NO. 12-142

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,
Petitioner,

v.

KAREN L. BARTLETT,
Respondent.

On Writ of Certiorari
to the United States Court of Appeals
for the First Circuit

AMICI CURIAE BRIEF OF THE AMERICAN ASSOCIATION FOR JUSTICE AND PUBLIC JUSTICE IN SUPPORT OF RESPONDENT

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INTERESTS OF *AMICI CURIAE*[1]

The American Association for Justice ("AAJ") and Public Justice submit this brief as amici curiae in support of Respondent Karen L. Bartlett.

AAJ is a voluntary national bar association whose trial-lawyer members primarily represent individual plaintiffs in civil suits, including personal injury actions, consumer lawsuits, and employment-related cases. Many AAJ-member attorneys represent consumers who have been harmed by dangerous prescription drugs, including consumers who live in New Hampshire. AAJ believes that holding drug makers accountable justly compensates those they have harmed and provides drug companies with a strong incentive to minimize the risk of harm to consumers.

AAJ has also appeared as an amicus curiae in litigation concerning whether federal regulation of prescription drugs and medical devices preempts traditional state-law causes of action. AAJ believes that state tort litigation generally complements and furthers the purposes of the federal regulatory scheme and, therefore, that few state tort claims should be held to be preempted by federal law.

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[1] Pursuant to Supreme Court Rule 37.6, amici state that no counsel for a party authored any part of this brief, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae, its members, or its counsel made a monetary contribution to the brief's preparation or submission. The parties' blanket consents to the filing of amicus curiae briefs are on file with the Clerk.

Public Justice is a national public interest law firm dedicated to pursuing justice for victims of corporate and government wrongdoing. Through involvement in precedent-setting and socially significant litigation, Public Justice seeks to ensure that tort law compensates those injured by wrongful conduct and deters similar conduct in the future. As part of its work, Public Justice has represented consumers injured by prescription drugs and litigated many tort cases involving preemption defenses, including as co-counsel for Gladys Mensing in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Public Justice is concerned that if tort remedies against generic drug manufacturers are limited through improper application of preemption principles, injured patients will be left without compensation and generic manufacturers will not have adequate incentive to ensure that their drugs are safe.

INTRODUCTION AND SUMMARY OF ARGUMENT

Petitioner Mutual Pharmaceutical Company, Inc., a generic manufacturer of a non-steroidal anti-inflammatory drug (NSAID) with the nonproprietary name sulindac, seeks a ruling that Congress, in enacting and amending the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq*., intended to deprive injured parties like Respondent of longstanding compensation for defective drugs.[2]

Congress has not expressly preempted state tort actions against prescription drug manufacturers, even as it has periodically enlarged the Food and Drug Administration's (FDA's) power to administer federal law. *See Wyeth v. Levine*, 555 U.S. 555, 566-67 (2009). Petitioner argues, however, that preemption may be inferred because it is "impossible" for drug manufacturers to comply with both state law and federal law; and because state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" as expressed in the FDCA. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-373 (2000).

The question is ultimately one of congressional intent. When "'Congress has legislated . . . in a field which the States have traditionally occupied, . . . [courts] start with the assumption that the historic police powers of the States were not to be superseded

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[2] These amendments include the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Sept. 24, 1984), known commonly as the Hatch-Waxman Act.

by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Levine*, 555 U.S. at 565 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); some internal quotation marks omitted). That is particularly true as to matters of health and safety, which traditionally are areas of State concern. *Lohr*, 518 U.S. at 485. The presumption against preemption has added force in this context. *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985).

Strictly as a matter of impossibility preemption, there is no basis to infer a conflict. Nothing in federal law prohibits a drug manufacturer from complying with a state-law judgment obligating it to pay compensation to a patient injured by a drug found to be unreasonably dangerous on the record in the case. Indeed, federal law does not even require a manufacturer, whether brand-name or generic, to sell a non-life-saving drug that has met FDA approval. *See* 21 U.S.C. § 356c; 21 C.F.R. § 314.161. Federal law permits both brand-name and generic manufacturers independently to stop selling a drug. *See id*.

