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PREEMPTION

PRODUCT LIABILITY

The U.S. Supreme Court ruling in *PLIVA Inc. v. Mensing* will immunize generic drug manufacturers facing failure-to-warn claims from state-law liability, and may also have implications for preemption jurisprudence more generally, says attorney Brian Wolfman and co-author Dena Feldman in this BNA Insight. The authors analyze the ruling, and offer their views on the questions that *PLIVA* raises about the ongoing vitality of the presumption against preemption, the standard for determining “impossibility” preemption, and the propriety of deference to an agency’s views on preemption.

***PLIVA v. Mensing* and Its Implications**

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On June 23, 2011, the Supreme Court ruled in *PLIVA, Inc. v. Mensing*¹ that FDA regulations governing the labeling of prescription drugs preempt state-law failure-to-warn claims against generic drug manufacturers. The Court’s ruling in *PLIVA* comes just two years after its decision in *Wyeth v. Levine*,² which held that the FDA’s approval of a brand-name prescription drug label generally does not preempt a state-law damages action premised on the manufacturer’s failure to warn of a hazard associated with the drug.

¹ 131 S. Ct. 2567 (2011).

² *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187 (2009).

This article describes the Court's decision and assesses its impact. Because it is difficult to understand *PLIVA* without appreciating its facts and the basics of generic drug regulation, those topics are addressed in Part I below. Part II describes the Supreme Court's decision, and Part III discusses its likely effects.

I. Background

A. The Facts

In March 2001, Gladys Mensing's doctor prescribed her the brand-name drug Reglan to treat diabetic gastroparesis, a paralysis that delays emptying of the stomach.³ In 2002, Julie Demahy's doctor prescribed Reglan to treat her gastroesophageal reflux disorder.⁴ Reglan promotes contractions of the esophagus, stomach, and intestines by blocking the body's dopamine receptors.⁵

Under their states' generic drug substitution laws, Mensing's and Demahy's pharmacists filled their Reglan prescriptions with generic metoclopramide, Reglan's active ingredient.⁶ All 50 states have adopted a form of these laws, which allow or require pharmacists to substitute a generic drug when presented with a prescription for a brand-name drug.⁷ Mensing and Demahy took generic metoclopramide, as prescribed, for four years, and both developed tardive dyskinesia.⁸ Tardive dyskinesia is a neurological disorder characterized by flagrant involuntary movements.⁹

Mensing and Demahy filed separate state-law damages suits alleging that "despite mounting evidence that long term metoclopramide carries a risk of tardive dyskinesia far greater than indicated on the label," the generic drug manufacturers had failed to modify their labels adequately to warn of the risk.¹⁰ The drug manufacturers argued in both cases that the plaintiffs' state-law tort claims were preempted by federal law.

B. Relevant FDA Regulation of Generic Drugs

1. The Hatch-Waxman Amendments and Initial Generic Drug Approval. In 1984, seeking to expand the availability of less expensive prescription drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act, popularly known as the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA). Hatch-Waxman streamlined the approval process for generic drugs. Ordinarily, a manufacturer of a new drug must go through an extensive approval process dictated by the federal Food and Drug Administration (FDA), often involving long and costly clinical trials to assure that the drug is safe and effective for its intended use.¹¹ Hatch-Waxman, on the other hand, allows generic drugs to bypass the clinical trial process required for new drugs. Under Hatch-Waxman,

once the patent for a brand-name drug expires, manufacturers may apply to market a generic version of the drug and piggyback off the brand-name drug's demonstrations of safety and effectiveness.¹²

Instead of the lengthy approval process required for new drugs, under Hatch-Waxman, generic drug manufacturers seek approval under the abbreviated new drug application (ANDA) process.¹³ In an ANDA, manufacturers must show that the generic drug is "bio-equivalent" to the brand-name drug — that is, the same in terms of active ingredients, safety, and efficacy.¹⁴ As part of the ANDA process, the FDA approves the generic drug's label, which must be "the same as the labeling approved for the [brand-name] drug[.]"¹⁵ According to the Solicitor General's amicus brief in *PLIVA*, the FDA places "a very high priority [on] assuring consistency in labeling" between the brand-name drug and its generic equivalent "to minimize any cause for confusion among health care professionals and consumers as well as to preclude a basis for lack of confidence in the equivalency of generic versus brand name products."¹⁶

Taken together, Hatch-Waxman and state generic drug substitution laws "have proved wildly successful" in bringing generic drugs to the market.¹⁷ Since Hatch-Waxman's enactment, the market share for generic prescription drugs has gone from roughly 19 percent to 75 percent,¹⁸ and, when a drug has a generic equivalent, about 90 percent of that drug's prescriptions are filled with the generic.¹⁹ In an amicus brief in *PLIVA*, a group of experts in the fields of pharmaceutical regulation and health care conducted a market analysis showing that "out of 4,653 approved drugs with distinct ingredients, delivery routes, and strengths, more than half — 2,438 — are available in generic form. Of those, 1,062 are available solely in generic form[.]"²⁰

2. Post-Approval Requirements. After granting approval for the manufacture and sale of a generic drug, the FDA continues to regulate the drug's label. Recognizing that with the passage of time, more information on adverse side effects and risks associated with a drug will eventually come to light, the FDA requires that drug manufacturers keep track of adverse clinical experiences and submit annual reports to the FDA documenting "significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product" and a "description of actions the applicant has taken or intends to take as a re-

¹² See generally *id.* § 355(j).

¹³ *Id.*

¹⁴ See *id.* § 355(j)(2)(A)(ii)-(iv).

¹⁵ *Id.* § 355(j)(2)(A)(v).

¹⁶ Brief for the United States as Amicus Curiae Supporting Respondents at 4, in *PLIVA, Inc. v. Mensing*, No. 09-993 (filed Mar. 2, 2011) (hereafter "SG Brief") (citing Division of Generic Drugs, Food & Drug Administration, *Policy and Procedure Guide* 37 (1989)), available at 2011 WL 741927, *4.

¹⁷ *PLIVA*, 131 S. Ct. at 2584 (Sotomayor, J., dissenting).

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ Brief for Mark T. Law, et al., at 18 (emphasis in original), in *PLIVA, Inc. v. Mensing*, No. 09-993 (filed Mar. 2, 2011) (hereafter "Experts Brief"), available at 2011 WL 794111, *18; see also *PLIVA*, 131 S. Ct. at 2584 (Sotomayor, J., dissenting) (citing same and similar data showing that "from one-third to one-half of generic drugs no longer have a marketed brand-name equivalent").

³ Brief for Respondents at 4, in *PLIVA, Inc. v. Mensing*, No. 09-993 (filed Feb. 23, 2011) (hereafter "Brief for Respondents"), available at 2011 WL 686400, *4.

⁴ *Id.*

⁵ *Id.* at *6.

⁶ *Id.* at *4-*5.

⁷ *PLIVA*, 131 S. Ct. at 2583.

⁸ Brief for Respondents, 2011 WL 686400, *4-*5.

⁹ *PLIVA*, 131 S. Ct. at 2572-73.

¹⁰ See, e.g., *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009).

