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

REPLY BRIEF OF PETITIONER MUTUAL PHARMACEUTICAL COMPANY, INC.

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CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rules 24.1(b) and 29.6, Petitioner Mutual Pharmaceutical Company, Inc. ("Mutual") is a wholly owned subsidiary of URL Pharma, Inc. URL Pharma, Inc. is a wholly owned subsidiary of Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"). Caraco's shares are owned in part by Sun Pharmaceutical Industries, Ltd. ("Sun Limited"), and in part by Sun Pharma Global, Inc. Sun Pharma Global, Inc. is wholly owned by Sun Limited. Shares of Sun Limited are traded on both the National Stock Exchange and the Bombay Stock Exchange in India. No other publicly held corporation owns 10 percent or more of Mutual's stock.

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INTRODUCTION

Respondent does not dispute that the federal sameness mandate *Mensing* found dispositive applies equally to generic warnings and generic design. And she essentially abandons the First Circuit's stop-selling theory, which only highlights the direct conflict between state and federal law. Instead, she tries to distinguish *Mensing* on the curious ground that it involved only "negligence-based failure-to-warn claims," Red Br. 1, whereas her strict-liability claim "is not premised on any underlying standard" because it only requires "paying compensatory damages." *Id.*

That distinction is wrong at every turn. As a factual matter, *Mensing* involved both negligence-based and strict liability failure-to-warn claims—as the *Mensing* plaintiffs themselves told this Court. As a constitutional matter, this Court's preemption jurisprudence has *never* distinguished between negligence and strict-liability claims that conflict with federal standards. Instead, the Court's cases repeatedly have found *both* kinds of claims preempted, because the Supremacy Clause prohibits enforcement of any state-law standard that federal law bars a regulated party from satisfying.

Finally, respondent's distinction has no basis in state law, which does not remotely establish the standardless liability scheme respondent imagines. Instead, the New Hampshire Supreme Court has made clear that strict liability does "*not* … impose absolute liability on manufacturers or make them insurers of their products." *Price v. BIC Corp.*, 702

A.2d 330, 333 (1997).[1] Under well-settled law, design-defect plaintiffs injured by a prescription drug thus can recover damages *only if* a jury concludes the drug's benefits outweighed its risks *and* that its warnings were insufficient. No less than in *Mensing*, Hatch-Waxman's sameness mandate bars generic companies from satisfying this state-law standard. The judgment should be reversed.

ARGUMENT

I. Respondent's Design-Defect Claim Directly Conflicts With Federal Law.

Respondent's basic argument is that the Supremacy Clause categorically distinguishes between strict-liability and negligence claims for preemption purposes. Red Br. 18-30. But that distinction is drawn from whole cloth. This Court long ago made clear that federal preemption depends not on whether state law is grounded in negligence or strict liability, but instead on the substantive standard it seeks to enforce: At its core, the Supremacy Clause bars states from enforcing any standard that federal law precludes a regulated party from satisfying. *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985); *AT&T Co. v. Cent. Office Tel., Inc.*, 524 U.S. 214, 221-26 (1998); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

[1] All emphases added unless otherwise noted.

A. The Supremacy Clause Does Not Distinguish Between Negligence And Strict-Liability Claims.

Respondent's principal contention is that the Supremacy Clause preempts state-law claims that enforce a fault-based "duty of care" but not those that impose liability "absent traditional legal fault." *Id.* 20 (quotations omitted). She then claims that distinguishes *Mensing*, which allegedly involved only "negligence claims." *Id.* 24; *id.* 1, 14. Not so.

Factually speaking, it is demonstrably false that *Mensing* involved only negligence claims. As Mutual previously noted with record citations, the *Mensing* complaints included *strict liability* failure-to-warn claims. Blue Br. 14. Respondent never even acknowledges this fact. Instead, she suggests this Court must have *assumed* the plaintiffs' claims sounded only in negligence because that allegedly is how the parties described the claims. Red Br. 25. But the *Mensing* plaintiffs expressly noted their claims sounded in both strict liability and negligence. Br. for Resps. 42, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) ("The principal causes of action asserted by both Ms. Mensing and Ms. Demahy in these cases are traditional products liability claims for inadequate warnings. JA106-13 (strict liability); 115-21 (negligence); 143-45 (implied warranty); JA442-45 (La. Prods. Liab. Act)."). It is unlikely that this Court ignored both the record and the plaintiffs' explicit invocation of their strict-liability claims when it held without qualification that "federal law pre-empts *these lawsuits*." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011).

