No. 12-142

IN THE
Supreme Court of the United States

MUTUAL PHARMACEUTICAL CO., INC.,

Petitioner,

v.

KAREN L. BARTLETT,

Respondent.

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

BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

Richard A. Samp
(Counsel of Record)
Cory L. Andrews
Washington Legal Foundation
2009 Mass. Ave., NW
Washington, DC 20036
(202) 588-0302
rsamp@wlf.org

Date: January 22, 2013

QUESTION PRESENTED

Whether federal law preempts state law design-defect claims against the manufacturer of a generic version of a prescription drug whose design has been approved by the federal Food and Drug Administration.

TABLE OF CONTENTS

Page

Page

TABLE OF AUTHORITIES

Page(s)

Cases:

Page(s)

Statutes and Constitutional Provisions:

Page(s)

Regulations:

Miscellaneous:

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government.

To that end, WLF has frequently appeared as *amicus curiae* in this and other federal courts in cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek simultaneously to regulate the same business activity. *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *United States v. Locke*, 529 U.S. 89 (2000).

The Allied Educational Foundation (AEF) is a non-profit charitable foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared as *amicus curiae* in this Court on a number of occasions.

Amici are particularly concerned that individual freedom and the American economy both suffer when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that

---

[1] Pursuant to Supreme Court Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, made a monetary contribution intended to fund the preparation and submission of this brief. All parties have consented to the filing of this brief; letters of consent have been lodged with the clerk.

frustrates the objectives or operation of specific regulatory regimes, such as (in this case) the Food, Drug, and Cosmetic Act (FDCA), and that make it impossible for regulated businesses to operate in compliance with both federal and state laws.

At issue here is whether Congress intended to preempt Respondent's cause of action. *Amici* agree with Petitioner that the "sameness" rationale set forth in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), is dispositive in this case and requires a finding that design-defect claims against generic drug companies such as Petitioner are preempted. *Amici* write separately to focus on an even more fundamental reason why the design-defect claim is preempted. Congress has granted the Food and Drug Administration (FDA) authority to determine whether, based on its safety and effectiveness, a drug should be available for sale in interstate commerce. FDA's statutory authority extends to determining that a previously-approved drug should be removed from the market. Any effort by a State to determine whether an FDA-approved drug should be removed from the market frustrates Congress's statutory scheme. Moreover, state-law mandates of the sort at issue in this case make it impossible for drug companies, whether brand-name or generic, to comply with both federal and state law. Accordingly, basic principles of conflict preemption require dismissal of *all* design-defect claims against the manufacturers of FDA-approved drugs.

Amici have no direct interests, financial or otherwise, in the outcome of this case. They are filing due solely to their interests in the important

preemption issues raised herein.

STATEMENT OF THE CASE

Respondent Karen Bartlett suffered serious and permanently disabling injuries after taking sulindac, an FDA-approved drug manufactured by Petitioner Mutual Pharmaceutical Co., Inc. Sulindac has been widely used to treat arthritis since its initial approval by FDA in 1978. Sulindac was initially marketed by Merck & Co. under the brand name Clinoril®; after Merck's patent expired, Mutual began marketing a generic version in 1991. As required by the FDCA, the sulindac marketed by Mutual has at all times been bioequivalent to, and has borne the same labeling as, Clinoril®.

Bartlett's 2008 suit against Mutual raised a variety of claims under New Hampshire law, including that Mutual inadequately warned Bartlett and/or her physician regarding the dangers of sulindac and that the drug was defectively designed. All claims except the design-defect claim were dismissed from the lawsuit. In particular, the trial judge dismissed the failure-to-warn claim based on lack of causation because Bartlett's doctor did not read the product labeling and thus could not have relied on Mutual's (allegedly inadequate) warning in deciding to prescribe sulindac. Pet. App. 117a-121a.

The only claim presented to the jury was the defective-design claim. The jury awarded Bartlett over $21 million in damages, including $16.5 million in non-economic damages. The trial court denied pre- and post-trial motions asserting that Bartlett's tort claim

was preempted by federal law.

The U.S. Court of Appeals for the First Circuit affirmed. Pet. App. 1a-24a. The appeals court held that Bartlett's design-defect claim was not impliedly preempted by the FDCA, relying on this Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009). *Id.* at 8a-11a. While conceding that "*Wyeth*'s holding was technically limited to failure-to-warn claims," it concluded that *Wyeth*'s "logic applies to design defect claims as well." *Id.* at 9a (citing 555 U.S. at 574). It interpreted the Court's 2011 *Mensing* decision as having merely "carved out an exception to *Wyeth*," applicable only to failure-to-warn claims asserted against manufacturers of generic drugs. *Id.*

The appeals court noted that Bartlett could have maintained a failure-to-warn claim against Merck had her druggist chosen to fill her prescription with Clinoril® rather than generic sulindac. The court concluded that that fact made it more likely that this Court would rule that Bartlett's design-defect claim was *not* preempted. Pet. App. 11a ("Bartlett having lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief."). The Court noted that Mutual was not forced to sell sulindac; "the decision to make the drug and market it in New Hampshire is wholly its own." *Id.* at 10a-11a.