As for obstacle preemption, Petitioner has not preserved that affirmative defense for this Court's review. *See* Resp't Br. 39-40. Had it been properly preserved, however, the argument would nonetheless fail on the merits. State-law liability based on significant new evidence that a drug is unreasonably dangerous if taken for its approved uses *parallels* the federal-law duty not to market a misbranded drug. In this circumstance, state law complements federal law's purposes and objectives.

The United States' discussion of conflict preemption in a hypothetical case concerning what it calls a "pure" design-defect claim contains two significant errors. First, the United States' account of post-marketing regulation fails either to acknowledge the agency's shortcomings, which hamper its ability to monitor the safety and efficacy of prescription drugs, or to credit product-liability litigation for providing a critical layer of consumer protection. The *Levine* Court made no such mistake. It recognized that the FDA lacks the resources to monitor the safety profiles of the more than 11,000 drugs on the market; and that the FDA is a largely reactive institution that depends on the press, manufacturers, *and* litigation to uncover safety hazards. *See* 555 U.S. at 578-79 & n.11.

Second, the United States errs in suggesting that an injured plaintiff must "prove that the manufacturer knew or should have known of new and scientifically significant evidence that rendered the drug 'misbranded' under federal law"; or that States must rewrite their tort laws accordingly. U.S. Br. 12, 16 & n.3. If the FDCA, by operation of the Supremacy Clause, is read to displace design-defect claims absent such evidence, then such evidence will be required only as a consequence of preemption. Because the burden of establishing the affirmative defense of preemption rests with the defendant, the defendant manufacturer should be required to prove that all of plaintiff's evidence of defect had already been considered by the FDA and had been found insufficient to render a drug misbranded. Further, the States need not rewrite their tort laws to accommodate possible preemption defenses. The Supremacy Clause displaces contrary state law, but it does not require any affirmative action by the

States. The United States' contrary suggestion fails to appreciate this feature of our federalism.

ARGUMENT

CONGRESS DID NOT INTEND TO DEPRIVE PERSONS INJURED BY UNREASONABLY DANGEROUS DRUGS OF LONG AVAILABLE COMPENSATION.

A. Even a State-Law Prohibition Against the Sale of a Particular, Unreasonably Dangerous Drug Would Not Pose an Impossibility Conflict with Federal Law When Federal Law Does Not Require Drug Manufacturers to Sell Drug Products.

1. In order to show 'impossibility,' a defendant must prove that "compliance with both federal and state [law] is a physical impossibility," *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). Such '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.'" *Barnett Bank of Marion Cnty., NA v. Nelson*, 517 U.S. 25, 31 (1996). But "physical impossibility" does not exist where state law merely authorizes an action that federal law forbids. *Michigan Canners & Freezers Ass'n, Inc. v. Agricultural Marketing & Bargaining Bd.*, 467 U.S. 461, 478 n.21 (1984) ("Because the Michigan Act is cast in permissive rather than mandatory terms—an association may, but need not, act as exclusive bargaining representative—this is not a case in

which it is impossible for an individual to comply with both state and federal law.").

Petitioner cannot make that demanding showing here. It cannot show that state law *requires* anything that federal law *forbids*, or vice-versa—the only circumstances in which compliance with state and federal law is physically impossible. *See Barnett Bank*, 517 U.S. at 31; *Michigan Canners*, 467 U.S. at 478 n.21

The district court in this case concluded that New Hampshire's "strict products liability requires[]" "that manufacturers compensate consumers for the damage caused by unreasonably dangerous products, not necessarily that they remove such products from the market." 2010 WL 3092649, at *8 (D. N.H. Aug. 2, 2010) (JA 305) (citing 5 Louis R. Frumer & Melvin I. Friedman, *Products Liability* § 57.01[4], at 57-9 (2010) for the proposition that "almost all of the opinions which have addressed the issue have found that there is no common law duty to recall or retrofit" unreasonably dangerous products)). The court of appeals' decision, though not explicit on this point, at least implicitly endorsed the district court's understanding that New Hampshire design-defect liability obligates a defendant to pay damages. *See* Pet. App. 10a-11a (noting that "the decision [of a manufacturer] to make the drug and market it is wholly its own").

