



PRODUCT SAFETY & LIABILITY



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The U.S. Supreme Court's decision in *Wyeth v. Levine* sharply limited the availability of implied preemption as a defense in pharmaceutical cases. In this Analysis & Perspective, attorney Brian Wolfman discusses the decision and its implications for prescription drug litigation as well as litigation in other areas that are regulated by the federal government.

After *Wyeth*, Wolfman says, a defendant in a prescription drug case must demonstrate a "tight fit between the labeling change proposed by the manufacturer (and rejected by the FDA) and the labeling change that the plaintiff contends would have prevented her injuries." Moreover, he says, in light of *Wyeth*, agency claims of preemption with respect to other products or services are likely to be subject to increased judicial scrutiny, and it is unlikely that these claims will be accorded substantial deference unless they are tethered to a congressional authorization regarding preemption.

Wyeth v. Levine and Its Implications

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I. Introduction

On March 2, the Supreme Court ruled in *Wyeth v. Levine*¹ that approval of the prescription drug Phenergan and its labeling by the Food and Drug Administration (FDA) did not preempt plaintiff Diana Levine's state-law tort claim premised on defendant Wyeth's failure to warn adequately about one of Phenergan's risks. My intent here is not to write from a plaintiff's or a defendant's perspective, but, rather, to

¹ 129 S. Ct. 1187 (2009).

describe the Court's decision and to assess how it may affect litigation involving prescription drugs and other federally regulated products and services.

Because it is difficult to understand *Wyeth* without appreciating the facts of the case and the basics of federal drug regulation, those topics are addressed in Part II below. Part III describes the Supreme Court's decision, and Part IV discusses its likely effects.

II. Background

A. The Facts

On April 7, 2000, Diana Levine, a Vermont musician, received injections of Wyeth's prescription drug Phenergan to treat nausea associated with a migraine headache.² The drug was first administered by intramuscular injection. Later that day, the drug was administered intravenously through a technique known as direct IV, or "IV-push."³ In this method, a syringe pushes medication directly into the patient's vein. The method is called "direct" to distinguish it from a more common means of intravenous administration in which the medication is placed into a stream of saline flowing from a hanging IV bag.⁴ As the Supreme Court noted, the latter method is nearly risk-free.⁵ On the other hand, when Phenergan is administered by the IV-push method, inadvertent exposure to arterial blood may result, which, in turn, may lead to gangrene and amputation.⁶ The testimony at trial showed that, prior to Ms. Levine's injection, there had been at least 20 reported cases in which IV-push administration of Phenergan had caused an amputation.⁷

As a result of IV-push administration of Phenergan, the drug penetrated Ms. Levine's artery.⁸ For seven weeks after the injection, Ms. Levine suffered severe physical and emotional pain as her right hand turned black and died.⁹ Ms. Levine endured two amputations. She first lost her right hand and then her right arm up to the elbow.¹⁰

B. The FDA Drug Approval Process, the FDCA's Relationship With State Law, and Approval of the Phenergan Label

1. FDA Approval and Drug Labeling

Since its enactment in 1938, the federal Food, Drug, and Cosmetic Act (FDCA) has governed the entry of prescription drugs on the market. A manufacturer seeking to market a prescription drug must file a new drug application (NDA) with the FDA.¹¹ The agency must approve the NDA "unless it fails to meet certain criteria, including whether test results and other information es-

tablish that the drug is 'safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof,' whether there is 'substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof,' and whether, 'based on a fair evaluation of all material facts, such labeling is false or misleading in any particular.'"¹²

Because prescription drug labeling provides information used by clinicians to prescribe and administer an approved drug, FDA regulations describe in detail the proper form and content for labeling.¹³ After FDA approval, a drug generally must be accompanied by labeling in the same form as approved by the FDA.¹⁴ The label's content is not, however, set in stone. Rather, a manufacturer is required to alter its labeling in certain circumstances. An FDA regulation provides that approved drug "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."¹⁵ In addition, the FDA is not required to approve all label changes before drug manufacturers make them. At the time of Ms. Levine's Phenergan injection, manufacturers were permitted, pursuant to the FDA's so-called "changes being effected," or CBE, regulation, to revise labels, without prior FDA approval, to "add or strengthen a contraindication, warning, precaution, or adverse reaction" [or to] "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product."¹⁶

In 2008, the FDA amended the CBE regulation to authorize only those label changes that "reflect newly acquired information."¹⁷ The revised regulation's definition of "'newly acquired information' is not limited to new data, but also encompasses 'new analyses of previously submitted data.'"¹⁸

2. The Relationship Between Federal Drug Regulation and State Law

In the 70 years since the FDCA's enactment, the states' common-law tort systems have provided compensation for injuries caused by prescription drugs, and, until recently, courts had held uniformly that federal law does not preempt tort claims seeking redress for such injuries.¹⁹ As contrasted with medical devices,²⁰ the FDCA contains no preemption provision regarding prescription drugs. And, as noted in *Wyeth*, an initial draft of the FDCA contained a right of action for damages sustained from drug-related injuries, which

¹² *Levine v. Wyeth*, 944 A.2d 179, 185 (Vt. 2006) (quoting 21 U.S.C. § 355(d)), *aff'd sub nom.*, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

¹³ See generally 21 C.F.R. Part 201.

¹⁴ See *id.* § 314.70(b)(2)(v).

¹⁵ *Id.* § 201.80(e).

¹⁶ *Id.* § 314.70(c)(6)(iii)(A), (C).

¹⁷ *Id.* § 314.70(c)(6)(iii); see 73 Fed. Reg. 49603 (2008).

¹⁸ *Wyeth*, 129 S. Ct. at 1196 (quoting 73 Fed. Reg. at 49604).

¹⁹ For cases stating the traditional no-preemption view, see, e.g., *Tobin v. Astra Pharm. Prods. Inc.*, 993 F.2d 528, 537 (6th Cir. 1993); *Osburn v. Anchor Labs.*, 825 F.2d 908, 911-13 (5th Cir. 1987); *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986); *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1113 (Cal. 1996); *Feldman v. Lederle Labs.*, 592 A.2d 1176, 1185-97 (N.J. 1991).