The appeals court conceded that its decision was "in tension . . . with part of [*Mensing*'s] rationale" because the generic defendant in *Mensing* was similarly capable of "avoid[ing] defective warning lawsuits by not making the drug." Pet. App. 11a. It nonetheless

concluded that *Mensing* should be limited to failure-to-warn claims and that any new "exceptions" to *Wyeth*'s "general no-preemption rule" ought to come only from this Court. *Id.*

SUMMARY OF ARGUMENT

Congress has delegated to FDA the power to determine when a prescription drug is sufficiently safe and effective to warrant its distribution and sale in interstate commerce. 21 U.S.C. § 355. FDA approved the marketing of sulindac for several arthritis-related indications after determining that although sulindac poses significant dangers to some patients, its utility outweighed its risks. The judgment against Mutual conflicts with that determination. It is based on a state law determination that sulindac is a defective product because, as currently formulated, "the magnitude of the danger [created by sulindac's use] outweighs the utility of the product." Pet. App. 7a.

In light of that conflict, and the impossibility of Mutual continuing with its business in compliance with both federal and state law, Bartlett's design-defect claim is preempted by virtue of operation of the Supremacy Clause, U.S. Const., Art. VI, cl. 2. As explained by *Mensing*, "impossibility" is established by demonstrating that there is no action that a drug manufacturer could take that would bring its drug into compliance with both federal and state law. 131 S. Ct. at 2577-78. Both the appeals court and Bartlett concede that Mutual would have violated federal law had it sought to alter the composition of sulindac in order to address the design defect identified by the jury in this case. Indeed, *no* drug manufacturer is permitted under

federal law to make unilateral changes in the composition of an FDA-approved drug. Yet, the courts below determined that Mutual is in violation of New Hampshire law by marketing the FDA-approved version of sulindac.

"Impossibility" is not eliminated simply because the manufacturer could bring itself into compliance with both federal and state law by exiting the business entirely. As the appeals court recognized, Pet. App. 11a, that same option was available to the defendant in *Mensing*, yet the Court in that case did not deem the availability of a go-out-of-business option as sufficient to avoid preemption under an impossibility theory.

The design defect claim is also impliedly preempted because it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. As this Court has recognized, "Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background." *Weinberger v. Bentex Pharms. Inc.*, 412 U.S. 645, 654 (1973). In recognition of courts' lack of technical expertise, Congress delegated to FDA responsibility for undertaking the careful balancing process necessary to determine which prescription drugs (all of which are recognized to be highly dangerous to at least some patients) are sufficiently safe and effective to warrant their availability on a prescription basis. Allowing non-expert jurors to second-guess that balancing process, and to determine that some drugs are too dangerous to be marketed despite being approved by FDA, would undermine Congress's purposes and objectives.

For the reasons stated above, *all* design-defect claims against the manufacturers of prescription drugs are preempted by federal law. *Amici* agree with Mutual, however, that the rationale for preempting design-defect claims is particularly strong when, as here, the defendant is a generic drug manufacturer. Congress adopted the Hatch-Waxman Act in 1984 for the purpose of facilitating development of and marketing approval for low-cost, generic versions of FDA-approved drugs following expiration of the brand-name manufacturer's patent. Permitting state juries to second-guess the design of FDA-approved generic drugs would significantly undercut Congress's purposes and objectives in adopting Hatch-Waxman. In particular, generic manufacturers would not be able to offer their products at the low prices contemplated by Congress if they could not rely on FDA's prior determination that a drug formulation is safe and effective and instead would need to undertake their own extensive clinical trials to ascertain safety.

Finding preemption in this case will not, of course, leave patients who suffer injury after taking a prescription drug without legal recourse. If a patient can demonstrate that the drug was manufactured in a negligent manner and thus contained impurities, a state law tort suit would not be preempted. If FDA obtains new safety information and thereby determines that the drug should be removed from the market, it is at least arguable that a state-law tort suit against the manufacturer does not conflict with federal law and thus is not preempted. Moreover, the patient can sue the prescribing physician if the physician was negligent in writing the prescription. When, as here, the prescribing physician fails to read strong warnings

contained on the product label before prescribing the drug in question, he or she may be a prime candidate for liability.

