Supplementary Material

Chapter 11: The Contemporary Era—Powers of the National Government

Wyeth v. Levine, 555 U.S. 555 (2009)

The pharmaceutical company Wyeth manufactured a drug Phenergan, which is used for the treatment of nausea. Injecting the drug directly into the bloodstream (intravenous (IV)-push delivery) poses significant risks. The federal Food and Drug Administration (FDA) regulates the safety of all drugs in the United States by controlling the approval of labels and marketing materials. The FDA approved the safety of the drug with a label indicating that IV-push delivery was the least preferred delivery option that carried health risks but not specifically advising against that method. In 2000, Diana Levine was treated at a clinic for a migraine headache and in the process was given Phenergan through an IV push. Levine developed gangrene that eventually required the amputation of her arm. Both the clinician and the health clinic reached a monetary settlement with Levine. She then brought suit in Vermont state court for damages, arguing that the drug was not reasonably safe when administered by IV push. The jury found that the drug was a defective product and awarded almost $7.5 million to Levine. The verdict was affirmed by the state supreme court. On appeal, the U.S. Supreme Court affirmed in a 7–2 decision. Wyeth argued throughout the litigation that federal drug regulation and FDA approval of the specific language of the drug label regarding delivery methods preempted any state law claim that the drug was defective or dangerous. The courts throughout held that Wyeth could have voluntarily chosen to issue stronger warnings against the IV-push method and that federal regulations established only a floor on safety standards. Both the states and the company could choose to adopt safety standards above that federally mandated floor.

How does the majority evaluate preemption claims in this case? Was there an actual conflict between the state law safety requirements and federal safety regulations? In what sense did the FDA establish a "floor"? Is there a tension between the federal administrative regulatory regime and the state tort regime in how they balance the costs and benefits of drugs and their uses? If the state had reached the same conclusion (that the IV-push delivery method should be barred) through a statutory mandate or administrative decree rather than through a jury determination, would the Supreme Court have reached the same conclusion that there was no conflict between the state and federal regulations? Can a state bar all uses of a given drug within its jurisdiction after the FDA has approved the drug as safe? Can a state authorize the use of a drug after the FDA has declared it unsafe?

JUSTICE STEVENS delivered the opinion of the Court.

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Wyeth makes two separate pre-emption arguments: first, that it would have been impossible for it to comply with the state-law duty to modify Phenergan's labeling without violating federal law, and second, that recognition of Levine's state tort action creates an unacceptable "obstacle to the accomplishment and execution of the full purposes and objectives of Congress," because it substitutes a lay jury's decision about drug labeling for the expert judgment of the FDA. . . .

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Our answer to that question must be guided by two cornerstones of our pre-emption jurisprudence. First, "the purpose of Congress is the ultimate touchstone in every pre-emption case."

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.'" . . .

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As it enlarged the FDA's powers to "protect the public health" and "assure the safety, effectiveness, and reliability of drugs," Congress took care to preserve state law. The 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a "direct and positive conflict" with the FDCA. Consistent with that provision, state common-law suits "continued unabated despite . . . FDA regulation." . . .

In 2007, after Levine's injury and lawsuit, Congress again amended the FDCA. . . . [At that time, Congress] adopted a rule of construction to make it clear that manufacturers remain responsible for updating their labels.

. . . . The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label. Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application. There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" . . . it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDS approval.

Wyeth argues that the CBE regulation is not implicated in this case because a 2008 amendment provides that a manufacturer may only change its label "to reflect newly acquired information." . . . Wyeth contends that it could have changed Phenergan's label only in response to new information that the FDA had not considered. And it maintains that Levine has not pointed to any such information concerning the risks of IV-push administration. Thus, Wyeth insists, it was impossible for it to discharge its state-law obligation to provide a stronger warning about IV-push administration without violating federal law. Wyeth's argument misapprehends both the federal drug regulatory scheme and its burden in establishing a pre-emption defense.

. . . . The FDCA does not provide that a drug is misbranded simply because the manufacturer has altered an FDA-approved label; instead, the misbranding provision focuses on the substance of the label and, among other things, proscribes labels that fail to include "adequate warnings." . . . And the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept—neither Wyeth nor the United States has identified a case in which the FDA has done so.

