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 FOR RANBAXY PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., IMPAX LABORATORIES, INC., AMNEAL PHARMACEUTICALS, LLC, AUROBINDO PHARMA USA, INC., ALKEM LABORATORIES, LTD., PERRIGO COMPANY AND MYLAN, INC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the First Circuit erred in holding that federal law does not preempt state law design-defect claims against generic pharmaceutical products because—despite the conceded conflict between such claims and the federal laws governing generic pharmaceutical design—the makers of generic pharmaceuticals can simply stop making their products.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

CONSTITUTIONAL PROVISIONS, STATUTES, AND REGULATIONS

OTHER AUTHORITIES

INTRODUCTION AND INTEREST OF *AMICI CURIAE*[*]

Recognizing that the Hatch-Waxman Act requires generic and brand-name drugs to carry the "same" labels—which generic manufacturers may not change —this Court recently held that federal law preempts state-law failure-to-warn claims against generics. *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2572 (2011). Despite *Mensing*'s sameness rationale, and its recognition that generics likewise must be "identical in active ingredients, safety, and efficacy" (*id.* at 2574 n.2), the court below held that state design-defect claims against generics are *not* preempted. The court offered no basis for distinguishing between failure-to-warn and design-defect claims. Yet it reasoned that the conceded conflict between design-defect claims and federal law can be avoided because generic drug makers "can choose not to make the drug at all." Pet. App. 10a.

This ruling ignores both the sameness rationale of *Mensing* and its result. After all, the conflict between the federal labeling requirements and state tort duties in *Mensing* likewise could have been avoided if the defendant generic drug makers had chosen "not to make the drug at all." And insofar as there is any basis for distinguishing between labeling-based and design-based claims for purposes of preemption, the case for preemption is even *stronger* when it comes to pharmaceutical product design.

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[*] The parties consented to the filing of this brief. The letters of consent are on file with the Clerk. In accordance with Rule 37.6, *amici* state that no counsel for any party authored this brief in whole or in part, and that no person or entity, other than the *amici*, has contributed monetarily to the preparation or submission of this brief.

Labels do not exist for their own sake. They are signposts concerning the *product* on the inside of the packaging. That is, generic labels must track their FDA-approved brand counterparts for a reason—namely, that the generic products represented by the labels likewise must be the same as their branded counterparts. A label no more controls the content of the packaged product than a tail wags a dog. And since labels are simply a proxy for their products, *Mensing* necessarily requires preemption. The First Circuit's contrary view not only runs afoul of the Hatch-Waxman Act, it is analytically incoherent.

Amici curiae are manufacturers and sellers of generic drugs. They or their affiliates are defendants in thousands of suits seeking to impose liability upon them under state-law standards with which they cannot comply without violating federal law. The concern of these *amici* is that the state-by-state approach to labeling rejected in *Mensing* not be revived under a new name. By disregarding the essential unity between labels and products, the decision below exposes generic drug makers to the same conflicting state law duties already rejected in *Mensing*. That is not what Congress intended when it commanded that a generic drug be a copy of the brand.

The decision below must be reversed.

STATEMENT

This case involves a collateral attack on the label of an FDA-approved prescription drug, after this Court in *Mensing* (in the words of the court below) "foreclosed a direct attack on the adequacy of the label." Pet. App. 4a. The drug at issue, sulindac, is a non-steroidal anti-inflammatory drug manufactured by petitioner. Pet. App. 1a-4a. Respondent suffered injuries and filed suit against petitioner after she was prescribed sulindac by her doctor, who "admitted that he had not read the box label or insert." Pet. App. 4a.

Respondent alleged that petitioner's product was defectively designed. When petitioner responded that federal law required its generic sulindac to be a *copy* of the branded drug, and that any design-defect claim was therefore preempted, the district court disagreed. According to that court, "one way to avoid violating state law * * * would be to refrain from distributing [the drug] at all." Pet. App. 165a. At trial, respondent's primary design-defect theory was that sulindac's risk exceeded its benefits, rendering it unreasonably dangerous and requiring its removal from the market. Pet. App. 4a-5a. The jury agreed.

While petitioner's appeal was pending, this Court held that, on account of the "ongoing federal duty of sameness" requiring that generic drugs copy their brand-name counterparts, federal law preempts state-law failure-to-warn claims against generic drug makers. *Mensing*, 131 S. Ct. at 2574-2575, 2577-2578. The upshot of the federal sameness requirements here, petitioner argued, was that petitioner could not comply with state law (as applied by the jury) by selling a version of sulindac materially different than the FDA-approved, branded version.

The First Circuit agreed that petitioner "cannot legally make sulindac in another composition," but, like the district court, reasoned that petitioner "can choose not to make the drug at all; and the FDCA might permit states to tell [petitioner] it ought not be doing so * * * despite what the Supreme Court made of similar arguments in the labeling context." Pet. App. 10a. The court acknowledged that "[t]his is second-guessing the FDA," but justified its decision on the basis of *Wyeth* v. *Levine*, 555 U.S. 555, 575 (2009), which stated in the context of brand-name drugs that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Pet. App. 9a.

The court below further recognized that *Mensing* post-dated *Wyeth* and, because of the generic sameness requirement, required preemption of failure-to-warn claims. Indeed, it recognized that *Mensing* distinguished *Wyeth* on the basis that, unlike generics, a brand-name drug maker could "unilaterally strengthen its warning without prior FDA approval." 131 S. Ct. at 2581; Pet. App. 9a-10a. Yet the court insisted that *Mensing* was a narrow, "carved out" exception to *Wyeth*'s "general no-preemption rule," and that it is up to this Court "to decide whether [*Mensing*'s] exception is to be enlarged to include design defect claims." Pet. App. 9a, 11a. This Court granted certiorari.

