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

BRIEF OF AMICI CURIAE SENATOR TOM HARKIN AND REPRESENTATIVE HENRY A. WAXMAN IN SUPPORT OF RESPONDENT

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INTEREST OF AMICI CURIAE[1]

This brief is submitted on behalf of amici curiae Senator Tom Harkin and Representative Henry A. Waxman, both members of Congress with an interest in the important issue presented in this case. Senator Harkin and Representative Waxman have extensive knowledge of pharmaceutical regulation under the Food, Drug, and Cosmetic Act (FDCA) and the Hatch-Waxman Amendments.

Senator Harkin has served in the United States Congress since 1975, first as a member of the House of Representatives and, since 1985, as a member of the Senate. He is the current chair of the Senate Committee on Health, Education, Labor & Pensions, the jurisdiction of which encompasses the Food and Drug Administration (FDA). Senator Harkin is also a member of the Senate Appropriations Committee, where he serves as a member of the subcommittee with jurisdiction over FDA funding and as chair of the Labor, Health and Human Services, and Education subcommittee, which has jurisdiction over many other programs of the Department of Health and Human Services.

Representative Waxman has served in the House of Representatives since 1974. He is currently Ranking Minority Member of the House Energy and Commerce Committee, the jurisdiction of which includes health care

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[1] Pursuant to Rule 37.6 of this Court, amici curiae states that this brief was not written in whole or in part by counsel for a party and that no one other than amici curiae or their counsel made a monetary contribution to the preparation or submission of this brief. Letters from both parties consenting to all amicus briefs are on file with the Clerk.

policy, regulation of prescription drugs and the pharmaceutical industry, and consumer protection, all of which are implicated by this case. Representative Waxman, long a leader on health issues, was one of the two principal sponsors of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the Hatch-Waxman Amendments. In addition, in 2008, Representative Waxman presided over legislative hearings concerning preemption under the FDCA.

Because preemption is a question of congressional intent, *see Wyeth v. Levine*, 555 U.S. 555, 565 (2009), amici are well situated to address the question presented in this case. Although amici submit this brief in their individual capacities, not on behalf of Congress, their views are informed by their experiences as Members of Congress.

SUMMARY OF ARGUMENT

This Court has often stated that preemption turns on congressional purpose. Neither the text nor the purpose of the FDCA or the Hatch-Waxman Amendments requires preemption of state-law design-defect claims brought by injured patients against prescription drug manufacturers.

The FDCA is a consumer protection statute, in existence for decades in largely its current form. During those decades, state-law claims against prescription drug manufacturers have been frequent, yet petitioner offers no evidence that such claims have created a dilemma for manufacturers, interfered with federal regulation, or undermined statutory objectives. During those same years, Congress enacted express preemption provisions with respect to other FDA-regulated products, but declined to do so with respect to prescription drugs, despite specific

consideration of the issue. In particular, Congress's decision expressly to save product liability claims from the scope of an express preemption provision applicable to over-the-counter drugs, which, like brand-name and generic drugs, the FDA allows to be marketed based on a risk-benefit analysis, demonstrates that state-law design claims do not interfere with the achievement of Congress's purposes in enacting the FDCA.

Likewise, state-law design-defect claims pose no threat to the goal of the Hatch-Waxman Amendments. In Hatch-Waxman, Congress sought to reduce anticompetitive barriers to the marketing of generic drugs. Although tort claims long preceded the 1984 Amendments, Congress said nothing during the legislative debate to suggest that it viewed claims brought by injured patients as such a barrier. The nearly 30 years since enactment of the Hatch-Waxman Amendments have shown that understanding to be correct: Despite the continued existence of lawsuits by injured patients, generics' share of the prescription drug market has dramatically increased.

Although neither the FDCA nor the Hatch-Waxman Amendments evinces an intent to preempt state-law design claims, the decision to preempt remains within Congress's authority. The Court should leave that policy decision to Congress.

