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

SUPREME COURT OF THE UNITED STATES

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PLIVA, INC., ET AL. *v*. MENSING

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

No. 09–993. Argued March 30, 2011—Decided June 23, 2011*

Five years after the Food and Drug Administration (FDA) first approved metoclopramide, a drug commonly used to treat digestive tract problems, under the brand name Reglan, generic manufacturers such as petitioners also began producing the drug. Because of accumulating evidence that long-term metoclopramide use can cause tardive dyskinesia, a severe neurological disorder, warning labels for the drug have been strengthened and clarified several times, most recently in 2009.

Respondents were prescribed Reglan in 2001 and 2002, but both received the generic drug from their pharmacists. After taking the drug as prescribed for several years, both developed tardive dyskinesia. In separate state-court tort actions, they sued petitioners, the generic drug manufacturers that produced the metoclopramide they took (Manufacturers). Each respondent alleged, *inter alia,* that long-term metoclopramide use caused her disorder and that the Manufacturers were liable under state tort law for failing to provide adequate warning labels. In both suits, the Manufacturers urged that federal statutes and FDA regulations pre-empted the state tort claims by requiring the same safety and efficacy labeling for generic metoclopramide as was mandated at the time for Reglan. The Fifth and Eighth Circuits rejected these arguments, holding that respondents' claims were not pre-empted.

Held: The judgment is reversed, and the cases are remanded.

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*Together with No. 09–1039, *Actavis Elizabeth, LLC* v. *Mensing,* also on certiorari to the same court, and No. 09–1501, *Actavis, Inc.* v. *Demahy,* on certiorari to the United States Court of Appeals for the Fifth Circuit.

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588 F. 3d 603 and 593 F. 3d 428, reversed and remanded.

JUSTICE THOMAS delivered the opinion of the Court with respect to all but Part III–B–2, concluding that federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt, these state claims. Pp. 4–14, 17–20.

(a) Because pre-emption analysis requires a comparison between federal and state law, the Court begins by identifying the state tort duties and federal labeling requirements applicable to the Manufacturers. Pp. 4–10.

(1) State tort law requires a manufacturer that is, or should be, aware of its drug's danger to label it in a way that renders it reasonably safe. Respondents pleaded that the Manufacturers knew, or should have known, both that the long-term use of their products carried a high risk of tardive dyskinesia and that their labels did not adequately warn of that risk. Taking these allegations as true, the state-law duty required the Manufacturers to use a different, stronger label than the one they actually used. Pp. 4–5.

(2) On the other hand, federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels. 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. Although the same rules originally applied to all drugs, the 1984 law commonly called the Hatch-Waxman Amendments allows a generic drug manufacturer to gain FDA approval simply by showing that its drug is equivalent to an already-approved brand-name drug, and that the safety and efficacy labeling proposed for its drug is the same as that approved for the brand-name drug. Respondents contend that federal law nevertheless provides avenues through which the Manufacturers could have altered their metoclopramide labels in time to prevent the injuries here. These include: (1) the FDA's "changes-being-effected" (CBE) process, which permits drug manufacturers, without preapproval, to add or strengthen a warning label; and (2) sending "Dear Doctor" letters providing additional warnings to prescribing physicians and other healthcare professionals. However, the FDA denies that the Manufacturers could have used either of these processes to unilaterally strengthen their warning labels. The Court defers to the FDA's views because they are not plainly erroneous or inconsistent with the regulations, and there is no other reason to doubt that they reflect the FDA's fair and considered judgment. *Auer* v. *Robbins*, 519 U. S. 452, 461, 462. Assuming, without deciding, that the FDA is correct that federal law nevertheless required the Manufacturers to ask for the agency's assistance in convincing the brand-name manufacturer to adopt a stronger label, the Court turns to the

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pre-emption question. Pp. 5–10.

(b) Where state and federal law directly conflict, state law must give way. See, *e.g., Wyeth* v. *Levine*, 555 U. S. 555, 583. Such a conflict exists where it is "impossible for a private party to comply with both state and federal requirements." *Freightliner Corp.* v. *Myrick*, 514 U. S. 280, 287. Pp. 11–14, 17–20.

(1) The Court finds impossibility here. If the Manufacturers had independently changed their labels to satisfy their state-law duty to attach a safer label to their generic metoclopramide, they would have violated the federal requirement that generic drug labels be the same as the corresponding brand-name drug labels. Thus, it was impossible for them to comply with both state and federal law. And even if they had fulfilled their federal duty to ask for FDA help in strengthening the corresponding brand-name label, assuming such a duty exists, they would not have satisfied their state tort-law duty. State law demanded a safer label; it did not require communication with the FDA about the possibility of a safer label. Pp. 11–12.

(2) The Court rejects the argument that the Manufacturers' pre-emption defense fails because they failed to ask the FDA for help in changing the corresponding brand-name label. The proper question for "impossibility" analysis is whether the private party could independently do under federal law what state law requires of it. See *Wyeth, supra*, at 573. Accepting respondents' argument would render conflict pre-emption largely meaningless by making most conflicts between state and federal law illusory. In these cases, it is possible that, had the Manufacturers asked the FDA for help, they might have eventually been able to strengthen their warning label. But it is also *possible* that they could have convinced the FDA to reinterpret its regulations in a manner that would have opened the CBE process to them, persuaded the FDA to rewrite its generic drug regulations entirely, or talked Congress into amending the Hatch-Waxman Amendments. If these conjectures sufficed to prevent federal and state law from conflicting, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. That Clause—which makes federal law "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding," U. S. Const., Art. VI, cl. 2—cannot be read to permit an approach to pre-emption that renders conflict pre-emption all but meaningless. Here, 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. Pp. 12–14, 17.

(3) *Wyeth* is not to the contrary. The Court there held that a

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state tort action against a brand-name drug manufacturer for failure to provide an adequate warning label was not pre-empted because it was possible for the manufacturer to comply with both state and federal law under the FDA's CBE regulation. 555 U. S., at 572–573. The federal statutes and regulations that apply to brand-name drug manufacturers differ, by Congress' design, from those applicable to generic drug manufacturers. And different federal statutes and regulations may, as here, lead to different pre-emption results. This Court will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme. Congress and the FDA retain authority to change the law and regulations if they so desire. Pp. 17–20.

THOMAS, J., delivered the opinion of the Court, except as to Part III–B–2. ROBERTS, C. J., and SCALIA and ALITO, JJ., joined that opinion in full, and KENNEDY, J., joined as to all but Part III–B–2. SOTOMAYOR, J., filed a dissenting opinion, in which GINSBURG, BREYER, and KAGAN, JJ., joined.