SUMMARY OF ARGUMENT

I. By exposing generic drug makers to the same failure-to-warn claims held preempted in *Mensing*—now dressed up as design-defect claims—the decision below puts generic manufacturers in an impossible situation. As the First Circuit itself recognized, if a drug is found to be defectively designed under state law, then generic manufacturers can either market a drug that complies with federal law (*i.e.*, one that has the same design as the brand-name equivalent) and incur substantial tort liability, or they can take the product off the market. Contrary to the First Circuit, however, this "choice" does not resolve the conflict; it confirms that state law is preempted.

After all, the reason generic labels must be the same as their brand-name equivalents is that the products themselves must be the same. And because design drives labeling, design-defect and failure-to-warn claims cannot be distinguished—one is preempted no less than the other.

II. Even if the First Circuit's stop-selling rule otherwise resolved the conflict between a state law purporting to forbid what federal law authorizes (and it does not), preemption is required here for another reason. State regulation of generic drug design would impose burdens that are directly at odds with the purposes and objectives of the Hatch-Waxman Act. The lower cost of generic drug development is precisely what enables generic drug makers to produce safe, affordable products in an efficient manner. But if generics are subject to claims such as the one sanctioned below, then they must either pay large jury verdicts and pull their products from the market or begin conducting comprehensive NDA-style clinical studies for themselves—which is to say, they must

become brands. But that is the very reinvention of the wheel that Congress sought to avoid in creating an abbreviated approval process for generic drugs. Either way, these tort claims threaten to undo Congress's work by raising the prices and decreasing the availability of generic drugs—to the ultimate detriment of consumers.

It is no answer to say that paying damage awards is merely a cost of doing business. If a conflict could be so easily dissipated, the Court could not have ruled as it did in *Mensing* and other prior decisions. Instead, as this Court has repeatedly held, "common law liability is premised on * * * [the defendant's] violat[ion] [of] a state-law obligation. And while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 324 (2008) (internal citation and quotation marks omitted).

Manufacturers and the economy suffer when complex products sold nationally and extensively regulated by the federal government must submit to yet another layer of "diverse, non-uniform, and confusing * * * regulations"—including state tort judgments. See *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 514, 521 (1992) (plurality). Indeed, where product design is not regulated uniformly, one State—even one *jury*—can effectively impose a controversial design upon, or withhold a beneficial product from, the entire nation. And as this Court has consistently observed, "one State's power to impose burdens on the interstate market" is "constrained by the need to respect the interests of other States." *BMW, Inc.* v. *Gore*, 517 U.S. 559, 571 (1996).

Far from imposing such burdens, the Hatch-Waxman process "is designed to speed the introduc-

tion of generic drugs to market." *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). That being so, federal law will not allow juries to decide that a generic drug ruled safe and effective by the FDA must be banned outright, thus multiplying costs and impeding the drug's availability to consumers in other States. Juries generally lack the institutional expertise needed to make judgments about the design of complex pharmaceutical products. As a practical matter, moreover, for generic drug makers seeking to distribute their products nationwide, a "stop selling" rule in just one State is likely to end the drug's sales in every State, as the cost-structures and logistical realities of the industry do not support a checkerboard approach to distribution.

III. Finally, if the fact that a manufacturer can "choose not to make [its product] at all" (Pet. App. 10a) allowed plaintiffs to skirt preemption, then conflict preemption could never be established for federally regulated manufacturers. *Any* conflict between state tort law and federal requirements—whether related to labeling, packaging, design, or something else—could be avoided by abandoning the product. Not surprisingly, this Court has repeatedly found conflict preemption despite the availability of a "choice" to cease marketing the allegedly defective product. *E.g., Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861 (2000); *Cipollone*, 505 U.S. at 521.

For all these reasons, this Court should reject the stop-selling rule adopted by the court below, and confirm that state-law design claims against generic drugs are categorically preempted.

ARGUMENT

I. For purposes of preemption under the Hatch-Waxman Act and *Mensing*, design-defect and failure-to-warn claims are inextricably intertwined.

According to the First Circuit, "it is up to the Supreme Court to decide" whether the rule of *Mensing* should be "enlarged" to cover design-defect claims. Pet. App. 11a. But no "enlarging" is needed. The reasoning of *Mensing* not only directly applies here, it applies *a fortiori*.

A. Hatch-Waxman requires a generic drug to be a copy of a brand-name drug, and thus identical in active ingredients.

As the First Circuit itself observed, under Hatch-Waxman, "[petitioner] cannot legally make sulindac in another composition" from that of the brand. Pet. App. 10a. Yet the court failed to draw the conclusion that necessarily follows from this premise: Because federal law dictates the design of a generic drug, state law may not hold that design "defective."

For new drugs (*i.e.*, brand-name products), a manufacturer must submit a new drug application ("NDA") establishing that the drug is safe and effective when used as labeled. 21 U.S.C. § 355(b); 21 C.F.R. § 314.50. To that end, an NDA must include the following: (1) data demonstrating that the drug is safe and effective; (2) analysis of the drug's composition; (3) an explanation of the methods and controls used for manufacturing, processing, and packing the drug; and (4) proposed labels. 21 U.S.C. § 355(b)(1)(A)-(F); 21 C.F.R. § 314.50(d)-(f). Further, before filing an NDA, the brand-name manufacturer must be authorized to conduct clinical trials to estab-

lish the drug's safety and efficacy. 21 U.S.C. § 355(i); 21 C.F.R. §§ 312.2, 312.20.