²⁰ See 21 U.S.C. § 360k.

² *Id.* at 1191.

³ *Id.*

⁴ *Id.* at 1192.

⁵ *Id.*

⁶ *Id.* at 1191.

⁷ *Id.* at 1197 (citing trial testimony).

⁸ *Id.* at 1190-91.

⁹ *Levine v. Wyeth*, trial transcript, Vol. III, at 38 (testimony of Dr. Mark Bucksbaum) ("Pain scales usually are run from one to ten. This is a ten. . . there's not much worse than this type of scenario."); *id.* at 165-66 (testimony of Diana Levine) (describing excruciating pain, terror, and fear of losing arm and dying).

¹⁰ *Wyeth*, 129 S. Ct. at 1191.

¹¹ See 21 U.S.C. § 355(a).

was apparently eliminated “because common-law claims were already available under state law.”²¹

Until earlier this decade, the FDA had never suggested that state-law product liability suits are preempted by the FDCA or by the agency’s approval of a drug’s labeling. In fact, on at least two occasions, the FDA took a different view. In 1979 and 1998, in preambles accompanying drug regulations, the agency stated that state tort law did not interfere with federal regulation and that federal regulation should not influence state-law liability.²²

In December 2000, the FDA proposed to amend its drug labeling regulations. At that time, the agency noted that the amended “rule would ‘not contain policies that have federalism implications or that preempt State law.’”²³ In 2006, however, in finalizing these labeling rules, the agency took a different view, claiming in the regulatory preamble that, in some circumstances, the FDA’s approval of a prescription drug’s labeling preempts a state tort claim premised on the manufacturer’s failure to warn of hazards associated with the drug.²⁴ Tort defendants claimed that the 2006 preamble was entitled to judicial deference in drug-injury litigation because it expressed the authoritative views of the agency charged with administering the FDCA. The lower courts split on that question, with some courts, including the Vermont Supreme Court in *Wyeth*, rejecting deference to the agency’s view on preemption,²⁵ and other courts embracing it.²⁶

3. History of The Phenergan Label

Phenergan and its labeling were first approved by the FDA in 1955.²⁷ As detailed in the Supreme Court’s opinion, between 1973 and 1998, the FDA and Wyeth engaged in sporadic exchanges concerning the drug’s labeling, prompted mainly by a 1981 submission made by Wyeth in response to new FDA labeling rules.²⁸ At one point, the agency requested a revised warning on arterial exposure to Phenergan, and Wyeth submitted a revision (which Wyeth later contended constituted a strengthened warning about the risks of IV-push administration). Ultimately, however, the agency did not approve Wyeth’s submission, but instead instructed the company to “[r]etain [the] verbiage in [the] current label.”²⁹

²¹ *Wyeth*, 129 S. Ct. at 1199 n.7 (citing FDCA’s legislative history).

²² See 63 Fed. Reg. 66378, 66384 (1998) (“FDA does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency’s regulations.”); 44 Fed. Reg. 37434, 37437 (1979) (“It is not the intent of the FDA to influence the civil tort liability of the manufacturer.”); see also *Wyeth*, 129 S. Ct. at 1201-02 & n.10 (also citing 59 Fed. Reg. 3948 (1994)).

²³ *Wyeth*, 129 S. Ct. at 1201 (quoting 65 Fed. Reg. 81082, 81103 (2000)).

²⁴ 71 Fed. Reg. 3922, 3933-36 (2006) (hereafter “2006 preamble”).

²⁵ See *Levine v. Wyeth*, 944 A.2d at 192-94; see also, e.g., *Desiano v. Warner-Lambert Co.*, 467 F.3d 85, 97 n.9 (2d Cir. 2006), *aff’d by equally divided court sub nom.*, *Warner-Lambert Co., LLC v. Kent*, 128 S. Ct. 1168 (2008).

²⁶ See, e.g., *In re Bextra & Celebrex Marketing Sales Practices and Prod. Liab. Litig.*, 2006 WL 2374742, *6-7 (N.D. Cal. 2006).

²⁷ *Wyeth*, 129 S. Ct. at 1192.

²⁸ See *id.*

²⁹ See *id.* (quoting FDA correspondence).

4. Proceedings in the Vermont Courts

Ms. Levine sued Wyeth in Vermont Superior Court to recover compensation for her life-altering injuries. The jury awarded damages based on its determination that Wyeth’s “inadequate label” caused Ms. Levine’s injury, and that “the critical defect in Phenergan’s label was the lack of an adequate warning about the risks of IV-push administration.”³⁰ The Vermont Supreme Court affirmed. It rejected Wyeth’s preemption arguments and found that there was “no evidence” that the FDA had considered, much less rejected, a specific request by Wyeth to strengthen the Phenergan label with respect to the risks of IV-push administration.³¹

III. The Supreme Court’s Decision

As noted at the outset, the Supreme Court ruled 6 to 3 for Diana Levine, rejecting Wyeth’s preemption argument and upholding the jury’s verdict in Ms. Levine’s favor. Justice John Paul Stevens wrote for a five-justice majority that included Justices Anthony M. Kennedy, David H. Souter, Stephen G. Breyer, and Ruth Bader Ginsburg. Justice Breyer, joining fully in the majority opinion, wrote a short concurring opinion expressing his views on regulatory preemption. Justice Clarence Thomas concurred in the judgment, but wrote separately to explain that the majority’s ruling went too far in its “implicit endorsement of far-reaching implied preemption doctrine.”³² Justice Samuel A. Alito Jr., joined by Chief Justice John G. Roberts Jr. and Justice Antonin Scalia, dissented. The first three opinions are discussed below, with emphasis on the majority opinion because it will likely have the greatest influence on future preemption doctrine. Justice Alito’s dissent provides a comprehensive rebuttal to the majority and explains why, in Justice Alito’s view, the Court’s Supremacy Clause precedents and the FDA’s role in assessing the risks and benefits of prescription drugs warranted a finding of preemption. Because the dissent is unlikely to influence future tort litigation, at least in the near term, it is not discussed further here.