¹¹ See generally 21 U.S.C. § 355(b)-(d).

sult of this new information.”²¹ The FDA requires that manufacturers revise their warning labels “as soon as there is reasonable evidence of an association of a serious hazard with a drug.”²² These requirements apply equally to manufacturers of generic and brand-name drugs.²³

Ordinarily, when a manufacturer seeks to change its label it files a supplemental application under the Prior Approval Supplement procedure, which requires the FDA’s approval *prior* to revision of the label.²⁴ However, a manufacturer seeking to “add or strengthen a contraindication, warning, precaution, or adverse reaction” may use the Changes Being Effected, or CBE, process.²⁵ Although the FDA must ultimately approve the change, the manufacturer need not wait for approval before revising the label under the CBE process.²⁶ FDA regulations also allow drug manufacturers to notify health providers of risks greater than those that appear on the product’s label through notices called “Dear Health Care Professional” (DHCP) letters.²⁷

As we shall see, the FDA believes that only brand-name manufacturers, and not generic drug manufacturers, may use the CBE process or unilaterally employ a DHCP letter to warn of new risks, and the Court in *PLIVA* agreed.

C. History of Reglan/Metoclopramide

The following regulatory history of Reglan is taken largely from the plaintiffs’ brief in *PLIVA*. The FDA first approved Reglan in 1980 to treat acute and recurrent diabetic gastric stress.²⁸ Reglan was initially approved for treatment periods of 2 to 8 weeks. In 1984, the agency added an indication for “short-term (4 to 12 weeks) therapy” to treat reflux.²⁹ In 1985, the FDA first approved the manufacture and sale of generic metoclopramide.³⁰

As noted above, metoclopramide enhances contractions in the gastrointestinal system.³¹ It works by blocking dopamine receptors, which affect the transfer of signals between nerves,³² including in the extrapyramidal system, the part of the brain that controls fine motor skills.³³ Tardive dyskinesia is a severe form of interference with the extrapyramidal system marked by “grotesque involuntary movements of the mouth, tongue, lips, and extremities, involuntary chewing movements, and a general sense of agitation.”³⁴

Metoclopramide’s label first warned of the risks of tardive dyskinesia in 1985. The “Warnings” section of the label identified tardive dyskinesia as a possible side

effect that would appear “far less frequently than the far more readily treatable” problems with the extrapyramidal system controlling fine motor movements.³⁵ Specifically, the label indicated that tardive dyskinesia would occur in far fewer patients than the 1 in 500 patients who experience some type of problem with the extrapyramidal system as a result of using metoclopramide.³⁶

However, “prior to mid-2003, at least 87 cases of tardive dyskinesia associated with metoclopramide had been reported to FDA’s Adverse Event Reporting System (AERS), most involving long-term use of the product.”³⁷ No metoclopramide manufacturer proposed to the FDA a label change to reflect this greater risk.³⁸

The warning on the metoclopramide label remained the same until 2009, after the injuries suffered by Mensing and Demahy.³⁹ In 2009, the FDA, acting on its own, ordered metoclopramide manufacturers to include a “boxed warning,” the strongest warning possible, about the increased risk of tardive dyskinesia associated with long-term use of the drug.⁴⁰ The boxed warning stated:

Chronic treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible Prolonged treatment (greater than 12 weeks) with metoclopramide should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risks to the patient of developing tardive dyskinesia.⁴¹

The boxed warning noted that a published study had found that tardive dyskinesia occurred in 20 percent of patients treated with metoclopramide for at least three months, “a hundred times greater than the 0.2 percent risk previously identified on the label.”⁴²

D. Lower Court Proceedings

In 2007, Mensing and Demahy sued *PLIVA, Inc.* and *Actavis, Inc.*, respectively, manufacturers of the generic version of metoclopramide that they had taken. They alleged that the labels accompanying metoclopramide failed adequately to warn about the risks of tardive dyskinesia associated with long-term use of the drug. In Mensing’s case, the federal district court in Minnesota granted the drug manufacturer’s motion to dismiss, holding that the Hatch-Waxman Amendments to the FDCA preempt state-law failure-to-warn claims.⁴³ The Eighth Circuit reversed, citing the Supreme Court’s then-recent decision in *Wyeth v. Levine*, which, as noted, held that state-law failure-to-warn claims against brand-name drug manufacturers generally are not preempted by the FDCA.⁴⁴ In Demahy’s case, a federal district court in Louisiana denied a similar motion to dismiss filed by the generic manufacturer.⁴⁵ The Fifth Circuit affirmed, holding that Demahy’s state-law claims

²¹ 21 C.F.R. 314.81(b)(2)(i).

²² *Id.* § 201.57(e) (2001).

²³ See SG Brief, 2011 WL 741927, at *7 (citing 21 C.F.R. § 314.97).

²⁴ 21 C.F.R. § 314.70(b).

²⁵ *Id.* § 314.70(c)(6)(iii)(A).

²⁶ 21 CFR § 314.70(c)(7); see also *Wyeth*, 555 U.S. at ___, 129 S. Ct. at 1196-98.

²⁷ SG Brief, 2011 WL 741927, at *7 (citing 21 C.F.R. § 200.5).

²⁸ Brief for Respondents, 2011 WL 686400, *6.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.* (quoting *McNeil v. Wyeth*, 462 F.3d 364, 366 (5th Cir. 2006)).

³⁵ *Id.* at *6.

³⁶ *Id.* at *8 n.10.

³⁷ *Id.* at *9.

³⁸ *Id.* at *10.

³⁹ *Id.* at *9.

⁴⁰ *Id.*

⁴¹ *Id.* at *10-*11; see also *PLIVA*, 131 S. Ct. at 2573 (quoting boxed warning).

⁴² Brief for Respondents, 2011 WL 686400, *11.

⁴³ See *Mensing v. Wyeth*, 588 F.3d 603, 605 (8th Cir. 2009).

⁴⁴ See *id.* at 607-08 (discussing *Wyeth*, 555 U.S. 555).

⁴⁵ *Demahy v. Wyeth*, 586 F. Supp. 2d 642 (E.D. La. 2008).

were not preempted, also based largely on *Wyeth*.⁴⁶ The Supreme Court granted both generic manufacturers' petitions for certiorari and consolidated the cases for review.

II. The Supreme Court's Decision

As noted above, the Supreme Court ruled 5-4 in favor of the generic drug companies, holding that the FDCA and regulations governing generic drugs preempted Mensing's and Demehy's state-law failure-to-warn claims. Justice Thomas wrote the majority opinion, joined in full by Chief Justice Roberts, and Justices Scalia and Alito. Justice Kennedy joined the majority opinion in all but one part. Justice Sotomayor dissented, joined by Justices Ginsburg, Breyer, and Kagan.

A. Justice Thomas's Majority Opinion

1. Framing the Issues. Justice Thomas began the majority opinion by noting the parties' agreement that, under state law in both Louisiana and Minnesota, the plaintiffs' allegations, if true, would have required the generic drug manufacturers to use a metoclopramide label with warnings about the risk of tardive dyskinesia that were different from warnings on the FDA-approved label.⁴⁷ Thus, the issue presented was whether the duties imposed on generic drug manufacturers by federal regulations conflicted with, and therefore preempted, the state-law duties that would have required a different drug label.

The majority decision that the federal requirements for generic drug labeling preempt state-law failure-to-warn claims was built on two pillars. First, the Court deferred to the FDA's interpretations of regulations regarding prescription drug labeling. Second, the Court announced a standard for determining when compliance with both state and federal law is impossible, thus triggering implied conflict preemption. We deal with each aspect of the decision in turn.