Facts aside, respondent's theory of preemption is untenable. The Supremacy Clause's plain terms do not distinguish between categories of tort claims for preemption purposes; they instead make federal law "the supreme Law of the Land … *any Thing* in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI cl. 2. It would strain credulity to suggest "the People" understood those broad, unqualified terms as drawing fine distinctions between particular theories of liability when assessing federal law's primacy. *See* S. Johnson, DICTIONARY OF THE ENG. LANGUAGE 2047 (1st ed. 1755) (primary definition of *thing*: "Whatever is; not a person. A general word."); *id.* 141 (primary definition of *any*: "Every; whoever he be; whatever it be. It is, in all its senses, applied *indifferently* to persons or things."). Indeed, the term "thing" historically referenced "[a] matter brought before a court of law; a legal process; a charge brought, a suit or cause pleaded before a court." 11 OXFORD ENG. DICTIONARY 308 (1st ed. reprinted 1970). In that sense, the Constitution's unqualified reference to "any Thing" included *all* legal claims.

Not surprisingly, respondent identifies *no case* where this Court has embraced her newly minted distinction between negligence and strict-liability claims for preemption purposes. Indeed, it is bizarre to think that when state law sanctions a party for violating a standard which federal law barred that party from satisfying, the supremacy of federal law hinges on whether the state deems the party's actions *unreasonable* (preempted) or imposes liability even if the party's actions were *reasonable* (not preempted). A state's moral assessment of "the blameworthiness of the tortfeasor," Torts Profs.' Br.

5, has no logical relevance to federal law's primacy; what matters is whether federal law allowed the regulated party to satisfy the state-law standard being enforced. *Mensing*, 131 S. Ct. at 2579.

That explains why this Court repeatedly has found both negligence and strict-liability claims preempted. *See, e.g.*, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 509 (1992) (complaint "rel[ied] on theories of strict liability, negligence, express warranty, and intentional tort"); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008) (complaint included "claims of strict liability; breach of implied warranty; and negligence"). In either situation, state tort law enforces legal "requirements":

> In *Lohr*, five Justices concluded that common-law causes of action for negligence *and* strict liability do impose "requirements" and would be pre-empted…. We adhere to that view. In interpreting two other statutes we have likewise held that a provision pre-empting state "requirements" pre-empted common-law duties.

Riegel, 552 U.S. at 323-24 (original alteration omitted; citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 512 (1996) (plurality); *id.* at 503-05 (Breyer, J., concurring); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005)).

Given the Court's express recognition that these cases involved negligence *and* strict-liability claims, its references to "duties" in these cases (as well as *Mensing*) could not possibly have been *negligence-specific*. Instead, the cases themselves make clear the term "duty" referenced any claim that enforces a state-law standard, including strict liability. *Riegel*,

552 U.S. at 325 ("[E]xcluding common-law *duties* from the scope of pre-emption would make little sense. State tort law that *requires* a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, *applied by juries under a negligence or strict-liability standard*, is less deserving of preservation.").

Respondent tries to distinguish these cases because they involved express preemption clauses. Red Br. 27-28. But that is irrelevant. Absent contrary indication (like a savings clause), state-law "requirements" which directly conflict with federal law are impliedly preempted. *Mensing*, 131 S. Ct. at 2577 n.5; *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 869 (2000); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995).

What matters, then, is this Court's longstanding recognition that "common-law causes of action for negligence *and* strict liability do impose 'requirements'" within the "normal meaning" of that term. *Riegel*, 552 U.S. at 323-24 (original alteration omitted). Respondent's assertion that strict-liability claims do not "require" anything beyond paying damages and thus *cannot* conflict with federal law is an assault on these decisions. And her suggestion that strict liability might impose "requirements" for purposes of express *but not* implied preemption, Red Br. 27-28, would mean express preemption clauses are *necessary* to preempt common-law claims, which *Mensing* itself refutes. 131 S. Ct. at 2577 n.5.

Indeed, this Court previously has found strict-liability claims impliedly preempted. *International*

Paper Co. v. Ouellette held that federal law preempts strict-liability nuisance claims, and in fact rejected the government's suggestion that such claims might survive preemption because "compensatory damages actions … only require the source to pay for the external costs created by the pollution, and thus do not 'regulate' in a way inconsistent with [federal law]." 479 U.S. 481, 498 n.19 (1987). And this Court elsewhere has found implied preemption where state law imposes no "duty" other than satisfying state standards or avoiding state proscriptions. *Plains Commerce Bank v. Long Family Land & Cattle Co.*, 554 U.S. 316 (2008) (preempting tribal tort law that limited land sales); *Chamber of Commerce of U.S. v. Brown*, 554 U.S. 60 (2008) (preempting state ban on using state funds to support or oppose unions); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992) (plurality) (preempting state standards for hazardous waste workers); *Douglas v. Seacoast Prods., Inc.*, 431 U.S. 265 (1977) (pre-empting state limits on noncitizen fishing rights); *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236 (1959) (preempting state claim that barred union picketing). Each of these cases was wrongly decided under respondent's approach.[2]

