No. 12-142

IN THE

Supreme Court of the United States

MUTUAL PHARMACEUTICAL COMPANY, INC.,

Petitioner,

v.

KAREN L. BARTLETT,

Respondent.

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

BRIEF OF THE GENERIC PHARMACEUTICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Of Counsel
Clem C. Trischler
Jason M. Reefer
Pietragallo Gordon Alfano Bosick & Raspanti, LLP
38th Floor, One Oxford Ctr
Pittsburgh, PA 15219
(412) 263-2000
cct@pietragallo.com
jmr@pietragallo.com

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Ray M. Aragon
Counsel of Record
McKenna Long & Aldridge LLP
1900 K Street, NW
Washington, DC 20006
(202) 496-7500
raragon@mckennalong.com

Counsel for Amicus Generic Pharmaceutical Association

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

Whether the First Circuit erred when it created a circuit split and held—in clear conflict with this Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), *reh'g denied*, 132 S. Ct. 55 (2011); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)—that federal law does not preempt state law design-defect claims targeting generic pharmaceutical products because the conceded conflict between such claims and the federal laws governing generic pharmaceutical design allegedly can be avoided if the makers of generic pharmaceuticals simply stop making their products.

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INTEREST OF *AMICUS CURIAE* AND SUMMARY OF ARGUMENT

The Generic Pharmaceutical Association ("GPhA") is a voluntary, non-profit association[1] comprised of

[1] Pursuant to Supreme Court Rule 37.2(a), all parties were informed ten days in advance of the filing of this brief, and have consented to its filing. Correspondence demonstrating advance notice to the parties and their consent to this filing

more than 70 manufacturers and distributors involved in the generic pharmaceutical industry. GPhA's members provide American consumers with generic medications that are as safe and effective as their brand-name counterparts, but at a fraction of the cost. "All generic drugs approved by [the Food and Drug Administration ("FDA")] have the same high quality, strength, purity and stability as brand-name drugs."[2] Generic drugs today account for nearly 80% of prescriptions dispensed in the United States, but just 27% of prescription spending.[3] Generic pharmaceutical products are used to fill more than 3.2 billion prescriptions each year, saving the American consumer $193 billion in 2011 and

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have been filed with the Clerk. Pursuant to Supreme Court Rule 37, *amicus* states that no counsel for a party authored any part of this brief and that no person or entity other than *amicus*, its members, and its counsel have made any monetary contribution intended to fund the preparation or submission of this brief.

[2] Generic Drugs: Questions and Answers, U.S. Food and Drug Administration, *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/default.htm (accessed August 24, 2012).

[3] IMS Institute for Health Care Informatics, *The Use of Medicines in the United States: Review of 2011*, at 26 (Apr. 2012) ("Use of Medicines 2011"); Generic Pharmaceutical Association, Generic Drug Savings in the U.S. (4th ed. 2012), *available at* http://www.gphaonline.org/sites/default/files/IMS%20Study%20Aug%202012%20WEB.pdf (accessed August 26, 2012) ("Generic Drug Savings 2012").

more than $1 trillion over the last 10 years. *Id.* GPhA's members are committed to providing safe, lower-cost medications to all Americans, including the poor and the elderly.

The case before the Court affects the interests of GPhA's members in that it re-opens avenues of liability that this Court decisively closed in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) *reh'g denied*, 132 S. Ct. 55 (2011). In *Mensing*, the Court made very clear that generic pharmaceutical manufacturers are required under federal law to produce products that are the "same as" their brand-name counterparts. *Id.* at 2474–75. State tort law requirements that conflict in any way with the federal duty of "sameness" are preempted. *Id.* at 2570–71, 2474–75.

Bartlett v. Mutual Pharmaceutical Co., 678 F.3d 30 (1st Cir. 2012) *petition for cert. filed* July 31, 2012 (No. 12-142), is logically and legally indistinguishable from *Mensing*. In both cases, the respective plaintiffs sought to impose a state law duty that ran afoul of the federal duty of sameness – that is, generic drugs must have the same design and label as their respective brand-name counterparts. *See* 21 U.S.C. § 355(j)(2)(A)(ii), (v). And in both cases, the plaintiffs argued that the generic manufacturers could have complied with both state and federal law by simply withdrawing their drugs from the market.

