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Renovations Needed: The FDA's Floor/Ceiling Framework, Preemption, and the Opioid Epidemic

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NOTE

Renovations Needed: The FDA's Floor/Ceiling Framework, Preemption, and the Opioid Epidemic

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The FDA's regulatory framework for pharmaceuticals uses a "floor/ceiling" model: administrative rules set a "floor" of minimum safety, while state tort liability sets a "ceiling" of maximum protection. This model emphasizes premarket scrutiny but largely relies on the state common law "ceiling" to police the postapproval drug market. As the Supreme Court increasingly holds state tort law preempted by federal administrative standards, the FDA's framework becomes increasingly imbalanced. In the face of a historic prescription-medication overdose crisis, the Opioid Epidemic, this imbalance allows the pharmaceutical industry to avoid internalizing the public health costs of their opioid products. This Note argues that the FDA's administrative design misallocates the costs of the Opioid Epidemic and fails to adequately compensate those injured by it. Part I summarizes the FDA's regulatory framework with respect to opioid medications. Part II explains how that framework creates a compensatory problem that prevents the internalization of negative externalities by pharmaceutical manufacturers. Part III proposes a victims' compensation fund as the best substitute for the functions long performed by state tort liability.

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Introduction

In January of 1980, the *New England Journal of Medicine* published a letter to the editor penned by Boston University medical researcher Dr. Hershel Jick and his assistant Jane Porter.[1] The five-sentence letter was titled "Addiction Rare in Patients Treated with Narcotics."[2] It reported that of 11,882 hospitalized patients who received at least one dose of narcotic pain killers in the researchers' files, "there were only four cases of reasonably well documented addiction in patients who had no history of addiction."[3] Thus, the researchers concluded, "despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction."[4]

The letter, referred to simply as "Porter and Jick," rose to notoriety.[5] Previously, "doctors had long been taught to avoid prescribing highly addictive opioids to patients."[6] But by the 1990s, the letter's conclusory observation about opioid addictiveness "was invoked by doctors, academics, pharmaceutical companies and others as evidence that few users would develop

1. Jane Porter & Hershel Jick, Correspondence, *Addiction Rare in Patients Treated with Narcotics*, 302 New Eng. J. Med. 123 (1980); Derek Hawkins, *How a Short Letter in a Prestigious Journal Contributed to the Opioid Crisis*, Wash. Post (June 2, 2017), https://www.washingtonpost.com/news/morning-mix/wp/2017/06/02/how-the-opioid-crisis-traces-back-to-a-five-sentence-scholarly-letter-from-1980/ [https://perma.cc/G3M6-LPR9].

2. Porter & Jick, *supra* note 1.

3. *Id.*

4. *Id.*

5. *See* Sarah Zhang, *The One-Paragraph Letter from 1980 That Fueled the Opioid Crisis*, Atlantic (June 2, 2017), https://www.theatlantic.com/health/archive/2017/06/nejm-letter-opioids/528840/ [https://perma.cc/RWR9-3L86].

6. Sonia Moghe, *Opioid History: From 'Wonder Drug' to Abuse Epidemic*, CNN (Oct. 14, 2016, 6:41 AM), http://www.cnn.com/2016/05/12/health/opioid-addiction-history/index.html [https://perma.cc/37BU-78EQ] ("[A]n 11-line letter . . . pushed back on the popular thought that using opioids to treat chronic pain was risky.").

addictions" to prescription narcotic pain killers.[7] An article in *Scientific American* cited Porter and Jick's one-paragraph letter as an "extensive study."[8] *Time* magazine referred to their "landmark" research as showing the "exaggerated fear that patients would become addicted" to prescription opioids was "basically unwarranted."[9] Almost forty years later, the *Journal* published a retrospective "bibliometric analysis" of the letter; this analysis found that the letter was cited at least 608 times and that some of these citations "grossly misrepresented the conclusions of the letter."[10]

Those citations fueled a shift in the healthcare industry's perspective on the treatment of pain.[11] Pharmaceutical and healthcare industry figures "aggressively pushed the concept of pain as the fifth vital sign."[12] With the introduction of subjective measures like the "pain scale" and the linking of pain treatment to patient satisfaction, new incentives pushed doctors to prescribe narcotic pain killers.[13] Concurrently, the pharmaceutical industry ramped up promotion of pain medications.[14] Purdue Pharma introduced OxyContin to the market as a long-term solution to chronic pain.[15] A 1998 OxyContin promotional video featured a doctor referencing the letter's data:

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7. Hawkins, *supra* note 1.

8. Ronald Melzack, *The Tragedy of Needless Pain*, Sci. Am., Feb. 1990, at 27, 29–30.

9. Sam Allis, *Less Pain, More Gain*, Time (June 24, 2001), http://content.time.com/time/magazine/article/0,9171,158154,00.html (on file with the *Michigan Law Review*).

10. Pamela T.M. Leung, et al., Correspondence, *A 1980 Letter on the Risk of Opioid Addiction*, 376 New Eng. J. Med. 2194, 2194 (2017). Contemporaneously published letters to the editor in the *Journal* were cited, on average, 11 times. *Id.*

11. *See* D. Andrew Tompkins et al., *Providing Chronic Pain Management in the "Fifth Vital Sign" Era: Historical and Treatment Perspectives on a Modern-Day Medical Dilemma*, 173 Drug & Alcohol Dependence S11, S13–S14 (2016) (finding that throughout the 20th century "physicians and patients alike had been afraid of developing addiction if placed on morphine or other opioids" but that "[d]uring the 1990s and early 2000s, . . . fears of addiction to prescribed opioids were minimized due to an overemphasis on the findings" of Porter and Jick).

12. Brian F. Mandell, Letter from the Editor, *The Fifth Vital Sign: A Complex Story of Politics and Patient Care*, 83 Clev. Clinic J. Med. 400 (2016) (citing Am. Pain Soc'y Quality of Care Comm., *Quality Improvement Guidelines for the Treatment of Acute Pain and Cancer Pain*, 274 JAMA 1874 (1995)). This concept posited that pain was undertreated due to a lack of reporting and assessment, and called on doctors to measure subjective pain just as they recorded heart rate or blood pressure. *Id.*

13. *See, e.g.*, Nat'l Pharm. Council, Inc. & Joint Comm'n on Accreditation of Healthcare Orgs., Pain: Current Understanding of Assessment, Management, and Treatments 17, 19–29 (2001) (providing guidelines for the measurement of pain, and citing the Porter and Jick letter to state that "[f]ear of causing addiction . . . reflects a lack of understanding of the risk of addiction with therapeutic drug use" and that "clinicians often overestimate this risk").

14. Mandell, *supra* note 12 ("[S]ome drug manufacturers in the early 2000s funded publications and physician presentations to encourage the expanded use of opioids and other medications for pain control."); *see also* Moghe, *supra* note 6 ("Purdue Pharma took out ads for OxyContin in medical journals across the nation in 2000.").

15. Moghe, *supra* note 6 (detailing Purdue's "I Got My Life Back" video promotion that "followed six people who suffered from chronic pain and were treated with OxyContin").

"There's no question that our best, strongest pain medicines are the opioids . . . in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent."[16] In 2017, Dr. Jick lamented, "I'm essentially mortified that that letter to the editor was used as an excuse to do what these drug companies did."[17]

Exactly what these drug companies did is now the subject of litigation.[18] And unlike previous public health courtroom battles, such as the tobacco litigation of the 1990s, the prescription drugs at the heart of this deadly outbreak are heavily regulated for safety by the federal government.[19] As a result, a diverse array of federal agencies have prioritized responding to the emergency.[20] To understand why, consider the extent of the damage: the

16. Our Amazing World, *Purdue Pharma OxyContin Commercial*, YouTube (Sept. 22, 2016), https://www.youtube.com/watch?v=Er78Dj5hyeI [https://perma.cc/RZS9-9EVH]. In 2007, the federal government brought criminal and civil charges against Purdue for the misbranding of OxyContin. Three top executives pleaded guilty to criminal charges, and the company paid $600 million in damages to the government and a class of private plaintiffs. Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), https://www.nytimes.com/2007/05/10/business/11drug-web.html (on file with the *Michigan Law Review*). The privately held, family-owned company generated billions of dollars in annual OxyContin sales, including as much as $3.1 billion in 2010. *See* Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Pub. Health 221, 223 (2009); Mike Mariani, *How the American Opiate Epidemic Was Started by One Pharmaceutical Company*, Week (Mar. 4, 2015), http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company [https://perma.cc/3RNW-2E2V].

17. Marilynn Marchione, *Painful Words: How a 1980 Letter Fueled the Opioid Epidemic*, Associated Press (May 31, 2017), https://apnews.com/9307eb6e8b3c4970bb2a6344a09b0170 [https://perma.cc/23M3-BMX2].

18. Jerry Mitchell, *Opioid Makers Face Hundreds of Lawsuits for Misleading Doctors About Drug's Addictive Nature*, USA Today (Jan. 29, 2018, 6:00 AM), https://www.usatoday.com/story/news/nation-now/2018/01/29/judge-stop-legal-fights-and-curb-opioid-epidemic/1072798001/ [https://perma.cc/8UVV-AM47].

19. Brian Eckert, *This Is How Opioid Lawsuits Differ from Big Tobacco's*, ClassAction.com (Jan. 19, 2018), https://www.classaction.com/news/opioid-lawsuits-big-tobacco/ [https://perma.cc/Q3DA-GCUS] (distinguishing between the opioids and tobacco litigation because "unlike tobacco, opioid painkillers were approved by the U.S. Food and Drug Administration"). During the 1990s tobacco litigation, the industry was still largely exempt from federal health and safety regulation. Tobacco Control Legal Consortium, Federal Regulation of Tobacco 2 (2009), http://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fda-summary.pdf [https://perma.cc/4B34-DS2A] (noting that before the passage of the Family Smoking Prevention and Tobacco Control Act of 2009, "tobacco products were largely exempt from regulation under the nation's federal health and safety laws").