A state-law obligation to compensate injured parties, standing alone, does not "directly" conflict with any FDCA requirement. Federal law does not forbid the payment of compensatory damages; therefore, it is not physically impossible to comply with both state and federal law. *See Barnett Bank*,

517 U.S. at 31; *Michigan Canners*, 467 U.S. at 478 n.21. This remains true even if the payment of damages once, twice, or even multiple times might induce a manufacturer to stop selling its product; "[a]n occurrence that merely motivates an optional decision does not qualify as a requirement." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005).

Even assuming for argument's sake that a design-defect claim were premised on the violation of an underlying duty not to sell an unreasonably dangerous drug, however, it still would not be physically impossible for a manufacturer to comply with both state law and federal law. This is because federal law expressly *permits* both brand-name and generic manufacturers to stop selling a non-life-saving drug. *See* 21 U.S.C. § 356c; 21 C.F.R. § 314.161.[3] That decision, moreover, is one that manufacturers can make independently of the FDA, *see id.*—in other words, "unilaterally," *see Mensing*, 131 S. Ct. at 2581. And it is one manufacturers make with some frequency; "studies show[] that anywhere from one-third to one-half of generic drugs no longer have a marketed brand-name equivalent." *Id.* at 2584 (Sotomayor, J., dissenting) (citing Brief for Marc T. Law, *et al.* as Amici Curiae 18).[4] Thus, even if this Court understood state law to be saying, "You

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[3] But where a drug company "is the sole manufacturer of a drug that is life-supporting; life-sustaining; or intended for use in the prevention of a debilitating disease or condition," federal law may require the company to give the FDA six months notice of its intent to discontinue selling the drug. 21 U.S.C. § 356c. Sulindac is not such a drug.

[4] As described below, where a drug is believed to be misbranded, it is common practice that a manufacturer is allowed to withdraw its product from the market voluntarily.

must stop selling your drug," federal law does not say, "You must sell your drug." It says only: "You *may* sell your drug." Under *Michigan Canners*, this is insufficient to establish physical impossibility. *See* 467 U.S. at 478 n.21 (in case where state law was permissive and federal law mandatory, compliance with federal and state law was not physically impossible).

2. Petitioner takes a decidedly different view of state and federal law. A manufacturer can only avoid liability for design defect, Petitioner argues, by redesigning its drug. That obligation, Petitioner maintains, conflicts with federal law, which does not permit a manufacturer to do so unilaterally; and in any event, a redesign is impossible here because sulindac is a one-molecule drug. Pet'r's Br. 30-36.

The impossibility conflict Petitioner describes is premised on a misunderstanding of design-defect law. Design-defect liability does not turn on the capacity to redesign a drug. Neither distributors nor retailers have control over the design of the product, yet both have been held liable for defective design. *See Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528 (6th Cir. 1993) (distributor; applying Kentucky law); Restatement (Second) of Torts § 402A cmt. f (1965) ("The rule stated in this Section applies to any person engaged in the business of selling products for use or consumption. It therefore applies to any manufacturer of such a product, to any wholesale or retail dealer or distributor, . . .").[5] This establishes

[5] *See also* Robert A. Sachs, *Product Liability Reform and Seller Liability: A Proposal For Change*, 55 Baylor L. Rev. 1031, 1032-33 (2003) ("Under the common law in almost all states, all sellers in the chain of distribution of a product are strictly liable for defects found in that product. It does not

that the power to redesign a product is not an element of the cause of action. It is not impossible, then, to comply with both federal law, which does not permit a manufacturer to unilaterally alter a drug's design, and state law, which extends liability to a manufacturer of a defectively designed drug without regard to whether it may redesign its drug. Because state law does not require what federal law forbids, there is no impossibility conflict here.

3. Petitioner and the United States suggest that *Mensing* and *Levine* foreclose the argument that state-law design-defect claims do not conflict with federal law because a manufacturer is not required to make its drug. A close reading of these cases suggests, however, that the Court did not examine this argument.

