SUPREME COURT OF THE UNITED STATES

Nos. 09–993, 09–1039, and 09–1501

PLIVA, INC., ET AL., PETITIONERS
09–993 *v.*
GLADYS MENSING

ACTAVIS ELIZABETH, LLC, PETITIONER
09–1039 *v.*
GLADYS MENSING

ACTAVIS, INC., PETITIONER
09–1501 *v.*
JULIE DEMAHY

ON WRITS OF CERTIORARI TO THE UNITED STATES COURTS OF APPEALS FOR THE EIGHTH AND FIFTH CIRCUITS

[June 23, 2011]

JUSTICE SOTOMAYOR, with whom JUSTICE GINSBURG, JUSTICE BREYER, and JUSTICE KAGAN join, dissenting.

The Court today invokes the doctrine of impossibility pre-emption to hold that federal law immunizes generic-drug manufacturers from all state-law failure-to-warn claims because they cannot unilaterally change their labels. I cannot agree. We have traditionally held defendants claiming impossibility to a demanding standard: Until today, the mere possibility of impossibility had not been enough to establish pre-emption.

The Food and Drug Administration (FDA) permits—and, the Court assumes, requires—generic-drug manufacturers to propose a label change to the FDA when they believe that their labels are inadequate. If it agrees that the labels are inadequate, the FDA can initiate a change

to the brand-name label, triggering a corresponding change to the generic labels. Once that occurs, a generic manufacturer is in full compliance with both federal law and a state-law duty to warn. Although generic manufacturers may be able to show impossibility in some cases, petitioners, generic manufacturers of metoclopramide (Manufacturers), have shown only that they *might* have been unable to comply with both federal law and their state-law duties to warn respondents Gladys Mensing and Julie Demahy. This, I would hold, is insufficient to sustain their burden.

The Court strains to reach the opposite conclusion. It invents new principles of pre-emption law out of thin air to justify its dilution of the impossibility standard. It effectively rewrites our decision in *Wyeth* v. *Levine*, 555 U. S. 555 (2009), which holds that federal law does not pre-empt failure-to-warn claims against brand-name drug manufacturers. And a plurality of the Court tosses aside our repeated admonition that courts should hesitate to conclude that Congress intended to pre-empt state laws governing health and safety. As a result of today's decision, whether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug. The Court gets one thing right: This outcome "makes little sense." *Ante*, at 18.

I

A

Today's decision affects 75 percent of all prescription drugs dispensed in this country. The dominant position of generic drugs in the prescription drug market is the result of a series of legislative measures, both federal and state.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585—commonly known as the Hatch-Waxman Amendments to

the Federal Food, Drug, and Cosmetic Act (FDCA)—to "make available more low cost generic drugs by establishing a generic drug approval procedure," H. R. Rep. No. 98–857, pt. 1, p. 14 (1984). As the majority explains, to accomplish this goal the amendments establish an abbreviated application process for generic drugs. *Ante*, at 5–6; see also 21 U. S. C. §355(j)(2)(A). The abbreviated approval process implements the amendments' core principle that generic and brand-name drugs must be the "same" in nearly all respects: To obtain FDA approval, a generic manufacturer must ordinarily show, among other things, that its product has the same active ingredients as an approved brand-name drug; that "the route of administration, the dosage form, and the strength of the new drug are the same" as the brand-name drug; and that its product is "bioequivalent" to the brand-name drug. §§355(j)(2)(A)(ii), (iii), (iv). By eliminating the need for generic manufacturers to prove their drugs' safety and efficacy independently, the Hatch-Waxman Amendments allow generic manufacturers to bring drugs to market much less expensively.

The States have also acted to expand consumption of low-cost generic drugs. In the years leading up to passage of the Hatch-Waxman Amendments, States enacted legislation authorizing pharmacists to substitute generic drugs when filling prescriptions for brand-name drugs. Christensen, Kirking, Ascione, Welage, & Gaither, Drug Product Selection: Legal Issues, 41 J. Am. Pharmaceutical Assn. 868, 869 (2001). Currently, all States have some form of generic substitution law. See *ibid.* Some States require generic substitution in certain circumstances. Dept. of Health and Human Servs., ASPE Issue Brief: Expanding the Use of Generic Drugs 7 (2010) (hereinafter Expanding the Use of Generic Drugs);[1] see, *e.g.*, N. Y.

