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***Mutual Pharmaceutical Co. v. Bartlett* and Its Implications**

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Product Liability

Preemption

The U.S. Supreme Court preemption ruling in *Mutual Pharmaceutical Co. v. Bartlett*, which generally shields generic drug manufacturers from state-law damages liability for design-defect claims, may also have implications for preemption jurisprudence more broadly, attorneys Brian Wolfman and Anne King say in this BNA Insight. The authors analyze the decision, offer guidance on how plaintiffs injured by defective or mislabeled generic prescription drugs may seek compensation after *Mutual*, and explain how federal regulators and Congress may respond.

Mutual Pharmaceutical Co. v. Bartlett and Its Implications



BY BRIAN WOLFMAN AND ANNE KING

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On June 24, 2013, the U.S. Supreme Court held 5–4 in *Mutual Pharmaceutical Co. v. Bartlett*¹ that federal law preempted a state-law design-defect damages claim against a manufacturer of generic prescription drugs. *Mutual* follows on the heels of two related Supreme Court rulings, *Wyeth v. Levine*,² decided in 2009, and *PLIVA, Inc. v. Mensing*,³ decided in 2011. In *Wyeth*, the Court held that federal law generally does not preempt state-law failure-to-warn claims against manufacturers of *brand-name* prescription drugs.⁴ In *PLIVA*, however, the Court concluded that federal law generally does preempt failure-to-warn claims against manufacturers of *generic* prescription drugs because federal law prohibits generic manufacturers from unilaterally amending their drug labels, and instead requires them invariably to use the label of the brand-name drug on which the generic product is based.⁵

This article describes the Supreme Court's decision in *Mutual* and evaluates how it may affect future products liability litigation. Part I provides an overview of the case's factual background and of federal generic drug regulation, while Part II discusses the Court's majority opinion and the dissents. Part III analyzes the im-

¹ 133 S. Ct. 2466 (2013).

² 555 U.S. 555 (2009).

³ 131 S. Ct. 2567 (2011).

⁴ *Wyeth*, 555 U.S. at 559.

⁵ *PLIVA*, 131 S. Ct. at 2577-78.

plications of the decision, offering ideas on how plaintiffs injured by defective or mislabeled generic prescription drugs may seek compensation after *Mutual* and how federal regulators and Congress may respond. Part III also briefly assesses *Mutual*'s potential impact on federal preemption doctrine.

I. Background

A. The Facts

In December 2004, Karen Bartlett received a prescription for the brand-name drug Clinoril to relieve shoulder pain.⁶ Clinoril is a non-steroidal anti-inflammatory drug (NSAID) prescribed to alleviate muscle pain.⁷ Other NSAIDs include ibuprofen (Advil) and naproxen (Aleve).⁸ Ms. Bartlett's pharmacist dispensed sulindac, a generic version of Clinoril, manufactured by Mutual Pharmaceutical (Mutual).⁹ New Hampshire law allows pharmacists to substitute a generic version for a prescribed brand-name drug.¹⁰ All 50 states and the District of Columbia have enacted generic substitution laws authorizing or, in some cases, mandating that pharmacists dispense a generic drug even when a doctor has prescribed the brand name.¹¹

For Ms. Bartlett, the results of taking sulindac were "horrific."¹² In early 2005, she developed Stevens-Johnson Syndrome and toxic epidermal necrolysis (SJS/TEN), related conditions characterized by "extensive loss of skin."¹³ Ms. Bartlett was "severely disfigured," with "sixty to sixty-five percent of the surface of [her] body deteriorated, . . . burned off, or turned into an open wound."¹⁴ SJS/TEN also adversely affects a patient's mucous membranes, and Ms. Bartlett's extensive injuries included damage to her eyes, rendering her legally blind, burns to her esophagus that required a year of tube feeding, and damage to her vagina and lungs.¹⁵ Ms. Bartlett's treatment included a medically-induced coma and numerous surgeries.¹⁶

Ms. Bartlett sued Mutual alleging state-law damages claims, including a design-defect claim.¹⁷ As explained in more detail below, Mutual argued that Ms. Bartlett's design-defect claim was preempted by federal law.

B. FDA Regulation of Generic Drugs

Under the Federal Food, Drug, and Cosmetic Act (FDCA), a drug manufacturer wanting to sell a new drug in interstate commerce must submit a new drug application (NDA) for approval by the Food and Drug Administration (FDA).¹⁸ Because FDA may approve a

drug for sale only if the drug is deemed "safe for use" under "the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," an NDA must include clinical trial results and other data showing that the drug is safe and effective.¹⁹ The Court in *Mutual* characterized the NDA process as "onerous and lengthy."²⁰ A drug approved through the NDA process is often referred to as a "brand-name" or "listed" drug.

In 1984, Congress amended the FDCA by enacting the Drug Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act.²¹ Hatch-Waxman established an alternative, less demanding approval process for generic copies of brand-name drugs. Manufacturers seeking to market a generic drug may submit an abbreviated new drug application (ANDA) instead of an NDA. An ANDA must indicate that the generic drug's prescribed, recommended, or suggested uses match those of a previously approved, listed drug, that the generic is "bioequivalent" to the listed drug, and that the generic's labeling is the same as the listed drug's labeling.²²

As noted earlier, in *PLIVA*, it was this sameness-in-labeling requirement, coupled with the Court's conclusion that federal law prohibits generic drug manufacturers from unilaterally altering their drug labels, that prompted the Court to hold that federal law preempts a failure-to-warn claim against the manufacturer of a generic drug.²³ Hatch-Waxman has resulted in significantly broader access to generic drugs, increasing generics' market share from 19 percent at the time of enactment to 75 percent in 2009.²⁴ When a brand-name drug has a generic equivalent, the generic generally captures 90 percent of the market.²⁵

C. Regulatory History of Clinoril/Sulindac

The following summary of the regulatory history of Clinoril and sulindac is taken from Karen Bartlett's Supreme Court brief and from reported decisions in the case. FDA approved the brand-name drug Clinoril in 1978.²⁶ At that time, clinical trial results assessed Clinoril's negative side effects as "relatively mild."²⁷ FDA approved Mutual Pharmaceutical's ANDA for generic sulindac in 1991.²⁸

When Ms. Bartlett was prescribed sulindac in 2004, Mutual's label listed SJS/TEN as "a possible adverse reaction."²⁹ In 2005, FDA recommended removal of the NSAID Bextra from the market based on Bextra's risk of severe skin reactions such as SJS/TEN.³⁰ In 2006, in response to a citizen petition, FDA recommended that NSAID manufacturers list SJS/TEN "in the 'Warnings' section of the prescription labels."³¹ Mutual then

⁶ *Mutual*, 133 S. Ct. at 2472.

⁷ Brief of Respondent Karen Bartlett, at 5, 10, *Mutual Pharm. Co. v. Bartlett*, No. 12-142 (U.S. filed Feb. 13, 2012) (hereafter "Resp. Br."), available at 2013 WL 602909, *5, *10.

⁸ *Mutual*, 133 S. Ct. at 2471.

⁹ *Id.* at 2472.

¹⁰ N.H. Rev. Stat. § 318:47-d.

¹¹ See *PLIVA*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting).

¹² *Mutual*, 133 S. Ct. at 2472.

¹³ Resp. Br. 5, 7, available at 2013 WL 602909, *5, *7.

¹⁴ *Mutual*, 133 S. Ct. at 2472.

¹⁵ *Id.*; *Bartlett v. Mutual Pharm. Co.*, 678 F.3d 30, 36, 43 (1st Cir. 2012); Resp. Br. 8, available at 2013 WL 602909, *8.

¹⁶ *Mutual*, 133 S. Ct. at 2472; *Bartlett*, 678 F.3d at 43; Resp. Br. 8, available at 2013 WL 602909, *8.

¹⁷ *Mutual*, 133 S. Ct. at 2472.

¹⁸ See 21 U.S.C. § 355(b) - (d).

¹⁹ 21 U.S.C. § 355(b), (d).

²⁰ *Mutual*, 133 S. Ct. at 2471.

²¹ 98 Stat. 1585 (codified at 21 USC 355(j)).

²² 21 U.S.C. § 355(j)(2)(A)(i) & (iv)-(v).

²³ *PLIVA*, 131 S. Ct. at 2577-78.

²⁴ *Id.* at 2584 (Sotomayor, J., dissenting).

²⁵ *Id.*

²⁶ *Mutual*, 133 S. Ct. at 2471; Resp. Br. 5.

²⁷ Resp. Br. 5, available at 2013 WL 602909, *5.

²⁸ *Mutual*, 133 S. Ct. at 2471; Resp. Br. 5, available at 2013 WL 602909, *5.

²⁹ Resp. Br. 7, available at 2013 WL 602909, *7.

³⁰ *Id.* at 6, available at 2013 WL 602909, *6.

³¹ Resp. Br. 7, available at 2013 WL 602909, *7. However, "FDA rejected the Citizen Petition's request for an even stronger 'boxed warning.'" *Id.*

changed its sulindac label to list SJS/TEN in the “Warnings” section rather than just as a possible adverse reaction.³²

FDA data on adverse patient reactions to sulindac included “89 reports of SJS/TEN from 1980 to 1997, increasing to 134 by 2004; 39 cases of death; and one of the highest SJS/TEN reporting rates among NSAIDs.”³³

D. Lower Court Proceedings

Ms. Bartlett’s suit against Mutual sought damages under New Hampshire tort law, claiming that Mutual had failed adequately to warn of sulindac’s hazards and that sulindac was defectively designed.³⁴ The district court dismissed Ms. Bartlett’s failure-to-warn claim because the prescribing physician acknowledged that he had not read the applicable warning.³⁵ However, Ms. Bartlett’s design-defect claim proceeded to trial, where a jury found in her favor and awarded her \$21.06 million in compensatory damages.³⁶

Mutual appealed, arguing that the FDCA and its regulations preempted Ms. Bartlett’s design-defect claim under *PLIVA*.³⁷ The First Circuit affirmed the jury verdict, distinguishing *PLIVA* on the rationale that Mutual could comply with state law by choosing not to market sulindac in New Hampshire and that, therefore, a state-law determination that sulindac was defectively designed did not conflict with the federal requirement that sulindac be sold as formulated when approved by FDA.³⁸ Moreover, the First Circuit noted, the Supreme Court had “adopted a general no-preemption rule in *Wyeth [v. Levine]*.”³⁹

II. The Supreme Court Decision

The Supreme Court ruled 5–4 in favor of Mutual, reversing the First Circuit and holding that “state-law design-defect claims that turn on the adequacy of a drug’s warnings are preempted by federal law under *PLIVA*.”⁴⁰ Justice Alito wrote the majority opinion, joined in full by Chief Justice Roberts and Justices Scalia, Kennedy, and Thomas. Justice Breyer dissented, joined by Justice Kagan, and Justice Sotomayor wrote a separate dissent, joined by Justice Ginsburg.

A. Justice Alito’s Majority Opinion

1. Assessing Mutual’s Duties Under State and Federal Law

After providing an overview of the factual and legal background of the case, Justice Alito briefly summarized the Court’s preemption doctrine, which is derived from the Supremacy Clause of the Constitution.⁴¹ Jus-

tice Alito explained that “it has long been settled that state laws that conflict with federal law are without effect.”⁴² Congress may state explicitly that federal law preempts state law, but a conflict may also arise “[e]ven in the absence of an express preemption provision.”⁴³ For example, Justice Alito went on, impossibility preemption arises “where it is impossible for a private party to comply with both state and federal requirements.”⁴⁴

And, obstacle preemption occurs where, even though compliance with state law does not render compliance with federal law impossible, state law nonetheless “stands as an obstacle to the accomplishment of federal objectives.”⁴⁵

Here, the Court focused on impossibility preemption, evaluating whether it was possible for Mutual to comply simultaneously with New Hampshire law and federal drug regulations. The Court first considered whether New Hampshire state law imposed a duty on Mutual and other drug manufacturers. After answering that question affirmatively, the Court analyzed the nature of Mutual’s state-law duty. Then, the Court assessed Mutual’s duty under federal law and concluded that the drug manufacturer’s federal-law and state-law duties conflicted.