ARGUMENT

I. BARTLETT'S DESIGN-DEFECT CLAIM IS PREEMPTED BECAUSE IT IS IMPOSSIBLE FOR MUTUAL TO BRING ITS DRUG INTO COMPLIANCE WITH BOTH FEDERAL AND STATE LAW

Mutual has cogently explained why this case is controlled by *Mensing* and why that decision requires a determination that Bartlett's design-defect claim is barred by a straight-forward application of conflict preemption principles.[2]

Amici write separately to focus on a different grounds for finding conflict preemption, one that applies without regard to the special Hatch-Waxman rules governing FDA approval of generic drugs. *See* Drug

---

[2] As Mutual explained, "the Hatch-Waxman Act imposes 'an on-going duty of sameness' that precludes generic drugs from deviating in any material respects from their brand-name equivalents." Petitioners Br. at 1 (quoting *Mensing*, 131 S. Ct. at 2574-75). *Mensing* concluded that state law claims are impliedly preempted under the Constitution to the extent that they require generic manufacturers to violate Hatch-Waxman's "sameness" mandate as a precondition to engaging interstate commerce. Although *Mensing* arose in the context of a failure-to-warn claim, Mutual has demonstrated that *Mensing*'s sameness rationale applies equally to design-defect claims, particularly when (as here) those claims take into account the adequacy of the product's health and safety warnings. *Id.* at 29-45.

Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"). For more than half a century, Congress has delegated to FDA extremely broad authority to determine which drugs are sufficiently safe and effective to be distributed and sold in interstate commerce. Pursuant to the FDCA, FDA requires manufacturers to conduct extensive clinical testing—often at a cost of hundreds of millions of dollars—to demonstrate that the *design* of the drug (*i.e.*, its precise molecular structure) is safe when administered to humans for its intended use. *See, e.g.*, 21 U.S.C. § 355(b)(1)(A), (d). Manufacturers of an FDA-approved drug are not permitted to alter the drug's chemical composition; the altered product would be deemed an unapproved new drug whose distribution would constitute a felony. 21 U.S.C. § 331(d). Accordingly, those federal requirements would prevent manufacturers from altering a drug's design in response to a state's determination, as here, that the drug is defectively designed. When, as here, it is impossible for a drug manufacturer to simultaneously bring its drug product into compliance with both federal and state requirements, the Constitution requires that the latter be deemed preempted.

A. The Jury's Determination That the Risks of Sulindac Outweigh Its Benefits Conflicts with the Federal Government's Opposite Determination

It is well recognized throughout the medical community that prescription drugs can pose risks to health, even when prescribed by a treating physician,

and administered in accordance with FDA-approved labeling. Thus, when FDA approves a prescription drug for marketing, it does so not on the basis of findings that the drug poses *no* health risks but rather with the understanding that the health risks are manageable and are outweighed by the benefits to public health to be derived from making the drug available. 21 U.S.C. § 355(d).[3] FDA's approval of Merck's new drug application for Clinoril® in 1978 required FDA to undertake just such a risk/benefit analysis.

As the First Circuit recognized, many States will not second-guess FDA determinations that the risk/benefit balance favors approval of a manufacturer's marketing application. Pet. App. 5a ("[C]ourts 'traditionally have refused to review the reasonableness of the designs of prescription drugs.'") (quoting *Restatement* (*Third*) *of Torts: Product Liability* § 6, cmt. f, at 156 (1998)). Indeed, Bartlett concedes that many state courts "have taken the view that prescription drugs are, by definition, 'unavoidably unsafe'" and thus not subject to strict product liability based on claims that the drugs are defective. Respondent Opp. Cert. Br. at 12. Bartlett characterizes design-defect claims as "rare and exceedingly difficult to prove." *Id.*

The First Circuit concluded that New Hampshire is a State that permits juries to make an independent evaluation of the risk/benefit balance, and it affirmed the jury's verdict on that basis. Pet. App. 7a. Bartlett

---

[3] Among the materials that FDA requires be included in new drug applications is "a discussion of why the benefits exceed the risks [of the drug] under the conditions stated in the labeling." 21 C.F.R. § 314.50(d)(5)(viii).

agrees with that characterization of New Hampshire law and the justification for the jury's verdict against Mutual:

> The question in New Hampshire is simply whether the product's risks outweigh its benefits; if so, the product is unreasonably dangerous, and the seller is subject to liability for injuries resulting from use of the product. . . . Applying those principles of New Hampshire law, the properly instructed jury in this case found that sulindac's risks outweighed its benefits, making it a defective product unreasonably dangerous to consumers.

Respondent Opp. Cert. Br. at 23.