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[1] Online at http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.pdf

Educ. Law Ann. §6816–a (West 2010). Others permit, but do not require, substitution. Expanding the Use of Generic Drugs 7; see, *e.g.*, Cal. Bus. & Prof. Code Ann. §4073 (West Supp. 2011). Some States require patient consent to substitution, and all States "allow the physician to specify that the brand name must be prescribed, although with different levels of effort from the physician." Expanding the Use of Generic Drugs 7.[2]

These legislative efforts to expand production and consumption of generic drugs have proved wildly successful. It is estimated that in 1984, when the Hatch-Waxman Amendments were enacted, generic drugs constituted 19 percent of drugs sold in this country. Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 27 (1998).[3] Today, they dominate the market. See Expanding the Use of Generic Drugs 2 (generic drugs constituted 75 percent of all dispensed prescription drugs in 2009). Ninety percent of drugs for which a generic version is available are now filled with generics. *Id.*, at 3–4. In many cases, once generic versions of a drug enter the market, the brand-name manufacturer stops selling the brand-name drug altogether. See Brief for Marc T. Law et al. as *Amici Curiae* 18 (citing studies

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(all Internet materials as visited June 17, 2011, and available in Clerk of Court's case file).

[2] In addition, many insurance plans are structured to promote generic use. See Congressional Budget Office, Effects of Using Generic Drugs on Medicare's Prescription Drug Spending 9 (2010), online at http://www.cbo.gov/ftpdoc/118xx/doc11838/09-15-PrescriptionDrugs.pdf. State Medicaid programs similarly promote generic use. See Kaiser Comm'n on Medicaid and the Uninsured, State Medicaid Outpatient Prescription Drug Policies: Findings from a National Survey, 2005 Update 10 (2005), online at www.kff.org/medicaid/upload/state-medicaid-outpatient-prescription-drug-policies-findings-from-a-national-survey-2005-update-report.pdf.

[3] Online at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf.

showing that anywhere from one-third to one-half of generic drugs no longer have a marketed brand-name equivalent). Reflecting the success of their products, many generic manufacturers, including the Manufacturers and their *amici*, are huge, multinational companies. In total, generic drug manufacturers sold an estimated $66 billion of drugs in this country in 2009. See *id.*, at 15.

B

As noted, to obtain FDA approval a generic manufacturer must generally show that its drug is the same as an approved brand-name drug. It need not conduct clinical trials to prove the safety and efficacy of the drug. This does not mean, however, that a generic manufacturer has no duty under federal law to ensure the safety of its products. The FDA has limited resources to conduct postapproval monitoring of drug safety. See *Wyeth*, 555 U. S., at 578. Manufacturers, we have recognized, "have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." *Id.*, at 578–579. Federal law thus obliges drug manufacturers—both brand-name and generic—to monitor the safety of their products.

Under federal law, generic manufacturers must "develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences" to the FDA.[4] 21 CFR §314.80(b);[5] see also §314.98 (making §314.80 applicable to generic manufacturers); Brief for United States as *Amicus Curiae* 6, and n. 2 (hereinafter U. S. Brief). They must review all reports of adverse drug experiences received from "any source."

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[4] An adverse drug experience is defined as "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related." 21 CFR §314.80(a) (2006).

[5] Like the majority, I refer to the pre-2007 statutes and regulations. See *ante*, at 5, n. 1.

§314.80(b). If a manufacturer receives a report of a serious and unexpected adverse drug experience, it must report the event to the FDA within 15 days and must "promptly investigate." §§314.80(c)(1)(i)–(ii); see also Tr. of Oral Arg. 8. Most other adverse drug experiences must be reported on a quarterly or yearly basis.[6] §314.80(c)(2). Generic manufacturers must also submit to the FDA an annual report summarizing "significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product," including a "description of actions the [manufacturer] has taken or intends to take as a result of this new information." §314.81(b)(2)(i); see also §314.98(c).

