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 RESPONDENT

STEVEN M. GORDON
CHRISTINE M. CRAIG
SHAHEEN & GORDON
107 Storrs Street
Concord, NH 03302
(603) 749-5000

KEITH M. JENSEN
JENSEN & ASSOCIATES, PLLC
1024 N. Main Street
Fort Worth, Texas 76164
(817) 334-0762

DAVID C. FREDERICK
Counsel of Record
BRENDAN J. CRIMMINS
JOSHUA D. BRANSON
KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900
(dfrederick@khhte.com)

Counsel for Respondent

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QUESTION PRESENTED

Whether federal law preempts the district court's judgment awarding compensatory damages to respondent for severe injuries resulting from use of a generic pain medication manufactured by petitioner.

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INTRODUCTION

Out of respect for state sovereignty and fundamental principles of federalism, this Court has established strict standards for determining when federal law displaces state law under the Supremacy Clause absent an express statement from Congress. State law directly conflicts with federal law, and is preempted, only when compliance with the laws of both sovereigns is physically impossible or when state law presents an unacceptable obstacle to Congress's objectives. Neither type of conflict is present here.

First, petitioner can comply with the district court's judgment without violating federal law. Under New Hampshire's law of strict products liability, a manufacturer of an unreasonably dangerous product – a product whose risks outweigh its benefits – is subject to liability for foreseeable injuries caused by that product. The New Hampshire Supreme Court has made clear that strict liability is not premised on any underlying standard of conduct or legal duty.

This case therefore differs fundamentally from the negligence-based failure-to-warn claims held preempted in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). In *PLIVA*, state law undisputedly required the manufacturers affirmatively to improve the drug's label. Here, however, the only state-law obligation is to compensate consumers for injuries caused by an unreasonably dangerous product. Nothing in federal law prohibits petitioner from paying compensatory damages to Ms. Bartlett.

Second, the judgment presents no obstacle to the fulfillment of Congress's purposes. The Federal Food, Drug, and Cosmetic Act ("FDCA") makes the Food and Drug Administration ("FDA") a gatekeeper,

charged with keeping unsafe and ineffective drugs out of interstate commerce. Requiring manufacturers to pay compensation for injuries that their drugs cause does not interfere with FDA's ability to perform that gatekeeping function.

In addition, nothing in the statute gives manufacturers a federal *right* to market FDA-approved drugs in interstate commerce, let alone a right to do so free from damages liability under state law. Nor does the statute support petitioner's and the government's contention that Congress intended to "establish[] both a floor and a ceiling for drug regulation." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). Rather, this case exemplifies why FDA has long regarded state tort actions as "a complementary form of drug regulation." *Id.* at 578. The litigation below unearthed important evidence about a dangerous drug, and the judgment provided compensation to a woman injured horribly by that drug.

STATEMENT

A. Statutory and Regulatory Background

1. With the emergence of centralized markets for drugs in the mid-nineteenth century came concerns about the spread of dangerous drugs. *See* Peter Barton Hutt et al., *Food and Drug Law* 7 (3d ed. 2007). Shortly thereafter, courts began to recognize common-law remedies for consumers injured by such drugs.[1]

In 1906, Congress enacted the first Federal Food and Drugs Act to "supplement[] the protection for

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[1] *See*, *e.g.*, *Thomas v. Winchester*, 6 N.Y. 397, 409 (1852); *Fisher v. Golladay*, 38 Mo. App. 531, 1889 WL 174, at *3 (1889); *Marx v. Schultz*, 175 N.W. 182, 184 (Mich. 1919); *Napier v. Greenzweig*, 256 F. 196, 198 (2d Cir. 1919).

consumers already provided by state regulation and common-law liability." *Levine*, 555 U.S. at 566. In 1938, Congress enacted the FDCA "for the purposes of safeguarding the public health [and] preventing deceit upon the purchasing public." H.R. Rep. No. 75-2139, at 3 (1938).

The FDCA's fundamental provision – then, as now – bars a "new drug" from interstate commerce unless "an application" filed under the Act is "effective with respect to such drug." 21 U.S.C. § 355(a). Under the FDCA as originally enacted, FDA "had to prove harm to keep a drug out of the market," *Levine*, 555 U.S. at 567, and an application became effective after 60 days unless FDA took action, FDCA § 505(c), 52 Stat. 1052. By contrast, when Congress enacted the Drug Amendments of 1962 ("1962 Amendments"), it provided that an application would become effective only if FDA affirmatively "approve[d]" it. 1962 Amendments § 104(b), 76 Stat. 784.

Even as the 1962 Amendments strengthened FDA's premarket-review authority, Congress provided that they should not "be construed as invalidating" state laws "unless there is a direct and positive conflict between such amendments and such provision of State law." *Id.* § 202, 76 Stat. 793. State-law actions against drug manufacturers continued, with courts rejecting preemption defenses in the rare instances in which they were raised.[2] Many of those

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[2] "Courts that have considered the question have overwhelmingly held that FDA approval of a new drug application does not preempt state tort suits." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 343 (2008) (Ginsburg, J., dissenting); *see id.* at 340 n.11, 343 n.16 (collecting cases).

actions included claims that drugs were unreasonably dangerous.[3]

2. The premarket-review procedure established by the 1962 Amendments requires a manufacturer seeking to market a branded drug to submit a new drug application ("NDA"). *See* 21 U.S.C. § 355(b). FDA must approve an NDA unless it finds that the drug fails one of the enumerated statutory standards, which include requirements that an NDA contain "adequate tests by all methods reasonably applicable to show" that the drug is "safe for use," as well as "substantial evidence that the drug will have the effect it purports." 21 U.S.C. § 355(d).

In the decades following the 1962 Amendments, the "serious anti-competitive effects" of the NDA process became apparent. H.R. Rep. No. 98-857, pt. 2, at 4 (1984). Branded drugs often obtained "monopoly" status because competing manufacturers could typically secure approval for generic substitutes only by making "enormous expenditures of money" for "duplicative tests." *Id.* Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, often called the "Hatch-Waxman Act," "to make available more low cost generic drugs by establishing a generic drug approval procedure." H.R. Rep. No. 98-857, pt. 1, at 14 (1984). An abbreviated new drug application ("ANDA") under Hatch-

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[3] *See, e.g.*, *Hill v. Searle Labs.*, 884 F.2d 1064, 1069-70 (8th Cir. 1989); *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 657 (1st Cir. 1981); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 134-35 (3d Cir. 1973); *Leibowitz v. Ortho Pharm. Corp.*, 307 A.2d 449, 457-58 (Pa. Super. Ct. 1973) (per curiam); *see also Riegel*, 552 U.S. at 340 (Ginsburg, J., dissenting) ("[S]tate common-law claims for drug labeling and design defects . . . continued unabated despite . . . FDA regulation.").

Waxman, unlike an NDA, need not contain clinical evidence of the drug's safety, but must demonstrate the generic drug's equivalence to a previously approved branded drug. *See* 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 320.1(c).

B. Factual Background

1. Sulindac is a non-steroidal anti-inflammatory drug ("NSAID") generally intended to relieve muscle pain. *See* App. 3a; JA553. Sulindac is "known to cause" a condition called "Stevens-Johnson Syndrome and its more generic cousin toxic epidermal necrolysis ('SJS/TEN')," App. 3a, a severe adverse reaction involving extensive loss of skin.

In 1978, FDA approved an NDA for the branded version of sulindac, called Clinoril. JA61 (¶ 22). In 1991, FDA determined that petitioner's generic version of sulindac was equivalent to Clinoril and approved petitioner's ANDA. *See* App. 144a-145a; 21 C.F.R. § 320.1(c). When FDA approved the Clinoril NDA, available "clinical studies" suggested that its side effects were "relatively mild." JA596 (Glen D. Park et al., *Serious Adverse Reactions Associated With Sulindac*, 142 Arch. Intern. Med. 1292 (July 1982)). Only later, as post-marketing "reports began to accumulate," did the drug's serious SJS/TEN risks emerge. *Id.* The record contains no evidence that FDA considered those risks in approving either Clinoril or petitioner's ANDA.

In February 2005, private citizens petitioned FDA to conduct a "risk assessment of SJS and TEN associated with ibuprofen," which (like sulindac) is an

NSAID.[4] The Citizen Petition requested that ibuprofen's labeling "include a specific warning" about SJS/TEN. Citizen Petition at 1-2. The Petition observed that the "ca[us]al relationship between NSAIDs" and SJS/TEN "is well-documented," and it supplied a table of "accumulated evidence" from the medical literature. *Id.* at 7, 10.

In April 2005, FDA staff issued a memorandum addressing cardiovascular risks in NSAIDs. That memorandum included a footnote stating that the Citizen Petition was "under review" and that FDA had "not reached a decision on the requested actions." JA580 n.8. The memorandum noted the lack of reliable data indicating that any one NSAID provided "greater relief of pain and inflammation" than any other. JA559. It further observed that adverse event reporting suggested that one NSAID, Bextra, was "associated with an increased rate of serious and potentially life-threatening skin reactions," including SJS/TEN. *Id.* Given the "absence of any demonstrated advantage over other NSAIDs," the staff recommended that Bextra be withdrawn from the market. JA559-60; *see* JA588.

More than a year later, FDA granted in part and denied in part the Citizen Petition. FDA agreed that labeling revisions were "necessary to make more explicit the risks associated with SJS and TEN," and it recommended that "all NSAID[]" manufacturers specifically identify SJS/TEN in the "Warnings" section

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[4] Citizen Petition at 1, FDA Docket No. 2005P-0072/CP1 (Feb. 15, 2005) ("Citizen Petition"), http://www.fda.gov/ohrms/dockets/dockets/05p0072/05p-0072-cp00001-01-vol1.pdf.

of the prescription labels.[5] FDA also noted that it had recently made a "comprehensive effort" to educate the public about SJS/TEN. 2006 Letter at 6. Given those efforts, FDA rejected the Citizen Petition's request for an even stronger "boxed warning" for ibuprofen products. *Id.* at 8. Neither the 2005 memorandum nor the 2006 Letter mentioned sulindac.

Pursuant to FDA's recommendation, petitioner updated the "Warnings" section of its label to refer explicitly to SJS/TEN, JA555; previously, it had been listed only as a possible adverse reaction, JA554. Sulindac remains on the market today with that strengthened warning. JA354.

2. In December 2004 – before FDA had received the Citizen Petition or taken any action regarding SJS/TEN – Karen Bartlett visited her doctor complaining of shoulder pain. JA450-51. Her physician prescribed sulindac "under the brand-name Clinoril," and her "pharmacist dispensed generic sulindac" manufactured by petitioner. App. 3a.