In determining that New Hampshire’s design-defect cause of action imposes an affirmative duty on Mutual and other drug manufacturers, the Court reasoned that New Hampshire’s design-defect cause of action creates strict liability, not absolute liability.⁴⁶ The former, the Court explained, imposes an affirmative duty on manufacturers, while the latter “merely serves to spread risk.”⁴⁷ The Court thus rejected Ms. Bartlett’s argument that New Hampshire law does not impose a duty because strict liability for selling a product in “defective condition” attaches “even though [the manufacturer] ‘has exercised all possible care.’”⁴⁸ The Court interpreted New Hampshire court decisions as imposing a duty on manufacturers to design products “reasonably safely” for foreseeable uses.⁴⁹ The Court left open the question whether a “true absolute-liability” tort regime would give rise to preemption.⁵⁰ That question is important, at least in theory, because an absolute-liability scheme that serves only to spread risk may not give rise to a state-law duty that would conflict with a federal-law duty.⁵¹ We take up that issue in more detail in Part III.B.1.

The Court then turned in more detail to Mutual’s duty under New Hampshire law. The majority characterized New Hampshire law as applying a “risk-utility” balancing test to determine whether a product is “unreasonably dangerous,” and identified three factors New Hampshire courts typically weigh in the risk-utility inquiry: the product’s “usefulness,” its “risk of danger,”

³² *Id.*

³³ *Bartlett*, 678 F.3d at 39.

³⁴ *Mutual*, 133 S. Ct. at 2472.

³⁵ *Id.*; *Bartlett*, 678 F.3d at 34. The district court’s dismissal of the failure-to-warn claim came in 2010, prior to the Supreme Court’s decision in *PLIVA*, which generally eliminated failure-to-warn claims against generic drug manufacturers on preemption grounds.

³⁶ *Mutual*, 133 S. Ct. at 2472; *Bartlett*, 678 F.3d at 35.

³⁷ *Bartlett*, 678 F.3d at 37.

³⁸ *Id.*

³⁹ *Id.* at 38.

⁴⁰ *Mutual*, 133 S. Ct. at 2470.

⁴¹ U.S. Const., Art. VI, cl. 2.

⁴² *Mutual*, 133 S. Ct. at 2473 (internal quotation marks and citation omitted).

⁴³ *See id.* at 2473 (majority opinion).

⁴⁴ *Id.* (internal quotation marks and citation omitted).

⁴⁵ *Id.* at 2491 (Sotomayor, J., dissenting) (citation omitted).

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *See id.* at 2473; Resp. Br. 19–21, available at 2013 WL 602909, *19–*21.

⁴⁹ *Mutual*, 133 S. Ct. at 2473 (quoting *Thibault v. Sears, Roebuck & Co.*, 395 A. 2d 843, 847 (N.H. 1978)).

⁵⁰ *Id.* at 2474 n.1.

⁵¹ *See id.* at 2473.

and “the presence and efficacy of a warning.”⁵² Therefore, the Court concluded, Mutual could satisfy its state-law duty to ensure that its products are not unreasonably dangerous only “by changing a drug’s design”—to increase the drug’s usefulness or to decrease its risk of danger—or by changing its labeling.”⁵³

Having defined Mutual’s state-law duty, the Court then considered whether the drug manufacturer could simultaneously carry out that duty and comply with federal law. The majority noted that, as explained in *PLIVA*, the FDCA and its regulations prohibit generic drug manufacturers from unilaterally changing their labels.⁵⁴ The FDCA, the Court explained, also does not authorize generic manufacturers to alter the composition of their products because approval depends on bioequivalency with a listed (brand-name) drug.⁵⁵ (Further, Justice Alito noted, it would not have even been possible to change sulindac’s composition because of its simple molecular make-up.⁵⁶)

Because New Hampshire law required Mutual to change either sulindac’s composition or its label to avoid liability, the Court said, it was impossible for Mutual to comply with both state and federal law.⁵⁷ Therefore, the Court held, “New Hampshire’s warning-based design-defect cause of action is pre-empted with respect to FDA-approved drugs sold in interstate commerce.”⁵⁸

2. *PLIVA* as Controlling Precedent

In the second part of its opinion, invoking *PLIVA*, the Court explained more expansively why it disagreed with the First Circuit and Justice Sotomayor’s dissent.

As noted earlier, the First Circuit had concluded that Ms. Bartlett’s suit was not barred by impossibility preemption because Mutual could avoid a state law-federal law conflict by suspending sulindac sales. By pulling the product from the market, the argument goes, Mutual would not violate any federal duty because federal law only allows, but does not require, the holder of an approved drug application to market its approved product.

The Supreme Court “reject[ed] this ‘stop-selling’ rationale as incompatible with [its] pre-emption jurisprudence,” reasoning that it would render impossibility preemption “all but meaningless.”⁵⁹ “In every instance in which the Court has found impossibility preemption,” Justice Alito wrote, “the ‘direct conflict’ between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting.” For this proposition, the majority cited *PLIVA*—and only *PLIVA*—pointing out that although it would have been possible for the drug manufacturers in that case to stop selling their generic drug products, the Court nevertheless found impossibility preemption.⁶⁰

The Court also drew on *PLIVA* in addressing arguments raised in Justice Sotomayor’s dissent. Her dissent, Justice Alito complained, incorrectly characterized New Hampshire common law as simply creating

an incentive for manufacturers to alter drug composition or labeling. Rather, he said, “common-law” duties have the same effect as “statutory mandates”: They require a manufacturer “to choose between leaving the market and accepting the consequences of its actions.”⁶¹ Here, the Court noted that *PLIVA* also involved state common-law duties that were held to conflict with federal law.⁶²

B. Dissent (Justice Breyer)

Justice Breyer’s dissent, joined by Justice Kagan, reasoned that impossibility preemption did not apply because it was not “literally impossible” for Mutual to comply with both federal and state law.⁶³ Mutual had the option to comply with state law by withdrawing from the New Hampshire market or continuing to market sulindac and pay tort remedies assessed against it.⁶⁴ However, Justice Breyer suggested that *obstacle* preemption—which asks whether state law “stands as an obstacle to the accomplishment of federal objectives”⁶⁵—could arise in some cases (although not in Ms. Bartlett’s case) where compliance with state law requires either removal of a drug from a market or payment of tort remedies *and* where those requirements were “so harmful that [they] would seriously undercut the purposes of the federal statutory scheme.”⁶⁶ “The more medically valuable the drug,” Justice Breyer explained, “the less likely Congress intended to permit a State to drive it from the marketplace.”⁶⁷

Justice Breyer’s dissent also discussed why he would not defer to FDA’s position, expressed in the Solicitor General’s *Mutual* amicus brief, that federal law pre-empted Ms. Bartlett’s state-law design-defect claim. FDA argued that *PLIVA* was controlling because New Hampshire’s design-defect law “includes a state-law duty to provide warnings,” which conflicted with the federal-law requirement that prohibits generic manufacturers from making “independent labeling changes.”⁶⁸

Normally, Justice Breyer explained, he would give an agency’s position special weight in assessing preemption “[w]here the statute”—like the FDCA—“contains no clear pre-emption command” because, in that circumstance, “courts may infer that the administrative agency has a degree of leeway to determine the extent to which governing statutes, rules, regulations, or other administrative actions have pre-emptive effect.”⁶⁹ But in *Mutual*, the agency’s position was expressed only in its amicus brief and was not based on agency hearings or other public input or developed “in regulations, interpretations, or similar agency work product.”⁷⁰ Moreover, in Justice Breyer’s view, FDA had flip-flopped on “the general matter” of tort preemption “in different

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.* at 2480-81 (Breyer, J., dissenting).

⁶⁴ *Id.* at 2481.

⁶⁵ *Id.* at 2491 (Sotomayor, J., dissenting) (citation omitted).

⁶⁶ *Id.* at 2482 (Breyer, J., dissenting).

⁶⁷ *Id.* at 2481.

⁶⁸ Brief of the United States as Amicus Curiae Supporting Petitioner in *Mutual Pharm. Co. v. Bartlett*, at 12, No. 12-142 (U.S. filed Jan. 22, 2013), available at 2013 WL 314460, *12.

⁶⁹ *Mutual*, 133 S. Ct. at 2481 (Breyer, J., dissenting).

⁷⁰ *Id.* (citing *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212-13 (1988); *Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000)).

⁵² *Id.* at 2474-75 (citing *Vautour v. Body Masters Sports Industries, Inc.*, 784 A.2d 1178, 1182 (N.H. 2001)).

⁵³ *Id.* at 2474.

⁵⁴ *Id.* at 2476.

⁵⁵ *Id.* at 2475.

⁵⁶ *Id.*

⁵⁷ *Id.* at 2476-77.

⁵⁸ *Id.* at 2477.

⁵⁹ *Id.* at 2477 (quoting *PLIVA*, 131 S. Ct. at 2579).

⁶⁰ *Id.* at 2478 (citing *PLIVA*, 131 S. Ct. at 2577-78).

briefs filed at different times,”⁷¹ further undermining any basis for deference.

C. Dissent (Justice Sotomayor)

Justice Sotomayor’s dissent characterized the majority opinion as broadening the Court’s “traditionally narrow” impossibility preemption doctrine.⁷² Her dissent opened by outlining “two cornerstones of our preemption jurisprudence”: that congressional purpose is the doctrine’s “ultimate touchstone,” and the presumption against preemption,⁷³ which is based in the “assumption that the historic police power of the States” is not “superseded” by federal law “unless that was the clear and manifest purpose of Congress.”⁷⁴

Justice Sotomayor highlighted these two cornerstones in her overview of impossibility preemption, which she characterized as a “demanding defense” requiring an “uphill climb” for *Mutual*.⁷⁵ Courts may find that Congress intended federal law to preempt state law, she explained, only where there is a “direct conflict between two mutually incompatible legal requirements.”⁷⁶ Therefore, “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.”⁷⁷

Turning to Ms. Bartlett’s case, Justice Sotomayor concluded that, contrary to the majority’s understanding, New Hampshire law did not require *Mutual* to change the drug’s design or label. Justice Sotomayor explained that “[t]o determine whether a product is unreasonably dangerous” under New Hampshire law, “a jury is asked to make a risk-benefit assessment by considering a nonexhaustive list of factors,” not only the three factors the majority had identified (“usefulness,” “risk of danger,” and “the presence and efficacy of a warning”).⁷⁸ Therefore, although New Hampshire law may create incentives for drug manufacturers to change a product’s composition or label, it does not mandate that manufacturers do so.⁷⁹ In fact, Justice Sotomayor noted, a manufacturer has multiple options when faced with strict liability, including changing the design or label, removing the drug from the market, and/or paying compensation.⁸⁰

After questioning the Court’s interpretation of state law, Justice Sotomayor explained that the majority’s characterization of federal law also missed the mark. In Justice Sotomayor’s view, the Court’s opinion mistakenly “rel[ie]d] principally on an implicit assumption about rights conferred by federal premarket approval under the FDCA.”⁸¹ There is no right, she continued, under federal law to “continue to sell a drug free from

liability once it has been approved” by FDA.⁸² For that reason, states have the power to impose on manufacturers the choice to either remove their product from the market or pay compensation “to protect [their] citizens from dangerous drugs or at least ensure that seriously injured consumers receive compensation.”⁸³

Justice Sotomayor also observed that the majority made assumptions about the relationship between federal and state law in promoting drug safety without examining congressional purpose.⁸⁴ Instead, she wrote, the Court “effectively” “treat[ed] the FDA as the sole guardian of drug safety” without examining whether Congress intended that FDA “set a maximum safety threshold (in which case state tort law would undermine [congressional] purpose)” or a “minimal safety threshold” that may be supplemented by state law.⁸⁵

III. Mutual’s Future Effect

Just as *PLIVA* immunized generic drug manufacturers facing failure-to-warn claims from state-law damages liability, *Mutual* will do the same for design-defect claims (with potential exceptions discussed below in Part III.B). *Mutual* also underscores the need for regulatory or congressional action that has been evident at least since *PLIVA*. The Court’s ruling in *Mutual* may also have implications for preemption jurisprudence more generally. We address these issues in turn.

A. Design Defect Claims Against Generic Drug Manufacturers Generally

Mutual’s principal effect is to immunize generic prescription drug manufacturers from most, if not all, state-law design-defect claims. The Court’s initial rendition of its holding—“that state-law design-defect claims that turn on the adequacy of a drug’s warnings are preempted by federal law under *PLIVA*”⁸⁶—could be viewed as limited to a warning-related subset of design-defect claims. On this reading, what we will call a “pure” design-defect claim—one that turns solely on the assertion that the manufacturer should have used an alternative design or should not have marketed the product at all, and, thus, does not rely on alleged inadequacies in the product’s label—would not be affected by the Court’s ruling.