2. Deference to the FDA. The plaintiffs, on the one hand, and the generic drug manufacturers and the FDA, on the other, presented different views of the actions that generic manufacturers may take under federal drug labeling regulations. Not surprisingly, the Supreme Court deferred to the FDA. Mensing and Demahy maintained that the generic drug companies could have, and should have, used the "changes being effected," or CBE, process unilaterally to modify their labels to warn of the true risks of metoclopramide.⁴⁸ They argued that the CBE process is one way that generic drug manufacturers "bring evidence of the need for a new warning to FDA's attention and initiate consideration of whether the labels for both the [brand-name] and generic drugs should be changed."⁴⁹ If the FDA ultimately approves the changes made by a generic manufacturer under the CBE process, the agency will then require that the same change take place on the brand-name label. Thus, the plaintiffs argued, a temporary departure in identical labeling between the generic and brand manufacturer "reflects FDA's determination

that such temporary differences are justified in the interest of drug safety."⁵⁰ They maintained that the generic drug companies also could have sent a DHCP letter to health professionals warning of the adverse risks associated with metoclopramide.⁵¹ They argued, as they had argued with respect to the CBE process, that all drug companies may send a DHCP letter without prior FDA approval.⁵²

But the Solicitor General's amicus brief explained that, in the FDA's view, federal regulations do not afford generic manufacturers the option unilaterally to alter their labels because of the overriding statutory and regulatory requirement that generic drugs labels mirror the labels of their brand-name counterparts. Thus, the FDA maintained, the federal labeling scheme precluded generic manufacturers from unilaterally changing their labels, even under the CBE process.⁵³ The unilateral use of a DHCP, the Solicitor General maintained, is likewise unavailable to generic drug manufacturers (at least under the circumstances presented in *PLIVA*).⁵⁴ Although the FDA conceded that no regulation precludes generic drug manufacturers from sending these letters, it argued that such a letter "would only be appropriate in tandem with a corresponding change to the [brand-name] drug's approved labeling."⁵⁵ And, because a generic manufacturer could not take advantage of the CBE process, the appearance of new risk information in a DHCP letter would be "contrary to [FDA] approved" labeling.⁵⁶

The Supreme Court deferred to the FDA's reading of the regulations regarding the CBE and DHCP processes, holding that the agency's views are "controlling unless plainly erroneous or inconsistent with the regulation[s]."⁵⁷ Unusually, the majority opinion did not even address the interpretations of the regulations offered by the parties. Rather, in a consummate application of administrative deference, it just noted that in the absence of any reason to doubt the agency's views, those views would control.⁵⁸ Thus, the Court accepted the FDA's argument that generic manufacturers cannot unilaterally change their labels under the CBE process or unilaterally issue DHCP letters.

Despite its position that generic manufacturers could not act unilaterally via the CBE process or through a DHCP letter, the FDA told the Supreme Court that the FDCA does not preempt state-law failure-to-warn claims against generic manufacturers.⁵⁹ The FDA claimed that generic drug manufacturers had various opportunities to inform the agency about adverse reactions and risks caused by their products and seek permission to revise their labels.⁶⁰ In this regard, the FDA pointed to the preamble to the final rule implementing the ANDA process:

If an ANDA applicant believes new safety information should be added to a product's labeling, it should

⁵⁰ *Id.* at *35.

⁵¹ *Id.* at *36.

⁵² *Id.* at *37.

⁵³ SG Brief, 2011 WL 741927, *19.

⁵⁴ *Id.* at *18 (citing 21 CFR § 200.5).

⁵⁵ *Id.* at *18.

⁵⁶ *Id.* at *19 (citing 21 CFR § 21.201.100(d)(1)).

⁵⁷ *PLIVA*, 131 S. Ct. at 2575 (quoting *Auer v. Robbins*, 519 U.S. 457, 461 (1997)).

⁵⁸ *Id.*; accord *id.* at 2585 (Sotomayor, J., dissenting).

⁵⁹ SG Brief, 2011 WL 741927, *22-35.

⁶⁰ *Id.* at *14, *20.

⁴⁶ *Demahy v. Actavis*, 593 F.3d 428 (5th Cir. 2010).

⁴⁷ *PLIVA*, 131 S. Ct. at 2574.

⁴⁸ Brief for Respondents, 2011 WL 686400, *34.

⁴⁹ *Id.*

contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised.⁶¹

The FDA noted as well that its Office of Generic Drugs is available to ANDA holders to resolve concerns with their products and will give high priority to “ANDAs with possible serious safety concerns.”⁶² After notification from an ANDA holder of possible adverse health risks caused by an approved drug, the Solicitor General told the Court, the FDA can evaluate the risk, and, if necessary, request that the brand-name manufacturer change its label or withdraw the drug’s approval.⁶³ Because generic drug manufacturers are not powerless to set in place a process that could lead to safety-enhancing label changes or product removal, both of which could be consistent with state-law duties, FDA maintained, state-law failure-to-warn claims are not preempted.

Although the Supreme Court deferred to FDA’s interpretation of its CBE and DHCP regulations, the Court relegated to a footnote another, arguably inconsistent holding: that it would not defer at all to the agency’s “ultimate conclusion about whether state law should be preempted.”⁶⁴ And, as explained in the next section of this Article, with the Court now free to consider the preemption question *de novo*, the Court rejected the FDA’s no-preemption position.

3. Impossibility Preemption. The Supreme Court based its holding that the plaintiffs’ failure-to-warn claims were preempted on a finding that “it was impossible for the [generic] Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.”⁶⁵ As indicated earlier, the plaintiffs and the FDA argued that, to claim preemption by impossibility, the generic manufacturers were required to show that they went to the FDA with a label change that could have prevented the plaintiffs’ injuries and that the FDA would have denied any requested label change. Thus, according to the plaintiffs and the FDA, only after the manufacturers had asked the FDA for a stronger warning after learning about the link between their product and tardive dyskinesia, and the FDA had rejected a label change to provide that warning, could the manufacturers claim that compliance with a state-law failure-to-warn duty is truly impossible. In *PLIVA*, the generic metoclopramide manufacturers had failed even to ask the FDA to strengthen the label, a course of action that the manufacturers conceded was open to them. Thus, the plaintiffs argued, their claims were not preempted.⁶⁶

⁶¹ *Id.* at *20 (citing 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992)).

⁶² *Id.* at *21 (quoting Center for Drug Evaluation & Research, Manual of Policies & Procedures 5200.6 (May 9, 2001)).

⁶³ *Id.* at *21–*22 (citing 21 U.S.C. § 355(e); 21 C.F.R. §§ 314.70, 314.150(a)(2)).

⁶⁴ *PLIVA*, 131 S. Ct. at 2575 n.3 (citing *Wyeth*, 555 U.S. at 576). We discuss the significance of this no-deference holding in Part III.B.3 below.

⁶⁵ *PLIVA*, 131 S. Ct. at 2578.