"The consequences were," in the First Circuit's words, "disastrous." *Id.* In early 2005, Ms. Bartlett developed SJS/TEN. *Id.* "TEN is diagnosed when 30 percent or more of the outer skin layer on a patient's total body surface area has deteriorated, been burned off or turned into an open wound." *Id.* In Ms. Bartlett's case, "the percentage rose to 60-65 percent of her body." *Id.*

Ms. Bartlett's injuries, which the First Circuit characterized as "truly horrific," App. 22a, are pic-

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[5] Decision Letter at 7, FDA Docket No. 2005P-0072/CP1 (June 22, 2006) ("2006 Letter"), http://www.fda.gov/ohrms/dockets/dockets/05p0072/05p-0072-pav0001-vol1.pdf.

tured in part at JA640-44. The pictures reveal some of the physical manifestations of Ms. Bartlett's injuries: the burns (JA641), disfigurement (JA643), and eye damage that has left her legally blind (JA640, 644). But no picture can convey fully Ms. Bartlett's experience with SJS/TEN, which her burn surgeon described as "'hell on earth.'" App. 23a. She "spent months in a medically-induced coma," spent 100 days in five different hospitals, was fed by tube for a year, and "endured two major septic shock episodes." App. 22a-23a; C.A. App. 2809-29. "She suffered through 12 eye surgeries and has many more ahead of her." App. 23a. She "cannot eat normally due to esophageal burns, cannot have sexual relations due to vaginal injuries, and cannot engage in aerobic activities due to lung injuries." *Id.* Nor will she likely ever be able to return to work, because she cannot drive or read. JA440. As the district court stated, "[n]o one who witnessed the trial in this case could deny the horror" that Ms. Bartlett has suffered. App. 101a.

C. Proceedings Below

1. Ms. Bartlett filed suit against petitioner in New Hampshire Superior Court. JA34-35. After petitioner removed the action to federal court, Ms. Bartlett filed an amended complaint alleging various state-law claims. JA81-124. One claim alleged that petitioner had breached its "duty to warn" about sulindac's risks, JA102 (¶ 44), while another alleged that petitioner was strictly liable for selling an "unreasonably dangerous" drug, JA106 (¶ 57). Ms. Bartlett sought only damages, not an injunction requiring petitioner to change sulindac's design or label. JA120-22.

The court granted summary judgment for petitioner on the failure-to-warn claims. App. 115a-116a.

The court concluded, in light of the testimony of Ms. Bartlett's doctor that he had not read the drug's label, that Ms. Bartlett could not prove that a stronger warning would have avoided her injury. App. 117a-121a. In contrast, the court denied petitioner's motion as to Ms. Bartlett's "defective design claims." App. 128a. Although petitioner argued that those claims were "really failure-to-warn claims," the court held that was "not accurate" and that Ms. Bartlett's design-defect allegations were "independent of any inadequacy in the product's safety warning." App. 124a-125a.[6]

The court noted, however, that petitioner could still "use Sulindac's safety warning as part of its defense." App. 125a. New Hampshire has adopted the theory of strict products liability set forth in Section 402A of the Restatement (Second) of Torts (1965). *See id.* The court observed that petitioner might "be able to avoid liability" under comment k to Section 402A if it could prove, as an "affirmative defense," that "Sulindac is unavoidably unsafe and had an adequate safety warning." App. 128a. But petitioner subsequently abandoned its "comment k" defense "on the eve of trial, without explanation." App. 36a. With that defense "out of the case, the adequacy of sulindac's warning . . . was no longer an issue for trial." *Id.*

2.a. In August–September 2010, the district court held a 14-day trial on Ms. Bartlett's strict-liability design-defect claim. Her experts presented a "litany of specific facts, most of them drawn directly from the medical literature or published FDA analyses,"

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[6] The court subsequently granted petitioner summary judgment on Ms. Bartlett's negligence claims. JA317.

demonstrating that sulindac's risks outweigh its benefits. App. 42a. The evidence showed that, although all NSAIDs carry risks of SJS/TEN, *see* App. 42a-43a, FDA received more adverse event reports of SJS/TEN attributed to sulindac than "any other NSAID on the market." App. 44a. Moreover, an unpublished manuscript ("Pharmacia Report," *see* JA626-34) drafted by petitioner's expert indicated that sulindac's adjusted reporting rate of SJS/TEN from 1980-1997 "was the highest of any NSAID." App. 45a. Those facts made sulindac's "'risk/benefit profile'" comparable to that of Bextra, whose removal from the market FDA had recommended based on similar reporting data. App. 46a. One of Ms. Bartlett's experts testified that the Pharmacia Report's author had never given it to FDA, and that FDA was unaware of sulindac's adjusted reporting rate of SJS/TEN. JA429-31.

The testimony further indicated that sulindac was unlike a drug that is the "only one available . . . to cure a cancer." 8/24/2010 p.m. Tr. 12:23-24. Rather, sulindac was prescribed for shoulder pain, and the evidence established that "[no] one NSAID – including sulindac – provides greater relief of pain and inflammation than other NSAIDs." App. 46a; *see* JA559. Tylenol and aspirin, the evidence showed, "carry no risk of SJS/TEN" and are "equally effective as sulindac" in treating the "shoulder pain" that Ms. Bartlett experienced. App. 47a. Given those safer alternatives, an expert opined that sulindac is "unreasonably dangerous" to the public as a whole and thus "shouldn't be on the market." 8/24/2010 p.m. Tr. 29:20-21.

Petitioner had designated its own expert on that topic, as well as other witnesses. *See* App. 5a. But

petitioner "chose not to call any of its own witnesses at trial, foregoing the opportunity to rebut Bartlett's evidence and put sulindac in a better light." App. 30a-31a.

b. The district court instructed the jury that sulindac was "defective as designed if the magnitude of the danger outweighs the utility or usefulness of the product." JA513. The relevant inquiry was not whether sulindac was beneficial for Ms. Bartlett in particular; the court instructed the jury to "consider the usefulness and desirability of the product to the public as a whole." *Id.* The court also explained that the jury could find sulindac "unreasonably dangerous" even without any "evidence of an alternative design that could have made the product safer." *Id.*

The instructions also required Ms. Bartlett to prove that sulindac was "unreasonably dangerous even with its warning" and allowed the jury to consider whether sulindac's warning was "effective to avoid [any] unreasonable danger." JA513-14. But the court emphasized that the "claim is focused on the product Sulindac and whether its design was in a defective condition," not on "[petitioner's] conduct other than selling Sulindac." 9/2/2010 p.m. Tr. 99:9-14. The court thus instructed the jury that "whether [petitioner] knew of Sulindac's safety risks or any of [its] conduct in seeking or responding to such knowledge is not an issue in this case" and that the jury "should put [those considerations] out of your mind." *Id.* at 99:15-20.

Finally, the jury was instructed that, if it found petitioner liable, it "should award a sum of money which will fairly compensate her for her injuries." JA519-20. The jury was "not permitted to award punitive damages or any other money damages for the

purpose of punishing [petitioner] or . . . preventing [petitioner] and others from similar conduct." JA522.

c. The jury rendered a verdict for Ms. Bartlett and awarded $21.06 million in compensatory damages. JA376-77. The district court denied petitioner's motions for a new trial and for judgment as a matter of law. App. 29a-103a. Relevant here, the court first rejected petitioner's argument that federal law preempted the damages judgment because the jury had "'second-guess[ed]' the FDA's risk/benefit analysis" of sulindac. App. 69a. The court noted that Ms. Bartlett's claim had much "in common with" *Levine*, in which this Court explained that "'state law offers an additional, and important, layer of consumer protection that complements FDA regulation.'" App. 70a (quoting *Levine*, 555 U.S. at 579).

The court also rejected petitioner's argument that federal law prohibited it from complying with the judgment. App. 72a-73a. It observed that petitioner was held liable not "for failing to change sulindac's design" but "for selling an unreasonably dangerous product." App. 72a. It further stated that New Hampshire law requires "manufacturers [to] compensate consumers for the damage caused by unreasonably dangerous products, not necessarily that they remove such products from the market." *Id.* (internal quotations omitted). Because "[f]ederal law did not require [petitioner] to sell sulindac," and certainly did not forbid it from paying damages, the court concluded that "it was not 'impossible' for [petitioner] to comply with both federal and state law." *Id.*

3. The First Circuit affirmed. Writing for the court, Judge Boudin upheld the district court's conclusion that compliance with New Hampshire law

was not impossible, reasoning that petitioner could "certainly" comply with both federal and state law by "choos[ing] not to make [sulindac] at all." App. 10a.

The court explained that *PLIVA* did not require a different result. There, this Court held that federal law "preempts failure-to-warn claims against generic drug manufacturers" because those manufacturers "cannot unilaterally change their labels" under federal law, and thus cannot comply with state-law duties to provide a stronger warning. App. 9a-10a. Here, however, the manufacturer can comply with state law consistent with federal law: although "the generic maker has no choice as to label," "the decision to make the drug and market [sulindac] in New Hampshire is wholly its own." App. 10a-11a.

The First Circuit also agreed that Ms. Bartlett's damages judgment posed no obstacle to any congressional purpose. In so concluding, it relied on *Levine*'s holding "that 'Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness' and that state law serves as a 'complementary form of drug regulation.'" App. 9a (quoting *Levine*, 555 U.S. at 575, 578) (citation omitted).

SUMMARY OF ARGUMENT

I. Compliance with the district court's judgment and federal law is not physically impossible.

A. Federal law permits petitioner to comply with the judgment by compensating Ms. Bartlett for her injuries. New Hampshire law requires nothing more of petitioner. The New Hampshire Supreme Court has made clear that strict products liability is not premised on any legal duty to alter a product's design. Under longstanding federalism principles, this Court is bound by the state supreme court's authoritative construction of state law.

PLIVA involved fundamentally different claims. The failure-to-warn claims in *PLIVA* rested on negligence principles, and all parties agreed that the manufacturers' state-law duty was to improve the labels affixed to their generic drug. *PLIVA*'s holding that compliance with that affirmative duty was impossible under federal law does not support preemption of Ms. Bartlett's claim, which involved no similar duty.

Nor do the express-preemption cases on which petitioner relies support finding implied-conflict preemption here. Those cases hold only that the term "requirement" in an express-preemption provision signals Congress's intent to displace common-law claims. Congress has not expressly preempted tort claims against prescription-drug manufacturers, and there is no warrant to treat the reach of *implied* preemption as broadly as *express* preemption.

B. Petitioner failed to preserve the argument that the district court's judgment is preempted because it was premised on a failure to improve sulindac's label.

Regardless, in New Hampshire, strict liability for selling an unreasonably dangerous product is not based on a duty to improve the product's warning. And in this case petitioner's withdrawal of its "comment k" defense meant that the adequacy of sulindac's label was not even an issue at trial. Moreover, petitioner cannot claim that the judgment was premised on a failure to improve sulindac's labeling, because petitioner cannot show that it would have avoided liability had sulindac carried a stronger warning of SJS/TEN.

C. Even if the judgment were premised on an underlying duty not to sell sulindac, nothing in federal law would prohibit compliance with that duty. Petitioner derides the First Circuit's so-called "stop-selling theory," but the court was correct that federal law permits compliance with a state-law duty not to sell an unreasonably dangerous drug. Contrary to petitioner's claim, that reasoning creates no conflict with *PLIVA*, because withdrawing the product offered only an indirect means of avoiding future liability in that case. It was not the act – changing a warning label in contravention of federal labeling rules – required by the state-law duty.

II. Petitioner's obstacle-preemption argument, which it did not raise in the petition, has no merit.

A. State damages actions complement federal drug regulation by compensating injured consumers and exposing hidden dangers. Ms. Bartlett's action did both. Reversal would not only thwart the FDCA's core purpose of consumer protection, but also extinguish the only remaining avenue of judicial relief for patients injured by generic drugs.

