HEALING A FRACTURED PREEMPTION DOCTRINE: THE IMPACT OF *MERCK SHARP & DOHME CORP. V. ALBRECHT* ON IMPOSSIBILITY PREEMPTION DEFENSES

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Patient safety depends on tort litigation to identify a brand-name drug's undisclosed risks, illuminate flaws in a drug's design, and raise concerns that a drug requires further study before it is safe for patient use. However, since the U.S. Supreme Court's landmark decision in Wyeth v. Levine*, which permitted the plaintiff to move forward but recognized an in-principle impossibility preemption defense, drug manufacturers have shielded themselves from liability under a range of circumstances. Under this defense, federal law preempts state law tort actions against brand-name drug manufacturers in any court across the country. Yet, the scope of the impossibility preemption defense remains unclear.*

On May 20, 2019, the Supreme Court clarified its interpretation of impossibility preemption in Merck Sharp & Dohme Corp. v. Albrecht*. This case involved state law claims regarding Merck's alleged failure to adequately warn patients and physicians of the risks of femoral fractures associated with Fosamax, a drug used to treat osteoporosis in postmenopausal women. In* Albrecht*, the Supreme Court decided that impossibility preemption is a question of law for judges to decide, rather than a question of fact for a jury. The Court also elaborated on* Wyeth*'s requirements for a viable impossibility preemption defense. Ultimately, rather than deciding whether or not the plaintiffs' state law claim in* Albrecht *was preempted, the Court remanded the case. For now, the future of impossibility preemption defenses is left for lower courts to decide, but* Albrecht *provides the framework within which they must decide it.*

The Supreme Court's decision in Albrecht *marks a step forward in the muddled path the Court has forged in this area. While the Court attempts to provide a simple analytical framework for determining when impossibility preemption defenses succeed, questions remain about the power and*

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applicability of this defense for brand-name drug manufacturers. This Note seeks to provide lower courts deciding impossibility preemption questions with a functional understanding of where the doctrine stands after Albrecht*. Given the increasing pace of new brand-name drug approvals and the rise of product liability litigation involving pharmaceuticals, it is crucial that future litigants are aware of the status of the impossibility preemption defense. If this defense still exists after* Albrecht*, it is also imperative that courts know it when they see it.*

INTRODUCTION

> [T]he question that we're all kind of struggling with here seems to me to be this, or something along these lines: Reading the statute your way, do we create a moral hazard that encourages manufacturers to supply the FDA with a lot of information, overwhelming with data, but maybe not the most artfully drafted and maybe deliberately inartfully drafted warning that it thinks is reasonably calculated to be refused, so that it can avoid having to shoulder or . . . internalize its own costs of negligence?
>
> —Justice Neil Gorsuch[1]

It is a settled expectation that if a prescription drug manufacturer fails to provide adequate warnings about the risks of a medication and a patient taking the medication as intended suffers an unexpected injury as a result of the inadequate warning, the patient has a remedy at law. For decades, however, pharmaceutical manufacturers have advocated an impossibility preemption defense: that the Food and Drug Administration's (FDA) approval of a drug label or rejection of a proposed label change prevents patients from bringing state law tort actions alleging deficient labeling because compliance with both state and federal law is impossible.

In *Wyeth v. Levine*,[2] the U.S. Supreme Court addressed whether FDA regulations preempt state law failure-to-warn claims against brand-name drug manufacturers. In this landmark decision, the Court held that a state law failure-to-warn claim could proceed *even if* the FDA had fully approved a drug's label.[3] Defendant-manufacturers could only escape liability if they could provide "clear evidence that the [FDA] would not have approved a change to [the drug's] label."[4] The Court noted that Wyeth, the drug manufacturer, did not present such evidence,[5] but the Court left the standard otherwise undefined. On its face, *Wyeth* presented a major win for plaintiffs and potentially signaled the death of impossibility preemption for manufacturers who could not establish this "demanding defense."[6] However, a more sophisticated interpretation of *Wyeth* permitted brand-name drug manufacturers to pursue exactly the strategy Justice Gorsuch adverted to in