The NDA process is exhaustive. A typical NDA spans thousands of pages and is grounded in clinical trials conducted over several years. GAO, *New Drug Development, Report to Congressional Committees*, 26 Biotech. L. Rep. 82, 94 (2007). On average, evaluating an NDA takes the FDA some 442 days. *Id*. at 86.

The abbreviated ("ANDA") process for generic drugs is altogether different. "Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Caraco*, 132 S. Ct. at 1676 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)). That is, a generic is "designed to be a copy" of the brand-name drug. *Mensing*, 131 S. Ct. at 2574 n.2.

To ensure its safety, the generic copy must be "identical" to an approved NDA drug with respect to active ingredient, route of administration, dosage form, strength, and conditions of use. 21 U.S.C. § 355(j)(2)(A)(i); 21 C.F.R. § 314.92(a)(1).[1] Moreover,

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[1] In limited circumstances and subject to the FDA's discretion, the ANDA process may also be used for a drug with one different active ingredient, or whose route of administration, dosage form, or strength differs from the NDA product. 21 U.S.C. § 355(j)(2)(C); 21 C.F.R. § 314.93; see generally 57 Fed. Reg. 17950, 17951-17952 (Apr. 28, 1992). But no such difference is involved in this case, and no such difference factored into the decision below. In addition, as discussed below (at 31-33), the Court in *Mensing* considered and unequivocally rejected the argument that conflict preemption can be defeated based on what a generic manufacturer *could have* asked FDA to do, and how FDA *could have* responded. 131 S. Ct. at 2578-2579.

an ANDA must establish that the generic drug is therapeutically equivalent or "bioequivalent" to, and will be given the same labeling as, the brand-name drug. 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94(a). Use of the same label is critical because "[d]rug labeling serves as the standard under which FDA determines whether a product is safe and effective." 50 Fed. Reg. 7452, 7470 (Feb. 22, 1985).

Generic manufacturers need not (and do not) produce evidence of safety or efficacy by conducting clinical trials. That has already been done by the brand; no trials are needed to ensure the safety and efficacy of the copy. Rather, the point of Hatch-Waxman was "to speed the introduction of low-cost generic drugs to market." *Caraco*, 132 S. Ct. at 1676 (citing *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990)).[2] To that end, Congress directed the FDA to approve any product that is a true generic—*i.e.*, bioequivalent to the branded drug and sold with identical labeling. The FDA will reject an ANDA drug that flunks these criteria. 21 C.F.R. § 314.127.

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[2] See also, *e.g.*, "P.L. 98-417, Drug Price Competition and Patent Term Restoration Act," H.R. Rep. No. 857(I), 98th Cong., 2d Sess. (1984), reprinted in 1984 U.S.C.C.A.N. 2647, Pet. App. 122a; New Drug Application: Hearings on H.R. 3605 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong., 1st Sess. (1983), Pet. App. 114a; Drug Price Competition and Patent Term Restoration Act of 1984, Committee Notes, 130 Cong. Rec. 24416, H.R. 3605 (Sept. 6, 1984), Pet. App. 136a; Drug Price Competition and Patent Term Restoration Act, Committee Notes, 130 Cong. Rec. 24970, S. 1538 (Sept. 12, 1984).

In short, to the extent that state tort law may impose a different standard for the design of an FDA-approved drug, it is impossible for a generic manufacturer to comply. Whatever choices a brand-name manufacturer may have, the generic manufacturer has none. That is why generic manufacturers are required to submit the proposed product and the proposed label to the FDA at the same time. 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8). The ANDA product must be same as the NDA product; the generic drug maker's federal obligations are as simple as that.

The court below did not adopt a different reading of these straightforward federal requirements. Instead, it declared that generic manufacturers have a "choice": Although federal law imposes a duty of "sameness" on generic products, in any State where a jury concludes that the law requires a different design than that adopted by the brand-name manufacturer and approved by the FDA, the generic manufacturer can simply cease doing business. Pet. App. 10a.

This analysis is flatly inconsistent with settled principles of conflict preemption, as well as the rationale and result of *Mensing* (where the very same arguments were made and rejected). Further, as discussed below (at 15-19), if allowed to stand, the decision below will make needed generic drugs both more expensive and more scarce—directly harming consumers and undermining Congress's intention in passing the Hatch-Waxman Act.

B. The notion that failure-to-warn claims are preempted but design-defect claims are not is analytically incoherent.

The decision below is also analytically incoherent. Drug product design drives labeling, not the other way around. As the FDA has instructed, "the ANDA product's labeling must be the same as the listed drug product's labeling *because the listed drug product is the basis for ANDA approval*." 57 Fed. Reg. at 17961 (emphasis added); see also *Mensing*, 131 S. Ct. at 2574 (describing parallel sameness requirements for generic products and labels).

A label no more controls product design than a tail wags a dog. To say, as did the court below, that a state law claim against a *label* is preempted, but a claim against the *product design* is not, is thus fundamentally to misunderstand the nature of the label-product relationship. Indeed, it is to get that relationship exactly backwards. If the labeling claim is preempted, the design-defect claim must be preempted, because the label is merely a proxy for the product. The reason a generic's label must track the brand's label verbatim is that the product itself must likewise be "the same as" the branded product.

Just last Term, in finding preemption under another federal statute, this Court recognized the close relationship between failure-to-warn and design-defect claims. See *Kurns* v. *Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1268 (2012) (noting that "[a] failure-to-warn claim alleges that the product itself is unlawfully dangerous unless accompanied by sufficient warnings or instructions" and explaining that, where "failure-to-warn claims are * * * directed at the equipment [at issue]," the "'gravamen' of

[those] failure to warn claims" is sufficiently similar to warrant preemption under the same rationale). Indeed, many jurisdictions (including New Hampshire, where this case originated) recognize that an adequate warning is sufficient to defeat design-defect claims. Pet. App. 7a; *Fellows* v. *USV Pharm. Corp.*, 502 F. Supp. 297, 300 (D. Md. 1980) (collecting cases establishing that "prescription drugs are not considered unusually dangerous under section 402A, and the manufacturer will not incur liability under that section, unless the manufacturer has failed to provide adequate warnings of the drug's possible dangers"). That is all the more true in cases involving pharmaceuticals.

