injury. In the context of government-entity lawsuits, however, the distinction between direct-injury claims and *parens patriae* claims has caused undue confusion.<sup>117</sup> Both of these terms relate to the damages asserted by the plaintiff and describe whether the damages are asserted on behalf of the citizens (*parens patriae*) or on behalf of the government itself (direct injury).

*Parens patriae* directly translates to “parent of the nation,” and the name is derived from the king’s duty “‘to take care of his subjects as are legally unable’ to care for themselves . . . including children and those afflicted by mental infirmity, as well as the oversight of charitable trusts.”<sup>118</sup> The modern American *parens patriae* claim can be asserted by cities, counties, and states but is not limited to “children and those afflicted by mental infirmity.”<sup>119</sup> *Parens patriae* standing cannot be invoked by cities or counties because they are not considered sovereigns;<sup>120</sup> municipalities must pair their *parens patriae* claims with direct-injury claims to satisfy standing requirements. To assert a *parens patriae* claim, the government entity must prove that it is “more than a nominal party” in the suit—meaning that the government must prove injury to its own interests and not just the interests of a small group of citizens.<sup>121</sup> There must be an injury to a “quasi-sovereign” interest of the state: “an interest apart from the interests of particular private parties,” which involves either a wide-sweeping injury to “the health and well-being—both physical and economic—of its residents in general” or a violation of the state’s right to “not be[] discriminatorily denied its rightful status within the federal system.”<sup>122</sup>

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117. This complex distinction has led even federal judges to confuse the two types of claims. See *Texas v. Am. Tobacco Co.*, 14 F. Supp. 2d 956, 962–63 (E.D. Tex. 1997) (evaluating standing for a direct-injury claim by the state of Texas under the quasi-sovereign interest test as if the claim was *parens patriae*); Jack Ratliff, *Parens Patriae: An Overview*, 74 TUL. L. REV. 1847, 1853 n.39 (2000) (“It is not entirely clear to me why the *parens* doctrine was important in [*Texas v. American Tobacco Co.*], as it was brought by the State of Texas for its own damages.”).

118. Margaret S. Thomas, *Parens Patriae and the States’ Historic Police Power*, 69 SMU L. REV. 759, 769 (2016) (quoting JOSEPH CHITTY, A TREATISE ON THE LAW OF THE PREROGATIVES OF THE CROWN AND THE RELATIVE DUTIES AND RIGHTS OF THE SUBJECT 155 (1820)). The “Universal Sovereignty Theory” involves the belief that the American *parens patriae* doctrine is derived directly from the old king’s authority. See *id.* at 769–84. Although some prominent American *parens patriae* cases claim roots in the Universal Sovereignty Theory, the *parens patriae* doctrine invoked by government entities today originates from an American doctrine that echoes similar themes to the king’s notion of *parens patriae* but lacks direct relation. See *id.*

119. *Id.* at 769. In fact, the first American *parens patriae* case involved government entities suing on behalf of charities that lacked an appointed guardian. See generally *Vidal v. Girard’s Ex’rs*, 43 U.S. (2 How.) 127 (1844).

120. Kathleen C. Engel, *Do Cities Have Standing? Redressing the Externalities of Predatory Lending*, 38 CONN. L. REV. 355, 368 & n.54 (2006).

121. *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 607 (1982).

122. *Id.*

*Parens patriae* claims are distinct from direct-injury claims, where the government asserts injury to itself. In *Massachusetts v. EPA*,<sup>123</sup> a *parens patriae* lawsuit against the Environmental Protection Agency (EPA) for its failure to properly regulate greenhouse gases, the U.S. Supreme Court made clear that “a claim of *parens patriae* standing is distinct from an allegation of direct injury.”<sup>124</sup> When the state itself has been injured by tortious conduct, there is no need to assert a *parens patriae* claim because the state “can directly vindicate its interests as fully as any other litigant.”<sup>125</sup>

In the case of the opioid litigation, it is easy to imagine every claim as being both *parens patriae* and direct injury. If the government entity alleges damages to its treasury (due to, for example, medical costs and infrastructure costs expended upon opioid addicts) or lost tax revenue due to lost productivity from addiction,<sup>126</sup> then there is quite clearly injury to the state’s proprietary interests.<sup>127</sup> That same government entity can easily reword its argument to make a *parens patriae* assertion. For example, the government can argue that large numbers of consumers have been tricked by opioid manufacturers’ claims or that its citizens are endangered by the prevalence of opioid addiction across communities and allege injury to “the health and well-being—both physical and economic—of its residents in general,” thereby establishing a viable *parens patriae* claim.<sup>128</sup> For this reason, many states and counties assert both direct-injury and *parens patriae* claims (or *parens patriae* standing) in the ongoing opioid litigation.<sup>129</sup> One could view direct-injury claims as a worse, better, or equivalent substitute for *parens patriae* claims when battling opioid companies. Direct-injury claims in the

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123. 549 U.S. 497 (2007).

124. *Id.* at 538; *see also* *Wyoming v. Oklahoma*, 502 U.S. 437, 448–51 (1992).

125. Richard P. Ieyoub & Theodore Eisenberg, *State Attorney General Actions, the Tobacco Litigation, and the Doctrine of Parens Patriae*, 74 TUL. L. REV. 1859, 1882 (2000).

126. Many of the nuisance claims brought by government entities allege damages based on law enforcement and health services expenditures. *See, e.g.*, Union County Complaint, *supra* note 101; Complaint, Hocking Cty. Bd. of Comm’rs v. AmerisourceBergen Drug Corp., No. 2:17-CV-00769-GCS-KAJ (S.D. Ohio Aug. 31, 2017), ECF No. 1; Illinois Complaint, *supra* note 101.

127. *See* 15 MOORE’S FEDERAL PRACTICE § 101.60(4)(b)–(c) (Daniel R. Coquillette et al. eds., 3d ed. 2018) (distinguishing direct injury to a state’s propriety interests from *parens patriae* injury to quasi-sovereign interests).

128. *See* *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 607 (1982).

129. *See, e.g.*, Illinois Complaint, *supra* note 101 (asserting “recovery for [the state’s] own harm” throughout the complaint but also claiming *parens patriae* standing); San Joaquin Complaint, *supra* note 101 (asserting damages to the state’s proprietary interests and then incorporating all of its claims on behalf of its citizens through *parens patriae*); Complaint at 14, *City of Dayton v. Purdue Pharma, L.P.*, No. 3:17-CV-00229-TMR (S.D. Ohio July 10, 2017), ECF No. 3 [hereinafter *Dayton Complaint*] (“Plaintiff brings this action on its own behalf *and also as a subrogee of its employees and residents . . .*” (emphasis added)). In *Staubus v. Purdue Pharma, L.P.*, the attorneys general for three judicial districts of Tennessee asserted direct injury to the government entities’ interests but also brought a creative *parens patriae* claim on behalf of all the babies in those districts who were born addicted to opioids as a result of manufacturers’ allegedly negligent marketing. Complaint, *Staubus v. Purdue Pharma, L.P.*, No. 2:17-CV-00122 (E.D. Tenn. July 27, 2017), ECF No. 1-1.

context of the opioid epidemic come in two forms: false or misleading advertising claims and failure to monitor claims.

*B. Different Types of Direct-Injury Lawsuits*

Direct-injury government-entity lawsuits against opioid manufacturers and distributors employ a variety of liability theories and can be categorized into two types of claims, based on the defendant's identity and allegedly tortious conduct. The first type of claim is generally made against manufacturers for misleading marketing.<sup>130</sup> The second type of claim is generally made against distributors for a failure to monitor suspicious orders.<sup>131</sup> Some lawsuits include both types of claims in their complaint.<sup>132</sup>

For both types of claims, the government asserts that the defendants performed a wrongful act and that, as a result, the plaintiff (the government itself) suffered damages. The distinguishing features between each type of claim is the asserted act and the set of named defendants. For the first type of claim, the wrongful conduct is the misrepresentation that occurs when defendants disseminate false or misleading information regarding the risks or benefits of prescription opioids.<sup>133</sup> Thus, these claims target the companies responsible for marketing and advertising prescription opioids, usually prescription opioid manufacturers such as Purdue Pharma, Teva, Cephalon, Inc., Johnson & Johnson, and Janssen Pharmaceuticals, Inc.<sup>134</sup> For the second type of claim, the wrongful conduct is an alleged failure to monitor, otherwise known as "diversion," which "charg[es] that the defendants breached duties to secure the distribution chain from diversion of large quantities of opioid-containing prescription drugs to criminals."<sup>135</sup> The "diversion theory was not used in the tobacco litigation and seems to be unique to the opioid cases."<sup>136</sup> These claims target the parties responsible

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130. See, e.g., Dayton Complaint, *supra* note 129, at 79–197; Original Petition at 12–20, Oklahoma *ex rel.* Hunter v. Purdue Pharma L.P., No. CJ-2017-816 (Okla. Dist. Ct. June 30, 2017) [hereinafter Oklahoma Complaint]; Verified Complaint at 80–203, County of Nassau v. Purdue Pharma L.P., No. 605477/2017 (N.Y. Sup. Ct. June 12, 2017), NYSCEF No. 2 [hereinafter Nassau County Complaint].

131. See, e.g., Union County Complaint, *supra* note 101, at 18–26; Illinois Complaint, *supra* note 101, at 11–28; Complaint at 19–42, City of Portsmouth v. AmerisourceBergen Drug Corp., No. 2:17-CV-00723 (S.D. Ohio Aug. 16, 2017), ECF No. 1 [Portsmouth Complaint].

132. See Complaint, County of Wayne v. Purdue Pharma L.P., No. 2:17-CV-13334-JCO-EAS (E.D. Mich. Oct. 12, 2017), ECF No. 1.

133. See, e.g., Dayton Complaint, *supra* note 129, at 79–197; Oklahoma Complaint, *supra* note 130, at 12–20; Nassau County Complaint, *supra* note 130, at 80–203.

134. See, e.g., Dayton Complaint, *supra* note 129, at 14–29; Oklahoma Complaint, *supra* note 130, at 4–6; Nassau County Complaint, *supra* note 130, at 14–29.

135. Scruggs, *supra* note 112; see, e.g., Union County Complaint, *supra* note 101, at 18–26; Illinois Complaint, *supra* note 101, at 11–28; Portsmouth Complaint, *supra* note 131, at 19–42.