1. Transcript of Oral Argument at 13, Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019) (No. 17-290).
2. 555 U.S. 555 (2009).
3. *See id.* at 581.
4. *Id.* at 571.
5. *Id.* at 572 ("Wyeth has offered no such evidence.").
6. *Id.* at 573.

the *Merck Sharp & Dohme Corp. v. Albrecht*[7] oral arguments: overwhelming the FDA with data in an effort to ensure a proposed label was rejected.[8] Unfortunately, courts have reached opposite conclusions about the limits of the impossibility preemption defense over the last decade, so it remains unclear when state law failure-to-warn claims can proceed.[9]

For example, a district court judge in New Jersey recently threw out hundreds of state law failure-to-warn claims that the Third Circuit later vacated and remanded based on conflicting interpretations of *Wyeth*.[10] This litigation culminated in *Albrecht*, where, "[i]n light of differences and uncertainties among the courts of appeals and state supreme courts in respect to the application of *Wyeth*," the Supreme Court further clarified the procedure for deciding impossibility preemption defenses.[11] The question presented in *Albrecht* was simple: whether a judge or a jury should decide impossibility preemption defenses.[12] In an opinion by Justice Breyer, the Court succinctly reasoned that judges are "better equipped" than juries "to evaluate the nature and scope of an agency's determination . . . and to interpret agency decisions in light of the governing statutory and regulatory context."[13] Therefore, the Court held preemption is a question of law for judges to decide.[14]

The Court's analysis did not stop there. As part of his opinion for the Court, Justice Breyer elaborated on *Wyeth*'s impossibility preemption requirements. The Court defined *Wyeth*'s "clear evidence" standard as "evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning."[15] The Court also held that "clear evidence" is not a heightened evidentiary standard but rather a requirement that the court consider "whether the relevant federal and state laws 'irreconcilably conflict.'"[16] Lastly, the Court noted that the only agency actions that can determine the answer to preemption questions are those "taken pursuant to the [FDA's] congressionally delegated authority."[17]

On its face, the 9-0 *Albrecht* decision resolved an easy case—the opinion settles a narrow procedural question and appears to define *Wyeth*'s clear

7. 139 S. Ct. 1668 (2019).

8. Transcript of Oral Argument, *supra* note 1, at 13.

9. *See, e.g.*, Mason v. Smithkline Beecham Corp., 596 F.3d 387, 391 (7th Cir. 2010) ("The Supreme Court, however, did not clarify what constitutes 'clear evidence.'"); Dobbs v. Wyeth Pharm., 797 F. Supp. 2d 1264, 1270 (W.D. Okla. 2011) ("[L]ower courts are left to determine what satisfies this 'clear evidence' standard in each case." (quoting Schilf v. Eli Lilly & Co., No. CIV 07-4015, 2010 WL 3909909, at *4 (D.S.D. Sept. 30, 2010))).

10. *See In re* Fosamax (Alendronate Sodium) Prods. Liab. Litig., 852 F.3d 268, 302 (3d Cir. 2017), *vacated sub nom. Albrecht*, 139 S. Ct. 1668.

11. *Albrecht*, 139 S. Ct. at 1676.

12. *Id.* at 1672.

13. *Id.* at 1680.

14. *Id.* at 1679.

15. *Id.* at 1672.

16. *Id.* at 1679 (quoting Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982)).