But *Mutual*’s reasoning is not so limited. According to the *Mutual* majority, Ms. Bartlett’s claim necessarily turned on the label’s inadequacy because both sulindac’s “basic chemistry” and “federal law” rendered *Mutual* “unable to change sulindac’s composition.”⁸⁷ Perhaps the chemistry of a drug more complex than sulindac could be “redesigned” to meet a design-defect duty imposed by state law. But the dictates of federal law are static (absent congressional or regulatory amendment).⁸⁸ The majority explained that because “the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form,

⁷¹ *Id.* at 2481-82 (citing FDA’s anti-preemption views in *Wyeth* and *PLIVA* and pro-preemption view in *Mutual*).

⁷² *Mutual*, 133 S. Ct. at 2494, 2496 (Sotomayor, J., dissenting).

⁷³ *Id.* at 2483 (citations omitted).

⁷⁴ *Id.* (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

⁷⁵ *Id.* at 2485 (quoting *Wyeth*, 555 U.S. at 573).

⁷⁶ *Id.* at 2486.

⁷⁷ *Id.*

⁷⁸ *Id.* at 2487 (Sotomayor, J., dissenting); see *id.* at 2474-75 (majority opinion).

⁷⁹ *Id.* at 2488 (Sotomayor, J., dissenting).

⁸⁰ *Id.* at 2491.

⁸¹ *Id.* at 2490.

⁸² *Id.* at 2491.

⁸³ *Id.*

⁸⁴ *Id.* at 2483, 2493.

⁸⁵ *Id.*

⁸⁶ *Id.* at 2470 (majority opinion) (emphasis added).

⁸⁷ *Id.*; see also *id.* at 2575 (quoting *Bartlett*, 678 F.3d at 37).

⁸⁸ See *infra* Part III.C (discussing potential regulatory and statutory amendments that would override the results in *Mutual* and *PLIVA*).

strength, and labeling as the brand-name drug on which it is based,”⁸⁹ the First Circuit was “correct . . . that ‘Mutual cannot legally make sulindac in another composition.’ ”⁹⁰ “Indeed,” the Court went on, “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.”⁹¹

Given this reasoning, a “pure” design-defect claim—that is, one not based on labeling inadequacies—is likely to meet the same preemption fate as one based in whole or in part on labeling inadequacies. After *Mutual*, generic drug manufacturers will argue with considerable force that if the federal duty not to change the label of a generic prescription drug triggers impossibility preemption of a state-law failure-to-warn claim, as the Court held in *PLIVA*, so, too, the federal duty not to change a generic drug’s design would trigger impossibility preemption of a state-law claim based solely on the product’s defective design.⁹² Taken together with *PLIVA*, then, *Mutual* means that consumers harmed by generic drugs that are defectively designed or mislabeled generally will be unable to hold manufacturers liable under state law.

These holdings are significant because, as noted earlier, about 75 percent of all drug prescriptions are for generic drugs,⁹³ and every state has a substitution law that permits or requires pharmacists who receive a prescription for a brand-name drug to fill it with that drug’s generic equivalent.⁹⁴ Generic substitution often occurs without the consumer’s consent or knowledge, as occurred in both *Mutual* and *PLIVA*. Even in states where pharmacists are only permitted (but not required) to substitute generic for brand-name drugs, consumers tend to opt for generics because insurance companies often charge higher co-pays for a brand-name drug when a generic is available.⁹⁵ And, as noted, about 90 percent of prescriptions for drugs available in both brand-name and generic forms are filled with generics.⁹⁶ In an amicus brief in *PLIVA*, a group of drug regulation and health care experts conducted a market analysis showing that “out of 4,653 approved drugs with distinct ingredients, delivery routes, and strengths, more than half—2,438—are available in generic form. Of those, 1,062 are available *only* in generic form[.]”⁹⁷

⁸⁹ *Id.* at 2475 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii)-(v) & (8)(B); 21 C.F.R. § 320.1(c)).

⁹⁰ *Id.* (quoting *Bartlett*, 678 F.3d at 37).

⁹¹ *Id.* (citing 21 C.F.R. § 310.3(h)).

⁹² See *In re Fosamax Prods. Liab. Litig.*, ___ F. Supp. 2d ___, 2013 WL 4306434, *6 (Aug. 15, 2013) (holding “pure” design-defect claim preempted under *Mutual*).

⁹³ *PLIVA*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting).

⁹⁴ See *id.*

⁹⁵ Brief of Mark T. Law, et al., at 20 (emphasis in original), in *PLIVA, Inc. v. Mensing*, No. 09-993 (filed Mar. 2, 2011) (hereafter “Experts Brief”), available at 2011 WL 794111, *20 (citing Geoffrey F. Joyce et al., *Employer Drug Benefit Plans and Spending on Prescription Drugs*, 288 J. Am. Med. Ass’n 1733, 1733-34 (2002); Haiden A. Huskamp et al., *The Effect of Incentive-based Formularies on Prescription-Drug Utilization and Spending*, 349 New Eng. J. Med. 2224, 2225 (2003)); see also *PLIVA*, 131 S. Ct. at 2584 n.2 (Sotomayor, J., dissenting).

⁹⁶ *PLIVA*, 131 S. Ct. at 2584.

⁹⁷ Experts Brief, at 18, available at 2011 WL 794111, *18; see also *PLIVA*, 131 S. Ct. at 2584 (Sotomayor, J., dissenting) (citing same and similar data showing that “from one-third to one-half of generic drugs no longer have a marketed brand-name equivalent”).

In sum, the upshot of *Mutual* and *PLIVA* is that most people harmed by prescription generic drugs have lost their access to the courts.

B. Exceptions to *PLIVA-Mutual* No-Liability Rule?

Taken together, do *PLIVA* and *Mutual* eliminate any possibility that patients injured by generic drugs may recover compensation under state law? Absent congressional or regulatory action to overrule the effect of these holdings, three potential exceptions come to mind, two suggested by the *Mutual* majority and one based on imposing liability on brand-name manufacturers for injuries caused by generic drugs. None is likely to provide a complete replacement for the generally applicable state-law remedies that existed before the Supreme Court’s *PLIVA* and *Mutual* rulings, although two offer promise for injured patients seeking damages under state law. We discuss each in turn.

1. Absolute Liability

The *Mutual* majority left open the question whether federal law would preempt a state-law claim that a generic drug manufacturer is absolutely liable for injuries caused by its products.⁹⁸ As mentioned earlier, Justice Alito distinguished what he called a “true absolute-liability state-law system” from one based on “strict liability.”⁹⁹ In the former scheme, “liability does not reflect the breach of any duties at all, but merely serves to spread risk.”¹⁰⁰ In a “true” absolute-liability system, then, causation is the liability trigger, and once the plaintiff establishes that the defendant’s product caused the plaintiff’s injury, the defendant is liable regardless of whether the defendant breached a duty to the plaintiff or, more generally, to the class of consumers for whom the product was intended.

By contrast, Justice Alito explained, although strict liability “does not depend on negligence, [it] still signals breach of a duty.”¹⁰¹ And, New Hampshire law—the law applicable in *Mutual*—he went on, “has consistently held that the manufacturer of a product has a ‘duty to design his product reasonably safely for the uses which he can foresee.’ ”¹⁰²

Why all the fuss over whether New Hampshire design-defect law does or does not impose a duty? Assume, as the majority held, that New Hampshire law imposes a duty to act to design products “reasonably safely,” and a jury finds that that duty was breached because the product was marketed in its current, unreasonably dangerous design or should have been marketed with another “reasonably safe” design. At the same time, the argument goes, federal law both authorizes the product’s sale, as it did with sulindac, and prohibits the seller from unilaterally changing the product’s design (to meet the dictates of state law or for any other reason). As the majority viewed the law, the con-

⁹⁸ *Mutual*, 133 S. Ct. at 2474 n.1.

⁹⁹ *Id.* at 2473-74.

¹⁰⁰ *Id.* at 2473.

¹⁰¹ *Id.*

¹⁰² *Id.* (quoting *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 847 (N.H. 1978)); see also *id.* at 2474 (quoting other New Hampshire Supreme Court decisions for the same and similar propositions).

fluence of these facts made meeting both the federal and state duties impossible.¹⁰³

But if state law imposes no duty—that is, if a state requires a seller to compensate anyone injured by its product regardless of whether the product violated a standard for its design—it is difficult to see a conflict with federal law, whether typed “impossibility” or otherwise. In that scenario, the state has decided that its residents should be insured against injuries caused by all products—whether federally approved or not—and, presumably for reasons of efficiency, the state has designated the seller as the insurer (with the “premiums,” at least in part, effectively included in the products’ retail prices).

Strict liability is sometimes equated with (or confused with) absolute liability, even in prestigious quarters.¹⁰⁴ But Justice Alito eliminated any potential confusion, first, when he characterized New Hampshire strict-liability design-defect law as imposing a duty on the seller, and, second, when he said, more generally, that “most common-law causes of action for negligence and strict liability do not exist merely to spread risk, but rather to impose affirmative duties.”¹⁰⁵

Justice Alito may have understated the latter point. Although exceptions may exist for certain types of products or activities, no jurisdiction of which we are aware generally imposes absolute liability on the sellers of products, but rather authorizes suit under theories of negligence and/or strict liability. Common-law negligence is premised on a duty to use reasonable care.¹⁰⁶

As for strict liability, a minority of jurisdictions do not recognize design-defect claims against the manufacturers of prescription drugs at all.¹⁰⁷ Many jurisdictions adopted the Second Restatement of Torts, which endorsed strict products liability, including for design defects, even where the seller had used “all possible care” in preparing and selling its product.¹⁰⁸ But the plaintiff was required to show that the seller sold a “product in a defective condition unreasonably dangerous to the user or consumer or to his property”—that is, the seller had a duty to design a non-defective product and could escape liability if it did so.¹⁰⁹

Though courts and commentators struggled to define that duty, they were “search[ing] mightily for standards

¹⁰³ The dissenting justices did not view compliance with federal law impossible because, in response to a state-law duty to design the product other than as federally approved, the manufacturer could, among other things, remove the product from the market (which, of course, is not prohibited by federal law). *Id.* at 2480-81 (Breyer, J., dissenting); *id.* at 2491 (Sotomayor, J., dissenting).

¹⁰⁴ See, e.g., Restatement (Second) of Torts (1965) (Index) (“ABSOLUTE LIABILITY See Strict Liability”).

¹⁰⁵ *Mutual*, 133 S. Ct. at 2474 n.1 (citations omitted). The dissenters did not disagree with the majority either with this general statement, or that New Hampshire law imposed a design-related duty on *Mutual*; instead, they disagreed on the characteristics of that duty and whether it conflicted with duties imposed by federal law. See *id.* at 2480-81 (Breyer, J., dissenting); *id.* at 2487-88 (Sotomayor, dissenting).

¹⁰⁶ See, e.g., Restatement (Second) of Torts § 282, at 9 (1965); Prosser and Keeton, *The Law of Torts* § 28, at 160-61 (5th ed. 1984).

¹⁰⁷ See *Mutual*, 133 S. Ct. at 2487 (Sotomayor, J., dissenting).

¹⁰⁸ Restatement (Second) of Torts § 402A(2)(a), at 348 (1965).

¹⁰⁹ *Id.* § 402A(1), at 347; see *Mutual*, 122 S. Ct. at 2473.

or ‘tests’ of liability that would stop liability well short of absolute.”¹¹⁰ Generally, they favored the imposition of liability only where a product’s risks outweighed its benefits.¹¹¹ The Third Restatement of Torts followed this trend. Its section devoted exclusively to liability for the sale of defective prescription drugs and medical devices expressly adopted a risk-benefit-based duty for design-defect claims.¹¹²

In sum, although absolute liability provides a theoretical basis for escaping the preemption holdings of *Mutual* and *PLIVA*, it currently provides no real-world basis for doing so.