Generic manufacturers, the majority assumes, also bear responsibility under federal law for monitoring the adequacy of their warnings. I agree with the majority's conclusion that generic manufacturers are not permitted unilaterally to change their labels through the "changes-being-effected" (CBE) process or to issue additional warnings through "Dear Doctor" letters. See *ante*, at 6–9. According to the FDA, however, that generic manufactur-

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[6]At congressional hearings on the Hatch-Waxman Amendments, representatives of the generic drug manufacturers confirmed both their obligation and their ability to conduct postapproval investigation of adverse drug experiences. See Drug Legislation: Hearings on H. R. 1554 et al. before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 98th Cong., 1st Sess., 45 (1983) (statement of Kenneth N. Larsen, chairman of the Generic Pharmaceutical Industry Association (GPhA)) (generic manufacturers "are sensitive to the importance of looking at adverse reactions"); *id.*, at 47–48 ("[W]e will do and provide whatever is required to be performed to meet the regulatory requirement to provide for the safety and well-being of those that are using the drug, this is our role and responsibility. This is an obligation to be in this business"); *id.*, at 50–51 (statement of Bill Haddad, executive officer and president of GPhA) ("Every single generic drug company that I know has a large research staff. It not only researches the drug that they are copying, or bringing into the market but it researches new drugs, researches adverse reaction[s]").

ers cannot disseminate additional warnings on their own does not mean that federal law permits them to remain idle when they conclude that their labeling is inadequate. FDA regulations require that labeling "be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." 21 CFR §201.57(e) (2006), currently codified at 21 CFR §201.80(e) (2010); see also *Wyeth*, 555 U. S., at 570–571. The FDA construes this regulation to oblige generic manufacturers "to seek to revise their labeling and provide FDA with supporting information about risks" when they believe that additional warnings are necessary.[7] U. S. Brief 20.

The Manufacturers disagree. They read the FDA regulation to require them only to ensure that their labels match the brand-name labels. See Brief for Petitioner PLIVA et al. 38–41. I need not decide whether the regulation in fact obliges generic manufacturers to approach the FDA to propose a label change. The majority assumes that it does. And even if generic manufacturers do not have a duty to propose label changes, two points remain undisputed. First, they do have a duty under federal law

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[7]The FDA's construction of this regulation mirrors the guidance it provided to generic manufacturers nearly 20 years ago in announcing the final rule implementing the abbreviated application process for generic drugs:

"If an ANDA [*i.e.*, application for approval of a generic drug] applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised." 57 Fed. Reg. 17961 (1992).

FDA's internal procedures recognize that the Office of Generic Drugs will have to consult with other FDA components on "some labeling reviews." Manual of Policies and Procedures 5200.6, p. 1 (May 9, 2001). Consultations involving "possible serious safety concerns" receive the highest priority. *Id.*, at 3.

to monitor the safety of their products. And, second, they may approach the FDA to propose a label change when they believe a change is required.

II

This brings me to the Manufacturers' pre-emption defense. State law obliged the Manufacturers to warn of dangers to users. See *Hines* v. *Remington Arms Co.*, 94–0455, p. 10 (La. 12/8/94), 648 So. 2d 331, 337; *Frey* v. *Montgomery Ward & Co.*, 258 N. W. 2d 782, 788 (Minn. 1977). The Manufacturers contend, and the majority agrees, that federal law pre-empts respondents' failure-to-warn claims because, under federal law, the Manufacturers could not have provided additional warnings to respondents without the exercise of judgment by the FDA. I cannot endorse this novel conception of impossibility pre-emption.

A

Two principles guide all pre-emption analysis. First, "'the purpose of Congress is the ultimate touchstone in every pre-emption case.'" *Wyeth*, 555 U. S., at 565 (quoting *Medtronic, Inc.* v. *Lohr*, 518 U. S. 470, 485 (1996)). Second, "'[i]n all pre-emption 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 by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Wyeth*, 555 U. S., at 565 (quoting *Lohr*, 518 U. S., at 485; some internal quotation marks omitted; alterations in original).