17. *Id.*

evidence requirement along the way. But the Court's deeper analysis of *Wyeth* raises complex questions about when state law failure-to-warn claims involving brand-name prescription drugs can proceed. This Note elaborates on the framework sketched by Justice Breyer in the majority opinion, identifies the gaps that remain, and suggests how those gaps may be filled. Manufacturers raising impossibility preemption defenses and courts deciding preemption questions must both understand what "fully inform[s]" the FDA under Justice Breyer's framework.[18] Future litigants and judges must also understand when state and federal laws "irreconcilably conflict"[19] and what agency actions fall within the FDA's "congressionally delegated authority."[20] The concurring opinions in *Albrecht* and lower court decisions after *Wyeth* offer important clues to inform this analysis. Without answers to these lingering questions, impossibility preemption will remain an area where "muddle . . . dominates over clarity."[21]

This Note is organized into three parts. Part I examines the impossibility preemption landscape leading up to *Albrecht*, including the landmark *Wyeth* decision and its aftermath. Part II examines the *Albrecht* decision and identifies three core interpretive issues that arise from the majority opinion, which must be resolved before courts can uniformly address impossibility preemption defenses. Part III explores how lower courts should approach the interpretive issues identified in Part II and argues that while the *Albrecht* decision is more complex than it appears, it is nonetheless illuminating for courts deciding impossibility preemption defenses as a matter of law.

I. THE DEVELOPMENT OF IMPOSSIBILITY PREEMPTION IN BRAND-NAME PRESCRIPTION DRUG CASES

Part I of this Note examines the evolution of federal preemption jurisprudence. Part I.A provides an overview of federal preemption principles in the context of brand-name prescription drugs and highlights the confusion among courts deciding impossibility preemption defenses before *Wyeth*. Part I.B examines the Supreme Court's landmark *Wyeth* decision. Part I.C assesses *Wyeth*'s impact on federal preemption jurisprudence over the last decade, which culminated in the *Albrecht* case that is the focus of this Note.

A. Preemption Principles

The Supremacy Clause of the U.S. Constitution states that the "Constitution, and the Laws of the United States . . . shall be the supreme

18. *Id.* at 1672.
19. *Id.* at 1679.
20. *Id.*
21. Ashutosh Bhagwat, Wyeth v. Levine *and Agency Preemption: More Muddle, or Creeping to Clarity*, 45 TULSA L. REV. 197, 229 (2009); *see also* Brief of Tort Law Professors John C. P. Goldberg and Benjamin C. Zipursky as Amici Curiae in Support of Respondents at *4, *Albrecht*, 139 S. Ct. 1668 (No. 17-290) ("The application of implied preemption doctrine untethered from any guiding text carries great risk of undermining federalism values.").

Law of the Land."[22] This language serves as the foundation for the federal preemption doctrine, which mandates that when state and federal laws conflict, the federal law takes precedence and the state law is preempted.[23] "[T]he purpose of Congress is the ultimate touchstone in every pre-emption case,"[24] and there is a "presumption against pre-emption."[25] While there is serious debate among the Justices about the purpose of Congress regarding preemption, as well as the scope of the presumption against preemption, these principles remain cornerstones of modern preemption law.[26]

The Supreme Court has identified three types of preemption: "express preemption," in which a federal law expressly states that it preempts state law; "field preemption," in which federal law occupies the entire field of an issue; and "conflict preemption," in which either simultaneous compliance with federal and state regulations is impossible ("impossibility preemption") or state law poses an obstacle to the accomplishment of federal goals ("obstacle preemption").[27] This Note will focus on brand-name drug manufacturers' use of the impossibility preemption defense.

1. Federal Drug Labeling Regulations

Manufacturers of brand-name pharmaceutical products are subject to the product approval and labeling standards articulated by the Federal Food, Drug, and Cosmetic Act[28] (FDCA). To distribute a drug, a manufacturer must demonstrate to the FDA that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling."[29] Before a drug is approved for distribution, the FDA must approve the exact text of the label.[30] Drug manufacturers are also required to submit proposed label changes to the FDA as new information arises to ensure that labels remain accurate while the drug is on the market.[31]

To propose labeling changes, manufacturers may submit a Prior Approval Supplement (PAS) application, which the FDA then must approve before changes can be implemented.[32] Alternatively, under the FDA's "Changes Being Effected" (CBE) regulation, manufacturers may unilaterally add to or strengthen a label "to reflect newly acquired information."[33] Manufacturers who file a supplemental application under the CBE regulation can make these