In *Mensing*, this Court found preemption. In *Bartlett*, however, the First Circuit did not find

preemption, reasoning that conflicts "might" be avoided if Petitioner decided not to manufacture generic drugs at all. *Bartlett,* 678 F.3d. at 37.

The proposition that conflict preemption is inapplicable because a generic manufacturer can remove its drug from the market was rejected by this Court in *Mensing* and every other Circuit Court to have considered it since. Quite simply, if the possibility of withdrawing a drug from the market was sufficient to satisfy the Supremacy Clause, then *Mensing* would have come out the other way. Moreover, the First Circuit's approach would render conflict preemption meaningless, because state and federal regulatory and tort law can (almost) always be satisfied by leaving the regulated business.

Perhaps more troubling is that *Bartlett* directly undermines the expressly stated purposes of Congress in enacting the Hatch-Waxman Amendments: to promote the availability of lower-cost generic drugs. *See generally* 21 U.S.C. § 355(j). In order to curb rising costs of prescription medication, Congress streamlined the market entry process for generic drugs and established the federal duty of sameness – applicable to both design and warnings.

The results have been nothing short of astonishing. While it typically costs more than one billion dollars to bring a brand product to market, the research and development costs for a generic

drug are only 1 to 2 million.[4] These savings are then passed on to all consumers, not the least of which is the federal government. And the bottom line for Congress and American taxpayers is that generic drugs have saved the American healthcare system more than $1 trillion over the last 10 years.[5] When the Hatch-Waxman Amendments were passed, their proponents estimated that they would save American consumers $920 million over the following *twelve years.*[6] These savings are now achieved every *two days.*

The driving force behind these benefits is the availability of low-cost generic drugs made possible by the Hatch-Waxman Amendments. *Bartlett* threatens to upend this statutory purpose by forcing generic drugs out of the market altogether. The First Circuit upheld the imposition of state tort liability – to the tune of $21.06 million, 678 F.3d at 43 – based on nothing more than Petitioner's decision to distribute a generic drug that carries inherent, but recognized risks – risks that were well known by the FDA, understood by the medical community decades before Respondent's injuries occurred, and disclosed in the FDA-approved

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[4] *See* U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Office of Science and Data Policy, ASPE Issue Brief, Expanding Use of Generic Drugs at 4–5 (2010), *available at* http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.shtml.

[5] Generic Drug Savings 2012.

[6] *See* H.R. Rep. No. 98-857(I) (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2649.

labeling. *Id.* at 44 (noting that sulindac has a "miniscule" but "recognized" risk of Stevens-Johnson Syndrome ("SJS") and toxic epidermal necrolysis ("TEN")).

This Court acknowledged the "unfortunate hand that federal drug regulation has dealt" those who suffer rare-but-warned-about side effects from generic drugs. *Mensing*, 131 S. Ct. at 2581. Nevertheless, the Court stressed that the Supremacy Clause may not be distorted "in order to create similar pre-emption across a dissimilar statutory scheme." *Id.* at 2582. The converse is also true; the Supremacy Clause should not be distorted to create dissimilar preemption across a similar statutory scheme.

Yet this is exactly what the lower court did in *Bartlett*. The First Circuit, faced with the same regulatory scheme at issue in *Mensing*, fabricated a crude remedy for injuries sustained while using generic drugs. Along the way, it ignored the rationale of *Mensing* and ran roughshod over the statutory scheme carefully crafted by Congress.

The Food, Drug, and Cosmetic Act ("FDCA") 21 U.S.C. § 301 *et seq.*, and the Hatch-Waxman Amendments involve a delicate balance of private and public interests, which is precisely why it is left to "Congress and the FDA . . . to change the law and regulations if they so desire." *Id.* Courts may not ignore controlling law, nor may they concoct remedies that frustrate Congress' clearly stated legislative goals.

As the *Bartlett* Court's decision ignores these bedrock principles, GPhA respectfully requests that this Court grant Petitioner's petition for writ of certiorari and accept the First Circuit's invitation to provide "a decisive answer from the only court that can supply it." 678 F.3d at 38.