A. Justice Stevens’s Majority Opinion

1. Framing the Issues

Justice Stevens’s opinion begins by summarizing the facts, the issue before the Court, and the majority’s conclusion:

Directly injecting the drug Phenergan into a patient’s vein creates a significant risk of catastrophic consequences. A Vermont jury found that petitioner Wyeth, the manufacturer of the drug, had failed to provide an adequate warning of that risk and awarded damages to respondent Diana Levine to compensate her for the amputation of her arm. The warnings on Phenergan’s label had been deemed sufficient by the federal Food and Drug Administration (FDA) when it approved Wyeth’s new drug application in 1955 and when it later approved changes in the drug’s labeling. The question we must decide is whether the FDA’s approvals provide Wyeth with a complete defense to

³⁰ *Id.* at 1194.

³¹ *Levine v. Wyeth*, 944 A.2d at 93.

³² *Wyeth*, 129 S. Ct. at 1205 (Thomas, J., concurring in the judgment).

Levine's tort claims. We conclude that they do not.³³

Thereafter, the Court framed Wyeth's preemption arguments. Because the FDCA does not expressly preempt state authority with respect to prescription drugs, the question before the Court, Justice Stevens explained, was whether Ms. Levine's state-law claims were impliedly preempted either because "it would have been impossible for [Wyeth] to comply with the state-law duty to modify Phenergan's labeling without violating federal law,"³⁴ or because Ms. Levine's suit posed an "unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" ³⁵

Justice Stevens made two preliminary legal observations. The first was boilerplate and not in dispute: that "the purpose of Congress is the ultimate touchstone in every preemption case."³⁶ The second, very much in dispute, concerned the so-called presumption against preemption of state law: that " 'the historic police powers of the States were not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress,' " particularly " 'in a field which the States have traditionally occupied.' " ³⁷ This presumption has long been targeted by tort defendants because, as the Court has explained, it applies to state tort law as well as state positive law.³⁸ Justice Stevens rejected the drug industry's broad claim "that the presumption against preemption should not apply to claims of implied conflict preemption at all,"³⁹ noting that "this Court has long held to the contrary."⁴⁰ He also rejected Wyeth's narrower claim that the presumption should not apply to Ms. Levine's case because the federal government has a long history of regulating drug labeling. "That argument," Justice Stevens explained, "misunderstands" the presumption against preemption, which "accounts for the historic presence of state law but does not rely on the absence of federal regulation."⁴¹

2. "Impossibility" Preemption

The Court then turned to Wyeth's "impossibility" argument: that Wyeth could not comply with both the state-law duty to warn Ms. Levine's physicians of the risks of IV-push administration of Phenergan and its federal labeling obligations under the FDCA. The Court rejected this argument, first, on the basis of the CBE regulation, which, as explained above, authorizes a drug manufacturer unilaterally to update a drug label to add or strengthen warnings, including warnings about methods of drug administration.⁴²

The Court did not reach the question whether the 2008 amendment to the CBE regulation, which states

that manufacturers may only unilaterally amend their labels "to reflect newly acquired information,"⁴³ applied retroactively to Ms. Levine's claim, or, as Wyeth maintained, did no more than "reaffirm[] the interpretation of the regulation in effect when this case was tried."⁴⁴ Rather, the Court held that, because the amended regulation defined "newly acquired information" to include new analyses of existing data,⁴⁵ after learning of at least 20 amputations resulting from IV-push injections of Phenergan prior to Ms. Levine's injury, "Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug."⁴⁶ The Court also emphasized that, in 2007, when Congress amended the FDCA to provide the FDA authority to require manufacturers to amend their labels to enhance safety, Congress reiterated that, despite the FDA's new authority, manufacturers could still use the CBE regulation to make label changes on their own.⁴⁷

The Court rejected Wyeth's claim that a Phenergan label updated through the CBE regulation would have been misbranded under federal law. The Court noted that, under the FDCA, a label is misbranded if it fails to contain "adequate warnings,"⁴⁸ and that, presumably, a label is not rendered inadequate simply because it has been updated using the CBE regulation, which is an FDA-authorized means for unilaterally amending a drug label. As Justice Stevens put it: "[T]he 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."⁴⁹ The Court also explained that a drug is not misbranded based on "FDA's belief" that misbranding has occurred,⁵⁰ rather, a jury (or, presumably, some other adjudicator) makes conclusive misbranding determinations.⁵¹

Having rejected Wyeth's "cramped reading of the CBE regulation" and its view of misbranding,⁵² Justice Stevens turned to what he termed Wyeth's "more fundamental" misunderstanding of the FDCA.⁵³ Dismissing Wyeth's view that the FDA "bears primary responsibility for drug labeling,"⁵⁴ Justice Stevens reviewed FDA regulations that, he said, make the manufacturer responsible for the content of drug labels "at all times."⁵⁵ He pointed primarily to 21 C.F.R. § 201.80(e), which requires all prescription drug manufacturers to

⁴³ *Wyeth*, 129 S. Ct. at 1196 (quoting 73 Fed. Reg. at 49609).

⁴⁴ *Id.*

⁴⁵ *Id.* at 1197 (discussing 73 Fed. Reg. at 49604, 49607).

⁴⁶ *Id.*

⁴⁷ *Id.* at 1198 (Congress "reaffirmed the manufacturer's obligations and referred specifically to the CBE regulation, which both reflects the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to FDA approval.") (citing 121 Stat. 925–26). The relevant FDCA amendment is codified at 21 U.S.C. § 355(o)(4)(I).

⁴⁸ *Id.* at 1197 (quoting 21 U.S.C. § 352(f)).

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.* (citing 21 U.S.C. §§ 331, 332, 334(a)-(b)).

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.* at 1198 (citing 21 C.F.R. §§ 201.80, 314.80(b); 73 Fed. Reg. at 49605).

³³ *Wyeth*, 129 S. Ct. at 1190–91.

³⁴ *Id.* at 1193 (citing *Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U. S. 141, 153 (1982)).