⁶⁶ *Id.*

The Supreme Court majority disagreed, reasoning that had the manufacturers undertaken the courses of action advocated by the plaintiffs and the FDA, and asked for a label change, they still would not have satisfied the state-law duty on which the plaintiffs relied: “State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label.”⁶⁷ If the generic manufacturers had alerted the FDA to the increased risk, rather than satisfying their state-law tort law duties, the Court wrote, they would have done no more than “started a Mouse Trap game that eventually [could have led] to a better label on generic metoclopramide.”⁶⁸

But, in the Court’s view, the Mouse Trap game was not enough to avoid preemption. Instead, the Court devised a new test for escaping preemption by impossibility: “whether the private party could *independently* do under federal law what state law requires of it.”⁶⁹ By contrast, the Court characterized the plaintiffs’ and the FDA’s position as relying on “conjectures” about what *might* have transpired had the manufacturers sought a label change.⁷⁰ Allowing hypothetical scenarios — such as the defendant’s non-existent request for a label change and the FDA’s non-existent response — to drive preemption analysis, Justice Thomas proclaimed, “would render conflict pre-emption largely meaningless because it would make most conflicts between state and federal law illusory.”⁷¹

The Court emphasized that the generic manufacturers could not satisfy the state-law duty for a safer label until they secured FDA approval for that label. The requirement of federal government cooperation in satisfying state-law tort duties, particularly when dependent on the exercise of judgment by a federal agency, necessarily meant that the regulated party — here, the generic manufacturer — could not “*independently*” comply with both state and federal law.⁷² Put another way, because “ask[ing] the FDA for help” in changing the label, and not changing the label on their own, was the only action the manufacturers could “*independently*” take, the Court concluded that the plaintiffs’ failure-to-warn claims were preempted.⁷³

B. Justice Thomas’s Plurality Opinion

Part III.B.2 of Justice Thomas’s opinion was a plurality opinion joined by Justices Roberts, Scalia, and Alito, but not by Justice Kennedy, who joined fully in the rest of the opinion and provided one of the five votes for the judgment in the generic manufacturers’ favor. The plurality set out a novel, originalist view of preemption based on a law review article by University of Virginia law professor Caleb Nelson. Justice Thomas focused on the text of the Supremacy Clause, particularly the phrase “any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”⁷⁴ This phrase, Justice Thomas explained, is a “*non obstante* provi-

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.* at 2579 (emphasis added) (citing *Wyeth*, 555 U.S. at 573).

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

sion,” that is, a phrase in a new statute that “repeal[s] older, potentially conflicting statutes in the same field.”⁷⁵ These provisions were often used in the 1770s and 1780s, Justice Thomas maintained, as an instruction to courts “not to apply the general presumption against implied repeals.”⁷⁶ Thus, according to Justice Thomas, the presence of such a phrase in the Supremacy Clause suggested that the Constitution’s drafters intended that “federal law should be understood to impliedly repeal conflicting state law.”⁷⁷ For this reason, when engaged in conflict-preemption analysis, “courts should not strain to find ways to reconcile federal law with seemingly conflicting state law.”⁷⁸

Justice Thomas sought support for this new theory in his concurring opinion in *Wyeth v. Levine*, explaining that under the Supremacy Clause’s *non obstante* language, courts should not “distort federal law to accommodate conflicting state law,” and instead should look to a statute’s “ordinary meaning.”⁷⁹ For Justice Thomas, the ordinary meaning of the federal regulations governing generic drug labels and state tort law evidenced conflicting duties. And, allowing “contingencies,” such as FDA approval of a hypothetical request for a label change, to determine the meaning of federal law would go beyond its “ordinary meaning,”⁸⁰ and runs headlong into the Supremacy Clause’s textual demand that conflicting state law is impliedly repealed.⁸¹

C. Justice Sotomayor’s Dissent

Justice Sotomayor dissented, joined by Justices Ginsburg, Breyer, and Kagan. The dissent accused the majority of rewriting the Court’s recent decision in *Wyeth*, ignoring longstanding precedents regarding “impossibility” preemption, and undermining the presumption against preemption.

1. Impossibility. Justice Sotomayor characterized the majority’s impossibility analysis as having “no basis in [the Court’s] precedents.”⁸² A company’s ability to “independently” change its label cannot be the test for impossibility; after all, she wrote, even when brand-name manufacturers change their labels through the CBE process, these changes are not truly independent, but rather, ultimately subject to FDA approval.⁸³ In *Wyeth*, the Court held that, to establish preemption, the brand-name drug manufacturer was required to produce “‘clear evidence that the FDA would not have approved a change to [the] label.’”⁸⁴ So, Justice Sotomayor explained, the same test should apply to a generic manufacturer, whose claim of impossibility preemption also ought to depend on FDA rejection of a requested label change.⁸⁵ Only then, the dissent argued, would manu-

facturers be able to show that compliance with both federal and state law was genuinely impossible.⁸⁶

In response to the majority’s position that any narrower impossibility doctrine would render conflict preemption meaningless, the dissent noted that conflict preemption also exists “where the state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”⁸⁷ Thus, the majority’s broad definition of impossibility was, Justice Sotomayor maintained, “unnecessary to prevent conflict pre-emption from losing all meaning.”⁸⁸

2. Response to Justice Thomas’s Plurality Opinion and Concerns About the Presumption Against Preemption.

Justice Sotomayor disputed Justice Thomas’s view that the *non obstante* language of the Supremacy Clause directs courts to find that federal law impliedly repeals conflicting state law. She argued that the plurality had “invent[ed] new principles of preemption law out of thin air” in “a direct assault” on more than half a century of Supreme Court precedents in which the Court has cautioned against presuming that federal law supersedes state law.⁸⁹ She explained:

“Whereas we have long presumed that federal law does not pre-empt, or repeal, state law, the plurality today reads the Supremacy Clause to operate as a provision instructing courts ‘not to apply the general presumption against implied repeals.’ And whereas we have long required evidence of a ‘clear and manifest’ purpose to preempt, the plurality now instructs courts to ‘look no further than the ordinary meaning of federal law’ before concluding that Congress must have intended to cast aside state law.”⁹⁰

According to Justice Sotomayor, if the Court had applied the presumption against preemption in *PLIVA*, and thus accepted the plausible reading of federal law offered by the plaintiffs and the FDA, it would have come to a different result and required the generic manufacturers to “attempt to comply with state law before being heard that compliance is impossible.”⁹¹

In addition to noting the departure from precedent establishing that courts should hesitate to find state law preempted, the dissent referred repeatedly to the decision’s “absurd” consequences.⁹² Under the majority’s reasoning, she explained, whether an injured consumer may bring a failure-to-warn claim against a drug manufacturer will depend on “the happenstance” of whether the consumer’s pharmacist dispensed the brand-name or generic version of the drug.⁹³

The dissent argued that this result is at odds with Hatch-Waxman’s purpose of increasing the availability and use of lower priced, generic prescription drugs.⁹⁴ The elimination of tort liability for generic drugs could,

⁷⁵ *Id.*

⁷⁶ *Id.* (quoting Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 241-42 (2000)).

⁷⁷ *Id.* at 2580.

⁷⁸ *Id.*

⁷⁹ *Id.* (citing *Wyeth*, 555 U.S. at 588 (Thomas, J., concurring in the judgment)).

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.* at 2589 (Sotomayor, J., dissenting).

⁸³ *Id.*

⁸⁴ *Id.* at 2588 (quoting *Wyeth*, 555 U.S. at 571).

⁸⁵ *Id.*

⁸⁶ *Id.* at 2588-89.

⁸⁷ *Id.* at 2590 (quoting *Crosby v. National Foreign Trade Council*, 530 U.S. 360, 373 (2000)).

⁸⁸ *Id.*

⁸⁹ *Id.* at 2591.

⁹⁰ *Id.* (internal citations omitted) (emphasis in original); see also, e.g., *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (when faced with two plausible interpretations of a statute, the Court has “a duty to accept the reading that disfavors preemption.”).

⁹¹ *PLIVA*, 131 S. Ct. at 2592.

⁹² *Id.* at 2593.

⁹³ *Id.* at 2592.

⁹⁴ *Id.* at 2593.