22. U.S. CONST. art. VI, cl. 2.
23. Murphy v. Nat'l Collegiate Athletic Ass'n, 138 S. Ct. 1461, 1476 (2018).
24. Wyeth v. Levine, 555 U.S. 555, 565 (2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).
25. *Id.* at 565 n.3.
26. *See* Bhagwat, *supra* note 21, at 213.
27. *See* Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 373 (2000).
28. 21 U.S.C. §§ 301–399(h).
29. *Id.* § 355(d).
30. *Id.*
31. *See* 21 C.F.R. § 314.70(b)–(c) (2019).
32. *See id.* § 314.70(b).
33. *See id.* § 314.70(c).
33. *See id.*

label changes immediately without FDA approval.[34] However, the FDA will reject CBE revisions if it determines there is insufficient evidence of a causal link between use of the drug and the risk at issue.[35] These types of label rejections reflect the FDA's concern that excessive or unnecessary warnings may discourage appropriate use of a valuable drug.[36]

2. State Law Failure-to-Warn Claims

Although the FDA must approve a drug's label before it reaches the market, FDA approval does not automatically bar state law tort actions alleging that a label is incomplete.[37] Indeed, the Court's decision in *Wyeth* states that Congress declined to include a private right of action for damages when it enacted the FDCA in 1938, specifically because damages claims were widely available under state law.[38] In the eighty-one years since the FDCA's enactment, no express preemption clause has been added.[39] The Supreme Court has also rejected field preemption in the pharmaceutical and medical device areas.[40]

In the early 2000s, pharmaceutical defendants began to pursue the only remaining avenue for preemption by raising conflict preemption defenses.[41] Manufacturers argued that state tort law required them to act in ways that federal regulations precluded.[42] Specifically, manufacturers argued that simultaneous compliance with both federal and state law was impossible because the FDA either rejected or would have rejected a warning label required under state law.[43]

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34. *See id.*

35. 21 U.S.C. § 355(d).

36. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,605–06 (Aug. 22, 2008) (to be codified at 21 C.F.R. pts. 314, 601, and 814).

37. *See* Wyeth v. Levine, 555 U.S. 555, 567 (2009) ("The 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA."(quoting Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 781, 793)).

38. *See id.* at 574 n.7 (citing the legislative history of the FDCA).

39. *See id.* at 567 (noting that Congress amended the FDCA to include an express preemption clause for medical devices, but that "it declined to enact such a provision for prescription drugs").

40. *See* Hillsborough County v. Automated Med. Lab'ys, Inc., 471 U.S. 707, 717 (1985) (explaining that courts should not infer field preemption "whenever an agency deals with a problem comprehensively," because such an inference would be inconsistent with "the federal-state balance embodied in [the Court's] Supremacy Clause jurisprudence").

41. *See* Mason v. Smithkline Beecham Corp., 596 F.3d 387, 390–91 (7th Cir. 2010) ("Interestingly enough, the idea of conflict preemption in prescription drug cases is relatively new. Until the early 2000s, prescription drug companies infrequently invoked the preemption defense, and when they did, it rarely succeeded."(first citing Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528, 537 (6th Cir. 1993); and then citing Hill v. Searle Lab'ys, 884 F.2d 1064, 1068 (8th Cir. 1989))).

42. *See* Brief for Petitioner at 26–27, *Wyeth*, 555 U.S. 555 (No. 06-1249) ("Respondent's state-law tort claims conflict with the regime Congress established in the FDCA . . . .").

43. *Id.* at 26 (noting that "it would have been impossible for Wyeth to comply with the purported state-law duty to modify Phenergan's labeling to contraindicate intravenous administration of Phenergan without violating the FDCA").