. . . . [I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. . . .

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Of course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplemental applications. But absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.

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Impossibility pre-emption is a demanding defense. On the record before us, Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements. The CBE regulation permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA approved Phenergan's label does not establish that it would have prohibited such a change.

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Wyeth contends that the FDCA establishes both a floor and a ceiling for drug regulation: Once the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue. The most glaring problem with this argument is that all evidence of Congress' purposes is to the contrary. . . .

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If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs. . . . Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. . . .

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In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. . . .

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We conclude that it is not impossible for Wyeth to comply with its state- and federal-law obligations and that Levine's common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA. Accordingly, the judgment of the Vermont Supreme Court is *affirmed*.

JUSTICE BREYER, concurring.

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JUSTICE THOMAS, concurring.

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I write separately, however, because I cannot join the majority's implicit endorsement of far-reaching implied pre-emption doctrines. In particular, I have become increasingly skeptical of this Court's "purposes and objectives" pre-emption jurisprudence. Under this approach, the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law. Because implied pre-emption doctrines that wander far from the statutory text are inconsistent with the Constitution, I concur only in the judgment.

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JUSTICE ALITO, with whom the CHIEF JUSTICE and JUSTICE SCALIA join, dissenting.

This case illustrates that tragic facts make bad law. The Court holds that a state tort jury, rather than the Food and Drug Administration (FDA), is ultimately responsible for regulating warning labels for prescription drugs. That result cannot be reconciled with *Geier v. American Honda Motor Co.* (2000), or general principles of conflict pre-emption. I respectfully dissent.

The Court frames the question presented as a "narro[w]" one—namely, whether Wyeth has a duty to provide "an adequate warning about using the IV-push method" to administer Phenergan. But that ignores the antecedent question of who—the FDA or a jury in Vermont—has the authority and responsibility for determining the "adequacy" of Phenergan's warnings. . . .

More to the point, the question presented by this case is not a "narrow" one, and it does not concern whether Phenergan's label should bear a "stronger" warning. Rather, the real issue is whether a

state tort jury can countermand the FDA's considered judgment that Phenergan's FDA-mandated warning label renders its intravenous (IV) use "safe." Indeed, respondent's amended complaint alleged that Phenergan is "not reasonably safe for intravenous administration." . . .

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Where the FDA determines, in accordance with its statutory mandate, that a drug is on balance "safe," our conflict pre-emption cases prohibit any State from countermanding that determination. . . .

[A]s the Court itself recognizes, it is irrelevant in conflict pre-emption cases whether Congress "enacted an express pre-emption provision at some point during the FDCA's 70-year history." . . . Rather, the ordinary principles of conflict pre-emption turn solely on whether a State has upset the regulatory balance struck by the federal agency. . . .

Geier arose under the National Traffic and Motor Safety Vehicle Act of 1966, which directs the Secretary of the Department of Transportation (DOT) to "establish by order . . . motor vehicle safety standards." . . .

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Notwithstanding the statute's saving clause [providing that compliance with federal standards did not exempt a person from any liability under common law], and notwithstanding the fact that Congress gave the Secretary authority to set only "minimum" safety standards, we held Geier's state tort suit pre-empted. In reaching that result, we relied heavily on the view of the Secretary of Transportation—expressed in an amicus brief—that Standard 208 "'embodies the Secretary's policy judgment that safety would best be promoted if manufacturers installed alternative protection systems in their fleets rather than one particular system in every car.'" . . .

The same rationale applies here. Through Phenergan's label, the FDA offered medical professionals a menu of federally approved, "safe" and "effective" alternatives—including IV push—for administering the drug. Through a state tort suit, respondent attempted to deem IV push "unsafe" and "ineffective." . . .

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To be sure, state tort suits can peacefully coexist with the FDA's labeling regime, and they have done so for decades. . . . But this case is far from peaceful coexistence. The FDA told Wyeth that Phenergan's label renders its use "safe." But the State of Vermont, through its tort law, said: "Not so."

The state-law rule at issue here is squarely pre-empted. Therefore, I would reverse the judgment of the Supreme Court of Vermont.