As the Restatement (Second) of Torts explains, a product may be "unavoidably unsafe," a classification "common in the field of drugs," which often have undesirable side-effects and carry serious risks. "Such a product, properly prepared and accompanied by proper directions and warning, is not defective." Restatement (Second) of Torts, § 402A cmt. k (1965); see also *Bruesewitz* v. *Wyeth LLC*, 131 S. Ct. 1068, 1077 (2011) ("Comment k exempts from * * * strict-liability rule 'unavoidably unsafe' products."). The reason is that the potential side-effects of such drugs are not a product of bad design; they are simply an unavoidable risk. In fact, the First Circuit itself acknowledged that, under New Hampshire law, claims of design-defects can collapse into claims of failure-to-warn. Pet. App. 7a.

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In summary, in the context of prescription drugs, "design-defect" claims are a red herring. There is no meaningful distinction between such claims and

claims for failure-to-warn: The law requires generic labels *and* products to match their branded counterparts; labels are derived from the products, not vice versa; and the adequacy of generic product warnings (which *Mensing* immunizes from challenge) is a complete defense to design-defect liability.

It is telling that the court below did not propose any rationale whatsoever for distinguishing these two types of claims in substance. But given that any attack on the drug labels here is preempted under *Mensing*, preemption of any attack on the design of the labeled products should be a foregone conclusion—as every other court had recognized before the ruling below. Design-defect claims against generic drugs, no less than failure-to-warn, are preempted.

II. State regulation is an added burden on generic manufacturers and consumers and, as such, conflicts with the federal regime.

The decision below is not only unlawful and analytically unsound, it is also destabilizing to the generic drug industry and threatens significant costs to consumers and the nation's health care system—all in direct conflict with the Hatch-Waxman Act's objectives. State law juries cannot be permitted to "second guess[] the FDA." Pet. App. 10a. Nor can this conflict be resolved on the theory that paying tort judgments is merely a cost of doing business. As a long line of this Court's precedents confirms, common law obligations, enforced by jury verdicts, must be obeyed no less than positive enactments of state law.

Further, of all types of tort claims, design-defect claims—particularly those involving complex pharmaceutical products—are among those least suitable for resolution by juries and most suitable for preemp-

tion. Yet instead of *federal preemption*, the First Circuit authorized *state prohibition*. This turns the Supremacy Clause on its head. After all, where the FDA, acting in response to Congress's instructions, has declared a product "safe and effective," it is plainly "to the Contrary" to ban the product. U.S. Const., Art. VI, cl. 2. Indeed, it is both unlawful and unwise to deprive citizens in "prohibition States" of low-cost, federally approved medicines, while adding to the burdens on drug makers attempting to serve a national market.

A. State regulation of product design would raise prices and decrease the availability of generic drugs—in square conflict with the central purposes and objectives of the Hatch-Waxman Act.

1. As discussed above, under *Mensing*'s impossibility-preemption analysis, conflicting federal and state obligations cannot be reconciled by the First Circuit's stop-selling rule. But even if they could, requiring a generic manufacturer to "comply" with federal law by withholding its product from the market would defeat Congress's carefully calibrated approach to introducing generic drugs, which gave birth to the modern generic drug industry that ultimately benefits consumers. See *Arizona* v. *United States*, 132 S. Ct. 2492, 2501 (2012) (conflict preemption includes not only cases where "compliance with both federal and state regulations is a physical impossibility," but also "those instances where the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress") (citations omitted). "[I]t is 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.

This was not happenstance. The animating purpose of the Hatch-Waxman Act was to *increase* the availability, and *lower* the cost, of generic drugs. See *Caraco*, 132 S. Ct. at 1676; *supra* n.2 (collecting authorities). But allowing state tort claims here would thwart this federal policy by forcing generic manufacturers to undertake comprehensive, NDA-style clinical trials—on pain of substantial liability—effectively turning generics into brands. That is not what Congress intended. Cf. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (explaining that, "[a]s a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants" and may "discourage[] [them] from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer * * * to unpredictable civil liability").

On the contrary, as this Court recognized in *Mensing*, the central and immutable federal obligation imposed on generic manufacturers is to produce a drug "the same as" a branded equivalent. 131 S. Ct. at 2574-2575 & n.2. To be sure, federal law does not forbid generic manufacturers from assessing drug safety and efficacy by conducting independent clinical trials. But it puts the *obligation* to do so on the brands, through the NDA process. If state law can oblige generics to perform the same analysis, the ANDA process is overthrown: Under the old regime, generics had to be priced to reflect the fact that each would-be generic manufacturer independently had to establish safety and efficacy. Congress passed the

Hatch-Waxman Act and created the ANDA process—an *abbreviated* NDA process—precisely to spare generic manufacturers from undertaking unnecessary and duplicative studies, which drive up the cost of needed generic medicines.

To this day, generic companies such as the undersigned *amici* are able to provide generic medicines in an efficient manner—and thus to compete—because of the streamlined Hatch-Waxman process. "While estimates of the cost to bring a new branded drug to market are in excess of a billion dollars, the research and development costs for a new generic drug are only 1 to 2 million dollars." ASPE Issue Brief: Office of the Assistant Secretary for Planning & Evaluation, Office of Science and Data Policy–U.S. Department of Health and Human Services, *Expanding the Use of Generic Drugs* 4-5 (Dec. 2010).[3]

Moreover, "growth in the use of generic drugs has generated substantial savings for American consumers" (*id.* at 2): "In 2010 alone, the use of FDA-approved generics saved $158 billion, an average of $3 billion every week,"[4] and such use has saved "*$1.07 trillion* over the past decade."[5] Not only does

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[3] Available at: http://aspe.hhs.gov/sp/reports/2010/ GenericDrugs/ib.shtml.