Impossibility preemption arguments became the subject of intense policy debate. Consumer advocates argued that state tort liability was necessary to ensure patient safety, while manufacturers claimed that the threat of tort liability limited patient access to beneficial drugs by leaving innovators vulnerable to costly litigation and undermining the FDA's authority.[44] Courts were also split on the validity of impossibility preemption defenses. Some courts rejected preemption defenses,[45] while others were persuaded by defendants' impossibility arguments.[46] As impossibility preemption defenses gained traction, the FDA's position on preemption defenses also shifted, causing further division among courts.[47] In the preamble to a January 2006 FDA rule ("2006 preamble") and several amicus briefs filed in favor of defendant-manufacturers, the FDA stated that the FDCA established both a floor and a ceiling for labeling regulations, rendering all state law claims preempted.[48] As cases flooded courts and confusion mounted, it became clear that the Supreme Court needed to weigh in on the issue.[49]

B. Wyeth v. Levine*: A Landmark Rejection of Impossibility Preemption*

In its seminal *Wyeth* decision in 2009, the Supreme Court held that impossibility preemption defenses do not necessarily shield brand-name drug manufacturers from state law liability.[50] The Court created a fact-specific test for deciding whether failure-to-warn claims against brand-name drug

44. *See* KATHRYN B. ARMSTRONG, CONG. RSCH. SERV., LSB10064, IS IMPOSSIBILITY PREEMPTION IMPOSSIBLE?: FEDERAL DRUG LAW AND PREEMPTION OF STATE TORT CLAIMS 1 (2018), https://fas.org/sgp/crs/misc/LSB10064.pdf [https://perma.cc/X99N-UJ3R].

45. *See, e.g.*, Knipe v. SmithKline Beecham Corp., 583 F. Supp. 2d 553 (E.D. Pa. 2008) (rejecting defendant's impossibility preemption defense); Tucker v. SmithKline Beecham Corp., 596 F. Supp. 2d 1225 (S.D. Ind. 2008) (same); *In re* Vioxx Prods. Liab. Litig., 501 F. Supp. 2d 776 (E.D. La. 2007) (same).

46. *See, e.g.*, Mason v. Smithkline Beecham Corp., 546 F. Supp. 2d 618, 627 (C.D. Ill. 2008), *rev'd*, 596 F.3d 387 (7th Cir. 2010) (accepting defendant's impossibility preemption defense); Dobbs v. Wyeth Pharm., 530 F. Supp. 2d 1275, 1291 (W.D. Okla. 2008) (accepting defendant's impossibility preemption defense), *vacated*, 606 F.3d 1269 (10th Cir. 2010).

47. *See Tucker*, 596 F. Supp. 2d at 1232 (rejecting defendant's impossibility preemption defense and noting that the "FDA's current position on preemption is not 'long standing' but in fact a '180-degree reversal' from its earlier stance" (quoting David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 474 n.59 (2008))).

48. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–36 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601); *see also* Brief for the United States as Amicus Curiae Supporting Petitioner at 19, Wyeth v. Levine, 555 U.S 555 (2009) (No. 06-1246); Amicus Brief for the United States in Support of the Defendant-Appellee and Cross-Appellant, and in Favor of Reversal of the District Court's Order Denying Partial Summary Judgment to Defendant-Appellee and Cross-Appellant at 2, Motus v. Pfizer, Inc., 358 F.3d 659 (9th Cir. 2002) (Nos. 02-55372 & 02-55498); Brief of United States as Amicus Curiae in Support of Defendants-Appellees at 5–6, Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 06-3107).

49. *See Mason*, 596 F.3d at 391 ("Not surprisingly, courts began to issue contradicting opinions, which led the Supreme Court to grant certiorari in *Levine* to decide the issue.").