136. Scruggs, *supra* note 112.

for maintaining a closed distribution chain: usually<sup>137</sup> the “Big 3” opioid distributors.<sup>138</sup>

Besides alleging that an inequitable act (either misrepresentation or diversion) caused direct injury to the plaintiff’s interests, the plaintiffs employ either a tort-based theory or equitable theory to complete the direct-injury claim. On the one hand, tort-based theories urge the court to award damages in favor of the plaintiff by establishing that the defendants had a duty of care toward the plaintiff and that they breached that duty of care through their wrongful conduct. On the other hand, non-tort-based equitable theories overlook duties of care and “do not hinge on fault, but rather on who should pay when the public is damaged by the conduct of a legal business.”<sup>139</sup> For example, when the state of Illinois sued opioid distributors for diversion, they used four tort-based theories and one equitable theory.<sup>140</sup> The tort theories established a duty of care based upon the following statutes: the federal Racketeer-Influenced and Corrupt Organizations (RICO) Act; Illinois’s Narcotics Profit Forfeiture Act, which is very similar to the federal RICO statute; Illinois’s Consumer Fraud and Deceptive Business Practices Act; and the Uniform Deceptive Trade Practices Act (adopted by Illinois and other states across the country).<sup>141</sup> The sole equitable theory was based upon the common-law concept of public nuisance.<sup>142</sup> Richard Scruggs, a prominent lawyer during the tobacco litigation, argues that non-fault-based equity claims are strongest for government plaintiffs because they “enable the states to say ‘so what’ to the industry’s defensive claims that the FDA preemptively regulated opioids and that their addiction warning labels were ipso facto sufficient.”<sup>143</sup> Other scholars argue that the objective legal strength of government-entity claims does not matter because their collective strength will drive defendants toward settlement.<sup>144</sup> This Note suggests that the government is willing to make arguably dubious direct-injury claims because their other options are bleak.

### C. *The Challenges for Opioid Plaintiffs in Other Forms of Civil Litigation*

The first lawsuits against opioid companies were brought by addicted individuals or their families and were directed at Purdue Pharma, the company responsible for creating and marketing OxyContin. By 2003, Purdue faced over 300 such lawsuits and had spent “tens of millions of

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137. In some rare cases, cities make allegations of diversion solely against manufacturers. See Everett Complaint, *supra* note 101.

138. See *supra* note 91.

139. Scruggs, *supra* note 112.

140. Illinois Complaint, *supra* note 101, at 44–78.

141. *Id.*

142. *Id.* at 44–53.

143. Scruggs, *supra* note 112.

144. See Richard L. Cupp, Jr., *State Medical Reimbursement Lawsuits After Tobacco: Is the Domino Effect for Lead Paint Manufacturers and Others Fair Game?*, 27 PEPP. L. REV. 685, 687–90 (2000). Rather than focus on the strength or specifics of particular liability theories, this Note focuses on the general role of direct-injury claims as they relate to other forms of civil litigation.

dollars in legal fees maintaining an aggressive no settlement stance.”<sup>145</sup> The individual and class action lawsuits continued to grow in numbers over the next several years. It is contested whether these lawsuits were “successful” or “failed” attempts<sup>146</sup> because, while Purdue won most of the cases at the summary judgment stage,<sup>147</sup> information gathered through these lawsuits was the driving factor behind the criminal prosecution of Purdue in 2007.<sup>148</sup>

It is also difficult to gauge the success of the individual lawsuits because so many were settled before courts made any judgment on the substantive claims. In 2006, two firms that represented around “5,000 claimants reportedly settled their cases . . . for a total of \$75 million.”<sup>149</sup> In 2007, Purdue made another series of big settlements: two in July totaling \$40 million, a mass settlement of 1000 lawsuits in February for \$75 million,<sup>150</sup> and many of the remaining 370 lawsuits during the criminal prosecution for \$130 million.<sup>151</sup> Regardless of whether these lawsuits are labeled as successes or failures, there are multiple obstacles that both individual and class action lawsuits will face in the future.

### 1. Blameworthy Victims in Opioid Litigation

When individual addicts (or their families) sue large pharmaceutical companies, regardless of the type of liability theory they use, they are hindered by two features: blameworthiness and an unequal balance of resources. The blameworthiness of the plaintiff (or decedent) in individual lawsuits has allowed opioid defendants to assert the following defenses: product misuse,<sup>152</sup> wrongful conduct,<sup>153</sup> and contributory or comparative negligence.<sup>154</sup> Individual victims simply cannot escape the fact that their blameworthy behavior has contributed to their own addiction and makes them less deserving of relief from opioid companies.

#### *a. Product Misuse*

One form of blameworthy opioid-addict behavior is the misuse of prescription opioids, which involves a disregard for product labels or unorthodox methods of drug ingestion. A product-manufacturer defendant may assert the product-misuse defense whenever an alleged injury to the plaintiff is the result of “abnormal handling, abnormal preparation for use, or

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145. Frederickson, *supra* note 74, at 134.

146. See STEVEN GARBER, ECONOMIC EFFECTS OF PRODUCT LIABILITY AND OTHER LITIGATION INVOLVING THE SAFETY AND EFFECTIVENESS OF PHARMACEUTICALS 27, 38 n.29 (2013).

147. Ausness, *supra* note 66, at 1122.

148. See Joseph, *supra* note 76.

149. GARBER, *supra* note 146, at 38 n.29.

150. *Id.*

151. See United States v. Purdue Frederick Co., 495 F. Supp. 2d 569, 572 (W.D. Va. 2007).

152. See Labzda v. Purdue Pharma, L.P., 292 F. Supp. 2d 1346, 1356 (S.D. Fla. 2003).

153. See Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693, 704 (E.D. Ky. 2003).

154. See *infra* notes 194–205 and accompanying text.

abnormal consumption of the product” at issue.<sup>155</sup> The exact definition of product misuse has varied across jurisdictions, but the Model Uniform Product Liability Act states that misuse occurs whenever “the product user does not act in a manner that would be expected of an ordinary reasonably prudent person who is likely to use the product in the same or similar circumstances.”<sup>156</sup>

Different courts have held that product misuse is synonymous with unintended, unforeseeable, unanticipated, or unexpected uses of a product.<sup>157</sup> Depending on the jurisdiction, misuse is interpreted either as a part of the defendant’s burden of proof (an affirmative defense) or a part of the plaintiff’s burden of proof (effectively negating an essential element of the plaintiff’s case).<sup>158</sup> For example, in *Sherk v. Daisy-Heddon*,<sup>159</sup> fourteen-year-old Robert Saenz shot his friend James Sherk using a Daisy-Heddon BB gun.<sup>160</sup> The families of Sherk and Saenz brought an action against the manufacturer, asserting that Daisy-Heddon failed to warn its consumers that their pump-up BB rifle was more powerful than others.<sup>161</sup> The issue was that Saenz shot Sherk in the head from close range, despite his knowledge that BBs fired from close range “could kill animals and blind a person.”<sup>162</sup> The Supreme Court of Pennsylvania applied the second interpretation of product misuse, found that Saenz’s misuse of the product negated the element of proximate cause, and dismissed the case.<sup>163</sup>

For individual lawsuits against opioid companies, the second interpretation of product misuse is similarly detrimental to a plaintiff’s case. *Labzda v. Purdue Pharma*,<sup>164</sup> a wrongful death claim brought by the family of an opioid addict who died of an overdose, illustrates this point. Labzda’s family asserted that Purdue was aware of their son’s doctor overprescribing OxyContin but “did not attempt to curtail the inappropriate prescriptions,” which was “a breach of the duty of care in the marketing and distribution of the product.”<sup>165</sup> The court dismissed the case because, on the night of his death, in addition to consuming two 80-milligram tablets of OxyContin, Labzda smoked marijuana, drank a substantial quantity of alcohol,<sup>166</sup> “and took approximately three tablets of the strongest strength of Xanax.”<sup>167</sup> Moreover, he chose to crush and inhale his OxyContin pills rather than ingest

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155. Annotation, *Product Misuse Defense*, 65 A.L.R. 4th 263 § 2[a] (1988).

156. Model Uniform Product Liability Act, 44 Fed. Reg. 62,714, 62,737 (Oct. 31, 1979).

157. Annotation, *supra* note 155, pt. VII.

158. Alfred W. Gans et al., Annotation, *Misuse, Abuse or Abnormal Use of Product*, 6 Am. L. Torts § 18:158 (2017).

159. 450 A.2d 615 (Pa. 1982).

160. *Id.* at 618.

161. *Id.* at 616.

162. *Id.* at 618.

163. *Id.* at 618–20.

164. 292 F. Supp. 2d 1346 (S.D. Fla. 2003).

165. *Id.* at 1349.

166. “Michael drank approximately 14 beers (eight of them after 1:00 a.m.), shared approximately five marijuana cigarettes, drank a shot of rum, drank at least two rum and Cokes . . .” *Id.* at 1350.

167. *Id.*

them orally as instructed.<sup>168</sup> The case was dismissed at the summary judgment stage as the court found that the patient's "intentional misuse of an intoxicating product [OxyContin] [wa]s the sole proximate cause of the injury."<sup>169</sup>

The court in *Labzda* made clear that, like the Pennsylvania court in *Sherk*, "Florida courts routinely apply the doctrine of sole proximate cause when the user intentionally misuses a product to his detriment."<sup>170</sup> *Labzda* had misused OxyContin despite being aware that crushing, snorting, and mixing alcohol with the pills was dangerous.<sup>171</sup> Thus, *Labzda* had destroyed any chances for recovery because his misuse of the product was considered the sole cause of injury under the laws of the state. The court argued that, like alcohol distributors, opioid manufacturers cannot be held liable for a plaintiff's injuries if the plaintiff voluntarily misused their product.<sup>172</sup>

### b. The Wrongful Conduct Rule

Another obstacle for lawsuits by individuals arises whenever an individual plaintiff engages in unlawful or wrongful conduct.<sup>173</sup> As a general rule, a plaintiff "cannot maintain an action if he or she must rely, in whole or in part, on an illegal or immoral act or transaction to which he or she is a party in order to establish a cause of action."<sup>174</sup> The "wrongful conduct" or "serious misconduct" rule is a way to completely bar a plaintiff's claim and avoid even partial damages through comparative fault.<sup>175</sup> This ancient doctrine derives from Lord Mansfield's proclamation in *Holman v. Johnson*,<sup>176</sup> "*ex dolo malo non oritur actio*," meaning "no Court will lend its aid to a man who founds his cause of action upon an immoral or an illegal act."<sup>177</sup> The wrongful conduct rule has been resurrected in the U.S. common-law system under limited circumstances as a method to effectively "short-circuit" a plaintiff's claim.<sup>178</sup>

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168. *Id.*

169. *Id.* at 1356.

