

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

MUTUAL PHARMACEUTICAL CO., INC. v. BARTLETT**CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR
THE FIRST CIRCUIT**

No. 12–142. Argued March 19, 2013—Decided June 24, 2013

The Federal Food, Drug, and Cosmetic Act (FDCA) requires manufacturers to gain Food and Drug Administration (FDA) approval before marketing any brand-name or generic drug in interstate commerce. 21 U. S. C. §355(a). Once a drug is approved, a manufacturer is prohibited from making any major changes to the “qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.” 21 CFR §314.70(b)(2)(i). Generic manufacturers are also prohibited from making any unilateral changes to a drug’s label. See §§314.94(a)(8)(iii), 314.150(b)(10).

In 2004, respondent was prescribed Clinoril, the brand-name version of the nonsteroidal anti-inflammatory drug (NSAID) sulindac, for shoulder pain. Her pharmacist dispensed a generic form of sulindac manufactured by petitioner Mutual Pharmaceutical. Respondent soon developed an acute case of toxic epidermal necrolysis. She is now severely disfigured, has physical disabilities, and is nearly blind. At the time of the prescription, sulindac’s label did not specifically refer to toxic epidermal necrolysis. By 2005, however, the FDA had recommended changing all NSAID labeling to contain a more explicit toxic epidermal necrolysis warning. Respondent sued Mutual in New Hampshire state court, and Mutual removed the case to federal court. A jury found Mutual liable on respondent’s design-defect claim and awarded her over \$21 million. The First Circuit affirmed. As relevant, it found that neither the FDCA nor the FDA’s regulations pre-empted respondent’s design-defect claim. It distinguished *PLIVA, Inc. v. Mensing*, 564 U. S. ___—in which the Court held that failure-to-warn claims against generic manufacturers are pre-empted by the FDCA’s prohibition on changes to generic drug labels—by ar-

Syllabus

guing that generic manufacturers facing design-defect claims could comply with both federal and state law simply by choosing not to make the drug at all.

Held: State-law design-defect claims that turn on the adequacy of a drug’s warnings are pre-empted by federal law under *PLIVA*. Pp. 6–20.

(a) Under the Supremacy Clause, state laws that conflict with federal law are “without effect.” *Maryland v. Louisiana*, 451 U. S. 725, 746. Even in the absence of an express pre-emption provision, a state law may be impliedly pre-empted where it is “impossible for a private party to comply with both state and federal requirements.” *English v. General Elec. Co.*, 496 U. S. 72, 79. Here, it is impossible for Mutual to comply with both its federal-law duty not to alter sulindac’s label or composition and its state-law duty to either strengthen the warnings on sulindac’s label or change sulindac’s design. Pp. 6–13.

(1) New Hampshire’s design-defect cause of action imposes affirmative duties on manufacturers, including a “duty to design [their products] reasonably safely for the uses which [they] can foresee.” *Thibault v. Sears, Roebuck & Co.*, 118 N. H. 802, 809, 395 A. 2d 843, 847. Pp. 7–8.

(2) To assess whether a product’s design is “unreasonably dangerous to the user,” *Vautour v. Body Masters Sports Industries, Inc.*, 147 N. H. 150, 153, 784 A. 2d 1178, 1181, the New Hampshire Supreme Court employs a “risk-utility approach,” which asks whether the danger’s magnitude outweighs the product’s utility, *id.*, at 154, 784 A. 2d, at 1182. The court has repeatedly identified three factors as germane to that inquiry: “the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product’s effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.” *Ibid.* Increasing a drug’s “usefulness” or reducing its “risk of danger” would require redesigning the drug, since those factors are direct results of a drug’s chemical design and active ingredients. Here, however, redesign was not possible for two reasons. First, the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as its brand-name drug equivalent. Second, because of sulindac’s simple composition, the drug is chemically incapable of being redesigned. Accordingly, because redesign was impossible, Mutual could only ameliorate sulindac’s “risk-utility” profile by strengthening its warnings. Thus, New Hampshire’s law ultimately required Mutual to change sulindac’s labeling. Pp. 9–13.

(3) But *PLIVA* makes clear that federal law prevents generic

Syllabus

drug manufacturers from changing their labels. See 564 U. S., at _____. Accordingly, Mutual was prohibited from taking the remedial action required to avoid liability under New Hampshire law. P. 13.

(4) When federal law forbids an action required by state law, the state law is “without effect.” *Maryland, supra*, at 746. Because it was impossible for Mutual to comply with both state and federal law, New Hampshire’s warning-based design-defect cause of action is pre-empted with respect to FDA-approved drugs sold in interstate commerce. Pp. 13–14.

(b) The First Circuit’s rationale—that Mutual could escape the impossibility of complying with both its federal- and state-law duties by choosing to stop selling sulindac—is incompatible with this Court’s pre-emption cases, which have presumed that an actor seeking to satisfy both federal- and state-law obligations is not required to cease acting altogether. Pp. 14–16.

678 F. 3d 30, reversed.

ALITO, J., delivered the opinion of the Court, in which ROBERTS, C. J., and SCALIA, KENNEDY, and THOMAS, JJ., joined. BREYER, J., filed a dissenting opinion, in which KAGAN, J., joined. SOTOMAYOR, J., filed a dissenting opinion, in which GINSBURG, J., joined.

Opinion of the Court

NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D. C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

SUPREME COURT OF THE UNITED STATES

No. 12–142

MUTUAL PHARMACEUTICAL COMPANY, INC.,
PETITIONER *v.* KAREN L. BARTLETT

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF
APPEALS FOR THE FIRST CIRCUIT

[June 24, 2013]

JUSTICE ALITO delivered the opinion of the Court.

We must decide whether federal law pre-empts the New Hampshire design-defect claim under which respondent Karen Bartlett recovered damages from petitioner Mutual Pharmaceutical, the manufacturer of sulindac, a generic nonsteroidal anti-inflammatory drug (NSAID). New Hampshire law imposes a duty on manufacturers to ensure that the drugs they market are not unreasonably unsafe, and a drug’s safety is evaluated by reference to both its chemical properties and the adequacy of its warnings. Because Mutual was unable to change sulindac’s composition as a matter of both federal law and basic chemistry, New Hampshire’s design-defect cause of action effectively required Mutual to change sulindac’s labeling to provide stronger warnings. But, as this Court recognized just two Terms ago in *PLIVA, Inc. v. Mensing*, 564 U. S. ____ (2011), federal law prohibits generic drug manufacturers from independently changing their drugs’ labels. Accordingly, state law imposed a duty on Mutual *not* to comply with federal law. Under the Supremacy Clause, state laws that require a private party to violate federal

Opinion of the Court

law are pre-empted and, thus, are “without effect.” *Maryland v. Louisiana*, 451 U. S. 725, 746 (1981).

The Court of Appeals’ solution—that Mutual should simply have pulled sulindac from the market in order to comply with both state and federal law—is no solution. Rather, adopting the Court of Appeals’ stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in this Court’s pre-emption case law.

Accordingly, we hold that state-law design-defect claims that turn on the adequacy of a drug’s warnings are pre-empted by federal law under *PLIVA*. We thus reverse the decision of the Court of Appeals below.

I

Under the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U. S. C. §301 *et seq.*, drug manufacturers must gain approval from the United States Food and Drug Administration (FDA) before marketing any drug in interstate commerce. §355(a). In the case of a new brand-name drug, FDA approval can be secured only by submitting a new-drug application (NDA). An NDA is a compilation of materials that must include “full reports of [all clinical] investigations,” §355(b)(1)(A), relevant nonclinical studies, and “any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source,” 21 CFR §§314.50(d)(2) and (5)(iv) (2012). The NDA must also include “the labeling proposed to be used for such drug,” 21 U. S. C. §355(b)(1)(F); 21 CFR §314.50(c)(2)(i), and “a discussion of why the [drug’s] benefits exceed the risks under the conditions stated in the labeling,” 21 CFR §314.50(d)(5)(viii); §314.50(c)(2)(ix). The FDA may approve an NDA only if it determines that the drug in question is “safe for use” under “the conditions of use pre-

Opinion of the Court

scribed, recommended, or suggested in the proposed labeling thereof.” 21 U. S. C. §355(d). In order for the FDA to consider a drug safe, the drug’s “probable therapeutic benefits must outweigh its risk of harm.” *FDA v. Brown & Williamson Tobacco Corp.*, 529 U. S. 120, 140 (2000).

The process of submitting an NDA is both onerous and lengthy. See Report to Congressional Requesters, Government Accountability Office, Nov. 2006, *New Drug Development*, 26 *Biotechnology L. Rep.* 82, 94 (2007) (A typical NDA spans thousands of pages and is based on clinical trials conducted over several years). In order to provide a swifter route for approval of generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, popularly known as the “Hatch-Waxman Act.” Under Hatch-Waxman, a generic drug may be approved without the same level of clinical testing required for approval of a new brand-name drug, provided the generic drug is identical to the already-approved brand-name drug in several key respects.

First, the proposed generic drug must be chemically equivalent to the approved brand-name drug: it must have the same “active ingredient” or “active ingredients,” “route of administration,” “dosage form,” and “strength” as its brand-name counterpart. 21 U. S. C. §§355(j)(2)(A)(ii) and (iii). Second, a proposed generic must be “bioequivalent” to an approved brand-name drug. §355(j)(2)(A)(iv). That is, it must have the same “rate and extent of absorption” as the brand-name drug. §355(j)(8)(B). Third, the generic drug manufacturer must show that “the labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug.” §355(j)(2)(A)(v).

Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the “qualitative or quantitative formulation of the drug product, including active ingredients, or in

Opinion of the Court

the specifications provided in the approved application.” 21 CFR §314.70(b)(2)(i). Generic manufacturers are also prohibited from making any unilateral changes to a drug’s label. See §§314.94(a)(8)(iii), 314.150(b)(10) (approval for a generic drug may be withdrawn if the generic drug’s label “is no longer consistent with that for [the brand-name] drug”).

II

In 1978, the FDA approved a nonsteroidal anti-inflammatory pain reliever called “sulindac” under the brand name Clinoril. When Clinoril’s patent expired, the FDA approved several generic sulindacs, including one manufactured by Mutual Pharmaceutical. 678 F. 3d 30, 34 (CA1 2012) (case below); App. to Pet. for Cert. 144a–145a. In a very small number of patients, NSAIDs—including both sulindac and popular NSAIDs such as ibuprofen, naproxen, and Cox2-inhibitors—have the serious side effect of causing two hypersensitivity skin reactions characterized by necrosis of the skin and of the mucous membranes: toxic epidermal necrolysis, and its less severe cousin, Stevens-Johnson Syndrome. 678 F. 3d, at 34, 43–44; Dorland’s Illustrated Medical Dictionary 1872 (31st ed. 2007); Physicians’ Desk Reference 146–147, 597 (6th ed. 2013); Friedman, Orlet, Still, & Law, Toxic Epidermal Necrolysis Due to Administration of Celecoxib (Celebrex), 95 Southern Medical J. 1213, 1213–1214 (2002).