B. Petitioner's argument that FDA approval of a drug impliedly immunizes its manufacturer from

strict-liability claims lacks any statutory basis. FDA's function under the FDCA is to screen dangerous drugs from interstate commerce. The statute makes clear that initial FDA approval removes a barrier to marketing but provides no federal *right* to sell a drug. Damages actions do not interfere with FDA's ability to perform its gatekeeping function.

C. The government's asserted conflict between the district court's judgment and FDA regulation is even less persuasive. The government's newly minted preemption position has no grounding in any lawful regulation and represents yet another inexplicable departure from FDA's previous positions. As in *Levine*, the government's brief deserves no weight.

The government also provides no support for its premise that strict-liability claims will deprive patients of access to FDA-approved drugs. Given that such claims have existed for decades, the lack of evidence weighs heavily against the government's position.

The government's assertion that the jury here "second-guessed" FDA also misstates the record. FDA was never presented with the critical data on which Ms. Bartlett relied at trial. And, even if FDA had access to those data, there is no evidence the agency actually considered them.

D. The Hatch-Waxman Act, like the FDCA, evinces no intent to preempt state-law claims. Hatch-Waxman aims not to maximize the sale of generic drugs in all circumstances at all costs, but to minimize federal regulatory obstacles to generic drug development. State-law damages actions pose no conflict with that narrow purpose.

III. Even if the Court were to accept the government's new theory – which petitioner did not raise

below – that state law is preempted unless the plaintiff proves the drug was misbranded under federal law, the Court should nonetheless affirm. Sulindac was misbranded under federal law because the evidence at trial showed that sulindac was "'dangerous to health' when used as provided in the labeling." U.S. Br. 23 (quoting 21 U.S.C. § 352(j)).

ARGUMENT

Analysis of petitioner's conflict-preemption defense begins with the "two cornerstones" of this Court's "pre-emption jurisprudence." *Levine*, 555 U.S. at 565. First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Id.* (internal quotations omitted). Second, this Court presumes that Congress did not supplant the "historic police powers of the States" unless it made such a purpose "clear and manifest." *Id.* (internal quotations omitted).

Petitioner must demonstrate an "actual conflict," *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (internal quotations omitted), between federal law and New Hampshire law "strong enough to overcome the presumption" that Congress intended them to "coexist," *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 716 (1985). An actual conflict exists when "it is impossible for a private party to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Sprietsma*, 537 U.S. at 64 (internal quotations and citation omitted). Petitioner demonstrates neither type of conflict.

I. PETITIONER CAN COMPLY WITH THE DISTRICT COURT'S JUDGMENT AND FEDERAL LAW

Petitioner's first theory (at 29-45) is that compliance with the district court's judgment and federal law is impossible. "Impossibility pre-emption is a demanding defense," *Levine*, 555 U.S. at 573, which this Court has applied only in "very narrow" circumstances, *id.* at 590 (Thomas, J., concurring in the judgment). Petitioner must show that compliance with federal and state law is a "physical impossibility." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

A. The Judgment Is Not Premised On A Duty To Change Sulindac's Design

Petitioner argues (at 42-43) that compliance with federal and state law is physically impossible because New Hampshire law requires it to change the design of its generic drug sulindac, whereas federal law forbids it from doing so. That argument fails. Under the well-settled New Hampshire law applied in this case, a damages judgment based on strict products liability does not require a manufacturer to alter its product.

1. New Hampshire law obligates sellers of unreasonably dangerous products to compensate injured consumers, not to redesign their products

a. New Hampshire has adopted the "doctrine of strict liability of manufacturers for product defects in section 402A(1) of the *Restatement (Second) of Torts*." *Kelleher v. Marvin Lumber & Cedar Co.*, 891 A.2d 477, 492 (N.H. 2005). Under that standard, "'[o]ne who sells any product in a defective condition unreasonably dangerous . . . is subject to liability for the

physical harm thereby caused.'" *Id.* (quoting Restatement (Second) of Torts § 402A(1)) (emphasis omitted).

Two key features of New Hampshire's law of strict products liability establish that it imposes no duty on manufacturers to redesign their products. *First*, the New Hampshire Supreme Court has made clear that strict liability is not premised on the "violation" of any underlying "common law or statutory duty." *Bagley v. Controlled Env't Corp.*, 503 A.2d 823, 825 (N.H. 1986) (Souter, J.). In fact, the very essence of strict liability is the possibility of "liability absent proof of a violation of a legal duty." *Royer v. Catholic Med. Ctr.*, 741 A.2d 74, 76 (N.H. 1999). Untethered from traditional tort duties, strict liability simply redresses injuries; it does not punish a manufacturer for "depart[ing]" from any "required standard of conduct." *LeFavor v. Ford*, 604 A.2d 570, 572 (N.H. 1992).

Strict liability imposes no substantive duties on manufacturers because its purpose is compensatory, not regulatory. As it became apparent that many "products contain chemical compounds" whose "side effects . . . cannot be anticipated," New Hampshire courts concluded that "the risk of liability is best borne by the companies that profited from their sale, rather than by the unfortunate individual consumers" who suffered from their side effects. *Heath v. Sears, Roebuck & Co.*, 464 A.2d 288, 293 (N.H. 1983).[7] In negligence cases, however, the "burden" of

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[7] *Heath* noted that "[d]eterrence is also a valid consideration" justifying strict liability, for, "without the stimulus of plaintiffs' products liability actions, the incentive to improve products . . . would not exist." 464 A.2d at 293. But the state supreme court has subsequently confirmed that strict liability is not intended,

"establish[ing] traditional legal fault" on the part of manufacturers frequently deprived injured consumers of any remedy. *Bagley*, 503 A.2d at 826. Strict liability eliminates that burden when the plaintiff can show that a product's risks outweigh its benefits, requiring a manufacturer to pay compensatory damages even absent "traditional legal fault." *Id.*[8] It thus "offer[s] relief" to injured consumers who cannot "show that a . . . duty of care ha[s] been breached." *Waid v. Ford Motor Co.*, 484 A.2d 1152, 1155 (N.H. 1984).

Moreover, New Hampshire courts award only compensatory damages in strict-liability (indeed, all tort) cases. "Punitive damages are not allowed in New Hampshire," and civil remedies may not aim to "'warn[]'" or "'deter'" defendants. *Stewart v. Bader*, 907 A.2d 931, 943 (N.H. 2006) (quoting *Aubert v. Aubert*, 529 A.2d 909, 914 (N.H. 1987)). Consistent with that principle, the district court here forbade the jury from awarding any "damages for the purpose of . . . preventing [petitioner] and others from similar conduct." JA522. The damages award thus "com-

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nor does it function, as a tool for coercing changes in behavior. *See infra* pp. 20-21.

[8] An early case stated that "strict liability is not a no-fault system of compensation" that wholly abolishes the "principle that fault and responsibility are elements of our legal system." *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 845-46 (N.H. 1978). The New Hampshire Supreme Court later clarified that the role of "fault" in strict liability is not to enforce substantive duties on manufacturers, but to shield manufacturers from the financial burden of acting as blanket "insurers of their products." *Price v. BIC Corp.*, 702 A.2d 330, 333 (N.H. 1997). Hence, the only "fault" in a strict-liability case is the sale of an unreasonably dangerous product whose risks outweigh its benefits.

pensate[d]" Ms. Bartlett for "her injuries," JA519-20; it explicitly was *not* intended to coerce petitioner into redesigning its drug. *Cf. Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 275 n.3 (1984) (Powell, J., dissenting) (calling the "distinction" between compensatory and punitive damages "of major importance" and discerning "no element of regulation when compensatory damages are awarded").

Second, strict liability in New Hampshire is not premised on any duty to improve a product's design because the existence of a better design is not an element of a strict-liability claim. *See Kelleher*, 891 A.2d at 492 ("[T]he plaintiff is not required to present evidence of a safer alternative design."); App. 58a-61a. Instead, liability turns on whether a product is "unreasonably dangerous" under New Hampshire's "risk-utility balancing test." *Price*, 702 A.2d at 332. That test calls for an assessment whether "'the magnitude of the danger outweighs the utility of the product.'" *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001) (quoting W. Page Keeton et al., *Prosser and Keeton on the Law of Torts* 699 (5th ed. 1984)).[9]

The outcome of that risk-utility balancing does not reflect any opinion about "the care exercised" by the manufacturer "to design a safe product." *Chellman v. Saab Scania AB*, 637 A.2d 148, 150 (N.H. 1993). Indeed, the "focus" of strict liability is not "on the

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[9] The risk-utility test involves a "'multifaceted balancing process,'" in which a possible design improvement is "neither a controlling factor nor an essential element that must be proved in every case." *Vautour*, 784 A.2d at 1182, 1183 (quoting *Thibault*, 395 A.2d at 847). It was not a factor here: sulindac "is a one-molecule drug" that cannot even theoretically be "made in a different and safer form." App. 6a.

conduct of the manufacturer" at all, but "on whether the design itself was unreasonably dangerous." *Connelly v. Hyundai Motor Co.*, 351 F.3d 535, 542 (1st Cir. 2003) (internal quotations omitted). Because a manufacturer can be held strictly liable "even though [it] exercised the highest degree of care," *Bolduc v. Herbert Schneider Corp.*, 374 A.2d 1187, 1189 (N.H. 1977), strict liability is not based on violation of any duty to design a safer product.

b. Although petitioner argues repeatedly that "respondent's tort claim" "embodie[s]" a "state design requirement," Pet. Br. 30; *see id.* at 42-43, it makes virtually no effort to ground that erroneous contention in New Hampshire cases. Citing an isolated snippet from a single decision, petitioner incorrectly asserts that New Hampshire law imposes a "basic duty . . . to 'design [its drug] reasonably safely for the uses [Mutual] can foresee.'" *Id.* at 42 (quoting *Thibault*, 395 A.2d at 847) (brackets added by petitioner).

But *Thibault* stated merely that a plaintiff's burden to "prove that . . . his use of the product was foreseeable by the manufacturer" is "predicated on the manufacturer's duty to design his product reasonably safely for the uses which he can foresee." 395 A.2d at 847. That statement *limited* manufacturers' liability to cases involving foreseeable uses of their products; it did not impose on manufacturers any free-standing duty of care. Indeed, in discussing whether a product poses unreasonable dangers in the first place – the element at issue here – *Thibault* did not reference any affirmative duty to design safe products. *See id.* at 846. And the New Hampshire Supreme Court has confirmed before and after *Thibault* that strict liability is not premised on any "violation of a common law

. . . duty." *Bagley*, 503 A.2d at 825; *see Kelton v. Hollis Ranch, LLC*, 927 A.2d 1243, 1246 (N.H. 2007); *LeFavor*, 604 A.2d at 572; *Moulton v. Groveton Papers Co.*, 289 A.2d 68, 71 (N.H. 1972).