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[2] As for respondent's assertion that common-law claims somehow are less susceptible to preemption than positive law, Red Br. 29-30, this Court has said the opposite: "[T]ort law, applied by juries under a negligence or strict-liability standard, is *less* deserving of preservation" than "state regulatory law." *Riegel*, 552 U.S. at 325; *Lohr*, 518 U.S. at 504 (Breyer, J., concurring). Respondent's contrary suggestion cites only Justice Blackmun's partial *dissent* in *Cipollone* and cases interpreting savings clauses that *explicitly preserved* state

B. New Hampshire's Design-Defect Standard Directly Conflicts With Hatch-Waxman's Sameness Requirement.

This Court's decision in *Mensing* compels reversal. Just as in *Mensing*, Hatch-Waxman's sameness requirement made it *impossible* for Mutual to satisfy New Hampshire's design-defect standard, because it forbade Mutual from altering generic sulindac's risk-benefit profile—whether by modifying the drug's active ingredient or altering its warnings. *Mensing*, 131 S. Ct. at 2574 n.2, 2575 (holding that generic drugs must be "identical [to their branded equivalents] in active ingredients, safety, and efficacy" as well as "warning[s]").

The First Circuit tried to evade this conceded problem with the stop-selling theory. PA10a-11a. But respondent barely defends that theory here, and then only as an afterthought. Red Br. 37-39. Instead, she makes the astonishing claim that "strict liability is not premised on *any* underlying standard" except "to compensate consumers." *Id.* 1; *id.* 18-24.

That claim is manifestly incorrect. As respondent elsewhere concedes, New Hampshire's design-defect tort does *not* permit the vast majority of injured

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common-law claims, and which thus are irrelevant here. Red Br. 29-30 (citing *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63-64 (2002) (finding it "rational" for Congress to provide that satisfying federal regulations "does not relieve a person from liability at common law") (quotation omitted); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 186 (1988) (construing savings clause and stating "Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not")).

consumers to recover damages. Instead, damages are available *only if* the injured party can prove the drug was "unreasonably dangerous" because its "risks outweigh its benefits," Red Br. 1; *id*. 21 ("[Strict] liability *turns on whether a product is* '*unreasonably dangerous*' *under [the] 'risk-utility balancing test*.'") (quoting *Price*, 702 A.2d at 332), and that test necessarily requires consideration of both the drug's FDA-mandated active ingredient and its FDA-mandated warnings. PA18a ("[T]he lack of a clearer warning made the product itself more dangerous under [New Hampshire's] risk-benefit test.") (citing *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001)).

That is why the New Hampshire Supreme Court has held that strict liability does "*not* … impose absolute liability on manufacturers or make them insurers of their products." *Price*, 702 A.2d at 333; *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 845-46 (N.H. 1978) ("[S]trict liability is *not* a no-fault system of compensation."). Again, as respondent's own state-law discussion shows, design-defect liability in New Hampshire necessarily hinges on application of a legal standard—one its Supreme Court calls a safety-based design "duty." *Chellman v. Saab-Scania AB*, 637 A.2d 148, 150 (N.H. 1993) ("The duty to warn is part of the general *duty to design, manufacture and sell products that are reasonably safe* for their foreseeable uses.") (citing *Thibault*, 395 A.2d at 847 (describing "manufacturer's *duty to design his product reasonably safely* for the uses which he can foresee")).

In this case, it was *impossible* for Mutual to satisfy New Hampshire's design standard without

violating federal law. State law required the jury to find that sulindac's "risks outweigh its benefits," Red Br. 1; JA539, and respondent herself concedes that inquiry necessarily required consideration of *both* the drug's inherent risks *and* the FDA-mandated "warning's potential to lower [those] risks." Red Br. 32 (citing *Vautour*, 784 A.2d at 1182). Hatch-Waxman's sameness mandate, however, barred Mutual from changing sulindac's FDA-mandated risk-benefit profile, whether by altering the molecule itself or the warnings. U.S. Br. 15 ("[P]etitioner could *not* make changes that created a different active ingredient or strengthened the warning."). That made it impossible for Mutual to comply with New Hampshire's design standard without violating federal law, foreclosing liability as a matter of law.

Mensing is directly on point. Its *rationale* controls, because Mutual had no more power to alter the sulindac molecule than the *Mensing* defendants had to alter the warnings. And *Mensing*'s *holding* controls, because New Hampshire law impermissibly conditioned design-defect liability on the adequacy of Mutual's FDA-mandated warnings—which *Mensing* makes clear Mutual likewise was powerless to alter. 131 S. Ct. at 2574-75.