In December 2004, respondent Karen L. Bartlett was prescribed Clinoril for shoulder pain. Her pharmacist dispensed a generic form of sulindac, which was manufactured by petitioner Mutual Pharmaceutical. Respondent soon developed an acute case of toxic epidermal necrolysis. The results were horrific. Sixty to sixty-five percent of the surface of respondent’s body deteriorated, was burned off, or turned into an open wound. She spent months in a

Opinion of the Court

medically induced coma, underwent 12 eye surgeries, and was tube-fed for a year. She is now severely disfigured, has a number of physical disabilities, and is nearly blind.

At the time respondent was prescribed sulindac, the drug's label did not specifically refer to Stevens-Johnson Syndrome or toxic epidermal necrolysis, but did warn that the drug could cause "severe skin reactions" and "[f]atalities." App. 553; 731 F. Supp. 2d 135, 142 (NH 2010) (internal quotation marks omitted). However, Stevens-Johnson Syndrome and toxic epidermal necrolysis were listed as potential adverse reactions on the drug's package insert. 678 F. 3d, at 36, n. 1. In 2005—once respondent was already suffering from toxic epidermal necrolysis—the FDA completed a "comprehensive review of the risks and benefits, [including the risk of toxic epidermal necrolysis], of all approved NSAID products." Decision Letter, FDA Docket No. 2005P-0072/CP1, p. 2 (June 22, 2006), online at <http://www.fda.gov/ohrms/dockets/dockets/05p0072/05p-0072-pav0001-vol1.pdf> (as visited June 18, 2013, and available in Clerk of Court's case file). As a result of that review, the FDA recommended changes to the labeling of all NSAIDs, including sulindac, to more explicitly warn against toxic epidermal necrolysis. App. 353–354, 364, 557–561, 580, and n. 8.

Respondent sued Mutual in New Hampshire state court, and Mutual removed the case to federal court. Respondent initially asserted both failure-to-warn and design-defect claims, but the District Court dismissed her failure-to-warn claim based on her doctor's "admi[ssion] that he had not read the box label or insert." 678 F. 3d, at 34. After a 2-week trial on respondent's design-defect claim, a jury found Mutual liable and awarded respondent over \$21 million in damages.

The Court of Appeals affirmed. 678 F. 3d 30. As relevant, it found that neither the FDCA nor the FDA's regu-

Opinion of the Court

lations pre-empted respondent’s design-defect claims. It distinguished *PLIVA, Inc. v. Mensing*, 564 U. S. ___ —in which the Court held that failure-to-warn claims against generic manufacturers are pre-empted by the FDCA’s prohibition on changes to generic drug labels—by arguing that generic manufacturers facing design-defect claims could simply “choose not to make the drug at all” and thus comply with both federal and state law. 678 F. 3d, at 37. We granted certiorari. 568 U. S. ___ (2012).

III

The Supremacy Clause provides that the laws and treaties of the United States “shall be 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. Accordingly, it has long been settled that state laws that conflict with federal law are “without effect.” *Maryland v. Louisiana*, 451 U. S., at 746; *McCulloch v. Maryland*, 4 Wheat. 316, 427 (1819). See also *Gade v. National Solid Wastes Management Assn.*, 505 U. S. 88, 108 (1992) (“[U]nder the Supremacy Clause, from which our pre-emption doctrine is derived, any state law, however clearly within a State’s acknowledged power, which interferes with or is contrary to federal law, must yield” (internal quotation marks omitted)).

Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly pre-empted where it is “impossible for a private party to comply with both state and federal requirements.” *English v. General Elec. Co.*, 496 U. S. 72, 79 (1990). See also *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U. S. 132, 142–143 (1963) (“A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce”).

Opinion of the Court

In the instant case, it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label. Accordingly, the state law is pre-empted.

A

We begin by identifying petitioner's duties under state law. As an initial matter, respondent is wrong in asserting that the purpose of New Hampshire's design-defect cause of action "is compensatory, not regulatory." Brief for Respondent 19. Rather, New Hampshire's design-defect cause of action imposes affirmative duties on manufacturers.

Respondent is correct that New Hampshire has adopted the doctrine of strict liability in tort as set forth in Section 402A of the Restatement (Second) of Torts. See 2 Restatement (Second) of Torts §402A (1963 and 1964) (hereinafter Restatement 2d). See *Buttrick v. Arthur Lessard & Sons, Inc.*, 110 N. H. 36, 37–39, 260 A. 2d 111, 112–113 (1969). Under the Restatement—and consequently, under New Hampshire tort law—"[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused" even though he "has exercised all possible care in the preparation and sale of the product." Restatement 2d §402A, at 347–348.

But respondent's argument conflates what we will call a "strict-liability" regime (in which liability does not depend on negligence, but still signals the breach of a duty) with what we will call an "absolute-liability" regime (in which liability does not reflect the breach of any duties at all, but merely serves to spread risk). New Hampshire has adopted the former, not the latter. Indeed, the New Hampshire Supreme Court has consistently held that the manufacturer of a product has a "duty to design his product

Opinion of the Court

reasonably safely for the uses which he can foresee.” *Thibault v. Sears, Roebuck & Co.*, 118 N. H. 802, 809, 395 A.2d 843, 847 (1978). See also *Reid v. Spadone Mach. Co.*, 119 N. H. 457, 465, 404 A.2d 1094, 1099 (1979) (“In New Hampshire, the manufacturer is under a general duty to design his product reasonably safely for the uses which he can foresee” (internal quotation marks omitted)); *Chellman v. Saab-Scania AB*, 138 N. H. 73, 78, 637 A.2d 148, 150 (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”); cf. *Simoneau v. South Bend Lathe, Inc.*, 130 N. H. 466, 469, 543 A.2d 407, 409 (1988) (“We limit the application of strict tort liability in this jurisdiction by continuing to emphasize that liability without negligence is not liability without fault”); *Price v. BIC Corp.*, 142 N. H. 386, 390, 702 A.2d 330, 333 (1997) (cautioning “that the term ‘unreasonably dangerous’ should not be interpreted so broadly as to impose absolute liability on manufacturers or make them insurers of their products”). Accordingly, respondent is incorrect in arguing that New Hampshire’s strict-liability system “imposes no substantive duties on manufacturers.” Brief for Respondent 19.¹

¹We can thus save for another day the question whether a true absolute-liability state-law system could give rise to impossibility pre-emption. As we have noted, most common-law causes of action for negligence and strict liability do not exist merely to spread risk, but rather impose affirmative duties. See *Riegel v. Medtronic, Inc.*, 552 U. S. 312, 323–324 (2008) (“In [*Medtronic, Inc. v. Lohr*, 518 U. S. 470 (1996)], five Justices concluded that common-law causes of action for negligence and strict liability do impose ‘requirement[s]’ and would be pre-empted by federal requirements specific to a medical device. . . . We adhere to that view”); *id.*, at 324 (“Absent other indication, reference to a State’s ‘requirements’ includes its common-law duties. As the plurality opinion said in *Cipollone v. Liggett Group*, 505 U. S. 504, 522 (1992), common-law liability is ‘premised on the existence of a legal duty,’ and a tort judgment therefore establishes that the defendant has

Opinion of the Court

B

That New Hampshire tort law imposes a duty on manufacturers is clear. Determining the content of that duty requires somewhat more analysis. As discussed below in greater detail, New Hampshire requires manufacturers to ensure that the products they design, manufacture, and sell are not “unreasonably dangerous.” The New Hampshire Supreme Court has recognized that this duty can be satisfied either by changing a drug’s design or by changing its labeling. Since Mutual did not have the option of changing sulindac’s design, New Hampshire law ultimately required it to change sulindac’s labeling.

Respondent argues that, even if New Hampshire law does impose a duty on drug manufacturers, that duty does not encompass either the “duty to change sulindac’s design” or the duty “to change sulindac’s labeling.” Brief for Respondent 30 (capitalization and emphasis deleted). That argument cannot be correct. New Hampshire imposes design-defect liability only where “the design of the product created a defective condition unreasonably dangerous to the user.” *Vautour v. Body Masters Sports Industries, Inc.*, 147 N. H. 150, 153, 784 A.2d 1178, 1181 (2001); *Chellman, supra*, at 77, 637 A.2d, at 150. To determine whether a product is “unreasonably dangerous,” the New Hampshire Supreme Court employs a “risk-utility approach” under which “a product is defective as designed if the magnitude of the danger outweighs the utility of the product.” *Vautour, supra*, at 154, 784 A.2d, at 1182 (internal quotation marks omitted). That risk-utility approach requires a “multifaceted balancing process involving evaluation of many conflicting factors.” *Ibid.* (internal quotation marks omitted); see also *Thibault, supra*, at 809, 395 A.2d, at 847 (same).

While the set of factors to be considered is ultimately an

violated a state-law obligation”).

Opinion of the Court

open one, the New Hampshire Supreme Court has repeatedly identified three factors as germane to the risk-utility inquiry: “the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product’s effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.” *Vautour, supra*, at 154, 784 A. 2d, at 1182; see also *Price, supra*, at 389, 702 A. 2d, at 333 (same); *Chellman, supra*, at 77–78, 637 A. 2d, at 150 (same).

In the drug context, either increasing the “usefulness” of a product or reducing its “risk of danger” would require redesigning the drug: A drug’s usefulness and its risk of danger are both direct results of its chemical design and, most saliently, its active ingredients. See 21 CFR §201.66(b)(2) (2012) (“Active ingredient means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure of any function of the body of humans” (italics deleted)).

In the present case, however, redesign was not possible for two reasons. First, the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based. 21 U. S. C. §§355(j)(2)(A)(ii)–(v) and (8)(B); 21 CFR §320.1(c). Consequently, the Court of Appeals was correct to recognize that “Mutual cannot legally make sulindac in another composition.” 678 F. 3d, at 37. Indeed, were Mutual to change the composition of its sulindac, the altered chemical would be a new drug that would require its own NDA to be marketed in interstate commerce. See 21 CFR §310.3(h) (giving examples of when the FDA considers a drug to be new, including cases involving “newness for drug use of any

Opinion of the Court

substance which composes such drug, in whole or in part”). Second, because of sulindac’s simple composition, the drug is chemically incapable of being redesigned. See 678 F. 3d, at 37 (“Mutual cannot legally make sulindac in another composition (nor it is apparent how it could alter a one-molecule drug anyway”).