Justice Sotomayor posited, reduce consumer demand for generic drugs and pose an “ethical dilemma” for prescribing physicians,⁹⁵ who, on the one hand, want to reduce costs for their patients by prescribing generic drugs, but, on the other hand, do not want to immunize the manufacturer from liability every time they do so.⁹⁶

The dissent found this result striking in the absence of any evidence that Congress considered immunizing generic manufacturers from tort liability,⁹⁷ which, in the past, the Court has required before “depriv[ing] injured parties of a long available form of compensation.”⁹⁸

III. *PLIVA*’s Future Effect

PLIVA will immunize generic drug manufacturers facing failure-to-warn claims from state-law liability. It may also have implications for preemption jurisprudence more generally. We address these issues in turn.

A. Failure-to-Warn Claims Against Generic Drug Manufacturers

The obvious effect of *PLIVA* is to eliminate failure-to-warn claims against the manufacturers of generic drugs. Consumers harmed by a mislabeled generic drug will be unable to hold the manufacturers liable under state law. This holding is significant because, as explained earlier, about 75 percent of all drug prescriptions are for generic drugs,⁹⁹ and every state has a substitution law that permits or requires pharmacists who receive a prescription for a brand-name drug to fill it with that drug’s generic equivalent.¹⁰⁰ As occurred with the plaintiffs in *PLIVA*, generic substitution typically occurs without the consumer’s consent or knowledge.

Even in states where pharmacists are only permitted (not required) to substitute generic for brand-name drugs, because insurance companies often charge higher co-pays for a brand-name drug when a generic is available,¹⁰¹ consumers tend to opt for generics. As noted earlier, about 90 percent of prescriptions for drugs available in both brand-name and generic forms are filled with generics.¹⁰² Thus, the Court’s holding

eliminating state-law remedies for failure-to-warn claims will have significant consequences.

It remains to be seen whether the incongruous liability rules established by *Wyeth* and *PLIVA* will hold. The majority and dissent in *PLIVA* agreed on one thing: Leaving the states free to impose liability for failure to warn on a brand-name label while immunizing the makers of generic drugs “makes little sense[.]”¹⁰³ Indeed, the *PLIVA* majority “acknowledge[d] the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated.”¹⁰⁴ Thus, the Court’s unanimity on the ruling’s unfortunate policy implications may prompt an effort to rationalize the drug-labeling and/or liability rules governing brand-name and generic drugs.

Until the ruling in *PLIVA*, state-law damages remedies had been “long available” against both brand-name and generic manufacturers,¹⁰⁵ and in light of the Court’s ruling in *Wyeth v. Levine* that failure-to-warn claims against brand-name manufacturers generally are not preempted, it is exceedingly unlikely that Congress will harmonize the liability regime by immunizing the manufacturers of brand-name drugs. Rather, harmonization will occur, if at all, by overruling the result in *PLIVA*, either by regulation or legislation.

1. Potential Regulatory Action. Because the ruling in *PLIVA* turned on the asserted impossibility of a manufacturer’s simultaneous compliance with both federal labeling rules for generic drugs and a state-law duty to make safety-based revisions to a generic drug label, the FDA could amend its labeling rules to eliminate the impossibility identified by the Supreme Court majority. Recall that, in *Wyeth*, the Court had rejected preemption by impossibility because, among other reasons, the FDA’s CBE regulation authorized brand-name drug manufacturers unilaterally to amend their labels to add warnings, rendering a state-law claim premised on a duty to have issued such warnings consistent with, not in conflict with, federal law.¹⁰⁶

PLIVA came to the opposite conclusion because, the Court held, FDA regulations did *not* authorize unilateral changes to generic drug labels.¹⁰⁷ Presumably, then, if the FDA were to amend its rules to authorize generic drug manufacturers to use the CBE regulation in some or all of the circumstances under which brand-name manufacturers currently have that authority, the federal regulatory basis for *PLIVA*’s impossibility holding would no longer exist. This amendment would eliminate the absurd consequences of having inconsistent state-law tort duties for brand-name and generic drug manufacturers highlighted in Justice Sotomayor’s *PLIVA* dissent.

It bears emphasis, however, that whatever the benefits of state-law tort liability in enhancing patient safety and providing compensation for injuries, and the Court in *Wyeth* thought them considerable,¹⁰⁸ the FDA’s principal consideration here should be to rationalize and modernize its generic drug labeling rules.

⁹⁵ *Id.* (citing Brief for American Medical Association et al. as *Amici Curiae* Supporting Respondents at 29).

⁹⁶ Justice Sotomayor’s concern that doctors might prescribe brand-name drugs to protect their patients’ state-law rights is not rendered irrelevant by state generic substitution laws. A doctor generally can override even the purportedly mandatory versions of those laws by prescribing the brand-name product and writing “dispense as written,” or “DAW,” on her prescription pad. See Ranit Mishori, “Some doctors insist on brand-name drugs even when cheaper generics are available,” *The Washington Post*, July 11, 2011, available at http://www.washingtonpost.com/national/some-doctors-insist-on-brand-name-drugs-even-when-cheaper-generics-are-available/2011/06/13/gIQAmlCOL9H_story.html.

⁹⁷ *PLIVA*, 131 S. Ct. at 2593.

⁹⁸ *Bates*, 554 U.S. at 449.

⁹⁹ *PLIVA*, 131 S. Ct. at 2884 (Sotomayor, J., dissenting).

¹⁰⁰ *But see supra* note 96.

¹⁰¹ Experts Brief, 2011 WL 794111, *20 (citing Geoffrey F. Joyce et al., “Employer Drug Benefit Plans and Spending on Prescription Drugs,” 288 J. Am. Med. Ass’n 1733, 1733-34 (2002); Haiden A. Huskamp et al., “The Effect of Incentive-based Formularies on Prescription-Drug Utilization and Spending,” 349 *New Eng. J. Med.* 2224, 2225 (2003)); *see also PLIVA*, 131 S. Ct. at 2584 n.2 (Sotomayor, J., dissenting).

¹⁰² *Id.* at 2584.

¹⁰³ *Id.* at 2581 (majority opinion).

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* at 2592 (Sotomayor, J., dissenting); *see also Wyeth*, 555 U.S. at ___, 129 S. Ct. at 1199-1200.

¹⁰⁶ *Wyeth*, 555 U.S. at ___, 129 S. Ct. at 1196-97; *accord id.* at 1209-10 (Thomas, J., concurring in the result).

¹⁰⁷ *PLIVA*, 131 S. Ct. at 2575-76.

¹⁰⁸ *Wyeth*, 555 U.S. at ___, 129 S. Ct. at 1202.

The FDA promulgated its CBE regulation because it wanted to provide a mechanism for companies to amend their labels when new safety information “require[d] prompt corrective action,”¹⁰⁹ without forcing the products off the market until the agency approved (or rejected) the amended label. The idea, then, was to protect patients both by putting the most up-to-date information into their (and their doctors’) hands and by assuring their continued access to needed medications.

There is no reason why this same mechanism should not be available to generic manufacturers. In 1982, when the CBE regulation was first proposed,¹¹⁰ the generic drug revolution spurred by Hatch-Waxman, whose enactment was two years into the future, might not have been anticipated. Today, however, as explained earlier, when a particular drug is available in generic form, generic products dominate the market, with an average 90 percent market share, and, often, the presence of low-cost generics push the brand-name drugs off the market entirely.¹¹¹

Moreover, as discussed briefly in Part I.B.2 above, both brand-name and generic drug manufacturers must comply with regulations designed to ensure the post-approval safety of their drugs and must “promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers.”¹¹² Any report of a “serious and unexpected” drug experience must be reported to the FDA within 15 days and must be promptly investigated by the manufacturer.¹¹³ Most other adverse event reports must be submitted quarterly for three years after the application is approved and annually after that.¹¹⁴ These periodic reports must include “a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).”¹¹⁵ The upshot of these regulatory requirements is that generic manufacturers, like their brand-name counterparts, participate actively in post-market surveillance of their products and are in a good position to know about adverse events and the need, if any, for labeling changes that would enhance patient safety.