2. The New Hampshire Supreme Court's articulation of state law controls here

This Court is bound by the New Hampshire Supreme Court's articulation of New Hampshire law. It is fundamental to "the federal design" that "federal and state courts" exist not in "competition and conflict," but as "complementary systems for administering justice in our Nation." *Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 586 (1999). Consistent with that bedrock principle, a "State's highest court is unquestionably the ultimate expositor of state law." *Riley v. Kennedy*, 553 U.S. 406, 425 (2008) (internal quotations and brackets omitted). Thus, this Court has long considered itself "bound to accept the interpretation of [state] law" provided "by the highest court of the State." *Hortonville Joint Sch. Dist. No. 1 v. Hortonville Educ. Ass'n*, 426 U.S. 482, 488 (1976).

This Court's practice of deferring to a State's highest court's construction of state law extends fully to the preemption context. *See Levine*, 555 U.S. at 565 (relying on the Vermont Supreme Court's definition of the "state-law duty at issue"); *Perez v. Campbell*, 402 U.S. 637, 644 (1971) (Court was "bound" by Arizona's "construction of its legislation"). In fact, the danger that a finding of preemption will trample on a State's police powers makes such deference all the more important. *Cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (emphasizing that preemption analysis must account for "federalism concerns"); *Levine*, 555 U.S. at 583-84 (Thomas, J., concurring in the judgment). Given the vital federalism interests at

stake, this Court should avoid any "interference with a state supreme court's ability to determine the content of state law." *Riley*, 553 U.S. at 427.[10]

* * *

Applying the principles of New Hampshire law described above, the properly instructed jury found that sulindac's risks outweighed its benefits. *See* App. 30a. That finding imposed only one obligation on petitioner: once the jury found that Ms. Bartlett proved that sulindac's risks outweighed its benefits based on the evidence adduced at trial, petitioner was required to compensate Ms. Bartlett for the injuries that sulindac caused her. As the district court explained, petitioner "was not held liable for failing to change sulindac's design; it was held liable for selling an unreasonably dangerous product." App. 72a.

3. *PLIVA* addressed a fundamentally different kind of common-law claim

Petitioner's main argument (at 29) is that "there is no principled basis for reaching a different result here than in [*PLIVA*]." New Hampshire strict-liability law, however, differs fundamentally from the state law at issue in *PLIVA*.

PLIVA addressed whether federal law preempted state negligence claims brought by injured patients

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[10] Although the New Hampshire Supreme Court has made clear that strict liability is not based on an underlying duty to modify the product, if this Court perceives any uncertainty regarding the content of state law, the appropriate course would be to certify the question to the state supreme court. *See* N.H. Sup. Ct. R. 34; *see also*, *e.g.*, *United States v. Juvenile Male*, 130 S. Ct. 2518, 2520 (2010); *Fiore v. White*, 528 U.S. 23, 29 (1999) (certifying question to State's highest court where answer would "help determine the proper state-law predicate for our determination of the federal constitutional questions raised").

against manufacturers of generic metoclopramide. *See* 131 S. Ct. at 2572. This Court began its preemption analysis by "identifying the state tort duties" at issue. *Id.* at 2573. That identification was straightforward: the patients alleged that the manufacturers "were liable under state tort law (specifically, that of Minnesota and Louisiana) for failing to provide adequate warning labels" warning of the risk of tardive dyskinesia. *Id.* The parties "did not dispute that," under the facts alleged by the plaintiffs, "state law required the Manufacturers to use a different, safer label." *Id.* at 2574.[11]

The parties' agreement in *PLIVA* obviated any need for a searching analysis of the relevant state-law duties. This Court, after all, is an "'arbiter[] of legal questions presented and argued by the parties before [it],'" and it generally refrains from deciding issues without "the benefit of briefing by the parties." *NASA v. Nelson*, 131 S. Ct. 746, 756 n.10 (2011) (quoting *Carducci v. Regan*, 714 F.2d 171, 177 (D.C. Cir. 1983) (Scalia, J.)). Because the parties in *PLIVA* agreed about the underlying content of state law, the Court accepted that "state law imposed on the Manu-

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[11] Given the plaintiffs' concession about the state-law duties, it makes no difference that the original complaints in *PLIVA* contained design-defect claims. *Cf.* Pet. Br. 31. As the case came to this Court, all the claims undisputedly rested on the manufacturers' duty to provide an adequate label. *See Demahy v. Actavis, Inc.*, 593 F.3d 428, 430 (5th Cir. 2010) (characterizing the "one issue on appeal" as whether the FDCA preempts "failure-to-warn claims"), *rev'd*, *PLIVA*, *supra*; *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009) (noting that Mensing did "not challenge[] the district court's characterization" that "all" her claims "at the core . . . assert[ed] failure to warn") (internal quotations omitted), *rev'd*, *PLIVA*, *supra*.

facturers a duty to attach a safer label" to metoclopramide. 131 S. Ct. at 2578.[12]

PLIVA thus turned on whether federal law permitted the manufacturers to comply with that undisputed state-law duty to strengthen the warnings on their drug labels. *See id.* at 2574-77. The Court held that it did not. *Id.* at 2577 (federal law "prevented the Manufacturers from independently changing their generic drugs' safety labels"). Thus, when the Court "compare[d]" the manufacturers' duties under "federal and state law," it concluded that the manufacturers could not possibly "comply with both [the] state and federal requirements." *Id.* at 2573, 2577 (internal quotations omitted). That conclusion flowed directly from the parties' mutual characterization of the state-law duty at issue: had the manufacturers "independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id.* at 2578.

In short, *PLIVA* holds that federal law preempts common-law claims against generic drug manufacturers based on a duty, rooted in negligence, to provide a safer label. It does not address whether

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[12] The Court's understanding of Minnesota and Louisiana law also comported with the statements of those States' highest courts. In Minnesota, a manufacturer's "'knowledge of danger to users'" gives rise to a "'duty to give warning of such dangers.'" *PLIVA*, 131 S. Ct. at 2573 (quoting *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn. 1977)). That duty is an affirmative obligation "based on a concept of negligence." *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 622 (Minn. 1984). Louisiana law likewise imposes on manufacturers a "duty . . . to use reasonable care to provide an adequate warning." *Marks v. OHMEDA, Inc.*, 871 So. 2d 1148, 1155 (La. Ct. App. 2004) (cited by *PLIVA*, 131 S. Ct. at 2573) (internal quotations omitted).

strict-liability claims that involve no such duty are preempted.[13]

4. *Riegel* and *Cipollone* do not support disregarding the New Hampshire Supreme Court's interpretation of state law

Relying on *Riegel* and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), petitioner contends that "common-law liability is" always "premised on the existence of a legal duty" to take some affirmative action. Pet. Br. 41 (internal quotations omitted). But those cases construed *express*-preemption clauses in federal statutes; neither addressed *implied* conflict preemption of state law.

a. *Riegel* and *Cipollone* held that Congress's use of the term "requirement" in an express-preemption provision signals its intent to capture duties imposed by state common law. *See Riegel*, 552 U.S. at 323-25; *Cipollone*, 505 U.S. at 520-24 (plurality). "Congress," the Court explained in *Riegel*, "is entitled to know what meaning this Court will assign to terms regularly used in its enactments." 552 U.S. at 324. Thus, the Court concluded that, "[a]bsent other indication," Congress's explicit "reference to a State's 'requirements' includes its common-law duties." *Id.*

That statutory-interpretation holding does not support finding implied conflict preemption here. It is one thing to interpret the word "requirement" in a statutory phrase as conveying Congress's explicit intent to preempt common-law duties; it is quite an-

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[13] *See Halperin v. Merck, Sharpe & Dohme Corp.*, No. 11-cv-9076, 2012 WL 1204728, at *3 (N.D. Ill. Apr. 10, 2012) (*PLIVA* does not "address strict liability design defect claims" and therefore does not require preemption of claims involving no substantive "state law duty").

other to *infer* conflict preemption where no express-preemption provision evidences Congress's intent to displace state law. *Riegel* made clear that its holding could not justify the latter. Had "Congress wanted" the regimes for medical devices and prescription drugs "to be alike," it "could have applied the pre-emption clause to the entire FDCA." *Id.* at 327. Of course, "[i]t did not do so, but instead wrote a pre-emption clause that applies only to medical devices." *Id.* Congress's preemptive intent regarding medical devices – conveyed by the term "requirement" – therefore has no bearing on the implied-preemption analysis for strict-liability claims.

b. More fundamentally, preemption here turns on the content of petitioner's "state tort duties." *PLIVA*, 131 S. Ct. at 2573. Given the absence of an express congressional statement on preemption, defining those "duties" here is not – as in *Riegel* and *Cipollone* – a matter of divining Congress's perception of state law. Instead, the content of state law in this case is determined by the authoritative decisions of New Hampshire's highest court. *See supra* Part I.A.2.

Invalidating New Hampshire law based on *Cipollone*'s and *Riegel*'s generalized understanding of the common law would eviscerate the principle that this Court defers to state courts' interpretations of state law. Preemption cannot arise from an abstract conflict with state law; it requires a conflict between the FDCA and New Hampshire law as it is actually "interpreted and applied" in the case at hand. *Jones v. Rath Packing Co.*, 430 U.S. 519, 526 (1977). Determining whether such a conflict exists demands deference to the sole body with ultimate authority to interpret New Hampshire law. *See Riley*, 553 U.S. at

425-27. Accordingly, whatever this Court has concluded about Congress's intent to preempt common-law actions in express-preemption statutes, it must accept, for purposes of implied impossibility preemption, New Hampshire's conclusion that its product-liability rules impose no substantive "common law . . . duty" on manufacturers. *Bagley*, 503 A.2d at 825.

c. The plurality's statement in *Cipollone*, repeated in *Riegel*, 552 U.S. at 324, that a damages award "'can be, indeed is designed to be, a potent method of governing conduct'" is not to the contrary. 505 U.S. at 521 (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)). That statement, derived from this Court's decision in *Garmon*, was originally premised on a "special presumption of federal pre-emption relating to the primary jurisdiction of the National Labor Relations Board." *Id.* at 537 n.3 (Blackmun, J., concurring in part, concurring in the judgment in part, and dissenting in part) (internal quotations omitted). The opposite presumption applies here. *See Levine*, 555 U.S. at 565 & n.3, 575; *see also Lohr*, 518 U.S. at 485 (recognizing "the historic primacy of state regulation of matters of health and safety"). And, whatever the merits of *Garmon*'s understanding of state law in general, it does not accurately describe New Hampshire's strict-liability law. *See LeFavor*, 604 A.2d at 572 (strict liability is not a means of enforcing any "required standard of conduct").

Moreover, even this Court's express-preemption cases have acknowledged relevant differences for preemption purposes between state common law as applied in damages actions and direct regulation. *See Cipollone*, 505 U.S. at 538 (Blackmun, J., concurring in part) (noting "the recognized distinction in

this Court's jurisprudence between direct state regulation and the indirect regulatory effects of common-law damages actions"). As the unanimous Court in *Sprietsma* recognized, "unlike most administrative and legislative regulations," common-law claims "perform an important remedial role in compensating accident victims." 537 U.S. at 64. Even leaving aside the particular features of New Hampshire law, therefore, it is "perfectly rational" to treat common-law claims differently when considering an implied-preemption defense. *Id.*; *see Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988) ("incidental regulatory effects" of tort law differ from the "significantly more intrusive" effects of "direct regulation").