20. *See, e.g.*, *The Federal Response to the Opioid Crisis: Hearing Before the S. Comm. on Health, Educ., Labor &Pensions*, 115th Cong. 2 (2017) (written testimony of Elinore McCance-Katz, Assistant Sec'y for Mental Health & Substance Abuse, Substance Abuse & Mental Health Servs. Admin. et al. on behalf of the Dep't of Health and Human Servs.) (describing the Department of Health and Human Services' "five-point Opioid Strategy") [hereinafter McCance-Katz Testimony]; *Press Release: CDC Awards $28.6 Million to Help States Fight Opioid Overdose Epidemic* Centers for Disease Control & Prevention, (Sept. 5, 2017), https://

Substance Abuse and Mental Health Services Administration's annual survey found that "over 11 million Americans misused prescription opioids" and "2.1 million had an opioid use disorder due to prescription opioids or heroin" in 2016.[21] Drug overdose deaths in 2016 totaled 63,000, which (after adjusting for age) represents a 21 percent increase over the prior year.[22] This is "the largest annual jump ever recorded in the United States," reaching a total greater than any peak number of annual deaths caused by car crashes, HIV, or guns throughout history.[23] Opioids are responsible for 66 percent of those overdose deaths, killing more Americans annually than breast cancer.[24] And 2017 estimates show those numbers rising across all races and nearly all age groups.[25] In 2017, Stanford Professor of Psychiatry Keith Humphreys compared "the amount of standard daily doses of opioids consumed in Japan"—a nation with an "older population than us, you would think more aches and pains"—to that of the United States by saying, "double it. And then double it again. And then double it again. And then double it again. And then double it a fifth time. That would make Japan number two in the world behind the United States."[26] According to one forecast, opioids could kill 500,000 Americans over the next ten years.[27]

Dire as they are, the nationwide numbers mask the extent of the damage in the most heavily impacted localities. The highest-prescribed state sees three times as many opioid prescriptions per person as the lowest-prescribed state, despite "[h]ealth issues that cause people pain . . . not vary[ing] much

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www.cdc.gov/media/releases/2017/p0905-opioid-funding.html [https://perma.cc/9ZQJ-NQ3Z] (announcing CDC funding for states to "strengthen prevention efforts and better track opioid-related overdoses"); *DEA 360 Strategy*, Drug Enforcement Admin., https://www.dea.gov/prevention/360-strategy/360-strategy.shtml [https://perma.cc/8GPJ-HM6N] (describing the "DEA 360 Strategy," an "innovative three-pronged approach to combating heroin/opioid use").

21. McCance-Katz Testimony, *supra* note 20, at 2.

22. Holly Hedegaard et al., Ctrs. for Disease Control & Prevention, Drug Overdose Deaths in the United States, 1999–2016, at 1 (2017), https://www.cdc.gov/nchs/data/databriefs/db294.pdf [https://perma.cc/YRN7-F8JT].

23. Josh Katz, *Drug Deaths in America Are Rising Faster Than Ever*, N.Y. Times: The Upshot (June 5, 2017), https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html (on file with the *Michigan Law Review*).

24. Nadia Kounang, *Opioids Now Kill More People Than Breast Cancer*, CNN (Dec. 21, 2017, 12:14 AM), http://www.cnn.com/2017/12/21/health/drug-overdoses-2016-final-numbers/ [https://perma.cc/9UTC-USVP].

25. *Opioid Overdose: Data Overview*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/drugoverdose/data/index.html [https://perma.cc/N7F9-JPPC].

26. Stanford University (@Stanford), Twitter (Sept. 16, 2017, 2:29 PM), https://twitter.com/stanford/status/909167301349593094 [https://perma.cc/2XKT-4MWY] (showing Dr. Humphreys speaking at the 2017 Medicine X Conference).

27. Max Blau, *STAT Forecast: Opioids Could Kill Nearly 500,000 Americans in the Next Decade*, STAT (June 27, 2017), https://www.statnews.com/2017/06/27/opioid-deaths-forecast/ [https://perma.cc/C5DV-6XR7] (basing the estimate on an expert panel of public health researchers and including a model of the data and possible outcomes in the article).

from place to place."[28] Between 2007 and 2012, drug wholesalers shipped 780 million pills of just hydrocodone and oxycodone to West Virginia.[29] In Kermit, West Virginia, a town of 392, drug companies shipped nearly nine million pills of hydrocodone to a single pharmacy.[30] In 2016, Montgomery County, Ohio saw a record 349 opioid deaths, but local officials estimate that 2017 deaths could surpass 800.[31] County coroners are overwhelmed by the influx and struggling to find the physical space necessary to store bodies and conduct autopsies; some coroners have resorted to the use of refrigerated trailers.[32] In New Hampshire, the backlog of autopsies is putting the state medical examiner's office "at risk of losing accreditation."[33] That state has seen a nearly tenfold increase in overdose deaths since 2000.[34]

This human cost, in lost life and welfare, translates to a gargantuan toll on the economy. A 2017 study estimated the societal cost (including lost productivity, healthcare expenses, criminal justice costs, etc.) of the Opioid Epidemic at over $95 billion for 2016 alone.[35] The White House Council of Economic Advisers, additionally placing a value on the loss of human life, estimated the 2015 cost of the crisis at over $500 billion, or 2.8 percent of GDP.[36] These calculations do not incorporate the further costs of patients

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28. *Opioid Overdose: Prescribing Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/data/prescribing.html [https://perma.cc/49Y4-B6L8].

29. Eric Eyre, *Drug Firms Poured 780M Painkillers into WV amid Rise of Overdoses*, CHARLESTON GAZETTE-MAIL (Dec. 17, 2016), https://www.wvgazettemail.com/news/cops_and_courts/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html [https://perma.cc/3FCX-4A62]. The state has a population under 2 million. *Quick Facts: West Virginia*, U.S. CENSUS BUREAU, https://www.census.gov/quickfacts/WV [https://perma.cc/Z5Z3-VVU8]. Over that same period, 1,728 West Virginians died of overdoses on those two medications. Eyre, *supra*.

30. Eyre, *supra* note 29.

31. Poppy Harlow & Zach Wasser, *Here, Heroin Spares No One, Not Even the Sheriff's Wife*, CNN (Aug. 8, 2017), http://www.cnn.com/2017/08/06/health/ohio-heroin-opioid-crisis-morgue-full/ [https://perma.cc/EMM9-YSKE].

32. *See Ohio Coroner Runs Out of Room for Bodies Due to Spike in Opioid Deaths*, CBS NEWS (May 23, 2017, 2:40 PM), https://www.cbsnews.com/news/ohio-coroner-runs-out-of-room-for-bodies-spike-in-opioid-deaths/ [https://perma.cc/WK6T-XGAA]; Corky Siemaszko, *Too Many Bodies in Ohio Morgue, so Coroner Gets Death Trailer*, NBC NEWS (Mar. 14, 2017, 4:00 PM), https://www.nbcnews.com/news/us-news/too-many-bodies-ohio-morgue-so-coroner-gets-death-trailer-n733446 [https://perma.cc/Z2HS-PLZU].

33. Katharine Q. Seelye, *As Overdose Deaths Pile Up, a Medical Examiner Quits the Morgue*, N.Y. TIMES (Oct. 7, 2017), https://www.nytimes.com/2017/10/07/us/drug-overdose-medical-examiner.html (on file with the *Michigan Law Review*).

34. *Id.*

35. *See* CORWIN N. RHYAN, THE POTENTIAL SOCIETAL BENEFIT OF ELIMINATING OPIOID OVERDOSES, DEATHS, AND SUBSTANCE USE DISORDERS EXCEEDS $95 BILLION PER YEAR (2017), https://altarum.org/sites/default/files/uploaded-publication-files/Research-Brief_Opioid-Epidemic-Economic-Burden.pdf [https://perma.cc/LE63-L5BX].

36. THE COUNCIL OF ECON. ADVISERS, THE UNDERESTIMATED COST OF THE OPIOID CRISIS 1 (2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20

"initiated" into opioid addiction by prescription medications who then transition to cheaper, more widely available black-market heroin.[37] The damage is sizable enough to cause macroeconomic impact: economists from Princeton University, Goldman Sachs, and the Federal Reserve postulate that the perplexing decline in the labor participation rate is linked to opioids.[38]

This unprecedented rate of addiction and death amounts to the largest drug-related public health emergency in American history.[39] Six states and the White House have declared official emergencies.[40] And, because these drugs are FDA-approved medicines with legitimate applications, the challenge is distinct from past epidemics like the rise of heroin or crack cocaine. According to Scott Gottlieb, the commissioner of the FDA, "Most people who become addicted to opioids become medically addicted. Their first exposure is going to be a clinical prescription that they receive in a clinical setting, and then they'll go on to develop an addiction."[41] Indeed, "many public health experts have traced the roots of the current surge in opioid addic-

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Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf [https://perma.cc/L4Q5-Q6TU].

37. *Prescription Opioid Use Is a Risk Factor for Heroin Use*, NAT'L INST. ON DRUG ABUSE (Jan. 2018), https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use [https://perma.cc/QW6B-V92J].

38. Alan B. Krueger, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*, BROOKINGS PAPERS ON ECON. ACTIVITY, Fall 2017, at 1, 1 ("[P]articipation has fallen more in areas where relatively more opioid pain medication is prescribed, causing the problem of depressed labor force participation and the opioid crisis to become intertwined."); Mamta Badkar, *Yellen: Opioid Crisis Weighing on US Labour Force Participation*, FIN. TIMES (July 13, 2017), https://www.ft.com/content/776ba9e3-d47c-3554-8421-9238f79ef1b7 (on file with the *Michigan Law Review*); Danielle Paquette, *The Stunning Prevalence of Painkiller Use Among Unemployed Men*, WASH. POST: WONKBLOG (Sept. 7, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/09/07/the-stunning-prevalence-of-painkiller-use-among-unemployed-men/ [https://perma.cc/2446-9CBY]; Jeanna Smialek, *Goldman Economists See Drug Epidemic Taking Toll on U.S. Economy*, BLOOMBERG (July 6, 2017, 4:52 PM), https://www.bloomberg.com/news/articles/2017-07-06/goldman-economists-see-drug-epidemic-taking-toll-on-u-s-economy [https://perma.cc/4RQN-Y7Y3].

39. German Lopez & Sarah Frostenson, *How the Opioid Epidemic Became America's Worst Drug Crisis Ever, in 15 Maps and Charts*, VOX (Mar. 29, 2017, 12:51 PM), https://www.vox.com/science-and-health/2017/3/23/14987892/opioid-heroin-epidemic-charts [https://perma.cc/9SSP-BAX2].

40. Erin Mershon & Andrew Joseph, *These States Declared an Emergency Over the Opioid Crisis, Here's What Happened*, PBS (Aug. 10, 2017, 10:02 AM), https://www.pbs.org/newshour/health/states-declared-emergency-opioid-crisis-heres-happened [https://perma.cc/JN48-7TD4]; *President Donald J. Trump Is Taking Action on Drug Addiction and the Opioid Crisis*, WHITE HOUSE (Oct. 26, 2017), https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis [https://perma.cc/9E73-YVGK].

41. *FDA's Scott Gottlieb: Opioid Addiction is FDA's Biggest Crisis Now*, CNBC (July 21, 2017, 8:24 AM), https://www.cnbc.com/video/2017/07/21/fdas-scott-gottlieb-opioid-addiction-is-fdas-biggest-crisis-now.html [https://perma.cc/RAS7-2BPG].

tion . . . to . . . prescription drugs"[42] because "[t]he misuse of prescription opioids is intertwined with that of illicit opioids."[43] Four out of five new heroin users began by misusing a prescription opioid.[44] Between 1996 and 1997, retail sales of hydrocodone increased by 244%, oxycodone by 732%, and methadone by 1,177%, coinciding with the trend of "increased rates of abuse and mortality associated with prescription opioid[s]."[45] Thus, understanding the FDA scheme that regulates the prescription drugs in question is crucial.