2. Liability Based on Misbranding

a. After concluding that Ms. Bartlett’s “warning-based design-defect cause of action” was preempted,¹¹³ the *Mutual* majority noted that it was not “address[ing] state design-defect claims that parallel the federal misbranding statute.”¹¹⁴ This reference to “parallel” claims picks up on a recent strain in the Court’s tort preemption jurisprudence that has offered some hope to plaintiffs seeking compensation in otherwise preempted fields. Beginning with *Medtronic, Inc. v. Lohr*,¹¹⁵ and then in *Bates v. Dow Agrosciences LLC*,¹¹⁶ and *Riegel v. Medtronic, Inc.*,¹¹⁷ the Court held that express provisions of federal law that preempt state requirements that are “different from” or “in addition to” federal requirements do not preempt state requirements that “parallel” federal requirements.¹¹⁸ A state-law duty premised on violations of a federal duty, the Court has explained, is not “different” or “in addition to” the federal duty, even when the state-law duty is invoked to provide a state-law damages remedy that goes beyond what federal law provides.¹¹⁹

¹¹⁰ David G. Owen, *Design Defects*, 73 Mo. L. Rev. 291, 299 (2008) (emphasis added); see also *id.* (“In considering the concept of design defectiveness, it is crucial to remember that a manufacturer’s liability for harm from a product’s design characteristics, even if labeled ‘strict,’ is not absolute.”).

¹¹¹ *Id.* at 299-321.

¹¹² Restatement (Third) of Torts: Products Liability § 6(c), at 145 (1998) (requiring inquiry into whether “the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits. . .”).

¹¹³ *Mutual*, 133 S. Ct. at 2477.

¹¹⁴ *Id.* at 2477 n.4.

¹¹⁵ 518 U.S. 470 (1996) (interpreting 21 U.S.C. § 360k (“different from, or in addition to”).

¹¹⁶ 544 U.S. 431 (2005) (interpreting 7 U.S.C. § 136v(b) (“in addition to or different from”).

¹¹⁷ 552 U.S. 312 (2008) (interpreting 21 U.S.C. § 360k).

¹¹⁸ *Lohr*, 518 U.S. at 495 (“Nothing in [21 U.S.C.] § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.”); accord *id.* at 513 (O’Connor, J., concurring in part and dissenting in part); *Riegel*, 552 U.S. at 330; *Bates*, 544 U.S. at 447.

¹¹⁹ *Lohr*, 518 U.S. at 495 (“The presence of a [state-law] damages remedy does not amount to the additional or different ‘requirement’ that is necessary [to trigger preemption] under the [federal] statute; rather, it merely provides another reason for manufacturers to comply with identical existing ‘requirements’ under federal law.”); *id.* at 513 (O’Connor, J., concurring in part and dissenting in part) (“Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is ‘different from, or in addition to,’ requirements under federal law.”).

b. The FDCA’s misbranding provision provides that a drug or device is misbranded if, among other things, “it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.”¹²⁰ The *Mutual* majority noted that “even an FDA-approved drug” must be “pull[ed] . . . from the market” if it violates this misbranding provision,¹²¹ and then added, with apparent approval, a “*cf.*” citation to the Court’s decision in *Bates*, which held that a “state-law pesticide labeling requirement [was] not preempted under [an] express pre-emption provision, provided it was ‘equivalent to, and fully consistent with, [federal] misbranding provisions.’”¹²²

In our view, the Court’s discussion of misbranding could become the source of a meaningful exception to the general preemption rule established in *Mutual*. It bears noting that because misbranding under the FDCA is based on deficiencies in drug labeling,¹²³ a state-law claim based on misbranding must be pleaded, to use Justice Alito’s words, as “a warning-based design-defect cause of action,”¹²⁴ and not as what we have called here a “pure” design-defect claim based solely on a duty to change the drug’s chemical composition or not to market the product as currently formulated.

A state-law misbranding claim likely will not, however, provide a basis for an exception to *PLIVA*, which held that state-law failure-to-warn claims against generic drug manufacturers are preempted because federal law bars generic drug sellers from unilaterally amending their labels to comply with state-law duties (a federal prohibition that persists even when the product is misbranded). Indeed, in *PLIVA*, the Court rejected FDA’s argument that a generic manufacturer’s duty under the misbranding statute to propose “stronger warning labels to the agency,” which in turn might result in “a new label for both the brand-name and generic drug,” was sufficient to defeat the manufacturer’s claim of impossibility preemption.¹²⁵ A misbranding-based claim thus must remain a design-defect claim, and it escapes preemption because when federal law demands that a manufacturer remove an approved product from the market, a state-law duty that also may be heeded by leaving the market cannot give rise to impossibility preemption.

c. We expect generic drug manufacturers to argue that if a state-law misbranding-based claim may survive preemption under *Mutual* at all, FDA itself must have found the drug in question misbranded. We think that this argument will fail for several reasons.

First, that argument would be inconsistent with the Supreme Court’s understanding of a “parallel” requirement, which provides an exception from preemption for “a state rule insofar as it duplicates the federal rule.”¹²⁶ As *Mutual* explained, it is the presence of conflicting state and federal duties, not that regulated actors might avoid a conflict by taking or refraining from certain conduct (such as the possibility that a manufacturer

might remove its product from the market), that gives rise to preemption.¹²⁷ That same principle should apply when federal and state duties coincide. When that happens, “the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ.”¹²⁸

Second, in *Bates*, the Court held that a state-law misbranding-based claim escaped preemption, under an express preemption provision that overrides “different” or “additional” state requirements, so long as that claim was “equivalent to, and fully consistent with, [the relevant federal] misbranding provisions.”¹²⁹ In *Bates*, no federal finding of misbranding of the pesticide in question had been made, and the Court nonetheless was clear that it would allow a state-law misbranding-based claim to proceed regardless of whether the federal regulator had weighed in.

Indeed, the Court in *Bates* rejected the defendant’s argument that allowing state law to operate would “give juries in 50 States the authority to give content to [the federal statute’s] misbranding prohibition, establishing a crazy-quilt of anti-misbranding requirements different from the one defined by [the federal statute] itself.”¹³⁰ *Mutual*’s citation to *Bates* suggests that the same “equivalent to, and fully consistent with” standard should apply to a state-law misbranding-based claim against a generic drug manufacturer,¹³¹ but not that the federal government first must make its own misbranding finding.

Finally, in *Mutual*, Justice Alito knew well that FDA had not found sulindac misbranded, yet he held the “misbranding provision . . . not applicable here” not on that basis, but 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.”¹³² This statement suggests that a properly instructed jury may consider a misbranding-based state-law claim absent an FDA misbranding finding without offending the Supremacy Clause.¹³³

d. As we see it, a misbranding-based exception to preemption would provide injured plaintiffs access to the courts in some circumstances, but would not swallow the *PLIVA-Mutual* rule. As *Mutual* explained, FDA maintains 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.”¹³⁴ If FDA does, in fact, interpret and enforce the misbranding statute in this way, it is likely that the courts will defer to FDA’s interpretation and require plaintiffs to show that their state-law misbranding

¹²⁰ 21 U.S.C. § 352(j).

¹²¹ *Mutual*, 133 S. Ct. at 2477 n.4.

¹²² *Id.* (quoting *Bates*, 544 U.S. at 447).

¹²³ See generally 21 U.S.C. § 352.

¹²⁴ *Id.* at 2477.

¹²⁵ *PLIVA*, 131 S. Ct. at 2576 (citing 21 U.S.C. 352(f)(2)).

¹²⁶ *Lohr*, 518 U.S. at 495 (emphasis added).

¹²⁷ *Mutual*, 133 S. Ct. at 2477-78.

¹²⁸ *Lohr*, 518 U.S. at 513 (O’Connor, J., concurring in part and dissenting in part).

¹²⁹ *Bates*, 544 U.S. at 447.

¹³⁰ *Id.* at 448 (quoting defendant’s brief).

¹³¹ See *Mutual*, 133 S. Ct. at 2477 n.4.

¹³² *Id.*

¹³³ See also *Bates*, 544 U.S. at 454 (“If a case proceeds to trial, the court’s jury instructions must ensure that nominally equivalent labeling requirements are genuinely equivalent. If a defendant so requests, a court should instruct the jury on the relevant [federal] misbranding standards, as well as any regulations that add content to those standards.”).

¹³⁴ *Mutual*, 133 S. Ct. at 2477 n.4.

claims are based only on this type of “new and scientifically significant information.”¹³⁵

Courts will view this limit as reasonable because preemption is often premised on an aversion to second-guessing agency expertise, and a “new-information” requirement—which operates only when the agency has not exercised its judgment—is consistent with that premise. FDA’s Supreme Court brief in *Mutual* made this point. The agency repeatedly derided “[t]ort judgments that second-guess FDA’s expert [risk-benefit] determination[s].”¹³⁶ It urged a preemption finding in part because it had previously considered the scientific evidence that had been put before the jury in *Ms. Bartlett’s* case and had “conducted a ‘comprehensive review’ of the risks and benefits of all NSAIDs but did not conclude that sulindac or other NSAIDs . . . should be withdrawn from the market based on incidents of SJS/TEN.”¹³⁷

At the same time, however, FDA acknowledged that there should have been no preemption if “notwithstanding FDA’s approval of sulindac and its review of its safety in 2005, new evidence concerning the rare occurrence of SJS/TEN rendered sulindac so dangerous as to be misbranded under that federal standard.”¹³⁸ Thus, in cases where the relevant evidence had not been before FDA at the time of the product’s approval or was not otherwise the subject of formal FDA review before the plaintiff was prescribed the drug, in our view, that evidence may form the basis of a state-law misbranding-based claim unaffected by preemption.

e. Assuming that lower courts hold that state-law misbranding-based claims escape preemption if they meet a “new evidence” standard, how often will plaintiffs be able to meet that standard? The Court in *PLIVA* doubted the impact of its preemption holding, noting that “FDA informs us that ‘[a]s a practical matter, genuinely new information about drugs in long use (as generic drugs typically are) appears infrequently.’”¹³⁹ It called situations like those that befell the *PLIVA* plaintiffs—who *did* allege injuries based on the seller’s failure to convey information that arose after the product’s approval—“apparently so rare that the FDA has no ‘formal regulation’ establishing generic drug manufacturers’ duty to initiate a label change. . . .”¹⁴⁰

¹³⁵ Cf. *PLIVA*, 131 S. Ct. at 2575-76 (deferring to FDA’s interpretation of generic drug labeling statutes and regulations because that interpretation was not “plainly erroneous”). FDA’s interpretation may also garner deference from courts as consistent with the agency’s view that brand-name manufacturers may unilaterally change their labels without prior agency approval “to reflect newly acquired information.” 21 C.F.R. § 314.70(c)(6)(iii) (emphasis added).

¹³⁶ Brief of the United States as Amicus Curiae Supporting Petitioner, at 29, in *Mutual Pharm. Co., Inc. v. Bartlett*, No. 12-142 (U.S. filed Jan. 22, 2013), available at 2013 WL 314460, *29; see also *id.* at 13, 28, 34, available at 2013 WL 314460, *13, *28, *34.

¹³⁷ *Id.* at 30, available at 2013 WL 314460, *30.

¹³⁸ *Id.* at 24, available at 2013 WL 314460, *24.

¹³⁹ *PLIVA*, 131 S. Ct. at 2581 n.9 (quoting Brief for the United States as Amicus Curiae Supporting Respondents, at 34-35, in *PLIVA, Inc. v. Mensing*, No. 09-993 (U.S. filed Mar. 2, 2011), available at 2011 WL 741927, *34-35).

¹⁴⁰ *Id.* (quoting Brief for the United States as Amicus Curiae Supporting Respondents, at 21, in *PLIVA, Inc. v. Mensing*, No. 09-993 (U.S. filed Mar. 2, 2011), available at 2011 WL 741927, *21).

Though generic products generally do enter the market well after their brand-name equivalents, we think *PLIVA’s* reasoning here is questionable (or of questionable relevance) for two reasons. *First*, that “genuine[] new-information” cases arise only rarely may mean only that suits involving generic-drug injuries are rare, not that suits alleging injuries from generic drugs, if unobstructed by preemption, rarely would involve new information. Indeed, given that generic-drug injury suits necessarily arise well after the product was first marketed, we expect that many (if not all) of them allege that the plaintiff’s injury could have been avoided if she or her doctors had been made aware of information not available to FDA at the time the product was approved.

Second, *PLIVA’s* surmise that there is little relevant “new” safety information about generic drugs may be incorrect. FDA’s failure to have a “formal regulation” establishing a duty to initiate label changes probably reflects the agency’s failure to keep up with the increasing marketplace dominance of generic drugs rather than proof that there is no need for generic manufacturers to initiate safety-related label changes. As explained below in Part III.C.1., the agency recently announced plans to propose a regulation that would authorize generic drug manufacturers to update labels based on new safety information, which would make no sense if FDA thought it unnecessary.