Indeed, New Hampshire law is crystal clear about this. *First*, it incorporates warnings into its general risk-utility calculus for *all* design-defect cases. *Chellman*, 637 A.2d at 150 ("If the design of a product makes a warning necessary to avoid an unreasonable risk of harm from a foreseeable use, the lack of warning or an ineffective warning causes the product to be defective and unreasonably dangerous."). That is why the jury instructions

(which respondent concedes were "proper," Red Br. 24) provided that liability could be imposed *only* if "a warning was *not* present and effective to avoid [an] unreasonable danger." JA539. The verdict thus condemned both the drug's FDA-mandated active ingredient (violating *Mensing*'s rationale) and its FDA-mandated warnings (violating *Mensing*'s holding).

Second, with regard to pharmaceuticals in particular, New Hampshire's design-defect law follows comment k, which in respondent's own words renders prescription drugs "exempt from strict liability" if "'properly prepared, and accompanied by proper directions and warning.'" BIO 4 (quoting *Restatement (Second) of Torts* § 402A (1965), cmt. k); Blue Br. 34-36.

Respondent now claims Mutual waived the warnings-related aspects of its preemption argument. But this Court can reverse purely on the ground that Hatch-Waxman's sameness mandate barred Mutual from altering the sulindac molecule, and respondent's waiver claim is baseless in any event. Throughout the proceedings, Mutual argued that the sameness mandate preempts any claim challenging generic warnings, starting with its motion for judgment on the pleadings. Blue Br. 21 (discussing Mutual's argument and the court's erroneous response that Mutual could alter its labeling unilaterally). And at summary judgment, Mutual expressly tied this argument to respondent's design-defect claim: "[D]rugs are unavoidably unsafe products, and as such, cannot be defective in design as long as they are accompanied by adequate warnings. As such, any design claim directly

implicates warnings and thus, falls under the same preemption analysis." Preemption MSJ, 2010 WL 1371985, at 31 (citation omitted).

The trial court expressly *agreed* with Mutual that New Hampshire follows comment k, and that this rendered the adequacy of Mutual's FDA-mandated warnings dispositive. PA128a. But it denied summary judgment *solely* because "the adequacy of Sulindac's safety warning is a matter of genuine dispute" requiring trial. *Id*. That was error: Its holding that the adequacy of Mutual's warnings presented a triable issue of fact necessarily depended on rejecting Mutual's purely legal argument that Hatch-Waxman's sameness requirement places the adequacy of generic warnings beyond state law's reach—a conclusion the court reached without the benefit of this Court's subsequent decision in *Mensing*. PA140a (affirming prior rejection of Mutual's warnings-based arguments, PA142-202a). Indeed, the district court cited as authority the very appellate court decisions *Mensing* reversed. *Id*. Had the trial court not made the very error *Mensing* corrected, but instead recognized that Hatch-Waxman's sameness mandate forecloses any challenge to the adequacy of generic product warnings, its holding that comment k rendered the adequacy of Mutual's warnings dispositive would have entitled Mutual to summary judgment.

Mutual's subsequent withdrawal of its comment k *defense* "'for purposes of the trial,'" Blue Br. 23 (quoting record), has no bearing on the purely legal comment k *argument* Mutual advanced at summary judgment. Mutual's point is and always was that Hatch-Waxman's sameness mandate established the

adequacy of its warnings *as a matter of law*, and thus that there was no basis for holding a trial at all. Mutual never retreated from this argument, and given this Court's eventual decision in *Mensing*, Mutual was entitled to reversal *from the moment the court denied summary judgment*.

As for respondent's claim that Mutual needed to renew this argument at Rule 50, Red Br. 31, it is well-settled that purely legal claims rejected at summary judgment need not be renewed. *Chemetall GMBH v. ZR Energy, Inc.*, 320 F.3d 714, 719-20 (7th Cir. 2003) (collecting cases); *Ruyle v. Continental Oil Co.*, 44 F.3d 837, 841 (10th Cir. 1994) (same). Respondent's cases do not remotely suggest otherwise. *Rekhi v. Wildwood Indus., Inc.*, 61 F.3d 1313 (7th Cir. 1995), actually *rejected* waiver claims because renewing the summary-judgment argument was unnecessary "to avoid unfair surprise [or] give the district court an opportunity to correct its own errors." *Id.* at 1318. Those factors are irrelevant here.[3] And unlike *Exxon Shipping Co. v. Baker*,

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[3] Indeed, Mutual gave both respondent and the court "multiple notices of, and a full opportunity to meet, the argument." *TVT Records v. Island Def Jam Music Group*, 412 F.3d 82, 88 n.4 (2d Cir. 2005). Mutual repeatedly pressed its warnings-based arguments in dispositive motions, *supra*; at the charge conference, 9/2/2010 Tr. at 53 (The Court: "How is preemption even an issue anymore?" Mutual: "We shouldn't be here at all."); and indeed post-trial (albeit in reply), where the court again made clear it "would reject Mutual's argument on the merits, for the reasons explained in its earlier opinion" and the Fifth Circuit's soon-to-be-reversed decision in *Demahy*. PA74-75a. No one can claim "unfair surprise," and Mutual gave the court ample opportunity to correct its error—to no avail.