Given the market presence of generic products and the role of generic manufacturers in post-market surveillance, it is sensible for both brand-name and generic manufacturers to be authorized to use the CBE process. After a brand-name manufacturer employs the CBE process, the FDA determines whether the proposed label change is appropriate and should therefore be adopted across the board by all sellers of the drug. The FDA can make the same determinations when a generic manufacturer employs the CBE process.

¹⁰⁹ 47 Fed. Reg. 46,622, 46,635 (Oct. 19, 1982).

¹¹⁰ See *id.* at 46,650; see also 50 Fed. Reg. 7452, 7498 (Feb. 22, 1985) (final rule).

¹¹¹ *PLIVA*, 131 S. Ct. at 2584 (Sotomayor, J., dissenting).

¹¹² 21 C.F.R. § 314.80(b) (made applicable to ANDA holders by 21 C.F.R. § 98(a)).

¹¹³ *Id.* § 314.80(c)(1)(i-ii).

¹¹⁴ *Id.* § 314.80(c)(2)(i).

¹¹⁵ *Id.* § 314.80(c)(2)(ii).

2. Potential Congressional Action. Congress could overrule *PLIVA* in one of two ways (or, presumably, in both ways). First, it could amend the Food, Drug, and Cosmetic Act to provide that neither the Act nor its regulations preempt state-law failure-to-warn claims. Second, just as the FDA might do, Congress could provide directly that generic drug manufacturers, like brand-name manufacturers, are authorized to use the CBE process. The first route may be more appropriate, as Congress can and frequently has expressly patrolled the dividing line between state and federal law,¹¹⁶ and the FDA is not charged by Congress with determining the best means to compensate patients injured by the products it regulates. On the other hand, it is probably best to leave the nuances of drug labeling policy to the FDA, the agency charged by Congress with creating and enforcing that policy. In any event, whether Congress will have the votes in the near term to overrule *PLIVA* is questionable.¹¹⁷

B. Effects on Preemption Jurisprudence

PLIVA raises questions about the Court’s preemption jurisprudence regarding the ongoing vitality of the presumption against preemption, the standard for determining “impossibility” preemption, and the propriety of deference to an agency’s views on preemption. We address each issue below.

1. Is the presumption against preemption on life support? For decades, in both express and implied preemption cases,¹¹⁸ the Court has applied a presumption against preemption — that is, “a duty to accept the reading that disfavors preemption” when a federal statute plausibly admits of both a preemptive and non-preemptive reading.¹¹⁹ The Court has grounded this principle in federalism, in the idea that unless Congress ousts state law with unmistakable clarity, the states should be free to chart their own course, particularly in areas traditionally regulated by the states:

[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. In 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.”¹²⁰

¹¹⁶ See, e.g., 7 U.S.C. § 136v (preemption and anti-preemption provisions for federally regulated pesticides); 21 U.S.C. § 360k (preemption provision for medical devices, with exemption from preemption in some circumstances); 21 U.S.C. § 379r (preemption provision for over-the-counter drugs, with savings clause for product liability actions).

¹¹⁷ In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court held that 21 U.S.C. § 360k(a) preempts most state-law damages claims for injuries caused by medical devices that go through full FDA premarket approval. Shortly thereafter, legislation was introduced to overrule *Riegel*, see H.R. 1346 (2009); S. 540 (2009), but it has not been enacted.

¹¹⁸ See 131 S. Ct. at 2591 (Sotomayor, J., dissenting) (citing both express and implied preemption cases that invoke the presumption against preemption); see also, e.g., *Lohr*, 518 U.S. at 485.

¹¹⁹ *Bates*, 544 U.S. at 449.

¹²⁰ *Lohr*, 518 at 485 (citations omitted).

The Court has applied the presumption against preemption with special force where a pro-preemption outcome would ascribe to Congress an intent to eliminate all remedies for consumers injured by unlawful conduct.¹²¹

It is difficult to square *PLIVA* with this longstanding reluctance to preempt state law. The *PLIVA* majority did not even mention the presumption against preemption. This silence is noteworthy because *PLIVA* involved the availability of tort remedies for consumers injured by faulty or mislabeled products, an area that the Court consistently has considered “a field which the States have traditionally occupied” and, thus, especially subject to the presumption against preemption.¹²²

Moreover, as noted earlier, Justice Thomas’s four-Justice plurality opinion suggests that there is a battle raging on the Court over the presumption’s propriety. Adoption of Justice Thomas’s interpretive theory of the Supremacy Clause, based on its *non obstante* language, arguably would nullify the presumption against preemption. Rather than demanding “clear and manifest” congressional intent to preempt state law, as the Court has traditionally done, Justice Thomas’s theory views federal law, by force of the Supremacy Clause itself, as “impliedly repeal[ing] conflicting state law,” thus requiring a judge to look only to the text of relevant federal law and engage in ordinary statutory analysis. It is difficult to see how these two approaches peaceably could coexist.

In *Wyeth*, the dissenters —Justice Alito, joined by Chief Justice Roberts and Justice Scalia — maintained that the presumption against preemption does not apply in implied conflict preemption cases.¹²³ On the other hand, most of the Justices have joined opinions endorsing the presumption against preemption, and, indeed, Justice Thomas himself penned a partial dissent in an express preemption case that relied forcefully on the presumption against preemption, arguing that the Court erroneously had held a state common-law claim preempted and noting that the majority had not accorded sufficient “[r]espect for the presumptive sanctity of state law[.]”¹²⁴ Most important, in *PLIVA*, Justice Kennedy did not join Justice Thomas’s plurality opinion, suggesting that he, like the four dissenters,¹²⁵ was concerned that Justice Thomas’s views of the Supremacy Clause would, if adopted by a Court majority, effectively kill off the presumption against preemption of state law. Time will tell whether, and, if so, in what types of preemption cases, the presumption against preemption still lives.

2. A New Standard for ‘Impossibility’ Preemption?

PLIVA arguably established a new principle of “impossibility” preemption. Stated most generally, this sub-species of conflict preemption holds that state law is preempted when it is impossible for a person subject to

the demands of both state and federal law simultaneously to comply with both.¹²⁶ In *PLIVA*, the plaintiffs argued that compliance with both federal and state law was not impossible — or, at least, that the generic manufacturers had not met their burden of showing that dual compliance was impossible — because if the FDA had been asked by the manufacturers to approve an amended metoclopramide label, it might not have rejected that request. And if the manufacturers could not show that the FDA would have rejected an amended label, the argument goes, federal law would not conflict with state-law principles demanding an amended (safer) label.

As explained earlier, Justice Thomas rejected this argument, holding that because the manufacturers could not *independently* change their labels under federal law without violating the asserted state-law duty (to change the labels), state law conflicted with, and was thus preempted by, federal law.¹²⁷ In Justice Thomas’s view, to allow a plaintiff to escape preemption based on the conjecture of what a third party might do would unduly limit the scope of impossibility preemption to only those circumstances where the third party took action that made certain the conflict between state and federal law.