Given the impossibility of redesigning sulindac, the only way for Mutual to ameliorate the drug’s “risk-utility” profile—and thus to escape liability—was to strengthen “the presence and efficacy of [sulindac’s] warning” in such a way that the warning “avoid[ed] an unreasonable risk of harm from hidden dangers or from foreseeable uses.” *Vautour, supra*, at 154, 784 A. 2d, at 1182. See also *Chellman*, 138 N. H., at 78, 637 A. 2d, at 150 (“The duty to warn is part of the general duty to design, manufacture and sell products that are reasonably safe for their foreseeable uses. 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” (citation omitted)). Thus, New Hampshire’s design-defect cause of action imposed a duty on Mutual to strengthen sulindac’s warnings.

For these reasons, it is unsurprising that allegations that sulindac’s label was inadequate featured prominently at trial. Respondent introduced into evidence both the label for Mutual’s sulindac at the time of her injuries and the label as revised in 2005 (after respondent had suffered her injuries). App. 553–556. Her counsel’s opening statement informed the jury that “the evidence will show you that Sulindac was unreasonably dangerous and had an inadequate warning, as well. . . . You will hear much more evidence about why this label was inadequate in relation to this case.” Tr. 110–112 (Aug. 17, 2010). And, the District Court repeatedly instructed the jury that it should evaluate sulindac’s labeling in determining whether

Opinion of the Court

Mutual’s sulindac was unreasonably dangerous. See App. 514 (jury instruction that the jury should find “a defect in design” only if it found that “Sulindac was unreasonably dangerous and that a warning was not present and effective to avoid that unreasonable danger”); *ibid.* (jury instruction that no design defect exists if “a warning was present and effective to avoid that unreasonable danger”). Finally, the District Court clarified in its order and opinion denying Mutual’s motion for judgment as a matter of law that the adequacy of sulindac’s labeling had been part of what the jury was instructed to consider. 760 F. Supp. 2d 220, 231 (2011) (“if the jury found that sulindac’s risks outweighed its benefits, then it could consider whether the warning—regardless of its adequacy—reduced those risks . . . to such an extent that it eliminated the unreasonable danger”).²

Thus, in accordance with New Hampshire law, the jury was presented with evidence relevant to, and was in-

²That Mutual’s liability turned on the adequacy of sulindac’s warnings is not unusual. Rather, New Hampshire—like a large majority of States—has adopted comment *k* to §402A of the Restatement (Second) of Torts, which recognizes that it is “especially common in the field of drugs” for products to be “incapable of being made safe for their intended and ordinary use.” Restatement 2d, at 353; *Bellotte v. Zayre Corp.*, 116 N. H. 52, 54–55, 352 A. 2d 723, 725 (1976). Under comment *k*, “[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.” Restatement 2d, at 353–354. This Court has previously noted that, as of 1986, “a large number of courts” took comment *k* to mean that manufacturers “did not face strict liability for side effects of properly manufactured prescription drugs that were accompanied by adequate warnings.” *Bruesewitz v. Wyeth*, 562 U.S. ___, ___, n. 41 (2011) (slip op., at 10, n. 41).

Mutual withdrew its comment *k* defense “for purposes of the trial of this matter.” Defendant’s Notice of Withdrawal of Defenses, in Case No. 08–cv–358–JL (D NH), p. 1. However, as noted above, both respondent and the trial court injected the broader question of the adequacy of sulindac’s label into the trial proceedings.

Opinion of the Court

structed to consider, whether Mutual had fulfilled its duty to label sulindac adequately so as to render the drug not “unreasonably dangerous.” In holding Mutual liable, the jury determined that Mutual had breached that duty.

C

The duty imposed by federal law is far more readily apparent. As *PLIVA* made clear, federal law prevents generic drug manufacturers from changing their labels. See 564 U. S., at ____ (slip op., at 10) (“Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs’ safety labels”). See also 21 U. S. C. §355(j)(2)(A)(v) (“[T]he labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug”); 21 CFR §§314.94(a)(8)(iii), 314.150(b)(10) (approval for a generic drug may be withdrawn if the generic drug’s label “is no longer consistent with that for [the brand-name] drug”). Thus, federal law prohibited Mutual from taking the remedial action required to avoid liability under New Hampshire law.

D

When federal law forbids an action that state law requires, the state law is “without effect.” *Maryland*, 451 U. S., at 746. Because it is impossible for Mutual and other similarly situated manufacturers to comply with both state and federal law,³ New Hampshire’s

³JUSTICE BREYER argues that it is not “literally impossible” for Mutual to comply with both state and federal law because it could escape liability “either by not doing business in the relevant State or by paying the state penalty, say damages, for failing to comply with, as here, a state-law tort standard.” *Post*, at 1 (dissenting opinion). But, as discussed below, *infra*, at 15–16—leaving aside the rare case in which state or federal law actually requires a product to be pulled from the market—our pre-emption cases presume that a manufacturer’s ability to stop selling does not turn impossibility into possibility. See, *e.g.*,

Opinion of the Court

warning-based design-defect cause of action is pre-empted with respect to FDA-approved drugs sold in interstate commerce.⁴

IV

The Court of Appeals reasoned that Mutual could escape the impossibility of complying with both its federal- and state-law duties by “choos[ing] not to make [sulindac] at

Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 143 (1963) (There would be “impossibility of dual compliance” 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”). And, of course, *PLIVA, Inc. v. Mensing*, 564 U.S. ___ (2011), forecloses any argument that impossibility is defeated by the prospect that a manufacturer could “pa[y] the state penalty” for violating a state-law duty; that prospect would have defeated impossibility in *PLIVA* as well. See *id.*, at ___ (slip op., at 12) (“[I]t was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same”). To hold otherwise would render impossibility pre-emption “all but meaningless.” *Id.*, at ___ (slip op., at 14).

⁴We do not address state design-defect claims that parallel the federal misbranding statute. The misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it is “dangerous to health” even if “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); cf. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005) (state-law pesticide labeling requirement not pre-empted under express pre-emption provision, provided it was “equivalent to, and fully consistent with, [federal] misbranding provisions”). The parties and the Government appear to agree that a drug is misbranded under federal law only when liability is based on new and scientifically significant information that was not before the FDA. Because the jury was not asked to find whether new evidence concerning sulindac that had not been made available to the FDA rendered sulindac so dangerous as to be misbranded under the federal misbranding statute, the misbranding provision is not applicable here. Cf. 760 F. Supp. 2d 220, 233 (NH 2011) (most of respondent’s experts’ testimony was “drawn directly from the medical literature or published FDA analyses”).

Opinion of the Court

all.” 678 F. 3d, at 37. We reject this “stop-selling” rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be “all but meaningless.” 564 U. S., at ____ (slip op., at 14).

The incoherence of the stop-selling theory becomes plain when viewed through the lens of our previous cases. In every instance in which the Court has found impossibility pre-emption, the “direct conflict” between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting.

PLIVA is an obvious example: As discussed above, the *PLIVA* Court held that state failure-to-warn claims were pre-empted by the FDCA because it was impossible for drug manufacturers like *PLIVA* to comply with both the state-law duty to label their products in a way that rendered them reasonably safe and the federal-law duty not to change their drugs’ labels. *Id.*, at ____ (slip op., at 11). It would, of course, have been possible for drug manufacturers like *PLIVA* to pull their products from the market altogether. In so doing, they would have avoided liability under both state and federal law: such manufacturers would neither have labeled their products in a way that rendered them unsafe nor impermissibly changed any federally approved label.

In concluding that “it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same,” *id.*, at ____ (slip op., at 12), the Court was undeterred by the prospect that *PLIVA* could have complied with both state and federal requirements by simply leaving the market. The Court of Appeals decision below had

Opinion of the Court

found that Mensing’s state-law failure-to-warn claims escaped pre-emption based on the very same stop-selling rationale the First Circuit relied on in this case. See *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (CA8 2009) (“[G]eneric defendants were not compelled to market metoclopramide. If they realized their label was insufficient . . . they could have simply stopped selling the product”). Moreover, Mensing advanced the stop-selling rationale in its petition for rehearing, which this Court denied. *PLIVA, supra*; Pet. for Reh’g in No. 09–993 etc., p. 2. Nonetheless, this Court squarely determined that it had been “impossible” for PLIVA to comply with both its state and federal duties. 564 U. S., at ___ (slip op., at 12).⁵

Adopting the First Circuit’s stop-selling rationale would mean that not only *PLIVA*, but also the vast majority—if not all—of the cases in which the Court has found impossibility pre-emption, were wrongly decided. Just as the prospect that a regulated actor could avoid liability under both state and federal law by simply leaving the market did not undermine the impossibility analysis in *PLIVA*, so it is irrelevant to our analysis here.

V

The dreadful injuries from which products liabilities

⁵Respondent attempts to distinguish this case from *PLIVA*, arguing that “[w]here, 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.” Brief for Respondent 39. But that difference is purely semantic: the state-law duty in *PLIVA* to amend metoclopramide’s label could just as easily have been phrased as a duty not to sell the drug without adequate warnings. At least where a State imposes liability based on a balancing of a product’s harms and benefits in light of its labeling—rather than directly prohibiting the product’s sale—the mere fact that a manufacturer may avoid liability by leaving the market does not defeat a claim of impossibility.

Opinion of the Court

cases arise often engender passionate responses. Today is no exception, as JUSTICE SOTOMAYOR’s dissent (hereinafter the dissent) illustrates. But sympathy for respondent does not relieve us of the responsibility of following the law.

The dissent accuses us of incorrectly assuming “that federal law gives pharmaceutical companies a right to sell a federally approved drug free from common-law liability,” *post*, at 1, but we make no such assumption. Rather, as discussed at length above, see *supra*, at 8–13, we hold that state-law design-defect claims like New Hampshire’s that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling. The dissent is quite correct that federal law establishes no safe-harbor for drug companies—but it does prevent them from taking certain remedial measures. Where state law imposes a duty to take such remedial measures, it “actual[ly] conflict[s] with federal law” by making it “impossible for a private party to comply with both state and federal requirements.” *Freightliner Corp. v. Myrick*, 514 U. S. 280, 287 (1995) (quoting *English*, 496 U. S., at 78–79). The dissent seems to acknowledge that point when it concedes that, “if federal law requires a particular product label to include a complete list of ingredients while state law specifically forbids that labeling practice, there is little question that state law ‘must yield.’” *Post*, at 6–7 (quoting *Felder v. Casey*, 487 U. S. 131, 138 (1988)). What the dissent does not see is that *that is this case*: Federal law requires a very specific label for sulindac, and state law forbids the use of that label.