REASONS FOR GRANTING THE PETITION

A. THE DECISION OF THE FIRST CIRCUIT IS WHOLLY INCONSISTENT WITH THE HOLDING IN *MENSING*

Last year in *Mensing*, this Court embraced three propositions that control this case:

1. "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it";
2. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes"; and
3. The Court will not "permit an approach to pre-emption that renders conflict pre-emption all but meaningless" by rendering "most conflicts between state and federal law illusory."

131 S. Ct. at 2579–81.

Here, Respondent purports to proceed on a design defect theory. A traditional design defect claim is

based on a manufacturer's duty to change the design of a product to render it safer. But, as recognized by the overwhelming majority of courts to consider the question, such a duty would fail for the same reason that the claims failed in *Mensing*; the federal duty of "sameness" applies equally to both warnings and design.[7] The First Circuit agrees. *See Bartlett*, 678

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[7] *See, e.g., In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012) (holding that the duty of "sameness" also preempts design defect claims); *In re Accutane Prods. Liab.*, MDL No. 1626, 2012 WL 3194952, at *2–3 (M.D. Fla. Aug. 7, 2012) (dismissing design defect claim based on the federal duty of "sameness"); *Aucoin v. Amneal Pharms., LLC*, Civ. A. No. 11-1275, 2012 WL 2990697, at *9 (E.D. La. July 20, 2012) (same); *Lashley v. Pfizer, Inc.*, --- F.Supp.2d ----, Civ. A. No. 1:09CV749HSO-JMR, 2012 WL 2459148, at *11 (S.D. Miss. June 27, 2012) ("Because [the generic manufacturer] could not have altered their package inserts without FDA approval, Plaintiffs' claim based upon defective design is preempted by federal law."); *Johnson v. Teva Pharms. USA, Inc.*, No. 2:10 CV 404, 2012 WL 1866839, at *4 (W.D. La. May 21, 2012) (dismissing design defect claim under *Mensing*); *Eckhardt v. Qualitest Pharms. Inc.*, --- F. Supp. 2d ----, Civ. A. No. M-11-235, 2012 WL 1511817, at *6–7 (S.D. Tex. Apr. 30, 2012) (holding that design defect claim is preempted, because "Generics were required to produce a drug that was equivalent to the brand-name drug"); *Metz v. Wyeth LLC*, Civ. A. No. 8:10-CV-2658-T-27AEP, 2012 WL 1058870, at *4 (M.D. Fla. Mar. 28, 2012) ("A claim that Actavis should have redesigned metoclopramide to alleviate the risks associated with its long-term use would be preempted under *Mensing*."); *Lyman v. Pfizer, Inc.*, No. 2:09-CV-262, 2012 WL 368675, at *4 (D. Vt. Feb. 3, 2012) (holding that design-defect claims "are preempted as well by *Mensing*'s logic"); *In re: Fosamax (Alendronate Sodium) Prods. Liab. Litig (No. II).*, MDL No. 2243,, 2011 WL 5903623, at *6 (D.N.J. Nov. 21, 2011) (holding that design defect claims are preempted, "because FDA requires generic Fosamax to have the same active ingredient as Fosamax"); *and*

F.3d at 37 ("Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway)").

But rather than accept this reality, the *Bartlett* Court recognized a state law duty for manufacturers of generic drugs to withdraw their FDA-approved drugs from the market. *Id.* at 38 ("[W]hile the generic maker has no choice as to label—the decision to make the drug and market it in New Hampshire is wholly its own."). This claim, of course, has absolutely nothing to do with the design of sulindac – a "one-molecule drug" with inherent risks and no possible alternative design. *Id.* at 37.

In any event, the option of withdrawing a product from the market does not represent an end around *Mensing*. As a preliminary matter, the same argument could have been – and, indeed, was – made in *Mensing*, and this Court found that the plaintiffs' state law claims were preempted anyway.

