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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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WYETH *v.* LEVINE

CERTIORARI TO THE SUPREME COURT OF VERMONT

No. 06–1249. Argued November 3, 2008—Decided March 4, 2009

Petitioner Wyeth manufactures the antinausea drug Phenergan. After a clinician injected respondent Levine with Phenergan by the "IV-push" method, whereby a drug is injected directly into a patient's vein, the drug entered Levine's artery, she developed gangrene, and doctors amputated her forearm. Levine brought a state-law damages action, alleging, *inter alia,* that Wyeth had failed to provide an adequate warning about the significant risks of administering Phenergan by the IV-push method. The Vermont jury determined that Levine's injury would not have occurred if Phenergan's label included an adequate warning, and it awarded damages for her pain and suffering, substantial medical expenses, and loss of her livelihood as a professional musician. Declining to overturn the verdict, the trial court rejected Wyeth's argument that Levine's failure-to-warn claims were pre-empted by federal law because Phenergan's labeling had been approved by the federal Food and Drug Administration (FDA). The Vermont Supreme Court affirmed.

Held: Federal law does not pre-empt Levine's claim that Phenergan's label did not contain an adequate warning about the IV-push method of administration. Pp. 6–25.

(a) The argument that Levine's state-law claims are pre-empted because it is impossible for Wyeth to comply with both the state-law duties underlying those claims and its federal labeling duties is rejected. Although a manufacturer generally may change a drug label only after the FDA approves a supplemental application, the agency's "changes being effected" (CBE) regulation permits certain preapproval labeling changes that add or strengthen a warning to improve drug safety. Pursuant to the CBE regulation, Wyeth could have unilaterally added a stronger warning about IV-push administration, and there is no evidence that the FDA would ultimately have rejected

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such a labeling change. Wyeth's cramped reading of the CBE regulation and its broad assertion that unilaterally changing the Phenergan label would have violated federal law governing unauthorized distribution and misbranding of drugs are based on the fundamental misunderstanding that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. It is a central premise of the Food, Drug, and Cosmetic Act (FDCA) and the FDA's regulations that the manufacturer bears responsibility for the content of its label at all times. Pp. 11–16.

(b) Wyeth's argument that requiring it to comply with a state-law duty to provide a stronger warning would interfere with Congress' purpose of entrusting an expert agency with drug labeling decisions is meritless because it relies on an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law. The history of the FDCA shows that Congress did not intend to pre-empt state-law failure-to-warn actions. In advancing the argument that the FDA must be presumed to have established a specific labeling standard that leaves no room for different state-law judgments, Wyeth relies not on any statement by Congress but on the preamble to a 2006 FDA regulation declaring that state-law failure-to-warn claims threaten the FDA's statutorily prescribed role. Although an agency regulation with the force of law can pre-empt conflicting state requirements, this case involves no such regulation but merely an agency's assertion that state law is an obstacle to achieving its statutory objectives. Where, as here, Congress has not authorized a federal agency to pre-empt state law directly, the weight this Court accords the agency's explanation of state law's impact on the federal scheme depends on its thoroughness, consistency, and persuasiveness. Cf., *e.g., Skidmore* v. *Swift & Co.*, 323 U. S. 134. Under this standard, the FDA's 2006 preamble does not merit deference: It is inherently suspect in light of the FDA's failure to offer interested parties notice or opportunity for comment on the pre-emption question; it is at odds with the available evidence of Congress' purposes; and it reverses the FDA's own longstanding position that state law is a complementary form of drug regulation without providing a reasoned explanation. *Geier* v. *American Honda Motor Co.*, 529 U. S. 861, is distinguished. Pp. 17–25.

___ Vt. ___, 944 A. 2d 179, affirmed.

STEVENS, J., delivered the opinion of the Court, in which KENNEDY, SOUTER, GINSBURG, and BREYER, JJ., joined. BREYER, J., filed a concurring opinion. THOMAS, J., filed an opinion concurring in the judgment. ALITO, J., filed a dissenting opinion, in which ROBERTS, C. J., and SCALIA, J., joined.