ARGUMENT

I. Federal Regulation of Prescription Drugs Does Not Preempt State-Law Design-Defect Claims.

A. Drug Regulation Under the FDCA Does Not Preempt State Common Law.

Petitioner and the Solicitor General argue that FDA approval of a prescription drug preempts state-law design-defect claims, barring an injured patient from pur-

suing compensation from the drug's manufacturer, whether the drug at issue is a brand-name drug or a generic. Four years ago, this Court considered and rejected a similar argument that regulation under the FDCA establishes both a floor and a ceiling for drug regulation, such that allowing a state-law remedy for injuries caused by a prescription drug would obstruct the purposes and objectives of federal regulation. As the Court said at that time, "[t]he most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary." *Wyeth v. Levine*, 555 U.S. 555, 574 (2009).

The FDCA, as the Court has explained, was enacted "to bolster consumer protection against harmful products." *Id.* (citing *Kordel v. United States*, 335 U.S. 345, 349 (1948), & *United States v. Sullivan*, 332 U.S. 689, 696 (1948)). But in enacting this consumer protection law in 1938, Congress did not create a federal remedy for consumers harmed by unsafe or ineffective drugs. To the contrary, Congress rejected a provision that would have created a federal damages remedy, *see* H.R. 6110, 73d Cong., 1st Sess. § 25 (1933), specifically because state common law already provided that remedy. *See Wyeth*, 555 U.S. at 574 & n.7. Indeed, "[c]ourts entertained tort suits against [drug] manufacturers since well before the passage" of the FDCA, and such litigation has long been a "common feature of the legal landscape." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 441 (2005) (discussing pesticides). Legislating against this backdrop, Congress may well have "recognized that state-law remedies further consumer protection by motivating manufacturer to produce safe and effective drugs and to give adequate warnings." *Wyeth*, 555 U.S. at 574.

Although the drug provisions of the FDCA have been amended many times since 1938, including significant

amendments in 1962, 1984, 1997, 2007, and 2012, arguments that product liability suits (whether based on design or labeling) against drug manufacturers were preempted by the FDCA were seldom made and, until the mid-2000s, rarely successful.[2] Significantly, in 1962, when Congress amended the FDCA to require, for the first time that drug manufacturers demonstrate effectiveness, in addition to safety, prior to receiving marketing approval, *Wyeth*, 555 U.S. at 567, Congress addressed preemption only to state that the new provisions do not preempt state law.[3]

Later, beginning in 1976, Congress enacted provisions expressly preempting categories of state laws with respect to other FDA-regulated products, including foods, medical devices, and cosmetics. *See* 21 U.S.C. §§ 343-1(a), 360k(a), & 379s. As these preemption provisions reflect, Congress has been particularly attentive to federalism concerns in connection with regulation under the FDCA and has crafted provisions to address these concerns where, in Congress's view, those changes were appropriate. Yet Congress never enacted an express preemption provision concerning prescription drugs,

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[2] *See*, *e.g.*, *Tobin v. Astra Pharm. Prods., Inc.*, 993 F.2d 528, 537 (6th Cir. 1993) (no preemption); *Osburn v. Anchor Labs.*, 825 F.2d 908, 911-13 (5th Cir. 1987) (same); *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986) (same); *Feldman v. Lederle Labs.*, 592 A.2d 1176, 1195-97 (N.J. 1991) (same).

[3] *See* Pub. L. No. 87-781, § 202 (1962) ("Nothing in the amendments made by this Act to the federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.").

much less a provision directed at state-law damages suits.

Furthermore, in 1997, when Congress enacted an express preemption provision concerning over-the-counter (OTC) drugs, it explicitly provided that state product liability law would not be affected. *See* 21 U.S.C. § 379r(e) ("No Effect on State Product Liability law—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."). Yet there are no differences between OTC and prescription drugs that would warrant a different rule for preemption of product liability claims: For both kinds of drugs, the FDA's risk-benefit analysis has, since 1962, been a prerequisite to marketing.

