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

Michael R. Abrams*

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 pre-market 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

3. Id.
4. Id.
addictions” to prescription narcotic pain killers. An article in *Scientific American* cited Porter and Jick’s one-paragraph letter as an “extensive study.”* Time* magazine referred to their “landmark” research as showing the “exaggerated fear that patients would become addicted” to prescription opioids was “basically unwarranted.” 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.”

Those citations fueled a shift in the healthcare industry’s perspective on the treatment of pain. Pharmaceutical and healthcare industry figures “aggressively pushed the concept of pain as the fifth vital sign.” 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. Concurrently, the pharmaceutical industry ramped up promotion of pain medications. Purdue Pharma introduced OxyContin to the market as a long-term solution to chronic pain. A 1998 OxyContin promotional video featured a doctor referencing the letter’s data:

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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).
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


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 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


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

30. Eyre, supra note 29.
34. Id.
“initiated” into opioid addiction by prescription medications who then transition to cheaper, more widely available black-market heroin. 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.

This unprecedented rate of addiction and death amounts to the largest drug-related public health emergency in American history. Six states and the White House have declared official emergencies. 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.” Indeed, “many public health experts have traced the roots of the current surge in opioid addic-


tion...to...prescription drugs” because “[t]he misuse of prescription opioids is intertwined with that of illicit opioids.” Four out of five new heroin users began by misusing a prescription opioid. 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].” 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. The FDCA “imposes an elaborate system” requiring premarket approval of new drugs following “extensive


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).

testing and stringent risk/benefit analysis.” The approval process is notoriously onerous. 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. 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. 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.” The FDCA implements a “risk-benefit assessment framework” to determine when a drug poses an acceptable degree of risk in light of its benefits. 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. But that is the FDA’s task every time it evaluates whether a new drug meets the “safe and effective” stand-


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 . . . .”).


50. See § 355.


A drug is never entirely risk free, so warning labels are crucial. An approved warning label informs doctors and patients about the risks they assume in prescribing and taking a drug respectively. 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.” 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. The FDA primarily relies on manufacturers supplying information through the CBE process to detect postmarket risks. 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.”

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. The Supreme Court interpreted this omission as Congress’s determination “that widely

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.


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


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.


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.”

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.” 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.” 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. 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. Because “federal law reigns supreme,” it “preempts any conflicting law or law that federal legislation deems preempted.” Preemption can be “based on an express or implied legislative or regulatory determination.” Express preemption clauses speak for themselves, while implied preemption is broken into three main categories. 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); 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)).


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.


69. Id. at 183–86.

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); 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 the 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)).


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) (“Tort 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.”).

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-

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] the agency’s views on state law are inherently suspect in light of this procedural failure.”).
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).
86. Bartlett, 570 U.S. at 475; Mensing, 564 U.S. at 609.
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.\footnote{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.’).} 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.\footnote{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.’).} The Court reached this conclusion despite the FDA’s objections.\footnote{Mensing, 564 U.S. at 616.} 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.\footnote{Id.} 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.\footnote{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.’).} Prior to these cases, the “impossibility” category of preemption was reserved for physical impossibilities.\footnote{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))).} 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.”\footnote{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.’).}

The Supreme Court’s post-Wyeth pharmaceutical preemption decisions amount to a novel application of the doctrine with seismic social policy implications.\footnote{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.’).} This line of cases immunizes most drug manufacturers from...
state common law liability. Under this regime, when two plaintiffs suffer
the same injury from a defective brand-name drug and its generic equiva-
 lent, only the former has a claim against the manufacturer. Even the Court
acknowledged this outcome “makes little sense” for pharmaceutical con-
sumers, and commentators found the decisions “bizarre.” To the pharma-
ceutical industry, the decisions signaled an increasing preference by the Court
for immunizing manufacturers from state common law liability. In the
face of the Opioid Epidemic, the Supreme Court has severely obstructed a
major pathway to remediying consumer injuries and penalizing manufac-
turers.

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 adminis-
trative design. This prevents internalization of prescription opioids’ external-
ities and compensation for the injured. The Court’s increasing preference for
centralized, standard-setting regulation over localized, market-based com-
 pensatory 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 ar-
gues 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.

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 dis-
 pensed 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.

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.
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 postapproval103 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


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.”).


that role, as the FDCA imagined, given they are likely the cheapest cost avoider. Drug manufacturers “are better able to control product safety” and “possess superior capacity for risk distribution.” 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. That is why the strict-liability common law tort scheme preempted in Bartlett was an essential element in the federal regulatory design. 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. 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.” Thus, “[w]ho can doubt that the pharmaceutical companies have, to this extent, an important distributional reason to push for preemption and regulation?"