Mutual's preemption argument was not based on "newly cited statutes" raised "for the first time 13 months after … verdict," 554 U.S. 471, 486-87 (2008), but on the federal sameness requirement invoked from the outset. Mutual fully preserved this argument. *City of St. Louis v. Praprotnik*, 485 U.S. 112, 120 (1988).

Respondent's claim that Mutual waived its alleged "challenge to the jury instruction" fares no better, Red Br. 30-31, because Mutual is not "challeng[ing] the jury instruction" under New Hampshire law—which it faithfully reflected. *Price*, 702 A.2d at 333; *Vautour*, 784 A.2d at 1182. The problem instead is with New Hampshire law itself, which (as the instruction accurately stated) required exactly what Mutual always said *Mensing* prohibits: a finding that sulindac's FDA-mandated warnings were inadequate. Respondent's assertion that Mutual was required "to seek an appropriate instruction" thus is baffling, Red Br. 31; Mutual's point is and always was that there never should have been a jury to instruct.

Waiver aside, respondent ultimately claims the instruction is irrelevant because "the basis for liability remains the product's overall dangerousness, not the warning." *Id.* 32; *id.* 35-36. But the First Circuit rejected that assertion, explaining that the warning's alleged inadequacy in fact was critical:

> [T]he label was relevant to the design defect claim since, although unalterable by Mutual, its arguable inadequacies put limits on the extent to which [sulindac's] dangerousness was offset by adequate warnings; *so the lack of*

> *a clearer warning made the product itself more dangerous under the risk-benefit test prescribed by* Vautour. The district court's instructions, in a section covering 'The Warning' [JA539] did make clear that this was the relevance of the label.

PA18a. This holding explains why even respondent ultimately concedes the jury had to consider the "warning's potential to lower a product's risks" in its design-defect calculus. Red Br. 32 (citing *Vautour*, 784 A.2d at 1182).[4]

There is thus no dispute that New Hampshire law made the adequacy of Mutual's FDA-mandated warnings an essential component of the design-defect standard.[5] Indeed, that is why respondent repeatedly attacked Mutual's FDA-mandated label in her case-in-chief. Blue Br. 23-25. Whether viewed

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[4] Respondent seeks to mute this concession by concocting a distinction between the warning's "effect" and its "adequacy." Red Br. 36. But that is not what the appellate court said, and respondent's own cases foreclose that distinction. *Cheshire Med. Ctr. v. W.R. Grace & Co.*, 49 F.3d 26, 32 (1st Cir. 1995) ("The existence *and adequacy of a warning* is relevant not only to a warning defect claim, but also to a design defect claim.") (cited at Red Br. 33 n.18).

[5] It thus is irrelevant that this Court distinguished between the preemptive consequences of design-defect and failure-to-warn claims in *Bates*. Red Br. 33 (citing *Bates*, 544 U.S. at 444, 453). When an express preemption clause covers requirements "*for labeling or packaging*," 544 U.S. at 444 (emphasis original), a verdict's implications for labeling may not matter if (in contrast to this case) a particular claim does not address labeling directly. *Id.* at 445-46.

through comment k or the instructions at a trial that never should have happened, this case was infected with the very conflict *Mensing* found dispositive.[6]

C. The Stop-Selling Theory Is No Solution.

Mutual therefore had two options for avoiding enforcement of New Hampshire's design-defect standard: It could have either (1) altered the drug or its warnings to satisfy state law, and thereby violated federal law; or (2) withdrawn from New Hampshire given the dilemma posed by these directly conflicting standards.