Importantly, the same new drug application (NDA) process by which the FDA evaluates new prescription drugs before they can be marketed applies to new OTC drugs that are not covered by a monograph. *See* FDA, *Drug Applications for Over-the-Counter Drugs* (Oct. 18, 2012).[4] For other OTC drugs, the FDA develops a monograph, which is "a kind of 'recipe book' covering acceptable ingredients, doses, formulations, and labeling" for a particular drug. *Id.*; *see* 21 C.F.R. § 330.10. After the FDA publishes a drug monograph, any manufacturer can sell that OTC drug if it follows the "recipe"—a situation analogous for present purposes to approval of an abbreviated new drug application (ANDA) for a generic prescription drug, which must follow a brand-name product

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[4] *At* http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/over-the-counterdrugs/default.htm.

in terms of active ingredients, dosage form, labeling, and other characteristics. *See* 21 U.S.C. § 355(j). Although the FDA does not review individually each OTC monograph drug as it does each generic drug, both types of drugs must meet FDA-required specifications (as set forth either in the monograph or through the brand-name drug) that are based on the FDA's weighing of risks and benefits.

The fact that some drugs, for example, Claritin and Zyrtec, begin as prescription drugs and are later switched to OTC, *see* 21 C.F.R. § 310.200, further reveals the illogic of the preemption argument in this context. Again, not only has Congress never passed a provision to preempt state-law damages claims concerning OTC drugs, it expressly provided in § 379r(e) that these claims are not preempted.

This Court has repeated time and again that "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth*, 555 U.S. at 565.[5] The OTC provision explicitly carving out product liability suits from the scope of an express preemption provision evinces Congress's understanding that those suits pose no obstacle to the purpose of federal regulation of OTC drugs. Rather, Congress has made plain that state product liability law should coexist with federal approval of such drugs.

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[5] *See also*, *e.g.*, *Altria Group v. Good*, 555 U.S. 70, 76 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992); *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978); *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963).

Moreover, the FDA licenses vaccines through a premarket review process that is similar to the review process for new drugs. *See* 42 U.S.C. § 262(j); 21 C.F.R. § 601; FDA, *Vaccine Product Approval Process* (updated June 18, 2009). In 1986, Congress enacted the National Childhood Vaccine Injury Act, which provides a federal remedy for vaccine-related injuries as a substitute for state damages actions, 42 U.S.C. § 300aa-21(a), "[t]o stabilize the vaccine market and facilitate compensation." *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1073 (2011). This Court recently held that the Act's express preemption provision preempts design-defect claims. *Id.* at 1075 (discussing 42 U.S.C. § 300aa–22(b)(1)). But the premise underlying the Court's discussion, like the premise under which Congress operated in enacting the Vaccine Act, is that, absent that Act, such claims would not be preempted. The Vaccine Act thus confirms that, in Congress's view, FDA regulation of drugs does not preempt state-law design-defect claims where preemption is not specifically provided by federal statute.

Notably, although FDA approval is not a basis for preemption, the approval nonetheless plays an important role in design-defect cases. Under traditional tort law, federal approval of a product for marketing and compliance with federal requirements for product safety plays a role, often a very powerful role, in product liability cases. Consistent with this tradition, the current law in most states allows a manufacturer that is alleged to have sold a defective product to use compliance with federal standards or regulations as non-dispositive evidence that the product was not defective or that the manufacturer acted non-negligently. *Restatement (Third) of Torts* § 4(b) (1998); *accord* 63B *Am. Jur. 2d Products Liability* § 2022 (2008) ("As a general rule, compliance with appli-

cable federal standards is relevant but not conclusive evidence in a products liability case.").[6]

In sum, the notion that FDA regulation broadly preempts design-defect claims against prescription drug manufacturers finds no support in the text or purpose of the FDCA, runs counter to the OTC provision addressing product liability law, and ignores more than 75 years of history in which damages suits and federal drug approval have co-existed.