The First Circuit recognized that the jury's verdict amounted to "second-guessing the FDA" with respect to the risk/benefit balance for sulindac. Pet. App. 10a. It nonetheless concluded that New Hampshire law was not preempted because Congress viewed FDA product approval as establishing a *minimum* design standard which States are permitted to exceed: "state law serves as a complementary form" of regulation of a drug's design. *Id.* at 9a.

The language and structure of the FDCA make plain that the appeals court erred in determining that Congress intended to permit juries applying state law to "second-guess[ ] the FDA" with respect to the design of prescription drugs. In particular, Congress provided that once FDA has approved the marketing of a prescription drug, it may seek to withdraw that approval only in accordance with elaborate rules set

forth in 21 U.S.C. § 355(e). FDA is required to provide "due notice" and an "opportunity for hearing" with respect to any such withdrawal. *Id.* Section 355(e) sets forth a limited number of grounds that would justify a decision to pull a drug from the market. The listed grounds have an important element in common: they all require FDA to be acting on the basis of information that became available *after* the drug was initially approved for marketing. In other words, Congress did not permit FDA officials to second-guess the product-approval decisions of their predecessors based solely on a difference of opinion regarding the risk/benefit evidence submitted to FDA in the initial product-approval application.

Congress cannot plausibly be understood to have intended to limit *FDA*'s power to revoke marketing authority for a prescription drug, yet at the same time to have granted *a State* unlimited power to declare FDA-approved drugs to be defectively designed and thereby to bar their distribution within the State.

Nor is there reason to conclude that Congress intended to grant a State the more limited authority to bar the distribution of drugs that fail (in the State's view) to meet the product design standards established by FDA, or that arguably should have had their marketing approval withdrawn under § 355(e). This Court has rejected efforts by anyone other than the United States to enforce federal drug laws. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4, 352 (2001) (citing 21 U.S.C. § 337(a)). *Buckman* held that state-law tort claims based on allegations that a drug manufacturer obtained FDA marketing authority by supplying false information to FDA were impliedly

preempted because they conflicted with FDA's own enforcement responsibilities. *Id.* at 348. The Court explained that FDA uses its powers to punish and deter fraud "to achieve a somewhat delicate balance of statutory objectives," and that to allow others to play a role in enforcing those powers might upset that balance. *Id.* Similarly, granting States a role in determining whether a drug's risk/benefit balance is sufficiently unfavorable to justify a product ban would undercut the risk/benefit balancing role that Congress assigned to FDA.

B. Impossibility Preemption Is Not Eliminated Simply Because Mutual Could Bring Itself Into Compliance with Both Federal and State Law by Ceasing Production

The Supremacy Clause requires preemption of state laws whenever they conflict with federal law. *Arizona v. United States*, 132 S. Ct. 2492, 2501 (2012). "This includes cases where compliance with both federal and state regulations is a physical impossibility and those instances where the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* (citations omitted).

The Court deems compliance with both federal and state laws to be a "physical impossibility" when "[i]t is not lawful under federal law" for drug manufacturers "to do what state law required of them." *Mensing*, 131 S. Ct. at 2577. That definition fits this case precisely. The jury concluded that, under New Hampshire law, sulindac is defectively designed and thus may not

continue to be marketed with its current formulation. Yet, as noted above, federal law prohibits drug manufacturers from altering the formulation of FDA-approved drugs. Thus, it is a "physical impossibility" for Mutual to operate its business in a manner that satisfies both federal and state law.

The First Circuit recognized that conundrum but nonetheless deemed impossibility preemption inapplicable because Mutual "certainly can choose not to make the drug at all," thereby bringing itself into compliance with both federal and state law. Pet. App. 10a. That conclusion is inconsistent with the Court's holding in *Mensing*. The defendant in that case had the identical ability to bring itself into compliance with both federal and state law by ceasing production of metoclopramide, the drug whose labeling was at issue. The Court nonetheless had no difficulty in concluding that the state regulation at issue (which prohibited distribution of metoclopramide unless the manufacturer included a stronger health warning on the product label) was barred under impossibility preemption principles. 131 S. Ct. at 2577-79.