What is more, if the ability to withdraw a product from the market were sufficient to defeat impossibility preemption, "it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force." *Mensing*, 131 S. Ct. at 2579. *Mensing* bars "an approach to pre-emption that renders conflict pre-emption all but

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Stevens v. PLIVA, Inc., Civ. A. No. 6:10-0886, 2011 WL 6224569, at *2 (W.D. La. Nov. 15, 2011) (holding that "federal law pre-empts state laws imposing the duty to change a drug's design").

meaningless." *Id.* So yet again, the possibility that the manufacturer of a generic drug could have chosen to stop doing business is constitutionally irrelevant.

In sum, as a generic manufacturer, Petitioner has no more freedom to change the design of its drug than it does to change the warnings. The First Circuit was fully aware of these facts, but strained to avoid preemption with the unremarkable observation that Petitioner was never obligated to market its drug in the first place. This approach ignores the teachings of *Mensing* and renders conflict preemption largely meaningless. But because *Bartlett* involved the same regulations and same arguments as *Mensing*, the First Circuit was not at liberty to reach a different result. GPhA urges this Court to correct the decision below.

B. THE DECISION BELOW CONFLICTS WITH THE *MENSING* ANALYSES OF OTHER CIRCUITS

The First Circuit below embraced a failure-to-withdraw theory under the guise of a design defect claim, but acknowledged "tension" with *Mensing*'s "rationale." *Bartlett*, 678 F.3d at 38. Describing *Mensing* as setting forth a "policy of encouraging generics by preempting state tort claims," *id.* at 37, the *Bartlett* Court challenged this Court to provide a "decisive answer" to the viability of Respondent's so-called design defect claim. *Id.*

But this Court has already done so. For that reason, the First Circuit's decision stands as an outlier from at least two of its sister circuits (which considered and rejected this argument after plaintiffs raised it in post-*Mensing* briefs)[8] and

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[8] *See, e.g., Strayhorn v. Wyeth Pharms., Inc.*, Nos. 11-2058-STA-CGC, et al., 2012 WL 3261377, at *16 (W.D. Tenn. Aug. 8, 2012) ("[A]ll of Plaintiffs' assorted claims raising allegations that the Generic Defendants failed to remove metoclopramide from the market are invalid due to *Mensing* and *Smith*'s rejection of this theory."); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, Nos. 2:11-MD-2226-DCR, et al., 2012 WL 2457825, at *1 (E.D. Ky. June 22, 2012) (observing that the plaintiffs' failure-to-withdraw claims "failed to persuade either the Supreme Court or the Eighth Circuit on remand in *Mensing*, and the Sixth Circuit in *Smith*"); *Johnson*, 2012 WL 1866839, at *5 (rejecting "failure-to-withdraw" argument based on Supreme Court and Eighth Circuit's rejection of the precise argument); *Fulgenzi v. PLIVA, Inc.*, Case No. 5:09CV1767, 2012 WL 1110009, at * 7 n.5 (N.D. Ohio Mar. 31, 2012) (noting that the failure-to-withdraw argument was "overruled" by the Supreme Court in *Mensing*); *Bowman v. Wyeth, LLC*, Civ. No. 10-1946 JNE/SER, 2012 WL 684116, at *6 (D. Minn. Mar. 2, 2012) (dismissing failure-to-withdraw claim, because it was already rejected by both the Supreme Court and the Eighth Circuit); *Moretti v. PLIVA, Inc.*, No. 2:08-CV-00396-JCM, 2012 WL 628502, at *5–6 (D. Nev. Feb. 27, 2012) (dismissing failure-to-withdraw theory based on, *inter alia*, the Sixth and Eighth Circuits' rejection of this very theory); *Moretti v. Mut. Pharm. Co.*, Civ. No. 10-896, 2012 WL 465867, at *5 (D. Minn. Feb. 13, 2012) (rejecting proposition that a generic defendant can circumvent *Mensing* preemption by simply withdrawing from the market, because this argument was rejected by the Eighth Circuit on remand); *Lyman*, 2012 WL 368675, at *4 n.5 (recognizing that the Eighth Circuit rejected the failure-to-withdraw theory upon remand in *Mensing*); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 658–59 (D. Md. 2011) (noting that the proposition that the ability to

dozens of federal district courts that have addressed the issues.