B. The District Court's Judgment Is Not Premised On A Duty To Change Sulindac's Labeling

1. Petitioner forfeited that argument

Although the petition presented the question whether *PLIVA* applies to "design-defect claims," Pet. i, petitioner and the government now contend that *PLIVA* "squarely forecloses" Ms. Bartlett's claim, because the district court's judgment assertedly "reflects a duty to alter" sulindac's "labeling." Pet. Br. 36; U.S. Br. 12.[14]

Petitioner failed to preserve that argument. Petitioner's opening post-trial briefs contained no "warning-related pre-emption argument," and the district court held any such argument "waived." App. 73a; *see also* App. 67a. The First Circuit subsequently re-

[14] Not until its certiorari reply did petitioner raise the claim – later advanced by the government (at 9-10, 17) – that "the [jury] instructions in this case make clear that the jury's verdict hinged on . . . a finding that petitioner's FDA-mandated warnings were inadequate." Cert. Reply 1, 8.

jected petitioner's attempt to resurrect the argument as a challenge to the jury instructions, because petitioner "failed to seek" an appropriate instruction "before the jury retired." App. 19a.[15] The appellate court thus had no occasion to pass on whether the judgment is preempted because it purportedly rests on a duty to warn. This Court should not address that question in the first instance.[16]

Petitioner's summary-judgment motion did not preserve its warning-related preemption argument. *Cf.* Pet. Br. 22. To preserve an argument that is rejected "at the summary-judgment stage," a litigant must "renew[]" the argument in its post-trial briefing to "avoid surprise" and "to give the district court an opportunity to correct its own mistakes." *Rekhi v. Wildmood Indus., Inc.*, 61 F.3d 1313, 1318 (7th Cir. 1995) (Posner, J.). That principle is particularly important here, because petitioner's warning-preemption argument requires consideration of the actual evidence, argument, and jury instructions given at trial.[17] Petitioner's argument, therefore, does

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[15] Unchallenged jury instructions generally are binding on the parties. This Court has noted a "considerable prudential objection to reversing a judgment because of instructions that petitioner accepted." *City of Springfield v. Kibbe*, 480 U.S. 257, 259 (1987) (per curiam).

[16] *See Adarand Constructors, Inc. v. Mineta*, 534 U.S. 103, 110 (2001) (per curiam) ("this is a court of final review and not first view") (internal quotations omitted); *Davis v. United States*, 495 U.S. 472, 489 (1990) ("Because this argument was neither raised before nor decided by the Court of Appeals, we decline to address it here.").

[17] *Cf. Dunlap v. G&L Holding Group, Inc.*, 381 F.3d 1285, 1297 (11th Cir. 2004) ("any case of federal preemption of state law is highly dependent upon the facts presented and the claims actually pled by the parties") (internal quotations omitted).

not "present neat abstract issues of law," but rather implicates complex fact-bound issues that should have been raised in a "postverdict motion." *Ortiz v. Jordan*, 131 S. Ct. 884, 893 (2011) (internal quotations omitted).

Nor is petitioner's warning theory simply another "argument" supporting its preemption "claim." The courts below did not see it that way, and this Court has rejected the argument that "'statutory preemption' [is] a sufficient claim to give [a petitioner] license" to raise new preemption theories on appeal. *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 486-87 & n.6 (2008).

2. Strict liability in New Hampshire is not premised on a duty to change a product's labeling

Petitioner's and the government's warning theory also fails on the merits. In New Hampshire, "design defect and failure to warn claims are separate." *LeBlanc v. American Honda Motor Co.*, 688 A.2d 556, 562 (N.H. 1997). A strict-liability design-defect claim asks a jury to evaluate a product's overall risks and benefits to determine if it is "unreasonably dangerous." *Id.* In some cases, a jury can consider a warning's potential to lower a product's risks. *See Vautour*, 784 A.2d at 1182. But the basis for liability remains the product's overall dangerousness, not the warning. *See LeBlanc*, 688 A.2d at 562.[18]

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[18] The government erroneously relies (at 16-17) on *Chellman v. Saab-Scania AB*, but that case held only that a plaintiff asserting a design-defect claim was entitled to a jury "instruction on failure to warn" where his pre-trial statement explicitly asserted the defendant's "failure to warn." 637 A.2d at 150-51 (internal quotations omitted). *Chellman* "did not need to or purport to decide whether proving defective warning and prov-

In a strict-liability design-defect case, unlike in a failure-to-warn case, the legal adequacy of a warning is neither a necessary nor a sufficient condition for finding a product unreasonably dangerous. A legally adequate warning does not immunize a manufacturer from liability for selling an unreasonably dangerous product. *Id.* (strict product "'liability may attach even though . . . there was adequate warning'") (quoting *Thibault*, 395 A.2d at 847). Nor does a legally inadequate warning alone establish a design defect; a product whose benefits exceed its risks is not unreasonably dangerous, whatever its warning. *See id.* at 561-62. In either case, the warning is merely one of "many possible factors" that might influence the product's overall dangerousness. *Vautour*, 784 A.2d at 1182.

This Court squarely recognized that distinction in *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). There, the Court explained that a federal statute expressly preempting pesticide "requirements for 'labeling or packaging'" did not preempt design-defect claims because it is "perfectly clear" that common-law "claims for defective design" do not "require[] that manufacturers label or package their products in any particular way." *Id.* at 444. Thus, although federal law might preempt a failure-to-warn claim demanding that a manufacturer improve a "pesticide's label," *id.* at 453, it does not preempt claims alleging that the pesticide's underlying design is unreasonably dangerous.

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ing defective design in respects apart from warning were two separable ways of proving strict product liability." *Cheshire Med. Ctr. v. W.R. Grace & Co.*, 49 F.3d 26, 32 (1st Cir. 1995). *LeBlanc*, decided after *Chellman* and ignored by the government, confirms that strict-liability design-defect claims are not predicated on a failure to warn.

So too here. As with the design-defect claim in *Bates*, the district court's judgment does not require petitioner to "label or package [sulindac] in any particular way." *Id.* at 444. At most, a warning could have influenced the jury's overall assessment of sulindac's risks. The jury's ultimate conclusion that those risks outstripped sulindac's benefits, however, was not equivalent to a command that petitioner improve its warning. The mere possibility that "a finding of liability . . . would induce [petitioner] to alter [its] label" would not be a sufficient basis for preemption. *Id.* at 445 (internal quotations omitted; third alteration in original).[19]

3. The trial record confirms the judgment was not premised on a duty to improve sulindac's labeling

Petitioner's and the government's effort to equate Ms. Bartlett's claim with the failure-to-warn claim at issue in *PLIVA* also disregards the record. Ms. Bart-

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[19] *Kurns v. Railroad Friction Products Corp.*, 132 S. Ct. 1261 (2012), on which petitioner relies (at 34), addressed field preemption, not conflict preemption. There, the Court reasoned that the threat of liability for failure to warn of a danger posed by a locomotive's design "will inevitably influence a manufacturer's choice whether to use that particular design." 132 S. Ct. at 1268 n.4. Because Congress had occupied a "broad" field relating to "the design, the construction and the material" of locomotives, any "influence" on locomotive design sufficed to bring the claim within the preempted field. *Id.* at 1266, 1268 n.4 (internal quotations omitted). Here, however, petitioner must show an *actual* conflict between the district court's judgment and federal regulation of sulindac's label. *Bates* resolved a similar question in the express-preemption context by holding that design-defect claims do not impose labeling requirements that conflict with federal standards. There is no reason to impute a *greater* congressional intent to preempt design-defect claims here than in *Bates*.

lett's complaint asserted discrete counts alleging design defect (JA104-08) and failure to warn (JA102-04), and the parties litigated the two claims separately. The district court awarded petitioner summary judgment on the failure-to-warn claim because no evidence indicated that a stronger warning would have dissuaded Ms. Bartlett's doctor from prescribing sulindac. App. 116a. That conclusion, however, did not affect the separate strict-liability design-defect claim, whose "chain of causation . . . does not run through the warning." App. 68a.

Thereafter, petitioner "voluntarily withdrew" its comment k defense before trial. App. 36a, 60a-61a. With petitioner's "'comment k' defense out of the case, the adequacy of sulindac's warning . . . was no longer an issue for trial." App. 36a. In light of that tactical decision, petitioner's argument (at 35) that "design-defect and failure-to-warn claims . . . collapse together in cases targeting drugs" is mystifying. Petitioner's primary reason for asserting (at 34-35) that such claims "collapse together" is that most States "follow[] comment k." But, whatever implications comment k may have for design-defect claims in general, it assuredly played no role in the judgment here. *See* App. 36a.

Petitioner's tactical decision to withdraw its comment k defense meant that liability could not be premised on petitioner's failure to provide an adequate warning. True, the warning remained a factor in the overall inquiry: the jury was instructed to consider the possible "effectiveness of a warning" in determining sulindac's risks. JA513-14.[20] But that

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[20] Sulindac's warning remained relevant at petitioner's insistence: petitioner was "unwilling to accept" jury instructions that would have "ke[pt] the warning out of the case" by requir-

does not suggest that liability was predicated on a breach of any *duty* to improve the warning. *See* App. 74a. Only the warning's *effect* on sulindac's overall dangerousness remained relevant; its "adequacy" – whether it discharged petitioner's separate common-law duty to warn prescribers about SJS/TEN – was not a subject for the jury's assessment. App. 36a. Thus, "[t]he warning was not sulindac's defective condition; the unreasonable danger was." App. 67a.[21]

Petitioner cannot even show that it would have avoided liability by strengthening sulindac's warning. Ms. Bartlett presented a plethora of evidence that sulindac's risk of causing SJS/TEN swamped its comparative therapeutic benefits, *see supra* pp. 9-10, and she argued that sulindac thus was a "needless and useless drug," 9/2/2010 p.m. Tr. 48:8. By contrast, petitioner put on no affirmative case. App. 30a. Petitioner therefore lacks any evidentiary basis to argue now that sulindac would have been found reasonable with a better warning. In fact, a warning likely would not have made any difference: FDA staff has concluded that "there is no satisfactory method" for "preventing" SJS/TEN, "short of avoiding drugs altogether." JA639 (Lois La Grenade et al., *Comparison of Reporting of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in Association*

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ing the jury to analyze sulindac "'as if there were no warning.'" JA345.

[21] Contrary to the government's assertion (at 17), Ms. Bartlett's summation reflected the district court's careful distinction between the warning's legal adequacy and its effect on sulindac's overall risk-benefit profile. Counsel noted that the jury could "consider the presence or efficacy or effectiveness of a warning to avoid unreasonable danger" and explained that sulindac's "label [wa]s ineffective" to avoid its otherwise unreasonable danger of causing SJS/TEN. 9/2/2010 p.m. Tr. 83:2-6.

with Selective COX-2 Inhibitors, 28 Drug Safety 917, 922 (2005)). Petitioner therefore cannot say it was held liable for failing to change sulindac's labeling.