[4] FDA, *Facts about Generic Drugs* (Sept. 19, 2012) (citation omitted), available at: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm.

[5] Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.* 1 (4th ed. 2012), available at: http://www.gphaonline.org/sites/default/files/IMS%20Study%20Aug%202012%20WEB.pdf (emphasis added).

increased generic substitution drive down the price of the *brand*, but "[t]he relatively low costs to entry for generic drugs lead to increased competition, which drives prices for generic drugs down dramatically" too. ASPE Issue Brief, *supra*, at 4, 5. As the FDA has found, "the first [generic] entrant has a relatively small effect on price, but subsequent entrants dramatically reduce the average relative price." *Id*. at 5. More precisely, "the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price. * * * For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower."[6]

If generics are shut out from marketing in certain States—the lower court's "solution" to the federal-state conflict at issue here—these savings will dwindle, threatening generic drug makers' livelihoods and harming the consumers they serve. Fewer competitors in the market means higher prices. At a minimum, the ruling below threatens to work fundamental changes in the way generics do business—including by multiplying their costs—to the ultimate detriment of consumers and the nation's health care system. These results would be squarely at odds with the purpose of the Hatch-Waxman Act.

That Act is "the supreme Law of the Land," "any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. But where federal law is designed to foster inexpensive, widely available generic drugs, state regula-

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[6] FDA, *Generic Competition and Drug Prices*, available at: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

tion —in the form of prohibition or otherwise—would result in increased prices, decreased availability of generics as manufacturers exit the market, or both.

Even indulging the assumption that allowing juries to impose state tort liability might make drugs safer (which is doubtful), Congress has already struck a balance between safety and cost. And where federal law reconciles competing objectives, "that is not a judgment the States may second-guess." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989). Rather, state regulation "must yield to the extent that it clashes with the balance struck by Congress." *Ibid.*; accord *Geier*, 529 U.S. at 874-881 (state tort law is preempted insofar as it balances competing policy objectives—including issues of cost and safety—differently from federal law).

2. Nor can a role for state regulation be preserved on the theory that state tort law is merely providing "parallel" enforcement of federal drug safety requirements. In *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005), this Court held that state courts may enforce federal requirements for pesticide labels. 544 U.S. at 451-452. Although the express preemption provision at issue there barred States from imposing "any requirements for labeling or packaging in addition to or different from those required" by the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") (*id.* at 443 (citation omitted)), the Court determined that this did not preempt state law *remedies* for violations of federal standards. Under the statutory framework here, however, there is no place for "parallel requirements." *Id.* at 447.

First, in cases such as this, state and federal law impose different standards. Unlike the state law ap-

plied below, federal law does not require that generic drugs satisfy a "risk-benefit analysis" (Pet. App. 10a); it requires that generics be "the same as" their brand-name counterparts. Thus, state law is not enforcing applicable federal law at all; it is at best *extending* federal law such that generic drug makers are subject to a pair of mutually exclusive drug-design standards: As the First Circuit acknowledged, generics "cannot legally" differ from their brand counterparts. *Ibid.* Yet the court affirmed a jury verdict imposing liability based on petitioner's failure to do precisely that—depart from the brand-name design.

Second, and in any event, the authority and discretion to take action against a manufacturer for noncompliance with the FDCA rests "exclusively [with] the Federal Government." *Buckman*, 531 U.S. at 352. As this Court explained in *Buckman*, the FDA may well prefer a more "measured response" than that of a lay jury hearing one case in isolation. *Id.* at 349. Further, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" *Id.* at 349 n.4 (quoting 21 U.S.C. § 337(a)). The same is equally true of any federal requirement that state law might purport to enforce via drug design-defect liability—including prohibitions on "misbranding" (*e.g.*, 21 U.S.C. § 352(j)), the safety and efficacy requirements that must be met for *NDA* approval (*id.* § 355(d)(1)), and post-approval reporting requirements (21 C.F.R. § 314.98)—all of which are part of the FDCA and subject to § 337(a).

Notably, § 337(b)(1) provides a limited exception to § 337(a)'s rule that only the Federal Government may enforce the FDCA: A State may bring suit to enforce or restrain violations of certain federal rules with respect to "food" within its borders. 21 U.S.C. § 337(b)(1). This exception does not apply to drugs. And even with respect to food, a State may proceed *only* after giving notice to the Secretary of Health and Human Services, and *only* if the Secretary has not herself taken action. See *id.* § 337(b)(2).

It is thus by design that consumers claiming harm from FDA-approved drugs have no federal cause of action. Cf. *Shady Grove Orthopedic Assocs., P.A.* v. *Allstate Ins. Co.*, 130 S. Ct. 1431, 1438 (2010) ("The fact that Congress has created specific exceptions to [a rule] hardly proves that the [r]ule does not apply generally. In fact, it proves the opposite"; if the rule did not apply generally, "the statutory exceptions would be unnecessary"); *Block* v. *Community Nutrition Inst.*, 467 U.S. 340, 349 (1984) ("when a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded").[7] Instead, the FDA has several means of re-

[7] This Court recently rejected a similar argument in *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians* v. *Patchak*, 132 S. Ct. 2199 (2012), because the plaintiff there (in suing under the Administrative Procedure Act) was "bringing a different claim, seeking different relief, from the kind" that was "barred" (under the Quiet Title Act). See *id.* at 2208-2209. The premise of any "parallel requirements" defense of the design-defect claim here, however, has to be that it is the same claim (for violation

gulating the conduct of generic manufacturers and their products, including withdrawal of approval;[8] suspension of approval;[9] injunctions;[10] criminal penalties;[11] seizure;[12] and enforcement proceedings.[13] The FDCA also preserves the FDA's discretion to take less stringent action where appropriate.[14]

The availability of this range of regulatory options "is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349. And when it determines that the FDCA has been violated, the FDA has "complete discretion" to pursue the remedy that, in its judgment, best fits the violation. *Heckler* v. *Chaney*, 470 U.S. 821, 835 (1985).