Moreover, evidence suggests that new information implicating a drug’s safety *does* arise years after FDA approval. “Many serious [adverse drug reactions] are discovered only after a drug has been on the market for years. Only half of newly discovered serious adverse drug reactions are detected and documented in the Physicians’ Desk Reference [the doctors’ drug labeling bible] within 7 years after drug approval.”¹⁴¹

For these reasons, we believe that state-law misbranding-based claims remain legally viable after *Mutual* and should provide access to the courts for people injured by generic drugs in a meaningful number of cases.

3. Suits Against Brand-Name Manufacturers

Since at least the early 1990s, some plaintiffs alleging injuries from prescription generic drugs have sought damages from the manufacturers of the brand-name products on which the generic products were based. As discussed below, the brand-name manufacturers maintain that these suits fail as a matter of state law, while plaintiffs claim that they are authorized by traditional common-law tort principles. For convenience, we refer to these cases as “brand-name suits.”

These suits may take on added significance in light of the Supreme Court’s preemption holdings in *PLIVA* and *Mutual*, which largely (if not entirely) eliminated generic manufacturers’ state-law liability for injuries caused by their products, and *Wyeth v. Levine*, where the Court held that state-law inadequate-warning suits against brand-name manufacturers generally are *not* preempted by the FDCA, in significant part because brand-name manufacturers can make safety enhancing changes to their labels without prior FDA approval.¹⁴² That is, though brand-name suits raise a controversial

¹⁴¹ See Karen E. Lasser, *et al.*, *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, 287 J.A.M.A. 2215, 2218 (May 1, 2002).

¹⁴² 555 U.S. at 570-71.

question of state law, they do not raise federal preemption issues in light of *Wyeth*. We now consider whether brand-name suits are a viable future option for plaintiffs seeking compensation no longer available to them from generic prescription drug manufacturers.

Factually, brand-name suits are premised on a brand-name manufacturer's alleged labeling misstatements about its product's hazards or contraindications. These alleged misstatements, the plaintiff's complaint will allege, had their origins in the brand-name manufacturer's label. This brand-name label appeared on the generic manufacturer's label because the law required it. Moreover, an "exact copy" of the brand-name-generated label appeared in the *Physicians' Desk Reference*, which doctors use to learn about a product's safety and efficacy before making their prescribing decisions.¹⁴³ So, when doctors rely on labeling to prescribe a prescription drug (whether brand-name or generic), they are relying on the *brand-name manufacturer's* labeling. Thus, the plaintiff will maintain that the brand-name manufacturer's labeling misstatements foreseeably caused her injuries, even though she ingested only the generic equivalent, because the brand-name manufacturer knows that whenever one of its products is mislabeled, the generic product will be as well.

Legally, brand-name suits are not based on strict products liability, which imposes liability on the *sellers* of products.¹⁴⁴ Instead, they are premised on claims of negligent and/or intentional misrepresentation, which plaintiffs maintain authorizes liability against a non-seller who has reason to know that a third party could suffer harm.¹⁴⁵ Brand-name-suit plaintiffs claim support for these theories in Sections 310 and 311 of the Restatement (Second) of Torts. Section 311—entitled "Negligent Misrepresentation Involving Risk of Physical Harm"—provides that "one who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results . . . to such *third persons* as the actor should expect to be put in peril by the action taken."¹⁴⁶

The "one" who gives false information is the brand-name manufacturer who, the plaintiff claims, negligently (or intentionally) made false statements in its labeling. The "other" generally would be the prescribing doctor who relied on the false labeling. And the "third person" is the patient who relied on the doctor's misinformed prescription (and, in turn, was injured by the drug).

Is the doctor's reliance reasonable in these circumstances? And should the brand-name manufacturer have expected that patients would be put in peril?

¹⁴³ See *Gilbert v. Sec'y HHS*, 2005 WL 3320085, *8 n.22 (Fed. Cl. 2005); see also, e.g., *Garvey v. O'Donoghue*, 530 A.2d 1141, 1144 n.4 (D.C. 1997).

¹⁴⁴ See Restatement (Second) of Torts § 402A, at 347 (1965).

¹⁴⁵ See *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 309-10 (Cal. App. 2008) (explaining differences in strict products liability and misrepresentation theories in case brought by generic drug user who sued brand-name manufacturer on misrepresentation theory).

¹⁴⁶ Restatement (Second) of Torts § 311(b), at 106 (1965) (emphasis added). Section 310 imposes similar liability for knowing misrepresentations. See *id.* § 310, at 103.

Here is what the California Court of Appeal said on those topics in *Conte v. Wyeth, Inc.*:

In California, as in most states, pharmacists have long been authorized by statute to fill prescriptions for name-brand drugs with their generic equivalents unless the prescribing physician expressly forbids such a substitution. . . . It is therefore highly likely that a prescription for [the brand-name drug] written in reliance on [the brand-name's] product information will be filled with [the] generic. . . . And, because by law the generic and name-brand versions of drugs are biologically equivalent . . . , it is also eminently foreseeable that a physician might prescribe [the] generic . . . in reliance on [the brand-name's] representations about the [brand-name drug]. In this context, we have no difficulty concluding that [the brand-name manufacturer] should reasonably perceive that there could be injurious reliance on its product information by a patient taking [the] generic [drug].¹⁴⁷

Although we find this logic persuasive, *Conte* remains an outlier. Most courts presented with the question have held that brand-name suits are not viable under state law. The lead case is the Fourth Circuit's decision in *Foster v. American Home Products Corp.*,¹⁴⁸ which rejected what it viewed as an impermissible end-run around the standard products-liability action against the seller.¹⁴⁹ A negligent misrepresentation suit against a brand-name manufacturer, the court added, "stretch[ed] the concept of foreseeability too far."¹⁵⁰ Though *Foster* involved only an interpretation of Maryland common law, many other courts, applying the law of a variety of states, have followed its lead.¹⁵¹

Despite the lopsided split in the case law, patients injured by generic drugs as a result of labeling inadequacies should give serious thought to brand-name suits for three reasons.

¹⁴⁷ 85 Cal. Rptr. 3d 299, 313 (Cal. App. 2008) (internal citations omitted); accord *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 705-09 (D. Vt. 2010).

¹⁴⁸ 29 F.3d 165 (4th Cir. 1994).

¹⁴⁹ *Id.* at 168 ("Although actions for negligent misrepresentation arise in many contexts other than products liability, in this case the allegations of negligent misrepresentation are an effort to recover for injuries caused by a product without meeting the requirements the law imposes in products liability actions. Maryland law requires a plaintiff seeking to recover for an injury by a product to demonstrate that the defendant manufactured the product at issue.")

¹⁵⁰ *Id.* at 171.

¹⁵¹ See, e.g., *Schrock v. Wyeth, Inc.*, ___ F.3d ___, 2013 WL 4529359, *7-11 (Aug. 28, 2013); *Smith v. Wyeth*, 657 F.3d 420 (6th Cir. 2011); *Finnicum v. Wyeth, Inc.*, 708 F. Supp. 2d 616, 619-21 (E.D. Tex. 2010); *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1358 (N.D. Ga. 2008); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 540-41 (E.D. Pa. 2006); *rev'd on other grounds*, 521 F.3d 253 (3d Cir. 2008); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34-35 (La. Ct. App. 2008); *Sharp v. Leichus*, 952 So. 2d 555 (Fla. Dist. Ct. App. 2007); *Flynn v. American Home Products Corp.*, 627 N.W. 2d 342, 350 (Minn. Ct. App. 2001). But see *Wyeth, Inc. v. Weeks*, ___ So. 3d ___, 2013 WL 135753, *21-*26 & n.8, *30 (Ala. Jan. 11, 2013) (Murdock, J., dissenting) (reviewing dozen of decisions rejecting brand-name suits). In *Weeks*, the Alabama Supreme Court held 8-1 that Alabama law authorized suit by a generic drug user against a brand-name manufacturer on fraud and misrepresentation theories. The court issued its decision without hearing oral argument and now is reconsidering its ruling. It heard oral argument on September 4, 2013, and a decision is pending. See <http://pubcit.typepad.com/clpblog/2013/06/alabama-supreme-court-grants-rehearing-on-whether-brand-name-drug-co-can-be-held-liable-for-inadequa.html>.

First, most (though not all) of the rulings that have rejected brand-name suits pre-date the Supreme Court's decision in *PLIVA*. Before *PLIVA*, plaintiffs regularly maintained that FDA's so-called "changes-being-effected" (CBE) regulation, 21 C.F.R. § 314.70, authorized generic manufacturers, like their brand-name parents, to make safety-related label changes without first obtaining FDA's approval. Under that view, a generic manufacturer's right to amend its label, on its own, weakens a claim that the name-brand manufacturer is responsible for the generic manufacturer's label deficiencies, which is critical to the misrepresentation theory underlying a brand-name suit.

Indeed, in *Foster*, the Fourth Circuit held a brand-name suit non-viable in significant part because "[m]anufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products."¹⁵² The court explained that although generic manufacturers do "not initially formulate the warnings and representations," they are "permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval."¹⁵³

PLIVA rejected that position, deferring to FDA's view that the CBE regulation authorizes only brand-name manufacturers, and not generic manufacturers, "to unilaterally strengthen their labels,"¹⁵⁴ effectively holding that generic manufacturers are in the labeling straight-jacket that *Foster* maintained did not exist. *PLIVA*'s bedrock premise, in other words, is the same one that forms the basis for a brand-name suit: that a brand-name manufacturer bears sole responsibility for a generic manufacturer's label.¹⁵⁵

Second, although the case law generally holds that brand-name suits are not authorized by state law, almost all of the case law involves federal district court predictions of state law. Very few are state-court decisions, and none is from a state court of last resort, the only court that possesses final authority on whether state-law brand-name suits are viable.

On the other hand, an intermediate appellate court (*Conte*) has backed brand-name suits under California law, and, as noted earlier, the Alabama Supreme Court is poised to decide the issue in *Wyeth v. Weeks*.¹⁵⁶ *Weeks* arrived at the Alabama Supreme Court from the U.S. District Court for the Middle District of Alabama, which had certified the state-law issue to it.¹⁵⁷ Other federal courts should follow the Alabama district court's lead. Because most suits against drug manufacturers are filed in, or removed to, federal court on diversity-of-citizenship grounds,¹⁵⁸ certification will al-

low the state courts to weigh in on a question that is rightfully theirs.¹⁵⁹

Third, absent congressional or FDA action,¹⁶⁰ brand-name suits may be the only option for patients seeking compensation for injuries suffered from their use of mislabeled generic prescription drugs. *PLIVA* and *Mutual* may provide complete (or at least substantial) immunity to generic manufacturers, but their reasoning—that generic drug labels are the province of brand-name manufacturers—is consistent with a state-law duty that makes brand-name manufacturers responsible.

C. Potential Regulatory and/or Congressional Action

Whatever one thinks of the Supreme Court's legal analyses in *Wyeth*, *PLIVA*, and *Mutual*, the results of those decisions, taken together, make nonsensical public policy. A state-law failure-to-warn suit—the traditional claim against drug makers—may be brought against a brand-name manufacturer for alleged product mislabeling, but a suit against the generic manufacturer of the same drug for the same alleged mislabeling is barred by federal law. Nor does the same claim against the generic manufacturer escape preemption if it is pleaded as a design-defect claim (with limited potential exceptions discussed above in Parts II.A & B).

Justice Sotomayor noted the "absurd" consequences of the Supreme Court's rulings in her *PLIVA* dissent. An injured consumer's ability to recover for her injuries from a culpable drug manufacturer depends, she said, on "the happenstance" of whether the consumer's pharmacist dispensed the brand-name or generic version of the drug.¹⁶¹

Justice Thomas, speaking for the majority in *PLIVA*, also acknowledged the irrationality of the current regime. He noted that had the plaintiffs there taken the "brand-name drug prescribed by their doctors," instead of the generic drug substituted by their pharmacists, "Wyeth would control and their lawsuits would not be pre-empted."¹⁶² From the plaintiffs' perspective, he acknowledged, "finding preemption [in *PLIVA*] but not in *Wyeth* makes little sense."¹⁶³

We now turn to whether FDA and/or Congress can make sense of the scheme left in the wake of the Supreme Court's recent decisions.

1. Potential FDA Regulatory Action

Because the rulings in *Mutual* and *PLIVA* turned on the asserted impossibility of a manufacturer's simultaneous compliance with both federal labeling rules for generic drugs and a state-law duty to make safety-based revisions to a generic drug label, FDA could amend its labeling rules to eliminate the impossibility identified by the Supreme Court majority.