Indeed, the case for application of impossibility preemption is even stronger here than it was in *Mensing*. In the latter case, state law provided the generic drug manufacturer with an option that offered it at least some hope that it could eventually resume the marketing of metoclopramide. It could have asked FDA and the brand-name drug company to sufficiently strengthen warnings on metoclopramide's labeling to satisfy state-law requirements; and those parties possessed statutory authority to grant the request. *Id.* at 2578. In contrast, both the First Circuit and Bartlett

recognized that a similar request in this case could never provide Mutual with a solution to the impossibility conundrum, not even in the long term. Pet. App. 10a ("Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)."). Thus, the *only* option available to Mutual in the face of conflicting regulations is to cease production altogether.[4]

The "impossibility" conundrum facing manufacturers is heightened by the fact that, if the decision below is affirmed, they are likely to face multiple product design standards from different States. Indeed, it is quite plausible that they will face

---

[4] Similarly unavailing is Bartlett's effort to distinguish *Mensing* by arguing that in that case the state law "required the manufacturers to attach a safer label to their generic metoclopramide," not to withdraw its product from the market. Respondent Opp. Cert. Br. 26. Bartlett asserts:

> When, as in [*Mensing*], a holding under state law would obligate a party to take an action (such as changing the label for its product) that federal law prohibits, that claim is preempted, even if the party could avoid liability by removing its product from the market. Here, by contrast, the holding under New Hampshire law did not require petitioner to perform any act that federal law prohibits it from doing independently.

Id. The distinction Bartlett seeks to draw between this case and *Mensing* is mere word-play. As the First Circuit recognized, the jury verdict in *Mensing* provided the drug company defendant with the same "out" that New Hampshire provided to Mutual: withdrawal from the market. Pet. App. 10a. The duty imposed by the jury verdict in *Mensing* was the duty to cease marketing metoclopramide in the absence of labeling providing health warnings that were not authorized by FDA.

conflicting design standards from two juries within a single State. Such multiple conflicting standards would all but guarantee that a manufacturer would respond by withdrawing from the market on a nationwide basis, thereby depriving patients of medical products that FDA has deemed beneficial to public health. In the context of medical devices, this Court concluded that Congress barred state-law regulation of the design of Class III medical devices at least in part because it feared that conflicting regulation of product design would stifle development of new and useful medical products. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 326 (2008).

In light of the clear "impossibility" conflict between the jury's verdict and FDA's approval of sulindac's current design, the Court should not strain to save the jury verdict from preemption. As the *Mensing* plurality observed, the Supremacy Clause was drafted in the form of a *non obstante* provision and therefore "suggests that federal law should be understood to impliedly repeal conflicting state law." *Mensing*, 131 S. Ct. at 2580 (plurality opinion). Accordingly, "courts should not strain to find ways to reconcile federal law with seemingly conflicting state law." *Id.* Under the facts of this case, it would require considerable straining for the Court to conclude that Congress intended to permit States to prevent the marketing of a prescription drug despite FDA's considered judgment that the drug's benefits outweigh its risks.

The appeals court's reliance on *Wyeth* was misplaced; that decision is clearly distinguishable. *Wyeth* found that failure-to-warn claims against brand-name drug companies were not subject to impossibility

preemption because federal law permitted the companies to unilaterally strengthen their labeling for the purpose of improving drug safety pursuant to FDA's "changes being effected" regulation, 21 C.F.R. § 314.70(c)(6)(iii)(A), (C). *Wyeth*, 555 U.S. at 568. There is no analogous federal regulation that permits manufacturers to make unilateral changes in a drug's design.

Indeed, Justice Thomas's concurring opinion in *Wyeth* makes clear the limited nature of that decision. Justice Thomas deemed impossibility preemption to be inapplicable in *Wyeth* in part because federal drug laws "do not give drug manufacturers an unconditional right to market their federally approved drug at all times *with the precise label initially approved by the FDA*," but rather require brand-name manufacturers to add new warnings "as soon as there is reasonable evidence of an association of a serious hazard with a drug." *Id*. at 592 (Thomas, J., concurring in the judgment) (emphasis added) (quoting 21 C.F.R. § 201.80(e)). In contrast, federal drug laws *do* provide manufacturers with a right to continue marketing their FDA-approved products as designed, until such time as FDA complies with statutory requirements that constrain its power to withdraw marketing authority. *See, e.g.,* 21 U.S.C. § 355(e).

Finally, a decision in Mutual's favor will not produce the anomalous result that the *Mensing* dissenters found so troubling. When *Mensing* and *Wyeth* are considered together, the result is that an injured patient can maintain a failure-to-warn claim against a brand-name drug company, but he loses that right if his pharmacy elects to fill his prescription by

substituting a generic drug for the brand-name drug prescribed by the doctor. While *Mensing* explained that distinction by pointing to federal drug law's disparate treatment of brand-name and generic manufacturers (the former are entitled to make unilateral label changes while the latter are not), the Court recognized that "from the perspective of [the plaintiffs], finding preemption here but not in *Wyeth* makes little sense." *Mensing*, 131 S. Ct. at 2581.