In fact, before *Mensing* reached the Supreme Court, the Eighth Circuit had accepted the plaintiff's argument that a generic manufacturer could satisfy state and federal law by withdrawing the drug from the market. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009), *rev'd*, 131 S. Ct. 2567 (2011). In reversing the Eighth Circuit, this Court rejected this reasoning and refused to rehear the case based on the plaintiffs' suggestion that the Court had "overlook[ed] the fact that the [generic manufacturers] could have 'independently' complied with both state and federal law simply by suspending sales of generic metoclopramide with warnings that they knew or should have known where inadequate." Respondents' Petition for Rehearing, *PLIVA, Inc. v. Mensing*, Nos. 09-993, 09-1039, 09-1501, 2011 WL 2874547, at *1 (July 18, 2011).

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withdraw a product serves as an end around *Mensing* was rejected by the Supreme Court, Eight Circuit, and Sixth Circuit); *Fullington v. PLIVA, Inc.*, No. 4:10CV00236 JLH, 2011 WL 6153608, at *6 (E.D. Ark. Dec. 12, 2011) *reconsideration denied*, 2012 WL 2918711 (E.D. Ark. July 17, 2012) (noting that plaintiff's suggestion that preemption could be avoided by removing the drug from the market had been "overruled" by the Supreme Court and the Eighth Circuit on remand in *Mensing*); *and In re Fosamax (Alendronate Sodium) Products Liab. Litig.*, 2011 WL 5903623, at *6 n.5 (recognizing that the plaintiffs' arguments regarding an alleged failure to withdraw are "essentially a re-argument of *Mensing*," such that dismissal of these claims is necessitated by "binding law").

On remand, the Eighth Circuit vacated the portion of its earlier opinion that embraced the failure-to-withdraw theory and denied the plaintiff's motion to file a supplemental brief on that issue. *See Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011). In doing so, the Eighth Circuit understood that this Court had settled the question of whether the ability to withdraw a drug from the market allows a plaintiff to avoid preemption.

The Sixth Circuit also rejected this "failure-to-withdraw" argument. *See Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) *cert. denied*, 132 S. Ct. 2103 (2012). The district court in *Smith* granted the generic manufacturers' motion for summary judgment on preemption grounds. On appeal, the plaintiffs suggested a "failure to suspend sales" theory would be "wholly consistent with *Mensing*," because "no federal statute or regulation prohibited [generic manufacturers] from 'independently' suspending sales of their product out of concern that their labeling lacked adequate warnings." Appellants' Supplemental Letter Brief, *Smith v. Wyeth, Inc.*, Nos. 09-5460, 5461, 5509, 2011 WL 3662688, at *6 (Aug. 15, 2011). The Sixth Circuit was not persuaded, and affirmed summary judgment. *Smith*, 657 F.3d at 423.

Thus, the First Circuit – without even addressing the merits of the Sixth and Eighth Circuit's positions, not to mention the fact that the failure-to-withdraw argument *twice* failed to persuade this Court – has created a circuit split. GPhA respectfully requests that the Court grant Mutual's

petition for certiorari and bring the First Circuit into line with the well-reasoned decisions from nearly every other court to have addressed the issue.[9]