¹⁵² *Foster*, 29 F.3d at 179.

¹⁵³ *Id.* at 169-70 (citing 21 C.F.R. § 314.70).

¹⁵⁴ *PLIVA*, 131 S. Ct. at 2575.

¹⁵⁵ See *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 747-48 (8th Cir. 2013) (Murphy, J., concurring) (explaining in dicta that *PLIVA* and *Mutual* "severely eroded the foundation of th[e] analysis" of the courts that have rejected brand-name suits because that analysis has "generally been predicated on the assumption that the generic manufacturers could independently safeguard and strengthen their own labels.").

¹⁵⁶ See *supra* note 151.

¹⁵⁷ *Wyeth v. Weeks*, ___ So. 3d at ___, 2013 WL 135753, *1 (setting out certified question).

¹⁵⁸ See *id.* at ___; 2013 WL 135753, *26 & n.8.

¹⁵⁹ See *id.* at ___, 2013 WL 135753, *2 ("Certification is appropriate here to resolve the disagreement among the federal district courts within Alabama and to prevent both federal courts within the State and state courts around the country from having to 'mak[e] unnecessary *Erie* guesses' about unsettled questions of Alabama law.") (quoting *Tobin v. Michigan Mut. Ins. Co.*, 398 F.3d 1267, 1274 (11th Cir.2005)); see also *Arizonans for Official English v. Arizona*, 520 U.S. 43, 79-80 (1997) (discussing benefits of federal-court certification of state-law questions to state high courts).

¹⁶⁰ See *infra* Part III.C.

¹⁶¹ *PLIVA*, 131 S. Ct. at 2592 (Sotomayor, J., dissenting).

¹⁶² *Id.* at 2581 (majority opinion).

¹⁶³ *Id.*

In *Wyeth*, the Court had rejected preemption-by-impossibility because, among other reasons, FDA's CBE regulation authorized brand-name drug manufacturers unilaterally to amend their labels to add warnings, rendering a state-law claim premised on a duty to have issued these warnings consistent with, and not in conflict with, federal law.¹⁶⁴

As noted earlier, *PLIVA* came to the opposite conclusion because, the Court held, FDA regulations did *not* authorize unilateral changes to generic drug labels.¹⁶⁵ Presumably, then, if FDA were to amend its rules to authorize generic drug manufacturers to use the CBE regulation in the circumstances under which brand-name manufacturers currently have that authority, the federal regulatory basis for *PLIVA*'s impossibility holding would no longer exist. This amendment would eliminate the absurd consequences of having inconsistent state-law tort duties for brand-name and generic drug manufacturers highlighted in Justice Sotomayor's *PLIVA* dissent.

The tort system operates to provide compensation and to induce safer behavior in the future, but only after someone has suffered an injury. It bears emphasis, therefore, that authorizing generic manufacturers to make labeling changes would be aimed principally at enhancing drug safety and preventing injuries that might otherwise occur.¹⁶⁶

In considering whether to provide generic manufacturers access to the CBE process, FDA's principal consideration should be to rationalize and modernize its generic drug labeling rules. FDA promulgated its CBE regulation because it wanted to provide a mechanism for companies to amend their labels when new safety information "require[d] prompt corrective action,"¹⁶⁷ without forcing the products off the market while the agency was considering the labeling changes. The idea, then, was to protect patients both by putting the most up-to-date information into their (and their doctors') hands and by ensuring their continued access to needed medications. There is no reason why this same mechanism should not be available to generic manufacturers and—given the growing market dominance of generic drugs—every reason why it should.

Like their brand-name counterparts, generic manufacturers will be capable of using the CBE process when appropriate. Both brand-name and generic drug manufacturers must comply with regulations designed to ensure the post-approval safety of their drugs, and must "promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers."¹⁶⁸

Any report of a "serious and unexpected" drug experience must be reported to FDA within 15 days and must be promptly investigated by the manufacturer.¹⁶⁹

¹⁶⁴ *Wyeth*, 555 U.S. at 568-69; *accord id.* at 591-92 (Thomas, J., concurring in the judgment).

¹⁶⁵ *PLIVA*, 131 S. Ct. at 2575-76.

¹⁶⁶ See *Wyeth*, 555 U.S. at 578-79.

¹⁶⁷ 47 Fed. Reg. 46,622, 46,635 (Oct. 19, 1982).

¹⁶⁸ 21 C.F.R. § 314.80(b) (made applicable to ANDA holders by 21 C.F.R. § 98(a)).

¹⁶⁹ *Id.* § 314.80(c)(1)(i-ii).

Most other adverse event reports must be submitted quarterly for three years after the application is approved and annually after that.¹⁷⁰ These periodic reports must include "a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated)."¹⁷¹ Thus, generic manufacturers, like brand-name manufacturers, participate actively in post-market surveillance of their products and are in a good position to know about adverse events and the need, if any, for labeling changes that would enhance patient safety.

After a brand-name manufacturer employs the CBE process, FDA must determine whether the label changes are appropriate. If FDA approves the label changes as submitted or in modified form, it then requires that the new label be adopted across the board by all sellers of the drug. FDA can make the same determinations when a generic manufacturer employs the CBE process.

FDA appears to be moving toward establishing uniformity between brand-name and generic manufacturers. Soon after the Supreme Court's ruling in *PLIVA*, the non-profit consumer organization Public Citizen petitioned FDA to revise its generic drug labeling regulations to authorize generic manufacturer to update their labels, without prior FDA approval, as currently authorized for brand-name manufacturers in the CBE process.¹⁷²

For nearly a year and a half, FDA did not comment publicly on Public Citizen's petition. Then, in its Supreme Court brief in *Mutual*, FDA acknowledged that it "is considering a regulatory change that would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances[.]" adding that "[i]f such a regulatory change is adopted, it could eliminate preemption of failure-to-warn claims against generic-drug manufacturers."¹⁷³

Thereafter, in July 2013, the federal Office of Management and Budget announced that FDA planned to issue "proposed revisions to FDA's regulations [that] would create parity between NDA holders and ANDA holders with respect to submission of CBE labeling supplements."¹⁷⁴ The proposed rule, which was slated for publication in September 2013 (but has yet to appear), would "revise and clarify procedures for changes to the labeling of an approved drug to reflect certain types of newly acquired information in advance of FDA's review of such change."¹⁷⁵

Justice Alito ended his decision in *Mutual* by claiming that although Ms. Bartlett's "tragic circumstances" "evoke[d] deep sympathy," his preemption ruling was demanded by "a straightforward application of pre-

¹⁷⁰ *Id.* § 314.80(c)(2)(i).

¹⁷¹ *Id.* § 314.80(c)(2)(ii).

¹⁷² See [Public Citizen] Citizen Petition (Aug. 29, 2011), available at <http://www.citizen.org/documents/1965.pdf>.

¹⁷³ Brief for the United States as Amicus Curiae Supporting Petitioner in *Mutual Pharm. Co. v. Bartlett*, at 15 n.2, No. 12-142 (U.S. filed Jan. 22, 2013), available at 2013 WL 314460, *15 n.2.

¹⁷⁴ See Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, RIN 0910-AG94, available at <http://www.reginfo.gov/public/servelet/ForwardServlet?SearchTarget=Agenda&textfield=0910-AG94>.

¹⁷⁵ *Id.*

emption law,” triggered by a regulatory scheme that “leaves generic drug manufacturers incapable of modifying either the drugs’ compositions or their warnings.”¹⁷⁶ An FDA rule authorizing generic drug manufacturers to amend their labeling to make safety-related enhancements would put those manufacturers in the same position as brand-name manufacturers and effectively overrule *PLIVA*.

That rule would not affect *Mutual* directly because it would not authorize manufacturers to make unilateral changes to a drug’s design. But because “[f]ailure to instruct or warn is the major basis of liability for manufacturers of prescription drugs,”¹⁷⁷ an FDA regulation that empowered generic drug manufacturers to modify their warnings would lift the bar to state-law tort compensation erected by *PLIVA* and render *Mutual* largely irrelevant. More importantly, that regulation would help prevent drug-related injuries by freeing generic drug manufacturers to put new safety information in the hands of doctors and patients before injuries occur.

2. Potential Congressional Action

Congress is unlikely to consider legislation to overrule *Mutual*. As noted above, state-law suits seeking compensation for injuries caused by prescription drugs generally allege a failure to warn of the product’s hazards, not defects in the drug’s design. Legislation aimed at *Mutual* alone would not free plaintiffs to maintain state-law inadequate warning claims and thus would fail to give them parity with patients injured by brand-named drugs. That is, from the patients’ perspective, a liability scheme altered to overrule *Mutual* alone would, to use Justice Thomas’s words, still “make[] little sense.”¹⁷⁸

On the other hand, overruling *PLIVA* would make sense. Congress could accomplish that in one of two ways. *First*, it could amend the FDCA to provide that neither the Act nor its regulations preempt state-law damages claims premised on a failure to warn. If Congress were to do this, it would make sense to overrule *Mutual* as well by aiming not only at failure-to-warn claims but by explicitly exempting from preemption state-law damages suits alleging injuries from prescription drugs. Congress has taken similar action with respect to over-the-counter drugs by preempting some state regulatory requirements that differ or add to federal regulatory requirements but, at the same time, expressly exempting products-liability actions.¹⁷⁹

Second, as FDA now is contemplating, Congress could provide that generic drug manufacturers, like brand-name manufacturers, are authorized to use the CBE process. Indeed, in April 2012, legislation was introduced in both the Senate and the House of Representatives to authorize “the holder of an approved [ANDA to] . . . change the labeling of a drug . . . in the same manner authorized by regulation for the holder of an approved new drug application.”¹⁸⁰ The bill has not received a committee vote, let alone reached the floor, in either chamber. That stagnation comes as no surprise. In 2008, three years before it decided *PLIVA*, the Su-

preme Court held that federal law preempts most state-law damages claims for injuries caused by medical devices that go through full FDA premarket approval.¹⁸¹ Shortly thereafter, legislation was introduced to overrule the decision,¹⁸² but it, too, has languished.

In our view, the first route—congressional passage of an anti-preemption provision—would be more appropriate because it would allow Congress to patrol the borderline between state and federal law without dictating the details of federal labeling regulation. As noted, Congress has exempted from preemption state-law products-liability claims concerning over-the-counter drugs,¹⁸³ and it has taken the same or similar approaches in other contexts.¹⁸⁴ And FDA, like most regulators, is not charged by Congress with determining the best means to compensate patients injured by the products it regulates.

Put another way, it is sensible for Congress to step in when it believes that the preemptive effect of federal law threatens the states’ traditional role in providing compensation for consumers harmed by products. At the same time, Congress can leave the nuances of drug labeling policy to FDA, the expert agency it charged with creating and enforcing that policy.

In any event, it is doubtful the votes are there to overrule *PLIVA* or *Mutual*. As noted, bills to overrule *PLIVA* by authorizing generic drug manufacturers to employ the CBE process have gone nowhere. In sum, if change is to come anytime soon, it is going to come from FDA.

D. Effects on Preemption Doctrine

Mutual raises questions about the Supreme Court’s preemption doctrine regarding the presumption against preemption and the differences, if any, between federal preemption of state positive law and federal preemption of state damages liability.

1. The Precarious Status of the Presumption Against Preemption

a. For decades, in both express and implied preemption cases, the Supreme Court has applied a presumption against preemption.¹⁸⁵ The Court has grounded this principle in federalism, in the idea that, unless Congress ousts state law with unmistakable clarity, the states should be free to chart their own course, especially in areas that they have historically regulated:

[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state law causes of action. In all preemption cases, and particularly in those in which Congress has ‘legislated . . . in a field which the States have traditionally occupied,’ we ‘start with the assumption that the historic police powers of the States were not to be superseded

¹⁸¹ *Riegel*, 552 U.S. 312.

¹⁸² See H.R. 1346 (2009); S. 540 (2009).

¹⁸³ 21 U.S.C. § 379r(a), (e).

¹⁸⁴ See, e.g., 7 U.S.C. § 136v (preemption and anti-preemption provisions for federally regulated pesticides); 21 U.S.C. § 360k (preemption provision for medical devices, with exemption from preemption in some circumstances); 49 U.S.C. § 30103 (preemption provision regarding motor vehicle standards, with savings clause for common-law liability).

