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 THOMAS delivered the opinion of the Court, except as to Part III–B–2.*

These consolidated lawsuits involve state tort-law claims based on certain drug manufacturers' alleged failure to provide adequate warning labels for generic metoclopramide. The question presented is whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt, these state-law claims. We hold that they do.

*JUSTICE KENNEDY joins all but Part III–B–2 of this opinion.

I

Metoclopramide is a drug designed to speed the movement of food through the digestive system. The Food and Drug Administration (FDA) first approved metoclopramide tablets, under the brand name Reglan, in 1980. Five years later, generic manufacturers also began producing metoclopramide. The drug is commonly used to treat digestive tract problems such as diabetic gastroparesis and gastroesophageal reflux disorder.

Evidence has accumulated that long-term metoclopramide use can cause tardive dyskinesia, a severe neurological disorder. Studies have shown that up to 29% of patients who take metoclopramide for several years develop this condition. *McNeil* v. *Wyeth*, 462 F. 3d 364, 370, n. 5 (CA5 2006); see also Shaffer, Butterfield, Pamer, & Mackey, Tardive Dyskinesia Risks and Metoclopramide Use Before and After U. S. Market Withdrawal of Cisapride, 44 J. Am. Pharmacists Assn. 661, 663 (2004) (noting 87 cases of metoclopramide-related tardive dyskinesia reported to the FDA's adverse event reporting system by mid-2003).

Accordingly, warning labels for the drug have been strengthened and clarified several times. In 1985, the label was modified to warn that "tardive dyskinesia . . . may develop in patients treated with metoclopramide," and the drug's package insert added that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." Physician's Desk Reference 1635–1636 (41st ed. 1987); see also Brief for Petitioner PLIVA et al. 21–22 (hereinafter PLIVA Brief). In 2004, the brand-name Reglan manufacturer requested, and the FDA approved, a label change to add that "[t]herapy should not exceed 12 weeks in duration." Brief for United States as *Amicus Curiae* 8 (hereinafter U. S. Brief). And in 2009, the FDA ordered a black box warning—its strongest—which states: "Treatment with metoclopramide can cause

tardive dyskinesia, a serious movement disorder that is often irreversible. . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases." See Physician's Desk Reference 2902 (65th ed. 2011).

Gladys Mensing and Julie Demahy, the plaintiffs in these consolidated cases, were prescribed Reglan in 2001 and 2002, respectively. Both received generic metoclopramide from their pharmacists. After taking the drug as prescribed for several years, both women developed tardive dyskinesia.

In separate suits, Mensing and Demahy sued the generic drug manufacturers that produced the metoclopramide they took (Manufacturers). Each alleged, as relevant here, that long-term metoclopramide use caused her tardive dyskinesia and that the Manufacturers were liable under state tort law (specifically, that of Minnesota and Louisiana) for failing to provide adequate warning labels. They claimed that "despite mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than that indicated on the label," none of the Manufacturers had changed their labels to adequately warn of that danger. *Mensing* v. *Wyeth, Inc.*, 588 F. 3d 603, 605 (CA8 2009); see also *Demahy* v. *Actavis, Inc.*, 593 F. 3d 428, 430 (CA5 2010).

In both suits, the Manufacturers urged that federal law pre-empted the state tort claims. According to the Manufacturers, federal statutes and FDA regulations required them to use the same safety and efficacy labeling as their brand-name counterparts. This means, they argued, that it was impossible to simultaneously comply with both federal law and any state tort-law duty that required them to use a different label.

The Courts of Appeals for the Fifth and Eighth Circuits rejected the Manufacturers' arguments and held that Mensing and Demahy's claims were not pre-empted. See

588 F. 3d, at 614; 593 F. 3d, at 449. We granted certiorari, 562 U. S. ___ (2010), consolidated the cases, and now reverse each.

II

Pre-emption analysis requires us to compare federal and state law. We therefore begin by identifying the state tort duties and federal labeling requirements applicable to the Manufacturers.