State tort law, by contrast, operates in a vacuum, divorced from any obligation or incentive to balance the goal of product safety against other worthy (and sometimes competing) policy objectives—such as patients' interest in access to life-saving medicines with potentially significant side effects, and the financial interest of consumers or our health care system as a

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of federal safety standards), seeking the same relief (a safer drug design).

[8] 21 U.S.C. § 355(e); 21 C.F.R. §§ 314.150, 314.151.

[9] 21 C.F.R. § 314.153.

[10] 21 U.S.C. § 332(a).

[11] *Id*. § 333(a).

[12] *Id*. § 334(a).

[13] *Id*. § 337(a).

[14] *Id*. §§ 336, 375(b).

whole in the billions of dollars of savings provided by widely available, low-cost generic drugs. Even if state and federal law share the same ultimate goal, "[t]he fact of a common end hardly neutralizes conflicting means." *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363, 379 (2000). Accordingly, state law is still preempted if it "interferes with the methods by which the federal statute was designed to reach this goal." *Int'l Paper Co.* v. *Ouellette*, 479 U.S. 481, 494 (1987); see also *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959) ("[S]ince remedies form an ingredient of any integrated scheme of regulation, to allow the State to grant a remedy here which has been withheld from the [federal agency] only accentuates the danger of conflict.").

Here, state common law regulation would impose substantial costs on generic manufacturers. These costs cannot be brushed aside as extra incentive to comply with federal law; instead, they "would exert an extraneous pull on the scheme established by Congress," and "[are] therefore pre-empted." *Buckman*, 531 U.S. at 353.

B. This Court's precedents foreclose any argument that jury verdicts are just a cost of doing business.

It is no answer to say that any conflict here can be avoided by the generic continuing to sell its product while paying state-court judgments. Such an argument is inconsistent not only with *Mensing*, but also with a long line of this Court's precedent, and with the Supremacy Clause—neither of which draws any distinction between state positive or regulatory law and state common law.

Mensing easily could have avoided any finding of a conflict between state and federal law by holding that state-law failure-to-warn judgments were simply a cost of doing business. Not surprisingly, however, the parties there did not even "dispute that * * * state law required the Manufacturers to use a different, safer label." 131 S. Ct. at 2574. As this Court held in *Riegel*, "common law liability is premised on the existence of a legal duty, and a tort judgment therefore establishes that the defendant has violated a state-law obligation. And while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy." 552 U.S. at 324 (internal citation and quotation marks omitted).

Riegel is but one decision in a long line of precedents to the same effect. The leading case is *Garmon*, which over 50 years ago recognized that "regulation can be as effectively exerted through an award of damages as through some form of preventive relief." 359 U.S. at 247. And just last Term, this Court reiterated that "[t]he obligation to pay compensation" is "a potent method of governing conduct and controlling policy." *Kurns*, 132 S. Ct. at 1269 (quoting *Garmon*).

In keeping with these authorities, federal preemption of "state tort suit[s]" is a settled component of "ordinary conflict preemption principles." *Williamson* v. *Mazda Motor of Am., Inc.*, 131 S. Ct. 1131, 1136 (2011) (citing *Cipollone* and *Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141 (1982)); see also *Erie R.R. Co.* v. *Tompkins*, 304 U.S. 64, 78 (1938) ("whether the law of the State shall be declared by its Legislature in a statute or by its highest court in a decision is not a matter of federal concern"); *Shelley* v. *Kraemer*, 334 U.S. 1, 17 n.19 (1948) ("common-law rules enunciated by state courts in judicial opinions

are to be regarded as a part of the law of the State"). And, of course, the Supremacy Clause itself draws no distinction between state positive and common law: It preempts "any Thing in the Constitution or Laws of any State" that is "Contrary" to federal law. U.S. Const., Art. VI, cl. 2.

The only case in which this Court has even arguably wavered from this rule is *Bates*, where Justice Stevens' opinion for the Court observed that "[a] requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action." 554 U.S. at 445 (internal citation omitted). But the Court there was interpreting FIFRA's express preemption provision—which preempted "any requirements for labeling or packaging in addition to or different from those required" by FIFRA itself—and its distinction between "jury verdicts" and "common-law duties" rested on the "best reading" of "requirement" in that provision. *Id*. at 443. As *Riegel* later reiterated: "Absent other indication, reference to a State's 'requirements' includes its common law duties." 552 U.S. at 324; cf. *Cipollone*, 505 U.S. at 521 (plurality per Stevens, J.).

Indeed, if *Bates* were read to suggest that complying with a state "common-law duty" is obligatory, but complying with a jury verdict that implements that duty is "optional," it would run headlong into the precedents discussed above, which both pre- and postdate *Bates*. It would also violate a basic premise of the jury system—that juries follow the law. If a jury's tort verdict did not implement an applicable

common-law duty, any resulting award of damages would be lawless. *Riegel*, 552 U.S. at 324 ("common law liability is 'premised on the existence of a legal duty,' and a tort judgment therefore establishes that the defendant has violated a state-law obligation").