B. The Hatch-Waxman Amendments Do Not Support Preemption of Design-Defect Claims Concerning Generic Drugs.

In addition to asserting that the FDCA preempts design-defect claims against both brand-name and generic drug manufacturers, petitioner and the Solicitor General argue that preemption of such suits against generic drug manufacturers is essential to fulfilling the purposes of the Hatch-Waxman Amendments, which created the current system for FDA approval of generic replacements for brand-name drugs. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417,

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[6] S*ee, e.g.*, Ind. Code § 34-20-5-1; Kan. Civ. Proc. Code Ann. § 60-3304; Tenn. Code Ann. § 29-28-104; Utah Code Ann. § 78B-6-703(2); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) (North Carolina law); *O'Neill v. Novartis Consumer Health, Inc.*, 55 Cal. Rptr. 3d 551, 557 (Cal. Ct. App. 2007); *Wagner v. Clark Equip. Co.*, 700 A.2d 38, 50 (Conn. 1997); *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 675 (Ga. 1994); *Toner v. Lederle Labs.*, 732 P.2d 297, 311 n.12 (Idaho 1987); *Malek v. Lederle Labs.*, 466 N.E.2d 1038, 1039–40 (Ill. App. Ct. 1984); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70–71 (Mass. 1985); *Brooks v. Beech Aircraft Corp.*, 902 P.2d 54, 63 (N.M. 1995); *Sherman v. M. Lowenstein & Sons, Inc.*, 282 N.Y.S.2d 142, 143–44 (N.Y. App. Div. 1967); *Zacher v. Budd Co.*, 396 N.W.2d 122, 133–34 (S.D. 1986).

98 Stat. 1585. As all parties seem to agree, the Hatch-Waxman Amendments were intended to foster the speedy availability of generic versions for brand-name drugs, so that the resulting competition would lower prices for consumers. Congress sought to achieve this purpose, however, by eliminating regulatory and patent-based barriers to the approval and marketing of generic drugs, not by eliminating remedies for patients injured by defective drugs.

1. The Hatch-Waxman Amendments aimed "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H.R. Rep. No. 98-857, Pt. 1, at 14 (June 21, 1984). The Amendments reflect congressional dissatisfaction with then-existing FDA procedures for approval of generic drugs, which required generic drug manufacturers to obtain approval of their products as if they were completely new drugs, including through new clinical studies of safety and effectiveness, although the generic versions were the same as brand-name drugs that the FDA had already approved. This time-consuming and expensive process, which could only be initiated after patents protecting the brand-name drug expired, "had serious anti-competitive effects," and resulted in "the practical extension of the monopoly position of the patent holder beyond the expiration of the patent." H.R. Rep. No. 98-857, Pt. 2, at 4 (Aug. 1, 1984).

Through the ANDA procedure, 21 U.S.C. § 355(j), which speeds a generic's entry onto the market, the Hatch-Waxman Amendments sought to combat these anticompetitive effects and to "implement the policy objective of getting safe and effective generic substitutes on the market as quickly as possible after the expiration of the patent" on the original drug. H.R. Rep. No. 98-857,

Pt. 2, at 9. To achieve these goals, the Amendments allow the FDA to approve a generic drug based on a showing of bioequivalence to an approved drug without requiring additional clinical testing for safety and effectiveness, and to do so "before the patent on the drug has expired" if the generic manufacturer alleges "that the existing patent is invalid or will not be infringed." *Id.* at 5. In this manner, Congress in the Hatch-Waxman Amendments sought to achieve the ultimate objective of protecting consumers by "provid[ing] low-cost, generic drugs for millions of Americans," resulting in "a significant savings to people who purchase drugs." 130 Cong. Rec. 24427 (Sept. 6, 1984) (statement of Rep. Waxman).