No similar distinction exists between brand-name and generic manufacturers with respect to product design. Neither category of manufacturer is entitled under federal drug law to make unilateral changes in product design. "Impossibility preemption" applies to a state law design-defect claim, regardless whether the defendant is a brand-name or a generic manufacturer. Because the "impossibility preemption" rule espoused here applies in a predictable and uniform manner, there is no reason to question the likelihood that Congress would have intended to adopt such a rule.

II. BARTLETT'S CLAIM IS ALSO PREEMPTED BECAUSE IT OBSTRUCTS ACCOMPLISHMENT OF CONGRESS'S PURPOSES

Conflict preemption doctrine also requires that a challenged state law give way when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 132 S. Ct. at 2501. The reasons previously articulated for finding "impossibility" preemption also suffice to find that the jury's verdict is subject to "purposes and objectives" preemption.

As this Court has recognized, "Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background." *Weinberger v. Bentex Pharms. Inc.*, 412 U.S. 645, 654 (1973). In recognition of courts' lack of technical expertise, Congress delegated to FDA responsibility for undertaking the careful balancing process necessary to determine which prescription drugs (all of which are recognized to be highly dangerous to at least some patients) are sufficiently safe and effective to warrant their availability on a prescription basis. Allowing non-expert jurors to second-guess that balancing process, and to determine that some drugs are too dangerous to be marketed despite being approved by FDA, would undermine Congress's purposes and objectives.[5]

"Evaluation of conflicting reports as to the

---

[5] Bartlett contends that Mutual has waived its right to assert "purposes and objectives" preemption because it allegedly failed to articulate that argument in its certiorari petition. Respondent Opp. Cert. Br. at 21, 28 n.22. That contention is without merit. The Court granted certiorari to consider the issue of whether conflict preemption doctrine bars Bartlett's design-defect claim. Once review is granted to consider an issue, the Court has never limited the parties to the specific arguments on that issue that were raised or considered previously. *See Lebron v. Nat'l Railroad Passenger Corp.*, 513 U.S. 374, 379 (1995) ("Our traditional rule is that 'once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they raised below.'") (quoting *Yee v. Escondido*, 503 U.S. 519, 534 (1992)). Accordingly, with respect to the conflict preemption issue, Mutual is entitled to argue both "impossibility" preemption and "purposes and objectives" preemption without regard to the extent to which those arguments have previously been raised.

reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background." *Id.* Thus, federal courts of appeals have repeatedly held that whether a drug is safe and effective is squarely within the primary scope of FDA's regulatory authority.[6]

FDA's requirements as to drug safety and labeling are imposed through a regulatory scheme that closely parallels the regulatory scheme for Class III medical devices that the Court found to have a preemptive effect in *Riegel*. And as with Class III medical devices, FDA's determinations as to which

---

[6] *See*, *e.g.*, *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 257 (3d Cir. 2008) ("FDA is charged with promoting the public health" by, *inter alia*, "ensuring that drugs are safe and effective") (internal quotations and citation omitted); *Zeneca, Inc. v. Shalala*, 213 F.3d 161, 170 (4th Cir. 2000) ("FDA's 'judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us.'") (quoting *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995), and *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995)); *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) (same); *Rutherford v. United* States, 806 F.2d 1455, 1461 (10th Cir. 1986) ("[T]he intent behind the [FDCA] was to give the agency primary jurisdiction to determine evidentiary matters concerning drugs about which it has a special expertise"); *United States v. Undetermined Quantities of Various Articles of Drug Equidantin Nitrofurantion Suspension*, 675 F.2d 994, 1000 (8th Cir. 1982) ("A district court is not empowered to evaluate the actual safety and effectiveness of a drug product. That determination is committed to the FDA due to its superior access to technical expertise."); *Premo Pharm. Labs. Inc. v. United States,* 629 F.2d 795, 803 (2d Cir. 1980) (question whether a drug is safe and effective "is to be determined by the FDA which, as distinguished from a court, possesses superior expertise, usually of a complex scientific nature, for resolving the issue").

drugs should be approved reflects "a cost-benefit analysis" in which FDA balances how many "lives will be saved" by the drug against the "risk of harm." *Riegel*, 552 U.S. at 325. *Riegel* noted that, by way of contrast, juries considering state-law tort claims engage in no such cost-benefit analysis. A jury "sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court." *Id.*

The need for FDA to pursue this balanced approach was recognized by Congress in its amendment of the FDCA in 1962. As set forth in the Senate Report accompanying the 1962 Amendments, the new drug application approval procedures were designed to "strike [ ] a balance between the need for government control to assure that new drugs are not placed on the market until they have passed the relevant tests and the need to insure that government control does not become so rigid that the flow of new drugs to the market, and the incentive to undergo the expense involved in preparing them for market, become stifled." Drug Amendments of 1962, S. Rep. No. 87-1744 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 2884.