A

It is undisputed that Minnesota and Louisiana tort law require a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe. Under Minnesota law, which applies to Mensing's lawsuit, "where the manufacturer . . . of a product has actual or constructive knowledge of danger to users, the . . . manufacturer has a duty to give warning of such dangers." *Frey* v. *Montgomery Ward & Co.*, 258 N. W. 2d 782, 788 (Minn. 1977). Similarly, under Louisiana law applicable to Demahy's lawsuit, "a manufacturer's duty to warn includes a duty to provide adequate instructions for safe use of a product." *Stahl* v. *Novartis Pharmaceuticals Corp.*, 283 F. 3d 254, 269–270 (CA5 2002); see also La. Rev. Stat. Ann. §9:2800.57 (West 2009). In both States, a duty to warn falls specifically on the manufacturer. See *Marks* v. *OHMEDA, Inc.*, 2003–1446, pp. 8–9 (La. App. 3/31/04), 871 So. 2d 1148, 1155; *Gray* v. *Badger Min. Corp.*, 676 N. W. 2d 268, 274 (Minn. 2004).

Mensing and Demahy have pleaded that the Manufacturers knew or should have known of the high risk of tardive dyskinesia inherent in the long-term use of their product. They have also pleaded that the Manufacturers knew or should have known that their labels did not adequately warn of that risk. App. 437–438, 67–69, 94–96.

The parties do not dispute that, if these allegations are true, state law required the Manufacturers to use a different, safer label.

B

Federal law imposes far more complex drug labeling requirements. We begin with what is not in dispute. Under the 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act, 76 Stat. 780, 21 U. S. C. §301 *et seq.,* a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate.[1] See, *e.g.,* 21 U. S. C. §§355(b)(1), (d); *Wyeth* v. *Levine*, 555 U. S. 555, 567 (2009). Meeting those requirements involves costly and lengthy clinical testing. §§355(b)(1)(A), (d); see also D. Beers, Generic and Innovator Drugs: A Guide to FDA Approval Requirements §2.02[A] (7th ed. 2008).

Originally, the same rules applied to all drugs. In 1984, however, Congress passed the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585, commonly called the Hatch-Waxman Amendments. Under this law, "generic drugs" can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA.[2] 21 U. S. C. §355(j)(2)(A). This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug. A generic drug application must also "show that the [safety and

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[1] All relevant events in these cases predate the Food and Drug Administration Amendments Act of 2007, 121 Stat. 823. We therefore refer exclusively to the pre-2007 statutes and regulations and express no view on the impact of the 2007 Act.

[2] As we use it here, "generic drug" refers to a drug designed to be a copy of a reference listed drug (typically a brand-name drug), and thus identical in active ingredients, safety, and efficacy. See, *e.g., United States* v. *Generix Drug Corp.*, 460 U. S. 453, 454–455 (1983); 21 CFR §314.3(b) (2006) (defining "reference listed drug").

efficacy] labeling proposed . . . is the same as the labeling approved for the [brand-name] drug." §355(j)(2)(A)(v); see also §355(j)(4)(G); Beers §§3.01, 3.03[A].

As a result, brand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. See, *e.g.,* 21 U. S. C. §§355(b)(1), (d); *Wyeth*, *supra,* at 570–571. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's. See, *e.g.,* §355(j)(2)(A)(v); §355(j)(4)(G); 21 CFR §§314.94(a)(8), 314.127(a)(7).

The parties do not disagree. What is in dispute is whether, and to what extent, generic manufacturers may change their labels *after* initial FDA approval. Mensing and Demahy contend that federal law provided several avenues through which the Manufacturers could have altered their metoclopramide labels in time to prevent the injuries here. The FDA, however, tells us that it interprets its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of "sameness." U. S. Brief 16; see also 57 Fed. Reg. 17961 (1992) ("[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval"). The FDA's views are "controlling unless plainly erroneous or inconsistent with the regulation[s]" or there is any other reason to doubt that they reflect the FDA's fair and considered judgment. *Auer* v. *Robbins*, 519 U. S. 452, 461, 462 (1997) (internal quotation marks omitted).[3]