That is a paradigmatic impossibility conflict, and the First Circuit was wrong that withdrawing from the regulated activity somehow resolves it. Blue Br. 37-45. The preemption inquiry pre-supposes that parties engage in the regulated conduct, which is why many preemption cases arise from *pre-enforcement litigation* to enjoin state laws. *See, e.g.*, *Brown*, 554 U.S. at 62; *United States v. Locke*, 529 U.S. 89, 97 (2000); *Gade*, 505 U.S. at 93-94; *Douglas*, 431 U.S. at 270-71. And if preemption is defeated because a party can refrain from the regulated conduct, these cases would have been either dismissed or resolved the other way. State law would trump even when federal law expressly bars

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[6] Respondent now claims "a warning likely would not have made any difference," but that was not her argument below—where she told the jury to find Mutual's FDA-mandated label "'inadequate'" because a reference to SJS/TEN was moved into "'the warning section of the label'" from the previously cross-referenced "'adverse reactions section.'" Blue Br. 23-24 (quoting record).

the regulated party from satisfying state standards; the Supremacy Clause would become irrelevant. *In re Darvocet*, 2012 WL 718618, *3 (E.D. Ky. 2012) ("[T]he idea that [the generic defendants] should have simply stopped selling propoxyphene is an oversimplified solution that could apply anytime the issue of impossibility preemption arises: avoid a conflict between state and federal law by withdrawing from the regulated conduct."). *Mensing*, however, pointedly refused to embrace "an approach to pre-emption that renders conflict pre-emption all but meaningless." 131 S. Ct. at 2579.

Rather than defend the stop-selling rationale on its own terms, respondent claims Mutual was and remains free to market sulindac in violation of state law; it simply must pay damages. Red Br. 1 ("[T]he only state-law obligation is to compensate consumers for injuries."); *also id*. 20, 45, 50. But that is true in every personal-injury case; virtually without exception, damages are the only available relief. Yet this Court has never hesitated to find damages claims preempted, because "'state regulation can be as effectively exerted through … damages as through some form of preventive relief.'" *Cipollone*, 505 U.S. at 521 (quoting *Garmon*, 359 U.S. at 247); *Riegel*, 552 U.S. at 324 ("[A] liability award can be … a potent method of governing conduct.") (quotations omitted).[7] What matters is *the standard* being enforced, not *the relief* sought for a violation. Were it otherwise,

[7] Even where tort claims might seek injunctive relief—as in nuisance—this Court has rejected distinctions based on the form of relief sought. *Ouellette*, 479 U.S. at 498 n.19.

Mensing would have rejected preemption; after all, those claims merely would have resulted in damages.

Finally, respondent asserts there "*would be*" no conflict with federal law "*if* suspending sales is the state-law duty," Red Br. 38 (emphasis shifted), and she claims this distinguishes *Mensing*, where "state law impose[d] an affirmative duty … to improve the product's label." *Id.* 39. But she of course denies that suspending sales *actually is* the state-law duty, and her argument in any event hinges on wordplay. Saying PLIVA would have been liable in *Mensing* "for not improving the label" is the same as saying PLIVA would have been liable "for selling a drug with an unimproved label." And saying Mutual is liable "for selling an unreasonably dangerous product" is the same as saying Mutual is liable "for not making the product less dangerous." However you phrase it, liability hinges on a state-law standard that federal law precludes generic manufacturers from satisfying.

That is the paradigmatic impossibility conflict. Indeed, this Court's classic illustration of impossibility is directly on point: It posits a "situation [where] federal orders forbade the picking and marketing of any avocado testing more than 7% oil, [while] the California test excluded from the State any avocado measuring less than 8% oil content." *Florida Lime*, 373 U.S. at 143. That is this case: Hatch-Waxman forbade Mutual from selling generic sulindac *that differed materially* from brand-name Clinoril®, while New Hampshire's design-defect tort effectively barred the sale of generic sulindac *unless it differed materially* from Clinoril®. If "stop selling" is an answer, *Florida Lime*'s oft-cited

explanation of impossibility is wrong. Yet that formulation has stood the test of time, and it makes clear the stop-selling evasion is no answer where state and federal standards irreconcilably conflict.

D. The Government's Misbranding Theory Is Unavailing.

The United States unqualifiedly agrees that federal law preempts respondent's claim. U.S. Br. 14. It nonetheless proceeds to address the hypothetical question whether "a 'pure' design-defect claim under another State's law that did not consider labeling would be preempted." *Id.* It answers that "such a claim would be preempted unless the claim was based on new and scientifically significant information that rendered the drug misbranded under [the FDCA]." *Id.* 21.

As the government concedes, "this Court … need not decide" that question here. *Id.* 20. To the best of Mutual's knowledge, no state recognizes such a claim. And barring a revolution in the law—roughly 40 states recognize a version of comment k, Blue Br. Add. B—it is doubtful any state will. Lest silence be mistaken for agreement, however, two points bear mention here. First, the government unsuccessfully advanced virtually the same theory in *Mensing*—where it claimed the plaintiffs' failure-to-warn claims survived preemption because they mirrored the misbranding statute. U.S. Br., *Mensing*, 25-30. The government's brief, however, does not reconcile its theory with *Mensing*'s failure to embrace the analogue.