³⁵ *Id.* at 1194 (quoting *Hines v. Davidowitz*, 312 U. S. 52, 67 (1941)).

³⁶ *Id.* at 1194–95 (quoting *Medtronic Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

³⁷ *Id.* (quoting *Lohr*, 518 U.S. at 485).

³⁸ *Lohr*, 518 U.S. at 485 ("[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state law causes of action.").

³⁹ *Wyeth*, 129 U.S. at 1195 n.3.

⁴⁰ *Id.* (citing cases).

⁴¹ *Id.*

⁴² 21 C.F.R. §§ 314.70(c)(6)(iii)(A), (C).

revise their labels “to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.”⁵⁶

Acknowledging that the FDA has authority to reject a labeling change made pursuant to the CBE regulation, the Court then turned to the FDA’s review of the Phenergan label, explaining that “absent clear evidence” that the agency would not have approved a label change of the kind that would have prevented Ms. Levine’s injury, “we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.”⁵⁷ Based on the record of the case, as set out at some length by the Vermont Supreme Court,⁵⁸ the Court held that “Wyeth has offered no such evidence.”⁵⁹ The Court explained that the Vermont courts had rejected, “as a matter of fact,”⁶⁰ Wyeth’s contention that when the FDA had told Wyeth to retain the “current verbiage” in its label (and did not adopt Wyeth’s revised label), it had not rejected a strengthened warning against IV-push administration. The Court noted that even the FDA did not construe its rejection of Wyeth’s revised Phenergan label as relating to IV-push administration of the drug; rather, the agency acknowledged in its Supreme Court brief that Wyeth’s proposed revision was “non-substantive” and that the FDA had rejected it for “formatting reasons.”⁶¹ In sum, the Court concluded, “impossibility” preemption “is a demanding defense,”⁶² which Wyeth had not met.

3. “Obstacle” or “Frustration of Purposes” Preemption

Justice Stevens then turned to Wyeth’s argument that state-law liability would pose an obstacle to the objectives of federal drug labeling regulation. The Court’s response was plain: “The most glaring problem with this argument is that all evidence of Congress’ purposes is to the contrary.”⁶³ It noted that Congress (1) rejected a federal damages remedy in the bill that ultimately became the FDCA because damages remedies were already available under state law,⁶⁴ and (2) had not enacted an express preemption provision at any time during the FDCA’s 70-year history, as it had for medical devices in 1976.⁶⁵

The Court then turned to the FDA’s 2006 preamble, which, as explained above, concluded that state tort claims are preempted in some circumstances by the FDA’s approval of a drug’s label. For a number of reasons, the Court held that the preamble was “entitled to no weight.”⁶⁶

■ The preamble was an “agency proclamation[] of preemption,” not a regulation promulgated pursuant to

⁵⁶ 21 C.F.R. § 201.80.

⁵⁷ *Wyeth*, 129 S. Ct. at 1198.

⁵⁸ *Levine v. Wyeth*, 944 A.2d at 189.

⁵⁹ *Wyeth*, 129 S. Ct. at 1198.

⁶⁰ *Id.*

⁶¹ *Id.* at 1199 n.5 (quoting government’s amicus brief).

⁶² *Id.* at 1199.

⁶³ *Id.*

⁶⁴ *Id.* at 1199 & n.7 (citing initial version of FDCA and hearing testimony).

⁶⁵ *Id.* at 1200 (citing 21 U.S.C. § 360k(a)). The Court also noted that, in 1997, Congress preempted certain state requirements with respect to over-the-counter drugs, but preserved state product liability claims. *See id.* at 1200 n.8 (citing 21 C.F.R. §§ 379r(e), 379s(d)).

⁶⁶ *Id.* at 1204.

a statute authorizing agency preemption — that is, simply a “conclusion that state law is pre-empted.”⁶⁷ In contrast with situations in which agencies explain how state law would affect substantive federal regulation, “agencies have no special authority to pronounce on preemption absent delegation by Congress.”⁶⁸

■ The agency’s position was “inherently suspect” because its original notice of proposed rulemaking expressly stated that the rule would not preempt state law or have “federalism implications,” and offered no notice to the states of the FDA’s “sweeping position” on preemption set forth in the preamble accompanying the final rule.⁶⁹

■ The preamble could not be squared with the FDA’s longstanding position that federal labeling rules set a regulatory “floor” that is complemented, not undermined, by state tort law.⁷⁰

■ The preamble conflicted with the reality of drug regulation. The FDA, Justice Stevens maintained, has “limited resources to monitor the 11,000 drugs on the markets”; manufacturers are more likely than the FDA to observe post-marketing risks as they emerge; and tort suits help “uncover unknown drug hazards and provide incentives for” manufacturers to disclose risks expeditiously.⁷¹

* * *

In concluding its opinion, the majority left open the possibility that some state-law tort claims might frustrate congressional objectives, while reiterating that Ms. Levine’s claim had not done so and affirming the judgment of the Vermont Supreme Court.⁷²

B. Justice Breyer’s Concurrence

Although joining fully in the majority opinion, Justice Breyer wrote, as he has before,⁷³ to state that because state tort law may interfere with FDA labeling regulation, the agency could, through “lawful specific regulations,” seek to oust state law by deciding when FDA regulation is “a ceiling as well as a floor.”⁷⁴ “It is pos-

⁶⁷ *Id.* at 1201 (emphasis in original).

⁶⁸ *Id.* For this reason, Justice Stevens distinguished the 2006 preamble from the situation in *Geier v. American Honda Motor Co.*, 529 U. S. 861 (2000), which held that a Department of Transportation regulation providing manufacturers various options for passive restraints in automobiles preempted a damages suit premised on the defendant’s failure to install one type of passive restraint (air bags). The Court in *Geier* gave weight to “the agency’s explanation of how state law interfered with its regulation,” as “further support” for the Court’s “independent conclusion that the plaintiff’s tort claim obstructed the federal regime.” *Wyeth*, 129 S. Ct. at 1203.

⁶⁹ *Id.* at 1201.