These principles find particular resonance in these cases. The States have traditionally regulated health and safety matters. See *id.*, at 485. Notwithstanding Congress' "certain awareness of the prevalence of state tort litigation" against drug manufacturers, *Wyeth*, 555 U. S.,

at 575, Congress has not expressly pre-empted state-law tort actions against prescription drug manufacturers, whether brand-name or generic. To the contrary, when Congress amended the FDCA in 1962 to "enlarg[e] the FDA's powers to 'protect the public health' and 'assure the safety, effectiveness, and reliability of drugs,' [it] took care to preserve state law." *Id.*, at 567 (quoting 76 Stat. 780); see Pub. L. 87–781, §202, 76 Stat. 793 ("Nothing in the amendments made by this Act to the [FDCA] shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law"). Notably, although Congress enacted an express pre-emption provision for medical devices in 1976, see Pub. L. 94–295, §521, 90 Stat. 574, 21 U. S. C. §360k(a), it included no such provision in the Hatch-Waxman Amendments eight years later. Cf. *Wyeth*, 555 U. S., at 567, 574–575. Congress' "silence on the issue . . . is powerful evidence that [it] did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.*, at 575.

B

Federal law impliedly pre-empts state law when state and federal law "conflict"—*i.e.*, when "it is impossible for a private party to comply with both state and federal law" or when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby* v. *National Foreign Trade Council*, 530 U. S. 363, 372–373 (2000) (internal quotation marks omitted). The Manufacturers rely solely on the former ground of pre-emption.

Impossibility pre-emption, we have emphasized, "is a demanding defense." *Wyeth*, 555 U. S., at 573. Because pre-emption is an affirmative defense, a defendant seeking to set aside state law bears the burden to prove impossibil-

ity. See *ibid.; Silkwood* v. *Kerr-McGee Corp.*, 464 U. S. 238, 255 (1984). To prevail on this defense, a defendant must demonstrate that "compliance with both federal and state [law] is a physical impossibility." *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U. S. 132, 142–143 (1963); see also *Wyeth*, 555 U. S., at 573. In other words, there must be an "inevitable collision" between federal and state law. *Florida Lime*, 373 U. S., at 143. "The existence of a hypothetical or potential conflict is insufficient to warrant" pre-emption of state law. *Rice* v. *Norman Williams Co.*, 458 U. S. 654, 659 (1982); see also *Gade* v. *National Solid Wastes Management Assn.*, 505 U. S. 88, 110 (1992) (KENNEDY, J., concurring in part and concurring in judgment). In other words, the mere possibility of impossibility is not enough.

The Manufacturers contend that it was impossible for them to provide additional warnings to respondents Mensing and Demahy because federal law prohibited them from changing their labels unilaterally.[8] They concede, however, that they could have asked the FDA to initiate a label change. If the FDA agreed that a label change was required, it could have asked, and indeed pressured, the brand-name manufacturer to change its label, triggering a corresponding change to the Manufacturers' generic la-

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[8] In its decision below, the Eighth Circuit suggested that the Manufacturers could not show impossibility because federal law merely permitted them to sell generic drugs; it did not require them to do so. See *Mensing* v. *Wyeth, Inc.*, 588 F. 3d 603, 611 (2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product"); see also *Geier* v. *American Honda Motor Co.*, 529 U. S. 861, 873 (2000) (describing "a case of impossibility" as one "in which state law penalizes what federal law *requires*" (emphasis added)). Respondents have not advanced this argument, and I find it unnecessary to consider.

bels.[9] Thus, had the Manufacturers invoked the available mechanism for initiating label changes, they may well have been able to change their labels in sufficient time to warn respondents. Having failed to do so, the Manufacturers cannot sustain their burden (at least not without further factual development) to demonstrate that it was impossible for them to comply with both federal and state law. At most, they have demonstrated only "a hypothetical or potential conflict." *Rice*, 458 U. S., at 659.

Like the majority, the Manufacturers focus on the fact that they cannot change their labels unilaterally—which distinguishes them from the brand-name-manufacturer defendant in *Wyeth*. They correctly point out that in *Wyeth* we concluded that the FDA's CBE regulation authorized the defendant to strengthen its warnings before receiving agency approval of its supplemental application describing the label change. 555 U. S., at 568–571; see also 21 CFR §314.70(c)(6). But the defendant's label change was contingent on FDA acceptance, as the FDA retained "authority to reject labeling changes made pursuant to the CBE regulation." *Wyeth*, 555 U. S., at 571. Thus, in the long run, a brand-name manufacturer's compliance with a state-law duty to warn required action by two actors: The brand-name manufacturer had to change the label and the FDA, upon reviewing the supplemental application, had to agree with the change.[10] The need for

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[9] At the time respondents' cause of action arose, the FDA did not have authority to require a brand-name manufacturer to change its label. (It received that authority in 2007. See Pub. L. 110–85, §901, 121 Stat. 924–926, 21 U. S. C. §355(o)(4) (2006 ed., Supp. III). It did, however, have the equally significant authority to withdraw the brand-name manufacturer's permission to market its drug if the manufacturer refused to make a requested labeling change. See 21 U. S. C. §355(e) (2006 ed.); 21 CFR §314.150(b)(3).