170. *Id.*

171. The package insert for OxyContin clearly stated, in bold letters, that "TABLETS ARE TO BE SWALLOWED WHOLE, AND ARE NOT TO BE BROKEN, CHEWED OR CRUSHED. TAKING BROKEN CHEWED OR CRUSHED OxyContin TABLETS COULD LEAD TO THE RAPID RELEASE AND ABSORPTION OF A POTENTIALLY TOXIC DOSE OF OXYCODONE . . . . AVOID ALCOHOL while you are using this medicine." *Id.* at 1349–50.

172. "[F]oreseeable voluntary abuse of a non-defective product, such as alcohol, results in the legal conclusion that the proximate cause of the injury to the consumer was his voluntary abuse; the manufacturer of the substance is not liable for the injury to the user." *Id.* at 1356.

173. See Lauren Rosseau & I. Eric Nordan, Tug v. Mingo: *Let the Plaintiffs Sue—Opioid Addiction, the Wrongful Conduct Rule, and the Culpability Exception*, 34 T.M. COOLEY L. REV. 33, 52–60 (2017).

174. 1A C.J.S. *Actions* § 68 (2017).

175. Joseph H. King, Jr., *Outlaws and Outlier Doctrines: The Serious Misconduct Bar in Tort Law*, 43 WM. & MARY L. REV. 1011, 1017 (2002).

176. (1775) 1 Cowper 341 (KB).

177. *Id.* at 343.

178. See King, *supra* note 175, at 1017.

One of those limited circumstances has involved personal injury claims by prescription medication addicts and their families. In *Orzel v. Scott Drug Co.*,<sup>179</sup> a “drug user’s claim against [a] pharmacy for allegedly negligently and illegally filling [the] drug user’s purportedly valid prescriptions was barred since it was based, at least in part, on [the] drug user’s illegal conduct.”<sup>180</sup> The court in *Orzel* explained the rationale behind the wrongful conduct rule: (1) if courts made relief available for wrongdoers, they would be condoning illegal conduct; (2) courts must foreclose any possibility of wrongdoers profiting from or being compensated for their illegal acts; and (3) “related to the two previously mentioned results, the public would [otherwise] view the legal system as a mockery of justice.”<sup>181</sup>

*Foister v. Purdue Pharma, L.P.*<sup>182</sup> is another illustration of the wrongful conduct rule and involves the specific issue of opioid addiction rather than drug addiction in general.<sup>183</sup> In *Foister*, seven plaintiffs sued Purdue for failing to properly warn its consumers of OxyContin’s addictiveness.<sup>184</sup> All but one plaintiff illegally altered his or her prescription pills before ingesting them.<sup>185</sup> In order to satisfy their opioid cravings, some plaintiffs would crush their pills and snort them, and some intravenously injected up to eight pills a day.<sup>186</sup> The court held that the plaintiffs’ illegal alteration of the pills constituted wrongful conduct and was the proximate cause of their injuries.<sup>187</sup> The court justified its decision by citing the public policy concerns from *Orzel*.<sup>188</sup>

Other cases have reached similar results to *Foister* and involved much more sympathetic plaintiffs. In *Price v. Purdue Pharma Co.*,<sup>189</sup> the plaintiff’s opioid addiction began when doctors prescribed him OxyContin to treat “his sickle cell anemia and related pain.”<sup>190</sup> There was no evidence of illegal alteration of prescription pills, but there was evidence of doctor-

179. 537 N.W.2d 208 (Mich. 1995).

180. *Id.* at 208.

181. *Id.* at 213.

182. 295 F. Supp. 2d 693 (E.D. Ky. 2003).

183. *See id.* at 693–709.

184. *Id.* at 696–701. It is noteworthy that the plaintiffs in this case were far from sympathetic; one of them “had an extensive criminal history which included malicious wounding of a police officer, assault, criminal mischief, terroristic threatening, conspiracy to possess, sale [sic] and deliver cocaine, possession of cocaine, possession of drug paraphernalia, unlawful taking, contributing to the delinquency of a minor, criminal trespassing” and many other convictions. *Id.* at 700–01.

185. *See id.* at 703.

186. One plaintiff had a particularly complicated method for abusing prescription pills. *Id.* at 697. In his own words, he would

lick the coating off of [the OxyContin], bust them off, buy a bottle of water and pour it in a cap, and . . . just draw up seven units of water and throw on it, take it back to the rig and work it up, and take a piece of cotton off the filter and put it on the needle and filter it, draw it up and hit it.

*Id.*

187. *Id.* at 704.

188. *Id.*

189. 920 So. 2d 479 (Miss. 2006).

190. *Id.* at 482.

shopping<sup>191</sup> to satisfy his opioid cravings; Price traveled to three different cities, visited seven different pharmacies, attended ten different clinics, and consulted with ten different physicians to obtain as many prescription medications as possible.<sup>192</sup> Although much more sympathetic than the plaintiffs in *Foister*, Price had similarly engaged in illegal conduct to further his opioid addiction. Invoking Lord Mansfield's maxim from *Holman v. Johnson*, the Mississippi court barred the plaintiff's claim entirely.<sup>193</sup>

*c. Contributory and Comparative Negligence*

Even if a wrongful-conduct or product-misuse defense by opioid companies is rejected, there remains a potential obstacle for opioid addicts and their families when suing opioid manufacturers and distributors: contributory or comparative negligence. Although opioid lawsuits have not reached the question of contributory negligence because none have reached the jury-deliberation stage, it is highly likely that this issue will arise in future lawsuits and thus influence the likelihood of a successful settlement. The Second Restatement of Torts describes contributory and comparative negligence as “conduct on the part of the plaintiff which falls below the standard to which he should conform for his own protection, and which is a legally contributing cause co-operating with the negligence of the defendant in bringing about the plaintiff's harm.”<sup>194</sup> An opioid addict's decision to misuse drugs or ignore warning labels, for example, is likely to fit within the definition of contributory or comparative negligence. Contingent upon the law a state follows and the plaintiff's level of negligence, an opioid addict's negligent conduct may either bar her claim entirely or reduce the amount of damages she receives.<sup>195</sup>

Alabama, Maryland, North Carolina, Virginia, and the District of Columbia all follow a strict contributory negligence regime that makes it likely that an opioid addict's negligent behavior will completely bar her claim.<sup>196</sup> In those five jurisdictions, “a plaintiff's recovery is *completely barred* when the plaintiff's negligence contributes *in any degree* to the cause of the injury.”<sup>197</sup> Thus, if the plaintiffs in *Foister* or *Price* brought their action in an Alabama court, they would almost certainly be barred from recovery under the contributory negligence rule because their improper conduct in obtaining or ingesting prescription pills fell below the standard of

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191. *See supra* notes 38–39 and accompanying text.

192. *Price*, 920 So. 2d at 482.

193. *Id.* at 484–86.

194. RESTATEMENT (SECOND) OF TORTS § 463 (AM. LAW INST. 1966).

195. *See* 9 LOUIS R. FRUMER & MELVIN I. FRIEDMAN, PERSONAL INJURY: ACTIONS, DEFENSES, DAMAGES § 43.22 (2017).

196. *See id.*

197. *Id.* (emphasis added).

a reasonable person and contributed to some degree to their opioid addiction.<sup>198</sup>

The majority of states, however, have abandoned the contributory negligence doctrine. Most states instead follow a “modified comparative negligence” regime that will only bar a plaintiff’s claim if the plaintiff’s negligence was more than 50 percent responsible for the alleged injury.<sup>199</sup> The rest of the jurisdictions in America follow a “pure comparative negligence” regime, “allow[ing] a contributorily negligent plaintiff to recover damages . . . even when the plaintiff is 99 percent culpable.”<sup>200</sup> However, even in the pure comparative negligence jurisdictions, when the plaintiff’s negligence is 100 percent responsible or “the sole proximate cause of the loss or injury,” the plaintiff’s claim will be barred.<sup>201</sup> For example, in *Horton v. American Tobacco Co.*,<sup>202</sup> a decedent’s family sued a cigarette manufacturer under a negligence and strict liability theory.<sup>203</sup> The jury “returned a verdict . . . in favor of the plaintiffs but awarded zero damages” because it found his decision to continue smoking despite warnings of health dangers 100 percent responsible or the sole proximate cause of his cancer.<sup>204</sup>

Thus, if an opioid addict’s negligent conduct in obtaining or ingesting prescription pills is found to be more than 50 percent responsible for their addiction and the subsequent harm, the plaintiff’s claim will be completely barred in the states that follow a modified comparative negligence or contributory negligence regime. In the other jurisdictions, the plaintiff’s claim will be completely barred if the jury finds they are 100 percent responsible for their addiction and the subsequent harm. It is yet to be seen whether opioid addicts will reach the 50 percent or 100 percent threshold,<sup>205</sup> but it is likely that jurors will bar their claims as they have for tobacco smokers.

## 2. Why Aggregate Actions Are Useful for Opioid Victims

Another possible issue for individual victims (or even small groups of victims) concerns unequal resource allocation and a negative value of return for plaintiffs. A negative-value claim arises whenever the cost of a lawsuit

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198. The court in *Foister* repeatedly emphasizes the illegality of the plaintiff’s conduct and notes that their addictions were “dilemma[s] which they [themselves] created.” *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693, 705 (E.D. Ky. 2003).

199. Ten states follow a “not as great as” modified comparative negligence regime and require that the negligence of a defendant exceed 50 percent for the plaintiff to recover. *See* 9 FRUMER & FRIEDMAN, *supra* note 195, § 43.22. Twenty-one states adhere to a “not greater than” modified comparative negligence regime where a plaintiff’s claim will be barred if their negligence was more than 50 percent responsible for the alleged injury. *Id.*

200. *Id.*

201. *Id.*

202. 667 So. 2d 1289 (Miss. 1995).

203. *See id.* at 1290.

204. *Id.* at 1291–92.