Ultimately, the district judge who actually heard the evidence disagreed unequivocally with the government's post-hoc characterization (at 17) of Ms. Bartlett's claim as a "hybrid design-and-warning" claim. He explained, just before closing arguments, that "I want to avoid any suggestion to this jury that there's a duty to warn on [petitioner's] part because this is not a negligence case or even a products liability case that in some way implicates duty." JA496. As the judge emphasized, "[t]his is not a failure to warn case." *Id.* The district court's informed understanding of Ms. Bartlett's claims, as they were actually litigated, merits this Court's deference. *Cf. Sprint/United Mgmt. Co. v. Mendelsohn*, 552 U.S. 379, 384 (2008) (recognizing need for "deference to a district court's familiarity with the details of [a] case").

C. Even If The Judgment Were Premised On A Duty Not To Sell An Unreasonably Dangerous Product, Compliance With That Duty Would Be Possible

Petitioner and the government argue incorrectly that it would be impossible for petitioner to comply with a duty not to sell sulindac in New Hampshire. As the First Circuit correctly explained, the FDCA allows a manufacturer "not to make the drug at all." App. 10a. And numerous manufacturers have voluntarily withdrawn their drugs from the market without violating any federal mandate.[22] Physical impos-

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[22] Aside from an exception for certain life-saving drugs that is not applicable here, *see* 21 U.S.C. § 356c, the FDCA explicitly

sibility exists only where state and federal law "impose directly conflicting duties," as would be the case if "the federal law said, 'you must sell [sulindac],' while the state law said, 'you may not.'" *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 31 (1996). That is not the case here. *See Michigan Canners & Freezers Ass'n, Inc. v. Agricultural Mktg. & Bargaining Bd.*, 467 U.S. 461, 478 n.21 (1984) (no impossibility where law is "cast in permissive rather than mandatory terms").[23]

Petitioner assails what it calls the First Circuit's "stop-selling rationale" because a manufacturer assertedly can always "avoid a conflict between state and federal law by withdrawing from the regulated conduct altogether." Pet. Br. 43-44 (internal quotations omitted). But if suspending sales *is the state-law duty itself*, then the issue is not whether petitioner could "avoid" state law by suspending sales. Rather, it would be perfectly "lawful under federal law for [petitioner] to do what state law require[s] of

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contemplates that manufacturers will voluntarily discontinue drugs that become unsafe or obsolete. *See id.* §§ 355(j)(6), 360(j)(2)(B), 360bb(b)(1). Ten drugs were voluntarily withdrawn for safety reasons between 2000 and 2006. *See* U.S. Gov't Accountability Office, *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process* 10 (Mar. 2006), *available at* http://www.gao.gov/new.items/d06402.pdf; *see also* Wallace F. Janssen, *The Story of the Laws Behind the Labels* (June 1981) ("since 1962 thousands of prescription drugs have been taken off the U.S. market because they lacked evidence of safety and/or effectiveness"), *available at* http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm.

[23] As petitioner's *amicus* recognizes, "the FDCA does not affirmatively *require* [petitioner] to make sulindac or sell it in New Hampshire, so it would not be 'impossible' for [petitioner] to comply with both federal and state law." PLAC Br. 19 n.12.

[it]." *PLIVA*, 131 S. Ct. at 2577; *see* App. 10a (state law can "tell [petitioner] it ought not to [sell sulindac] if risk-benefit analysis weights against the drug").

That modest conclusion has no bearing on the vast majority of impossibility-preemption cases (and no bearing whatsoever on purposes-and-objectives preemption). Where, as in *PLIVA*, state law imposes an affirmative duty on a manufacturer to improve the product's label, suspending sales does not *comply* with the state-law duty; it merely offers an indirect means of avoiding liability for noncompliance with that duty.[24] By contrast, where liability is imposed for selling an unreasonably dangerous product that cannot be improved through a different design or label, a manufacturer's decision to remove its product from the market does not conflict with any federal mandate. If a State's strict-liability law imposes a tort duty on a manufacturer to withdraw an unreasonably dangerous drug from the market, nothing in federal law preempts that decision.

II. THE JUDGMENT POSES NO OBSTACLE TO THE FEDERAL REGIME

Petitioner now devotes an entire section of its merits brief (at 46-62) to arguing that the district court's judgment conflicts with Congress's purposes and objectives. Petitioner failed to raise that issue in its

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[24] *PLIVA*'s facts underscore that distinction. There, the injured patients took metoclopramide "for several years" and alleged that the manufacturers should have warned of the unique risks of "long-term" use. 131 S. Ct. at 2573. The duty alleged thus was not to withdraw metoclopramide from the market, but to instruct prescribers how to use it safely. Given those allegations, it is far from clear the manufacturers could have avoided liability even by suspending sales. *Cf. Hodder v. Goodyear Tire & Rubber Co.*, 426 N.W. 826, 833 (Minn. 1988) (noting that manufacturer's "duty to warn" can "continu[e] post-sale").

certiorari petition, which asserted a conflict with *PLIVA*. *See* Pet. i (asserting conflict with *PLIVA*); *PLIVA*, 131 S. Ct. at 2581 n.7 (noting purposes-and-objectives preemption not argued there); Opp. 21, 28 n.22. The Court should not consider that argument. *See* Sup. Ct. R. 14.1(a); *Beck v. PACE Int'l Union*, 551 U.S. 96, 104 n.3 (2007); *Exxon*, 554 U.S. at 486-87.

In any event, petitioner's new argument lacks merit. Obstacle preemption, like impossibility preemption, has "a high threshold." *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 110 (1992) (Kennedy, J., concurring in part and concurring in the judgment). An impermissible obstacle exists only if state law "impose[s] prohibitions or obligations which are in direct contradiction to Congress' primary objectives, as conveyed with clarity" in federal law. *Id.* Thus, obstacle-preemption analysis is not a "free-wheeling judicial inquiry into whether a state statute is in tension with federal objectives, but an inquiry into whether the ordinary meanings of state and federal law conflict." *Levine*, 555 U.S. at 588 (Thomas, J., concurring in the judgment) (internal quotations omitted). No obstacle exists here.

A. State-Law Claims Like Ms. Bartlett's Complement The FDCA

State damages actions further the FDCA's "high purpose" of "protect[ing] consumers who . . . are largely unable to protect themselves" from dangerous drugs. *Kordel v. United States*, 335 U.S. 345, 349 (1948). They "serve a distinct compensatory function," which "may motivate injured persons to come forward with information" useful to FDA. *Levine*, 555 U.S. at 579.

The incentive that tort law provides for injured patients to make their injuries known provides an

essential supplement to FDA regulation. *See id.* ("[s]tate tort suits uncover unknown drug hazards"); *Bates*, 544 U.S. at 451. The risk-benefit profile of FDA-approved drugs often changes during "the postmarketing phase" as "new risks emerge." *Levine*, 555 U.S. at 579; *see id.* at 569 (noting that "risk information accumulates over time"). As *Levine* recognized, FDA "has limited resources to monitor the 11,000 drugs on the market" and often lacks optimal information about post-approval risks. *Id.* at 578-79.[25] The agency thus depends on manufacturers to "maintain extensive clinical records and make numerous reports to FDA." U.S. Br. 26; *accord Levine*, 555 U.S. at 578-79 (noting manufacturers' "superior access to information about their drugs"). Damages actions – by opening a manufacturer's files to civil discovery and subjecting its assertions to adversarial rigor – facilitate the information-gathering process on which FDA surveillance depends.

This case well illustrates that principle. When FDA first approved sulindac, then-available "clinical studies" revealed "only relatively mild" side effects. JA596 (Park, 142 Arch. Intern. Med at 1292). Only during "postmarketing clinical experience" did "reports beg[i]n to accumulate" detailing the serious risks of SJS/TEN. *Id*. The evidence below highlighted that clinical experience, as experts offered a "litany of specific facts" to support their conclusion that sulindac's risks outweighed its benefits. App. 42a;

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[25] The government insinuates (at 10-11) that there must be conflict preemption because Ms. Bartlett's counsel at trial criticized FDA's post-market surveillance capabilities. But counsel's statements were premised directly on the very same studies on which this Court relied in *Levine*. *Compare* 9/2/2010 p.m. Tr. 78-80 *with Levine*, 555 U.S. at 578 n.11.

see App. 42a-47a (describing trial evidence). Ms. Bartlett unearthed several of those facts in discovery, including critical data contained in the unpublished Pharmacia Report. *See* JA166 (ordering supplemental deposition given "significance of the recently discovered manuscript"). Those data showed that sulindac's adjusted reporting rate of SJS/TEN from 1980-1997 "was the highest of any NSAID" on the market. App. 45a; *see* JA626-34.

That evidence, combined with FDA's own conclusion that no particular NSAID is more effective than any other at relieving muscle pain, *see* JA559, and petitioner's lack of affirmative evidence to the contrary, convinced the jury that sulindac's risk of SJS/TEN outweighed its benefits. The jury's determination that petitioner should remedy Ms. Bartlett's injuries fulfilled New Hampshire law's "distinct compensatory function." *Levine*, 555 U.S. at 579. This lawsuit also "aid[ed] in the exposure of new dangers," *Bates*, 544 U.S. at 451 (internal quotations omitted), by surfacing a critical new document revealing sulindac's high adjusted reporting rate for SJS/TEN.

Reversal thus would thwart the FDCA's core purpose of "bolster[ing] consumer protection against harmful products." *Levine*, 555 U.S. at 574. It also would extinguish "'all means of judicial recourse'" for injured consumers of generic drugs. *Lohr*, 518 U.S. at 487 (plurality) (quoting *Silkwood*, 464 U.S. at 251). As the First Circuit observed, patients like Ms. Bartlett have already "lost [their] warning claim[s] by the mere chance of [their] drug store's selection of a generic." App. 11a. This Court should not presume that Congress silently intended to eliminate their only "remaining avenue of relief." *Id.*; *see Bruesewitz*

v. Wyeth LLC, 131 S. Ct. 1068, 1080 (2011) (Court has "expressed doubt that Congress would quietly preempt product-liability claims without providing a federal substitute").

B. Petitioner's Obstacle-Preemption Arguments Lack Any Statutory Basis

Petitioner argues (at 53-58) that the FDCA's premarket approval provisions immunize manufacturers of FDA-approved drugs from state-law damages actions. But the FDCA's fundamental command is that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug" without first securing FDA approval. 21 U.S.C. § 355(a). That straightforward prohibitory language tasks FDA with ensuring that no manufacturer "market[s] a drug without federal approval," *not* with guaranteeing a manufacturer's "unfettered right, for all time, to market its drug." *Levine,* 555 U.S. at 592 (Thomas, J., concurring in the judgment).

Congress knows how to "explicitly grant[]" an entity "authorization, permission, or power" to engage in some activity; it typically does so by providing that an entity "may" engage in that activity. *Barnett Bank*, 517 U.S. at 34-35; *see id.* at 33 (collecting statutes conferring such authorization). Congress's failure to include similar language in the FDCA demonstrates it did not intend FDA approval to confer on manufacturers an affirmative right to market drugs free of common-law liability. Petitioner's repeated references (at 28, 40, 43) to a supposed "right to engage in interstate commerce" thus fundamentally mischaracterize the governing statute.