Presumably that is why *Geier* v. *American Honda Motor Corp.*, 529 U.S. 861 (2000), emphasized that "[t]his Court's pre-emption cases do not ordinarily turn on such compliance-related considerations as whether a private party in practice would ignore state legal obligations—paying, say, a fine instead—or how likely it is that state law actually would be enforced. Rather, this Court's pre-emption cases ordinarily *assume* compliance with the state-law duty in question." *Id.* at 882. Likewise, *Riegel* did not even *question* whether a jury verdict must be obeyed, but instead held that it was "implausible" that the statute there "was meant to 'grant greater power * * * to a single state jury than to state officials acting through state administrative or legislative lawmaking processes.'" 552 U.S. at 325 (quoting *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 504 (1996)). So too here.

C. State tort claims challenging the design of complex products that are heavily regulated by the federal government are especially unsuitable for juries and especially suitable for preemption.

In addition, for complex pharmaceutical products that are sold nationwide and heavily regulated by the FDA, it is especially appropriate for Congress to bar state law—and certainly juries—from regulating product design.

1. For complex products that are mass-produced, easily transported, and heavily regulated at the federal level, a patchwork quilt of additional state regu-

lation is quite problematic. It raises the costs of compliance and makes it difficult for consumers to discern what is safe and what is not.[15] Likewise, the national economy is weighed down if manufacturers of national products that are already closely controlled by federal rules must submit to "diverse, nonuniform, and confusing * * * regulations." *Cipollone*, 505 U.S. at 514.

This is particularly true where the product is as sophisticated as the chemical drug compounds at issue here. If there is a problem with the design of a pharmaceutical, it cannot be fixed by adding, say, a simple safety guard or turn-off switch. The costs of re-engineering drugs is astronomical—which is one reason why Hatch-Waxman prescribes that generic drugs simply be "the same as" the brand. But while the First Circuit seemed to grasp the impossibility of changing a drug's design (Pet. App. 10a), the court's cure—taking the product off the market entirely—was worse than the alleged disease. Rather than allowing juries to create a patchwork quilt of standards (which would have been forbidden as well), the deci-

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[15] See, *e.g.*, James A. Henderson, Jr., *Judicial Review of Manufacturer's Conscious Design Choices: The Limits of Adjudication*, 73 Colum. L. Rev. 1531, 1576 (1973) ("the legislative and administrative processes are institutionally suited" to "establishment of specific design standards."); Michael W. McConnell, *A Choice-of-Law Approach to Products-Liability Reform*, in New Directions in Liability Law, 37 Proceedings of the Acad. of Political Science 90, 91 (1988) ("[s]ince most products are made in one state and used in another, at least two states are usually involved," and "they will not all be able to get their way when their laws differ").

sion below would allow juries to create a patchwork quilt of *prohibitions*.

Again, if "[t]he obligation to pay compensation" is "a potent method of governing conduct" (*Kurns*, 132 S. Ct. at 1269 (citation omitted)), it is likewise potent to drive a product out of a state market altogether. Unlike brand-name drugs, generics typically have a thin profit margin—which means that a single jury verdict on the order of the one here ($21 million, for a single plaintiff) may demand abandoning a given market. Further, being shut out of entire markets can be a company killer, particularly for small companies. In *Buckman,* the Court recognized that the "fear" of "expos[ing] the manufacturer * * * to unpredictable civil liability" might "discourage [applicants] from seeking § 510(k) approval of devices." 531 U.S. at 350. So too may the prospect of being forced to drop products entirely in various States deter the development of needed low-cost generic medicines.

Allowing design-defect claims would also permit juries in 50 different States to reach judgments that differ from the FDA's—and from each other's. As the Court recognized in *Garner* v. *Teamsters*, 346 U.S. 485, 490-491 (1953), "[a] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law." Citing this danger, *Buckman* explained that allowing liability under "50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress." 531 U.S. at 350. The same is true of the design-defect claims here.

Indeed, because drugs cross state lines, the ruling below effectively allows the most pro-ban State to set

policy for the whole nation, undermining the Act's goal of quickly getting generic drugs to the national market. But "one State's power to impose burdens on the interstate market" is "constrained by the need to respect the interests of other States." *BMW*, 517 U.S. at 571. And where, as here, "[t]he subject-matter * * * peculiarly * * * calls for uniform law," States should not be permitted to "supplement" federal mandates, much less overrule them outright. *Penn. R.R.* v. *Public Serv. Comm'n*, 250 U.S. 566, 569 (1919). Yet that is exactly what the decision below accomplishes in allowing States to blacklist products that the FDA, after extensive study, has deemed safe and effective.

In fact, a generic company whose drug product is banned by a given State may well lose its ability to sell that product in any State. In the experience of these *amici*, national retailers facing a patchwork of state rules concerning a given drug—some permitting the drug to be sold, others prohibiting it—may simply refuse to sell a drug at all, rather than keep track of States and stores where the drug may be shipped and those where it may not. And for smaller generic manufacturers, the loss of an entire product can put the company under.

2. As this Court has recently emphasized in the context of medical device liability, these problems are further exacerbated where, as here, a ruling authorizes a ban to be imposed "by juries." *Riegel*, 552 U.S. at 325. "A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm?" *Ibid.* Juries, howev-

er, simply are not constituted or equipped to regulate products such as those at issue here. "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." *Ibid.* Similarly, "[i]t would be difficult for a jury focused on a single case to take into account 'the cumulative, systemic effects' of a series of verdicts. In contrast, the FDA possesses a broader perspective." *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 797 (8th Cir. 2001) (internal citation omitted) (quoting Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 Geo. L.J. 2167, 2175 (2000)).