50. *See* Wyeth v. Levine, 555 U.S. 555, 581 (2009).

manufacturers are preempted on conflict grounds.[51] The decision officially opened the door for injured plaintiffs filing state law failure-to-warn claims and established the fundamental principle that manufacturers are responsible for the contents of their drug labels at all times.[52]

1. The Facts of *Wyeth*

Diana Levine received two doses of Phenergan, an anti-nausea drug manufactured by Wyeth to treat nausea caused by migraine headaches.[53] Phenergan can be administered via the "IV push" method, where the drug is injected directly into a patient's vein, or the "IV drip" method, where the drug is presented in a saline solution in an intravenous bag and slowly enters a patient's vein through a catheter.[54] The drug is known to cause irreversible gangrene if it enters an artery.[55] After an IV drip dose of Phenergan failed to relieve Levine's nausea, a second dose was administered via the riskier IV push method. This dose somehow entered Levine's artery, resulting in gangrene and the eventual amputation of Levine's right forearm.[56]

Levine sued Wyeth in Vermont state court claiming that: (1) Wyeth's labeling was defective because it failed to instruct clinicians to use the IV drip method, rather than the high-risk IV push method and (2) more broadly, that Phenergan was not safe for intravenous administration.[57] Wyeth argued that Levine's failure-to-warn claims were impliedly preempted by federal law based on the 2006 preamble, which noted that FDA approval of a drug's label preempts state laws imposing liability for negligent labeling.[58] Wyeth also claimed that Phenergan labels adequately stated the risks of the IV push method and noted that the IV drip method was the preferable method of administration.[59] Lastly, Wyeth argued that the FDA's previous rejection of a label change concerning risks of arterial exposure illustrated that the FDA would have rejected stronger proposed warnings concerning the IV push method.[60]

The trial court rejected Wyeth's preemption defense, and a jury found that Wyeth failed to provide adequate warning of the catastrophic risks of injecting Phenergan directly into a patient's vein.[61] The court also found that Levine's claim was not preempted because neither Wyeth nor the FDA had

51. *Id.* at 571.
52. *Id.*
53. *Id.* at 558–59.
54. *Id.*
55. *Id.* at 559.
56. *Id.*
57. *Id.* at 560.
58. *Id.* at 560–61.
59. *Id.*
60. *Id.* at 562 (noting that the FDA instructed Wyeth to keep the verbiage in its current label regarding intra-arterial injections).
61. *Id.* at 558.

paid more than "passing attention" to the question of increased IV push warnings.[62]

The Vermont Supreme Court affirmed, holding that Wyeth could have added increased warnings against IV push administration without prior FDA approval and noting that federal labeling requirements create a floor, not a ceiling, for state regulation.[63] Wyeth appealed to the U.S. Supreme Court, arguing that: (1) the FDA's drug labeling judgments preempt state law failure-to-warn claims alleging that different labels were necessary to make drugs reasonably safe for use and (2) recognition of such state law failure-to-warn claims creates an unacceptable obstacle to achieving the purposes of Congress by unjustly substituting a lay jury's decision for the expert judgment of the FDA.[64] Conflicting preemption rulings across the country,[65] coupled with the FDA's shifting position on the role of state tort law[66] persuaded the Court to grant Wyeth's petition for certiorari.[67]

2. Creating a Clear Evidence Standard

In a majority opinion written by Justice John Paul Stevens,[68] the Supreme Court rejected Wyeth's impossibility preemption defense, noting that the FDA's CBE regulation permitted Wyeth to supplement its IV push warnings without FDA approval.[69] The Court held that, "absent *clear evidence* that the FDA would not have approved a change to Phenergan's label," Levine's claims were not preempted.[70] The Court assumed that there is a presumption against preemption and held that Wyeth failed to meet the "demanding" impossibility preemption defense.[71] As part of its analysis, the Court noted that Wyeth failed to provide the FDA with an evaluation of the specific dangers of the IV push method or sufficient evidence that it attempted to add stronger warnings as required by state law but was prohibited from doing so by the FDA.[72] The Court emphasized that notwithstanding FDA approval, a "manufacturer[] bears responsibility for the content of its label at all times."[73]