Why did Justice Thomas take this novel view of impossibility preemption? The answer is embedded, we believe, in his views on conflict preemption more generally. It has been established doctrine for decades that conflict preemption exists when compliance with both state and federal law is impossible or when “the state requirement [would] ‘stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’ ”¹²⁸ Standing alone on the Court, Justice Thomas rejects *any* form of “obstacle” or “frustration of purposes” preemption, a position he espoused at length in his concurrence in *Wyeth v. Levine*.¹²⁹ There, he maintained that this form of preemption is at odds with various constitutional imperatives of federalism, including the Tenth Amendment, which underscore the States’ retention of “substantial sovereign authority” and which seek “to protect [a] delicate balance of power” between state and federal authority.¹³⁰

In *Wyeth*, Justice Thomas also rejected obstacle preemption on two other, related grounds. First, he argued, that the Supremacy Clause, which makes “supreme” only those laws “made in Pursuance” of the Constitution,¹³¹ and the Bicameralism and Presentment Clauses, which demand that the “passage of legislation” follow “‘a step-by-step, deliberate and deliberative process,’ ” require “that preemptive 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

¹²¹ See, e.g., *Bates*, 544 U.S. at 449-50; *Sprietsma v. Mercury Marine*, 537 U.S. 51, 69 (2002); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); see generally *Wyeth*, 555 U.S. at ___ & n.3, ___ 129 S. Ct. at 1194-95 & n.3, 1200.

¹²² *Lohr*, 518 U.S. at 485 (citation omitted); see also, e.g., *Wyeth*, 555 U.S. at ___ 129 S. Ct. at 1194-95.

¹²³ *Wyeth*, 555 U.S. ___ & n.14, 129 S. Ct. at 1228-29 & n.14 (Alito, J., dissenting).

¹²⁴ *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 679 (1993) (Thomas, J., concurring in part and dissenting in part).

¹²⁵ *PLIVA*, 131 S. Ct. at 2591-92 (Sotomayor, J., dissenting).

¹²⁶ See, e.g., *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

¹²⁷ *PLIVA*, 131 S. Ct. at 2579.

¹²⁸ *Lohr*, 518 U.S. at 507 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

¹²⁹ *Wyeth*, 555 U.S. at ___ 129 S. Ct. at 1205-07, 1211-17 (Thomas, J., concurring in the judgment).

¹³⁰ *Id.* at 1205-06. Note, here, the tension between Justice Thomas’s deference to the states’ constitutional prerogatives in *Wyeth* and his apparent rejection of the presumption against preemption less than three years later in *PLIVA*.

¹³¹ *Id.* at 1206 (quoting U.S. Const. Art IV, cl. 2).

bicameral and presentment procedures.”¹³² Second, he explained that obstacle preemption “encourages an overly expansive reading of statutory text,” in a misguided and error-inducing search for a statute’s purposes.¹³³

Without having obstacle preemption as a residual form of preemption able to sweep in state laws that conflict with congressional purposes, Justice Thomas needed, it appears, a form of impossibility preemption that would be sufficiently broad, in his words, to avoid “render[ing] conflict preemption largely meaningless . . . [and] most conflicts between state and federal law illusory.”¹³⁴ Whether Justice Thomas’s overarching theory of preemption — which broadens impossibility preemption while eliminating obstacle preemption — will someday capture a Court majority is beyond the scope of this article. As we now explain, however, his views do appear to be at odds with the Court’s existing precedents.

First, as noted above, the obstacle preemption doctrine is routinely employed by every member of the Court except Justice Thomas. Second, even though Justice Thomas garnered five votes in *PLIVA* for his impossibility preemption ruling, it is difficult to square that ruling with *Wyeth*. The contingencies that Justice Thomas found insufficient to overcome a preemption finding in *PLIVA* — that the FDA had not been asked to review and therefore did not reject an allegedly safety-enhancing label change — are exactly the contingencies that led the Court in *Wyeth* to reject impossibility preemption. To be sure, in *Wyeth*, the Court said that it was not impossible to comply with both state and federal law because *Wyeth*, a brand-name manufacturer, was authorized by the CBE regulation unilaterally to amend its label.

But the Court rejected preemption by impossibility for what it termed a “more fundamental” reason:¹³⁵ that *Wyeth* could have asked the FDA to amend the label, and “absent clear evidence that the FDA would not have approved a change to [the drug’s] label,” it was not “impossible for *Wyeth* to comply with both federal and state requirements.”¹³⁶ Noting that “[i]mpossibility pre-emption is a demanding defense,”¹³⁷ the Court reviewed the record, found no evidence that the FDA would have rejected a label change, and concluded that “*Wyeth* has failed to demonstrate that it was impossible for it to comply with both federal and state requirements.”¹³⁸

¹³² *Id.* at 1207 (quoting *INS v. Chadha*, 462 U.S. 919, 959 (1983)).

¹³³ *Id.* at 1207-08, 1212. Justice Thomas’s rejection of any use of “obstacle” or “frustration of purposes” preemption was evident this past Term in *Williamson v. Mazda Motor of America, Inc.*, 131 S. Ct. 1131 (2011), where he joined in the Court’s no-preemption result, but not its opinion, and wrote separately to explain why he rejected the Court’s obstacle-preemption analysis. See *id.* at 1141-43 (Thomas, J., concurring in the judgment); see also *Chamber of Commerce v. Whiting*, 131 S. Ct. 1968, 1973 n.* (2011) (noting Justice Thomas’s non-joinder in Chief Justice Roberts’s obstacle-preemption analysis).

¹³⁴ *PLIVA*, 131 S. Ct. at 2579.

¹³⁵ *Wyeth*, 555 U.S. at ___, 129 S. Ct. at 1197.

¹³⁶ *Id.* at 1198.

¹³⁷ *Id.* at 1199.

¹³⁸ *Id.*

The Court seemingly should have come to the same conclusion in *PLIVA*: Because the generic manufacturers never asked the FDA for a label change on metoclopramide, let alone obtained a negative answer, the plaintiffs’ state-law claims should have escaped preemption under *Wyeth*. Instead, *PLIVA* came to the opposite conclusion, turning what *Wyeth* termed a “demanding defense” into no defense at all, and, consistent with Justice Thomas’s apparent evisceration of the presumption against preemption, effectively equating its holding that generic manufacturers may not employ the CBE process with a finding of impossibility preemption. *PLIVA* and *Wyeth* are so difficult to square in this regard that it seems prudent to wait for future regulatory preemption cases rather than trying to predict whether Justice Thomas’s new formulation of impossibility preemption will take hold.

One other tension between *PLIVA* and *Wyeth* bearing on impossibility preemption warrants a brief discussion. Justice Sotomayor’s dissent applied *Wyeth*’s impossibility framework, thus holding that, to obtain preemption, the generic manufacturers had to show that the FDA would have rejected the change to the metoclopramide label that the plaintiffs claimed would have prevented their injuries.¹³⁹ She noted also the Eighth Circuit’s suggestion that the generic manufacturer “could not show impossibility because federal law merely permitted them to sell generic drugs; it did not require them to do so.”¹⁴⁰ Justice Sotomayor did not reach that argument because the plaintiffs had not advanced it.¹⁴¹ In *Wyeth*, however, Justice Thomas himself appears to have endorsed a close variant of that argument. After agreeing with the majority that *Wyeth*’s right to use the CBE regulation demanded a no-preemption finding, he went on:

In addition, the text of the statutory provisions governing FDA drug labeling, and the regulations promulgated thereunder, do not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA. Thus, there is no “direct conflict” between the federal labeling law and the state-court judgment. The statute prohibits the interstate marketing of any drug, except for those that are federally approved. . . . To say, as the statute 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. Initial approval of a label amounts to a finding by the FDA that the label is safe for purposes of gaining federal approval to market the drug. It does not represent a finding that the drug, as labeled, can never be deemed unsafe by later federal action, or as in this case, the application of state law.¹⁴²

Justice Thomas appears to be saying that because there is no “unconditional [federal] right to market” drugs, there can be no conflict between federal law and a state-law duty that would impose marketing conditions on those drugs, including conditions on the label with which those drugs are marketed. Justice Thomas’s *PLIVA* opinion does not mention, let alone confront, this part of his *Wyeth* concurrence, even though, if ap-

¹³⁹ *PLIVA*, 131 S. Ct. at 2588 (Sotomayor, J., dissenting).