205. The author’s research for this Note could not identify a single opioid claim that reached jury verdict. The question of contributory and comparative negligence as applied to opioid claims remains to be addressed.

exceeds the amount at stake, thus disincentivizing a single individual from bringing forth the claim.<sup>206</sup> Many opioid addicts have such negative-value claims. Purdue Pharma, along with other pharmaceutical companies, is known to take an aggressive stance toward litigation and resolutely defends against every possible claim.<sup>207</sup> This makes the cost of pursuing litigation very high for plaintiffs, and even if the asserted damages are high, an uncertainty of success<sup>208</sup> will convert it into a negative-value claim. Most victims will resort to contingency fee agreements, and plaintiffs' lawyers find it preferable for addicts to pool resources and split the risks of litigation through aggregation. There are two types of aggregate lawsuits that could achieve that goal: joinder actions and representative actions.

The joinder action is a permissive method to combine multiple plaintiffs or defendants in the interest of convenience and to avoid "duplicate presentation of evidence relating to facts common to more than one demand for relief."<sup>209</sup> Joinder is beneficial because it allows for the efficient resolution of similar claims and only binds parties to the suit. The downside is that courts rarely allow massive joinder and are particularly adverse to massive joinder arising from the use of the same pharmaceutical product.<sup>210</sup> Injured parties who hope to aggregate identical claims of injury from the same pharmaceutical product are forced to turn to representative actions.

The most popular form of representative action is the class action, but other examples include *parens patriae* actions and qui tam litigation. Class actions allow thousands of injured persons to "achieve economies of time and effort."<sup>211</sup> The ability to aggregate claims and resources with other addicts is key to redressing their harms. Unfortunately, class actions have "fallen into disfavor as a means of resolving mass tort claims arising from personal injuries."<sup>212</sup> There are problems with the other forms of representative actions as well.

### 3. Aggregation Challenges in Opioid Litigation

Although representative actions are extremely beneficial to opioid addict plaintiffs, each form of representative action faces major difficulties when applied to prescription-opioid mass tort liability. *Parens patriae* actions are

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206. See *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 809 (1985) ("Class actions . . . may permit the plaintiffs to pool claims which would be uneconomical to litigate individually.").

207. Purdue did not enter into a single settlement related to opioid addiction until it had spent "an estimated \$250 million in sustained defensive efforts." Frederickson, *supra* note 74, at 134.

208. See *infra* notes 146–47 and accompanying text.

209. 7 CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 1652 (3d ed. 2001).

210. See PRINCIPLES OF THE LAW OF AGGREGATE LITIGATION § 1.02 cmt. b(1)(A) (AM. LAW INST. 2010).

211. *Buford v. Am. Fin. Co.*, 333 F. Supp. 1243, 1250 (N.D. Ga. 1971).

212. PRINCIPLES OF THE LAW OF AGGREGATE LITIGATION § 1.02 reporter's note cmt. b(1)(A) (AM. LAW INST. 2010).

inapplicable in the context of mass tort product liability, *qui tam* litigation<sup>213</sup> has been wholly ineffective against opioid defendants, and class actions face great difficulty obtaining class certification. Moreover, when analyzed as a whole, all three types of representative action can potentially produce inequitable results by binding nonparties to judgments.

*a. Parens Patriae Actions Are Inapplicable  
to Mass Tort Product Liability*

The Supreme Court has never granted *parens patriae* standing for a mass tort product liability claim. It is unlikely to do so in the future despite both the steady expansion of America's *parens patriae* doctrine and opioid companies' failure to challenge the doctrine.<sup>214</sup> In every Supreme Court case<sup>215</sup> where state governments have asserted *parens patriae* standing, "the harms suffered by the original (individual) victims were causally connected to their residency within a particular state . . . and not another jurisdiction."<sup>216</sup> By contrast, in the context of mass tort product liability actions, "the state of residence and the harm sustained are independent variables."<sup>217</sup> Unlike the typical *parens patriae* claim where the injury asserted is unique to residence within a particular state, a mass tort product liability claim against opioid manufacturers has no relation to one's state of residence because the opioid epidemic is ravaging the entire nation and not just a single state.<sup>218</sup>

Moreover, mass product liability cases are unlikely to fit within the one exception to the general rule: *Massachusetts v. EPA*. In that case, the state of Massachusetts (along with local governments and environmental organizations) sought to review the denial of a rulemaking petition by the

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213. See *infra* Part II.C.3.b.

214. *Parens patriae* standing was contested in the course of the tobacco litigation, but the court never addressed it and focused on other grounds for finding that the plaintiffs lacked standing. See *City & County of San Francisco v. Philip Morris, Inc.*, 957 F. Supp. 1130, 1142 (N.D. Cal. 1997) (dismissing claims for lack of standing because the harms asserted by San Francisco were too far removed from a tobacco manufacturer's misconduct); *City of Chicago v. Am. Cyanamid Co.*, 823 N.E.2d 126, 133–36 (Ill. App. Ct. 2005) (dismissing the claims of the City of Chicago for lack of standing due to failure to demonstrate causation).

215. There is one exception: *Massachusetts v. EPA*, 549 U.S. 497 (2007). See *infra* notes 219–24 and accompanying text.

216. DONALD G. GIFFORD, *SUING THE TOBACCO AND LEAD PIGMENT INDUSTRIES: GOVERNMENT LITIGATION AS PUBLIC HEALTH PRESCRIPTION* 126 (2010); see also, e.g., *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 600 (1982) (addressing *parens patriae* in the context of a farmer's decree that affected only Puerto Rican workers); *Georgia v. Pa. R.R.*, 324 U.S. 439, 443–44 (1945) (determining that a railroad company's price-fixing adversely affected Georgia citizens); *Missouri v. Illinois*, 180 U.S. 208, 248 (1901) (involving efforts by Missouri to stop the construction of a canal that would funnel 1500 tons of Chicago's trash to Missouri); *Louisiana v. Texas*, 176 U.S. 1, 16–17 (1900) (involving Texas's embargo on all goods from New Orleans to stop the spread of yellow fever).

217. GIFFORD, *supra* note 216, at 126.

218. See *supra* Introduction.

EPA that would have regulated motor vehicle emissions.<sup>219</sup> The Court determined that Massachusetts had *parens patriae* standing despite the fact that greenhouse gases affect everyone throughout the country (and throughout the world) because the state lost its power to regulate environmental threats when the federal government transferred that authority to the EPA.<sup>220</sup> This exception adheres to the general purpose of *parens patriae* claims: a method for states “to protect the general welfare—where they ha[ve] no other constitutional means of doing so.”<sup>221</sup>

Mass tort claims do not fit within the *Massachusetts v. EPA* exception nor do they align with the general rationale behind *parens patriae* standing. Although one could argue that the opioid epidemic qualifies as an “environmental harm”<sup>222</sup> similar to the greenhouse gases at issue in *Massachusetts v. EPA*, there are differences between the two cases that preclude *parens patriae* standing. First off, in the opioid litigation, the states are not suing the entities to whom they transferred regulatory powers (the FDA or the DEA) for their inability to properly monitor the opioid industry; they are suing the manufacturers directly. Secondly, government entities have plenty of other constitutional means available to them to address opioid addiction, and indeed they have pursued those other means.<sup>223</sup> Civil litigation is merely another method for the states to recover lost funds.

#### *b. Qui Tam Litigation: Rare and Ineffective*

Qui tam litigation is another form of representative action that is difficult to initiate because it requires the assistance of a “whistleblower.” Furthermore, in the one instance it has been used against opioid companies it was wholly ineffectual. In 1863, the government passed the False Claims Act, which gave rise to what are known as “qui tam” lawsuits, where a private party (usually a “whistleblower” exposing illegal activity from within a corporation) sues on behalf of themselves and the government.<sup>224</sup> Qui tam lawsuits became very popular<sup>225</sup> once the False Claims Act was amended to increase recovery amounts so relators could recover up to 30 percent of the proceeds and full recovery of their attorney’s fees.<sup>226</sup> Qui tam lawsuits have been a particularly useful tool against drug companies; according to the Assistant Attorney General, whistleblowers sued “over 200 drug manufacturers” in 2004.<sup>227</sup>

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219. *Massachusetts v. EPA*, 549 U.S. 497, 505 (2007).

220. See GIFFORD, *supra* note 216, at 126–27.

221. Thomas, *supra* note 118, at 791.

222. See GIFFORD, *supra* note 216, at 127.

223. See *supra* Part I.

224. Frederickson, *supra* note 74, at 123.

225. There were over four hundred qui tam lawsuits in 2004. Edward P. Lansdale, Note, *Used as Directed?: How Prosecutors Are Expanding the False Claims Act to Police Pharmaceutical Off-Label Marketing*, 41 NEW ENG. L. REV. 159, 176 (2006).

226. 31 U.S.C. § 3730(d)(1)–(2) (2012).

227. Jonathan K. Henderson & Quintin Cassidy, *Drug Deals in 2006: Cutting Edge and Regulatory Issues in the Pharmaceutical Industry*, 15 ANNALS HEALTH L. 107, 109 (2006).

Although qui tam lawsuits have led to many victories for the U.S. government against drug companies in general,<sup>228</sup> these lawsuits have been quite unsuccessful against opioid companies specifically. For one, qui tam lawsuits require the assistance of a “whistleblower,” someone willing to release secrets about their employer and initiate lengthy litigation. Mark Radcliffe is the only “whistleblower” to have fought the opioid industry; he targeted Purdue Pharma and failed repeatedly.<sup>229</sup> At first, Radcliffe sued on behalf of himself and the U.S. government, alleging that his former employer, Purdue Pharma, had “misrepresented to physicians the relative potency of Purdue’s pain medication, OxyContin, which resulted in federal and state agencies, such as Medicaid, paying more than was necessary in reimbursement.”<sup>230</sup> At the district court level, his complaint was dismissed because it failed to reach the high pleading standards of Rule 9(b) of the Federal Rules of Civil Procedure.<sup>231</sup> At the appellate level, the court dismissed his complaint on separate grounds: Radcliffe had apparently signed a release when leaving Purdue that “in exchange for a considerable sum of money and other benefits” discharged Purdue of “all liability.”<sup>232</sup> About two years after Radcliffe’s claims were dismissed, his wife resurrected his claims and initiated her own qui tam litigation with almost identical claims to her husband’s.<sup>233</sup> She failed at both the district<sup>234</sup> and appellate level, just like her husband.<sup>235</sup>

*c. The Difficulty of Class Certification in Opioid Litigation*

Class actions, although more successful than qui tam lawsuits, face major difficulties during the certification stage. To be certified as a class action, the prospective class must meet the requirements set forth in Rule 23.<sup>236</sup> First, the plaintiff must satisfy all four of Rule 23(a)’s requirements: (1) numerosity of class members, (2) commonality of legal or factual questions, (3) typicality of claims and defenses of the class representative, and (4) adequacy of class representation.<sup>237</sup> In addition to meeting the Rule

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228. See Erika Kelton, *Revival of Gilead Whistleblower’s Lawsuit Should Stoke Fear in Big Pharma*, FORBES (Sept. 26, 2017, 4:29 PM), <https://www.forbes.com/sites/erikakelton/2017/09/26/revival-of-gilead-whistleblowers-lawsuit-should-stoke-fear-in-big-pharma> [<https://perma.cc/4CAD-8D9E>] (discussing successful qui tam lawsuits by the U.S. government against Big Pharma companies).