At the same time, as this Court has repeatedly stated, "[n]o legislation pursues its purposes at all costs." *Freeman v. Quicken Loans*, 132 S. Ct. 2034, 2044 (2012) (quoting *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987)). Indeed, it "frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers [a] statute's primary objective must be the law." *Norfolk Southern Ry. v. Sorrell*, 549 U.S. 158, 171 (2007) (quoting *Rodriguez*, 480 U.S. at 526). A congressional intent to combat delays in the introduction of generic drugs is not equivalent to a purpose "to end every possible delay at all costs." *Holland v. Florida*, 130 S. Ct. 2549, 2562 (2010).[7]

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[7] The terms of Hatch-Waxman make clear that Congress did not place immediate introduction of generic drugs above all other considerations. The legislation, for example, provides for a stay of approval of a generic manufacturer's ANDA upon the institution of patent infringement proceedings by a brand-name manufacturer; allows a successful infringement action by the brand-name manufacturer to keep the generic substitute off the market; and gives the

(*Footnote continued*)

In particular, Congress's policy of promoting the availability of lower-cost drugs to consumers by eliminating legal barriers to competition between generic and brand-name manufacturers does not imply a policy of eliminating other legal constraints (applicable equally to generic and brand-name manufacturers) that help to protect consumers against unsafe drugs and that offer remedies when consumers are injured by such drugs. Indeed, the legislative history of the Hatch-Waxman Amendments nowhere suggests that Congress viewed tort liability as a barrier to the introduction of generic drugs, much less a barrier comparable to those posed by existing FDA procedures and patent doctrines. Tort liability is not mentioned in the reports and debates concerning the Hatch-Waxman Amendments, nor is there any hint that Congress was concerned that product-liability suits would impede the rapid introduction of generic substitutes for brand-name drugs that Congress anticipated would result from the Amendments.

Tort liability for manufacturers of FDA-approved drugs was well established at the time Congress enacted the Hatch-Waxman Amendments. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 340 & n.11 (2008) (Ginsburg, J., dissenting) ("in 1976, state common-law claims for drug labeling and design defects had continued unabated despite nearly four decades of FDA regulation" (citing cases)). In the face of this legal background, as well as Congress's inclusion of an express preemption provision in the Medical Device Amendments of 1976, Congress's complete silence with respect to the subject in the Hatch-

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first generic manufacturer to submit an ANDA a period of exclusivity in which no other generic manufacturer may enter the market. *See* 21 U.S.C. §§ 355(j)(5)(B)(iii), (iii)(II), (iv).

Waxman Amendments and the proceedings leading to their enactment is telling. As in *Silkwood v. Kerr–McGee Corp.*, 464 U.S. 238 (1984), it is "difficult to believe that Congress would, without comment, remove all means of judicial recourse" for consumers injured by generic drugs in a statute aimed at other objectives altogether. *Id.* at 251. Far from supporting a broad claim of implied preemption, the background, purposes, and history of the Hatch-Waxman Amendments stand as strong "evidence that Congress did *not* regard state tort litigation as an obstacle to achieving its purposes." *Wyeth*, 555 U.S. at 575 (emphasis added).

2. The notion that product liability claims against generic drug manufacturers would thwart the realization of the objectives of the Hatch-Waxman Amendments is also unsupported by the history of the Amendments' implementation. As Congress foresaw, the Hatch-Waxman Amendments brought about an almost immediate transformation of the marketplace for prescription drugs. The Amendments have produced a remarkable influx of generic drugs into the marketplace, notwithstanding the absence, until very recently, of significant precedential support for the idea that lawsuits for injuries caused by defective drugs might be preempted.

Thus, in little more than 15 years after Hatch-Waxman's enactment, generic drugs' share of the prescription drug market grew from only 19 percent of all prescriptions to nearly half, saving consumers and the government trillions of dollars.[8] The market for generic

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[8] GAO, *Drug Pricing: Research on Savings from Generic Drug Use* 2 (2012), *at* www.gao.gov/assets/590/588064.pdf; 149 Cong. Rec. S8187 (June 19, 2003) (Statement of Sen. Kohl) (generic drugs accounted for 45% of prescriptions in 2001).

drugs flourished despite the almost total absence of case law indicating that lawsuits against drug manufacturers might be preempted by federal law. *See Riegel*, 552 U.S. at 342, & n. 19 (Ginsburg, J., dissenting) (noting courts' overwhelming rejection of preemption claims in cases involving prescription drugs between 1976 and 2008). More recently, with the issue unsettled, the market share of generic drugs has continued to increase, with approximately 80 percent of all prescriptions now filled by generic drugs.[9] Meanwhile, the prices of generic drugs have steadily fallen, both in real and nominal dollars.[10] If potential tort liability has posed an obstacle to achievement of the purposes of the Hatch-Waxman Amendments, it has gone unnoticed in the marketplace.