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[9] *See Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1352 n.14 (N.D. Ga. 2012) ("[A]ny such state law duty [to stop selling a generic drug] would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce."); *Jacobsen v. Wyeth, LLC*, Civ. A. No. 10-0823, 2012 WL 3575293, at *11 (E.D. La. Aug. 20, 2012) ("To require a generic manufacturer to remove a drug from the market would repudiate the label approved by the FDA."); *Aucoin*, 2012 WL 2990697, at *9 (rejecting the viability of a failure-to-withdraw theory, because "[t]o require a generic manufacturer to remove a drug from the market would repudiate the label approved by the FDA"); *Brinkley v. Pfizer, Inc.*, No. 10-0274-CV-W-SOW, 2012 WL 1865402, at *3–5 (W.D. Mo. May 22, 2012) (dismissing claims for, *inter alia*, failure to stop selling metoclopramide, because "the Court fails to see how these allegations differ from those in *Mensing*"); *Eckhardt*, 2012 WL 1511817, at *6–7 ("[A] state law requirement that the drug be completely withdrawn from the market, based solely on a theory that the federally mandated label was inadequate, would also impermissibly conflict with federal law and be preempted."); *Metz*, 2012 WL 1058870, at *4 ("To the extent Plaintiffs contend that Actavis should have pulled the generic version of metoclopramide from the market, such claim is also preempted."); *Cooper v. Wyeth, Inc.*, Civ. A. No. 09-929-JJB, 2012 WL 733846, at *6 (M.D. La. Mar. 6, 2012) ("If state law could *require* a generic drug manufacturer to wholly withdraw from the market based on the unreasonable danger of the product (which is all a successful failure to withdraw from the market claim could be), it *necessarily* must repudiate the label approved by the FDA. But that is precisely what *Mensing* teaches state law cannot do.") (emphasis in original); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, MDL No. 2226, 2012 WL 718618, at *2–4 (E.D. Ky. Mar. 5, 2012)

C. THE DECISION BELOW WOULD UNDERMINE THE PURPOSE OF THE HATCH-WAXMAN AMENDMENTS

If allowed to stand, the First Circuit's opinion would erode the foundation of the pharmaceutical industry by allowing lay juries to second guess the FDA – the expert agency entrusted by Congress to determine which drugs should be on the market. Manufacturers of generic drugs would be forced to withdraw from the market or be subjected to the whims of 50 states' tort regimes simply for marketing a product with the FDA's approval.

(rejecting the viability of a failure-to-withdraw claim, because "the idea that [generic manufacturers] should have simply stopped selling propoxyphene is an oversimplified solution that could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether"); *Coney v. Mylan Pharms., Inc.*, No. 6:11-CV-35, 2012 WL 170143, at *5–6 (S.D. Ga. Jan. 19, 2012) (dismissing a failure-to-withdraw claim, because "[f]inding that state law prohibits Mylan from doing what federal law explicitly requires Mylan to do would be tantamount to conferring supremacy upon the state law"); *Gross*, 825 F. Supp. 2d at 659 (holding that a state law duty to withdraw an FDA-approved product is preempted, because it "would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce"); *and In re Reglan Litig.*, No. 289, 2012 WL 1613329 (N.J. Sup. Ct. May 4, 2012) (rejecting argument that generic manufacturers could independently meet both state and federal law by withdrawing the product from the market and noting that the "conflict between state and federal law would be much more pronounced if the state courts upheld a decision that an FDA-approved drug should not have been on the market").

In passing the Hatch-Waxman Amendments, Congress left nothing to the imagination as to the statute's goal:

> The purpose of [the Hatch-Waxman Amendments] is to make available more low cost generic drugs by establishing a generic drug approval procedure . . . .

H.R. Rep. No. 98–857, pt. 1, at 14 (1984).

As to the ends and means of the Hatch-Waxman Amendments, this Court spoke unanimously in *Mensing*:

> As the majority explains, to accomplish this goal the [Hatch-Waxman Amendments] establish an abbreviated application process for generic drugs. The abbreviated approval process implements the amendments' core principle that generic and brand-name drugs must be the "same" in nearly all respects . . . . By eliminating the need for generic manufacturers to prove their drugs' safety and efficacy independently, the Hatch-Waxman Amendments allow generic manufacturers to bring drugs to market much less expensively.

Mensing, 131 S. Ct. at 2583 (Sotomayor, J., dissenting) (citations omitted).

The federal duty of sameness allowed Congress to eliminate the need for generic manufacturers to repeat "costly and lengthy clinical testing," *id.* at

2574, thereby removing unnecessary hurdles to market entry.