¹⁸⁵ See *PLIVA*, 131 S. Ct. at 2591 (Sotomayor, J., dissenting) (citing both express and implied preemption cases that invoke the presumption against preemption); see also, e.g., *Lohr*, 518 U.S. at 485.

¹⁷⁶ *Mutual*, 133 S. Ct. at 2480.

¹⁷⁷ Restatement (Third) of Torts: Products Liability § 6, cmt. d, at 147 (1998).

¹⁷⁸ *PLIVA*, 131 S. Ct. at 131.

¹⁷⁹ 21 U.S.C. § 379r(a), (e).

¹⁸⁰ S. 2295, § 2 (2012); H.R. 4384, § 2 (2012).

by [a] Federal Act unless that was the clear and manifest purpose of Congress.’¹⁸⁶

The Court has applied the presumption against preemption with special force where a finding of preemption would ascribe to Congress an intent to eliminate all damages remedies for consumers injured by unlawful conduct.¹⁸⁷ The presumption arguably hit its high-water mark in the tort preemption area in *Bates v. DowAgrosciences*, which imposed on courts “a duty to accept the reading that disfavors preemption” when a federal statute plausibly admits of both a preemptive and non-preemptive reading.¹⁸⁸

But the presumption may not be with us for long. The *Mutual* majority made no mention of the presumption at all, not even bothering to respond to Justice Sotomayor’s criticism of the “majority’s failure to adhere to the presumption” despite its “call[] on Congress to provide greater clarity with regard to the ‘difficult preemption questions that arise in the prescription drug context.’”¹⁸⁹ As she put it, “the whole point of the presumption against pre-emption is that congressional ambiguity should cut in favor of preserving state autonomy.”¹⁹⁰

Mutual followed a recent trend. In *Wyeth*, Justice Alito, writing in dissent for himself, Chief Justice Roberts, and Justice Scalia, had strongly suggested that no presumption against preemption applies in implied conflict-preemption cases.¹⁹¹ And, then in *PLIVA*, the majority opinion, authored by Justice Thomas, also ignored the presumption. And, in a plurality section of his opinion, joined by the Chief Justice and Justices Scalia and Alito, Justice Thomas appears to have rejected the presumption against preemption entirely. Focusing on the Supremacy Clause’s text, he asserted that the phrase “any Thing in the Constitution or Laws of any State to the Contrary notwithstanding” is a “*non obstante* provision,”¹⁹² that is, a phrase in a new statute that “repeal[s] older, potentially conflicting statutes in the same field.”¹⁹³

These non obstante provisions were used at the time of the Founding, Justice Thomas maintained, as an instruction to courts “not to apply the general presumption against implied repeals.”¹⁹⁴ Thus, the Constitution’s drafters intended that “federal law should be understood to impliedly repeal conflicting state law.”¹⁹⁵ Under the Supremacy Clause’s non obstante language, Justice Thomas went on, courts should not “distort federal law to accommodate conflicting state law,” and instead should look to a statute’s “ordinary meaning.”¹⁹⁶

¹⁸⁶ *Lohr*, 518 at 485 (citations omitted).

¹⁸⁷ See, e.g., *Bates*, 544 U.S. at 449-50; *Sprietsma v. Mercury Marine*, 537 U.S. 51, 69 (2002); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); see generally *Wyeth*, 555 U.S. at 565 & n.3.

¹⁸⁸ *Bates*, 544 U.S. at 449.

¹⁸⁹ *Mutual*, 133 S. Ct. at 2483 n.1 (Sotomayor, J., dissenting) (citing *id.* at 2840 (majority opinion)) (emphasis added); see also *id.* at 2483, 2486.

¹⁹⁰ See *id.* at 2483 n.1.

¹⁹¹ *Wyeth*, 555 U.S. at 623-24 & n.14.

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ *Id.* (quoting Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 241-42 (2000)).

¹⁹⁵ *Id.* at 2580.

¹⁹⁶ *Id.* (citing *Wyeth*, 555 U.S. at 588 (Thomas, J., concurring in the judgment)).

Justice Thomas’s view that only the text of federal law, and not a presumption against preemption, should guide implied conflict-preemption analysis builds on his earlier four-justice dissent in *Altria Group, Inc. v. Good*, where he maintained that the presumption has no place in construing an express preemption clause.¹⁹⁷ Relying on a dissenting view expressed years earlier by Justice Scalia,¹⁹⁸ Justice Thomas argued in *Altria* that when Congress has said that it desires some preemption, and the only question is its scope, “[t]he text of the statute must control.”¹⁹⁹

Taken together, these recent rulings indicate that four justices—Chief Justice Roberts, along with Justices Scalia, Thomas, and Alito—are prepared to ditch the presumption against preemption in all cases. This movement represents a significant shift over the last two decades. For years, the Justices regularly joined opinions relying on the presumption. Indeed, early in his Supreme Court tenure, Justice Thomas himself penned a partial dissent arguing that the Court erroneously had held a state common-law claim preempted in part because it had not accorded sufficient “[r]espect for the presumptive sanctity of state law[.]”²⁰⁰

Is the presumption dead? For now, the answer likely depends on Justice Kennedy. In *PLIVA*, although Justice Kennedy joined the majority’s conclusion that impossibility preemption barred state-law failure-to-warn claims against generic drug manufacturers, he did not join Justice Thomas’s plurality, suggesting that he, like the four dissenters,²⁰¹ was concerned that Justice Thomas’s reading of the Supremacy Clause would, if adopted by a Court majority, kill off the presumption against preemption.

And in *Altria*, Justice Kennedy joined the majority opinion, which invoked the presumption and rejected Justice Thomas’s dissenting position that it does not apply in express-preemption cases.²⁰² On the other hand, Justice Kennedy joined the *Mutual* majority, which, like the *PLIVA* majority, found preemption without even a nod to the presumption. In sum, the preemption remains on life support, but it is not dead yet. Stay tuned.

b. But, it’s fair to ask, does any of this matter? Commentators have noted the inconsistency with which the presumption is invoked,²⁰³ suggesting that the presumption matters little. Others have said more bluntly

¹⁹⁷ 555 U.S. 70, 98-103 (2008) (Thomas, J., dissenting, joined by Roberts, C.J., Scalia, J., and Alito, J.).

¹⁹⁸ *Id.* at 98 (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 545 (1992) (Scalia, J., concurring in the judgment in part and dissenting in part)).

¹⁹⁹ *Id.* at 103. Justice Thomas’s reliance on text as the sole basis for express-preemption analysis is consistent with his view that the “obstacle” or “purposes and objectives” form of implied preemption is illegitimate because it permits courts to engage in freewheeling predictions about congressional intent and “encourages an overly expansive reading of statutory text[.]” *Wyeth*, 555 U.S. at 601 (Thomas, J., concurring in the judgment).

²⁰⁰ *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 679 (1993) (Thomas, J., concurring in part and dissenting in part); see also *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 116-17 (1992) (Souter, J., dissenting) (forceful reliance on presumption against preemption joined by Justice Thomas).

²⁰¹ *PLIVA*, 131 S. Ct. at 2591-92 (Sotomayor, J., dissenting).

²⁰² *Altria*, 555 U.S. at 98-103 (Thomas, J., dissenting).

²⁰³ See, e.g., Catherine M. Sharkey, *Against Freewheeling, Extratextual Obstacle Preemption: Is Justice Clarence Thomas*

that the Court's preemption doctrine owes far more to desired results than to principle, with the presumption serving as something on which to hang one's judicial hat when useful.²⁰⁴ The question whether federalism jurisprudence is governed more by raw politics than principle is beyond the scope of this article. Focusing here only on the presumption against preemption, we believe, for at least two reasons, that the presumption has some practical importance.

First, it strikes us as unlikely that the presumption's four opponents on the Court would have expended so much effort laying the groundwork for its demise if they thought it was never outcome-determinative. They have seen the cases litigated before them and debated within the Court, and if they thought that the presumption against preemption never moved its adherents to vote against preemption, the fight would not be worth it. In other words, if four Justices think it matters, there's a good chance it does matter, at least sometimes.

Second, most preemption cases, including most tort preemption cases, are not destined for the Supreme Court. The lower courts, both state and federal, are supposed to adhere to the presumption. Those courts have been instructed that they have "a duty to accept the reading [of a federal statute] that disfavors preemption" when the statute is ambiguous,²⁰⁵ and so it is likely that they will apply the presumption faithfully, at least as an anti-preemption tie-breaker in cases that they view as close.

2. Tort Preemption vs. Positive-Law Preemption

a. The majority and dissenting opinions in *Mutual* contain discussions of whether federal preemption questions should be viewed differently if the target of potential preemption is a state-law remedy that results only in the payment of damages as opposed to a state statute or regulation that purports to prohibit conduct directly. Frequently, this distinction is described as a difference between state common-law actions, which typically seek only an award of damages, and state "positive" law—that is, statutes and regulations—which often (if not always) may be enforced through prohibitions on unlawful conduct.²⁰⁶

These labels, which we will use here for convenience, are imprecise. On occasion, common-law remedies include injunctions that prohibit conduct, and sometimes violations of statutes or regulations may be redressed only by payment of a fine while the violator is free to continue to break the law. And some states have codified their common law, making tort damages remedies available by statute. In any event, the distinction we mean to draw is one between state-law damages remedies and direct prohibitions on conduct.

In his opinion for the Court in *Mutual*, Justice Alito was adamant that it was "impossible" simultaneously to comply with both the federal-law requirements governing labeling and design of generic prescription drugs and a state-law damages remedy premised on a

duty to label or design the drug differently.²⁰⁷ That view of impossibility preemption, as noted earlier, is one that focuses on the claimed conflict between federal requirements and the abstract state-law *duty* (for instance, the duty not to market an unreasonably dangerous product).²⁰⁸

The *Mutual* dissenters, on the other hand, explained that despite potential tension between federal and state law, simultaneous compliance with both was not impossible because the state-law *remedy* was one to pay damages (not actually to change the product's design or label).²⁰⁹ And, besides, the dissenters said, a defendant could choose not to sell the product at all (which is not prohibited by federal law) when faced with a state-law damages judgment premised on inadequacies in the design or labeling of its product.²¹⁰

The *Mutual* majority rejected the latter "stop-selling" rationale as incompatible with our pre-emption jurisprudence.²¹¹ The majority firmly held that "the mere fact that a manufacturer may avoid liability by leaving the market does not defeat a claim of impossibility."²¹² Thus, absent a re-evaluation of this holding that might come with a change in the Court's composition, the stop-selling argument appears dead, at least in the impossibility-preemption context.

b. But what of the argument that impossibility does not occur in the tort preemption context because a manufacturer confronting a state-law damages verdict can always just pay the verdict and continue to sell the product? The *Mutual* majority rejected that argument on the ground that common-law remedies and remedies for violations of positive-law obligations "do precisely the same thing."²¹³ Faced with either remedy, Justice Alito suggested, the manufacturer of the offending product can simply pay the money demanded for violating the state-law norm (whether in the form of a governmental fine or a damages verdict) and continue to market the product. As we now explain, that view overstates the Court's prior preemption doctrine and fails to come to grips with the practical differences between damages liability and direct government regulation.

We turn first to preemption doctrine. Has the Supreme Court embraced the idea that positive state regulation and a jury's award of damages are equivalent? Sometimes yes, and sometimes no.

The Court's first statement on this topic came in *San Diego Building Trades Council v. Garmon*.²¹⁴ *Garmon* involved a business's attempt to prevent union picketing through a suit under California law for an injunction and damages. In an earlier stage of the litigation, the Supreme Court held that the injunctive relief was preempted by the National Labor Relations Act.²¹⁵ In *Garmon*, the Court also rejected the attempt to impose damages under California law, explaining that "[state] regulation can be as effectively exerted through an

²⁰⁷ *Mutual*, 133 S. Ct. at 2476.

²⁰⁸ *Id.* at 2474-75.

²⁰⁹ *Id.* at 2481 (Breyer, J., dissenting); *id.* at 2491 (Sotomayor, J., dissenting).

²¹⁰ *Id.* at 2481 (Breyer, J., dissenting); *id.* at 2491 (Sotomayor, J., dissenting).

²¹¹ *Id.* at 2477 (majority opinion).

²¹² *Id.* at 2478 n.5.

²¹³ *Id.* at 2479.

²¹⁴ 359 U.S. 236 (1959).

²¹⁵ *See id.* at 238.

the Lone Principled Federalist?, 5 N.Y.U. J. L. & Liberty 63, 78 (2010).