Second, the government's theory is based on a seeming contradiction. Because the statute invoked by the government deems a drug misbranded if it is

"dangerous to health when used in the dosage or manner, or with the frequency or duration *prescribed, recommended, or suggested in the labeling thereof*," 21 U.S.C. § 352(j), it is hard to see how a hypothetical "'pure' design-defect claim … *that d[oes] not consider labeling*," U.S. Br. 20, could parallel that statute. Again, however, the government's brief fails to address this issue. As a result, we respectfully submit that resolution of the hypothetical question raised by the government should await a future case that squarely presents it.[8]

II. Respondent's Claim Frustrates The FDCA's Purposes And Objectives.

Impossibility aside, respondent's claim thoroughly undermines the FDCA's core purposes and objectives. It sanctions precisely what Congress encouraged. And it otherwise thwarts Congress's decision to centralize drug withdrawal decisions in

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[8] To the extent respondent attempts to shoehorn her way into this theory, Red Br. 57-58, the government's misbranding theory is completely different from a New Hampshire design-defect claim. U.S. Br. 20-21. And in any event, respondent did not produce "new and scientifically significant information that rendered [sulindac] misbranded." *Id.* 21. She now invokes a so-called "critical new document revealing sulindac's high adjusted reporting rate for SJS/TEN" relative to other NSAIDs. Red Br. 42. But the government had the data on which the draft was based. U.S. Br. 27, 30 (citing JA 297-98, JA366). And the district court itself deemed the draft "unreliable," 8/20/10 Trial Tr. 31, 38, 41—as did one of its authors, who explained the statements respondent touts were removed before publication because they likewise were considered "unreliable." D. Ct. Dkt. No. 236-7, ¶5.

FDA—which repeatedly has concluded that sulindac should remain available despite its known risks.[9]

A. The Stop-Selling Theory Undermines Hatch-Waxman.

Respondent claims that Mutual's "obstacle preemption arguments lack any statutory basis." Red Br. 43 (capitalization omitted). But Mutual's brief addressed a litany of specific statutory provisions manifesting Congress's intent to both encourage and ensure the sale of affordable generic drugs—with *the same design* and *the same labeling*—whenever their brand-name equivalents come off patent. Blue Br. 46-53.

Respondent's only answer is that Hatch-Waxman does not promote the sale of less-expensive drugs "at all costs." Red Br. 16, 55 n.33, 55-56. But no one is arguing Hatch-Waxman takes a no-holds-barred approach to lowering healthcare costs. As the government explains (U.S. Br. 24-28), Hatch-Waxman's specific statutory provisions require generic design and warnings to be "the same as" their approved branded equivalents—and thus to present *the same risk-benefit profile* embraced by FDA's experts. It is this "special, and different, regulation of generic drugs that allowed the generic

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[9] Respondent's waiver claim is frivolous. Mutual's petition clearly raised purposes-and-objectives arguments. Pet. 31-32. And obstacle preemption is also "fairly included" in the question presented, S. Ct. R. 14(1)(a), which in relevant part asked "Whether the First Circuit erred when it … held … that federal law does not preempt state law design-defect claims targeting generic pharmaceutical[s]." Pet. i.

drug market to expand," *Mensing*, 131 S. Ct. at 2582, and the statute's rigorous sameness requirement that led to "acceptance of, and trust in, generic drugs." *Id*. at 2593 (Sotomayor, J., dissenting).

Design-defect claims undermine Congress's carefully calibrated regime by effectively demanding a manufacturer "abandon a market it has been approved by FDA to enter in order to avoid violating … state tort law." U.S. Br. 28. Indeed, such claims pose the very risks identified by the *Mensing* dissent, without any of the benefits. While different liability rules for generic and branded drugs arguably "threaten to reduce consumer demand for generics," 131 S. Ct. at 2593, state claims that effectively demand withdrawal of generics threaten to leave consumers *without any generic to demand*, "depriving individuals of access to a drug that FDA has determined is safe and effective for sale in the national market." U.S. Br. 29. That is "directly at odds with the Hatch-Waxman Amendments' goal of increasing consumption of generic drugs." *Mensing*, 131 S. Ct. at 2593 (Sotomayor, J., dissenting).[10]

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[10] Respondent says these concerns are overblown because "drug manufacturers have been subject to design-defect liability for decades." Red Br. 50. But of the four cases she marshals, *id*. 4 n.3, three were comment k cases which turned on warnings. *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 655-60 (1st Cir. 1981); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 140 & n.26 (3d Cir. 1973); *Leibowitz v. Ortho Pharm. Corp.*, 307 A.2d 449, 457 (Pa. Super. Ct. 1973). And all four cases involved pre-Hatch-Waxman products, not commoditized generics whose slim sales margins can be overwhelmed by a single verdict. This case well illustrates the difference: According to data recently obtained from IMS Health, Mutual's U.S. sulindac