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[3]The brief filed by the United States represents the views of the FDA. Cf. *Talk America, Inc.* v. *Michigan Bell Telephone Co.*, 564 U. S. ___, ___, n. 1 (2011) (slip op., at 1, n. 1); *Chase Bank USA, N. A.* v. *McCoy*, 562 U. S. ___, ___ (2011) (slip op., at 8). Although we defer to the agency's interpretation of its regulations, we do not defer to an agency's

1

First, Mensing and Demahy urge that the FDA's "changes-being-effected" (CBE) process allowed the Manufacturers to change their labels when necessary. See Brief for Respondents 33–35; see also 593 F. 3d, at 439–444; *Gaeta* v. *Perrigo Pharmaceuticals Co.*, 630 F. 3d 1225, 1231 (CA9 2011); *Foster* v. *American Home Prods. Corp.*, 29 F. 3d 165, 170 (CA4 1994). The CBE process permits drug manufacturers to "add or strengthen a contraindication, warning, [or] precaution," 21 CFR §314.70(c)(6)(iii)(A) (2006), or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," §314.70(c)(6)(iii)(C). When making labeling changes using the CBE process, drug manufacturers need not wait for preapproval by the FDA, which ordinarily is necessary to change a label. *Wyeth*, *supra,* at 568. They need only simultaneously file a supplemental application with the FDA. 21 CFR §314.70(c)(6).

The FDA denies that the Manufacturers could have used the CBE process to unilaterally strengthen their warning labels. The agency interprets the CBE regulation to allow changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions. U. S. Brief 15, 16, n. 7 (interpreting 21 CFR §314.94(a)(8)(iv)); U. S. Brief 16, n. 8. The FDA argues that CBE changes unilaterally made to strengthen a generic drug's warning label would violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's. *Id.,* at 15–16; see also 21 U. S. C. §355(j)(4)(G); 21 CFR §§314.94(a)(8)(iii), 314.150(b)(10) (approval may be withdrawn if the generic drug's label "is no longer consistent with that for [the

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ultimate conclusion about whether state law should be pre-empted. *Wyeth* v. *Levine*, 555 U. S. 555, 576 (2009).

brand-name]").

We defer to the FDA's interpretation of its CBE and generic labeling regulations. Although Mensing and Demahy offer other ways to interpret the regulations, see Brief for Respondents 33–35, we do not find the agency's interpretation "plainly erroneous or inconsistent with the regulation." *Auer*, *supra*, at 461 (internal quotation marks omitted). Nor do Mensing and Demahy suggest there is any other reason to doubt the agency's reading. We therefore conclude that the CBE process was not open to the Manufacturers for the sort of change required by state law.

2

Next, Mensing and Demahy contend that the Manufacturers could have used "Dear Doctor" letters to send additional warnings to prescribing physicians and other healthcare professionals. See Brief for Respondents 36; 21 CFR §200.5. Again, the FDA disagrees, and we defer to the agency's views.

The FDA argues that Dear Doctor letters qualify as "labeling." U. S. Brief 18; see also 21 U. S. C. §321(m); 21 CFR §202.1(*l*)(2). Thus, any such letters must be "consistent with and not contrary to [the drug's] approved . . . labeling." 21 CFR §201.100(d)(1). A Dear Doctor letter that contained substantial new warning information would not be consistent with the drug's approved labeling. Moreover, if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly "misleading." U. S. Brief 19; see 21 CFR §314.150(b)(3) (FDA may withdraw approval of a generic drug if "the labeling of the drug . . . is false or misleading in any particular").

As with the CBE regulation, we defer to the FDA.

Mensing and Demahy offer no argument that the FDA's interpretation is plainly erroneous. See *Auer*, 519 U. S., at 461. Accordingly, we conclude that federal law did not permit the Manufacturers to issue additional warnings through Dear Doctor letters.