⁷⁰ *Id.* at 1201-02 & n.10 (relying on 63 Fed. Reg. 66378, 66384 (1998); 44 Fed. Reg. 37437 (1979); 59 Fed. Reg. 3948 (1994); Margaret Porter, “The *Lohr* Decision: FDA Perspective and Position,” 52 Food & Drug L. J. 7, 10 (1997)).

⁷¹ *Id.* at 1202 & nn.10-11 (citing governmental studies and views of former FDA Commissioners explaining inadequacy of FDA regulation and the agency’s inability to detect post-marketing risks).

⁷² *Id.* at 1204.

⁷³ *See, e.g., Lohr*, 518 U.S. at 505 (Breyer, J., concurring in part and concurring in the judgment).

⁷⁴ *Wyeth*, 129 S. Ct. at 1204 (Breyer, J., concurring).

sible,” Justice Breyer explained, that such a regulation could “have pre-emptive effect.”⁷⁵

C. Justice Thomas’s Concurrence in the Judgment

Justice Thomas concurred in the judgment in a lengthy opinion staking out bold new positions on implied preemption—both challenging the Court’s current view of “impossibility” or “direct conflict” preemption and calling for an end to “obstacle” or “frustration of purposes” preemption.⁷⁶ His opinion is likely to keep the law reviews buzzing for some time. Because Justice Thomas’s concurrence is unlikely to affect lower-court litigation in the near term, just a few comments are appropriate here.

Justice Thomas questioned whether “physical impossibility” is the appropriate standard for assessing whether federal and state law directly conflict, noting that “if federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior.”⁷⁷ But whether or not denominated “physical impossibility,” Justice Thomas rejected conflict preemption in *Ms. Levine’s* case for much the same reasons as had the majority: Wyeth’s ability under the CBE regulation to amend its label without FDA pre-approval,⁷⁸ and its obligation “to revise the federally approved label ‘to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.’”⁷⁹

Justice Thomas then rejected Wyeth’s claim of “impossibility” for another, more far-reaching reason: “To say, as the [FDCA] does, that Wyeth may not market a drug without federal approval (i.e., without an FDA-approved label) is not to say that federal approval gives Wyeth the unfettered right, for all time, to market its drug with the specific label that was federally approved.”⁸⁰ But the same point could be made with respect to any product that federal law allows on the market, either via a preapproval process or otherwise. After all, federal regulatory schemes always provide a manufacturer the choice whether to conform its conduct to the agency’s dictates or to remove its product from the market altogether. If Justice Thomas meant that conflict preemption does not apply whenever a manufacturer can remove its federally regulated product from the market, rather than subjecting itself to new federal regulatory obligations, it is difficult to see any room for conflict preemption regarding such a product.

Moreover, for three interrelated reasons, Justice Thomas expressed disapproval of any form of “obstacle” or “frustration of purposes” preemption. First, he maintained, it is at odds with various constitutional imperatives of federalism, including the Tenth Amendment, all of which underscore the States’ retention of “substan-

tial sovereign authority” and seek “to protect [a] delicate balance of power” between state and federal authority.⁸¹

Second, he said, it is an affront to two, interlocking constitutional commands: the Supremacy Clause, which makes “supreme” only those laws “‘made in Pursuance’ of the Constitution,”⁸² and the Bicameral and Presentment Clauses, which demand that the “‘passage of legislation’ follow ‘‘a step-by-step, deliberate and deliberative process.’”⁸³ According to Justice Thomas, “[t]he Supremacy Clause thus requires that pre-emptive effect be given only to those federal standards and policies that are set forth in, or necessarily follow from, the statutory text that was produced through the constitutionally required bicameral and presentment procedures.”⁸⁴

Third, “obstacle” or “frustration of purposes” preemption is “problematic because it encourages an overly expansive reading of statutory text,”⁸⁵ in a misguided and error-inducing search for a statute’s purposes.⁸⁶ In this regard, Justice Thomas chided the majority for relying on the fact that Congress had not enacted an express preemption clause for prescription drugs, noting that “the Court could just as easily rely on its own perceptions regarding congressional inaction to give unduly broad pre-emptive effect.”⁸⁷ Justice Thomas was particularly critical of the Court’s decision in *Geier*,⁸⁸ where, he explained, the Court’s search for meaning in “agency comments, regulatory history, and agency litigating positions was inherently flawed,” because it was contradicted by a statutory provision that expressly preserved common-law claims.⁸⁹

In sum, Justice Thomas would narrow the circumstances in which implied preemption operates by reformulating the concept of “impossibility” preemption and eliminating “obstacle” or “frustration of purposes” preemption, leaving most of the work of the Supremacy Clause to Congress, rather than the courts, by forcing Congress to speak clearly in the text of its enactments.

IV. Wyeth’s Future Effect

What effect will *Wyeth* have on future litigation and on preemption jurisprudence? It makes sense, first, to ask how the Court’s decision will affect tort cases involving name-brand and generic prescription drugs, and, then, to turn to its other implications.

A. Name-Brand Prescription Drugs

Wyeth will have its most immediate and important effect on state-law tort claims premised on a drug manufacturer’s alleged failure to warn of a risk associated

⁷⁵ *Id.*

⁷⁶ Justice Thomas briefly foreshadowed his *Wyeth* concurrence in 2005. See *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in the judgment in part and dissenting in part).

⁷⁷ *Wyeth*, 129 S. Ct. at 1209 (Thomas, J., concurring in the judgment) (citing Nelson, “Preemption,” 86 Va. L. Rev. 225, 260-61 (2000)).

⁷⁸ *Id.* at 1209-10.

⁷⁹ *Id.* at 1210 (quoting 21 C.F.R. § 201.80(e)).

⁸⁰ *Id.*

⁸¹ *Id.* at 1205-06.

⁸² *Id.* at 1206 (quoting U.S. Const. Art. VI, cl. 2)

⁸³ *Id.* at 1207 (quoting *INS v. Chadha*, 462 U.S. 919, 959 (1983)).

⁸⁴ *Id.*

⁸⁵ *Id.* at 1216.