And while the claim in *Mensing* that generic manufacturers should propose labeling changes to FDA arguably furthers the Agency's mission by aiding its decisionmaking, *id.* at 2588, the claim here depends purely on "second-guessing the FDA." PA10a. Respondent says otherwise, Red Br. 41-42, 52, but again, the government had the data, and the district court repeatedly declared the draft she touts to be "unreliable." *Supra* n.8. Her continued appeal to junk science only underscores the danger in sending these claims before an understandably sympathetic jury. *Riegel*, 552 U.S. at 325; U.S. Br. 28 ("[Second-guessing FDA] would undermine [its] drug-safety determinations, which are made based on sound scientific judgments by an expert federal agency with appropriate access to pertinent safety data.").

As for respondent's claim that damages actions "complement" the statute, Red Br. 40, because they do not actually force "withdrawal of sulindac from interstate commerce," *id.* 50 (quotation omitted), that is true of any claim. A verdict in *Geier*, for instance, would not have compelled Honda to stop selling the Accord; the plaintiff's negligence and design-defect claims merely sought damages because the car lacked airbags. 529 U.S. at 881. The Court found obstacle preemption anyway: Federal law "allow[ed] manufacturers to choose among different passive restraint mechanisms," *id.* at 878, and the

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sales totaled less than $7 million in 2005 (when respondent developed SJS/TEN). Left uncorrected, this single verdict would erase *over three years* of Mutual's *nationwide* sulindac revenues.

plaintiff's tort claims "in effect" created an airbag-only "duty" that "presented an obstacle to the variety and mix of devices that the federal regulation sought." *Id*. at 881.

The case for obstacle preemption is far stronger here. Federal law gave Honda *the option* of installing airbags, so it could have complied with the state standard. But Mutual had *no option* to comply: "[A] brand-name drug and its generic copy must always be the same." *Mensing*, 131 S. Ct. at 2575 (quotation omitted). Respondent says *Geier* is irrelevant because it involved "a 'specific agency regulation bearing the force of law.'" Red Br. 48 (quoting *Wyeth v. Levine*, 555 U.S. 555, 580 (2009)). But Hatch-Waxman's sameness mandate *is the law*, and one need not "wade[] into a sea of agency musings," *Williamson v. Mazda Motor of Am., Inc.*, 131 S. Ct. 1131, 1142 (2011) (Thomas, J., concurring), to recognize that it seeks to "increas[e] consumption of generic drugs" which are the same as their FDA-approved branded equivalents. *Mensing*, 131 S. Ct. at 2593 (Sotomayor, J., dissenting).

B. The Stop-Selling Theory Undermines The Broader FDCA.

Respondent's claim also undermines the broader FDCA, which centralizes authority to compel the withdrawal of approved drugs in FDA and balances that authority with strong due-process protections. Blue Br. 53-58; U.S. Br. 24-30. There is thus no merit to respondent's assertions that FDA is merely a "gatekeeper," Red Br. 1, that does not "confer … an affirmative right to market drugs." *Id.* 43. FDA long ago recognized that ANDA approval confers "rights and privileges that [are] constitutionally

protected," 54 Fed. Reg. 28872, 28904 (1989), and the statutory evolution of FDA's withdrawal authority makes clear that Congress put the Agency in charge of both opening the proverbial "gate" *and closing it*.

Wyeth is not to the contrary. That case had no occasion to consider the stop-selling theory or the evolution of FDA's withdrawal authority over decades. Blue Br. 53-62. As *Mensing* recognized, *Wyeth* instead turned on the fact that federal law specifically allowed Wyeth to alter its label unilaterally. *Wyeth*, 555 U.S. at 571. It thus could not be said that initial FDA approval "established a specific labeling standard that leaves no room for different … judgments," *id.* at 575, because federal law expressly empowered brand companies to deviate from FDA's *initial* labeling and thereby ensured they could accommodate different judgments about labeling. *Id.* at 583 (Thomas, J., concurring) ("[Federal laws] do not give drug manufacturers an unconditional right to market their federally approved drug at all times *with the precise label initially approved by the FDA*."). By contrast, Mutual *never* had authority to deviate from Hatch-Waxman's sameness requirement—and it would fundamentally undermine the statute's careful delegation of withdrawal authority to FDA if state law effectively could demand withdrawal of FDA-approved drugs precisely because they comply with federal standards from which no deviation is lawful.

CONCLUSION

The judgment should be reversed.

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Respectfully submitted,

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