The dissent responds that New Hampshire law “merely create[s] an incentive” to alter sulindac’s label or composition, *post*, at 7, but does not impose any actual “legal obligation,” *post*, at 13. The contours of that argument are

Opinion of the Court

difficult to discern. Perhaps the dissent is drawing a distinction between common-law “exposure to liability,” *post*, at 12, and a statutory “legal mandate,” *ibid.* But the distinction between common law and statutory law is irrelevant to the argument at hand: In violating a common-law duty, as surely as by violating a statutory duty, a party contravenes the law. While it is true that, in a certain sense, common-law duties give a manufacturer the choice “between exiting the market or continuing to sell while knowing it may have to pay compensation to consumers injured by its product,” *post*, at 16, statutory “mandate[s]” do precisely the same thing: They require a manufacturer to choose between leaving the market and accepting the consequences of its actions (in the form of a fine or other sanction). See generally Calabresi & Melamed, Property Rules, Liability Rules, and Inalienability: One View of the Cathedral, 85 Harv. L. Rev. 1089 (1972) (discussing liability rules). And, in any event, *PLIVA*—which the dissent agrees involved a state-law “requirement that conflicted with federal law,” *post*, at 13—dealt with *common-law* failure-to-warn claims, see *PLIVA*, *supra*, at ___ (slip op., at 4). Because *PLIVA* controls the instant case, the dissent is reduced to fighting a rearguard action against its reasoning despite ostensibly swearing fealty to its holding.

To suggest that *Bates v. Dow Agrosciences LLC*, 544 U. S. 431 (2005), is to the contrary is simply misleading. The dissent is correct that *Bates* held a Texas state-law design-defect claim not to be pre-empted. But, it did so because the design-defect claim in question was not a “requirement ‘for labeling or packaging’” and thus fell outside the class of claims covered by the express pre-emption provision at issue in that case. *Id.*, at 443–444 (emphasis in original). Indeed, contrary to the impression one might draw from the dissent, *post*, at 12–13, the *Bates* Court actually *blessed* the lower court’s determination

Opinion of the Court

that the State’s design-defect claim imposed a pre-emptable “requirement”: “The Court of Appeals did, however, correctly hold that the term ‘requirements’ in §136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties.” *Bates, supra*, at 443. The dissent offers no compelling reason why the “common-law duty” in this case should not similarly be viewed as a “requirement.” We agree, of course, that “determining precisely what, if any, specific requirement a state common-law claim imposes is important.” *Post*, at 12, n. 5. As *Bates* makes clear, “[t]he proper inquiry calls for an examination of the elements of the common-law duty at issue; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action.” 544 U. S., at 445 (citation omitted). Here, as we have tried to make clear, the duty to ensure that one’s products are not “unreasonably dangerous” imposed by New Hampshire’s design-defect cause of action, *Vautour*, 147 N. H., at 153, 784 A. 2d, at 1181, involves a duty to make one of several changes. In cases where it is impossible—in fact or by law—to alter a product’s design (and thus to increase the product’s “usefulness” or decrease its “risk of danger”), the duty to render a product “reasonably safe” boils down to a duty to ensure “the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.” *Id.*, at 154, 784 A. 2d, at 1182. The duty to redesign sulindac’s label was thus a part of the common-law duty at issue—not merely an action Mutual might have been prompted to take by the adverse jury verdict here.

Finally, the dissent laments that we have ignored “Congress’ explicit efforts to preserve state common-law liability.” *Post*, at 26. We have not. Suffice to say, the Court would welcome Congress’ “explicit” resolution of the difficult pre-emption questions that arise in the prescrip-

Opinion of the Court

tion drug context. That issue has repeatedly vexed the Court—and produced widely divergent views—in recent years. See, e.g., *Wyeth v. Levine*, 555 U. S. 555 (2009); *PLIVA*, 564 U. S. _____. As the dissent concedes, however, the FDCA’s treatment of prescription drugs includes neither an express pre-emption clause (as in the vaccine context, 42 U. S. C. §300aa–22(b)(1)), nor an express non-pre-emption clause (as in the over-the-counter drug context, 21 U. S. C. §§379r(e), 379s(d)). In the absence of that sort of “explicit” expression of congressional intent, we are left to divine Congress’ will from the duties the statute imposes. That federal law forbids Mutual to take actions required of it by state tort law evinces an intent to pre-empt.

* * *

This case arises out of tragic circumstances. A combination of factors combined to produce the rare and devastating injuries that respondent suffered: the FDA’s decision to approve the sale of sulindac and the warnings that accompanied the drug at the time it was prescribed, the decision by respondent’s physician to prescribe sulindac despite its known risks, and Congress’ decision to regulate the manufacture and sale of generic drugs in a way that reduces their cost to patients but leaves generic drug manufacturers incapable of modifying either the drugs’ compositions or their warnings. Respondent’s situation is tragic and evokes deep sympathy, but a straightforward application of pre-emption law requires that the judgment below be reversed.

It is so ordered.

BREYER, J., dissenting

SUPREME COURT OF THE UNITED STATES

No. 12–142

MUTUAL PHARMACEUTICAL COMPANY, INC.,
PETITIONER *v.* KAREN L. BARTLETT

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF
APPEALS FOR THE FIRST CIRCUIT

[June 24, 2013]

JUSTICE BREYER, with whom JUSTICE KAGAN joins,
dissenting.

It is not literally impossible here for a company like petitioner to comply with conflicting state and federal law. A company can comply with both either by not doing business in the relevant State or by paying the state penalty, say damages, for failing to comply with, as here, a state-law tort standard. See *post*, at 16–18 (SOTOMAYOR, J., dissenting). But conflicting state law that requires a company to withdraw from the State or pay a sizable damages remedy in order to avoid the conflict between state and federal law may nonetheless “‘stan[d] as an obstacle to the accomplishment’ of” the federal law’s objective, in which case the relevant state law is pre-empted. *Post*, at 17 (quoting *Crosby v. National Foreign Trade Council*, 530 U. S. 363, 373 (2000)).

Normally, for the reasons I set forth in *Medtronic, Inc. v. Lohr*, 518 U. S. 470, 503 (1996) (opinion concurring in part and concurring in judgment), in deciding whether there is such a conflict I would pay particular attention to the views of the relevant agency, here the Food and Drug Administration (FDA). Where the statute contains no clear pre-emption command, courts may infer that the administrative agency has a degree of leeway to determine the extent to which governing statutes, rules, regulations,

BREYER, J., dissenting

or other administrative actions have pre-emptive effect. See *id.*, at 505–506 (citing *Smiley v. Citibank (South Dakota), N. A.*, 517 U. S. 735, 739–741 (1996); *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U. S. 707, 721 (1985); *Lawrence County v. Lead-Deadwood School Dist. No. 40–1*, 469 U. S. 256, 261–262 (1985); *Chevron U. S. A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U. S. 837, 842–845 (1984)). See also *Wyeth v. Levine*, 555 U. S. 555, 576–577 (2009). Cf. *Skidmore v. Swift & Co.*, 323 U. S. 134, 140 (1944). The FDA is responsible for administering the relevant federal statutes. And the question of pre-emption may call for considerable drug-related expertise. Indeed, one might infer that, the more medically valuable the drug, the less likely Congress intended to permit a State to drive it from the marketplace.

At the same time, the agency can develop an informed position on the pre-emption question by providing interested parties with an opportunity to present their views. It can translate its understandings into particular pre-emptive intentions accompanying its various rules and regulations. And “[i]t can communicate those intentions . . . through statements in ‘regulations, preambles, interpretive statements, and responses to comments.’” *Medtronic, supra*, at 506 (opinion of BREYER, J.). (quoting *Hillsborough, supra*, at 718).

Here, however, I cannot give special weight to the FDA’s views. For one thing, as far as the briefing reveals, the FDA, in developing its views, has held no hearings on the matter or solicited the opinions, arguments, and views of the public in other ways. For another thing, the FDA has set forth its positions only in briefs filed in litigation, not in regulations, interpretations, or similar agency work product. See *Bowen v. Georgetown Univ. Hospital*, 488 U. S. 204, 212–213 (1988) (“[A]gency litigating positions that are wholly unsupported by regulations, rulings, or

BREYER, J., dissenting

administrative practice” are entitled to less than ordinary weight). Cf. *Christensen v. Harris County*, 529 U. S. 576, 587 (2000).

Finally, the FDA has set forth conflicting views on this general matter in different briefs filed at different times. Compare *Wyeth, supra*, at 577, 579, 580, n. 13 (noting that the FDA had previously found *no* pre-emption, that the United States now argued *for* pre-emption, and that this new position was not entitled to deference), with *PLIVA, Inc. v. Mensing*, 564 U. S. ____, ____, n. 3, ____ (2011) (slip op., at 6–7, n. 3, 8–11) (declining to defer to the United States’ argument against pre-emption and, instead, finding pre-emption), and with Brief for United States as *Amicus Curiae* 12–13 (now arguing, again, for pre-emption). See *National Cable & Telecommunications Assn. v. Brand X Internet Services*, 545 U. S. 967, 981 (2005) (agency views that vary over time are accorded less weight); *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 41–42 (1983) (same); *Verizon Communications Inc. v. FCC*, 535 U. S. 467, 502, n. 20 (2002) (same).

Without giving the agency’s views special weight, I would conclude that it is not impossible for petitioner to comply with both state and federal regulatory schemes and that the federal regulatory scheme does not pre-empt state common law (read as potentially requiring petitioner to pay damages or leave the market). As two former FDA Commissioners tell us, the FDA has long believed that state tort litigation can “supplemen[t] the agency’s regulatory and enforcement activities.” Brief for Donald Kennedy et al. as *Amici Curiae* 5. See also *Wyeth, supra*, at 578 (“In keeping with Congress’ decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation”).

Moreover, unlike the federal statute at issue in *Med-*

BREYER, J., dissenting

tronic, the statute before us contains no general pre-emption clause. See 518 U. S., at 481–482. Cf. *Wyeth, supra*, at 574 (presence of pre-emption clause could show that “Congress thought state-law suits posed an obstacle to its objectives”). Furthermore, I have found no convincing reason to believe that removing this particular drug from New Hampshire’s market, or requiring damage payments for it there, would be so harmful that it would seriously undercut the purposes of the federal statutory scheme. Cf. *post*, at 21–22.

Finally, similarly situated defendants in other cases remain free to argue for “obstacle pre-emption” in respect to damage payments or market withdrawal, and demonstrate the impossibility-of-compliance type of conflict that, in their particular cases, might create true incompatibility between state and federal regulatory schemes.

For these reasons, I respectfully dissent.

SOTOMAYOR, J., dissenting

SUPREME COURT OF THE UNITED STATES

No. 12–142

MUTUAL PHARMACEUTICAL COMPANY, INC.,
PETITIONER *v.* KAREN L. BARTLETT

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF
APPEALS FOR THE FIRST CIRCUIT

[June 24, 2013]

JUSTICE SOTOMAYOR, with whom JUSTICE GINSBURG joins, dissenting.

In *PLIVA, Inc. v. Mensing*, 564 U. S. ____ (2011), this Court expanded the scope of impossibility pre-emption to immunize generic drug manufacturers from state-law failure-to-warn claims. Today, the Court unnecessarily and unwisely extends its holding in *Mensing* to pre-empt New Hampshire’s law governing design-defects with respect to generic drugs.