3

Though the FDA denies that the Manufacturers could have used the CBE process or Dear Doctor letters to strengthen their warning labels, the agency asserts that a different avenue existed for changing generic drug labels. According to the FDA, the Manufacturers could have proposed—indeed, were required to propose—stronger warning labels to the agency if they believed such warnings were needed. U. S. Brief 20; 57 Fed. Reg. 17961. If the FDA had agreed that a label change was necessary, it would have worked with the brand-name manufacturer to create a new label for both the brand-name and generic drug. *Ibid.*

The agency traces this duty to 21 U. S. C. §352(f)(2), which provides that a drug is "misbranded . . . [u]nless its labeling bears . . . adequate warnings against . . . unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." See U. S. Brief 12. By regulation, the FDA has interpreted that statute to require that "labeling shall 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).

According to the FDA, these requirements apply to generic drugs. As it explains, a "'central premise of federal drug regulation is that the manufacturer bears responsibility for the content of its label at all times.'" U. S. Brief 12–13 (quoting *Wyeth*, 555 U. S., at 570–571). The FDA reconciles this duty to have adequate and accurate labeling with the duty of sameness in the following way:

Generic drug manufacturers that become aware of safety problems must ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug. U. S. Brief 20.

The Manufacturers and the FDA disagree over whether this alleged duty to request a strengthened label actually existed. The FDA argues that it explained this duty in the preamble to its 1992 regulations implementing the Hatch-Waxman Amendments. *Ibid.;* see 57 Fed. Reg. 17961 ("If a [generic drug manufacturer] 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"). The Manufacturers claim that the FDA's 19-year-old statement did not create a duty, and that there is no evidence of any generic drug manufacturer ever acting pursuant to any such duty. See Tr. of Oral Arg. 19–24; Reply Brief for Petitioner PLIVA et al. 18–22. Because we ultimately find pre-emption even assuming such a duty existed, we do not resolve the matter.

C

To summarize, the relevant state and federal requirements are these: State tort law places a duty directly on all drug manufacturers to adequately and safely label their products. Taking Mensing and Demahy's allegations as true, this duty required the Manufacturers to use a different, stronger label than the label they actually used. Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels. But, we assume, federal law also required the Manufacturers to ask for FDA assistance in convincing the brand-name manufacturer to adopt a stronger label, so that all corresponding generic drug manufacturers could do so as well. We turn now to the question of pre-emption.

III

The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U. S. Const., Art. VI, cl. 2. Where state and federal law "directly conflict," state law must give way. *Wyeth, supra,* at 583 (THOMAS, J., concurring in judgment); see also *Crosby* v. *National Foreign Trade Council*, 530 U. S. 363, 372 (2000) ("[S]tate law is naturally preempted to the extent of any conflict with a federal statute"). We have held that state and federal law conflict where it is "impossible for a private party to comply with both state and federal requirements."[4] *Freightliner Corp.* v. *Myrick*, 514 U. S. 280, 287 (1995) (internal quotation marks omitted).[5]

A

We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them. And even if they had fulfilled their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law.

If the Manufacturers had independently changed their

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[4] We do not address whether state and federal law "directly conflict" in circumstances beyond "impossibility." See *Wyeth*, 555 U. S., at 582, 590–591 (THOMAS, J., concurring in judgment) (suggesting that they might).

[5] The Hatch-Waxman Amendments contain no provision expressly pre-empting state tort claims. See *post*, at 9, 19 (SOTOMAYOR, J., dissenting). Nor do they contain any saving clause to expressly preserve state tort claims. Cf. *Williamson* v. *Mazda Motor of America, Inc.*, 562 U. S. ___, ___ (2011) (THOMAS, J., concurring in judgment) (discussing the saving clause in the National Traffic and Motor Vehicle Safety Act of 1966, 49 U. S. C. §30103(e)). Although an express statement on pre-emption is always preferable, the lack of such a statement does not end our inquiry. Contrary to the dissent's suggestion, the absence of express pre-emption is not a reason to find no *conflict* preemption. See *post*, at 19.

labels to satisfy their state-law duty, they would have violated federal law. Taking Mensing and Demahy's allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. See, *e.g.,* 21 CFR §314.150(b)(10). Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.