[10] A brand-name manufacturer's ability to comply with a state-law duty to warn would depend on its own unilateral actions only during the period after it should have changed its label but before the FDA

FDA approval of the label change did not make compliance with federal and state law impossible in every case. Instead, because the defendant bore the burden to show impossibility, we required it to produce "clear evidence that the FDA would not have approved a change to [the] label." *Ibid.*

I would apply the same approach in these cases. State law, respondents allege, required the Manufacturers to provide a strengthened warning about the dangers of long-term metoclopramide use.[11] Just like the brand-name manufacturer in *Wyeth*, the Manufacturers had available to them a mechanism for attempting to comply with their state-law duty to warn. Federal law thus "accommodated" the Manufacturers' state-law duties. See *ante*, at 18, n. 8. It was not necessarily impossible for the Manufacturers to comply with both federal and state law because, had they approached the FDA, the FDA may well have agreed that a label change was necessary. Accordingly, as in *Wyeth*, I would require the Manufacturers to show that the FDA would not have approved a proposed label change. They have not made such a showing: They do "not argue that [they] attempted to give the kind of warning required by [state law] but [were] prohibited from doing so by the FDA." *Wyeth*, 555 U. S., at 572.

This is not to say that generic manufacturers could never show impossibility. If a generic-manufacturer defendant proposed a label change to the FDA but the FDA rejected the proposal, it would be impossible for that defendant to comply with a state-law duty to warn. Likewise, impossibility would be established if the FDA had

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would have approved or disapproved the label change. The claim in *Wyeth* does not appear to have arisen during that period.

[11] Respondents' state-law claim is not that the Manufacturers were required to ask the FDA for assistance in changing the labels; the role of the FDA arises only as a result of the Manufacturers' pre-emption defense.

not yet responded to a generic manufacturer's request for a label change at the time a plaintiff's injuries arose. A generic manufacturer might also show that the FDA had itself considered whether to request enhanced warnings in light of the evidence on which a plaintiff's claim rests but had decided to leave the warnings as is. (The Manufacturers make just such an argument in these cases. See, *e.g.*, Brief for Petitioner Actavis et al. 11.) But these are questions of fact to be established through discovery. Because the burden of proving impossibility falls on the defendant, I would hold that federal law does not render it impossible for generic manufacturers to comply with a state-law duty to warn as a categorical matter.

This conclusion flows naturally from the overarching principles governing our pre-emption doctrine. See *supra*, at 8. Our "respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly pre-empt state-law causes of action.'" *Wyeth*, 555 U. S., at 565–566, n. 3 (quoting *Lohr*, 518 U. S., at 485). It is for this reason that we hold defendants asserting impossibility to a "demanding" standard. *Wyeth*, 555 U. S., at 573. This presumption against pre-emption has particular force when the Federal Government has afforded defendants a mechanism for complying with state law, even when that mechanism requires federal agency action. (The presumption has even greater force when federal law requires defendants to invoke that mechanism, as the majority assumes in these cases.) In such circumstances, I would hold, defendants will usually be unable to sustain their burden of showing impossibility if they have not even attempted to employ that mechanism. Any other approach threatens to infringe the States' authority over traditional matters of state interest—such as the failure-to-warn claims here—when Congress expressed no intent to pre-empt state law.