Consider first *Mensing*: The injured plaintiff in that case did not argue that the manufacturer there "could not show impossibility because federal law merely permitted them to sell generic drugs; it did not require them to do so." 131 S. Ct. at 2588 n.8 (Sotomayor, J., dissenting). Accordingly, neither the majority nor the dissent in *Mensing* considered the argument. Instead, the majority's holding rested on its understanding that federal law did not permit a unilateral labeling change, but that state law required a labeling change. *See id.* at 2573 (noting that this understanding of state law was "undisputed"). This clash of mandatory duties—*must*

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matter if the seller is a wholesaler or retailer who had no part in the creation of the defect, no control over the product's manufacture or design, or no reason to believe the product was defective.").

and *must not*—does not exist here, for the reasons just discussed.

Consider next *Levine*: The Court in that case did not have occasion to consider the stop-selling argument outlined here. In *Levine*, the Court concluded, in view of the record before it, that the brand-name manufacturer in that case had failed to establish, by clear evidence, that the FDA would not have approved a labeling change. 555 U.S. at 572-73. It therefore was not impossible for the manufacturer to comply with both federal labeling requirements and any state-law obligation to provide adequate warnings of health risks. *Id*. Given this conclusion, there was no reason for the *Levine* Court to consider any alternative argument against impossibility preemption, and none was advanced. *See id*.

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Impossibility preemption is a demanding defense because "respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly pre-empt state-law causes of action.'" *Levine*, 555 U.S. at 565-66, n.3 (quoting *Lohr*, 518 U.S. at 485); *see generally, Nw. Cent. Pipeline Corp. v. State Corp. Comm'n*, 489 U.S. 493, 515 (1989) ("conflict-pre-emption analysis must be applied sensitively in this area, so as to prevent the diminution of the role Congress reserved to the States while at the same time preserving the federal role"). Its demands should be particularly weighty here, given the longstanding co-existence of state tort liability and federal drug-safety law; and given that preemption would leave injured persons such as Respondent without a remedy. *Bruesewitz v. Wyeth LLC*, 131 S.

Ct. 1068, 1080 (2011) (recognizing the Court's longstanding "doubt that Congress would quietly preempt product-liability claims without providing a federal substitute").

Petitioner cannot satisfy this stringent test in this case. As discussed, it can readily comply with both state and federal law obligations, and it may do so unilaterally, meaning, "without the Federal Government's special permission and assistance." *Mensing*, 131 S. Ct. at 2581. Petitioner's belief that it was the clear and manifest purpose of Congress to wipe out longstanding product-liability suits for defective design therefore cannot be credited.

B. Design-Defect Claims Based on Significant New Evidence That a Drug Is Unreasonably Dangerous Complement the Purposes and Objectives of the FDCA.

Petitioner argues that design-defect liability stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, as expressed in the FDCA. But as Respondent demonstrates, Petitioner failed to preserve that argument for this Court's review. Resp't Br. 39-40.

Even had it been preserved, however, Petitioner's obstacle preemption argument would fail on the merits. State-law liability based on significant new evidence that a drug is unreasonably dangerous if taken for its approved uses *parallels* the federal-law duty not to market a misbranded drug. That federal duty is "triggered" (U.S. Br. 32) where there is significant new evidence that a drug is dangerous to health if taken in a manner consistent with its

labeling. *See* 21 U.S.C. § 352(j). In these circumstances, state tort law complements the purposes and objectives of the FDCA.

1. This conclusion follows from the structure and purpose of federal law. Congress, in enacting and amending the FDCA, intended for drug manufacturers like Petitioner—not the FDA—to maintain front-line responsibility for drug safety "at all times." *See Levine*, 555 U.S. at 570-71 ("[T]hrough many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."). This responsibility extends to all prescription drug manufacturers, whether brand-name or generic. *See* U.S. Br. 5 (noting that new drug applicants for brand-name drugs and abbreviated new drug applicants for generic versions of brand-name drugs must "promptly report to FDA serious adverse events associated with use of its drug in humans and periodically submit certain new information that may affect FDA's previous conclusions about the drug's safety or effectiveness").