The federal duty to ask the FDA for help in strengthening the corresponding brand-name label, assuming such a duty exists, does not change this analysis. Although requesting FDA assistance would have satisfied the Manufacturers' federal duty, it would not have satisfied their state tort-law duty to provide adequate labeling. State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label. Indeed, Mensing and Demahy deny that their state tort claims are based on the Manufacturers' alleged failure to ask the FDA for assistance in changing the labels. Brief for Respondents 53–54; cf. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U. S. 341 (2001) (holding that federal drug and medical device laws pre-empted a state tort-law claim based on failure to properly communicate with the FDA).

B

1

Mensing and Demahy contend that, while their state-law claims do not turn on whether the Manufacturers asked the FDA for assistance in changing their labels, the Manufacturers' federal affirmative defense of pre-emption does. Mensing and Demahy argue that if the Manufacturers had asked the FDA for help in changing the corre-

sponding brand-name label, they might eventually have been able to accomplish under federal law what state law requires. That is true enough. The Manufacturers "freely concede" that they could have asked the FDA for help. PLIVA Brief 48. If they had done so, and if the FDA decided there was sufficient supporting information, and if the FDA undertook negotiations with the brand-name manufacturer, and if adequate label changes were decided on and implemented, then the Manufacturers would have started a Mouse Trap game that eventually led to a better label on generic metoclopramide.

This raises the novel question whether conflict pre-emption should take into account these possible actions by the FDA and the brand-name manufacturer. Here, what federal law permitted the Manufacturers to do could have changed, even absent a change in the law itself, depending on the actions of the FDA and the brand-name manufacturer. Federal law does not dictate the text of each generic drug's label, but rather ties those labels to their brand-name counterparts. Thus, federal 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.

Mensing and Demahy assert that when a private party's ability to comply with state law depends on approval and assistance from the FDA, proving pre-emption requires that party to demonstrate that the FDA would not have allowed compliance with state law. Here, they argue, the Manufacturers cannot bear their burden of proving impossibility because they did not even *try* to start the process that might ultimately have allowed them to use a safer label. Brief for Respondents 47. This is a fair argument, but we reject it.

The question for "impossibility" is whether the private party could independently do under federal law what state law requires of it. See *Wyeth*, 555 U. S., at 573 (finding

no pre-emption where the defendant could "unilaterally" do what state law required). Accepting Mensing and Demahy's argument would render conflict pre-emption largely meaningless because it would make most conflicts between state and federal law illusory. We can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it. In these cases, it is certainly possible that, had the Manufacturers asked the FDA for help, they might have eventually been able to strengthen their warning label. Of course, it is also *possible* that the Manufacturers could have convinced the FDA to reinterpret its regulations in a manner that would have opened the CBE process to them. Following Mensing and Demahy's argument to its logical conclusion, it is also *possible* that, by asking, the Manufacturers could have persuaded the FDA to rewrite its generic drug regulations entirely or talked Congress into amending the Hatch-Waxman Amendments.

If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force.[6] We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless. The Supremacy Clause, on its face, makes federal law "the supreme Law of the Land" even absent an express statement by Congress. U. S. Const., Art. VI, cl. 2.

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[6]The dissent asserts that we are forgetting "purposes-and-objectives" pre-emption. *Post*, at 15–16. But as the dissent acknowledges, purposes-and-objectives pre-emption is a form of conflict pre-emption. *Post,* at 9, 16. If conflict pre-emption analysis must take into account hypothetical federal action, including possible changes in Acts of Congress, then there is little reason to think that pre-emption based on the purposes and objectives of Congress would survive either.