229. See *United States ex rel. May v. Purdue Pharma L.P.*, No. 5:10-CV-01423, 2012 WL 4056720 (S.D.W. Va. Sept. 14, 2012), *vacated and remanded*, 737 F.3d 908 (4th Cir. 2013); *United States ex rel. Radcliffe v. Purdue Pharma L.P.*, 582 F. Supp. 2d 766 (W.D. Va. 2008), *rev’d in part*, 600 F.3d 319 (4th Cir. 2010).

230. *United States ex rel. Radcliffe v. Purdue Pharma L.P.*, No. 1:05CV00089, 2009 WL 161003, at \*2 (W.D. Va. Jan 25, 2009), *aff’d on other grounds*, 600 F.3d 319 (4th Cir. 2010).

231. *Id.* Rule 9(b) requires that “a party must state with particularity the circumstances constituting fraud or mistake.” FED. R. CIV. P. 9(b).

232. *United States ex rel. Radcliffe*, 600 F.3d at 326.

233. *United States ex rel. May*, 2012 WL 4056720, at \*1.

234. *Id.* at \*8.

235. *United States ex rel. May v. Purdue Pharma L.P.*, 811 F.3d 636, 643 (4th Cir. 2016).

236. FED. R. CIV. P. 23.

237. *Id.* r. 23(a).

23(a) prerequisites, the plaintiff must fit into one of the categories set forth in Rule 23(b).<sup>238</sup> Many courts dismiss class actions against opioid companies for failure to satisfy Rule 23(a) and thus do not discuss Rule 23(b).<sup>239</sup>

For example, in *Campbell v. Purdue Pharma*,<sup>240</sup> two plaintiffs hoped to represent a class of Missouri residents who suffered harm as a result of being “prescribed and consum[ing] OxyContin for the treatment of any condition other than moderate to severe pain caused by terminal illness or moderate to severe pain caused by non-chronic condition.”<sup>241</sup> For the 23(a)(1) numerosity requirement, the plaintiff was required to establish a “reasonable estimate” of the number of prospective class members.<sup>242</sup> The plaintiff’s estimate that there would be “thousands of persons in the Class” was considered unreasonable.<sup>243</sup> Alternatively, the plaintiffs tried to prove numerosity by using the national sales data of OxyContin, noting that “in 2002, there were approximately 6.2 million OxyContin[] prescriptions for noncancer pain.”<sup>244</sup> In this particular case, the court accepted national sales data as sufficient evidence to establish numerosity.<sup>245</sup> But in another case, *Gevedon v. Purdue Pharma*,<sup>246</sup> the court held that information of “sales volume alone will not justify a finding of numerosity.”<sup>247</sup>

*Gevedon* is an interesting case because it also shows how difficult it is for opioid class actions to satisfy the 23(a)(2) requirement for commonality. The plaintiffs in *Gevedon* sought to certify a class of Kentucky residents “who have obtained OxyContin and/or who obtain OxyC[o]ntin in the future” in order to bring a product liability action against Purdue Pharma.<sup>248</sup> Judge Danny Reeves denied class certification because determinations of liability were reliant upon individualized questions of fact.<sup>249</sup> Judge Reeves had ruled the same way in the earlier case of *Foister v. Purdue Pharma, L.P.* when plaintiffs sought to certify a broader class of “all persons who have been harmed due to the addictive nature of OxyContin.”<sup>250</sup> The court held that cause-in-fact determinations were highly specialized and that individual inquiries were required to determine whether “dosage, use and manner of administration of the drug, individual and family medical and psychological histories, [or] level of personal awareness regarding the purported risks and medical reasons for use” were the actual causes of injury.<sup>251</sup> In the Southern

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238. *Id.* r. 23(b).

239. *See* Ausness, *supra* note 66, at 1137–44.

240. No. 1:02-CV-00163TCM, 2004 WL 5840206 (E.D. Mo. June 25, 2004).

241. *Id.* at \*1.

242. *Id.* at \*4.

243. *Id.*

244. *Id.*

245. *Id.* at \*11.

246. 212 F.R.D. 333 (E.D. Ky. 2002).

247. *Id.* at 338.

248. *Id.* at 336.

249. *Id.* at 336–37.

250. No. Civ. A. 01–268–DCR, 2002 WL 1008608, at \*1 (E.D. Ky. Feb. 26, 2002) (emphasis added).

251. *Id.* at \*8.

District of Ohio and in the Eastern District of Missouri, when dealing with fact patterns similar to *Foister*, courts have denied certification on similar grounds.<sup>252</sup>

Even the 23(a)(3) typicality requirement has created difficulties for class certification. The Missouri court in *Campbell* explained that, to pass typicality, the named plaintiff must “have the same essential characteristics as the claims of the class at large and is designed to prevent an instance where the legal theories of the named plaintiff may potentially conflict with those of absent plaintiffs.”<sup>253</sup> There were two named plaintiffs in *Campbell*, David and Belinda Campbell, who each took varied doses of OxyContin<sup>254</sup> and simultaneously ingested OxyContin with other drugs such as Xanax, Vioxx, and Zoloft.<sup>255</sup> Both of these factors would influence a finding of causation and open a range of conduct-based defenses that may conflict with the theories of the general class.<sup>256</sup> These essential factors “preclude[d] a finding that their claims are typical of the class.”<sup>257</sup> It is very difficult to create a class of opioid defendants large enough to fulfill numerosity and similar enough to pass typicality and commonality. Moreover, even if a class of addicts or consumers is somehow certified, class actions are problematic because they foreclose the possibility of future lawsuits.

#### d. Potential to Bind Nonparties to Judgment

In addition to their individualized problems, all traditional representative actions have the potential to bind nonparties to the judgment, which produces potentially inequitable results for future plaintiffs. All the traditional representative actions (class action, *qui tam*, *parens patriae*) are distinguished from other forms of aggregate lawsuits in that they have the potential to bind nonparties.<sup>258</sup> It is intuitive that a class action would bind nonparties because the named plaintiff is acting as a representative for similarly situated parties. In the case of *parens patriae* lawsuits, however, it is harder to imagine why the government has the ability to bind nonparties when it is representing the general welfare rather than a particular group of injured citizens.<sup>259</sup> Nevertheless, courts find that nonparties are bound to the judgment entered against a *parens patriae* representative just as they would

252. See *Campbell v. Purdue Pharma, L.P.*, No. 1:02-CV-00163 TCM, 2004 WL 5840206, at \*11 (E.D. Mo. June 25, 2004); *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 597 (S.D. Ohio 2003) (denying class certification because individualized inquiries such as product misuse “would trigger further individualized inquiries unique to those class members who abuse the drug”); *Wethington v. Purdue Pharma LP*, 218 F.R.D. 577, 581 (S.D. Ohio 2003).

253. *Campbell*, 2004 WL 5840206, at \*8 (quoting *Dhamer v. Bristol-Myers Squibb Co.*, 183 F.R.D. 520, 526 (N.D. Ill. 1998)).

254. David Campbell had filled 436 prescriptions and his wife Belinda filled 247. *Id.* at \*8–9.

255. *Id.*

256. *Id.* at \*9.

257. *Id.*

258. See PRINCIPLES OF THE LAW OF AGGREGATE LITIGATION § 1.02 reporter’s note cmt. b(1)(A) (AM. LAW INST. 2010).

259. See *supra* notes 121–22 and accompanying text.

be for a class action representative.<sup>260</sup> If a class action or *parens patriae* representative sues an opioid company, they may be foreclosing all future actions against those parties. Direct-injury claims would be preferable to other forms of civil litigation if they can function as representative actions without foreclosing future litigation by residents and citizens.

### III. DIRECT-INJURY GOVERNMENT CLAIMS AS A SOLUTION TO THE CHALLENGES OF OPIOID CIVIL LITIGATION

Direct-injury government-entity claims circumvent the obstacles that have hindered other forms of litigation against opioid companies. First of all, government plaintiffs foreclose conduct-based defenses previously available to opioid defendants<sup>261</sup> because the local governments are blameless in the context of the opioid epidemic. Second, unlike *parens patriae* actions,<sup>262</sup> direct-injury government-entity claims are definitively applicable in the context of mass tort product liability. In addition, direct-injury government-entity claims are inherently representative actions, allowing for the aggregation of interests without any certification requirement and with no potential to bind nonparties.<sup>263</sup> Direct-injury government-entity claims also allow for administrative and informal aggregation. Informal aggregation is particularly important in the context of mass tort liability because it incentivizes pharmaceutical defendants to settle early.

#### A. Circumventing Conduct-Based Defenses

Opioid addict plaintiffs and decedents are blameworthy individuals who arguably facilitated their own addictions despite being aware of the dangers.<sup>264</sup> Their illegal conduct, product misuse, or contributory negligence allows opioid companies to introduce conduct-based defenses that have the potential to entirely bar the plaintiffs' claims or diminish damage awards.<sup>265</sup> In contrast to opioid addicts, government entities have not contributed to the opioid epidemic and actually ameliorate opioid addiction through both proactive and reactive measures.<sup>266</sup> Thus, direct-injury government-entity

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260. See, e.g., *City of Tacoma v. Taxpayers of Tacoma*, 357 U.S. 320, 340 (1958) (finding the *parens patriae* judgment against the state binding “not only against the State, but also against its citizens, including the taxpayers of Tacoma, for they, in their common public rights as citizens of the State, were represented by the State in those proceedings, and, like it, were bound by the judgment”); *Wyoming v. Colorado*, 286 U.S. 494, 509 (1932) (binding water claimants in Wyoming and Colorado to the judgments entered against their representative states); *N. Cal. River Watch v. Humboldt Petroleum, Inc.*, 162 F. App’x 760, 764–65 (9th Cir. 2006) (holding that a public-interest group’s lawsuit was precluded because of a previous *parens patriae* action by the state of California).