C

The majority concedes that the Manufacturers might have been able to accomplish under federal law what state law requires. *Ante*, at 12–13. To reach the conclusion that the Manufacturers have nonetheless satisfied their burden to show impossibility, the majority invents a new preemption rule: "The question for 'impossibility' is whether the private party could *independently* do under federal law what state law requires of it." *Ante*, at 13 (emphasis added). Because the Manufacturers could not have changed their labels without the exercise of judgment by the FDA, the majority holds, compliance with both state and federal law was impossible in these cases.[12]

The majority's new test has no basis in our precedents. The majority cites only *Wyeth* in support of its test. As discussed above, however, *Wyeth* does not stand for the proposition that it is impossible to comply with both federal and state law whenever federal agency approval is required. To the contrary, label changes by brand-name manufacturers such as Wyeth are subject to FDA review and acceptance. See *supra*, at 11–12. And, even if *Wyeth* could be characterized as turning on the fact that the brand-name manufacturer could change its label unilaterally, the possibility of unilateral action was, at most, a sufficient condition for rejecting the impossibility defense in that case. *Wyeth* did not hold that unilateral action is a necessary condition in every case.

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[12] These cases do not involve a situation where a brand-name manufacturer itself produces generic drugs. See Okie, Multinational Medicines—Ensuring Drug Quality in an Era of Global Manufacturing, 361 N. Eng. J. Med. 737, 738 (2009); see also GPhA, Frequently Asked Questions About Generics, http://www.gphaonline.org/about-gpha/about-generics/faq ("Brand-name companies make about half of generic drugs"). In that case, the manufacturer could independently change the brand-name label under the CBE regulation, triggering a corresponding change to its own generic label.

With so little support in our case law, the majority understandably turns to other rationales. None of the rationales that it offers, however, makes any sense. First, it offers a *reductio ad absurdum:* If the possibility of FDA approval of a label change is sufficient to avoid conflict in these cases, it warns, as a "logical conclusion" so too would be the possibility that the FDA might rewrite its regulations or that Congress might amend the Hatch-Waxman Amendments. *Ante*, at 14. The logic of this conclusion escapes me. Conflict analysis necessarily turns on existing law. It thus would be ridiculous to conclude that federal and state law do not conflict on the ground that the defendant could have asked a federal agency or Congress to change the law. Here, by contrast, the Manufacturers' compliance with their state-law duty to warn did not require them to ask for a change in federal law, as the majority itself recognizes. See *ante*, at 13 ("[F]ederal law would permit the Manufacturers to comply with the state labeling requirements if, and only if, the FDA and the brand-name manufacturer changed the brand-name label to do so"). The FDA already afforded them a mechanism for attempting to comply with their state-law duties. Indeed, the majority assumes that FDA regulations *required* the Manufacturers to request a label change when they had "reasonable evidence of an association of a serious hazard with a drug." 21 CFR §201.57(e).

Second, the majority suggests that any other approach would render conflict pre-emption "illusory" and "meaningless." *Ante*, at 14. It expresses concern that, without a robust view of what constitutes conflict, the Supremacy Clause would not have "any force" except in cases of express pre-emption. *Ibid.* To the extent the majority's purported concern is driven by its *reductio ad absurdum*, see *ante*, at 14, n. 6, that concern is itself illusory, for the reasons just stated. To the extent the majority is concerned that our traditionally narrow view of what consti-

tutes impossibility somehow renders conflict pre-emption as a whole meaningless, that concern simply makes no sense: We have repeatedly recognized that conflict pre-emption may be found, even absent impossibility, where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U. S., at 373 (internal quotation marks omitted); see, *e.g.*, *Geier* v. *American Honda Motor Co.*, 529 U. S. 861, 886 (2000); *Barnett Bank of Marion Cty., N. A.* v. *Nelson*, 517 U. S. 25, 31 (1996); *Hines* v. *Davidowitz*, 312 U. S. 52, 67 (1941). The majority's expansive view of impossibility is thus unnecessary to prevent conflict pre-emption from losing all meaning.[13]

Third, a plurality of the Court adopts the novel theory that the Framers intended for the Supremacy Clause to operate as a so-called *non obstante* provision. See *ante*, at 15–17 (citing Nelson, Preemption, 86 Va. L. Rev. 225 (2000)). According to the plurality, *non obstante* provisions in statutes "instruc[t] courts not to apply the general presumption against implied repeals." *Ante*, at 15 (internal quotation marks omitted); see also *ante*, at 16 (stating that when a statute contains a *non obstante* provision, "'courts will be less inclined against recognizing repugnancy in applying such statutes'" (quoting J. Sutherland, Statutes and Statutory Construction §147, p. 199 (1891)). From this understanding of the Supremacy Clause, the plurality extrapolates the principle that "courts should not strain to find ways to reconcile federal law with seemingly

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[13] JUSTICE THOMAS, the author of today's opinion, has previously expressed the view that obstacle pre-emption is inconsistent with the Constitution. See *Williamson* v. *Mazda Motor of America, Inc.*, 562 U. S. ___, ___ (2011) (opinion concurring in judgment) (slip op., at 2–5); *Wyeth* v. *Levine*, 555 U. S. 555, 604 (2009) (opinion concurring in judgment). That position, however, has not been accepted by this Court, and it thus should not justify the majority's novel expansion of impossibility pre-emption.

conflicting state law." *Ante*, at 15.