II. The Decision Whether To Oust State Law Is Properly Left To Congress.

A. "Pre-emption analysis should not be a freewheeling judicial inquiry into whether a state statute is in ten-

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[9] *See* IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2011* at 26 (2012), www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf.

[10] *See* GAO, *Prescription Drugs: Trends in Usual and Customary Prices for Commonly Used Drugs*, at 18-19 (2011), *available at* gao.gov/assets/100/97284.pdf; Stephen W. Schondelmeyer & Leigh Purvis, *Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Medicare Beneficiaries 2005 to 2009*, at 3, 5 (2012), *at* www.aarp.org/content/dam/aarp/research/public_policy_institute/health/rx-pricewatch-march-2012-AARP-ppi-ealth.pdf; Express Scripts, *Drug Trend Quarterly* 15 (Nov. 2012), http://digital.turn-page.com/i/95262; GAO, *Prescription Drugs: Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004*, at 4, 7 (2005), *available at* www.gao.gov/new.items/d05779.pdf.

sion with federal objectives, but an inquiry into whether the ordinary meanings of state and federal law conflict." *Wyeth*, 555 U.S. at 588 (Thomas, J., concurring) (internal quotation marks omitted). Here, the weighing of policy concerns that underlies the arguments in favor of preemption reflects exactly this "inherently flawed" approach to preemption. *Id.* at 594.

Congress is well aware of its authority to preempt state damages actions, and with respect to prescription drugs, as with OTC drugs, it has not done so. Moreover, in recent years, following litigation addressing whether federal regulation preempts state-law claims regarding injuries caused by drugs, both Chambers of Congress have considered preemption of state-law claims concerning drugs. Yet Congress has taken no action to change the historical framework through which state law controls whether injured patients have a tort remedy. *See Regulatory Preemption: Are Federal Agencies Usurping Congressional and State Authority?*, Hearing Before the Senate Committee on the Judiciary, 110th Cong. 1st Sess. (Sept. 12, 2007); *Should FDA Drug and Medical Device Regulation Bar State Liability Claims?*, Hearing Before the House Committee on Oversight and Government Reform, 110th Cong. 2d Sess. (May 14, 2008).

The decision whether to preempt state-law claims, for decades left to Congress, properly remains with Congress.

B. Inevitably, some patients will be injured by dangerous drugs, yet federal law provides no avenue for seeking compensation for such injury. Accordingly, preemption would cut off patients from even the possibility of holding a prescription drug manufacturer accountable for harm caused by a defective product. Preemption,

where accepted, leaves no room for factual distinctions between individual cases, sweeping away traditional common-law approaches to assessing liability.

Moreover, damages suits advance public health. Product liability lawsuits help to uncover information that can lead to safer products. Material produced in litigation can help the public and the FDA to identify problems with particular drugs and can add to physicians' and public understanding of the risks of the products and flaws in the regulatory system. *See, e.g.*, David Brown, *Maker of Vioxx Is Accused of Deception*, Wash. Post, Apr. 16, 2008, at A1 (discussing article from the *Journal of the American Medical Association* evaluating information found in Vioxx discovery documents); Aaron Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. Am. Med. Ass'n 308, 309 (2007) (offering several examples).

In addition, knowledge of a drug's risks, particularly long-term risks, is never complete at the time of initial marketing approval. Prior to approval, drugs are tested, on average, on between 600 and 3,000 patients. *See* Inst. of Med. of the Nat'l Acads., *The Future of Drug Safety: Promoting and Protecting the Health of the Public* 36 (2006), *available at* www.nap.edu/openbook.php?record_id=11750&page=R1IOM. Thus, "[a]n adverse event (even a serious one) that occurs in less than one in 1,000 patients cannot be reliably detected except in the largest premarket trials but can pose a serious public health problem when hundreds of thousands or millions of people use the drug." *Id.* at 37-38. In general, only half of a drug's serious hazards are known and documented in the *Physicians' Desk Reference* seven years after the drug's approval. *See* Karen Lasser, et al., *Timing of New Black*

Box Warnings and Withdrawals for Prescription Medications, 287 J. Am. Med. Ass'n 2215, 2218 (2002).