261. See *supra* Part II.C.2.

262. See *supra* Part II.C.2.

263. This is in contrast to traditional representative actions, which have burdensome class certification requirements and have the potential to foreclose future litigation by similarly situated plaintiffs. See *supra* Part II.C.2.

264. See *supra* Part II.C.2.

265. See *supra* Part II.C.2.

266. See *supra* Part I.

claims circumvent all of the issues related to blameworthiness that encumbered lawsuits by individuals against opioid companies: product misuse, wrongful conduct, and contributory or comparative negligence.<sup>267</sup> Opioid company defendants would, in most cases, fail to establish any of these conduct-based defenses against a government plaintiff.

For one, opioid manufacturers and distributors are not provided with the requisite behavioral evidence if a government plaintiff, rather than individual addict, brings a claim. Whenever an opioid addict or a group of opioid addicts sues an opioid company, they are required to prove causation based on each opioid user's ingestion habits.<sup>268</sup> This requirement reveals blameworthy conduct by the plaintiffs and grants the opioid company defendant the necessary evidence to establish a conduct-based defense.<sup>269</sup> Unlike individual lawsuits, government-entity lawsuits rely upon general statistical data to establish causation and include no information regarding the conduct of particular addicts within their sovereignty.<sup>270</sup> The defendant manufacturer or distributor would have to research behavioral patterns for a huge population of addicts to prove that each addict was improperly ingesting prescription pills. This burden makes it practically impossible for opioid companies to assert any conduct-based defenses such as wrongful conduct, product misuse, or contributory or comparative negligence. Furthermore, even assuming that opioid defendants somehow find proof of widespread misuse or wrongful conduct, it is still unlikely the defenses will hold up in court.

### 1. Product Misuse

Even if the pharmaceutical companies find evidence of rampant prescription pill abuse, government plaintiffs can rebut assertions of product misuse. The product-misuse defense requires the moving party to establish "unintended, unforeseeable, unanticipated, or unexpected" consumption of the product that deviates from the conduct "of an ordinary reasonably prudent person."<sup>271</sup> This burden of proof places opioid defendants in a lose-lose scenario: On the one hand, if an opioid company admits that most addicts responsible for depleting the state budget were using prescription pills as they were intended, then they cannot assert the unintended-use defense. On the other hand, if the opioid companies assert that a majority of addicts responsible for depleting the state coffer *were* misusing their prescription

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267. See *supra* Part II.C.1.a.

268. See *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693, 702–04 (E.D. Ky. 2003); *Labzda v. Purdue Pharma, L.P.*, 292 F. Supp. 2d 1346, 1356 (S.D. Fla. 2003).

269. See *supra* Part II.C.3.a.

270. Similar to when state attorneys general sued tobacco companies, the benefit of a government-entity lawsuit in the context of the opioid epidemic is that it "decouple[s] the states' rights to recover from the expensive, time-consuming requirement of proving causation and damages for each [individual], relying instead on statistical information." Philip C. Patterson & Jennifer M. Philpott, *In Search of a Smoking Gun: A Comparison of Public Entity Tobacco and Gun Litigation*, 66 BROOK. L. REV. 549, 557–58 (2000).

271. See *supra* notes 155–57 and accompanying text.

opioids (either by snorting, crushing, or injecting pills despite warning labels or by combining those pills with other dangerous substances),<sup>272</sup> then it cuts against the argument that crushing, snorting, injecting, and mixing pills is truly an unintended purpose. If opioid companies are aware that a majority of users are crushing, snorting, injecting, and mixing prescription drugs, then that is arguably an intended, foreseeable, anticipated, or expected use of the product. Stated otherwise, if so many consumers are ignoring opioid warnings, then perhaps even the “reasonably prudent” person craves more powerful or immediate releases of opioids after experiencing withdrawal symptoms.<sup>273</sup> Opioid manufacturers face a Catch-22 because the product-misuse defense depends upon a showing of unforeseen circumstances and unreasonable behavior; but the companies cannot prove product misuse without conceding that the allegedly unintended actions were in fact foreseeable, clearly not “unexpected,” and perhaps even “reasonable.”

## 2. Wrongful Conduct

Government entities are also in a unique position to foreclose the possibility of a wrongful or illegal conduct defense. The wrongful conduct defense is only applicable where the plaintiff is the party to misuse the product at issue.<sup>274</sup> Regardless of whether opioid addicts within a government’s sovereignty illegally altered pills<sup>275</sup> or illegally obtained prescriptions,<sup>276</sup> the government itself did not engage in such wrongful conduct. Thus, the wrongful conduct defense will be unsuccessful against a city, county, or state. This makes sense because the rationale from *Orzel*,<sup>277</sup> which courts refer to when invoking the wrongful conduct bar to a plaintiff’s claim,<sup>278</sup> only applies when the plaintiff is a criminal or tortious actor. In fact, government entities actually punish the illegal alteration or purchase of prescription pills,<sup>279</sup> so there is no worry that courts are “in effect . . . condon[ing] and encourag[ing] illegal conduct.”<sup>280</sup> Furthermore, the possibility that wrongdoers will be unjustly enriched by the court’s decision is very low.<sup>281</sup> There is an arguably higher likelihood that a plaintiff’s verdict will go toward increased police enforcement and other infrastructure

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272. See, e.g., *Foister*, 295 F. Supp. 2d at 693–709 (plaintiffs crushed, snorted, and injected OxyContin rather than ingesting the pills as instructed); *Labzda*, 292 F. Supp. 2d at 1350 (decedent crushed his prescribed OxyContin pills, took a higher dose than instructed, and combined OxyContin with other drugs and alcohol).

273. See *supra* note 10 and accompanying text.

274. See *supra* notes 173–75 and accompanying text.

275. See *Foister*, 295 F. Supp. 2d at 703–04.

276. See *supra* note 38; see also *Price v. Purdue Pharma Co.*, 920 So. 2d 479, 482 (Miss. 2006).

277. See *supra* note 180 and accompanying text.

278. See *Foister*, 295 F. Supp. 2d at 704.

279. See *supra* Part I.B.2.

280. *Orzel ex rel. Orzel v. Scott Drug Co.*, 537 N.W.2d 208, 213 (Mich. 1995).

281. See *id.*

improvements designed to stop wrongdoers from “receiv[ing] a profit or compensation as a result of their illegal acts.”<sup>282</sup>

### 3. Contributory and Comparative Negligence

Government entities’ blameless qualities even foreclose opioid companies’ best defense: contributory or comparative negligence. Similar to the medical-cost-reimbursement lawsuits against tobacco companies in the 1990s, perhaps the greatest advantage of direct-injury government-entity lawsuits is their ability to circumvent this defense. In 1994, Mississippi Attorney General Mike Moore filed a lawsuit against tobacco companies seeking to recover Medicaid costs expended by Mississippi as a result of smoking-related illnesses.<sup>283</sup> Fourteen other states followed suit and alleged that they were entitled to recover their share of medical costs that resulted from tobacco companies’ tortious conduct.<sup>284</sup> That litigation bears striking similarities to the ongoing opioid lawsuits: both seek to recover medical costs expended upon the treatment of addictive products and both share similar causes of action (fraudulent misrepresentation, negligence, violation of consumer protection statutes, civil RICO claims, and equity-based claims such as restitution and public nuisance).<sup>285</sup> Most pertinent to the issue of contributory negligence is the fact that both sets of litigation “are not brought on behalf of the injured smokers [or opioid addicts]. Instead they are brought *on behalf of the states themselves* to recover the medical costs they have been forced to pay to care for indigent smokers [or opioid addicts].”<sup>286</sup>

The scholars Phillip Patterson and Jennifer Philpott explained the genius behind the state tobacco litigation as “effectively forestall[ing]” one of the tobacco industry’s best defenses: contributory negligence.<sup>287</sup> The defense of contributory negligence was no longer available to tobacco companies because “the tobacco industry could not plausibly argue that the states . . . contributed to the financial harm caused to them.”<sup>288</sup> Similarly, opioid manufacturers and distributors cannot plausibly argue that government entities contributed to the financial harm caused by the opioid epidemic. Thus, the contributory or comparative negligence defense for opioid companies is essentially foreclosed when the government is the plaintiff.

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282. *Id.*

283. Complaint, Moore *ex rel.* Mississippi v. Am. Tobacco Co., No. 94-1429 (Miss. Ch. May 23, 1994).

284. Graham E. Kelder & Richard A. Daynard, *The Role of Litigation in the Effective Control of the Sale and Use of Tobacco*, 8 STAN. L. & POL’Y REV. 63, 73–75 (1997).

285. *See id.* at 80; *supra* notes 141–42 and accompanying text.

286. Kelder & Daynard, *supra* note 284, at 82 (emphasis added).

287. Patterson & Philpott, *supra* note 270, at 557.

288. *Id.*; *see also* Kelder & Daynard, *supra* note 284, at 82–83 (“The tobacco industry cannot plausibly argue that the states chose to smoke or that they contributed to the financial harm caused to them.”).