This Note argues that the FDA's administrative design misallocates the costs of the Opioid Epidemic and fails to adequately compensate those injured by it. The FDA's regulatory framework emphasizes premarket scrutiny but largely relies on state common law liability to police the postapproval drug market. As the Supreme Court increasingly holds state tort law preempted by federal administrative standards, the FDA's framework becomes increasingly imbalanced. In the face of a historic prescription-medication overdose crisis, the FDA's scheme allows the pharmaceutical industry to avoid internalizing the dramatic public health costs of their opioid products. Part I summarizes the FDA's regulatory framework with respect to opioid medications. Part II explains how that framework creates a compensatory problem that prevents the internalization of negative externalities by pharmaceutical manufacturers. Part III proposes a victims' compensation fund as the best substitute for the function long performed by state tort liability.

I. The FDA's "Floor/Ceiling" Scheme and the Preemption Lever

A. *The FDA's Administrative Design*

Prescription drugs are regulated under the Food, Drug, and Cosmetics Act (FDCA), passed by Congress in 1938.[46] The FDCA "imposes an elaborate system" requiring premarket approval of new drugs following "extensive

42. *How Are Public Health Officials Fighting the Crisis of Opioid Addiction?*, U. Nev. Reno, https://onlinedegrees.unr.edu/blog/how-are-public-health-officials-fighting-the-crisis-of-opioid-addiction/ [https://perma.cc/KCT4-84YJ].

43. Rose A. Rudd et al., *Increases in Drug and Opioid-Involved Overdose Deaths—United States, 2010-2015*, 65 Morbidity & Mortality Wkly. Rep. 1445, 1450 (2016).

44. Am. Soc'y of Addiction Med., Opioid Addiction 2016 Facts & Figures (2016), https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf [https://perma.cc/B56H-88DQ].

45. Kathryn L. Hahn, *Strategies to Prevent Opioid Misuse, Abuse, and Diversion That May Also Reduce the Associated Costs*, 4 Am. Health & Drug Benefits 107, 108–09 (2011).

46. *How Did the Federal Food, Drug, and Cosmetic Act Come About?*, U.S. Food & Drug Admin., https://www.fda.gov/AboutFDA/Transparency/Basics/ucm214416.htm [https://perma.cc/E35H-RFY2].

testing and stringent risk/benefit analysis."[47] The approval process is notoriously onerous.[48] The process requires every manufacturer to submit a "New Drug Application" showing data from multiple phases of animal and human preclinical and clinical testing as well as results from a variety of other forms of research and investigation.[49] The burden is on the manufacturer to show by substantial evidence that its drug meets the standard of "safe and effective" under the conditions recommended for its use.[50] Because all drugs have "potential risks, contraindications, . . . and adverse reactions," the approval process also involves a rigorous labeling-approval process to ensure a drug's label "provides doctors information needed to make informed prescribing decisions."[51] The FDCA implements a "risk-benefit assessment framework" to determine when a drug poses an acceptable degree of risk in light of its benefits.[52]

That risk–benefit analysis is central to the FDA's regulatory scheme. Quantifying costs is especially challenging when an agency must analyze the risk of injury or death of human beings.[53] But that is the FDA's task every time it evaluates whether a new drug meets the "safe and effective" stand-

47. Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587, 587 (2005). *See generally* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 351–60 (2012) (providing the premarket approval requirements for drugs and devices).

48. In President Trump's first Joint Address to Congress, he noted that "our slow and burdensome approval process at the Food and Drug Administration keeps too many advances . . . from reaching those in need." *Remarks by President Trump in Joint Address to Congress*, WHITE HOUSE (Feb. 28, 2017), https://www.whitehouse.gov/the-press-office/2017/02/28/remarks-president-trump-joint-address-congress [https://perma.cc/42UW-4NR9]; *see also Big Pharma's Gripes About the FDA*, ECONOMIST (July 1, 2011), https://www.economist.com/blogs/schumpeter/2011/07/cancer-drugs [https://perma.cc/KD2A-XGGV] ("Talk to anyone in the pharmaceutical industry . . . and within three minutes Mr. Pharma will start griping about . . . the FDA's approval process . . . .").

49. *See* 21 U.S.C. § 355 (2012); *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (Nov. 24, 2017), https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm [https://perma.cc/4E3V-4YBF].

50. *See* § 355.

51. David C. Vladeck, *Preemption and Regulatory Failure Risks*, *in* PREEMPTION CHOICE 54, 65 (William W. Buzbee ed., 2009). *See generally* § 355 (establishing procedures for initial drug labeling and labeling revisions).

52. § 355; Marcia Boumil, *FDA Approval of Drugs and Devices: Preemption of State Laws for "Parallel" Tort Claims*, 18 J. HEALTH CARE L. & POL'Y 1, 4 (2015) ("The FDA employs a standard stating that the drugs' 'probable therapeutic benefits must outweigh its risk of harm.' "); JAMIE WILKINS PARKER, U.S. FOOD & DRUG ADMIN., RISK MANAGEMENT IN THE UNITED STATES (2013), https://www.fda.gov/downloads/drugs/resourcesforyou/healthprofessionals/ucm473163.pdf [https://perma.cc/6GS4-HHQE]; U.S. FOOD & DRUG ADMIN., STRUCTURED APPROACH TO BENEFIT-RISK ASSESSMENT IN DRUG REGULATORY DECISION-MAKING (2013), https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm329758.pdf [https://perma.cc/QZ6E-VDYB].

53. *See* Lewis A. Kornhauser, *The Value of Life*, 38 CLEV. ST. L. REV. 209 (1990). *See generally* GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES (1978).

ard.[54] A drug is never entirely risk free, so warning labels are crucial.[55] An approved warning label informs doctors and patients about the risks they assume in prescribing and taking a drug respectively.[56] When a label is inaccurate or incomplete, or when a drug is marketed for nonapproved uses, the manufacturer can face liability under the FDCA for "misbranding."[57] That potential penalty incentivizes manufacturers to update a drug's warning label for risks that arise following approval using the "Changes Being Effected" (CBE) process.[58] The FDA primarily relies on manufacturers supplying information through the CBE process to detect postmarket risks.[59] By the FDA's own account, "[s]ignificant, but substantially fewer, resources are devoted to postmarketing surveillance and risk assessment activities" compared to premarket approval.[60]

This raises the question of who bears the "costs" of a system built on cost-benefit analysis. The FDCA does not include any private right of action or other remedy for consumers injured by unforeseen risks.[61] The Supreme Court interpreted this omission as Congress's determination "that widely

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54. *See* TASK FORCE ON RISK MGMT., FOOD & DRUG ADMIN., MANAGING THE RISKS FROM MEDICAL PRODUCT USE 29–30 (1999) ("The Agency establishes and enforces product quality standards intended to prevent defective products from reaching the market . . . The majority of FDA program resources are devoted to premarketing scientific risk identification and assessment and approval or nonapproval.").

55. Vladeck, *supra* note 51, at 65.

56. MARY E. KREMZNER & STEVEN F. OSBORNE, U.S. FOOD & DRUG ADMIN., AN INTRODUCTION TO THE IMPROVED FDA PRESCRIPTION DRUG LABELING 50, https://www.fda.gov/downloads/training/forhealthprofessionals/ucm090796.pdf [https://perma.cc/QV9Q-B4XR].

57. *See* §§ 331(a), 333(a), 352(a); *see also* 21 C.F.R. § 201.1 (2017) (further defining "misbranded" under the FDCA).

58. *See* 21 U.S.C. § 356(a) (2012); 21 C.F.R. § 314.70 (2017); *see also* Stacey B. Lee, PLIVA v. Mensing*: Generic Consumers' Unfortunate Hand*, 12 YALE J. HEALTH POL'Y L. & ETHICS 209, 242–43 (2012) ("The potential damage awards from state failure-to-warn litigation provides drug manufacturers with incentives to quickly provide full and clear information to physicians and the FDA that otherwise may not come to light."); FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: CHANGES TO AN APPROVED NDA OR ANDA, https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm077097.pdf [https://perma.cc/JL9D-AC9T].

59. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,986–88 (Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601) ("Application holders also must comply with requirements for other postmarketing reports . . . . These requirements include submission of an annual report (including a brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product, and a description of actions the applicant has taken or intends to take as a result of this new information) and, if appropriate, proposed revisions to product labeling . . . ."); Lee, *supra* note 58, at 250–52.

60. TASK FORCE ON RISK MGMT., FOOD & DRUG ADMIN., *supra* note 54, at 29–30.

61. Wyeth v. Levine, 555 U.S. 555, 574 (2009) ("Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment.").

available state rights of action provide[] appropriate relief for injured consumers" in part because "state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings."[62]

The FDCA framework was therefore designed as a "floor" of oversight and regulation, where state common law liability provided the complementary "ceiling." This model of regulation takes advantage of the layers of redundant governance: "[T]he federal government sets a minimum required level of stringent protection, and states, local governments, and common law regimes can lead to even more protective results."[63] The preservation of state common law liability "creates ongoing private incentives to challenge the status quo," a "particularly valuable antidote[] to complacency and ineffective regulation."[64] But when common law liability lurks in the background of an industry's compliance with a complex federal scheme, regulated entities face increased uncertainty and expenditure.[65] These competing interests of consumer protection and regulatory efficiency are balanced between the FDCA's floor and ceiling.

B. *The Role of Preemption and the Shifting Balance*

The constitutional doctrine of preemption is a lever for optimizing this balance between consumer protection and regulatory efficiency. Preemption arises out of the Supremacy Clause.[66] Because "federal law reigns supreme," it "preempts any conflicting law or law that federal legislation deems preempted."[67] Preemption can be "based on an express or implied legislative or regulatory determination."[68] Express preemption clauses speak for themselves, while implied preemption is broken into three main categories.[69] The three categories of implied preemption are as follows: "Field" preemption, where the federal government intentionally or effectively has exclusive authority to "occupy the field" alone (such as issues of foreign affairs);[70] and

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62. *Id.*; *see also id.* at 567 ("As it enlarged the FDA's powers to protect the public health and assure the safety, effectiveness, and reliability of drugs, Congress took care to preserve state law." (citations omitted) (quoting Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780, 780)).

63. William W. Buzbee, *Federal Floors, Ceilings, and the Benefits of Federalism's Institutional Diversity*, *in* PREEMPTION CHOICE, *supra* note 51, at 104.

64. *Id.* at 114.

65. Additional expense and uncertainty result from the need for state-by-state analysis of variable common law tort standards and the injection of a jury's judgment. *See id.*

66. U.S. CONST. art. VI, cl. 2.

67. William W. Buzbee, *Introduction* to PREEMPTION CHOICE, *supra* note 51, at 1.

68. Barbara L. Atwell, *Products Liability and Preemption: A Judicial Framework*, 39 BUFF. L. REV. 181, 183 (1991).

69. *Id.* at 183–86.