The Court takes this step by concluding that petitioner Mutual Pharmaceutical was held liable for a failure-to-warn claim in disguise, even though the District Court clearly rejected such a claim and instead allowed liability on a distinct theory. See *infra*, at 13–15. Of greater consequence, the Court appears to justify its revision of respondent Karen Bartlett’s state-law claim through an implicit and undefended assumption that federal law gives pharmaceutical companies a right to sell a federally approved drug free from common-law liability. Remarkably, the Court derives this proposition from a federal law that, in order to protect consumers, prohibits manufacturers from distributing new drugs in commerce without federal regulatory approval, and specifically disavows any intent to displace state law absent a direct and positive conflict.

Karen Bartlett was grievously injured by a drug that a

SOTOMAYOR, J., dissenting

jury found was unreasonably dangerous. The jury relied upon evidence that the drug posed a higher than normal risk of causing the serious skin reaction that produced her horrific injuries; carried other risks; and possessed no apparent offsetting benefits compared to similar pain relievers, like aspirin. See 760 F. Supp. 2d 220, 233–241, 243–244 (NH 2011). The Court laments her “tragic” situation, *ante*, at 20, but responsibility for the fact that Karen Bartlett has been deprived of a remedy for her injuries rests with this Court. If our established pre-emption principles were properly applied in this case, and if New Hampshire law were correctly construed, then federal law would pose no barrier to Karen Bartlett’s recovery. I respectfully dissent.

I

I begin with “two cornerstones of our pre-emption jurisprudence,” *Wyeth v. Levine*, 555 U. S. 555, 565 (2009), that should control this case but are conspicuously absent from the majority opinion. First, “the purpose of Congress is the ultimate touchstone’ in every pre-emption case.” *Ibid.* (quoting *Medtronic, Inc. v. Lohr*, 518 U. S. 470, 485 (1996)). Second, we start from the “assumption that the historic police powers of the States [are] not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress.” *Rice v. Santa Fe Elevator Corp.*, 331 U. S. 218, 230 (1947). “That assumption,” we have explained, “applies with particular force when,” as is the case here, “Congress has legislated in a field traditionally occupied by the States.” *Altria Group, Inc. v. Good*, 555 U. S. 70, 77 (2008).¹

¹The majority’s failure to adhere to the presumption against pre-emption is well illustrated by the fact that the majority calls on Congress to provide greater clarity with regard to the “difficult pre-emption questions that arise in the prescription drug context.” *Ante*, at 19–20. Certainly, clear direction from Congress on pre-emption questions is

SOTOMAYOR, J., dissenting

The Court applied both of these principles to the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U. S. C. §301 *et seq.*, in *Levine*, where we held that a state failure-to-warn claim against a brand-name drug manufacturer was not pre-empted by federal law. 555 U. S., at 581. Tracing the history of federal drug regulation from the 1906 Federal Food and Drugs Act, 34 Stat. 768, up to the FDCA and its major amendments, the Court explained that federal drug law and state common-law liability have long been understood to operate in tandem to promote consumer safety. See *Levine*, 555 U. S., at 566–568, 574. That basic principle, which the majority opinion elides, is essential to understanding this case.

The FDCA prohibits the “introduction into interstate commerce [of] any new drug” without prior approval from the United States Food and Drug Administration (FDA). 21 U. S. C. §355(a). Brand-name and generic drug manufacturers are required to make different showings to receive agency approval in this premarketing review process. See *ante*, at 2–3. But in either case, the FDA’s permission to market a drug has never been regarded as a final stamp of approval of the drug’s safety. Under the FDCA, manufacturers, who have greater “access to information about their drugs” than the FDA, *Levine*, 555 U. S., at 578–579, retain the ultimate responsibility for the safety of the products they sell. In addition to their ongoing obligations to monitor a drug’s risks and to report adverse drug responses to the FDA, see 21 CFR §§314.80, 314.81, 314.98 (2012), manufacturers may not sell a drug that is “deemed to be misbranded” because it is “danger-

useful. But the whole point of the presumption against pre-emption is that congressional ambiguity should cut in favor of preserving state autonomy. See *Rice v. Santa Fe Elevator Corp.*, 331 U. S. 218, 230 (1947).

SOTOMAYOR, J., dissenting

ous to health” when used in the dosage or manner called for in the drug’s label. 21 U. S. C. §352(j); see §331(a); Brief for United States as *Amicus Curiae* 30–31 (hereinafter U. S. Brief) (indicating that the misbranding prohibition may apply to a drug that was previously approved for sale when significant new scientific evidence demonstrates that the drug is unsafe).

Beyond federal requirements, state common law plays an important “complementary” role to federal drug regulation. *Levine*, 555 U. S., at 578. Federal law in this area was initially intended to “supplemen[t] the protection for consumers already provided by state regulation and common-law liability.” *Id.*, at 566. And as Congress “enlarged the FDA’s powers,” it “took care to preserve state law.” *Id.*, at 567. In the 1962 amendments to the FDCA, which established the FDA’s premarketing review in its modern form, Congress adopted a saving clause providing that the amendments should not be construed to invalidate any provision of state law absent “a direct and positive conflict.” §202, 76 Stat. 793. And in the years since, with “state common-law suits ‘continu[ing] unabated despite . . . FDA regulation,’” *Levine*, 555 U. S., at 567 (quoting *Riegel v. Medtronic, Inc.*, 552 U. S. 312, 340 (2008) (GINSBURG, J., dissenting)), Congress has not enacted a pre-emption provision for prescription drugs (whether brand-name or generic) even as it enacted such provisions with respect to other products regulated by the FDA.²

Congress’ preservation of a role for state law generally,

²See 21 U. S. C. §360k(a) (medical devices); §379r (labeling requirements for nonprescription drugs); §379s (labeling and packaging requirements for cosmetics); 42 U. S. C. §300aa–22(b)(1) (vaccines). Instructively, Congress included a saving clause in the statutes addressing nonprescription drugs and cosmetics, which makes clear that the express pre-emption provisions in these statutes do not affect state product liability law. See 21 U. S. C. §§379r(e), 379s(d).

SOTOMAYOR, J., dissenting

and common-law remedies specifically, reflects a realistic understanding of the limitations of *ex ante* federal regulatory review in this context. On its own, even rigorous preapproval clinical testing of drugs is “generally . . . incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies.” Kessler & Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims*, 96 *Geo. L. J.* 461, 471 (2008); see National Academies, Institute of Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* 37–38 (2007) (hereinafter *Future of Drug Safety*) (discussing limitations “inherent” to a system of premarket clinical trials). Moreover, the FDA, which is tasked with monitoring thousands of drugs on the market and considering new drug applications, faces significant resource constraints that limit its ability to protect the public from dangerous drugs. See *Levine*, 555 U. S., at 578–579, and n. 11; Brief for Former FDA Commissioner Donald Kennedy et al. as *Amici Curiae* 6–7, 12–20. Tort suits can help fill the gaps in federal regulation by “serv[ing] as a catalyst” to identify previously unknown drug dangers. *Bates v. Dow Agrosciences LLC*, 544 U. S. 431, 451 (2005).

Perhaps most significant, state common law provides injured consumers like Karen Bartlett with an opportunity to seek redress that is not available under federal law. “[U]nlike most administrative and legislative regulations,” common-law claims “necessarily perform an important remedial role in compensating accident victims.” *Sprietsma v. Mercury Marine*, 537 U. S. 51, 64 (2002). While the Court has not always been consistent on this issue, it has repeatedly cautioned against reading federal statutes to “remove all means of judicial recourse for those injured” when Congress did not provide a federal remedy. *Silkwood v. Kerr-McGee Corp.*, 464 U. S. 238, 251 (1984); see

SOTOMAYOR, J., dissenting

e.g., *Bates*, 544 U. S., at 449; *Lohr*, 518 U. S., at 487 (plurality opinion). And in fact, the legislative history of the FDCA suggests that Congress chose not to create a federal cause of action for damages precisely because it believed that state tort law would allow injured consumers to obtain compensation. See *Levine*, 555 U. S., at 574–575, and n. 7.

II

In light of this background, Mutual should face an uphill climb to show that federal law pre-empts a New Hampshire strict-liability claim against a generic drug manufacturer for defective design. The majority nevertheless accepts Mutual’s argument that “compliance with both federal and state [law was] a physical impossibility.” *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U. S. 132, 142–143 (1963); see *ante*, at 7. But if state and federal law are properly understood, it is clear that New Hampshire’s design-defect claim did not impose a legal obligation that Mutual had to violate federal law to satisfy.

A

Impossibility pre-emption “is a demanding defense,” *Levine*, 555 U. S., at 573, that requires the defendant to show an “irreconcilable conflict” between federal and state legal obligations, *Silkwood*, 464 U. S., at 256. The logic underlying true impossibility pre-emption is that when state and federal law impose irreconcilable affirmative requirements, no detailed “inquiry into congressional design” is necessary because the inference that Congress would have intended federal law to displace the conflicting state requirement “is inescapable.” *Florida Lime*, 373 U. S., at 142–143. So, for example, if federal law requires a particular product label to include a complete list of ingredients while state law specifically forbids that labeling practice, there is little question that state law “must

SOTOMAYOR, J., dissenting

yield.” *Felder v. Casey*, 487 U. S. 131, 138 (1988).

The key inquiry for impossibility pre-emption, then, is to identify whether state and federal law impose directly conflicting affirmative legal obligations such that state law “require[s] the doing of an act which is unlawful under” federal law. *California Fed. Sav. & Loan Assn. v. Guerra*, 479 U. S. 272, 292 (1987). Impossibility does not exist where the laws of one sovereign permit an activity that the laws of the other sovereign restricts or even prohibits. See *Barnett Bank of Marion Cty., N. A. v. Nelson*, 517 U. S. 25, 31 (1996); *Michigan Cannery & Freezers Assn., Inc. v. Agricultural Marketing and Bargaining Bd.*, 467 U. S. 461, 478, n. 21 (1984). So, to modify the previous example, if federal law permitted (but did not require) a labeling practice that state law prohibited, there would be no irreconcilable conflict; a manufacturer could comply with the more stringent regulation. And by the same logic, impossibility does not exist where one sovereign’s laws merely create an incentive to take an action that the other sovereign has not authorized because it is possible to comply with both laws.

Of course, there are other types of pre-emption. Courts may find that state laws that incentivize what federal law discourages or forbid what federal law authorizes are pre-empted for reasons apart from impossibility: The state laws may fall within the scope of an express pre-emption provision, pose an obstacle to federal purposes and objectives, or intrude upon a field that Congress intended for federal law to occupy exclusively. See *Crosby v. National Foreign Trade Council*, 530 U. S. 363, 372–373 (2000). But absent a direct conflict between two mutually incompatible legal requirements, there is no impossibility and courts may not automatically assume that Congress intended for state law to give way. Instead, a more careful inquiry into congressional intent is called for, and that inquiry should be informed by the presumption against

SOTOMAYOR, J., dissenting

pre-emption.