In enacting the 1997 FDA Modernization Act, Congress reaffirmed this basic principle, declaring "a clearly defined, balanced mission for the FDA" which reflects both the federal objectives of "protecting the public health by ensuring that the products [FDA] regulates meet the appropriate FDA regulatory standards" and of "taking appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability." Food and Drug Administration Modernization Act of

1997, S. Rep. No. 105-43 (1997), as printed in 1997 WL 394244, at *2-*4; *see also id.* at *10 (mission statement added to FDCA because "[c]lear statutory guidance is needed to assist the Agency to find this delicate balance"). Congress instructed: "the agency should be guided by the principle that expeditious approval of useful and safe new products enhances the health of the American people. Approving such products can be as important as preventing the marketing of harmful or ineffective products." *Id.* at *8, *15. This balanced mission statement is set forth in FDA regulation, 21 U.S.C. §§ 393(b)(1) & (b)(2)(B) (2008),[7] and is reflected in the Court's discussion in *Buckman* of FDA's "often competing" regulatory objectives. *Buckman*, 531 U.S. at 348, 349-50 (2001).

Permitting individual juries to second-guess FDA's product approval decisions is inconsistent with Congress's intent that FDA should adopt a "balanced" approach when making those decisions. By prohibiting the sale and distribution of a prescription drug whose benefits, FDA has determined, outweigh its risks, the jury verdict in this case stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

---

[7] FDA is charged under these regulations with "promot[ing] the public health by promptly and efficiently reviewing [drug manufacturers'] clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and "protecting the public health by ensuring that…drugs are safe and effective." 21 U.S.C. §§ 393 (b)(1) & (b)(2)(B) (2008).

III. FINDING PREEMPTION HERE WILL NOT LEAVE PATIENTS WITHOUT LEGAL RECOURSE

The First Circuit based its decision in part on a desire to be fair to tort plaintiffs who allege that a generic drug caused them injury: "Bartlett having lost her warning claim by the mere chance of her drug store's selection of a generic, the Supreme Court might be less ready to deprive Bartlett of her remaining avenue of relief." Pet. App. 11a. But this Court has never based its product liability preemption decisions on a "sporting chance" rationale, whereby every injured plaintiff ought to have at least one shot at receiving compensation for his damages. Rather, the Court looks solely to congressional intent in determining whether state regulations are preempted. *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978) ("The purpose of Congress is the ultimate touchstone" of preemption analysis).

At least as importantly, a decision favoring Mutual in this case will not leave patients without legal recourse for their injuries. The appeals court referred to "the perennial trio of products liability claims: design defect, failure to warn, and manufacturing defect." Pet. App. 3a. Bartlett asserted all three of those claims against Mutual. *Id.* The failure-to-warn and manufacturing-defect claims did not survive to trial—not because the trial court deemed them preempted but because they were found deficient as a matter of New Hampshire law. *Wyeth* ensures that injured plaintiffs can continue to assert failure-to-warn claims against brand-name drug companies, and *amici* are unaware of *any* appellate court that has held that a

manufacturing-defect claim is preempted by federal law.[8]

Moreover, an injured patient can sue the prescribing physician if the physician was negligent in writing the prescription. When, as here, the prescribing physician fails to read strong warnings contained on the product label before prescribing the drug in question, he or she may be a prime candidate for liability. *See Wyeth*, 555 U.S. at 619-21 (Alito, J., dissenting).

Finally, if FDA obtains new safety information and thereby determines that the drug is unreasonably unsafe and should be removed from the market, it is at least arguable that a state-law design-defect suit against the manufacturer does not conflict with federal law and thus is not preempted. Under those circumstances, a tort suit might be viewed as serving to supplement and facilitate the federal enforcement scheme. Thus, in *Buckman*, Justices Stevens and Thomas opined that the preempted fraud-on-the-FDA claim "would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the [product-approval] process and had then taken the necessary steps to remove the

---

[8] Moreover, a finding that design-defect claims are preempted will affect only a small fraction of legal claims filed by those claiming injury as a result of using a prescription drug. Indeed, Bartlett concedes that many state courts "have taken the view that prescription drugs are, by definition, 'unavoidably unsafe'" and thus not subject to strict product liability based on claims that the drugs are defective. Respondent Opp. Cert. Br. at 12. Bartlett characterizes design-defect claims as "rare and exceedingly difficult to prove." *Id.*

harm causing product from the market. . . . In such a case, a plaintiff would be able to establish causation without second-guessing the FDA's decision-making." *Buckman*, 531 U.S. at 355 (Stevens, J., concurring in the judgment).