70. *See* English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990) (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)) (noting that a field can be preempted when the federal

two kinds of "conflict" preemption: where complying with both state and federal law at once is "physically impossible" (such as a federal regulation imposing one standard that is directly at odds with a state standard);[71] and where state law poses a sufficient "obstacle" to fulfilling Congress's intent (such as a state imposing additional regulation in an interfering manner on top of existing federal requirements).[72]

In a floor/ceiling model, the degree to which federal standards preempt common law liability sets the height of the regulatory ceiling. As the contemporary administrative state expands, "it is not surprising that federal preemption has become an increasingly popular defense."[73] A regulated entity, such as a pharmaceutical manufacturer, might argue that its compliance with the FDCA regulatory framework preempts concurrent state common law liability.[74] The FDCA's regulation of drugs, however, includes no express preemption clause (unlike its section on medical devices).[75] And for nearly all of the FDCA's history, courts and the FDA did not take the position that multilayered pharmaceutical regulation amounted to an implied preemption.[76]

In recent years though, the FDA's stance on preemption has shifted. In 2006, without prior warning, the FDA "slipped a preemptive statement into

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regulatory scheme is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it"). Field preemption can also apply to areas where the federal interest is dominant, regardless of the extent of regulation. *See, e.g.*, Hines v. Davidowitz, 312 U.S. 52, 62 (1941) ("[T]he supremacy of the national power in the general field of foreign affairs . . . is made clear by the Constitution.").

71. *See, e.g.*, Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963) ("A holding of federal exclusion of state law is inescapable . . . where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce." (citations omitted)).

72. *See, e.g.*, Arizona v. United States, 567 U.S. 387, 402–03 (2012) (holding that Arizona law authorizing police to inspect a person's immigration status posed an obstacle to federal immigration law).

73. Atwell, *supra* note 68, at 181.

74. *See* W. Kip Viscusi et al., *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 SETON HALL L. REV. 1437, 1438 (1994) ("[T]ort liability is generally inappropriate in cases where manufacturers have complied with the FDCA.").

75. John C.P. Goldberg & Benjamin C. Zipursky, *The Supreme Court's Stealth Return to the Common Law of Torts*, 65 DEPAUL L. REV. 433, 451 (2016) ("To be sure, the FDCA, unlike the MDA, contained no express preemption provision.").

76. *See* Wyeth v. Levine, 555 U.S. 555, 567 (2009) ("The 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA. Consistent with that provision, state common-law suits continued 'unabated despite . . . FDA regulation.' " (citation omitted) (quoting Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (codified at 21 U.S.C. § 301 (2016)), and Riegel v. Medtronic, Inc., 552 U.S. 310, 340 (2008) (Ginsburg, J., dissenting))).

the preamble of its rulemaking on the format of prescription drug labels."[77] The preamble stated a new interpretation of the FDA's regulatory scheme as establishing both floor *and* ceiling, a dramatic departure from the FDCA's historical interpretation.[78]

Initially, the Supreme Court rebuffed this logic. In the 2009 landmark case *Wyeth v. Levine*, the Court was not swayed by the FDA's changed stance.[79] In a decision hailed as "one of the most important Supreme Court victories for consumers in many years,"[80] the Court rejected a pharmaceutical manufacturer's impossibility preemption defense that argued the "FDCA establishes both a floor and a ceiling for drug regulation."[81] The Court held that a state law failure-to-warn claim against a brand-name pharmaceutical manufacturer, whose drug caused the plaintiff to lose an arm to gangrene, was not preempted by the FDA's approval of the drug's warning label.[82] The Court reasoned that it was not "impossible" to comply with both federal and state standards because the manufacturer could update its warning label using the CBE process.[83]

The Supreme Court's subsequent decisions, however, undermined *Wyeth* and embraced preemption of state law in most pharmaceutical litigation. In 2011 and 2013, the Court expanded impossibility preemption in *PLIVA, Inc. v. Mensing*[84] and in *Mutual Pharmaceutical Co. v. Bartlett*.[85] Those cases involved generic drugs, as opposed to the brand-name drug at issue in *Wyeth*.[86] In 2016, generic drugs accounted for nearly 90 percent of prescriptions dispensed.[87] Under the FDCA, a generic drug manufacturer cannot unilater-

77. Nina A. Mendelson, *A Presumption Against Agency Preemption*, 102 NW. U. L. REV. 695, 703 (2008) (referring to Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (codified at 21 C.F.R. pts. 201, 314, 601 (2017))).

78. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935.

79. 555 U.S. at 577 ("[T]he FDA's 2006 preamble does not merit deference [because] the agency finalized the rule . . . without offering States or other interested parties notice or opportunity for comment, articulat[ing] a sweeping position on the FDCA's pre-emptive effect[such that t]he agency's views on state law are inherently suspect in light of this procedural failure.").

80. Erwin Chemerinsky, Wyeth *Is Victory for Consumers, Blow to Preemption*, TRIAL, May 2009, at 54, 54.

81. *Wyeth*, 555 U.S. at 573–74 (finding the argument inadequate because "all evidence of Congress' purposes is to the contrary").

82. *Id.* at 559, 581.

83. *Id.* at 570–71 ("[A]s amputations continued to occur, Wyeth could have analyzed the accumulating data and added a stronger warning . . . .").

84. 564 U.S. 604 (2011) (plurality opinion in part).

85. 570 U.S. 472 (2013).

86. *Bartlett*, 570 U.S. at 475; *Mensing*, 564 U.S. at 609.

87. *Proportion of Branded Versus Generic Drug Prescriptions Dispensed in the United States from 2005 to 2016*, STATISTA (May 2017), https://www.statista.com/statistics/205042/proportion-of-brand-to-generic-prescriptions-dispensed/ (on file with the *Michigan Law Review*).

ally modify its drug's composition or its warning label using the CBE process, because of the "duty of 'sameness,' " which requires the generic warning label to be identical to the brand-name label.[88] Therefore, the Court held that subjecting a generic manufacturer to both the federal duty of sameness and state tort law liability for a design defect or inadequate warning label amounted to an "impossibility" conflict.[89] The Court reached this conclusion despite the FDA's objections.[90] The agency argued that a generics manufacturer in this position could seek permission "to work toward strengthening the label that applies to both the generic and brand-name" drugs, rather than taking no action at all.[91] Moreover, state law did not require the manufacturer to change the drug's composition or modify its label if the manufacturer simply compensated the injured consumers.[92] Prior to these cases, the "impossibility" category of preemption was reserved for *physical* impossibilities.[93] But here, the Court found impossibility in situations where only the avoidance of *liability* is impossible, a result that Justice Sotomayor characterized as "frankly astonishing."[94]

The Supreme Court's post-*Wyeth* pharmaceutical preemption decisions amount to a novel application of the doctrine with seismic social policy implications.[95] This line of cases immunizes most drug manufacturers from

88. *Mensing*, 564 U.S. at 613 ("[T]he warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.' ").

89. *Bartlett*, 570 U.S. at 480 ("In the instant case, it was impossible for Mutual to comply with both its state-law duty . . . and its federal-law duty . . . ."); *Mensing*, 564 U.S. at 618 ("We find impossibility here.").

90. *Mensing*, 564 U.S. at 616.

91. *Id.*

92. *Bartlett*, 570 U.S. at 514 (Sotomayor, J., dissenting) ("New Hampshire, through its design-defect law, has made a judgment that some drugs . . . should . . . not be sold unless the manufacturer is willing to compensate injured consumers.").

93. *See Amici Curiae* Brief of the Am. Ass'n for Justice & Pub. Justice in Support of Respondent at 6, *Bartlett*, 570 U.S. 472 (No. 12-142) ("[Physical] 'impossibility' can only exist when two statutes impose 'directly conflicting duties'—'as they would, for example, if the federal law said, "you must sell insurance," while the state law said, "you may not." ' But 'physical impossibility' does not exist where state law merely authorizes an action that federal law forbids." (citations omitted) (quoting Barnett Bank of Marion Cty., N.A. v. Nelson, 517 U.S. 25, 31 (1996))).

94. *Bartlett*, 570 U.S. at 514–18 (Sotomayor, J., dissenting) ("[T]he majority . . . finds impossibility where it does not exist by relying on a question-begging assumption that Congress intended for Mutual to have a way to continue selling sulindac without incurring common-law liability.").

95. *See* Brian Wolfman & Anne King, Mutual Pharmaceutical Co. v. Bartlett *and Its Implications*, 82 U.S.L. WK. 667, 669 (2013) ("Whatever one thinks of the Supreme Court's legal analyses in *Wyeth*, *PLIVA*, and *Mutual*, the results of those decisions, taken together, make nonsensical public policy.").

state common law liability.[96] Under this regime, when two plaintiffs suffer the same injury from a defective brand-name drug and its generic equivalent, only the former has a claim against the manufacturer.[97] Even the Court acknowledged this outcome "makes little sense" for pharmaceutical consumers,[98] and commentators found the decisions "bizarre."[99] To the pharmaceutical industry, the decisions signaled an increasing preference by the Court for immunizing manufacturers from state common law liability.[100] In the face of the Opioid Epidemic, the Supreme Court has severely obstructed a major pathway to remedying consumer injuries and penalizing manufacturers.

II. The Supreme Court's New Step in Preemption's Doctrinal Thicket Creates a Compensation Problem

By expanding the concept of impossibility preemption, the Supreme Court reduced the essential role of state common law in the FDA's administrative design. This prevents internalization of prescription opioids' externalities and compensation for the injured. The Court's increasing preference for centralized, standard-setting regulation over localized, market-based compensatory torts shelters industry at the expense of consumers. Section II.A contends that the Court's novel preemption analysis marginalizes the tort system's essential role in the FDA's administrative design. Section II.B argues that the remaining federal regulatory scheme is inadequate on its own. Section II.C acknowledges that, even at the proper floor/ceiling balance, torts alone cannot compensate all victims of the Opioid Epidemic.

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96. *See id.* (stating that the vast majority of prescriptions are for generics, such that "the upshot of *Mutual* and *PLIVA* is that most people harmed by prescription generic drugs have lost their access to the courts").

97. *Id.* ("An injured consumer's ability to recover for her injuries from a culpable drug manufacturer depends . . . 'on the happenstance' of whether the consumer's pharmacist dispensed the brand-name or generic version of the drug." (quoting PLIVA, Inc. v. Mensing, 564 U.S. 604, 627 (2011) (Sotomayor, J., dissenting))).

98. *Mensing*, 564 U.S. at 625.

99. Opinion, *A Bizarre Outcome on Generic Drugs*, N.Y. Times (Mar. 23, 2012) http://www.nytimes.com/2012/03/24/opinion/a-bizarre-outcome-on-generic-drugs.html (on file with the *Michigan Law Review*); *see also* Erwin Chemerinsky, Opinion, *Justice for Big Business*, N.Y. Times (July 1, 2013), http://www.nytimes.com/2013/07/02/opinion/justice-for-big-business.html (on file with the *Michigan Law Review*) (characterizing the decisions as part of a trend wherein the Court "closed the courthouse doors to employees, consumers and small businesses seeking remedy for serious injuries").