*B. An Effective Substitute for Parens Patriae Claims*

In addition to avoiding the challenges that impeded individual lawsuits, direct-injury government claims are an effective substitute for *parens patriae* actions because they are definitively applicable in the context of mass tort product liability. Moreover, they can be asserted by cities and counties as the sole basis for standing whereas *parens patriae* claims cannot.<sup>289</sup>

The Supreme Court has never found *parens patriae* standing in a mass tort product liability action, and it is unlikely that it will.<sup>290</sup> *Parens patriae* is a legitimate basis for standing when government entities have “no other constitutional means” of protecting the general welfare.<sup>291</sup> In order for *parens patriae* to apply, “the harms suffered by the original (individual) victims [must be] causally connected to their residency within a particular states.”<sup>292</sup> The sole exception to this general rule, the only circumstance in which the Supreme Court has found *parens patriae* standing despite the harm suffered being independent of residence within a particular state, is when one government entity sues another government entity to which they have transferred sovereign power.<sup>293</sup> Mass tort claims by government entities do not fit the *parens patriae* doctrine because: (1) government entities have plenty of other constitutional means to address the opioid epidemic besides civil litigation;<sup>294</sup> (2) the opioid epidemic has affected the entire nation and involves an injury disconnected from residence within a particular state;<sup>295</sup> and (3) government entities are suing opioid companies, not federal agencies to whom they have transferred regulatory powers.<sup>296</sup>

Direct-injury lawsuits, unlike *parens patriae* lawsuits, can be brought even when the plaintiff’s alleged injury is disconnected from residence within a particular state or when there are plenty of other constitutional means of addressing a particular problem. Government entities can assert direct-injury claims like any other litigant so long as there is injury to a sovereign or proprietary interest of the state.<sup>297</sup> The loss of tax revenue, for example, qualifies as a direct injury to the state’s proprietary interests.<sup>298</sup> There is definitive national data on productivity lost due to opioid addiction that states may utilize to prove lost tax revenue.<sup>299</sup> So long as states are careful to

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289. Cities and counties must always pair their *parens patriae* claims with a direct-injury claim. See *supra* note 120 and accompanying text. There is no such requirement for direct-injury claims.

290. See Part II.C.

291. Thomas, *supra* note 118, at 791.

292. See GIFFORD, *supra* note 216, at 126.

293. See *supra* notes 219–21 and accompanying text.

294. See *supra* Part I.

295. See *supra* notes 217–18 and accompanying text.

296. See *supra* notes 130–32 and accompanying text.

297. See Ieyoub & Eisenberg, *supra* note 125, at 1882; see also 15 MOORE’S FEDERAL PRACTICE, *supra* note 127, § 101.60(4)(a).

298. See *Wyoming v. Oklahoma*, 502 U.S. 437, 447–50 (1992); *Wyoming v. U.S. Dep’t of Interior*, 674 F.3d 1220, 1234–35 (10th Cir. 2012).

299. See *supra* notes 18–19.

provide specific evidence of lost revenue rather than mere speculation, government plaintiffs will successfully establish standing.<sup>300</sup>

*C. Direct-Injury Government Claims Are Inherently Representative Litigation*

Direct-injury government-entity claims are especially fascinating because they inherently function as representative actions, allowing for the aggregation of interests without any certification requirement and with no potential to bind nonparties. Aggregation is particularly important in the context of the opioid litigation because the costs of litigation may outweigh the projected benefits.<sup>301</sup> Pharmaceutical giants like Purdue Pharma are known to take an aggressive no-settlement stance toward litigation,<sup>302</sup> and the probability of success is uncertain.<sup>303</sup> For these reasons, the ability to pool resources and split the risks of litigation is especially important. Unfortunately, courts are unwilling to allow massive joinder involving the same pharmaceutical product<sup>304</sup> and traditional representative actions such as class actions have great difficulty satisfying Rule 23(a).<sup>305</sup> Direct-injury claims have the ability to effectively aggregate citizen interests while bypassing the obstacles that hindered representative actions.

Furthermore, direct-injury government-entity lawsuits are not subject to traditional aggregation requirements because they do not fit the mold of mass joinder or representative actions. A direct-injury claim is not a joinder action because it does not necessarily join the claims of multiple plaintiffs into one proceeding; it often involves just one plaintiff (a city, municipality, or state).<sup>306</sup> Furthermore, it is not a representative action because the government is suing on behalf of itself, not on behalf of citizens or consumers.<sup>307</sup>

Although direct-injury government-entity claims are not aggregate actions in the formal sense, they are *inherently* representative actions because the government functions as an inherent representative of nonparties to the suit. When a state sues on behalf of itself it is disguising the fact that government entities always represent the interests of their constituents. This concept of inherent representation is best understood through analogy. Imagine a company suing a third party for injuries that the company itself (not its stakeholders) sustained. On paper, the company is acting only as a representative of itself. In reality, however, the company is acting as an inherent representative of its stakeholders because any injury to the company's interest necessarily hurts its employees, creditors, and other

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300. See *Wyoming v. U.S. Dep't of Interior*, 674 F.3d at 1234–35.

301. See *supra* Part II.C.2.

302. Frederickson, *supra* note 74, at 134.

303. See *supra* notes 146–48 and accompanying text.

304. See *supra* note 210.

305. See *supra* Part II.C.3.c.

306. Of course, direct-injury claims may utilize the joinder rules to join more than one plaintiff or more than one defendant, but the claims themselves are not joinders.

307. See *supra* Part II.A.

constituents (in the form of lower salaries, fewer benefits, and higher risk of debt default). Likewise, any verdict in favor of the company will trickle down to its stakeholders either in the form of higher salaries, increased benefits, and so on.

A direct-injury claim by a government entity is similar to a direct-injury claim by a company. When the government incurs higher infrastructure costs due to opioid addiction, its citizens end up bearing those costs through higher taxes or reduced benefits.<sup>308</sup> Similarly, when the government wins a verdict against a third party (e.g., a tortious opioid manufacturer or distributor), the citizens receive the fruits of the verdict through added benefits or lower taxes.<sup>309</sup> Although the court views a government entity's direct-injury claim as being solely representative of its own interests, in reality, the government is acting as a representative for all of its citizens. This allows its citizens to aggregate their resources (tax money) toward a collective litigation effort lead by their attorney general.

Although direct-injury claims are inherently representative and reap the benefits of aggregation, it is unlikely that courts will subject them to the formal requirements of representative actions. Direct-injury claims will not face Rule 23 class action certification and will not bind nonparties to the judgment because courts are respectful of the form in which government-entity claims are brought; in general, the court is unwilling to look past the stated parties in a complaint.<sup>310</sup> In *Purdue Pharma L.P. v. Kentucky*,<sup>311</sup> Purdue tried to remove a *parens patriae* action to federal court by arguing that the state attorney general was acting as a class action representative. Purdue “urged [the court] to look past the pleadings, the named parties, and the stated causes of action to deduce the true nature of this proceeding.”<sup>312</sup> Purdue highlighted how the “real part[y] in interest” was not the county or the state “but individual consumers for whom the Attorney General is acting, in effect, as a disguised class representative.”<sup>313</sup> Despite Purdue's description of the claim, the court stuck to the form of the pleadings and

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308. See John Caniglia, *Cost of Opioid Epidemic Soars, Hitting Taxpayers Harder Than Ever*, CLEVELAND.COM (Oct. 8, 2017), [http://www.cleveland.com/metro/index.ssf/2017/10/the\\_cost\\_of\\_the\\_opioid\\_epidemi.html](http://www.cleveland.com/metro/index.ssf/2017/10/the_cost_of_the_opioid_epidemi.html) [<https://perma.cc/3RCR-PS4A>] (explaining how taxpayers end up covering the rising costs in child services, jail expenses, social services, and so on); Brandon Morse, *Opioid Epidemic Costs Taxpayers over \$500 Billion a Year According to White House*, REDSTATE (Nov. 20, 2017, 3:30 PM), [https://www.redstate.com/brandon\\_morse/2017/11/20/opioid-epidemic-costs-taxpayers-500-billion-year-according-white-house/](https://www.redstate.com/brandon_morse/2017/11/20/opioid-epidemic-costs-taxpayers-500-billion-year-according-white-house/) [<https://perma.cc/29UY-LARQ>].

309. Although it is possible that settlements or verdicts in favor of the government will go toward unrelated causes, it is certain that the money will go towards programs intended to help constituents. See *15 Years Later, Where Did All the Cigarette Money Go?*, NPR (Oct. 13, 2013, 5:52 PM), <https://www.npr.org/2013/10/13/233449505/15-years-later-where-did-all-the-cigarette-money-go> [<https://perma.cc/SQ56-86KQ>] (describing how money from the Master Settlement Agreement went toward smoking programs or other state programs focused on unrelated causes such as literacy or agriculture).

310. See, e.g., *Purdue Pharma L.P. v. Kentucky*, 704 F.3d 208, 217 (2d Cir. 2013).

311. 704 F.3d 208 (2d Cir. 2013).

312. *Id.* at 217.

313. *Id.*

refused to view the *parens patriae* claim as a disguised class action.<sup>314</sup> The Supreme Court in *Mississippi ex rel. Hood v. AU Optronics Corp.*<sup>315</sup> affirmed the Second Circuit's view and made evident that courts are unwilling to look past the pleadings and will ignore real parties in interest.<sup>316</sup> There, the Court held that a *parens patriae* action against an LCD manufacturer did not constitute a "mass action" under the Class Action Fairness Act, despite the fact that "100 or more unnamed persons . . . [we]re real parties in interest as beneficiaries to any of the plaintiffs' claims."<sup>317</sup> The Court's unwillingness to classify government-entity claims as mass actions proves that it is unlikely to classify direct-injury claims (a subset of government-entity claims) as aggregate actions. Although courts will not view a single direct-injury government-entity cause of action as a formal aggregation in itself, a series of direct-injury claims may be formally aggregated through administrative aggregation.

#### D. Judicial Intervention—Administrative Aggregation

A group of direct-injury government-entity claims may be aggregated through administrative means just like any other form of litigation. Administrative aggregation "enable[s] judges to coordinate separate lawsuits for efficient processing."<sup>318</sup> Unlike representative actions, which may be initiated as a single action, administrative aggregation begins with separate trials that are later consolidated by judges.<sup>319</sup> Separate trials are consolidated either as authorized by special procedural rules through formal administrative aggregation or "outside the ambit of specific rules or statutes" through informal administrative aggregation.<sup>320</sup> One type of formal administrative aggregation is federal multidistrict consolidation,<sup>321</sup> which allows a judicial panel of seven judges to aggregate claims with common facts in the interest of convenience, efficiency, and fairness.<sup>322</sup>

On September 25, 2017, a private attorney involved in the opioid litigation moved to consolidate over sixty government-entity lawsuits from across the country through multidistrict litigation.<sup>323</sup> As the number of lawsuits filed by government entities grew in numbers, so did the case list for Multidistrict Litigation Request Number 2804 ("MDL 2804"). On December 5, the Judicial Panel on Multidistrict Litigation (JPML) ordered consolidation of more than one hundred lawsuits listed under MDL 2804, to be heard by Judge

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314. *Id.* at 220.

315. 134 S. Ct. 736 (2014).