Moreover, the text of the Clause—that federal law shall be supreme, "any Thing in the Constitution or Laws of any State to the Contrary notwithstanding"—plainly contemplates conflict pre-emption by describing federal law as effectively repealing contrary state law. *Ibid.;* see Nelson, Preemption, 86 Va. L. Rev. 225, 234 (2000); *id.,* at 252–253 (describing discussion of the Supremacy Clause in state ratification debates as concerning whether federal law could repeal state law, or vice versa). The phrase "any [state law] to the Contrary notwithstanding" is a *non obstante* provision. *Id.,* at 238–240, nn. 43–45. Eighteenth-century legislatures used *non obstante* provisions to specify the degree to which a new statute was meant to repeal older, potentially conflicting statutes in the same field. *Id.,* at 238–240 (citing dozens of statutes from the 1770's and 1780's with similar provisions). A *non obstante* provision "in a new statute acknowledged that the statute might contradict prior law and instructed courts not to apply the general presumption against implied repeals." *Id.,* at 241–242; 4 M. Bacon, A New Abridgment of the Law 639 (4th ed. 1778) ("Although two Acts of Parliament are *seemingly* repugnant, yet if there be no Clause of *non Obstante* in the latter, they shall if possible have such Construction, that the latter may not be a Repeal of the former by Implication"). The *non obstante* provision in the Supremacy Clause therefore suggests that federal law should be understood to impliedly repeal conflicting state law.

Further, the provision suggests that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law. Traditionally, courts went to great lengths attempting to harmonize conflicting statutes, in order to avoid implied repeals. *Warder* v. *Arell*, 2 Va. 282, 296 (1796) (opinion of Roane, J.) ("[W]e ought to seek for such a construction as will reconcile [the statutes] to-

gether"); *Ludlow's Heirs* v. *Johnston*, 3 Ohio 553, 564 (1828) ("[I]f by any fair course of reasoning the two [statutes] can be reconciled, both shall stand"); *Doolittle* v. *Bryan*, 14 How. 563, 566 (1853) (requiring "the repugnance be quite plain" before finding implied repeal). A *non obstante* provision thus was a useful way for legislatures to specify that they did not want courts distorting the new law to accommodate the old. Nelson, *supra,* at 240–242; see also J. Sutherland, Statutes and Statutory Construction §147, p. 199 (1891) ("[W]hen there is inserted in a statute a provision [of *non obstante*] . . . . It is to be supposed that courts will be less inclined against recognizing repugnancy in applying such statutes"); *Weston's Case*, 73 Eng. Rep. 780, 781 (K. B. 1576) ("[W]hen there are two statutes, one in appearance crossing the other, and no clause of *non obstante* is contained in the second statute . . . the exposition ought to be that both should stand in force"); G. Jacob, A New Law Dictionary (J. Morgan ed., 10th ed. 1782) (definition of "statute," ¶6: "[W]hen there is a seeming variance between two *statutes,* and no clause of *non obstante* in the latter, such construction shall be made that both may stand"). The *non obstante* provision of he Supremacy Clause indicates that a court need look no further than "the ordinary meanin[g]" of federal law, and should not distort federal law to accommodate conflicting state law. *Wyeth*, 555 U. S., at 588 (THOMAS, J., concurring in judgment) (internal quotation marks omitted).

To consider in our pre-emption analysis the contingencies inherent in these cases—in which the Manufacturers' ability to comply with state law depended on uncertain federal agency and third-party decisions—would be inconsistent with the *non obstante* provision of the Supremacy Clause. The Manufacturers would be required continually to prove the counterfactual conduct of the FDA and brand-name manufacturer in order to establish the supremacy of federal law. We do not think the Supremacy Clause con-

templates that sort of contingent supremacy. The *non obstante* provision suggests that pre-emption analysis should not involve speculation about ways in which federal agency and third-party actions could potentially reconcile federal duties with conflicting state duties. When the "ordinary meaning" of federal law blocks a private party from independently accomplishing what state law requires, that party has established pre-emption.

3

To be sure, whether a private party can act sufficiently independently under federal law to do what state law requires may sometimes be difficult to determine. But this is not such a case. Before the Manufacturers could satisfy state law, the FDA—a federal agency—had to undertake special effort permitting them to do so. To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.

Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action. The only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern. Mensing and Demahy's tort claims are pre-empted.