Congress' efforts to promote the availability of generic drugs have borne fruit. Today, nearly 80% of all prescriptions are filled with generic products, but they account for only 27% of prescription drug costs.[10] The Congressional Budget Office ("CBO") estimated that the availability of generic drugs saved between $8 billion and $10 billion in 1994.[11] By 2011, these savings increased to $193 billion annually – more than $1 billion every two days – with total savings exceeding one trillion dollars over the last ten years.[12]

These data illustrate with clarity that the Hatch-Waxman Amendments have benefited consumers by making it faster and cheaper for manufacturers of generic drugs to enter the market. The savings are the direct result of lower costs of market entry and, by extension, the availability of generic drugs as low-cost alternatives to brand-name products. While costs typically exceed one billion dollars to bring a name-brand drug to market, the research and development costs for a generic drug under the ANDA process are only one-to-two million.[13] By

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[10] *See* Generic Drug Savings 2012; Use of Medicines 2011.

[11] CBO Report, "How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" at 5 (July 1998) ("Generics and Drugs 1998").

[12] Generic Drug Savings 2012.

[13] *See* U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Office of

streamlining market access, the Hatch-Waxman Amendments foster competition, thereby driving down prices, because generic counterparts to almost all branded drugs are now available. As noted by the CBO, "Before the [Hatch-Waxman Amendments], only 35 percent of the top-selling drugs no longer under patent had generic copies available. Today, nearly all do."[14]

In the specific case of sulindac, the regulatory scheme created by Hatch-Waxman has worked exactly as Congress intended: Eight generic preparations of sulindac are currently approved by the FDA.[15]

The First Circuit's decision in *Bartlett* threatens to roll back the achievements of the Hatch-Waxman Amendments by creating an unacceptable risk that manufacturers such as Petitioner will pull their products from the market rather than face state liability simply for selling an FDA-approved drug. Whereas "the purpose of . . . the [Hatch-Waxman Amendments] is to make available more low cost generic drugs," the First Circuit's ruling would drive

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Science and Data Policy, ASPE Issue Brief, Expanding Use of Generic Drugs at 4–5 (2010), *available at* http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.shtml.

[14] Generic and Pricing 1998, at 37.

[15] *See* U.S. Food and Drug Administration, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, *available at* www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm (accessed August 24, 2012).

generics from the market – essentially winding back the clocks to 1983, when skyrocketing healthcare costs prompted Congress to take action in the first place.

In sum, if this Court were to allow the First Circuit's decision to stand, the "special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public," *Mensing*, 131 S. Ct. at 2582, would be completely gutted. Congress' goal of "get[ing] generic drugs into the hands of patients at reasonable prices – fast" would be directly undermined. *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001).

But a when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), the state law is "without effect." *M'Culloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 427 (1819). A state-law duty is not cognizable if it frustrates the purpose of federal law, regardless of "whether that 'obstacle' goes by the name of 'conflicting; contrary to; . . . repugnance; difference; irreconcilability; inconsistency; violation; curtailment; . . . interference,' or the like." *Geier v. Am. Honda Co.*, 529 U.S. 861, 873 (2000) quoting *Hines*, 312 U.S. at 67 (alterations in original).

Significantly, "pre-emption cases ordinarily *assume* compliance with the state-law duty in question." *Id.* at 882 (emphasis in original). The question, therefore, is whether compliance with a

state law duty to remove generic drugs from the market would conflict with Hatch-Waxman's purpose "to make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 4.

The conflict between state law and federal objectives in *Bartlett* is even more pronounced than in *Geier*. Unlike *Geier*, which involved an agency *regulation*, Respondent's failure-to-withdraw claim strikes at the heart of a landmark federal *statute*. In passing the Hatch-Waxman Amendments, Congress' express purpose was to ensure that generic drugs are on the market to increase competition and decrease costs. Thus, a state tort duty to pull those drugs from the market – or face state tort liability if you don't – stands as an obstacle to the purposes and objective of the Hatch–Waxman Amendments.

The First Circuit's logic ignores this basic analysis. By sleight of hand it avoids "impossibility" preemption – but only by palming – and shredding – the card of Congressional intent. Accordingly, beyond the fact that *Bartlett* contravenes *Mensing*'s controlling holding, *see, generally* Cert. Pet. and *supra* Sections A–B, Respondent's failure-to-withdraw claim would frustrate the purposes and objectives of the Hatch-Waxman Amendments and, therefore, must fail.