This principle would have been news to the Congress that enacted the Hatch-Waxman Amendments in 1984: Our precedents hold just the opposite. For more than half a century, we have directed courts to presume that congressional action does *not* supersede "the historic police powers of the States . . . unless that was the clear and manifest purpose of Congress." *Rice* v. *Santa Fe Elevator Corp.*, 331 U. S. 218, 230 (1947); see also *Gade*, 505 U. S., at 111–112 (KENNEDY, J., concurring in part and concurring in judgment). We apply this presumption against pre-emption both where Congress has spoken to the pre-emption question and where it has not. See *Wyeth*, 555 U. S., at 566, n. 3. In the context of express pre-emption, we read federal statutes whenever possible not to pre-empt state law. See *Altria Group, Inc.* v. *Good*, 555 U. S. 70, 77 (2008) ("[W]hen the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily 'accept the reading that disfavors pre-emption'" (quoting *Bates* v. *Dow Agrosciences LLC*, 544 U. S. 431, 449 (2005))); see also *Cipollone* v. *Liggett Group, Inc.*, 505 U. S. 504, 518 (1992). And, when the claim is that federal law impliedly pre-empts state law, we require a "strong" showing of a conflict "to overcome the presumption that state and local regulation . . . can constitutionally coexist with federal regulation." *Hillsborough County* v. *Automated Medical Laboratories, Inc.*, 471 U. S. 707, 716 (1985).

The plurality's new theory of the Supremacy Clause is a direct assault on these precedents.[14] Whereas we have

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[14] The author of the law review article proposing this theory of the Supremacy Clause acknowledges as much. See Nelson, Preemption, 86 Va. L. Rev. 225, 304 (2000) ("The *non obstante* provision rejects an artificial presumption that Congress did not intend to contradict any state laws and that federal statutes must therefore be harmonized with state law"). The plurality, on the other hand, carefully avoids discuss-

long presumed that federal law does not pre-empt, or repeal, state law, the plurality today reads the Supremacy Clause to operate as a provision instructing courts "*not* to apply the general presumption against implied repeals." *Ante*, at 15 (internal quotation marks omitted; emphasis added). And whereas we have long required evidence of a "clear and manifest" purpose to pre-empt, *Rice*, 331 U. S., at 230, the plurality now instructs courts to "look no further than the ordinary meaning of federal law" before concluding that Congress must have intended to cast aside state law, *ante*, at 16 (internal quotation marks and alteration omitted).

That the plurality finds it necessary to resort to this novel theory of the Supremacy Clause—a theory advocated by no party or *amici* in these cases—is telling. Proper application of the longstanding presumption *against* pre-emption compels the conclusion that federal law does not render compliance with state law impossible merely because it requires an actor to seek federal agency approval. When federal law provides actors with a mechanism for attempting to comply with their state-law duties, "respect for the States as 'independent sovereigns in our federal system'" should require those actors to attempt to comply with state law before being heard to complain that compliance with both laws was impossible. *Wyeth*, 555 U. S., at 565–566, n. 3 (quoting *Lohr*, 518 U. S., at 485).

III

Today's decision leads to so many absurd consequences that I cannot fathom that Congress would have intended to pre-empt state law in these cases.

First, the majority's pre-emption analysis strips generic-

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ing the ramifications of its new theory for the longstanding presumption against pre-emption.

drug consumers of compensation when they are injured by inadequate warnings. "If Congress had intended to deprive injured parties of [this] long available form of compensation, it surely would have expressed that intent more clearly." *Bates*, 544 U. S., at 449. Given the longstanding existence of product liability actions, including for failure to warn, "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood*, 464 U. S., at 251; see also *Bruesewitz* v. *Wyeth LLC*, 562 U. S. ___, ___ (2011) (slip op., at 16) (noting our previously expressed "doubt that Congress would quietly preempt product-liability claims without providing a federal substitute"). In concluding that Congress silently immunized generic manufacturers from all failure-to-warn claims, the majority disregards our previous hesitance to infer congressional intent to effect such a sweeping change in traditional state-law remedies.