There is no cause for the Court to speculate on these counter-factual possibilities. FDA has not determined that sulindac is unreasonably unsafe. The drug continues to be marketed by Mutual and other drug manufacturers, and there is no evidence that Mutual obtained marketing approval by providing false information to FDA. It suffices to observe that a ruling in favor of Mutual will not (as some drug industry critics have charged) leave injured patients without any legal recourse against those that have wronged them.

IV. THE RATIONALE FOR PREEMPTING DESIGN-DEFECT CLAIMS IS PARTICULARLY STRONG WHEN THE DEFENDANT IS A GENERIC DRUG MANUFACTURER

For the reasons stated above, *all* design-defect claims against the manufacturers of prescription drugs are preempted by federal law. *Amici* agree with Mutual, however, that the rationale for preempting design-defect claims is particularly strong when, as here, the defendant is a generic drug manufacturer. Congress adopted the Hatch-Waxman Act in 1984 for the purpose of facilitating development of and marketing approval for low-cost, generic versions of FDA-approved drugs following expiration of the brand-name manufacturer's patent. Permitting state juries to second-guess the design of FDA-approved generic drugs

would significantly undercut Congress's purposes and objectives in adopting Hatch-Waxman.

Congress adopted the Hatch-Waxman Act "to make available more low cost generic drugs." H.R. Rep. 98-857, pt. 1, at 14. Under the law, generic drugs can gain FDA approval "simply by showing equivalence to" a brand name drug that has already been approved by FDA. *Mensing*, 131 S. Ct. at 2574. Indeed, FDA is not permitted to require one of these "abbreviated" new drug applications (ANDAs) to "contain information in addition to" the very limited categories of information specified in Hatch-Waxman. 21 U.S.C. § 355(j)(2)(A). As the Court has explained, Hatch-Waxman "allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." *Mensing*, 131 S. Ct. at 2574.

Permitting design-defect tort claims to be filed against generic manufacturers would undercut Congress's desire that generic drugs serve as a low-cost alternative to brand-name drugs. Faced with the prospect of multi-million dollar tort judgments, generic manufacturers would no longer be willing to accept at face value FDA's determination that a drug's benefits outweigh its safety risks and thus that the drug is not unreasonably unsafe. Instead, prudent generic manufacturers would begin undertaking extensive clinical trials of their own to satisfy themselves that the drug design is a safe one and thus that marketing the drug would not expose the company to potentially ruinous liability. Because the cost of such studies would invariably be incorporated into the prices charged by generic manufacturers, generic drugs would no longer

be available at the low prices contemplated by Congress when it adopted the Hatch-Waxman Act.

The legislative history is replete with statements indicating that Congress intended that generic drugs would, in fact, be produced at minimum cost and thus be made available for sale at very low prices. *See, e.g.*, H.R. Rep. 98-857, pt. 1, at 17 ("The availability of generic versions of pioneer drugs approved after 1962 would save American consumers $920 million over the next 12 years."); *id*. at 18 ("Enactment of the legislation, however, will result in significant cost savings to the Federal government. Unlike the costs of H.R. 3605, *these savings are certain*. The Federal government spent about $2.4 billion for drugs in 1983. Many of these drugs will be available as low cost generic after enactment of H.R. 3605.") (emphasis added). Congress could be "certain" that the cost structure for generic drugs would remain low only if generic manufacturers' pricing would not have to factor in costs associated with design-defect litigation and could reasonably rely on FDA findings that FDA-approved drugs are not unreasonably dangerous.

Moreover, Congress was adamant that generic manufacturers should *not* undertake their own clinical studies, not only because they were deemed "unnecessary and wasteful" but also because Congress considered them "unethical":

> The only difference between a NDA and an ANDA is that the generic manufacturer is not required to conduct human clinical trials. FDA considers such retesting to be unnecessary and wasteful because the drug has already been

> determined to be safe and effective. Moreover, such retesting is unethical because it requires that some sick patients take placebos and be denied treatment known to be effective.

Id. at 16. A Congress that deemed additional safety testing of FDA-approved drugs to be so unnecessary as to be "wasteful" and "unethical" cannot reasonably be understood to have simultaneously contemplated that state law would serve as a "complementary form of drug regulation," Pet. App. 9a, and that juries applying state law would be permitted to determine that FDA-approved drugs were unreasonably dangerous.

CONCLUSION

Amici curiae request that the Court reverse the decision of the court of appeals.

Respectfully submitted,

Richard A. Samp
(Counsel of Record)
Cory L. Andrews
Washington Legal Foundation
2009 Massachusetts Avenue, NW
Washington, DC 20036
(202) 588-0302
rsamp@wlf.org

Dated: January 22, 2013