In keeping with the strict standard for impossibility, cases that actually find pre-emption on that basis are rare. See Abrams, Plenary Power Preemption, 99 Va. L. Rev. 601, 608 (2013). *Mensing* is an outlier, as the Court found impossibility because a generic drug manufacturer could not strengthen its product label to come into line with a state-law duty to warn without the exercise of judgment by the FDA. See 564 U. S., at ___–___ (slip op., at 13–14). But nothing in *Mensing*, nor any other precedent, dictates finding impossibility pre-emption here.

B

To assess whether it is physically impossible for Mutual to comply with both federal and state law, it is necessary to identify with precision the relevant legal obligations imposed under New Hampshire’s design-defect cause of action.

The majority insists that Mutual was required by New Hampshire’s design-defect law to strengthen its warning label. In taking this position, the majority effectively re-characterizes Bartlett’s design-defect claim as a *de facto* failure-to-warn claim. The majority then relies on that re-characterization to hold that the jury found Mutual liable for failing to fulfill its duty to label sulindac adequately, which *Mensing* forbids because a generic drug manufacturer cannot independently alter its safety label. *Ante*, at 13; see *Mensing*, 564 U. S., at ___ (slip op., at 10). But the majority’s assertion that Mutual was held liable in this case for violating a legal obligation to change its label is inconsistent with both New Hampshire state law and the record.

For its part, Mutual, in addition to making the argument now embraced by the majority, contends that New Hampshire’s design-defect law effectively required it to change the chemical composition of sulindac. Mutual

SOTOMAYOR, J., dissenting

claims that it was physically impossible to comply with that duty consistent with federal law because drug manufacturers may not change the chemical composition of their products so as to create new drugs without submitting a new drug application for FDA approval. See 21 CFR §§310.3(h), 314.70(b)(2)(i). But just as New Hampshire’s design-defect law did not impose a legal obligation for Mutual to change its label, it also did not mandate that Mutual change the drug’s design.

1

a

Following blackletter products liability law under §402A of the Restatement (Second) of Torts (1963–1964) (hereinafter Second Restatement), New Hampshire recognizes strict liability for three different types of product defects: manufacturing defects, design defects, and warning defects. See *Cheshire Medical Center v. W. R. Grace & Co.*, 49 F. 3d 26, 29 (CA1 1995). Because the District Court granted Mutual summary judgment on Bartlett’s failure-to-warn claim, only New Hampshire’s design-defect cause of action remains at issue in this case.

A product has a defective design under New Hampshire law if it “poses unreasonable dangers to consumers.” *Thibault v. Sears, Roebuck & Co.*, 118 N. H. 802, 807, 395 A. 2d 843, 846 (1978). To determine whether a product is unreasonably dangerous, a jury is asked to make a risk-benefit assessment by considering a nonexhaustive list of factors. See *ante*, at 9–10. In addition, New Hampshire has specifically rejected the doctrine, advocated by the Restatement (Third) of Torts: Products Liability §2(b) (1997) (hereinafter Third Restatement), that a plaintiff must present evidence of a reasonable alternative design to show that a product’s design is defective. Instead, “while proof of an alternative design is relevant in a design defect case,” it is “neither a controlling factor nor an

SOTOMAYOR, J., dissenting

essential element.” *Vautour v. Body Masters Sports Industries, Inc.*, 147 N. H. 150, 156, 784 A. 2d 1178, 1183 (2001).

While some jurisdictions have declined to apply design-defect liability to prescription drugs, New Hampshire, in common with many other jurisdictions, does subject prescriptions drugs to this distinct form of strict products liability. See 678 F. 3d 30, 35 (CA1 2012) (citing *Brochu v. Ortho Pharmaceutical Corp.*, 642 F. 2d 652, 655 (CA1 1981)); see also Third Restatement §6, Comment *f* (collecting cases from other jurisdictions). Drug manufacturers in New Hampshire have an affirmative defense under comment *k* to §402A of the Second Restatement, which exempts “[u]navoidably unsafe products” from strict liability if the product is properly manufactured and labeled. As explained by the lower courts in this case, see 678 F. 3d, at 36; 731 F. Supp. 2d 135, 150–151 (NH 2010), New Hampshire takes a case-by-case approach to comment *k* under which a defendant seeking to invoke the defense must first show that the product is highly useful and that the danger imposed by the product could not have been avoided through a feasible alternative design. See *Brochu*, 642 F. 2d, at 657. Comment *k* did not factor into the jury’s assessment of liability in this case because Mutual abandoned a comment *k* defense before trial. *Ante*, at 12, n. 2.³

³Though the majority does not rely on comment *k* to find preemption, it misleadingly implies that New Hampshire, like “a large majority of States,” has applied comment *k* categorically to prescription drugs to exempt manufacturers from “strict liability for side effects of properly manufactured prescription drugs that [are] accompanied by adequate warnings.” *Ante*, at 12, n. 2 (quoting *Bruesewitz v. Wyeth LLC*, 562 U. S. ___, ___, n. 41 (2011) (slip op., at 10, n. 41)). That is incorrect. The majority also neglects to mention that while some courts have applied comment *k* categorically to prescription drug designs, “[m]ost courts have stated that there is no justification for giving all prescription drug manufacturers blanket immunity from strict liability under comment k.” 2 American Law of Products Liability 3d §17.45,

SOTOMAYOR, J., dissenting

b

The design-defect claim that was applied to Mutual subjects the manufacturer of an unreasonably dangerous product to liability, but it does not require that manufacturer to take any specific action that is forbidden by federal law. Specifically, and contrary to the majority, see *ante*, at 11, New Hampshire's design-defect law did not require Mutual to change its warning label. A drug's warning label is just one factor in a nonexclusive list for evaluating whether a drug is unreasonably dangerous, see *Vautour*, 147 N. H., at 156, 784 A. 2d, at 1183, and an adequate label is therefore neither a necessary nor a sufficient condition for avoiding design-defect liability. Likewise, New Hampshire law imposed no duty on Mutual to change sulindac's chemical composition. The New Hampshire Supreme Court has held that proof of an alternative feasible design is not an element of a design-defect claim, see *Kelleher v. Marvin Lumber & Cedar Co.*, 152 N. H. 813, 831, 891 A. 2d 477, 492 (2006), and as the majority recognizes, *ante*, at 11, sulindac was not realistically capable of being redesigned anyway because it is a single-molecule drug.⁴

To be sure, New Hampshire's design-defect claim creates an incentive for drug manufacturers to make changes to its product, including to the drug's label, to try to avoid liability. And respondent overstates her case somewhat when she suggests that New Hampshire's strict-liability law is purely compensatory. See Brief for Respondent 19. As is typically true of strict-liability regimes, New Hamp-

p. 108 (2010). Like New Hampshire courts, these courts apply comment *k* on a case-by-case basis. See 1 L. Frumer & M. Friedman, *Products Liability* §8.07[5], pp. 8–287 to 8–293 (2012).

⁴Because of this feature of New Hampshire law, it is unnecessary to consider whether the pre-emption analysis would differ in a jurisdiction that required proof of a feasible alternative design as an element of liability.

SOTOMAYOR, J., dissenting

shire’s law, which mandates compensation only for “defective” products, serves both compensatory and regulatory purposes. See *Heath v. Sears, Roebuck & Co.*, 123 N. H. 512, 521–522, 464 A. 2d 288, 293 (1983). But exposure to liability, and the “incidental regulatory effects” that flow from that exposure, *Goodyear Atomic Corp. v. Miller*, 486 U. S. 174, 185–186 (1988), is not equivalent to a legal mandate for a regulated party to take (or refrain from taking) a specific action. This difference is a significant one: A mandate leaves no choice for a party that wishes to comply with the law, whereas an incentive may only influence a choice.

Our cases reflect this distinction. In *Bates*, for example, we rejected an argument that design-defect claims brought against a pesticide manufacturer were pre-empted because they would likely “induce” the manufacturer to change its product label and thus run afoul of an express pre-emption provision forbidding state labeling “requirements” that were different or in addition to federal requirements. 544 U. S., at 444–446. A requirement, we explained, “is a rule of law that must be obeyed.” *Id.*, at 445. “[A]n event, such as a jury verdict, that merely motivates an optional decision,” does not rise to that level. *Ibid.*⁵

⁵The majority suggests my account of *Bates* is “simply misleading,” *ante*, at 18, but it simply misses the point. I recognize that, under the Court’s precedents, common-law duties may qualify as “requirements,” at least as that term has been used in express pre-emption provisions in federal law. See *Riegel v. Medtronic, Inc.*, 552 U. S. 312, 323–324 (2008). But determining precisely what, if any, specific requirement a state common-law claim imposes is important. In *Bates*, the lower court had accepted the same basic argument that the majority advances here: that the plaintiffs’ design-defect claim that a pesticide was “unreasonably dangerous” was “merely a disguised claim for failure to warn” because success on the claim that the pesticide was dangerous to crops in soil above a certain pH level would “necessarily induce” a manufacturer to change its product’s label to avoid liability. *Dow*

SOTOMAYOR, J., dissenting

So too here. The fact that imposing strict liability for injuries caused by a defective drug design might make a drug manufacturer want to change its label or design (or both) does not mean the manufacturer was actually required by state law to take either action. And absent such a legal obligation, the majority’s impossibility argument does not get off the ground, because there was no state requirement that it was physically impossible for Mutual to comply with while also following federal law. The case is therefore unlike *Mensing*, where it was “undisputed” that applicable state tort law “require[d] a drug manufacturer that is or should be aware of its product’s danger” to strengthen its label—a requirement that conflicted with federal law preventing the manufacturer from doing so unilaterally, 564 U. S., at ___, ___ (slip op., at 4, 11–12). New Hampshire’s design-defect law did not require Mutual to do anything other than to compensate consumers who were injured by an unreasonably dangerous drug.

2

Moreover, the trial record in this case confirms that, contrary to the majority’s insistence, Mutual was not held liable for “breach[ing] [its] duty” “to label sulindac adequately.” *Ante*, at 13.

When Bartlett filed suit against Mutual, she raised distinct claims based on design defect and failure to warn.

Agrosciences LLC v. Bates, 332 F. 3d 323, 332–333 (CA5 2003). This Court explicitly rejected the notion that because design-defect liability might lead a manufacturer to make a label change, it meant that the State’s design-defect claim imposed a requirement for labeling or packaging. See 544 U. S., at 445–446. The majority contends that this case is different because the duty to redesign sulindac’s label was an element of New Hampshire’s design-defect law. *Ante*, at 19. But it is not. See *supra*, at 11. Rather, altering a product label is merely one step a manufacturer might take to prevent its product from being considered unreasonably dangerous, and it is a step that New Hampshire law recognizes may be insufficient. See *infra*, at 16.