The structure and purpose of the FDCA and its animating regulations also demonstrate that FDA approval of a drug is not intended to "represent a singular moment of clarity about risks and benefits associated with a drug." Inst. of Med. of the Nat'l Acads., *The Future of Drug Safety, Promoting and Protecting the Health of the Public* 27 (2007); *see Levine*, 555 U.S. at 575 (rejecting the argument that, although "the FDCA requires the FDA to determine that a drug is safe and effective under the conditions set forth in its labeling, the agency must be presumed to have performed a precise balancing of

risks and benefits and to have established a specific labeling standard that leaves no room for different state-law judgments"); *see id.* at 592 (Thomas, J., concurring in the judgment) (FDA approval "does not represent a finding that the drug, as labeled, can never be deemed unsafe by later federal action, or as in this case, the application of state law.").[6] Risks and benefits emerge over time as a drug is introduced into the population; accordingly, "[a]ll consumers of prescription drugs serve as guinea pigs for the pharmaceutical industry." Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 20 (1973). It is only after a drug is widely sold that "risks that are relatively rare, that manifest themselves only after an extended period of time, or that affect vulnerable subpopulations, begin to emerge." 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, 466 (2008).

The FDA monitors these risks, but not by itself. "[S]tate law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Levine*, 555 U.S. at 579. This added layer of consumer protection is essential:

> The FDA has limited resources to monitor the 11,000 drugs on the

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[6] *See also* 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, 598 (2005) ("Even if it is rigorously conducted, a process that focuses on prior approval inevitably will fail to capture all relevant information.").

> market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information.

Id. at 578-79.

2. The United States considers at length whether a hypothetical suit alleging what it calls a "pure" design-defect claim would conflict with the FDCA. This discussion fails to appreciate the FDA's limitations or state tort law's consumer-protection role. And it suggests (erroneously) that conflict preemption principles here require States to rewrite their tort laws to place new burdens of proof on injured plaintiffs—even though preemption is an affirmative defense which defendant manufacturers must establish.

a. The United States' account of the FDA's role in monitoring the safety profiles of drugs is deficient because it fails to acknowledge the agency's serious shortcomings in post-market regulation. *See* U.S. Br. 24-28. "The agency's powers and resources in new drug review, however inadequately they are perceived by some critics, appear cosmic when contrasted with the tools available for post-market regulation." Daniel Carpenter, *Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA* 586 (Princeton Univ. Press

2010) (hereinafter Carpenter). In *this* area, the FDA's "weaknesses are glaring and are the subject of extensive study and lament in contemporary medicine and politics." *Id*.

Three recent, independent studies of the FDA, cited by the Court in *Levine*, exposed these glaring weaknesses. FDA Science Board, *Report of the Subcommittee on Science and Technology: FDA Science and Mission at Risk* 2, 6 (2007) ("[T]he Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities"); Inst. of Med. of the Nat'l Acads., *The Future of Drug Safety: Promoting and Protecting the Health of the Public* 193-94 (2007) ("The [FDA] lacks the resources needed to accomplish its large and complex mission. . . . There is widespread agreement that resources for postmarketing drug safety work are especially inadequate and that resource limitations have hobbled the agency's ability to improve and expand this essential component of its mission"); GAO, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process* 5 (GAO-06-402, 2006) ("FDA lacks a clear and effective process for making decisions about, and providing management oversight of, postmarket safety issues"), *cited approvingly in* 555 U.S. at 578-79 n.11.

The United States ignores this aspect of *Levine*, and does not engage these studies. But they remain highly relevant. More recent reporting, moreover, only reinforces their central conclusion: The FDA is incapable of carrying out its mission. As reported by Marcia Angell, a former editor-in-chief of The New England Journal of Medicine,

> [T]here is growing evidence that the Center for Drug Evaluation and Research (CDER, pronounced "cedar"), the part of the agency that regulates prescription drugs, has become the servant of the industry it regulates. This has resulted in the sale of drugs of uncertain benefits, some with serious side effects, and in the agency's failure to respond promptly to evidence that a drug is dangerous.

Marcia Angell, *FDA: This Agency Can Be Dangerous*, N.Y. Review of Books, Sept. 30, 2010, at 66 (hereinafter Angell).[7]

Angell describes the FDA's 2005 review of the COX-2 inhibitor Bextra, which the United States now suggests also included a review of all NSAIDs (including sulindac), *see* U.S. Br. 24. She lays bare conflicts of interest and deficiencies in the review process that the United States' account ignores. For example, Angell writes that a special FDA panel, consisting of two standing advisory committees, was convened to consider whether Vioxx, Bextra, and Celebrex were safe enough to remain on the market. The panel recommended that all three drugs remain on the market "perhaps with strong warnings on the labels and a moratorium on advertising directly to consumers." Angell, at 67.