⁸⁶ *Id.* at 1207-08, 1212.

⁸⁷ *Id.* at 1217.

⁸⁸ See *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000).

⁸⁹ *Wyeth*, 129 S. Ct. at 1214 (Thomas, J., concurring in the judgment); see also *id.* at 1214 n.6 (suggesting manipulability of preemption analysis that looks to statutory purpose); see *id.* at 1217 (“‘purposes’ doctrine ‘leads to decisions giving improperly broad pre-emptive effect to judicially manufactured policies’”).

with its name-brand prescription drug. Wyeth may not eliminate the preemption defense in all such cases, but, at the least, it will make that defense considerably more difficult to sustain.⁹⁰

The Supreme Court rejected “impossibility” preemption both because the CBE regulation permits a manufacturer unilaterally to update a label to provide safety information *and* because a manufacturer is under a continuing duty, under 21 C.F.R. § 201.80(e), to revise its label as soon as it learns of a safety-related problem associated with the drug. Moreover, the Court rejected preemption on the facts of Ms. Levine’s case because, even though the label warned of the serious risks of arterial exposure to Phenergan, “the FDA had not made an affirmative decision to preserve the IV-push method or intended to prohibit Wyeth from strengthening its warning about IV-push administration.”⁹¹

Taken together, these holdings place a significant burden on tort defendants in drug-injury cases. The Court itself explained that “[i]mpossibility preemption is a demanding defense,”⁹² which, in *Wyeth*, required “clear evidence” that the FDA would have prohibited a strengthened warning about IV-push administration.⁹³ In drug-injury cases where evidence of the relevant harm is not known to the public or the medical community until after the product has been marketed, the concern may not have been before the FDA at the time the label was approved.⁹⁴ After the FDA has approved a drug, if patients are encountering injuries associated with a risk not adequately disclosed on the label, it will be a rare case in which the manufacturer had earlier requested a label change that, if made, would have prevented the patient’s injury.

In *Wyeth*, the Court indicated that the agency’s *general* consideration of the relevant risk (in *Wyeth*, of gangrene from arterial exposure to Phenergan) or the *general* risks of the form of drug administration (in *Wyeth*, of intravenous versus intramuscular injection) are not sufficient to trigger preemption when the plaintiff complains of a more *specific* inadequacy in the label. Rather, to have preemptive effect, the agency’s focus must be specific. And it must also be intense. Thus, the Court noted with apparent approval that the FDA’s

“‘passing attention to the issue of IV-push versus IV-drip administration’⁹⁵ was not enough, in the Vermont trial court’s view, to warrant preemption. The Court went on to explain that Wyeth had failed to provide the FDA “with an evaluation or analysis concerning the *specific* dangers posed by the IV-push method,”⁹⁶ and never “attempted to give the *kind* of warning” that led to the jury’s decision to impose liability.⁹⁷ In sum, it appears that, after *Wyeth*, the defendant must demonstrate a tight fit between the labeling change proposed by the manufacturer (and rejected by the FDA) and the labeling change that the plaintiff contends would have prevented her injuries.

Even in the unusual case where the manufacturer can plausibly claim that it asked the FDA to amend the label to include a warning of the kind that the plaintiff alleges would have prevented her injuries, a drug company defendant may find it difficult to show that the FDA would not have approved a stronger warning. Agency officials are unlikely to cooperate in a search of its files to determine what it “would have done” (but did not do) with regard to label changes. If a manufacturer asks for a label change, and the agency does not issue a formal rejection, that likely means that the agency is still studying the question or is otherwise indifferent, not that there is, in *Wyeth*’s words, “clear evidence” that the agency has rejected the proposed change. As the Supreme Court has said repeatedly, agency *inaction* is generally insufficient to preempt state law because it cannot be understood to reflect the official position of the federal government.⁹⁸

For all of these reasons, after *Wyeth*, implied preemption of failure-to-warn claims involving injuries from prescription drugs is likely to be rare.⁹⁹

B. Generic Prescription Drugs

Phenergan is a name-brand prescription drug that entered the market after the FDA approved Wyeth’s NDA. The second main pathway to marketing approval is the Abbreviated New Drug Application (ANDA) established by the 1984 Hatch-Waxman Amendments to the FDCA,¹⁰⁰ which sought to speed generic drugs to market. Under Hatch-Waxman, after a name-brand drug loses patent protection, a manufacturer may file

⁹⁰ This section addresses *Wyeth*’s impact on drug-injury claims alleging a failure to warn, which is the principal type of claim in drug-injury litigation. It does not address *Wyeth*’s impact, if any, on claims not premised on a failure to warn, such as claims alleging design defect or breach of implied warranty. Post-*Wyeth*, one court has found preemption where the plaintiff claimed that no warning would have been adequate because the drug was unreasonably dangerous. See *Longs v. Wyeth*, 2009 WL 754524, *3-4 (N.D. Ohio Mar. 20, 2009); but see *Myers-Armstrong v. Actavis Totowa LLC*, 2009 WL 1082026, *5 (N.D. Cal. Apr. 22, 2009) (applying standard set forth in *Wyeth* and rejecting preemption of claim that FDA-approved drugs should not have been marketed in light of safety hazards).

⁹¹ *Wyeth*, 129 S. Ct. at 1199.

⁹² *Id.*

⁹³ *Id.* at 1198.

⁹⁴ See Lasser, et al., “Timing of New Black Box Warnings and Withdrawals for Prescription Medications,” 287 J.A.M.A. 2215, 2218 (May 1, 2002) (“Many serious ADRs [adverse drug reactions] are discovered only after a drug has been on the market for years. Only half of newly discovered serious adverse drug reactions are detected and documented in the *Physicians’ Desk Reference* [the doctors’ drug labeling bible] within 7 years after drug approval.”).

⁹⁵ *Wyeth*, 129 S. Ct. at 1193 (quoting trial court finding).

⁹⁶ *Id.* at 1198 (emphasis added).

⁹⁷ *Id.* (emphasis added).