²⁰⁴ *See id.* at 65 ("Notwithstanding alternative explanations of the Court's preemption jurisprudence, the one with the greatest staying power is that which attributes everything to ideology and politics.") (internal citation omitted).

²⁰⁵ *Bates*, 544 U.S. at 449.

²⁰⁶ *See Mutual*, 133 S. Ct. at 2479.

award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy.”²¹⁶

Garmon was not a products liability case, and federal labor law, unlike most federal statutes that regulate consumer products and services, authorizes monetary and other remedies. Thus, *Garmon* presented a situation distinguishable from cases such as *Mutual* and *PLIVA* and other recent tort preemption cases that have reached the Supreme Court, where the relevant federal regulatory scheme did not provide a means to compensate people harmed by federally regulated products. Nonetheless, it is easy to see why modern preemption-seeking defendants would rely heavily on *Garmon*. Its exclusive focus on damages as a regulatory, rather than a compensatory, tool is useful to defendants seeking to equate positive law with tort law. Whenever positive state law is preempted, they argue, so is state-law damages liability.

But even after *Garmon*, the prevailing assumption remained that state regulatory standards and state tort law or other state compensation schemes occupied separate spheres, with the latter largely unaffected by federal preemption.²¹⁷ The best example is probably *Goodyear Atomic Corp. v. Miller*,²¹⁸ where the Court considered whether an Ohio administrative agency could, consistent with federal preemption principles, award additional workers’ compensation benefits based on violations of state safety standards at a federally owned, privately operated nuclear production facility. The Court held that the additional award was not preempted. Acknowledging that state positive-law safety requirements might be preempted, the Court viewed damages liability as fundamentally different:

Congress’ reluctance to allow direct state regulation of federal projects says little about whether Congress was likewise concerned with the incidental regulatory effects arising from the enforcement of a workers’ compensation law, like Ohio’s, that provides an additional award when the injury is caused by the breach of a safety regulation. The effects of direct regulation on the operation of federal projects are significantly more intrusive than the incidental regulatory effects of such an additional award provision. Appellant may choose to disregard Ohio safety regulations and simply pay an additional workers’ compensation award if an employee’s injury is caused by a safety violation. We believe Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not.²¹⁹

Until the 1990s, the Supreme Court had never held a state-law tort claim preempted by federal regulation, at least not where the federal law itself did not provide a right of action for damages. In 1992, the Court began to change course. A plurality opinion in a tobacco liability case, *Cipollone v. Liggett Group, Inc.*²²⁰ relied on the

language from *Garmon* quoted above, and concluded that the Public Health Cigarette Smoking Act of 1969, which requires specific warnings on cigarette packages, preempted some (but not all) tort claims based on a failure to warn about the dangers of smoking.²²¹ Since then, defendants in tort preemption cases have relied on this language from *Garmon* and *Cipollone* in an effort to show that state tort law and state positive law have the same regulatory effect, that is, that the two are inherently the same.

But the Court has continued to send contradictory signals. In the majority portion of the *Cipollone* decision, which addressed the preemptive effect of an earlier, 1965 version of the cigarette labeling law, just a few paragraphs above the plurality’s endorsement of *Garmon*, the same justice who wrote the plurality (Justice Stevens) said something quite different: that the 1965 Act, because of its particular wording, preempts “only positive enactments by legislatures or administrative agencies that mandate particular warning labels,” and “not . . . common-law damages actions.”²²² In responding to the tobacco industry’s arguments that the 1965 Act was preemptive, the Court seemed to reject the *Garmon* principle as a general, overarching justification for preemption:

There is no general, inherent conflict between federal preemption of state warning requirements and the continued vitality of state common-law damages actions.²²³

The internal tension evident in *Cipollone* was carried over to *Medtronic, Inc. v. Lohr*,²²⁴ a case involving claimed preemption of a tort suit by the federal medical-device law. There, a four-Justice plurality suggested that a rational Congress could treat state common-law duties damages actions differently from positive state law,²²⁵ while dissenters and a concurring Justice appeared to equate the two as a general proposition.²²⁶

And, finally, *Garmon*’s tort-as-regulation viewpoint cannot be squared with another important tort preemption case, *Sprietsma v. Mercury Marine*.²²⁷ There, a boater had died tragically when she fell overboard and was struck by the boat’s propeller blades. One of the questions presented in *Sprietsma* was whether a state common-law duty premised on a boat manufacturer’s failure to install a propeller guard was preempted by the Federal Boat Safety Act’s express preemption provision, which the manufacturer claimed preempted all positive law and all common law regarding boat safety.

The Court rejected that argument, maintaining that it is “perfectly rational” for Congress to preempt state positive law, but not “common-law claims, which—unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims.”²²⁸ This statement is important because tort law’s ability to compensate is one way

²¹⁶ *Id.* at 247.

²¹⁷ See, e.g., *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984); *Hurley v. Lederle Labs.*, 863 F.2d 1173, 1176-78 & n.2 (5th Cir. 1988) (rejecting preemption and reviewing case law); *Osburn v. Anchor Labs., Inc.*, 825 F.2d 908, 911-13 (5th Cir. 1987); *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1539-43 (D.C. Cir. 1984); *Feldman v. Lederle Labs.*, 479 A.2d 374 (N.J. 1984).

²¹⁸ 486 U.S. 174 (1988).

²¹⁹ *Id.* at 185-86.

²²⁰ 505 U.S. 504 (1992).

²²¹ *Id.* at 521 (quoting *Garmon*, 359 U.S. at 247).

²²² *Id.* at 519.

²²³ *Id.* at 518.

²²⁴ 518 U.S. 470.

²²⁵ *Id.* at 486-91.

²²⁶ See *id.* at 504-05 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 510 (O’Connor, J., concurring in part and dissenting in part) (relying on *Garmon*).

²²⁷ 537 U.S. 51 (2002).

²²⁸ *Id.* at 64.

that tort law and most regulatory requirements indisputably are not the same.

c. Having shown that the Supreme Court's preemption doctrine has both embraced and rejected the claim that positive law and tort law have the same purpose and effect, we turn to the question whether the claim makes real-world, empirical sense. In our view, it does not.

It is a significant leap from the proposition endorsed in *Garmon* that tort law is meant to and does to some degree have regulatory effect on defendants' future behavior to the proposition that its impact is *equivalent* to direct, positive-law regulation. Although this point can be illustrated by reference to most state or federal regulatory schemes, we use FDA as an example because its regulations were at issue in *Mutual*, *PLIVA*, and *Wyeth*.

If FDA wants to get a food, drug, or device off the market, it can do so swiftly. If FDA determines that a product is misbranded because its labels create a hazard for consumers, it would not seek only payment of a fine to the government, which would do nothing to protect current consumers. Rather, it would insist on changes to the label or the product's removal from the market. The *Mutual* majority understood this basic point when it acknowledged that a misbranded product may no longer be sold in interstate commerce.²²⁹

Thus, if FDA determines that a product is misbranded, it can obtain an injunction to halt its sale,²³⁰ and even seize products if need be,²³¹ as former FDA Commissioner David Kessler did with misbranded orange juice when he first took office.²³² We recognize that state and federal agencies often do not exercise their full regulatory authority because of indifference, insufficient resources, lack of political will, or "capture" by the regulated industry. Our point here, however, is that positive-law authority often gives those regulators the ability to quickly alter the conduct of the regulated industry.

Contrast these direct regulatory powers with the tort system. Most prominently, damages are the *only* form of relief available in the types of tort suits that regularly populate the Supreme Court's preemption docket. For people like Ms. Bartlett, who have already been hurt, and are no longer using the product, it is damages or nothing.

Moreover, large industry players generally react very slowly, and sometimes not at all, to liability pressures. Most instances of liability are absorbed without any change in manufacturer conduct of the kind that can be obtained swiftly by a regulator. As the Supreme Court has recognized, after the imposition of damages liability, the defendant is never legally compelled to alter its future conduct.²³³

Thus, to the extent that tort law exerts regulatory effect against a drug manufacturer generally, the effect occurs only after repeated suits, settlements, and findings of liability, and, even then, the cause-and-effect re-

lationship is rarely clear (which is hardly the case when a regulator takes products off retailers' shelves). The Supreme Court stated this well in *Goodyear Atomic*, when it said that "the effects of direct state regulation on the operation of federal government are significantly more intrusive than the incidental regulatory effects of state [compensation] law."²³⁴

Of course, there is some symbiosis between direct regulation and damages liability, as the regulatory system imposes pressures on the tort system and vice versa. Both exert financial and political pressure on industry and government, and both are capable of making public information that would otherwise stay locked away in corporate file cabinets. But some interaction and overlap between the tort and regulatory systems do not alter our basic position: Preemption doctrine should not be built on a claim of equivalency between direct regulation and damages liability because the equivalency does not exist—that is, the claim does not reflect reality on the ground.

d. But none of this matters if *Mutual* definitively has held otherwise. We do not think it has. Compared to its clear rejection of the stop-selling rationale, the *Mutual* majority's consideration of the positive-law/common-law distinction was less emphatic and more ambiguous.

First, Justice Alito began his discussion by noting that "the distinction between common law and statutory law is irrelevant to the argument at hand,"²³⁵ a reference to Justice Sotomayor's statement that application of New Hampshire tort law in the case had not "impose[d] any actual 'legal obligation,'" ²³⁶ suggesting that the majority was not making an all-encompassing pronouncement for tort preemption cases generally.

Second, the *Mutual* majority said that state common-law remedies and direct state regulation "do precisely the same thing" because "[t]hey 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)."²³⁷ This statement suggests that a manufacturer has the same freedom of choice in responding to either a jury verdict or a regulator's edict. To be sure, in both situations, the manufacturer can voluntarily leave the market. But, as we have noted, the final result of state regulatory enforcement often is not payment of money (or at least not only payment of money) but a prohibition on the underlying offending conduct. That is, the "other sanction" referred to by Justice Alito may be the product's *forced* departure from the market, and if the state were to impose that sanction, the manufacturer would have no choice at all.

This latter point is important because when a state requires the removal from the market of a product that the federal government has approved, there is far greater potential for interference with federal regulatory objectives than if the product remains on the market and the manufacturer pays for the injuries that the product has caused.²³⁸ The latter scenario may increase the cost of the product to a small degree, but it does not make the product unavailable to consumers, which might be a concern to federal regulators.

²²⁹ *Mutual*, 133 S. Ct. at 2477 n.4.

²³⁰ See 21 U.S.C. §§ 331(a), (b), 332(a); see also FDA's "Recall, Market Withdrawals, & Safety Alerts" homepage, <http://www.fda.gov/Safety/Recalls/default.htm>.

²³¹ See 21 U.S.C. § 334 (seizure authority).

²³² Warren E. Leary, "Citing Labels, U.S. Seizes Orange Juice," *New York Times*, p. 18 (Apr. 25, 1991).

²³³ See, e.g., *Goodyear Atomic*, 486 U.S. at 185-86; see also, e.g., *Ferebee*, 736 F.2d at 1544 (D.C. Cir. 1984).

²³⁴ *Goodyear Atomic*, 486 U.S. at 185.

²³⁵ *Mutual*, 133 S. Ct. at 2479 (emphasis added).

²³⁶ *Id.* (quoting *id.* at 2489 (Sotomayor, dissenting)).

²³⁷ *Id.*

²³⁸ See *id.* at 2482 (Breyer, J., dissenting).

The *Mutual* majority confronted none of this. Its discussion of the tort-direct regulation distinction is brief and undeveloped, and if the Court had intended to put tort-preemption and regulatory-preemption cases on equal footing for all time, we would have expected it at least to have considered its prior discussions of the issue in cases such as *Cipollone* and *Goodyear Atomic*.

Finally, as noted earlier, the *Mutual* majority acknowledged that Congress expressly preempted state regulatory requirements for over-the-counter drugs while exempting from preemption product-liability suits against their manufacturers,²³⁹ including manu-

facturers of *generic* over-the-counter drugs, for whom, like the generic *prescription* drug manufacturers in *Mutual* and *PLIVA*, unilateral changes to drug labeling and design are impermissible. This acknowledgement suggests that the Court understands that the impact of state positive law and state-law damages liability are not inherently the same and that allowing the latter while preempting the former may not undermine federal regulatory objectives.

In sum, we think that *Mutual*'s off-hand statement that tort remedies and direct regulation do "the same thing" may fade away when the Court again is presented with the issue and has the opportunity to treat it with more care.

²³⁹ *Id.* at 2480 (citing 21 U.S.C. § 379r(a), (e)).