> About a week later, however, *The New York Times* revealed that ten of the thirty-two members of the panel had

[7] *Available at* http://www.nybooks.com/articles/archives/2010/sep/30/agency-can-be-dangerous/?pagination=false.

> financial ties to the makers of the drugs. If their votes had been discounted, the panel would have recommended that only Celebrex stay on the market. In a departure from its usual practice, CDER, no doubt embarrassed, rejected the advice of the full panel and allowed only Celebrex to stay on the market. If not for the revelations in *The New York Times*, the decision would probably have gone the other way.

Id.

According to Daniel Carpenter, of Harvard University, there exists also a structural "conflict of interest" in the FDA's post-market review process: "The very office of the FDA that approves new drugs—and which therefore has the least reputation-based incentives to revisit its past approval decisions—is also the office with legal authority over post-marketing." Carpenter, at 630. FDA officials have echoed this concern. *Id*. (quoting Office of Drug Safety epidemiologist David Graham as stating in testimony before Congress that "the new drug reviewing division that approved the drug in the first place and that regards it as its own child, typically proves to be the single greatest obstacle to effectively dealing with serious drug safety issues").

b. The United States also fails to credit product-liability litigation for providing a critical layer of consumer protection.

As already noted, state tort law complements federal law in two important ways: It serves a

remedial function, and it plays a critical role in uncovering unknown drug hazards and providing incentives for drug manufacturers to disclose safety risks promptly. *Levine*, 555 U.S. at 578-79.[8]

Some examples: There have been substantial delays between the time drug manufacturers had "reasonable evidence of an association of a serious hazard" with certain drugs, 21 C.F.R. §§ 201.57(c)(6)(i), 201.80(e), and when they either provided that information to the FDA; warned physicians and patients of emerging risks; or voluntarily withdrew the drug from the market. This has happened with Vioxx,[9] Celebrex,[10] Propulsid,[11]

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[8] Congress, in 2007, enhanced the FDA's regulatory authority and provided it with additional resources to monitor drug safety. *See* Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007). These amendments "reaffirmed" that front-line responsibility for drug safety rests with manufacturers. *Levine*, 555 U.S. at 571. But FDA's resources remain limited. *See* Angell, at 67 (noting that staffing for drug approval far exceeds staffing for drug safety); *see also* FDA, Update from the Office of Surveillance and Epidemiology, p. 5 (Dec. 10, 2012) (8 year staffing totals).

[9] *McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 241-44 (N.J. Super Ct. App. Div. 2008) (noting Merck's delays in reporting information about Vioxx's cardiovascular risks to FDA).

[10] Alex Berenson & Gardiner Harris, *Pfizer Says 1999 Trials Revealed Risks With Celebrex*, N.Y. Times, Feb. 1, 2005, at A1 (reporting that Pfizer acknowledged withholding from FDA for two years study showing serious cardiovascular risk with Celebrex), *available at* http://www.nytimes.com/2005/02/01/business/01drug.html.

[11] Gardiner Harris & Eric Koli, *Lucrative Drug, Danger Signals and the FDA*, N.Y. Times, June 10, 2005 (reporting that Johnson & Johnson delayed in submitting safety information on heartburn medication Propulsid to FDA), *available at*

Rezulin,[12] Darvon,[13] and Bextra.[14] State tort litigation was instrumental in uncovering these hazards, or in providing a fuller understanding of the manufacturers' conduct. Also, state tort law has provided (and may yet provide) critical compensation to the tens of thousands of persons injured by these drugs.

The importance of product-liability law is also evident outside the context of pharmaceutical drugs. For example, the history of so-called blood-shield laws, which foreclosed strict liability and implied warranty causes of action against blood collection centers, illustrates the consequences of foreclosing product-liability claims. States widely enacted such laws on the premise that blood banks were so important that their work should not be hampered by litigation. George C. Conk, *Is There A Design Defect In The Restatement (Third) Of Torts: Product Liability?,* 109 Yale L.J. 1087, 1100 (2000). Shielded from strict liability, the blood banks lacked a key

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http://www.nytimes.com/2005/06/10/business/10drug.html?pagewanted=all&_r=0.