⁹⁸ *Sprietsma v. Mercury Marine*, 537 U.S. 51, 67 (2002); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 286, 289-90 (1995); *Puerto Rico Dept. of Consumer Affairs v. ISLA Petroleum Corp.*, 485 U.S. 495, 503 (1988); cf. *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) (“The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute.”).

⁹⁹ The few post-*Wyeth* decisions issued to date suggest that defendants will face a heavy burden in establishing preemption in cases involving prescription drugs. See *Schrock v. Wyeth, Inc.*, ___ F. Supp.2d ___, 2009 WL 635415, *2-3 (W.D. Okla. Mar. 11, 2009); *Brockert v. Wyeth Pharmaceuticals Inc.*, ___ S.W. 3d ___, 2009 WL 997438 (Tex. App. Apr. 14, 2009); *McCarrell v. Hoffman La-Roche, Inc.*, ___ A.2d ___, 2009 WL 614484, *43 (N.J. Super. Ct. App. Div. Mar. 12, 2009) (noting that preemption is the “exception” and that defendant must establish that “it advocated . . . a stronger warning” and that “the FDA would not have approved [that] stronger warning”); see also *IMS Health Inc. v. Sorrell*, 2009 WL 1098474, *23 n.23 (D. Vt. Apr. 23, 2009).

¹⁰⁰ Pub. L. No. 98-417, 98 Stat. 1585 (1984).

an ANDA, seeking FDA approval to market a generic version of the name-brand drug.¹⁰¹ To simplify somewhat, a generic manufacturer need not submit independent evidence of the drug's safety and efficacy, but need only establish the generic product's "bioequivalence" to the name-brand drug.¹⁰²

In recent years, generic prescription drug manufacturers have argued that they are entitled to a special form of preemption, beyond any preemption that might be available to name-brand manufacturers, on the ground that they are locked-in to the label approved for the name-brand equivalent. In particular, they maintain that the CBE regulation does not apply to them, and they therefore lack authority to alter their labels without FDA pre-approval. On the other hand, plaintiffs have pointed to an FDA regulation that they claim expressly authorizes ANDA holders to employ the CBE regulation.¹⁰³ Prior to *Wyeth*, this issue had divided the courts.¹⁰⁴

This article is not the place to rehash those arguments, which, in light of *Wyeth*, may no longer be critical. Even assuming that the CBE regulation cannot be used by an ANDA holder to amend its label without FDA pre-approval, *Wyeth* may nevertheless apply with full force to cases involving generic drugs—that is, to the same extent that it applies to name-brand drugs. Recall that the CBE regulation was not the exclusive, or even the principal, basis for rejecting preemption in *Wyeth*.¹⁰⁵ Rather, Justice Stevens explained that *Wyeth*'s quest for preemption was based on a "more fundamental misunderstanding" of the regulatory regime: that the "FDA, rather than the manufacturer, bears primary responsibility for drug labeling."¹⁰⁶ To the contrary, "a central premise of federal drug regulation [is] that the manufacturer bears responsibility for the content of its label at all times."¹⁰⁷ As the primary authority for this attribute of federal drug regulation, the Court cited 21 C.F.R. § 201.80(e), which requires manufacturers to revise their labels "as soon as there is reasonable evidence of an association of a serious hazard with a drug." Section 201.80(e) applies to *all* manufacturers of prescription drugs, and the generic drug industry has not argued otherwise. Thus, after *Wyeth*, it would appear that the preemption defense is available to a generic drug manufacturer, if at all, only when it can show that it asked the FDA to authorize a label change of the kind that would have prevented the plaintiff's injury and that the FDA would not have permitted

that change—the same standard that *Wyeth* imposes on name-brand drug manufacturers.¹⁰⁸

C. Medical Devices

The Supreme Court held last year in *Riegel v. Medtronic Inc.*,¹⁰⁹ that most tort claims regarding class III medical devices that have gone through the FDA's pre-market approval process are preempted by the express preemption provision of the Medical Device Amendments to the FDCA.¹¹⁰ Earlier, the Court held in *Medtronic v. Lohr, Inc.*,¹¹¹ that tort claims involving medical devices that enter the market through less exacting forms of FDA scrutiny are not preempted.

Wyeth does not alter the legal terrain regarding preemption of tort claims involving medical devices. But *Wyeth* may be politically significant and hasten Congress's consideration and passage of the Medical Device Safety Act of 2009, which was introduced in both Houses of Congress on March 5,¹¹² and would overrule *Riegel* by rendering the Medical Device Amendment's express preemption provision inapplicable to state-law damages actions involving medical devices. Because the approval processes for drugs and medical devices are similar, and the purpose of FDA approval for both types of products—to enhance the safety and effectiveness of potentially dangerous but potentially life-saving products—are identical, Congress may view it as anomalous that injured drug patients, but not injured device patients, have access to the civil justice system. If, as Justice Stevens put it, "State tort suits uncover unknown drug hazards and provide incentive for drug manufacturers to disclose safety risks promptly," and "serve a distinct compensatory function that may motivate injured persons to come forward with information,"¹¹³ Congress may want such suits to serve the same functions with respect to medical devices. In sum, *Wyeth* may boost the chances for a congressional override of *Riegel*.

D. The Presumption Against Preemption

Wyeth emphatically reaffirmed the presumption against preemption, which tort defendants have been trying to eliminate for years. In particular, the Court rejected *Wyeth*'s argument that the presumption does not apply in light of the federal government's century-long involvement in drug labeling, explaining that the presumption depends on "the historic presence of state law," not "on the absence of federal regulation."¹¹⁴ In other words, longstanding federal domination and an absence of a significant state-law role, not simply long-

¹⁰¹ See 21 U.S.C. § 355(j).

¹⁰² See *id.* § 355(j)(8)(B) (defining bioequivalence); 21 C.F.R. § 320.1(e) (same).

¹⁰³ See 21 C.F.R. § 314.97.