Levine reinforces that conclusion. There, Wyeth argued that "the FDCA establishes both a floor and a ceiling for drug regulation" and that Ms. Levine's

damages action "interfere[d]" with FDA's efforts to "strike a balance between competing objectives." 555 U.S. at 573 (internal quotations omitted). The Court rejected those arguments because "all evidence of Congress' purposes is to the contrary." *Id.* at 574. It explained that Congress's apparent determination "that widely available state rights of action provided appropriate relief for injured consumers," and its decision not to "enact[] an express pre-emption provision at [any] point during the FDCA's 70-year history," were "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety." *Id.* at 574-75.

Levine's holding that the FDCA embodies no congressional purpose to preempt damages judgments in failure-to-warn cases applies equally to the district court's judgment here.[26] Petitioner fails to identify any statutory language not before the Court in *Levine*. Instead, it relies (at 54, 58) on FDA's authority to approve (and withdraw approval of) an application to market a drug. But Congress intended that authority to offer consumers "protection *against* harmful products" – not to subsidize the distribution of products that FDA deems safe. *Levine*, 555 U.S. at 574 (emphasis added); *see United States v. Dotterweich*, 320 U.S. 277, 280 (1943) (FDCA's core purpose is "to keep impure and adulterated food and

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[26] The government maintains (at 33) that the *Levine* Court's conclusion is inapplicable because the Court cited Justice Ginsburg's dissent in *Riegel*. The government asserts that the cases Justice Ginsburg cited (despite her statement to the contrary) "primarily involved failure-to-warn claims." *See Riegel*, 552 U.S. at 340 (Ginsberg, J., dissenting) (discussing "claims for drug labeling *and design defects*") (emphasis added). But for decades courts have considered design-defect claims independent of any free-standing duty to warn. *See supra* note 3.

drugs out of the channels of commerce").[27] Nothing about the district court's judgment affects – much less undermines – FDA's ability to perform its gatekeeping function.

Moreover, petitioner is mistaken (at 56) that the statute evinces an intent to prohibit "lay juries" from evaluating drug safety. The jury's determination that sulindac was unreasonably dangerous directly parallels the FDCA's misbranding provision, which provides that a drug is "misbranded" – and therefore cannot be sold in interstate commerce, *see* 21 U.S.C. § 331 – if it is "dangerous to health" when used as provided in the labeling. *Id.* § 352(j). The FDCA "contemplates that federal *juries* will resolve most misbranding claims," *Levine*, 555 U.S. at 570 (emphasis added), and FDA's "belief that a drug is misbranded is not conclusive," *id.* Thus, Congress did not intend to preclude juries wholesale from determining whether drugs are unreasonably "dangerous to health" in light of their labeling, 21 U.S.C. § 352(j). *See Bates*, 544 U.S. at 452 (rejecting preemption argument based on mistrust of juries because, in prosecutions under federal pesticide law, "juries necessarily pass on allegations of misbranding").[28]

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[27] The "statutory protections" cited by petitioner (at 54) confirm FDA's gatekeeper role: those protections apply to FDA's authority to "withdraw," "suspend," or "refus[e]" approval of a drug application. 21 U.S.C. § 355(e), (h). None suggests FDA authority affirmatively to promote drug sales.

[28] Petitioner also asserts (at 58) that the district court's judgment "strips" it of the "protections federal law grants [it] before [its] products lawfully can be ordered withdrawn from interstate commerce." But the judgment does not "order[]" petitioner to "withdraw[]" sulindac from interstate commerce; it simply requires petitioner to pay damages. *See supra* pp. 18-22.

C. The Government's Assertion That The District Court's Judgment Impedes FDA Regulation Is Unpersuasive

The government acknowledges (at 21) that "[s]everal factors do weigh" *against* finding design-defect claims preempted. Chief among those factors, which the government regards as "significant," is *Levine*'s holding that many "state-law tort actions have long been understood to complement FDA drug-safety regulation." *Id.* at 22.

Nonetheless, despite calling (at 12) the issue "difficult and close," the government concludes that Ms. Bartlett's claim conflicts with federal law because it assertedly allowed a jury to "second-guess FDA's safety determination" and thereby undermined the "assurance that FDA's approval provides" to drug manufacturers. *Id.* at 28 (internal quotations and brackets omitted). That asserted conflict, as the government essentially concedes, lacks any grounding in the statute. *See id.* at 21 (acknowledging nothing in FDCA requires a "manufacturer be guaranteed the ability" to sell an approved drug "in any particular State"); *supra* pp. 43-45. It also conflicts with FDA's previous positions, depends on unfounded assumptions about the effect of the district court's judgment, and misstates the record in this case.

Regardless, petitioner cross-examined Ms. Bartlett's witnesses, had an opportunity (and opted not) to put on its own witnesses and evidence, and received searching review of the verdict from both courts below. Petitioner, therefore, has received no shortage of process.

1. The government's brief deserves no weight because it lacks any basis in lawful regulations and conflicts with FDA's prior positions

This Court does "not defer to an agency's ultimate conclusion about whether state law should be pre-empted." *PLIVA*, 131 S. Ct. at 2575 n.3. The government's assertion that Ms. Bartlett's claim interferes with federal objectives is particularly unpersuasive because FDA has never "embod[ied] [that] determination[] in lawful specific regulations." *Levine*, 555 U.S. at 582 (Breyer, J., concurring). The pertinent regulations – like the FDCA's text – demonstrate that FDA approval merely allows a drug into interstate commerce. *See* 21 C.F.R. § 314.105(a) ("A new drug product . . . may not be marketed until an approval is effective."). FDA's approval decision reflects the agency's judgment that an approved drug "meets the statutory standards" – not that it must (or even should) be sold in any particular State. *Id.* § 314.105(c).

The government asserts that FDA approval has preemptive effect because it reflects the agency's determination that a "drug's likely 'therapeutic benefits . . . outweigh its risk of harm.'" U.S. Br. 24 (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000)) (alteration in original). In *Brown & Williamson*, however, this Court held that FDA's gatekeeper role does not give it authority to promote "public health" in general. 529 U.S. at 139-40 (FDA charged with making only the "specific safety determinations required by the FDCA[]") (internal quotations omitted). Indeed, FDA merely decides whether the FDCA bars a drug from interstate commerce; the medical "consequences of not permitting [a] product

to be marketed" are beyond FDA's purview. *Id.* at 139 (internal quotations omitted).

This case is thus quite unlike *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), on which both petitioner (at 50) and the government (at 28-29) rely. There, the Court found that a suit premised on an automaker's failure to install airbags conflicted with a binding regulation that "deliberately" sought "a mix of several different passive restraint systems." 529 U.S. at 878-79. As this Court later clarified, *Geier* reached that conclusion because the agency had "conducted a formal rulemaking" and embodied its decision to promote manufacturer flexibility in a "specific agency regulation bearing the force of law." *Levine*, 555 U.S. at 580. Like *Levine*, this case involves "no such regulation," but rather turns on FDA's "mere assertion that state law is an obstacle to achieving its statutory objectives." *Id.* at 576. The consideration to be given FDA's position therefore depends on its "thoroughness, consistency, and persuasiveness." *Id.* at 577.

Under that standard, the government's position deserves no weight. Indeed, FDA's position in recent years concerning the FDCA's preemption of state-law actions against drug manufacturers has been decidedly schizophrenic. For years, FDA endorsed the general premise that "product liability plays an important role in consumer protection." 59 Fed. Reg. 3944, 3948 (1994); *see* 63 Fed. Reg. 66,378, 66,384 (1998) ("FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations."). In 2006, FDA abruptly changed views and inserted language in a regulatory preamble propounding the same argument advanced here: that

"[s]tate law actions . . . threaten FDA's statutorily prescribed role as the expert Federal agency" by allowing "lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public." 71 Fed. Reg. 3922, 3935 (2006).

In *Levine*, this Court gave no weight to the preamble because FDA had reversed its "own longstanding position without providing a reasoned explanation." 555 U.S. at 577. Two years later, FDA explained that, in view of *Levine*, it had concluded that "the position on preemption articulated in the preamble . . . cannot be justified under legal principles governing preemption." 76 Fed. Reg. 61,565, 61,565 (2011). It therefore withdrew the entire preamble, including its excursus on the dangers of "lay" juries "second-guess[ing]" FDA's "assessment of benefits versus risks of a specific drug," 71 Fed. Reg. at 3935; *see* 76 Fed. Reg. at 61,565 (noting that preamble had "discussed [FDA's] views on the preemptive effect of both the [attached labeling] regulation[]" and, "more generally, the [FDCA]").

FDA's present attempt to change position *yet again* – without citing even a non-binding preamble in support – is utterly unpersuasive. Not only has the government abandoned its previous view, but it has again formulated its litigating position without providing the "notice or opportunity for comment" essential to a thorough consideration of whether strict-liability claims actually impede federal regulation. *Levine*, 555 U.S. at 577. Accordingly, the government's brief "does not merit deference." *Id.*

2. The government makes baseless assumptions about the effects of the district court's judgment

The government's position also rests on a faulty premise. The government asserts that a damages judgment "would undermine the federal regime *to the extent that* [it] forb[i]d[s] or significantly restrict[s] the marketing of an FDA-approved drug." U.S. Br. 13 (emphasis added). Its preemption position thus depends on the premise that the district court's judgment will force petitioner to "abandon" the market, "cause" the "withdrawal" of sulindac from interstate commerce, "materially increase [sulindac's] price," or "depriv[e] individuals of access to" sulindac. *Id.* at 27-29.

Those assertions are unfounded. Although drug manufacturers have been subject to design-defect liability for decades, *see supra* pp. 3-4, the government identifies no evidence that manufacturers have stopped selling drugs or materially increased their prices in response to state-law damages judgments. *See Bates*, 544 U.S. at 451-52 (rejecting government argument that "exaggerate[d] the disruptive effects of . . . common-law suits" and cited "no evidence" that "tort suits . . . created any real hardship for manufacturers").

Nor is there any evidence that affirming the judgment will have those effects. The jury was permitted to award only compensatory damages, and the record contains no evidence that those damages are sufficiently large to dissuade petitioner (or other manufacturers) from selling sulindac in New Hampshire. *Cf. Silkwood*, 464 U.S. at 258 n.18 (noting lack of "evidence" that damages would "put a licensee out of business" and thus "conflict with [federal] policy"

concerning nuclear safety) (internal quotations omitted).

It is similarly unlikely that the threat of liability in future cases would cause sulindac manufacturers to abandon the market or materially raise their prices. According to petitioner (at 19), "SJS/TEN is exceptionally rare." And the next case (if there is one) could well come out very differently. Petitioner's unorthodox litigating tactics were pivotal to the outcome of this case: petitioner "'engineered' a broader scope of liability by voluntarily withdrawing" its comment k defense "on the eve of trial." App. 60a. Other manufacturers (and presumably petitioner itself) would likely not repeat the same tactic.[29]

3. The government's position mischaracterizes the record

The government's obstacle-preemption argument also fails because the jury verdict in this case did not "second-guess" any "expert determination" by FDA. U.S. Br. 29. Sulindac's risks were not fully apparent when FDA first approved Clinoril in 1978. *See supra* p. 5. Indeed, when Ms. Bartlett's doctor prescribed Clinoril in December 2004, the information contained in Clinoril's NDA was decades out of date. The government does not contend that FDA, at that critical

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[29] The judgment would have no issue-preclusive effect in a subsequent suit against petitioner. In general, "[d]ispersed mass torts" have spurred "great[] distrust of nonmutual preclusion." 18A Charles A. Wright et al., *Federal Practice and Procedure* § 4465.3, at 783 (2d ed. 2002). Moreover, whatever the theoretical possibility of non-mutual issue preclusion, petitioner's decision to waive its comment k defense would negate such preclusion here. *See Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 330 (1979) (calling non-mutual estoppel "unfair" where defendant declines "to defend vigorously" on key issues in first action).

juncture, had analyzed whether its then-decades-old approval of Clinoril's NDA remained justified.