[12] Denise Grady, *FDA Reviews Accusations About Diabetes Drug*, N.Y. Times, Mar. 16, 2000 (reporting that FDA records showed that company failed to submit safety data on diabetes drug Rezulin), *available at* http://www.nytimes.com/2000/03/16/us/fda-reviews-accusationsabout-diabetes-drug.html.

[13] Rob Stein, *Controversial painkiller Darvon pulled at FDA's request*, Washington Post, Nov. 19, 2010, *available at* http://www.washingtonpost.com/wp-dyn/content/story/2010/11/20/ST2010112000477.html.

[14] Stephanie Saul, *Pfizer to Settle Claims Over Bextra and Celebrex*, N.Y. Times, Oct. 17, 2008, *available at* http://www.nytimes.com/2008/10/18/business/18drug.html?_r=0

"incentive to pursue research and development of pasteurization techniques to reduce the risk of contracting hepatitis (and later HIV) from the blood supply. The blood shield laws thus allowed the blood industry to continue to make blood products that were avoidably unsafe, at tremendous cost to human life." *Id.* at 1100.

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Statistics from 2005 to 2008 demonstrate that 47.9 percent of persons in the United States used at least one prescription drug in the last month reported; 21.4 percent used three or more; and 10.5 percent used five or more. Centers for Disease Control and Prevention, FastStats: Therapeutic Drug Use.[15] Given the ubiquity of prescription drugs, and the FDA's limited resources, the public would be at serious risk of harm if the consumer protection provided by the tort system were found to be preempted.

c. Lastly, the United States errs in suggesting that conflict preemption principles require that an injured plaintiff "prove that the manufacturer knew or should have known of new and scientifically significant evidence that rendered the drug 'misbranded' under federal law" (U.S. Br. 12), or that States must now redefine "the scope of [their] tort duties" accordingly (*see* U.S. Br. 16 n.3).[16]

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[15] *Available at* http://www.cdc.gov/nchs/fastats/drugs.htm.

[16] *See* 21 U.S.C. §§ 331(a)-(c), (g), and (k) (prohibiting the production or distribution of any drug that is misbranded); 21 U.S.C. § 352(j) (defining 'misbranded' partly to mean "dangerous to health when used in the dosage or manner, or

State product-liability law already incorporates risk-benefit analysis, *see* Restatement (Second) of Torts § 402A, and juries may consider evidence of FDA approval in reaching a verdict, *e.g.*, *Tobin*, 993 F.2d at 538. If, however, the FDCA, by operation of the Supremacy Clause, were read to displace design-defect claims absent evidence that a drug was misbranded under federal law, then the role of this evidence in product-liability litigation against a drug manufacturer would arise only as a result of the manufacturer's preemption defense. *Cf. Mensing*, 131 S. Ct. at 2588 n.11 (Sotomayor, J., dissenting). Because the burden of establishing a preemption defense rests with defendants, the defendant manufacturer should be required to prove that all of plaintiff's evidence of defect had already been considered by the FDA and had been found insufficient to render a drug misbranded. *See Levine*, 555 U.S. at 571 (requiring defendant manufacturer to show clear evidence that the FDA would not have approved a labeling change).

The United States' suggestion that States must rewrite their tort law (*see* U.S. Br. 16 n.3) misapprehends our federalism. The Supremacy Clause, though it displaces contrary state law, does not require any affirmative action by the States. *Cf. Haywood v. Drown*, 556 U.S. 729, 752 (2009) (Thomas, J., dissenting) ("This historical record makes clear that the Supremacy Clause's exclusive function is to disable state laws that are substantively inconsistent with federal law—not to require state courts to hear federal claims over which the courts lack jurisdiction."). The preemption

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with the frequency or duration prescribed, recommended, or suggested in the labeling thereof").

defense is available whether or not States explicitly anticipate it. *Cf. Bates*, 544 U.S. at 454 (recognizing that it would be "surprising" for state tort law to parallel federal requirements "in *identical* language" but that where some equivalency is required, defendants seeking to rely on preemption may ask for jury instructions on relevant federal standards (emphasis in original)).

CONCLUSION

For the foregoing reasons, the judgment under review should be affirmed.

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