SOTOMAYOR, J., dissenting

App. 102–108; see 659 F. Supp. 2d 279, 282 (NH 2009). Pursuing both claims was consistent with New Hampshire law’s recognition that “design defect and failure to warn claims are separate.” *LeBlanc v. American Honda Motor Co.*, 141 N. H. 579, 586, 688 A. 2d 556, 562 (1997). After the District Court granted summary judgment to Mutual on the failure-to-warn claim, the court repeatedly explained that an alleged failure to warn by Mutual could not and did not provide the basis for Bartlett’s recovery. See 760 F. Supp. 2d, at 248–249.⁶

The majority notes that the District Court admitted evidence regarding sulindac’s label. *Ante*, at 11–12. But the court did so because the label remained relevant for the more limited purpose of assessing, in combination with other factors, whether sulindac’s design was defective because the product was unreasonably dangerous. See 678 F. 3d, at 41. The District Court’s instructions to the jury adhered to this limited purpose. The court first told the jury to determine whether sulindac was unreasonably dangerous by weighing its danger against its utility. App. 513. The court further instructed the jury that if it determined that sulindac was unreasonably dangerous without reference to the warning label, it could then consider the

⁶For example, in a ruling on proposed jury instructions, the District Court made clear that “Bartlett cannot be allowed to circumvent this court’s summary judgment ruling by using Sulindac’s warning to establish that the drug is unreasonably dangerous (i.e., arguing that Sulindac is unreasonably dangerous *because* of its warning), where this court has already ruled that any inadequacy in the warning did not cause Bartlett’s injuries.” App. 343. Doing so, the court explained “would effectively turn this case back into a failure-to-warn case, rendering the summary judgment ruling meaningless.” *Ibid.*

The District Court later told counsel that it had removed a failure-to-warn instruction from the jury instructions because “[t]his is not a failure to warn case,” and the court admonished counsel to “tread carefully” in arguing about the warning label because the label’s adequacy was “not an issue before this jury.” *Id.*, at 496.

SOTOMAYOR, J., dissenting

presence and efficacy of the label to evaluate whether the product was unreasonably dangerous “even with its warning.” *Id.*, 513–514. In other words, to hold Mutual liable, the jury was required to find that sulindac “was unreasonably dangerous *despite* its warning, not because of it.” *Id.*, at 341. The District Court also explained to the jury that because Bartlett’s claim addressed only whether sulindac’s design was defective, Mutual’s conduct, “which included any failure to change its warning, was ‘not relevant to this case.’” 760 F. Supp. 2d, at 248.

The distinction drawn by the District Court between permissible and impermissible uses of evidence regarding sulindac’s label is faithful to New Hampshire law. That law recognizes that the effectiveness of a warning label is just one relevant factor in determining whether a product’s design is unreasonably dangerous, and that design-defect and failure-to-warn claims are “separate.” *LeBlanc*, 141 N. H., at 586, 688 A. 2d, at 562.⁷ In short, as the District Court made clear, Mutual was not held liable for “failing to change” its warning. 760 F. Supp., at 248–249.

C

Given the distinction that New Hampshire draws between failure-to-warn claims and design-defect claims, as well as the clear and repeated statements by the trial judge that Mutual’s liability was not predicated on breaching a duty to label sulindac adequately, on what basis does

⁷To the extent the majority believes that the District Court in practice allowed the adequacy of the warning label to play a greater role at trial than it should have, see *ante*, at 11–12, that is irrelevant to the question before the Court. Statements by counsel, even if improper, do not change the state law cause of action that we evaluate for pre-emption purposes. And the Court of Appeals specifically concluded that the District Court’s jury instructions were appropriate and that “[i]f Mutual wanted a further caution in the instructions” concerning its warning label, then Mutual “should have sought it.” 678 F. 3d 30, 41–42 (CA1 2012).

SOTOMAYOR, J., dissenting

the majority reach a contrary conclusion? Though the majority insists otherwise, *ante*, at 17, it appears to rely principally on an implicit assumption about rights conferred by federal premarket approval under the FDCA. After correctly observing that changing sulindac's chemical composition would create a new drug that would have to go through its own approval process, the majority reasons that Mutual must have been under a state-law duty to change its label because it had no other option to avoid liability while continuing to sell its product. *Ante*, at 10–11. But that conclusion is based on a false premise.

A manufacturer of a drug that is unreasonably dangerous under New Hampshire law has multiple options: It can change the drug's design or label in an effort to alter its risk-benefit profile, remove the drug from the market, or pay compensation as a cost of doing business. If federal law or the drug's chemical properties take the redesign option off the table, then that does not mean the manufacturer suddenly has a legal obligation under state law to improve the drug's label. Indeed, such a view of state law makes very little sense here because even if Mutual had strengthened its label to fully account for sulindac's risks, the company might still have faced liability for having a defective design. See *Thibault*, 118 N. H., at 808, 395 A. 2d, at 847 (explaining that strict liability “may attach even though . . . there was an adequate warning”). When a manufacturer cannot change the label or when doing so would not make the drug safe, the manufacturer may still choose between exiting the market or continuing to sell while knowing it may have to pay compensation to consumers injured by its product.⁸

⁸The majority's suggestion that a manufacturer's option of continuing to sell while paying compensation is akin to violating a statutory mandate and then suffering the consequence (such as paying a fine) is flawed. See *ante*, at 18. In that scenario, the manufacturer would have violated the law, and the fact that the law is enforced through mone-

SOTOMAYOR, J., dissenting

From a manufacturer’s perspective, that may be an unwelcome choice. But it is a choice that a sovereign State may impose to protect its citizens from dangerous drugs or at least ensure that seriously injured consumers receive compensation. That is, a State may impose such a choice unless the FDCA gives manufacturers an absolute right to sell their products free from common-law liability, or state law otherwise “stands as an obstacle to the accomplishment” of federal objectives. *Crosby*, 530 U. S., at 373 (internal quotation marks omitted). Because the majority does not rely on obstacle pre-emption, it must believe that a manufacturer that received FDA premarket approval has a right not only to keep its drug on the market unless and until the FDA revokes approval, but also to be free from state-law liability that makes doing so more expensive. That proposition is fundamentally inconsistent with the FDCA’s text, structure, saving clause, and history. See *supra*, at 3–6; *Levine*, 555 U. S., at 583 (THOMAS, J., concurring in judgment).

It is simply incorrect to say that federal law presupposes that drug manufacturers have a right to continue to sell a drug free from liability once it has been approved. Nothing in the language of the FDCA, which is framed as a prohibition on distribution without FDA approval, see 21 U. S. C. §355(a), suggests such a right. Federal law itself bars the sale of previously approved drugs if new information comes to light demonstrating that the drug is

tary sanctions (rather than through an injunction or imprisonment) would not change that. Here, no matter how many times the majority insists otherwise, *ibid.*, a manufacturer who sells a drug whose design is found unreasonably dangerous based on a balance of factors has not violated a state law requiring it to change its label. In both cases, the manufacturer may owe money. But only in the former will it have failed to follow the law. Cf. *National Federation of Independent Business v. Sebelius*, 567 U. S. ___, __ (2012) (slip op., at 32) (recognizing that a condition that triggers a tax is not necessarily a “legal command” to take a certain action).

SOTOMAYOR, J., dissenting

“dangerous to health” and thus “misbranded.” See §§331(a), 352(j); see *supra*, at 3–4.⁹ Even outside that scenario, manufacturers regularly take drugs off the market when evidence emerges about a drug’s risks, particularly when safer drugs that provide the same therapeutic benefits are available.¹⁰ According to the FDA, while it has formal authority to withdraw approval for a drug based on new adverse information, see §355(e), it is far more common for a manufacturer to stop selling its product voluntarily after the FDA advises the manufacturer that the drug is unsafe and that its risk-benefit profile cannot be adequately addressed through labeling changes or other measures. See U. S. Brief 5.

New Hampshire’s design-defect cause of action thus does no more than provide an impetus for an action that is permitted and sometimes encouraged or even required by federal law.

D

The majority derides any suggestion that Mutual’s ability to “stop selling” sulindac is relevant to the validity

⁹The majority properly leaves open the question whether state design-defect claims that parallel the federal misbranding statute are preempted. See *ante*, at 14, n. 4. The majority fails to appreciate, however, that this statute undermines its impossibility argument (as compared to an argument based on obstacle pre-emption) because it shows that there is no federal right or obligation to continue to sell a drug like sulindac that was previously approved. In fact, the statute demonstrates that sometimes a drug manufacturer like Mutual may have a federal duty not to sell its drug.

¹⁰See Government Accountability Office, Drug Safety: Improvement Needed in FDA’s Postmarket Decision-making and Oversight Process 10 (GAO–06–402, 2006) (noting that 10 drugs were voluntarily withdrawn for safety reasons between 2000 and 2006); Wysowski & Swartz, Adverse Drug Event Surveillance and Drug Withdrawals in the United States, 1969–2002, 165 *Archives Internal Med.* 1363 (2005) (noting that more than 75 drugs and drug products were withdrawn from the market for safety reasons between 1969 and 2002).

SOTOMAYOR, J., dissenting

of its impossibility pre-emption defense. *Ante*, at 2, 14–16. But the majority’s argument is built on the mistaken premise that Mutual is legally obligated by New Hampshire’s design-defect law to modify its label in a way that federal law forbids. It is not. See *supra*, at 11–13. For that reason, rejecting impossibility pre-emption here would not render the doctrine “a dead letter” or “all but meaningless.” *Ante*, at 2, 15 (quoting *Mensing*, 564 U. S., at ____ (slip op., at 14)). On the other hand, it is the majority that “work[s] a revolution in this Court’s [impossibility] pre-emption case law,” *ante*, at 2, by inferring a state-law requirement from the steps a manufacturer might wish to take to avoid or mitigate its exposure to liability.

Not all products can be made safe for sale with an improved warning or a tweak in design. New Hampshire, through its design-defect law, has made a judgment that some drugs that were initially approved for distribution turn out to be inherently and unreasonably dangerous and should therefore not be sold unless the manufacturer is willing to compensate injured consumers. Congressional intent to pre-empt such a cause of action cannot be gleaned from the existence of federal specifications that apply to the product if it is sold. Instead, whether New Hampshire’s design-defect cause-of-action is pre-empted depends on assessing whether it poses an obstacle to a federal policy to approve sulindac for use. Yet the majority skips that analysis and instead finds impossibility where it does not exist by relying on a question-begging assumption that Congress intended for Mutual to have a way to continue selling sulindac without incurring common-law liability. See *ante*, at 9–11.

The distinction between impossibility and obstacle pre-emption is an important one. While obstacle pre-emption can be abused when courts apply an overly broad conception of the relevant federal purpose to find pre-emption, see *Levine*, 555 U. S., at 601–602 (THOMAS, J., concurring

SOTOMAYOR, J., dissenting

in judgment), it is a useful framework for a case like this one because it would at least lead the Court to ask the right questions.