In enacting Hatch-Waxman, Congress acted to replace a patchwork of state tort standards with a uniform, feasible, safe, and economically sound set of rules established by an expert agency and imposed on a prospective basis. It is the FDA (not juries) that is charged with determining whether a product's benefits outweigh its risks—and hence whether it is safe and effective. Again, the involvement of juries is "not required or even suggested" by the Act, and the courts should not "turn somersaults" to create it. *Riegel*, 552 U.S. at 325. Particularly in light of *Mensing*, however, turning somersaults is an apt description of the approach taken below.

States generally may not provide causes of action that fail to give effect to federal administrative decisions that have neither been rescinded by the agency nor set aside by the federal courts. *Arkansas La. Gas Co.* v. *Hall*, 453 U.S. 571 (1981); *Chicago & North Western Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981). And yet the claim here proceeded on the theory that respondent should receive damages as

if marketing a drug approved by the FDA as "safe and effective" were unlawful. See Pet. App. 10a. Reversal is warranted to prevent this type of admitted second-guessing of the expert agency, contrary to the statutory scheme, as to a species of tort claim especially well-suited for uniform federal regulation.

III. Taken to its logical conclusion, the First Circuit's rationale would eliminate all application of the doctrine of conflict preemption to claims against manufacturers in federally regulated industries.

Finally, beyond being untenable in the particular context of Hatch-Waxman and generic drugs, the First Circuit's decision would effectively destroy the doctrine of conflict preemption as applied to federally regulated industries.

According to the First Circuit, a generic "certainly can choose not to make the drug at all; and the FDCA might permit states to tell [petitioner] it ought not be doing so if risk-benefit analysis weighs against the drug." Pet. App. 10a. But just this kind of counterfactual argument was rejected in *Mensing*. And if it were the law, a host of this Court's preemption decisions would have come out the other way.

The plaintiff in *Mensing* contended that, "if the Manufacturers had asked the FDA for help in changing the corresponding brand-name label, they might eventually have been able to accomplish under federal law what state law requires." 131 S. Ct. at 2578. That is, if the Manufacturers had asked, "and if the FDA decided" to help, "and if the FDA undertook negotiations," "and if adequate label changes were decided on and implemented, then the Manufacturers

would have started a Mouse Trap game that eventually led to a better label." *Ibid.*

This Court refused to accept that "conflict preemption should take into account these possible actions." *Ibid.* Instead, it held that "[t]he question for 'impossibility' is *whether the party could independently do under federal law what state law requires of it.*" *Id.* at 2579 (emphasis added). In other words, the law of preemption assumes stasis: The regulated party keeps producing the same product; and the federal government keeps enforcing the same law.

To assume away one of these fixed assumptions is to render any resulting harmony in the law illusory. As the Court put it in *Mensing*: "If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. We do not read the Supremacy Clause to permit an approach to preemption that renders conflict preemption all but meaningless." 131 S. Ct. at 2579. Similarly, the Court in *Geier* rejected an attempt to show the lack of a conflict based on the notion that the manufacturer could have complied with state law by selling "a *different* kind of" product. 529 U.S. at 882 (emphasis in original).

Such conjectures contain no limiting principle. No matter how clear an agency tries to be—even forbidding requests for rule changes themselves—the plaintiff could always say, "But 'they did not even try to start the process'" that might have alleviated the conflict. 131 S. Ct. at 2579. There would be no rational basis for preventing this infinite regression of one-upsmanship. See *Mensing* Oral Arg. Tr. 38:8-15

(Alito, J.) ("[S]uppose that the FDA issued a rule that says a generic drug manufacturer has no obligation to request a change in labeling. Could a generic drug manufacturer be held liable on a failure to warn claim on the theory that it could have lobbied the FDA to change the rule that says that the generic drug manufacturer has no obligation to ask for a change in labeling?").

The First Circuit took exactly the path forbidden in *Mensing*. To prevent federal and state law from conflicting, it relied on conjectures of the worst kind: assuming the generic abandoned its product. Pet. App. 10a. Insofar as abandoning the product is *always* an option, that view leaves conflict preemption without any force. After all, "if federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior." *Wyeth*, 555 U.S. at 590 (Thomas, J., concurring).

This holds true across federally regulated industries. Whether it is the automobile industry (*Geier*), the cigarette industry (*Cipollone*), the generic drug industry (*Mensing*), or others, it is untenable to say that the solution to federal-state conflicts is simply to stop making products. And if *Mensing* can be distinguished in this way, then so too can *Geier*, *Cipollone*, and like cases. Affirmance of the decision below cannot be reconciled with these precedents, as the response to every defense of conflict preemption involving a federally regulated product would be simple: Pull the product from the market. For this reason too, the decision below demands reversal.

* * * * *

The decision below should be reversed for at least three reasons. *First*, the First Circuit's distinction between design-defect and failure-to-warn claims is foreclosed by the Hatch-Waxman Act, logic, and binding precedent. *Second*, if allowed to stand, the decision below would upset the basic economic structure of the generic drug industry, and impose burdens on generic drug makers and consumers that fly in the face of Hatch-Waxman's core objectives. Indeed, the whole point of the Hatch-Waxman framework is to increase the availability of low-cost generic drugs—a goal circumvented if generic manufacturers can "comply" with conflicting state and federal drug design requirements only by taking their products off the market. *Third*, the stop-selling rationale would destroy the doctrine of conflict preemption as applied to manufacturers of federally regulated products.

If federal supremacy is to mean anything, state courts must not be permitted to ban complex pharmaceutical products whose compliance with the mandates of federal law brings them into conflict with state standards.

CONCLUSION

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

Respectfully submitted.

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