316. *See generally id.*

317. *Id.* at 742.

318. *See* PRINCIPLES OF THE LAW OF AGGREGATE LITIGATION § 1.02 illus. 5(2) (AM. LAW INST. 2010).

319. *Id.*

320. *Id.*

321. *Id.*

322. 28 U.S.C. § 1407 (2012).

323. MDL Brief, *supra* note 102; *see also* Amanda Bronstad, *Lawyers in Opioid Suits Aim for MDL to Handle Dozens of Cases*, NAT'L L.J. (Sept. 29, 2017), <https://www.law.com/nationallawjournal/almID/1202799291523/> [<https://perma.cc/39UY-2DK8>].

Dan Polster.<sup>324</sup> Although some government-entity lawsuits were excluded from the consolidation, the coordination is highly beneficial. It will ensure consistent pretrial rulings and allow parties—especially the defendants—to save resources “by litigating their case in a single court that’s most convenient for the parties.”<sup>325</sup> Although the JPML is the only entity that has the ability to formally aggregate a series of direct-injury government-entity claims,<sup>326</sup> lawyers have the ability to informally aggregate their claims through private aggregation.

### *E. Informal Aggregation Incentivizes Settlement*

In addition to being administratively aggregated by the judicial branch, the opioid litigation has been informally aggregated by private parties and state attorneys general. Informal (or private) aggregation occurs when parties involved in widespread litigation, rather than judges, “act as though the separate suits were formally aggregated, coordinating their efforts to such an extent as to amount to a treatment of the litigation as a single, integrated whole.”<sup>327</sup> Similar to administrative aggregations, these informal aggregations begin as separate trials.<sup>328</sup> However, unlike formal administrative aggregations, informal aggregations continue as separate trials.<sup>329</sup> Rather than relying on judicial oversight, plaintiffs exploit “the existence of multiple and related claims” and place management “in the hands of a few attorneys or even a single firm” to aggregate lawsuits themselves.<sup>330</sup> Some scholars “argue that informal aggregation can be as efficient as formal aggregation” and just as effective for the pooling of resources.<sup>331</sup>

Learning from the 1990s tobacco litigation, plaintiffs involved in the opioid litigation have informally aggregated their claims to pool resources and coordinate strategy. Famous litigators from the tobacco litigation are collaborating with private attorneys and state AGs to create a powerful force

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324. *In re Nat’l Prescription Opiate Litig.*, 290 F. Supp. 3d 1375 (J.P.M.L. 2017).

325. Clay Hodges, *Opioid Lawsuits Heading to Centralized Multidistrict Litigation (MDL 2804)*, N.C. PRODUCT LIABILITY LAW BLOG (Oct. 4, 2017), <https://www.northcarolinaproductliabilitylawyer.com/2017/10/are-the-opioid-epidemic-lawsuits-heading-to-multi-district-litigation.html> [<https://perma.cc/7EF5-NM8B>].

326. *See* 28 U.S.C. § 1407.

327. Howard M. Erichson, *Informal Aggregation: Procedural and Ethical Implications of Coordination Among Counsel in Related Lawsuits*, 50 DUKE L.J. 381, 383 (2000).

328. *See id.* at 383–84.

329. *See id.* at 386–408.

330. *See* PRINCIPLES OF THE LAW OF AGGREGATE LITIGATION § 1.02 cmt. b (AM. LAW INST. 2010).

331. *Id.* § 1.02 reporter’s note cmt. b(1)(A); *see* Richard L. Marcus, *Reassessing the Magnetic Pull of Megacases on Procedure*, 51 DEPAUL L. REV. 457, 467–68 (2001) (questioning the need for consolidation of 2000 antitrust actions in the electrical industry because “[d]uring roughly the same period of time, similar efficiencies were effected in [products liability] litigation by informal arrangements created among counsel without organized judicial oversight”).

against opioid companies.<sup>332</sup> Two lawyers in particular, Mike Moore and Paul Hanly, are leading the effort. Mike Moore has spearheaded a nationwide coalition against opioid companies. His name may only be listed on a series of lawsuits filed in Mississippi, but his involvement spreads beyond state boundaries.<sup>333</sup> He has built an alliance with his “longtime friends . . . includ[ing] former Arizona Attorney General Grant Woods, the first Republican state attorney general to join the anti-tobacco crusade, and Chip Robertson, a former chief justice of the Supreme Court of Missouri who helped his state sue tobacco companies.”<sup>334</sup> In July 2017 he met with “more than a dozen private attorneys” and coordinated legal strategies against opioid companies just as he did for the litigation against tobacco companies.<sup>335</sup> Paul Hanly plays a similar role. Based in New York, he has commenced lawsuits “for close to 30 of the state’s 62 counties.”<sup>336</sup> Hanly represented the thousands of private plaintiffs that settled with Purdue Pharma in 2007 and is using the knowledge gained from those previous lawsuits to garner a stronger force against opioid companies.<sup>337</sup> Some scholars view Hanly and Moore’s efforts as evidence of dangerous power concentrations and argue that private aggregation in the context of mass tort liability has grown so strong “that a small number of attorneys exercise a virtual monopoly over public tort litigation.”<sup>338</sup>

Despite their monopolistic qualities, informal aggregations are particularly useful in the context of mass tort liability because they increase the chances of securing the government’s true objective: a large settlement. State AGs already have “greater litigation resources and moral authority than is typically present in mass tort actions initiated by private attorneys.”<sup>339</sup> When these state AGs combine with other AGs and private attorneys, “their resources and moral authority are even more powerful.”<sup>340</sup> Informal aggregations as large in scope as the tobacco and opioid litigation create a “combined litigation muscle, moral authority, and [high] potential for winning overwhelming judgments.”<sup>341</sup> Most importantly, the combined

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332. Esmé E. Deprez & Paul Barrett, BLOOMBERG BUSINESSWEEK, *The Lawyer Who Beat Big Tobacco Takes On the Opioid Industry* (Oct. 5, 2017, 4:00 AM), <https://www.bloomberg.com/news/features/2017-10-05/the-lawyer-who-beat-big-tobacco-takes-on-the-opioid-industry> [<https://perma.cc/AP3K-8AA3>].

333. *Id.*

334. *Id.*

335. *Id.*

336. Caroline Lewis, *Meet the Manhattan Attorney Leading Local Governments’ Lawsuits Against Big Pharma*, CRAIN’S N.Y. BUS. (June 12, 2017), [http://www.crainsnewyork.com/article/20170612/HEALTH\\_CARE/170619990/meet-paul-hanly-jr-who-is-leading-the-lawsuits-accusing-big-pharma-for-contributing-to-opioid-epidemic](http://www.crainsnewyork.com/article/20170612/HEALTH_CARE/170619990/meet-paul-hanly-jr-who-is-leading-the-lawsuits-accusing-big-pharma-for-contributing-to-opioid-epidemic) [<https://perma.cc/JFJ6-7PMF>].

337. Joseph, *supra* note 76.

338. Richard C. Ausness, *Public Tort Litigation: Public Benefit or Public Nuisance?*, 77 TEMP. L. REV. 825, 908 (2004).

339. Cupp, *supra* note 144, at 689.

340. *Id.*

341. *Id.* at 690.

muscle allows plaintiffs to procure “large settlements even when their underlying legal claims are questionable.”<sup>342</sup>

The ability to speed up settlement talk is valuable for plaintiffs involved in public tort litigation because their best chance is the procurement of large settlements. The plaintiff’s side of the opioid litigation has learned valuable lessons from the tobacco litigation, when “State Attorneys General from across the country joined forces to launch a full scale, multi-state, multi-issue attack . . . recogniz[ing] that the most efficient approach to the litigation was a multi-state coordinated *negotiation* process.”<sup>343</sup> By focusing on negotiation rather than adjudication, these AGs made it evident that settlement was their true objective in the tobacco litigation. Similarly, when the FDA sued Purdue Pharma for its off-label marketing of OxyContin,<sup>344</sup> it relied upon “extensive collaboration among the state Attorneys General and the federal investigators to achieve a swift and extensive *settlement* against a company and its wrongdoers.”<sup>345</sup> Government entities are not concerned with arguing questionable legal theories because they “do not expect their cases to actually go to trial.”<sup>346</sup> Instead, plaintiffs hope to “survive a motion to dismiss” and settle without evaluating the “the doctrinal soundness of their position.”<sup>347</sup> Informal aggregation incentivizes defendants to settle their claims swiftly and avoids evaluation of the plaintiff’s dubious claims. In addition to bypassing certification requirements due to their inherently representative nature, the ability to informally aggregate separate actions makes direct-injury claims a mighty tool for opioid victims and the state and local governments that represent them.

#### CONCLUSION

All branches and levels of government have pursued both proactive and reactive measures to combat the opioid epidemic and recover societal costs incurred as a result of the epidemic. Direct-injury government-entity claims are perhaps the most interesting reactive measure because they allege injury to the interests of the government entity itself rather than its constituents. These direct-injury claims offer a more powerful alternative to *parens patriae* actions and can be asserted by any government entity as the sole basis for both recovery and standing. Echoing the tobacco litigation efforts of the 1990s, these government claims have been informally aggregated by plaintiffs’ lawyers to create a powerful force against opioid companies.

Most importantly, direct-injury government claims elude the challenges faced by both individual and aggregate actions in the opioid litigation. With a city, county, or state as the plaintiff, the government is able to effectively

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342. *Id.*

343. Ashley L. Taylor, Jr. et al., *State Attorneys General: The Robust Use of Previously Ignored State Powers*, 40 URB. LAW. 507, 512 (2008) (emphasis added).

344. *See supra* notes 74–76 and accompanying text.

345. Taylor et al., *supra* note 343, at 514.

346. Ausness, *supra* note 338, at 906.

347. *Id.*

foreclose conduct-based defenses reliant upon the plaintiff's blameworthy conduct. Furthermore, these direct-injury government-entity claims inherently function as representative actions that aggregate the interests of taxpayers into a single action led by their AG. As an inherent rather than formal representative action, these lawsuits reap the benefits of aggregation but bypass the Rule 23(a) certification requirements that hindered class actions against opioid companies. Furthermore, unlike class actions, they do not have the potential to bind nonparties to judgments. Considering all the benefits of direct-injury claims, it is no surprise that government entities across the country have chosen civil litigation as their weapon of choice against pharmaceutical giants.