Justice Stevens also rejected Wyeth's obstacle preemption defense because Levine's state law claims did not stand as an obstacle to Congress's

62. *Id.* at 563.
63. Levine v. Wyeth, 944 A.2d 179, 184 (Vt. 2006).
64. *Wyeth*, 555 U.S. at 563–64.
65. *See* Richard Ausness, *The Impact of* Wyeth v. Levine *on FDA Regulation of Prescription Drugs*, 65 FOOD & DRUG L.J. 247, 253–54 (2010).
66. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, and 601) (concluding that FDA approval of a drug's label preempts state laws imposing liability for negligent labeling).
67. *Wyeth*, 555 U.S. at 563.
68. Justice Stevens was joined by Justices Breyer, Ginsburg, Anthony Kennedy, and Souter. *Id.* at 556.
69. *Id.* at 568–69.
70. *Id.* at 571 (emphasis added).
71. *Id.* at 573.
72. *Id.* at 572–73.
73. *Id.* at 570–71.

purposes in the FDCA.[74] The Court held that the FDA's 2006 preamble did not merit deference because it conflicted with the purpose of Congress[75] and did not reflect the FDA's long-standing position that federal law serves as the floor for state regulation.[76] Justice Stevens also noted that the lack of a federal remedy or express preemption clause in the FDCA illustrated that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety.[77]

3. Concurring and Dissenting Opinions

While the clear evidence standard set by the majority appeared straightforward on its face, the other opinions issued in *Wyeth* illustrated the Justices' conflicting views about what constitutes impossibility preemption in the brand-name prescription drug context. The Justices' diverging understandings of statutory interpretation, separation of powers, and the role of federal agencies all led to vastly different conclusions about whether Levine's claims were preempted.

Although he joined the majority opinion, Justice Breyer wrote a separate concurrence acknowledging that federal regulations *could* preempt state tort law under certain circumstances, such as when state law interferes with the "FDA's desire to create a drug label containing a specific set of cautions and instructions"[78] or when the state law would force drug manufacturers to "raise prices to the point where those who are sick are unable to obtain the drugs they need."[79] Even so, Justice Breyer agreed with the majority that the 2006 preamble did not constitute such a regulation, and Levine's state law claims could proceed.[80]

Justice Thomas concurred in the judgment but wrote a separate opinion expressing concern that the court had approved "far-reaching implied pre-emption doctrines."[81] He argued that impossibility preemption analysis should turn on whether the text of state and federal laws contradict one another.[82] He also noted that a conflict may exist even if it is physically possible to comply with both laws, such as when a federal law creates a right (not a duty) to engage in particular behavior forbidden by state law.[83] In that case, an individual could comply with both federal and state law by refraining

74. *Id.* at 581.

75. *Id.* at 565 ("[T]he purpose of Congress is the ultimate touchstone in every preemption case." (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996))); *see also id.* at 577.

76. *Id.* at 577.

77. *Id.* at 575.

78. *Id.* at 582 (Breyer, J., concurring).

79. *Id.* (citing Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, *in* THE LIABILITY MAZE 334, 335–36 (Peter Huber & Robert E. Litan eds., 1991)).

80. *Id.*

81. *Id.* at 583 (Thomas, J., concurring in the judgment).

82. *Id.* (noting that "implied pre-emption doctrines that wander far from the statutory text are inconsistent with the Constitution").

