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 FOR MORTON GROVE PHARMACEUTICALS, INC., AUROBINDO PHARMA USA, INC., AMNEAL PHARMACEUTICALS, LLC, TEVA PHARMACEUTICALS USA, INC., IMPAX LABORATORIES, INC., AND RANBAXY PHARMACEUTICALS INC. AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the First Circuit erred in holding—in clear conflict with this Court's decisions in *PLIVA, Inc*. v. *Mensing*, 131 S. Ct. 2567 (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 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.

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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 such claims and federal law can be avoided because generic drug makers "can choose not to make the drug at all." Pet. App. 10a.

As confirmed by a host of conflicting decisions (see Pet. 25-26), 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 equally could have been avoided if the generics had chosen "not to make the drug at all." But it is worse than that: To the extent there is any basis for distinguishing between labeling-based and design-based claims for federal preemption purposes—and again, the court below failed to identify one—

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[*] Pursuant to Rule 37.2(a), *amici* provided timely notice of their intention to file this brief, and all parties have consented. 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*, contributed monetarily to the preparation or submission of this brief.

the case for federal preemption is even stronger in this context. As explained in Part I, labels do not exist for their own sake. They are signposts concerning the *product* on the inside of the container. 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 brand counterparts. And since labels merely serve as 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 of generic drugs and defendants in thousands of suits seeking to impose liability upon them under state-law standards with which they have no ability to comply. 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 Court should grant the petition, summarily reverse the appellate court's refusal to follow *Mensing*, and restore the uniformity among lower courts that existed before the appellate court's aberrant decision in this case.

If that were not enough, preemption is required here for another reason. As shown in Part II, it is well settled that design-defect claims such as those at issue here are especially suited for federal regulation. Manufacturers and the economy suffer when complex products that are sold nationwide and extensively regulated at the federal level must submit to an additional layer of "diverse, nonuniform, and confusing

* * * regulations." *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 514 (1992). Indeed, where product design is not regulated uniformly, one State—even one *jury*—can effectively impose a controversial design upon 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 at issue here "is designed to *speed* the introduction of generic drugs to market." *Caraco Pharm. Labs, Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (emphasis added). That being so, federal law will not allow juries to decide that a generic drug ruled safe and effective by FDA must be banned outright, thus multiplying costs and slowing the drug's introduction in the remaining States.

As shown in Part III, the petition should also be granted to prevent problems beyond the generic drug industry. By the First Circuit's lights, there can be no preemption where a manufacturer can choose "not to make [its] [product] at all." Pet. App. 10a. But if that "choice" 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 otherwise—can be avoided by ditching 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., Inc.*, 529 U.S. 861 (2000); *Cipollone*, 505 U.S.at 514.

Sensing the reach of its decision, the First Circuit stated that this case presents "a question of excep-

tional importance." Pet. App. 8a. We agree. By exposing generic manufacturers to the same failure-to-warn claims rejected 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, generic manufacturers have no options: They can market a drug that complies with federal law (*i.e.*, one that has the same design as the name-brand equivalent), or they can drop the product. If allowed to stand, therefore, the decision below will make generic drugs both more expensive and more scarce—directly undermining Congress's intention in passing Hatch-Waxman.

For all these reasons, the Court should grant the petition, quash the First Circuit's resistance to the *Mensing* mandate, and reaffirm that state-law design claims against generic drugs are categorically preempted.

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 product manufactured by petitioner. Pet. App. 1-4a. 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. Pet. App. 4a. The jury agreed.

While petitioner's appeal was pending, this Court held that federal law preempts state-law failure-to-warn claims against generic pharmaceuticals in light of the "ongoing federal duty of sameness" requiring that generic drugs copy their brand-name counterparts. *Mensing*, 131 S. Ct. at 2574-2575 & n.2. 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 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 the "general no-preemption rule" of *Wyeth*. Pet. App. 9a, 11a. Suggesting that its hands were tied, the court said it was "up to the Supreme Court to decide whether *Mensing*'s exception is to be enlarged to include design defect claims." Pet. App. 11a.

REASONS FOR GRANTING THE PETITION

In addition to those stated by petitioner, the petition should be granted for three reasons. *First*, the First Circuit's distinction between design-defect and failure-to-warn claims is not only foreclosed by the Hatch-Waxman Act, logic, and binding precedent, but if allowed to stand would upset the basic economic structure of the generic drug industry. *Second*, of all state-law claims challenging complex products that are sold in a national market and heavily regulated at the federal level, design-defect claims are particularly suited for preemption. *Third*, left undisturbed, the First Circuit's rationale would destroy the doctrine of conflict preemption as applied to manufacturers of federally regulated products. Indeed, so clear is *Mensing* and so flagrant the First Circuit's failure to follow it that the decision below warrants summary reversal.

I. By distinguishing between design-defect and failure-to-warn claims, the First Circuit misconceived both the text and structure of the Hatch-Waxman Act and the nature and economics of the generic drug industry.

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" was needed. Not only does the reasoning of *Mensing* directly apply here, as the court below recognized (Pet. App. 10a), it applies *a fortiori*. Summary reversal is warranted.

A. Hatch-Waxman requires a generic drug to be designed as 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 proper conclusion from this basic premise. Here is why.

1. 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 establish 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 FDA some 442 days. *Id.* at 86.

The abbreviated ("ANDA") process for generic drugs is very 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; Pet. 8-9.