C

Wyeth is not to the contrary. In that case, as here, the plaintiff contended that a drug manufacturer had breached a state tort-law duty to provide an adequate warning label. 555 U. S., at 559–560. The Court held that the lawsuit was not pre-empted because it was possible for Wyeth, a brand-name drug manufacturer, to comply with

both state and federal law. *Id.,* at 572–573.[7] Specifically, the CBE regulation, 21 CFR §314.70(c)(6)(iii), permitted a brand-name drug manufacturer like Wyeth "to unilaterally strengthen its warning" without prior FDA approval. 555 U. S., at 573; cf. *supra,* at 7–8. Thus, the federal regulations applicable to Wyeth allowed the company, of its own volition, to strengthen its label in compliance with its state tort duty.[8]

We recognize that from the perspective of Mensing and Demahy, finding pre-emption here but not in *Wyeth* makes little sense. Had Mensing and Demahy taken Reglan, the brand-name drug prescribed by their doctors, *Wyeth* would control and their lawsuits would not be pre-empted. But

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[7] Wyeth also urged that state tort law "creat[ed] an unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" 555 U. S., at 563–564 (quoting *Hines* v. *Davidowitz*, 312 U. S. 52, 67 (1941)). The Court rejected that argument, and that type of pre-emption is not argued here. Cf. *post*, at 16, n. 13 (opinion of SOTOMAYOR, J.).

[8] The FDA, however, retained the authority to eventually rescind Wyeth's unilateral CBE changes. Accordingly, the Court noted that Wyeth could have attempted to show, by "clear evidence," that the FDA would have rescinded any change in the label and thereby demonstrate that it would in fact have been impossible to do under federal law what state law required. *Wyeth*, *supra,* at 571. Wyeth offered no such evidence.

That analysis is consistent with our holding today. The Court in *Wyeth* asked what the drug manufacturer could independently do under federal law, and in the absence of clear evidence that Wyeth could not have accomplished what state law required of it, found no pre-emption. The *Wyeth* Court held that, because federal law accommodated state law duties, "the possibility of impossibility" was "not enough." *Post*, at 10; see also *Rice* v. *Norman Williams Co.*, 458 U. S. 654, 659 (1982) (rejecting "hypothetical" impossibility). But here, "existing" federal law directly conflicts with state law. *Post*, at 15 ("Conflict analysis necessarily turns on existing law"). The question in these cases is not whether the possibility of *impossibility* establishes pre-emption, but rather whether the possibility of *possibility* defeats pre-emption. *Post*, at 10.

because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits. See*, e.g.*, Minn. Stat. §151.21 (2010) (describing when pharmacists may substitute generic drugs); La. Rev. Stat. Ann. §37:1241(A)(17) (West 2007) (same). We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated.[9]

But "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre." *Cuomo* v. *Clearing House Assn., L. L. C.*, 557 U. S. ___, ___ (2009) (THOMAS, J., concurring in part and dissenting in part) (slip op., at 21) (internal quotation marks and brackets omitted). It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme. As always, Congress and the FDA retain the authority to change the

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[9]That said, the dissent overstates what it characterizes as the "many absurd consequences" of our holding. *Post*, at 18. First, the FDA informs us that "[a]s a practical matter, genuinely new information about drugs in long use (as generic drugs typically are) appears infrequently." U. S. Brief 34–35. That is because patent protections ordinarily prevent generic drugs from arriving on the market for a number of years after the brand-name drug appears. Indeed, situations like the one alleged here are apparently so rare that the FDA has no "formal regulation" establishing generic drug manufacturers' duty to initiate a label change, nor does it have any regulation setting out that label-change process. *Id.*, at 20–21. Second, the dissent admits that, even under its approach, generic drug manufacturers could establish pre-emption in a number of scenarios. *Post*, at 12–13.

law and regulations if they so desire.

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The judgments of the Fifth and Eighth Circuits are reversed, and the cases are remanded for further proceedings consistent with this opinion.

It is so ordered.