¹⁴⁰ *Id.* at 2587 n.8 (citing *Mensing*, 588 F.3d at 611).

¹⁴¹ See *id.*

¹⁴² *Wyeth*, 555 U.S. at ___, 129 S. Ct. at 1210 (Thomas, J., concurring in the judgment).

plied, it would have seemingly required a different result. After all, generic manufacturers, like their brand-name counterparts, have no “unconditional [federal] right” to market their products, and, thus, it cannot be said that a state-law marketing restriction, such as a labeling requirement, conflicts with federal law. We do not know whether Justice Thomas has now rejected this line of argument espoused in his *Wyeth* concurrence or, like Justice Sotomayor, did not confront it in *PLIVA* because it was not raised there.

3. Deference to Agency Views on Preemption. As explained above in Part II.A.2, the Supreme Court deferred to the FDA’s interpretations of its CBE and DHCP regulations in a routine application of administrative deference doctrine. The Court then stated, without further explanation: “Although we defer to the agency’s interpretation of its regulations, we do not defer to an agency’s ultimate conclusion about whether state law should be pre-empted.”¹⁴³ As noted earlier, this footnoted holding was arguably important to the result because it freed the majority to render its preemption ruling without giving any weight to the FDA’s no-preemption views.

Though the Court expressed this view as if it flowed from settled law, it did not. The notion that no deference is ever afforded an agency’s views on preemption cannot be reconciled with the Court’s recent precedents. The Supreme Court has said that an agency’s view on whether its regulations preempt state tort law is entitled to “some weight.”¹⁴⁴ The Court has explained that, especially when dealing with “technical” and “complex and extensive” subject matter or statutory schemes, “[t]he agency is likely to have a thorough understanding of its own regulation and its objectives and is ‘uniquely qualified’ to comprehend the likely impact of state requirements.”¹⁴⁵

Indeed, just four months before the decision in *PLIVA*, in *Williamson v. Mazda Motor of America, Inc.*,¹⁴⁶ a case involving whether a federal motor vehicle safety standard preempted a state-law damages action, the Court gave considerable weight to the preemption views of the Department of Transportation: “The Solicitor General tells us that DOT’s regulation does not preempt this tort suit. As in *Geier*, ‘the agency’s own views should make a difference.’”¹⁴⁷ The Court explained that it was dealing with complex regulatory matters and again noted that the agency was likely to understand its own regulatory structure and mission, and thus was “‘uniquely qualified’ to comprehend the likely impact of state requirements.”¹⁴⁸

In *PLIVA*, Justice Thomas cited *Wyeth* as support for the proposition that the Court “do[es] not defer” to an agency’s conclusions on preemption. That only tells part of the story. To be sure, *Wyeth* said that the Court has “not deferred to an agency’s conclusion that state law is pre-empted,”¹⁴⁹ but it also confirmed that courts may give weight to an agency’s views on preemption

because agencies “do have a unique understanding of the statutes they administer and an attendant ability to make informed determinations about how state requirements may pose an ‘obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’”¹⁵⁰ *Wyeth* went on to reject deference to the particular agency’s views on preemption expressed in that case, not because the agency rendered a conclusion as to whether preemption was appropriate, but because the agency’s views had not been expressed with the “thoroughness, consistency, and persuasiveness” that the Court looks for when it assesses whether, and to what degree, to accord administrative deference.¹⁵¹

Moreover, the distinction between deferring to an agency’s conclusion about preemption and an agency’s views about whether state requirements conflict with federal law, by posing an obstacle to the accomplishment of federal objectives, is illusory. A court finds preemption when state law conflicts with federal law, and deferring to the federal government’s view that such a conflict does (or does not) exist is tantamount to deferring to its views on the preemption “conclusion” itself. In fact, in cases where the Court has deferred to the agency’s views on preemption, such as *Geier* and *Williamson*, the Court gave weight to the agency’s view that federal law should or should not preempt state law because it believed that the agency was well positioned to evaluate whether state law conflicted with, or advanced, the objectives of federal law and that the agency’s evaluation had been thorough, persuasive, and not inconsistent with the agency’s other pronouncements on the topic.¹⁵²

A federal agency is not likely to come into court and ask the court to rubberstamp a legal conclusion about preemption. Rather, an agency will explain why its “unique understanding of the statutes [it] administer[s]” enables it to “make informed determinations about how state requirements” would advance or undermine its ability to carry out federal law.¹⁵³ *PLIVA* was no exception. There, the Solicitor General’s amicus brief did not simply cite the Court’s preemption jurisprudence, state its no-preemption “conclusion,” and ask for deference. Rather, it explained at length why, based on the agency’s experience and interpretations of its own regulations and policies, state-law failure-to-warn claims were consistent with the federal obligations of generic drug manufacturers not to misbrand their products and to bring new safety information to the agency’s attention.¹⁵⁴

The Solicitor General’s brief also urged the Court to reject the generic manufacturers’ claims that state-law suits would undermine the FDA’s ability to carry out its mission — for instance, by encouraging manufacturers to inundate the agency with insubstantial requests for labeling changes — as inconsistent with the agency’s on-the-ground experience.¹⁵⁵

¹⁴³ *PLIVA*, 131 S. Ct. at 2575 n.3.

¹⁴⁴ See, e.g., *Geier v. American Honda Motor Co.*, 529 U.S. 861, 883 (2000).

¹⁴⁵ *Id.* (citing *Lohr*, 518 U.S. at 496 (Breyer, J., concurring)).

¹⁴⁶ 131 S. Ct. 1131 (2011).

¹⁴⁷ 131 S. Ct. at 1139 (quoting *Geier*, 529 U.S. at 883).

¹⁴⁸ *Id.*

¹⁴⁹ *Wyeth*, 555 U.S. at ___, 129 S. Ct. at 1201 (emphasis in original).

¹⁵⁰ *Id.* (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

¹⁵¹ *Id.* (citing *United States v. Mead Corp.*, 533 U.S. 218, 234-35 (2001); *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

¹⁵² *Williamson*, 131 S. Ct. at 1139; *Geier*, 529 U.S. at 883-84.

¹⁵³ *Wyeth*, 555 U.S. at ___, 129 S. Ct. at 1201.

¹⁵⁴ SG Brief, 2011 WL 741927, *20-30.

¹⁵⁵ *Id.* at *30-35.

For these reasons, it is difficult to harmonize the Court's back-of-the-hand rejection of deference to the FDA's preemption views in *PLIVA* with the Court's more serious considerations of agencies' preemption views in cases like *Geier*, *Williamson*, and *Wyeth*. The Court has had a steady diet of regulatory preemption

cases in recent years, and agencies are eager to express their views on preemption in those cases. We are therefore likely to get more input from the Court soon on whether and to what degree agencies' views on preemption should be accorded weight.