A number of prescription drugs—Darvon, Meridia, Vioxx, Bextra, Baycol, Rezulin, and Raptiva, to name a few—have been withdrawn from the market because experience showed that their risks outweighed their benefits. According to one article, 21 drugs were pulled from the U.S. market from 1995 to 2010, half because the drugs was linked to heart complications. The products had been on the market from as few as 11 months to as many as 30 years. Catherine Larkin, *Recalled Drugs Tied to Heart Risk Spurs Call for FDA Review*, Bloomberg (Sept. 28, 2010). Thus, design-defect claims based on post-approval experience with a drug do not "second-guess" (U.S. Br. 13.) the FDA.

Of particular relevance here, although the FDA will not approve an ANDA that references a brand-name drug no longer on the market without first determining whether the brand-name drug was discontinued for reasons of safety or effectiveness, 21 C.F.R. § 314.161, when a manufacturer voluntarily withdraws a brand-name drug from the market, the withdrawal does not preclude continued sale of already approved generic versions. For example, the manufacturer of Serzone, the brand-name antidepressant nefazodone, stopped selling the product in the U.S. 2004, after some countries had discontinued sales due to concerns that the drug caused severe liver damage. Yet several generic formulations of nefazodone are still available.[11]

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[11] *See* FDA, Drugs@FDA, www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Search_Drug_Name (showing brand-name Serzone "discontinued" and generic nefazo-

(*Footnote continued*)

Given that a drug's safety profile is incomplete at the time of approval, the possibility of product liability lawsuits helps to protect patients by serving as a powerful incentive for drug companies (both brand-name and generic, prescription and OTC) to improve products as soon as a defect is identified and to remove from the market older products that do not provide the safety of newer ones. Because, as a matter of both resources and operation of the statutory scheme, manufacturers have primary responsibility for ensuring the safety of their products, this incentive is vitally important for protecting patients from unsafe drugs.

The Solicitor General suggests an exception to its broad preemption theory in cases where state law requires a plaintiff to show that the manufacturer "knew or should have known of scientifically significant evidence that rendered the drug misbranded under federal law." U.S. Br. 22. But if the fact of approval preempts damages claims in the absence of such evidence, an injured patient will rarely have a chance to make that showing because, without discovery, patients are unlikely to have access to that evidence. *See supra* p. 16 (citing articles discussing cases in which litigation uncovered new information). And even if patients had such evidence, manufacturers sued under state law that requires such a showing often successfully argue that the showing is precluded as a species of "fraud-on-the-FDA" claim preempted under this Court's decision in *Buckman v. Plaintiff's' Legal Committee*, 531 U.S. 341 (2001). *See*, *e.g.*, *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 380 (5th Cir. 2012) (holding exception to Texas law bar-

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done hydrochloride still sold by three companies as prescription generic).

ring suits against drug companies in cases where company withheld or misrepresented information to FDA to be preempted); *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965-66 (6th Cir. 2004) (holding exception to Michigan law barring suits against drug companies in cases where company misrepresented or withheld information that would have altered the FDA's decision to approve the drug to be preempted).

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Petitioner and its amici have offered no evidence that the coexistence of state-law design-defect claims and FDA drug approval has posed any impediment to federal regulation, either since enactment of the FDCA in 1938, its amendment in 1962, or the Hatch-Waxman Amendments in 1984. In our legal tradition, the decision about whether and how to compensate individuals injured by products, including drugs, has been left to the states. In the absence of compelling evidence that Congress sought to alter that tradition, this Court should not reach out to do so.

CONCLUSION

For the foregoing reasons, the decision below should be reversed.

Respectfully submitted,

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