As the majority itself admits, a drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings under our opinion in *Wyeth*. If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue. The majority offers no reason to think—apart from its new articulation of the impossibility standard—that Congress would have intended such an arbitrary distinction. In some States, pharmacists must dispense generic drugs absent instruction to the contrary from a consumer's physician. Even when consumers can request brand-name drugs, the price of the brand-name drug or the consumers' insurance plans may make it impossible to do so. As a result, in many cases, consumers will have no ability to preserve their state-law right to recover for injuries caused by inade-

quate warnings.

Second, the majority's decision creates a gap in the parallel federal-state regulatory scheme in a way that could have troubling consequences for drug safety. As we explained in *Wyeth*, "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." 555 U. S., at 579. Thus, we recognized, "state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Ibid.* Today's decision eliminates the traditional state-law incentives for generic manufacturers to monitor and disclose safety risks. When a generic drug has a brand-name equivalent on the market, the brand-name manufacturer will remain incentivized to uncover safety risks. But brand-name manufacturers often leave the market once generic versions are available, see *supra*, at 4–5, meaning that there will be no manufacturer subject to failure-to-warn liability. As to those generic drugs, there will be no "additional . . . layer of consumer protection." *Wyeth*, 555 U. S., at 579.

Finally, today's decision undoes the core principle of the Hatch-Waxman Amendments that generic and brand-name drugs are the "same" in nearly all respects.[15] See Brief for Rep. Henry A. Waxman as *Amicus Curiae* 9. The majority pins the expansion of the generic drug market on "the special, and different, regulation of generic drugs," which allows generic manufacturers to produce their drugs more cheaply. *Ante*, at 19. This tells only half the story. The expansion of the market for generic drugs has also flowed from the increased acceptance of, and trust in,

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[15] According to the GPhA, both the FDA and the generic drug industry "spend millions of dollars each year . . . seeking to reassure consumers that affordable generic drugs really are—as federal law compels them to be—*the same as* their pricier brand-name counterparts." Brief for GPhA as *Amicus Curiae* on Pet. for Cert. in Nos. 09–993, 09–1039, pp. 2–3.

generic drugs by consumers, physicians, and state legislators alike.

Today's decision introduces a critical distinction between brand-name and generic drugs. Consumers of brand-name drugs can sue manufacturers for inadequate warnings; consumers of generic drugs cannot. These divergent liability rules threaten to reduce consumer demand for generics, at least among consumers who can afford brand-name drugs. They may pose "an ethical dilemma" for prescribing physicians. Brief for American Medical Association et al. as *Amici Curiae* 29. And they may well cause the States to rethink their longstanding efforts to promote generic use through generic substitution laws. See Brief for National Conference of State Legislators as *Amicus Curiae* 15 (state generic substitution laws "have proceeded on the premise that . . . generic drugs are not, from citizens' perspective, materially different from brand ones, except for the lower price"). These consequences are directly at odds with the Hatch-Waxman Amendments' goal of increasing consumption of generic drugs.

Nothing in the Court's opinion convinces me that, in enacting the requirement that generic labels match their corresponding brand-name labels, Congress intended these absurd results. The Court certainly has not shown that such was the "*clear and manifest* purpose of Congress." *Wyeth*, 555 U. S., at 565 (internal quotation marks omitted; emphasis added). To the contrary, because federal law affords generic manufacturers a mechanism for attempting to comply with their state-law duties to warn, I would hold that federal law does not categorically pre-empt state-law failure-to-warn claims against generic manufacturers. Especially in light of the presumption against pre-emption, the burden should fall on generic manufacturers to show that compliance was impossible on the particular facts of their case. By holding that the

"possibility of *possibility*" is insufficient to "defea[t]" pre-emption in these cases, *ante*, at 18, n. 8, the Court contorts our pre-emption doctrine and exempts defendants from their burden to establish impossibility. With respect, I dissent.