For example, properly evaluating the asserted conflict here through the lens of obstacle pre-emption would allow the Court to consider evidence about whether Congress intended the FDA to make an optimal safety determination and set a maximum safety standard (in which case state tort law would undermine the purpose) rather than a minimal safety threshold (in which case state tort law could supplement it). See, *e.g.*, *Williamson v. Mazda Motor of America, Inc.*, 562 U. S. ___, ___ (2011) (slip op., at 11). By contrast, the majority's overbroad impossibility framework takes no account of how federal drug safety review actually works. Though the majority gestures to the rigorous nature of the FDA's review of new drug applications, *ante*, at 2–3, nothing in the majority's reasoning turns on how the FDA's premarketing review operates or on the agency's capacity to engage in postmarketing review.

In taking the approach it does, the majority replaces careful assessment of regulatory structure with an *ipse dixit* that pharmaceutical companies must have a way to “escape liability,” *ante*, at 11, while continuing to sell a drug that received FDA approval. As a result, the majority effectively makes a highly contested policy judgment about the relationship between FDA review and state tort law—treating the FDA as the sole guardian of drug safety—without defending its judgment and without considering whether that is the policy judgment that Congress made.¹¹

¹¹Defending a policy judgment that treats the FDA as the exclusive guarantor of drug safety would be no easy task in light of evidence that resource constraints and gaps in legal authority, among other factors, limit the agency's ability to safeguard public health. See Kessler & Vladeck, A Critical Examination of the FDA's Efforts to Preempt

SOTOMAYOR, J., dissenting

III

While the majority never addresses obstacle pre-emption, Mutual did argue in the alternative that Bartlett's design-defect cause of action is pre-empted because it conflicts with the purposes and objectives of the FDCA, as supplemented by the Hatch-Waxman Act, 98 Stat. 1585. Though it presents a closer question than the impossibility argument on which the majority relies, I would reject Mutual's obstacle pre-emption defense as well.

Mutual's most substantial contention is that New Hampshire's design-defect claim frustrates the policy underlying the FDCA's broader scheme of vesting authority in the FDA as an expert agency to determine which drug designs should enter and remain in interstate commerce. The FDA, through an *amicus* brief filed by the United States, generally supports this argument. The FDA states that the question whether a design-defect claim¹² is pre-empted is "difficult and close," and it recognizes that "[s]everal factors do weigh in favor of finding no preemption," including the absence of textual support in the FDCA for the idea that an approved drug must be made available in any particular State. See U. S. Brief 12, 21–22. But the FDA ultimately contends that design-defect claims are pre-empted unless they parallel the FDCA's misbranding prohibition because the agency believes that permitting juries to balance the health risks and benefits of an FDA-approved drug would undermine the FDA's drug-safety determinations and could reduce

Failure-to-Warn Claims, 96 Geo. L. J. 461, 483–495 (2008); see also *Wyeth v. Levine*, 555 U. S. 555, 578–579, and n. 11 (2009).

¹²The FDA purports to address what it calls a "pure" design-defect claim, and it references the Third Restatement §6 by way of illustration. The FDA's separate discussion of a "pure" design-defect claim is based on the premise that New Hampshire's design-defect claim turns on the adequacy of a drug's warning. See U. S. Brief 20. But that is incorrect. See *supra*, at 11.

SOTOMAYOR, J., dissenting

access to drugs that the FDA has determined are safe and effective.

Our cases have “given ‘some weight’ to an agency’s views about the impact of tort law on federal objectives when ‘the subject matter is technical[] and the relevant history and background are complex and extensive.’” *Levine*, 555 U. S., at 576 (quoting *Geier v. American Honda Motor Co.*, 529 U. S. 861, 883 (2000)). But courts do not “defe[r] to an agency’s *conclusion* that state law is pre-empted,” 555 U. S., at 576, and the tension that the FDA identifies in an effort to justify complete pre-emption of design-defect claims for prescription drugs does not satisfy the “high threshold [that] must be met if a state law is to be pre-empted for conflicting with the purposes of a federal Act,” *Chamber of Commerce of United States of America, v. Whiting*, 563 U. S. ___, ___ (2011) (slip op., at 22) (internal quotation marks omitted); see *Silkwood*, 464 U. S., at 256. Given the FDCA’s core purpose of protecting consumers, our recognition in *Levine* that state tort law generally complements the statute’s safety goals, the practical limits on the FDA’s ability to monitor and promptly address concerns about drug safety once a drug is in the market, see *supra*, at 5, 20–21, n. 11, and the absence of any federal remedy for injured consumers, I would reject this broad obstacle pre-emption argument as well.¹³

IV

The most troubling aspect of the majority’s decision to once again expand the scope of this Court’s traditionally narrow impossibility pre-emption doctrine is what it im-

¹³I note that we are not confronted with a case in which the FDA promulgated “lawful specific regulations describing” whether and under what circumstances state design-defect liability interferes with “the safe drug-related medical care” sought through the FDCA. *Levine*, 555 U. S., at 582 (BREYER, J., concurring). See also *ante*, at 2–3 (BREYER, J., dissenting).

SOTOMAYOR, J., dissenting

plies about the relationship between federal premarket review and state common-law remedies more generally. Central to the majority's holding is an assumption that manufacturers must have a way to avoid state-law liability while keeping particular products in commerce. See *ante*, at 9–11, 14–15. This assumption, it seems, will always create an automatic conflict between a federal premarket review requirement and state-law design-defect liability because premarket review, by definition, prevents manufacturers from unilaterally changing their products' designs.¹⁴ That is true, for example, of the designs (*i.e.*, the chemical composition) of brand-name drugs under the FDCA no less than it is for generic drugs. See *ante*, at 3–4.

If the creation of such an automatic conflict is the ultimate end-point of the majority's continued expansion of impossibility pre-emption, then the result is frankly astonishing. Congress adopted the FDCA's premarketing approval requirement in 1938 and then strengthened it in 1962 in response to serious public-health episodes involving unsafe drugs. See *Future of Drug Safety* 152. Yet by the majority's lights, the very act of creating that requirement in order to "safeguard the consumer," *United States v. Sullivan*, 332 U. S. 689, 696 (1948), also created by operation of law a shield for drug manufacturers to avoid paying common-law damages under state laws that are also designed to protect consumers. That is so notwithstanding Congress' effort to disclaim any intent to pre-empt all state law. See *supra*, at 4. The majority's reasoning thus "has the 'perverse effect' of granting broad immunity 'to an entire industry that, in the judgment of Congress, needed more stringent regulation.'" *Riegel*, 552

¹⁴Or at least it creates an automatic conflict with the caveat that design-defect claims that parallel a federal duty for manufacturers to withdraw a product might not be pre-empted. See *ante*, at 13–14, n. 3.

SOTOMAYOR, J., dissenting

U. S., at 338 (GINSBURG, J., dissenting) (quoting *Lohr*, 518 U. S., at 487 (plurality opinion)).

This expanded notion of impossibility pre-emption threatens to disturb a considerable amount of state law. The FDCA's premarket approval process for prescription drugs has provided a model for the regulation of many other products.¹⁵ In some statutes, Congress has paired premarket regulatory review with express pre-emption provisions that limit the application of state common-law remedies, including, in some instances, claims for defective product design. See, e.g., *Riegel*, 552 U. S., at 323–325; see *supra*, at 4, and n. 2. In other instances, such as with prescription drugs, it has not. Under the majority's approach, it appears that design-defect claims are categorically displaced either way, and Congress' efforts to set the boundaries of pre-emption more precisely were largely academic. This could have serious consequences for product safety. State design-defect laws play an important role not only in discovering risks, but also in providing incentives for manufacturers to remove dangerous products from the market promptly. See *Levine*, 555 U. S., at 578–579; *Bates*, 544 U. S., at 451; see also Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?* 109 *Yale L. J.* 1087, 1130 (2000) (“The tort system can encourage FDA regulatory vigor and competence”). If manufacturers of products that require preapproval are given *de facto* immunity from design-defect liability, then the public will have to rely exclusively on imperfect federal agencies with limited resources and sometimes limited legal authority to recall approved products. And consumers injured by those products will have no recourse.

¹⁵See, e.g., 7 U. S. C. §136a (pesticides); 21 U. S. C. §348 (food additives); §360b (animal drugs); §§360c(a)(1)(C), 360e (certain medical devices); §379e (color additives).

SOTOMAYOR, J., dissenting

The manner in which Congress has addressed pre-emption with respect to vaccines is particularly instructive. “[V]accines have been subject to the same federal pre-market approval process as prescription drugs,” and prior to Congress’ intervention, “compensation for vaccine-related injuries ha[d] been left largely to the States.” *Bruesewitz v. Wyeth LLC*, 562 U. S. ___, ___ (2011) (slip op., at 1). In 1986, in response to a rise in tort suits that produced instability in the vaccine market, Congress enacted the National Childhood Vaccine Injury Act (Vaccine Act), 42 U. S. C. §300aa–22(b)(1). The Act established a no-fault compensation program funded through an excise tax on vaccines to compensate individuals injured or killed by vaccine side effects. “The *quid pro quo* for this” system, the Court stated in *Bruesewitz*, “was the provision of significant tort-liability protections for vaccine manufacturers.” 562 U. S., at ___ (slip op., at 4).

While Members of this Court disagreed on the scope of the tort protections the Vaccine Act was intended to offer, the Act’s history demonstrates that Congress is perfectly capable of responding when it believes state tort law may compromise significant federal objectives under a scheme of premarket regulatory review for products it wants to make available. And it illustrates that “an important reason to require that preemption decisions be made by Congress,” rather than by courts on the basis of an expanded implied pre-emption doctrine, is Congress’ ability to tie its pre-emption decisions “to some alternative means for securing compensation.” Metzger, *Federalism and Federal Agency Reform*, 111 Colum. L. Rev. 1, 33 (2011). By instead reaching out to find pre-emption in a context where Congress never intended it, the majority leaves consumers like Karen Bartlett to bear enormous losses on their own.

SOTOMAYOR, J., dissenting

* * *

The Court recognizes that “[t]his case arises out of tragic circumstances.” *Ante*, at 20. And I do not doubt that Members of the majority personally feel sympathy for Karen Bartlett. But the Court’s solemn affirmation that it merely discharges its duty to “follo[w] the law,” *ante*, at 17, and gives effect to Congress’ policy judgment, rather than its own, is hard to accept. By once again expanding the scope of impossibility pre-emption, the Court turns Congress’ intent on its head and arrives at a holding that is irreconcilable with our precedents. As a result, the Court has left a seriously injured consumer without any remedy despite Congress’ explicit efforts to preserve state common-law liability.

I respectfully dissent.