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, “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

109. See Guido Calabresi & Jon T. Hirshcoff, 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 .001001 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.


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.”).


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.” The FDA’s inadequacy in this domain is well established. 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.” The FDA does not independently conduct safety testing when considering approval applications but rather relies upon the manufacturers. Nor does the FDA independently monitor for serious risks which arise postapproval (though it is aware that such problems will arise). The FDA instead relies on manufacturers’ self-reporting. While the FDA has a variety of enforcement tools for policing its postapproval jurisdiction, those mechanisms cannot effectively monitor the entire market. Without the specter of common law liability, manufacturers have little incentive to perform these information-generating functions.

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.”).


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

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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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, distributors, physicians and pharmacists, insurers, policymakers, and law-enforcement agencies.

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. 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.” For plaintiffs deemed “illegal users” who “intentionally defeated the time-release mechanism” of the pill’s design (i.e., crushing the pill, or taking


140. See Thomas & Ornstein, supra note 132.


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.

145. Prater, supra note 143, at 1419.
146. Ausness, supra note 144, at 1137–46.
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 . . . ”).
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? 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.” Courts can develop novel standards, such as the “substantial factor” test, in response to such problems. 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.

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. The Ohio attorney general’s complaint against the opioids manufacturers is testing the

theory: its first cause of action is a public nuisance claim.\textsuperscript{158} Some localities have indicated they are taking the same approach.\textsuperscript{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.\textsuperscript{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.”\textsuperscript{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.\textsuperscript{162} Indeed, prosecuting corporate executives guilty of intentionally or recklessly exacerbating the Opioid Epidemic is likely warranted.\textsuperscript{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.\textsuperscript{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


\textsuperscript{160}. See Gifford, supra note 156, at 745.

\textsuperscript{161}. Id. at 828.


\textsuperscript{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.”).
This aggravates the underlying public health problems. The costs of criminal enforcement “disproportionately impact low-income individuals and communities,” and “[t]he harms normally associated with drug addiction ... are exacerbated in prison.” 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.” 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. By contrast, “dollar for dollar, treatment” of the underlying addiction “reduces the societal costs of substance abuse more effectively than incarceration does.” 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. A compensation fund can mimic the functions of the tort system, achieving goals like internalization and deterrence, as well as compensation. The fund model is a comprehensive approach to public health crises because it “enable[s]
Compensation funds are uncommon but not unprecedented. 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.” Less well-known examples exist, including funds addressing childhood vaccine injuries, nuclear exposure, black lung disease, and Agent Orange victims.

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. Similarly, the Childhood Vaccination Compensation Program (CVCP) arose when “administratively costly tort liability did not provide injured consumers reliable compensation.” 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.” CVCP damage awards are funded through an excise tax on the sale of the vaccines and, occasionally, additional penalties against manufacturers. Like prescription opioids, childhood vaccines provide a clear public benefit while also causing injuries that tort liability cannot reliably compensate. The opioids compensation fund could also be financed through an excise tax, furthering the internalization goal. The CVCP is not primarily concerned with deterrence, but the opioids fund could additionally achieve deterrence goals (against irresponsible marketing, distributing, and

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 EMBRY 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, 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 drug abuse resources 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. This form of compensation remedies the injury at issue and achieves efficiency by relieving over-burdened local healthcare systems.

The fund would be an administrative scheme mimicking products liability. Industry stakeholders would provide financing, and affected consumers (patients with addiction injuries, families with wrongful death claims, etc.) would receive compensation. Congress would generate eligibility criteria sufficient to establish an applicant’s injury from a prescription opioid. 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. An administrative tribunal would preside over the fund to evaluate

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.


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 (“... 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.\textsuperscript{192} The damages would then be allocated among the opioids manufacturers and distributors currently in litigation with state attorneys general.\textsuperscript{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.\textsuperscript{194}

Thus, an opioids compensation fund could achieve the very functions that the post-	extit{Mensing}-and-	extit{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.\textsuperscript{195} While comparisons have been made by attorneys familiar with the tobacco litigation,\textsuperscript{196} the current stance of the opioids litigation is not as threatening to the pharmaceutical industry.\textsuperscript{197} Until industry players feel sufficient pressure to come to the table, this solution remains aspirational. But an unprece-

\begin{itemize}
\item \textsuperscript{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").
\item \textsuperscript{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.").
\item \textsuperscript{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].").
\item \textsuperscript{195} See Hanson & Logue, supra note 172, at 1334 n.708.
\end{itemize}
dent 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 dominant[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.

199. Id. at 914.