100. *See, e.g.*, James M. Beck, *Bartlett—A Big Win for Preemption*, Drug & Device L. (June 24, 2013), https://www.druganddevicelawblog.com/2013/06/bartlett-big-win-for-preemption.html [https://perma.cc/84UU-LKV4]; James M. Beck, *Ruminations on Independence and Inaction: Further Implications of Bartlett*, Drug & Device L. (July 3, 2013), https://www.druganddevicelawblog.com/2013/07/ruminations-on-independence-and.html [https://perma.cc/8KAT-MC42].

A. *The Court's Embrace of Preemption Minimizes the Crucial Role of Torts*

The Supreme Court's preemption cases displace the economic functions traditionally performed by the state tort system. After *Mensing* and *Bartlett*, manufacturers of generic drugs are "effectively immunized" from products liability schemes.[101] Given that nearly 90 percent of prescriptions are for generic drugs,[102] this leaves the vast majority of injured patients without a path to economic recovery. Tort liability incentivizes manufacturers to avoid liability by policing their drugs for adverse effects postapproval[103] and then compensates the victims effectively.[104] By embracing preemption, the Court has replaced the internalization and compensation that torts provide with the model codes of conduct of the federal administrative state.[105]

The federal regulatory scheme alone cannot perform the same economic functions as parallel tort regulation. Federal regulation "replace[s] the *ex post*, decentralized form of private regulation" that torts provide "with *ex ante*, centralized public administrative rules."[106] Because that ex ante determination is premised on a risk–benefit analysis,[107] the injuries that do still occur need to be compensated. The FDA, though, does not compensate the victims of its cost-benefit analyses.[108] Pharmaceutical companies should fill

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101. Goldberg & Zipursky, *supra* note 75, at 454.

102. QUINTILES IMS INST., MEDICINES USE AND SPENDING IN THE U.S. 43 (2017), https://structurecms-staging-psyclone.netdna-ssl.com/client_assets/dwonk/media/attachments/590c/6aa0/6970/2d2d/4182/0000/590c6aa069702d2d41820000.pdf?1493985952 [https://perma.cc/S6EC-FVEA].

103. Tyler W. Olson, Note, *The Supreme Court's Overreaching Preemption Interpretation and Its Consequences: Granting Generic Drug Manufacturers Legal Immunity Through "the Duty of Sameness" in* Mutual Pharmaceutical Co. v. Bartlett *and* PLIVA v. Mensing, 12 IND. HEALTH L. REV. 769, 771 (2015).

104. *See* Sprietsma v. Mercury Marine, 537 U.S. 51, 64 (2002) (explaining that "unlike most administrative and legislative regulations," common-law claims "necessarily perform an important remedial role in compensating accident victims"); Struve, *supra* note 47, at 590 ("Empirical data indicate that juries do better than their critics assert at handling technical issues, that juries are not as eager as some think to award damages against business defendants, and that punitive damages are awarded rarely in products liability suits. . . ." (footnotes omitted)).

105. *See* Goldberg & Zipursky, *supra* note 75, at 454 ("[A] judge or jury in a particular tort case. . . [finding] the defendant breached a duty of care by injuring the plaintiff is quite distinct from a state legislature or regulatory body declaring that certain conduct is prohibited or required," just as "a state's maintenance of laws, through which an actor can be held liable to provide redress to an injury-victim . . . is a far cry from state regulation.").

106. *See* Catharine M. Sharkey, *The Administrative State and the Common Law: Regulatory Substitutes or Complements?*, 65 EMORY L.J. 1705, 1710 (2016).

107. *See* U.S. GEN. ACCOUNTING OFFICE, FDA DRUG REVIEW: POST APPROVAL RISKS 1976-1985, at 2–3 (1990), http://archive.gao.gov/d24t8/141456.pdf [https://perma.cc/M2S9-NUMZ] (finding that between 1976 and 1985, 51 percent of FDA-approved drugs had serious unforeseen postapproval risks).

108. *See* Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 500 (2013) (Sotomayor, J., dissenting) ("Perhaps most significant, state common law provides injured consumers like Karen Bartlett

that role, as the FDCA imagined, given they are likely the cheapest cost avoider.[109] Drug manufacturers "are better able to control product safety" and "possess superior capacity for risk distribution."[110] Drug consumers, by contrast, are patients following the instructions of a doctor, and pharmaceutical companies "cultivate and profit from consumer reliance on the safety" of their drugs.[111] That is why the strict-liability common law tort scheme preempted in *Bartlett* was an essential element in the federal regulatory design.[112] Without that compensatory safety net, the manufacturer does not internalize the costs of a drug's harms, and consumers bear the burden. As Judge Calabresi put it, "the pharmaceutical industry's drive for federal preemption would have the effect of imposing direct, centralized, and high-level decisions as to the value of life and limb" on the FDA approval process.[113] Under the FDCA's intended design, "the costs of tort law are . . . borne by the drug companies," but when preemption is applied "costs . . . would be borne, pretty much entirely, by people other than those companies."[114] Thus, "[w]ho can doubt that the pharmaceutical companies have, to this extent, an important distributional reason to push for preemption and regulation[?]"[115]

The pharmaceutical industry may argue that the FDA's standards are sufficient, but the role of the torts "ceiling" in the FDCA framework is crucial. Despite the FDA's valuable expertise regarding drug safety and approval,[116] "safety issues plague FDA-approved drugs that remain on the market, as more than 100,000 consumers are killed every year as a consequence of

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with an opportunity to seek redress that is not available under federal law."); Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2073 (2000) ("Regulatory agencies are not in the business of compensating for accidental harm arising from activities within the ambit of their authority."); *see also* CASS R. SUNSTEIN, THE COST–BENEFIT STATE 55–68 (2002) (discussing how federal agencies regulate via standard setting based on cost/benefit analyses).

109. *See* Guido Calabresi & Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, 81 YALE L.J. 1055, 1062 (1972) ("The producer is in a position to compare the existing accident costs with the costs of avoiding this type of accident by developing either a new product or a test which would serve to identify the risky .0001 per cent. The consumer, in practice, cannot make this comparison. Relatively, the producer is the cheapest cost avoider, the party best suited to make the cost-benefit analysis and to act upon it."); Olson, *supra* note 103, at 780–81.

110. MARK C. RAHDERT, COVERING ACCIDENT COSTS 90 (1995).

111. *Id.*

112. *See Bartlett*, 570 U.S. at 514 (Sotomayor, J., dissenting) ("Not all products can be made safe for sale with an improved warning or a tweak in design. New Hampshire, through its design-defect law, has made a judgment that some drugs that were initially approved for distribution turn out to be inherently and unreasonably dangerous and should therefore not be sold unless the manufacturer is willing to compensate injured consumers.").

113. GUIDO CALABRESI, THE FUTURE OF LAW & ECONOMICS 37–38 (2016) (endnote omitted).

114. *Id.* at 39.

115. *Id.*

116. *See, e.g.*, Struve, *supra* note 47, at 591 ("[T]he FDA's expertise gives its views on product safety considerable authority. . . .").

medical devices and pharmaceutical use."[117] The FDA's inadequacy in this domain is well established.[118] It is itself evidence of Congress's "understanding of the limitations of *ex ante* federal regulatory review" and "preservation of a role for state law generally, and common-law remedies specifically."[119] The FDA does not independently conduct safety testing when considering approval applications but rather relies upon the manufacturers.[120] Nor does the FDA independently monitor for serious risks which arise postapproval[121] (though it is aware that such problems will arise).[122] The FDA instead relies on manufacturers' self-reporting.[123] While the FDA has a variety of enforcement tools for policing its postapproval jurisdiction,[124] those mechanisms cannot effectively monitor the entire market.[125] Without the specter of common law liability, manufacturers have little incentive to perform these information-generating functions.

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117. Boumil, *supra* note 52, at 6; *see also Bartlett*, 570 U.S. at 500 (Sotomayor, J., dissenting) ("On its own, even rigorous preapproval clinical testing of drugs is generally . . . incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies." (quoting David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 471 (2008))).

118. *See, e.g.*, INST. OF MED. OF THE NAT'L ACADS., THE FUTURE OF DRUG SAFETY 4 (2007), https://www.nap.edu/read/11750/chapter/1 [https://perma.cc/B4T5-YSEV] (considering the FDA's drug safety monitoring system, and finding that "FDA . . . and the pharmaceutical industry . . . do not consistently demonstrate accountability and transparency").

119. *See Bartlett*, 570 U.S. at 500 (Sotomayor, J., dissenting).

120. *See* 21 U.S.C. § 355(b) (2012) (prescribing the FDCA's filing requirements for new drugs); Rabin, *supra* note 108, at 2069 ("Even in the case of a comprehensive regulatory regime like FDA certification of new drugs . . . the burden is on the company to produce evidence in support of its new drug application, and the agency does not conduct its own testing and experimentation." (footnotes omitted)).

121. *See Bartlett*, 570 U.S. at 500 (Sotomayor, J., dissenting) ("[T]he FDA, which is tasked with monitoring thousands of drugs on the market and considering new drug applications, faces significant resource constraints that limit its ability to protect the public from dangerous drugs.").

122. *See* Rabin, *supra* note 108, at 2077 ("[P]rescription drugs have a dynamic and often unpredictable life *after* regulatory approval" that is "intrinsic to both . . . the nature of the product and the process by which it is approved.").

123. *See* 21 C.F.R. § 314.80 (2017) (requiring for the "postmarketing reporting of adverse drug experiences").

124. *See Guidance, Compliance, & Regulatory Information*, U.S. FOOD & DRUG ADMIN. https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/default.htm [https://perma.cc/5TK3-H34Y]; *Step 5: FDA Post-Market Drug Safety Monitoring*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405579.htm [https://perma.cc/H5KU-H7M4].

125. *See* Struve, *supra* note 47, at 601 (citing an internal FDA survey finding "two-thirds of respondents" were less than fully confident that FDA "adequately monitors the safety of prescription drugs once they are on the market," and stating that "[t]he FDA receives large amounts of data . . . from regulated companies" that "will sometimes be incomplete or lack sufficient detail").

B. *An Inadequate Regulatory Scheme Remains Post-Preemption*

The Opioid Epidemic presents a prime example of the compensatory problem that results from a lack of incentive to monitor the safety of approved drugs. Though the degree to which the manufacturers of opioids are responsible for the addiction crisis remains uncertain,[126] existing evidence indicates a significant contribution.[127] That evidence has led to an onslaught of litigation against the major opioids manufacturers and distributors.[128] So far, several state attorneys general, over sixty counties and municipalities, the Cherokee Nation, multiple labor unions, and private classes of plaintiffs have brought actions.[129] The dozens of lawsuits bring varied theories of liability, but they "generally allege the drug companies downplayed the addictive risks of the drugs in order to turn a profit."[130] The defendants raise preemption in response.[131]

The lawsuits allege the risk–benefit approval process underestimated the risk of addiction due to industry's obfuscation. Tort liability could allocate the externalities that result from such a miscalculation to the cheapest cost avoider. But market forces in the American healthcare system drive consumers to generic opioids,[132] where common law tort claims are preempted un-

126. *Opioid Crisis: Are Drug Companies Largely to Blame?*, APP. (July 7, 2017, 10:04 AM), http://www.app.com/story/opinion/columnists/2017/07/07/opioid-abuse-lawsuit-drug-companies/103493680/ [https://perma.cc/KG89-EFZZ] (interviewing law professor David Noll).