¹⁰⁴ Compare, e.g., *Foster v. Am. Home Prod. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) ("[G]eneric manufacturers . . . [are] permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval.") (dicta); *Block v. Wyeth, Inc.* 2003 WL 203067, *1 (N.D. Tex. 2003) (rejecting preemption because "manufacturer of a generic drug may alter a drug's labeling" under 21 C.F.R. §§ 314.70(c), 314.97), with, e.g., *Mensing v. Wyeth, Inc.*, 562 F. Supp.2d 1056, 1061-65 (D. Minn. 2008) (finding preemption on ground that ANDA holder cannot make label change).

¹⁰⁵ See *supra* Part III.A.2.

¹⁰⁶ *Wyeth*, 129 S. Ct. at 1997.

¹⁰⁷ *Id.* at 1197-98.

¹⁰⁸ In the two post-*Wyeth* generic drug-injury cases decided to date, the Court rejected preemption under *Wyeth* and held that the CBE regulation applies to generic drug manufacturers as well as to name-brand drug manufacturers. See *Kellogg v. Wyeth*, 2009 WL 975382, *4 (D. Vt. Apr. 10, 2009) (on denial of certification for interlocutory appeal under 28 U.S.C. § 1292 (b)); *Stacel v. Teva Pharmaceuticals, USA*, 2009 WL 703274, *4-7 (N.D. Ill. Mar. 16, 2009); see also *Schrock*, 2009 WL 635415 (rejecting preemption in light of *Wyeth* in case involving generic and name-brand drugs, but not analyzing generic-drug issue separately).

¹⁰⁹ 128 S. Ct. 999 (2008).

¹¹⁰ See 21 U.S.C. § 360k(a).

¹¹¹ 518 U.S. 470 (1996).

¹¹² See S. 540, 111th Cong. (2009); H.R. 1346, 111th Cong. (2009).

¹¹³ *Wyeth*, 129 S. Ct. at 1202.

¹¹⁴ *Id.* at 1195 n.3.

standing federal presence, is required before the presumption will be set aside. Moreover, the Court rejected the view, expressed in Justice Alito's dissent,¹¹⁵ that the presumption does not apply in implied conflict preemption cases.¹¹⁶ And earlier this Term, the Court noted that the presumption applies to "questions of express or implied preemption."¹¹⁷ At this point, the legitimacy of the presumption against express and implied preemption in state-law tort cases appears settled.

E. Deference to Agency Pronouncements Regarding Preemption

Wyeth provided guidance on the circumstances in which a court should and should not defer to agency rules or other pronouncements on preemption. The Court made clear that it would not give full-fledged *Chevron* deference to an agency's "assertion" or "conclusion" that state law is preempted, at least absent an express delegation from Congress instructing the agency to issue rules or to otherwise make decisions regarding preemption.¹¹⁸ Thus, the Court contrasted agency pronouncements such as the FDA's 2006 regulatory preamble on preemption, which may be entitled to "some weight,"¹¹⁹ because they represent only an agency's unsolicited opinion on preemption, with a statute that authorizes the FDA to grant states exemptions from the Medical Device Amendment's express preemption provision, and, thus, requires the agency to define the borderline between state and federal law.¹²⁰

Wyeth's holdings regarding deference are likely to be influential. Their impact may be seen later this Supreme Court Term when the court decides *Cuomo v. The Clearinghouse Association, L.L.C.*, No. 08-453 (argued April 28, 2009). In *Cuomo*, the federal Office of the

Comptroller of the Currency (OCC) claims that the National Bank Act bars states from bringing enforcement actions against national banks under generally applicable state laws that themselves are not substantively preempted by the Act. The questions presented in *Cuomo* involve the validity of, and claimed deference to, an OCC regulation that, the petitioner maintains, does nothing more than assert that state enforcement authority is preempted.¹²¹ *Wyeth* may make defense of the OCC's regulation more difficult.

In addition, the issuance of the FDA's 2006 preamble was not an isolated event, but rather part of a larger effort by Bush Administration agencies, including the National Highway Traffic Safety Administration,¹²² the Consumer Product Safety Commission,¹²³ and the Federal Railroad Administration,¹²⁴ to insert language in regulatory preambles and regulations purporting to preempt state tort law. The level of deference, if any, to be accorded these agency pronouncements will depend on the thoroughness, consistency, formality, and persuasiveness of each effort, and the degree to which the agency was acting, if at all, pursuant to a congressional delegation.¹²⁵ In light of *Wyeth*, however, agency claims of preemption are likely to be subject to increased judicial scrutiny, and it is unlikely that such claims will be accorded substantial deference unless they are tethered to a congressional authorization regarding preemption.¹²⁶

¹²¹ See 12 C.F.R. § 7.40000. To view the questions presented in *Cuomo*, see <http://origin.www.supremecourtus.gov/qp/08-00453qp.pdf>.

¹²² See, e.g., 70 Fed. Reg. 49223, 42245-46 (2005) (preamble to proposed rule on vehicle roof crush standards).

¹²³ 70 Fed. Reg. 13472, 13496 (2006) (preamble to final rule on mattress flammability).

¹²⁴ See, e.g., 72 Fed. Reg. 42016, 42028 (2007) (preamble to proposed rule on front-end strength of cab cars and multiple-unit locomotives).

¹²⁵ See *Wyeth*, 129 S. Ct. at 1201.

¹²⁶ See *City of Joliet v. New West, L.P.*, ___ F.3d ___, 2009 WL 937250, *4 (7th Cir. Apr. 9, 2009) (rejecting preemption views of Department of Housing and Urban Development in light of *Wyeth*).

¹¹⁵ See *id.* at 1228-29 & n.14 (Alito, J., dissenting).

¹¹⁶ See *id.* at 1195 n.3 (citing *California v. ARC America Corp.*, 490 U. S. 93, 10-102 (1989); *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U. S. 707, 716 (1985)).

¹¹⁷ *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2009).

¹¹⁸ *Wyeth*, 129 S. Ct. at 1201.

¹¹⁹ *Id.* (quoting *Geier*, 529 U.S. at 883).

¹²⁰ See *id.* (referring to 21 U.S.C. § 360k(b)); see also *id.* at 1201 n.9 (referring to other statutes that authorize agencies to determine scope of preemption).