D. THE DECISION TO PROVIDE A REMEDY TO THOSE WHO EXPERIENCE A KNOWN SIDE EFFECT OF A GENERIC DRUG MUST BE MADE BY CONGRESS, NOT THE COURTS, DUE TO THE DELICATE BALANCE OF PUBLIC AND PRIVATE INTERESTS INVOLVED

Bartlett simply cannot be reconciled with *Mensing*, and it clearly is inimical to the purposes of the Hatch-Waxman Amendments. Further, the First Circuit recognized that Respondent's injuries (SJS/TEN) were the product of a hypersensitivity reaction, a "miniscule" but "recognized" risk inherent with the drug. *Bartlett*, 678 F.3d at 44. It also acknowledged that the labeling for sulindac identified SJS/TEN as a potential adverse reaction.[16]

With full access to post-marketing surveillance data, scientific literature, and three decades of regulatory experience with sulindac, the FDA has approved, and continues to approve, the

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[16] Indeed, the risk of SJS from sulindac has been known for more than 30 years, long before Congress adopted the Hatch-Waxman Amendments. *See* Husain Z, Runge LA Jabbs JM, Hyla JA, *Sulindac-induced Stevens-Johnson syndrome: Report of 3 Cases*, J. Rheumatol (1981 Jan–Feb; 8(1):176–79); Glen D. Park et al., *Serious adverse reactions associated with sulindac,* 142 Arch. Internal Med. 1292–94 (1982). SJS and TEN are known risks other nonsteroidal anti-inflammatory drugs as well. Notwithstanding the known risks, these drugs are prescribed millions of times each year for their analgesic, fever-reducing, and anti-inflammatory properties.

manufacture and marketing of the drug. Thirty years of experience has not altered the FDA's view that sulindac is safe and effective when used in accordance with its FDA-approved labeling. *But see Bartlett*, 678 F.3d at 38 (allowing "second-guessing [of] the FDA" by lay juries).

Sulindac is one of many tools available for physicians, who evaluate the risks and benefits of a drug based on the unique circumstances of each patient. That sulindac, along with all prescription products, has inherent risks does not make its design defective: "Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." Restatement (Second) of Torts § 402A, cmt. k (1965).

However understandable, the First Circuit's desire to provide a remedy for Respondent's injury has no legal basis. In adopting such a construct, the First Circuit ignored Congress' clearly stated goals and abdicated its duty to follow controlling law.

In *Mensing*, this Court acknowledged the "unfortunate hand" dealt by federal drug regulations, *Mensing*, 131 S. Ct. 2581, but it also recognized that these same regulations were adopted to promote the expansion of the generic market and, by extension, lower the cost of prescription drugs. *Id.* at 2582. Because "different federal statutes and regulations may, as here, lead to different pre-emption results," this Court declined to second-guess Congress and "distort the

Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme." *Id.*

In passing the Hatch-Waxman Amendments, Congress struck a careful balance between public and private interests. As this litigation demonstrates, state tort law upsets this balance. A jury focuses on a particular plaintiff's injury, not on the overall benefits of a drug; "[t]he patients who reaped those benefits are not represented in court." *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008). For that reason (among others), it simply is not for the *Bartlett* Court, or any court for that matter, to second-guess Congress and recognize a state tort remedy that conflicts with federal law.

If and when Congress writes a different law, it will become subject to the Supremacy Clause, and must be followed by the courts. But in the current case, the *Bartlett* Court failed to follow controlling law, contravened Congressional purpose, and, therefore, must be reversed.

CONCLUSION

For the foregoing reasons, the petition should be granted and the decision of the First Circuit below should be reversed.

Respectfully submitted,

Of Counsel
Clem C. Trischler
Jason M. Reefer
Pietragallo Gordon Alfano
Bosick & Raspanti, LLP
38th Floor, One Oxford Ctr
Pittsburgh, PA 15219
(412) 263-2000
cct@pietragallo.com
jmr@pietragallo.com

Ray M. Aragon
Counsel of Record
McKenna Long &
Aldridge LLP
1900 K Street, NW
Washington, DC 20006
(202) 496-7500
raragon@mckennalong.com

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