127. Harriet Ryan et al., *'You Want a Description of Hell?' Oxycontin's 12-Hour Problem*, L.A. TIMES (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/ [https://perma.cc/5WJS-DJY7]; *see* Alana Semuels, *Are Pharmaceutical Companies to Blame for the Opioid Epidemic?*, ATLANTIC (June 2, 2017) https://www.theatlantic.com/business/archive/2017/06/lawsuit-pharmaceutical-companies-opioids/529020/ [https://perma.cc/YQG3-4ZSF] (explaining that "[t]here is some significant evidence that pharmaceutical companies may have engaged in some activities that led to the opioid crisis," and citing as an example Purdue Pharma's "12-hour" marketing campaign that led consumers to consume the drug in a manner that induced addiction).

128. *See generally* Andrew Westney, *Opioid Litigation Roundup: An Overview of Major Cases*, LAW360 (Oct. 20, 2017, 9:25 PM), https://www.law360.com/articles/975804 (on file with the *Michigan Law Review*).

129. *Id.*; Robert Storace, *CT Unions Sue Nation's Largest Pharma Companies over Opioids*, CONN. L. TRIB. (Dec. 20, 2017, 11:02 PM), https://www.law.com/ctlawtribune/sites/ctlawtribune/2017/12/19/4-connecticut-union-locals-file-suit-against-nations-largest-pharmaceutical-companies/ [https://perma.cc/UU6F-JVYM].

130. Westney, *supra* note 128; Emily Field, *Pharma Cos., States Battle over Opioid Litigation Transfer*, LAW360 (Oct. 24, 2017, 7:20 PM), https://www.law360.com/articles/977356 (on file with the *Michigan Law Review*).

131. *See, e.g.*, Jef Feeley & Jared S. Hopkins, *Ohio's Opioid Suit Should Be Thrown Out, Purdue Pharma Argues*, BLOOMBERG (Sept. 9, 2017, 3:14 PM), https://www.bloomberg.com/news/articles/2017-09-09/ohio-s-opioid-suit-should-be-thrown-out-purdue-pharma-argues [https://perma.cc/23CJ-SYRU] (quoting Purdue's attorneys who argued that a preemption defense justifies the Ohio lawsuit's dismissal).

132. Michelle Andrews, *Medicare Drug Plans Favor Generic Opioids over Those Designed to Avoid Abuse, Study Finds*, PBS (June 12, 2015, 12:52 PM), http://www.pbs.org/newshour/

der *Mensing* and *Bartlett*.[133] Indeed, the defendants in the opioid litigations have already raised blanket preemption defenses.[134] Consumers often play no role in the decision between a generic or brand-name drug that ends up impeding their path to recovery.[135] Moreover, the preempted plaintiffs tend to be disproportionately low income and more likely to lack access to alternative remedies.[136]

C. *Torts Alone Cannot Adequately Compensate the Victims of the Opioid Epidemic*

Restoring the balance between federal regulation and state common law liability in the FDCA's design would provide a remedy for at least some victims of this epidemic. That said, merely overruling *Mensing* and *Bartlett* would not provide a comprehensive solution. The vastness of the Opioid Epidemic makes assigning responsibility for the fallout challenging, in both a moral and legal sense. The crisis has been shaped by the actions (and inactions) of virtually every stakeholder involved in supplying prescription pain-

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rundown/medicare-drug-plans-favor-generic-opioids-designed-avoid-abuse-study-finds/ [https://perma.cc/M3LG-XAZN] ("Medicare drug plans are cutting back on coverage for a specially designated type of painkiller that deters abuse in favor of cheaper generics that don't have the same deterrent qualities, a new study found."); *see supra* note 87 and accompanying text; *see also* Katie Thomas & Charles Ornstein, *Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers*, N.Y. TIMES (Sept. 17, 2017), https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html (on file with the *Michigan Law Review*) ("At a time when the United States is in the grip of an opioid epidemic, many insurers are limiting access to pain medications that carry a lower risk of addiction or dependence, even as they provide comparatively easy access to generic opioid medications.").

133. *See* James M. Beck, *Generic Drug Preemption Scorecard*, DRUG & DEVICE L. (Sept. 20, 2011), https://www.druganddevicelawblog.com/2011/09/generic-drug-preemption-scorecard.html [https://perma.cc/J2XQ-D9KJ].

134. *See* Max Kennerly, *Stacking the Deck Against Opioid Plaintiffs*, LAW360 (Oct. 24, 2017, 11:03 AM), https://www.law360.com/articles/977446/ (on file with the *Michigan Law Review*); Nate Raymond, *U.S. State, Local Government Lawsuits over Opioids Face Uphill Battle*, REUTERS (June 2, 2017, 7:08 AM), http://www.reuters.com/article/us-ohio-opioids-lawsuit-analysis/u-s-state-local-government-lawsuits-over-opioids-face-uphill-battle-idUSKBN18T1H4 [https://perma.cc/9TMN-3A5M] (quoting corporate defense attorneys explaining that the FDA's regulation is the biggest obstacle to opioid litigation against manufacturers).

135. Frequently the prescribing physician, or even the pharmacist, decides whether a patient will receive the generic or brand-name drug. *See* PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011) ("Had [plaintiffs] taken Reglan, the brand-name drug prescribed by their doctors, *Wyeth* would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits.").

136. *See* Chen-Sen Wu, *Distributive Justice in Pharmaceutical Torts: Justice Where Justice Is Due?*, 69 L. & CONTEMP. PROBS., Autumn 2006, 207, 212 (2006) ("In . . . [pharmaceutical] circumstances, socioeconomic bias may rear its ugly head, whether it is in the form of caregivers providing more care to wealthier patients . . . or the inability of poorer patients to navigate the health care system.").

killers: manufacturers,[137] distributors,[138] physicians and pharmacists,[139] insurers,[140] policymakers,[141] and law-enforcement agencies.[142]

Beyond sheer magnitude, the nature of the harms at issue poses a challenge for tort plaintiffs. Where addiction is the actionable injury, tort doctrine limits feasible arguments. Only "legitimate" use of a prescription opioid fits a legal theory that alleges manufacturers misrepresented the addictive nature of their drugs and failed to warn consumers.[143] Manufacturers have succeeded in challenging causality by arguing "that misuse of OxyContin by drug abusers was a superseding cause sufficient to break the chain of causation."[144] For plaintiffs deemed "illegal users" who "intentionally defeated the time-release mechanism" of the pill's design (i.e., crushing the pill, or taking

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137. *See* Patrick Radden 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/53Y3-JNAU] (explaining the history of Purdue and its development of OxyContin, including how Purdue lobbied the FDA and medical community to support opioid painkillers).

138. *See* Charles Ornstein, *Drug Distributors Penalized for Turning Blind Eye in Opioid Epidemic*, NPR (Jan. 27, 2017, 5:00 AM), https://www.npr.org/sections/health-shots/2017/01/27/511858862/drug-distributors-penalized-for-turning-blind-eye-in-opioid-epidemic (on file with the *Michigan Law Review*) (explaining that major pharmaceutical distributors routinely fail to report suspicious ordering activity).

139. *See* John Keilman, *Almost All Doctors Routinely Overprescribe Pain Pills: Survey*, CHI. TRIB. (Mar. 24, 2016, 6:20 PM), http://www.chicagotribune.com/news/local/breaking/ct-prescription-painkiller-overuse-met-20160324-story.html (on file with the *Michigan Law Review*) (explaining how common healthcare practices have exacerbated the crisis); Brian Krans, *More 'Pill Mill' Doctors Prosecuted amid Opioid Epidemic*, HEALTHLINE (May 19, 2016), https://www.healthline.com/health-news/pill-mill-doctors-prosecuted-amid-opioid-epidemic [https://perma.cc/7WL2-DTG2] (explaining how unscrupulous doctors and pharmacies in pain clinics—"pill mills"—are a major source of abused medications).

140. *See* Thomas & Ornstein, *supra* note 132.

141. *See* Chris McGreal, *How Big Pharma's Money—and Its Politicians—Feed the US Opioid Crisis*, GUARDIAN (Oct. 19, 2017, 6:00 AM), https://www.theguardian.com/us-news/2017/oct/19/big-pharma-money-lobbying-us-opioid-crisis [https://perma.cc/LCN8-MD7V] (explaining how the pharmaceutical lobby has successfully shaped laws which play a role in the ongoing crisis).

142. *See* Scott Higham & Lenny Bernstein, *The Drug Industry's Triumph over the DEA*, WASH. POST (Oct. 15, 2017), https://www.washingtonpost.com/graphics/2017/investigations/dea-drug-industry-congress/ [https://perma.cc/VA2W-5HEM]; Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, 60 MINUTES (Oct. 15, 2017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/ [https://perma.cc/Z2A4-6BY9] (explaining, in part, that political appointees in the DEA adopted a soft enforcement policy against the pharmaceutical industry at the height of the opioid crisis).

143. Joseph B. Prater, Comment, *West Virginia's Painful Settlement: How the Oxycontin Phenomenon and Unconventional Theories of Tort Liability May Make Pharmaceutical Companies Liable for Black Markets*, 100 NW. U. L. REV. 1409, 1417 (2006) ("Distinguishing between the harms caused by legitimate use of OxyContin and those caused by its intentional abuse is crucial.").

144. Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L. REV. 1117, 1149 (2014).

multiple doses), "the extent of their deliberate misuse tended to render any sort of claim impracticable."[145] In the class action context, the same issue is an obstacle to meeting the standards of Rule 23.[146] Some courts have found addiction injuries complicate the rule's commonality and typicality requirements because they necessitate "individualized inquiries with respect to those class members who crushed or otherwise misused the drug."[147]

Causation will be central to any tort action but is likely to exclude addiction injuries. A court's inquiry into causation and drug abuse is inevitably moralistic. Many states' common law standards will not apply comparative negligence frameworks to "intentional abuse of a potentially intoxicating substance such as alcohol or OxyContin" but will instead consider this an issue of proximate cause.[148] The comparison is questionable—not many physicians prescribe a daily dosage of alcohol in a manner that naturally induces physiological addiction and high tolerance.[149] By contrast, OxyContin rose to prominence on a marketing campaign boasting of twelve-hour pain relief, but the drug "wears off hours early in many people," resulting in "excruciating symptoms of withdrawal, including an intense craving for the drug."[150] Though addiction science is often hotly contested, it is well-established that physiological addiction to opioids, among the most addictive substances known to man, impacts decisionmaking processes in the prefrontal cortex.[151] Despite this layer of complexity, courts in some of the states most acutely impacted by prescription-opioid abuse follow the proximate cause framework and hold illegal drug abuse to be a bar to recovery.[152]

Therefore, renovating the floor/ceiling model would only partially address the problem. The magnitude of the Opioid Epidemic goes beyond the personal responsibility of the Americans who have fallen prey to addiction. The solution to the problem must do so as well.