Rather, the government relies on the fact that, after FDA conducted its 2005 review of cardiovascular risks in NSAIDs – i.e., months *after* Ms. Bartlett's 100-day hospital stay began – the agency "did not conclude that sulindac . . . should be withdrawn from the market." U.S. Br. 30 (internal quotations omitted). FDA's failure to so conclude does not conflict in any way with the district court's judgment. First, FDA did not have all the information that was before the jury. Ms. Bartlett's case at trial rested in significant part on the unpublished Pharmacia Report depicting sulindac's adjusted reporting rate for SJS-TEN. *See supra* p. 10.[30] As the district court explained, the "testimony in the case" indicated that the Report's author "had not turned [it] over to the FDA," and the "evidence is that the FDA did not have it." 9/2/2010 p.m. Tr. 108:3-9. Notwithstanding the government's inexplicable, naked assertion (at 30) to the contrary, it identifies not a shred of evidence – in the trial record or elsewhere – to contradict that undisputed testimony.[31]

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[30] *See also*, *e.g.*, 9/2/2010 p.m. Tr. 56:11-18 (summation arguing that "FDA . . . cannot take action based upon information they don't have" and that petitioner's expert "never gave [his] report to the FDA").

[31] The government asserts vaguely (at 30) that FDA "had considered the relevant publication addressing spontaneous reporting rates." But the portions of the record the government cites show only that FDA received a *subsequent*, significantly abridged version of the Pharmacia Report. JA297-98, 364. That version contained the raw number of SJS/TEN reports attributed to sulindac; it omitted sulindac's more probative exact reporting *rate* – controlled for number of prescriptions – that Ms. Bartlett utilized at trial. C.A. App. 2368-73.

Moreover, even if FDA was aware of the Pharmacia Report, there is certainly no evidence that FDA actually considered it. FDA recommended that Bextra be withdrawn from the market because the "reporting rate" of serious skin reactions "appear[ed] to be greater for Bextra" than for certain other (non-sulindac) NSAIDs. JA589. In doing so, FDA never acknowledged, much less grappled with, the Pharmacia Report's conclusion that sulindac's SJS/TEN reporting rate from 1980-1997 "was the highest of any NSAID," App. 45a, or the data indicating that sulindac's "risk/benefit profile" was similar to Bextra's, App. 46a-47a; *see* JA477-85. In fact, neither the 2005 staff memorandum nor the 2006 FDA letter responding to the Citizen Petition even mentioned sulindac.

The record, in short, does not substantiate FDA's assertion that it performed a "comprehensive review" of sulindac's risks and benefits. 2006 Letter at 2. If FDA did perform such a review, it neither documented its decisionmaking process nor bothered to respond to the evidence on which Ms. Bartlett's experts based their conclusions. In such circumstances, the mere absence of agency action carries no weight. *See Levine*, 555 U.S. at 580 (finding no preemption where agency's "contemporaneous record" did not "reveal[] the factors the agency had weighed and the balance it had struck"); *see also Altria Group, Inc. v. Good*, 555 U.S. 70, 89-90 (2008) ("agency nonenforcement of a federal statute is not the same as a policy of approval").

In any event, even assuming FDA "considered the relevant publication" on which Ms. Bartlett relied, U.S. Br. 30, FDA's actions still would not demonstrate any conflict with the district court's judgment.

FDA determined after Ms. Bartlett's injuries that "revisions to labeling" for all NSAIDs were "necessary to make more explicit the risks associated with SJS and TEN." 2006 Letter at 7. When Ms. Bartlett took sulindac, the then-effective label lacked such warnings. JA553-54. As such, the jury's conclusion that sulindac *as labeled in 2004* was unreasonably dangerous did not "second-guess" FDA's expert judgment, because FDA had never opined on whether *that* version of sulindac had benefits that outweighed its risks. *See Lohr*, 518 U.S. at 501 (distinguishing case in which "the Federal Government has . . . reached an unambiguous conclusion about how [the relevant] considerations should be resolved in a particular case").[32]

D. The Hatch-Waxman Act Does Not Immunize Generic Drug Manufacturers From Tort Liability

Petitioner additionally contends (at 46-53) that the district court's judgment conflicts with the Hatch-Waxman Act. But that Act, like the FDCA more broadly, evinces no intent to preempt state-law tort actions. Hatch-Waxman was Congress's response to a specific problem: the burden imposed by the "unnecessary and wasteful" requirement that generic

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[32] Nor did the jury's conclusion turn on its ignorance of the "'patients who reaped [the] benefits'" of sulindac. Pet. Br. 56 (quoting *Riegel*, 552 U.S. at 325). The district court instructed the jury to "consider the usefulness and desirability of [sulindac] to the public as a whole." JA513. Thus, Ms. Bartlett's summation focused on the voluminous evidence showing that sulindac provides no benefit relative to other NSAIDs sufficient to justify its heightened reporting rate of SJS/TEN. 9/2/2010 p.m. Tr. 64-66. Petitioner's failure to rebut that evidence reflects not a flaw in the civil jury system, but its own "tactical decision[]" to forgo any affirmative case. App. 30a-31a.

manufacturers replicate a branded drug's regimen of "clinical trials." H.R. Rep. No. 98-857, pt. 1, at 16. Congress thus created the streamlined ANDA process, which was "designed to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).[33]

In so doing, Congress did not bestow on manufacturers a right to market generic drugs free from tort liability. Congress was presumably no less "aware[] of the prevalence of state tort litigation" when it enacted Hatch-Waxman than when it enacted the FDCA, yet it declined – as in the FDCA – to enact an express-preemption clause. *Levine*, 555 U.S. at 575. That is "powerful evidence" Congress "did not intend FDA oversight" of generic drugs to preempt common-law remedies. *Id.*

Petitioner's attempt to read into Hatch-Waxman a broader preemptive purpose is unpersuasive. Petitioner argues (at 52) Congress must have intended to preempt design-defect actions against generic-drug manufacturers because Congress's goal was to "encourage[] the sale of [generic drugs] in interstate commerce." But Hatch-Waxman did not aim to maximize the sale of generic drugs in all circumstances at

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[33] Hatch-Waxman also awards to certain generic-drug applicants a 180-day exclusivity period in which no other ANDAs will be approved. § 101, 98 Stat. 1589. As with the provisions streamlining the ANDA process, the exclusivity period does not evince Congress's intent to maximize generic-drug sales at all costs; it instead represents a measured attempt "to compensate [generic] manufacturers for research and development costs as well as the risk of litigation from patent holders." *Teva Pharm. USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008).

all costs.[34] Congress had a narrower purpose: "to make available *more* low cost generic drugs *by* establishing a generic drug approval procedure." H.R. Rep. No. 98-857, pt. 1, at 14 (emphases added). The common-law requirement that manufacturers compensate injured consumers is "no more a threat" to that narrow purpose than are requirements that generic drug manufacturers "comply with local fire prevention regulations and zoning codes." *Lohr*, 518 U.S. at 501-02.

Ultimately, petitioner views Hatch-Waxman as silently "preclud[ing] state courts from affording state consumers any protection from injuries resulting from a defective [generic drug]." *Id.* at 487 (plurality). That view not only lacks support in Hatch-Waxman itself, but conflicts with the "'statutory framework' surrounding it." *Id.* at 486 (majority) (quoting *Gade*, 505 U.S. at 111 (Kennedy, J., concurring in part and concurring in the judgment)). Hatch-Waxman, after all, forms part of the broader FDCA regulatory regime, which Congress intended "to bolster consumer protection against harmful products." *Levine*, 555 U.S. at 574. Immunizing generic-drug manufacturers from product-liability claims would vitiate that broader regime.

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[34] *See Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987) (per curiam) ("[N]o legislation pursues its purposes at all costs[,] . . . and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law."); *cf. Sprietsma*, 537 U.S. at 70 (although one "goal[]" of the Federal Boat Safety Act of 1971 is "fostering uniformity," that "interest is not unyielding" and cannot "justify the displacement of state common-law remedies . . . that serve the Act's more prominent objective . . . of promoting boating safety").

III. EVEN UNDER THE GOVERNMENT'S "MISBRANDING" THEORY, THE JUDGMENT SHOULD BE AFFIRMED

This Court also should affirm because the drug that petitioner marketed to Ms. Bartlett was misbranded under federal law. The government concedes (at 23) the FDCA does not preempt state-law duties "not to market" drugs in circumstances that "parallel the FDCA's drug 'misbranding' prohibition." The district court's judgment – to the extent it requires anything other than the payment of damages – fits that description. *See supra* p. 45.[35]

The record refutes the government's contention (at 21) that the jury verdict was not "based on new and scientifically significant information." Not only did FDA never consider the Pharmacia Report on which Ms. Bartlett relied, *see supra* pp. 52-53, but FDA only reexamined NSAIDs *after* Ms. Bartlett had taken sulindac, *see* JA580 n.8. And FDA's subsequent determination that sulindac should bear a strengthened warning suggests, if anything, that sulindac *as sold to Ms. Bartlett* was, in FDA's view, "'dangerous to health' when used as provided in the labeling." U.S. Br. 23 (quoting 21 U.S.C. § 352(j)).

Because the jury reasonably could have concluded that sulindac was misbranded under federal law, this Court should affirm. Alternatively, it should (at most) remand so that Ms. Bartlett is afforded an op-

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[35] Petitioner did not preserve a challenge to the sufficiency of the evidence based on the government's misbranding theory. *See Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 546 U.S. 394 (2006). Nor did it preserve an argument that the instructions should have required the jury expressly to find that the verdict was based on "new" evidence. *See* Fed. R. Civ. P. 51(d)(1).

portunity to prove her case under the government's newly minted standard, which petitioner never raised below. *See Bates*, 544 U.S. at 453 & n.27.

CONCLUSION

The judgment of the court of appeals should be affirmed or, in the alternative, remanded for retrial on misbranding.

Respectfully submitted,

STEVEN M. GORDON
CHRISTINE M. CRAIG
SHAHEEN & GORDON
107 Storrs Street
Concord, NH 03302
(603) 749-5000

KEITH M. JENSEN
JENSEN & ASSOCIATES, PLLC
1024 N. Main Street
Fort Worth, Texas 76164
(817) 334-0762

DAVID C. FREDERICK
Counsel of Record
BRENDAN J. CRIMMINS
JOSHUA D. BRANSON
KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900
(dfrederick@khhte.com)

Counsel for Respondent

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