To ensure 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 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. at 17951-17952. No such difference is involved in this case, much less factored into the decision below. In addition, as discussed below (at 19-20), 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) provide clinical evidence of safety or efficacy. That has already been done by the brand; no trials are needed to ensure the safety and efficacy of the copy. Rather, as this Court has repeatedly recognized, 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] Congress thus directed 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 any 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. The ANDA product must be same as the NDA product; the generic manufacturer's federal obligations are as simple as that.

2. 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 established principles of conflict preemption and both the rationale and result of *Mensing*, where the very same arguments were made and rejected. See Pet. 27-30. It also threatens to overthrow Congress's carefully calibrated approach to introducing generic drugs, which gave birth to the generic drug industry. And "it 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.

To this day, generic companies stay in business only because of the lower costs 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, "[t]he relatively low costs to entry for generic drugs lead to increased competition, which drive prices for generic drugs down dramatically." *Id*. at 5. And "growth in the use of generic drugs has generated substantial savings for American consumers"—savings recently estimated to be $139.6 billion. *Id*. at 2, 6.

But if generics are shut out from marketing in various States—the lower court's "solution" to the federal-state conflict here—these savings will dwindle and could put generics out of business. 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. That result would be squarely at odds with the purpose of the Hatch-Waxman Act.

That Act is "the supreme law of the land," "anything in the constitution or laws of any state to the contrary notwithstanding." U.S. Const. Art. VI, Cl. 2. And again, the First Circuit conceded that generics "cannot legally" differ from their brand counterparts. Pet. App. 10a. Yet it affirmed a jury verdict imposing liability based on petitioner's failure to do precisely that—depart from the brand-name design. For this reason alone, the petition should be granted and the judgment below summarily reversed.

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

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*." FDA, Abbreviated New Drug Application Regulations—Final Rule, 57 Fed. Reg. 17950, 17961 (Apr. 28, 1992) (emphasis added); see also *Mensing*, 131 S. Ct. at 2574 (describing parallel sameness requirements for generic products and labels).

For this reason, 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 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 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. 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").

As the Second Restatement 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; 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 downsides 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 short, in the context of prescription drugs, "design-defect" claims are a red herring. There is no meaningful distinction between such tort claims and

claims for failure-to-warn: The law requires generic labels *and* products to match their brand counterparts; labels are derived from the products, not vice versa; and the adequacy of product warnings (which *Mensing* immunizes from challenge in the context of generic drugs) 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 their corresponding products should be a foregone conclusion—as every other court had recognized before the ruling below. In reaching a contrary conclusion, 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. For this reason alone, the petition should be granted and the decision below summarily reversed.

II. State tort claims challenging the design of complex products that are heavily regulated by the federal government and sold in a national market are particularly suited for preemption.

The decision below is particularly worthy of review and reversal because, of all types of tort claims, design defects—particularly of pharmaceuticals—are among those most worthy of preemption. Yet instead of *federal preemption*, the First Circuit authorized *state prohibition*. This turns the law of supremacy on its head, and threatens to deprive citizens in "prohibition States" of drugs that FDA has approved, while adding to the burdens on manufacturers attempting to serve a national market.

1. For complex products that are mass-produced, easily transported, and heavily regulated at the federal level, a patchwork quilt of additional state regulation is quite problematic. It raises the costs of compliance and makes it difficult for consumers to discern what is safe and what is not. 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"). 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, Inc.*, 505 U.S. at 514. For these reasons, numerous courts have recognized the "need for national uniformity in product regulation." *E.g.*, *Horn* v. *Thoratec Corp.*, 376 F.3d 163, 176 n.20 (3d Cir. 2004); *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 797 (8th Cir. 2001).

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 a generic

drug be a copy of 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—entirely removing the product from the market—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 decision below would allow juries to create a patchwork quilt of *prohibitions*.

Make no mistake: If "[t]he obligation to pay compensation" is "a potent method of governing conduct and controlling policy" (*Kurns*, 132 S. Ct. at 1269, (quoting *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959)); accord *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 324 (2008)), it is likewise potent to drive a product out of a State market entirely. Unlike brand-name drugs, generics typically have a thin profit margin—which means both 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 from entire markets can be a company killer, particularly for small companies. In *Buckman Co.* v. *Plaintiffs' Legal Committee,* 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. 341, 350 (2001). 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.

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. The problem is that juries simply are not constituted or equipped to regulate products such as those at issue here:

> 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? A jury, on the other hand, 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, as the Eighth Circuit has observed, "[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*, 273 F.3d at 797 (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 not juries, but FDA, that is charged with determining whether a product is safe and effective, and hence whether its benefits outweigh its risks. 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. In light of *Mensing*, however, turning somersaults is an apt description of the approach taken below. As the court itself acknowledged, it was "second-guessing the FDA." Pet. App. 10a; *cf. Geier*, 529 U.S. at 882 (rejecting attempt to show lack of conflict based on suggestion that manufacturer could have complied with state law by selling "a *different* kind of" product) (emphasis in original).

Review is needed 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.

Review is needed for a third reason as well. Left uncorrected, the First Circuit's decision would 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 ac-

tions." *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*, "[i]f 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 pre-emption 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.

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. The decision below threatens to render these precedents dead letters, as the response to every defense of conflict preemption involving a federally regulated product will be simple: Pull the product from the market. For this reason too, the decision below demands review and reversal.

CONCLUSION

If federal supremacy is to mean anything, States must not be permitted to ban products whose compliance with the mandates of federal law brings them into direct conflict with state standards. The petition should be granted, and the judgment below summarily reversed.

Respectfully submitted.

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