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145. Prater, *supra* note 143, at 1419.

146. Ausness, *supra* note 144, at 1137–46.

147. *Id.* at 1142–43 (citing Harris v. Purdue Pharma, L.P., 218 F.R.D. 590, 597 (S.D. Ohio 2003) to show failure on commonality; Campbell v. Purdue Pharma, L.P., No. 1:02cv00163 TCM, 2004 WL 5840206, at *8–9 (E.D. Mo. June 25, 2004), to show failure on typicality).

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

149. *See* W. Michael Hooten et al., *Incidence and Risk Factors for Progression from Short-Term to Episodic or Long-Term Opioid Prescribing: A Population-Based Study*, 90 MAYO CLINIC PROC. 850 (2015) (finding that over one-in-four patients prescribed opioids on a short-term basis for acute pain ended up on longer-term opioid treatment).

150. Ryan et al., *supra* note 127.

151. *See* Peter W. Kalivas & Nora D. Volkow, *The Neural Basis of Addiction: A Pathology of Motivation and Choice*, 162 AM. J. PSYCHIATRY 1403, 1408, 1410 (2005) ("The cardinal behavioral feature of drug addiction" is vulnerability to "an intense desire for the drug and reduced capacity to control that desire" resulting from "profound activation of the prefrontal cortex . . . .").

152. Prater, *supra* note 143, at 1420 (first citing *Labzda*, 292 F. Supp. 2d, at 1355–56; then citing Foister v. Purdue Pharma, L.P., 295 F. Supp. 2d 693, 704–05 (E.D. Ky. 2003); and then citing Orzel v. Scott Drug Co., 537 N.W.2d 208, 212–15 (Mich. 1995)).

III. Calling for an Opioid Epidemic Victim's Compensation Fund

In an era where the Supreme Court's "hostility toward the common law of torts trumps even their caustic criticism of the ever-inflating administrative state," what are the alternative legal mechanisms for internalizing the costs of mass injustices like the Opioid Epidemic?[153] Section III.A explains why alternative solutions, like nontraditional tort schemes or enhanced criminal enforcement, would not solve the compensation problem. Section III.B proposes an opioid victims' compensation fund to replicate the original vision of the FDCA.

A. *Nontraditional Torts and Criminal Punishment Cannot Solve This Problem*

Beyond optimizing the preemption balance, some possible solutions exist within nontraditional tort frameworks. For example, in the case of mass-exposure accidents, injured parties "may in theory sue in tort for redress for their injuries," but in practice "they are unlikely to receive tort compensation" because "the indeterminacy of causation of the injury[]create[s] a basic incongruity with the tort system."[154] Courts can develop novel standards, such as the "substantial factor" test, in response to such problems.[155] Similarly, the late twentieth century saw a rise in the use of public nuisance doctrine to target mass damage resulting from dangerous products, such as tobacco, guns, or lead paint.[156]

Compensating victims of the Opioid Epidemic is likely a challenge that even these alternative standards are ill-suited to resolve. While mass-exposure theory addresses the causation obstacle, ultimately, an FDA-regulated and doctor-prescribed pharmaceutical drug is neither an environmental nor accidental harm and is ill-suited to the doctrine. Though analogizing between an addictive drug flooding the markets and a toxic substance flooding the environment is intriguing, it is probably more useful as a thought exercise than a practical litigation strategy.

Public nuisance theory is a closer call. Many legal commentators have already begun comparing the tidal wave of opioid litigation to that of the 1990s tobacco litigation, where public nuisance was utilized.[157] The Ohio attorney general's complaint against the opioids manufacturers is testing the

153. Sharkey, *supra* note 106, at 1733.

154. Palma J. Strand, Note, *The Inapplicability of Traditional Tort Analysis to Environmental Risks: The Example of Toxic Waste Pollution Victim Compensation*, 35 STAN. L. REV. 575, 575 (1983).

155. *See generally* David E. Bernstein, *Getting to Causation in Toxic Tort Cases*, 74 BROOK. L. REV. 51 (2008).

156. *See* Donald G. Gifford, *Public Nuisance as a Mass Products Liability Tort*, 71 U. CIN. L. REV. 741 (2003).

157. *See, e.g.*, Richard Scruggs, *Are Opioids the New Tobacco?*, LAW360 (Sept. 15, 2017, 11:04 AM), https://www.law360.com/articles/962715/ (on file with the *Michigan Law Review*).

theory: its first cause of action is a public nuisance claim.[158] Some localities have indicated they are taking the same approach.[159] But this theory requires the extension of a common law doctrine that was virtually never the basis for a manufacturer's liability to an injured consumer until the twenty-first century.[160] It is unlikely that a majority of courts would welcome such an approach. Even if public nuisance were a more promising scheme, "the scope of liability for damages is more restricted than it is for other torts such as strict products liability . . . where compensation is a principal goal."[161] Forcing the common law to serve as a substitute for products liability would fail to achieve comprehensive compensation for victims.

Outside of torts, some policymakers argue that an increased criminal justice response is needed.[162] Indeed, prosecuting corporate executives guilty of intentionally or recklessly exacerbating the Opioid Epidemic is likely warranted.[163] Law enforcement agencies argue that criminal enforcement improves norms of corporate ethics in the industry, thereby affirmatively reducing the harm done by the epidemic.[164]

But even when considering that possible shift in corporate culture, increased criminal enforcement could do more harm than good for victims of the epidemic. History reflects a tendency for the criminal response to substance abuse emergencies to take the form of a "war" waged on the same

158. *See Attorney General DeWine Files Lawsuit Against Opioid Manufacturers for Fraudulent Marketing; Fueling Opioid Epidemic*, OHIO ATT'Y GEN. (May 31, 2017), http://www.ohioattorneygeneral.gov/Media/News-Releases/May-2017/Attorney-General-DeWine-Files-Lawsuit-Against-Opio [https://perma.cc/7PG6-59WW].

159. *Is the Public Nuisance Universe Expanding?*, [Feb. 16, 2017] Envtl. Due Diligence Guide Rep. (BNA) No. 26-2, at 16.

160. *See* Gifford, *supra* note 156, at 745.

161. *Id.* at 828.

162. *See, e.g.*, Patricia Baldwin, *Prosecutors and Health Care Workers Need Tools to Fight Opiate Epidemic*, HERALD-TRIB. (Aug. 13, 2017), http://www.batesvilleheraldtribune.com/opinion/prosecutors-and-health-care-workers-need-tools-to-fight-opiate/article_b2ac6cfc-c0e5-5a27-9fb3-94f9bba21177.html [https://perma.cc/G6GR-LHG5] (stating that "[p]enalties for drug possession and dealing are too low" and that public health efforts will fail "without a comparable and equivalent improvement on the enforcement side").

163. *See, e.g.*, Cynthia Koons & Jef Feeley, *Opioid Billionaire's Indictment Opens New Window on Epidemic*, BLOOMBERG (Oct. 26, 2017, 11:55 AM), https://www.bloomberg.com/news/articles/2017-10-26/insys-therapeutics-founder-charged-in-opioid-fraud-case [https://perma.cc/LJH9-VJHX] (describing how billionaire pharmaceutical executive "found an aggressive way to sell even more" opioids by "bribing doctors to prescribe them").

164. *See, e.g.*, *Pharmaceutical Executives Charged in Racketeering Scheme*, U.S. DEP'T JUST. (Dec. 8, 2016), https://www.justice.gov/usao-ma/pr/pharmaceutical-executives-charged-racketeering-scheme [https://perma.cc/WVG2-WDVH] (statement of FBI Special Agent Harold Shaw) ("[I]ndictments reflect the steadfast commitment of . . . law enforcement . . . to confront the opioid epidemic impacting our communities [by] bringing to justice those who seek to profit from fraud or other criminal acts.").

communities burdened by crisis.[165] This aggravates the underlying public health problems. The costs of criminal enforcement "disproportionately impact low-income individuals and communities,"[166] and "[t]he harms normally associated with drug addiction . . . are exacerbated in prison."[167] When those struggling with addiction are incarcerated, their communities foot the bill: a *Medical Care* study estimates that opioid criminal justice–related costs in 2013 totaled $7.7 billion "borne directly by state and local governments."[168] For opioid addicts not seeking treatment, studies using a "cost-of-illness methodology" estimate an "average annual law enforcement and victimization societal burden" above $50,000 per individual.[169] By contrast, "dollar for dollar, treatment" of the underlying addiction "reduces the societal costs of substance abuse more effectively than incarceration does."[170] Legislators should look to solutions grounded in harm reduction rather than criminality when addressing the compensation problem.

B. *The Victim's Compensation Fund Model*

A compensation fund has the potential to address the costs problem where tort litigation is inadequate and criminal enforcement is counterproductive. In circumstances where litigation is not feasible or desirable, courts and legislatures have turned to the use of compensation funds.[171] A compensation fund can mimic the functions of the tort system, achieving goals like internalization and deterrence, as well as compensation.[172] The fund model is a comprehensive approach to public health crises because it "enable[s]

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165. *See* Lisa D. Moore & Amy Elkavich, *Who's Using and Who's Doing Time: Incarceration, the War on Drugs, and Public Health*, 98 AM. J. PUB. HEALTH 782 (2008).

166. Melissa S. Kearney, Op-Ed, *The Economic Challenges of Crime & Incarceration in the United States*, BROOKINGS INST. (Dec. 22, 2014), https://www.brookings.edu/opinions/the-economic-challenges-of-crime-incarceration-in-the-united-states/ [https://perma.cc/6FDD-GN4H].

167. Will Small et al., *Incarceration, Addiction and Harm Reduction: Inmates Experience Injecting Drugs in Prison*, 40 SUBSTANCE USE & MISUSE 831, 831 (2005).

168. Connie Hughes, *Costs of U.S. Prescription Opioid Epidemic Estimated at $78.5 Billion*, WOLTERS KLUWER (Sept. 14, 2016), http://wolterskluwer.com/company/newsroom/news/2016/09/costs-of-us-prescription-opioid-epidemic-estimated-at-usd78.5-billion.html [https://perma.cc/9FMC-9BT2].

169. *See* Emanuel Krebs et al., *Dynamics in the Costs of Criminality Among Opioid Dependent Individuals*, 144 DRUG & ALCOHOL DEPENDENCE 193, 194 (2014).

170. *See* DOUG MCVAY ET AL., JUSTICE POL'Y INST., TREATMENT OR INCARCERATION? 6 (2004), http://www.justicepolicy.org/uploads/justicepolicy/documents/04-01_rep_mdtreatmentorincarceration_ac-dp.pdf [https://perma.cc/Y4RT-KSFA] (summarizing studies finding the return-on-investment rate of drug treatment programs ranging from $1.91 to $3.30 per dollar spent).

171. *See generally* Linda S. Mullenix & Kristen B. Stewart, *The September 11th Victim Compensation Fund: Fund Approaches to Resolving Mass Tort Litigation*, 9 CONN. INS. L.J. 121 (2002).

172. *See* Jon D. Hanson & Kyle D. Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation*, 107 YALE L.J. 1163, 1260–62, 1283–96 (1998).

courts to overcome the problems posed by systematic causal indeterminacy."[173]

Compensation funds are uncommon but not unprecedented.[174] The best-known compensatory fund is likely the controversial September 11th Victim Compensation Fund, "the country's largest experiment in paying mass victims and their families without placing blame."[175] Less well-known examples exist, including funds addressing childhood vaccine injuries, nuclear exposure, black lung disease, and Agent Orange victims.[176]

The situations above are comparable to the current Opioid Epidemic compensation problem. For example, at the apex of the tobacco litigation, scholars suggested a variety of compensatory fund approaches as comprehensive solutions.[177] Similarly, the Childhood Vaccination Compensation Program (CVCP) arose when "administratively costly tort liability did not provide injured consumers reliable compensation."[178] The CVCP is a close analogue to the solution the Opioid Epidemic requires: it "creates something of a hybrid system between a fault-based system and a causation-based compensation system" and is "meant to be expeditious . . . accessible, and informal."[179] CVCP damage awards are funded through an excise tax on the sale of the vaccines and, occasionally, additional penalties against manufacturers.[180] Like prescription opioids, childhood vaccines provide a clear public benefit while also causing injuries that tort liability cannot reliably compensate.[181] The opioids compensation fund could also be financed through an excise tax, furthering the internalization goal. The CVCP is not primarily concerned with deterrence,[182] but the opioids fund could additionally achieve deterrence goals (against irresponsible marketing, distributing, and

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173. David Rosenberg, *The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System*, 97 HARV. L. REV. 849, 859 (1984).

174. *See* Jon D. Hanson, Kyle D. Logue & Michael S. Zamore, *Smokers' Compensation: Toward a Blueprint for Federal Regulation of Cigarette Manufacturers*, 22 S. ILL. U. L.J. 519, 535–50 (1998) (providing " 'real world' models of . . . compensation programs").

175. Mullenix & Stewart, *supra* note 171, at 123 (quoting Amanda Ripley, *What Is a Life Worth?, To Compensate Victims of Sept. 11, the Government Has Invented a Way to Measure Blood and Loss in Cash: A Look at the Wrenching Calculus*, TIME, Feb. 11, 2002, at 22).

176. *Id.* at 133–51.

177. The Hanson, Logue, and Zamore proposal relied on here extensively outlines how such a model achieves the goals of the tort system. *See supra* note 174. For other models of how to structure a tort-simulating victims' compensation fund, see Richard C. Ausness, *Compensation for Smoking-Related Injuries: An Alternative to Strict Liability in Tort*, 36 WAYNE L. REV. 1085 (1990), and Donald W. Garner, *Cigarettes and Welfare Reform*, 26 EMORY L.J. 269 (1977).

178. Hanson, Logue & Zamore, *supra* note 174, at 543.

179. *Id.* at 542–43.

180. *Id.*

181. *See id* at 543.

182. *Id.* at 544.

prescribing) through a partially fault-based component in addition to the tax funding.

While funds like the CVCP simply provide cash payouts,[183] the opioids fund should compensate in a manner that addresses the unique public health dimensions of the crisis. For applicants with ongoing addiction injuries at the time of application, the fund's payout schedules could provide sorely needed[184] drug abuse resources[185] rather than cash awards. Harm-reduction policies such as overdose-reversal medications, supervised-injection facilities, and addiction-treatment programs should be prioritized to slow the unprecedented rate of overdose deaths.[186] This form of compensation remedies the injury at issue and achieves efficiency by relieving over-burdened local healthcare systems.[187]

The fund would be an administrative scheme mimicking products liability.[188] Industry stakeholders would provide financing, and affected consumers (patients with addiction injuries, families with wrongful death claims, etc.) would receive compensation.[189] Congress would generate eligibility criteria sufficient to establish an applicant's injury from a prescription opioid.[190] The standard for establishing causation would be cursory by design, allowing for compensation beyond what the tort system could achieve and deterring manufacturers and distributors from facilitating overprescription.[191] An administrative tribunal would preside over the fund to evaluate

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183. CVCP applicants can receive "up to $250,000 in pain and suffering damages" and a wrongful death fee of $250,000. *Id.* at 542.

184. *See* Olga Khazan, *Why 80 Percent of Addicts Can't Get Treatment*, ATLANTIC (Oct. 13, 2015), https://www.theatlantic.com/health/archive/2015/10/why-80-percent-of-addicts-cant-get-treatment/410269/ [https://perma.cc/DHQ5-WZRJ].

185. *See* Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANN. REV. PUB. HEALTH 559, 569 (2015).

186. *See id.*; Andrew Lee Ball, *HIV, Injecting Drug Use and Harm Reduction: A Public Health Response*, 102 ADDICTION 684 (2007); *see also* Phillip O. Coffin & Sean D. Sullivan, *Cost-Effectiveness of Distributing Naloxone to Heroin Users for Lay Overdose Reversal*, 158 ANNALS INTERNAL MED. 1 (2013).

187. *See* Coffin & Sullivan, *supra* note 186, at 6 ("Naloxone distribution to heroin users would be expected to reduce mortality and be cost-effective even under markedly conservative assumptions of use, effectiveness, and cost.").

188. *See, e.g.*, Hanson, Logue & Zamore, *supra* note 174, at 550, 552 (explaining that a fund should "begin by appointing some sort of special commission or panel" that implements a "carefully molded system designed to compensate [a] class of injured consumers").

189. *See, e.g.*, *id.* at 591 ("The up-front start-up costs of setting up a [compensation fund] should be paid for through a single lump sum charge against the industry, in proportion to each manufacturer's market share over the past several decades.").

190. *See, e.g.*, *id.* at 574 ("A . . . common feature of proposed causation-based compensation systems is the use of evidentiary presumptions[,] . . . key features of both the Black Lung Benefits Program and the National Vaccine Injury Compensation Program.").

191. *See, e.g.*, *id.* at 565 (recommending a generous approach to causation that reduces "the obstacle facing claimants of proving a causal connection that is often difficult or costly to establish"); Hanson & Logue, *supra*, note 172, at 1260.

applications and calculate remedies based on predetermined schedules.[192] The damages would then be allocated among the opioids manufacturers and distributors currently in litigation with state attorneys general.[193] Allocations would be based on negotiated proportions (depending on the circumstances of the negotiations, this could include a fault-based component or simply follow market-share). For complying companies, participation in the fund would function like a settlement of the pending litigation through its offer of prospective tort immunity.[194]

Thus, an opioids compensation fund could achieve the very functions that the post-*Mensing*-and-*Bartlett* FDCA floor/ceiling balance cannot. By requiring industry participants to finance a portion of the awards, the fund imposes the negative-externality costs of opioids on their manufacturers and distributors. This internalization reduces inefficiency and alleviates some of the macroeconomic burden of the crisis. The more simplistic evaluation of causation means the fund would reach a wider population of injured parties. The sizable pool of potential applicants also acts as a deterrent against the irresponsible prescribing practices that led to the current crisis.

Feasibility is the primary obstacle to this solution. Manufacturers and distributors are unlikely to volunteer for new taxes and penalties in exchange for tort immunity unless the liability they face is potentially bankrupting. For example, during the tobacco litigation policymakers considered compensation funds while manufacturers were facing potential regulation by the FDA and a settlement with state attorneys general estimated at $368.5 billion.[195] While comparisons have been made by attorneys familiar with the tobacco litigation,[196] the current stance of the opioids litigation is not as threatening to the pharmaceutical industry.[197] Until industry players feel sufficient pressure to come to the table, this solution remains aspirational. But an unprece-

192. *See, e.g.*, Hanson, Logue & Zamore, *supra* note 174, at 552–53 (discussing the range of options for administrators of funds—from "administrative law judges," to "experts fluent in the language of scientific and epidemiological evidence," or even "relying on federal courts").

193. *See, e.g.*, *id.* ("[A]lthough state and federal legislatures have occasionally been willing to create some tort-law immunity for some industries, they have rarely done so without simultaneously substituting some form of ex post compensation system in its place.").

194. *See, e.g.*, *id.* at 588 ("A bar on tort claims could be characterized as the price [victims] would pay for the more lenient causation-based alternative [of the compensation fund].").

195. *See* Hanson & Logue, *supra* note 172, at 1334 n.708.

196. Esmé E. Deprez & Paul Barrett, *The Lawyer Who Beat Big Tobacco Takes on the Opioid Industry*, BLOOMBERG (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/VUN6-MXJP].

197. *See supra* Part II.C; *see also* Amanda Bronstad, *Is Opioid Litigation the New Tobacco? Not Quite, Even If There's a Family Resemblance*, NAT'L L.J. (Oct. 30, 2017, 5:44 PM), https://www.law.com/nationallawjournal/sites/nationallawjournal/2017/10/30/is-opioid-litigation-the-new-tobacco-not-quite-even-if-theres-a-family-resemblance/ [https://perma.cc/3E4T-MUPR].

dented crisis demands unprecedented solutions, and it is not too early to see that a compensation fund is an optimal option.

General critics of the compensation fund mechanism may raise concerns about manufacturing liability outside of courts. A program like the one suggested here requires "a single, powerful administrator . . . completely dominat[ing] the creation and implementation" of liability imposed upon private parties—a system that might "lack[] legitimacy in a democratic society."[198] A fund simulates the administration of justice in a vacuum removed from "the values of participation, accountability, transparency, rationality, personal autonomy, equality, due process, and other social capital values necessary to promote civil society."[199]

These concerns are justified. But, this kind of remedy is reserved for situations where existing legal mechanisms are inadequate. Prior examples, such as the CVCP or black lung fund, indicate that Congress's discretion is a sufficient barrier to wholesale abandonment of the civil process. Ultimately, these criticisms do not outweigh the social value of the fund. A legal system that provides no remedy to victims of the Opioid Epidemic is similarly removed from democratic values.

Conclusion

Reasonable minds can disagree on the optimal balance between federal regulation and state common law liability in the contemporary administrative state. The FDA's pharmaceutical regulatory framework, however, indisputably relies on *some* role for the states in compensating consumer injuries. Dramatically cutting back that role, just as an unprecedented prescription drug crisis grips the nation, protects the pharmaceutical industry's interests at the expense of working Americans.

Allocating costs and compensating injured consumers will alleviate this imbalance. The mechanisms of tort liability will force internalization by manufacturers and provide needed incentives for safety. But, in a nationwide addiction crisis, torts are ill-equipped to achieve this task alone. An Opioid Epidemic victims' compensation fund will achieve this outcome comprehensively.

198. Linda S. Mullenix, *Prometheus Unbound: The Gulf Coast Claims Facility as a Means for Resolving Mass Tort Claims—A Fund Too Far*, 71 La. L. Rev. 819, 824–825 (2011).

199. *Id.* at 914.