83. *Id.* at 590.

from engaging in the behavior, even though the laws are contradictory.[84] Still, Justice Thomas concluded that the text of the FDCA did not preempt Levine's claims because Wyeth could have strengthened Phenergan's warnings under the CBE regulation, and the FDCA did not provide Wyeth with a right that state law rescinded.[85] Justice Thomas also rejected the majority's analysis of the purposes and objectives of Congress and argued that the majority's broad interpretation permitted courts to find preemption even where Congress has not expressly preempted state law and where the text of federal and state laws are not in conflict.[86]

Justice Alito dissented,[87] arguing that it was "demonstrably untrue" that Phenergan "labeling did not contain a specific warning about the risks of IV-push administration" when it was administered to Levine.[88] Justice Alito reasoned that the FDA had properly considered the risks and benefits of the IV push method and had repeatedly concluded that Phenergan was safe and effective.[89] He also noted that the majority's holding that a jury, rather than the FDA, holds the power to regulate warning labels for brand-name prescription drugs was incompatible with the Court's previous understanding of conflict preemption.[90] Justice Alito claimed that the majority opinion "commit[ted] both factual and legal errors,"[91] and that "faithful application of [the] Court's conflict preemption cases compels the conclusion that the FDA's 40-year-long effort to regulate the safety and efficacy of Phenergan preempts [Levine's] tort suit."[92]

C. The Aftermath of Wyeth

Following *Wyeth*, courts were forced to make their own determinations about what constitutes clear evidence that the FDA would have prohibited brand-name drug manufacturers from adding stronger warnings required by state law.[93] Not surprisingly, confusion surrounding this standard led to what some commentators regarded as "a hodgepodge of judicial opinions that have

84. *Id.*
85. *Id.* at 593.
86. *Id.* at 594.
87. Justice Alito was joined by Chief Justice Roberts and Justice Antonin Scalia. *Id.* at 604 (Alito, J., dissenting).
88. *Id.* at 619.
89. *Id.* at 609.
90. *Id.* (citing Geier v. Am. Honda Motor Co., 529 U.S. 861, 884–85 (2000)).
91. *Id.* at 612.
92. *Id.* at 610.
93. *See, e.g.*, Mason v. Smithkline Beecham Corp., 596 F.3d 387, 391 (7th Cir. 2010) ("The Supreme Court [in *Wyeth*] . . . did not clarify what constitutes 'clear evidence.'"); Rheinfrank v. Abbott Lab'ys, Inc., 119 F. Supp. 3d 749, 762 (S.D. Ohio 2015) (noting that the *Wyeth* court "did not define the 'clear evidence' standard, nor did it suggest the level of proof required"), *aff'd*, 680 F. App'x 369 (6th Cir. 2017); Dobbs v. Wyeth Pharm., 797 F. Supp. 2d 1264, 1270 (W.D. Okla. 2011) ("[A]pplication of the clear evidence standard is necessarily fact specific."); Reckis v. Johnson & Johnson, 28 N.E.3d 445, 457 (Mass. 2015) ("*Wyeth* did not define 'clear evidence.'").

reached varying results."[94] For example, in 2010, on the same record and concerning the same label, the Seventh Circuit and the Massachusetts Supreme Judicial Court reached opposite conclusions about whether or not defendants showed clear evidence that the FDA would have rejected a proposed label change to Children's Motrin.[95] Courts also split on whether *Wyeth* mandated a showing that the FDA had previously rejected the exact warning deficiency under consideration.[96] Some jurisdictions held that the clear evidence standard is satisfied when the FDA had previously rejected an identical label change,[97] while others held that such rejection was not critical to a successful preemption defense.[98] Courts also disagreed on whether the FDA's denial of a citizen petition or rejection of a different warning constituted clear evidence under *Wyeth*[99] and whether impossibility preemption questions were questions of law for a judge or questions of fact for a jury.[100]

One clear doctrine emerged after *Wyeth*: in *PLIVA, Inc. v. Mensing*,[101] the Supreme Court held that in the context of *generic* drugs—as opposed to brand-name drugs, like Phenergan in *Wyeth*—state law failure-to-warn claims are *always* preempted by federal regulations.[102] Regulation of generic drugs is covered not by the FDCA but by the Hatch-Waxman Act.[103] Under the latter statute, passed in 1984, generic drug manufacturers can gain FDA approval by showing equivalence to an FDA-approved brand-name drug.[104] Changes under the CBE regulation are not available for generic drug labels

94. Michael M. Gallagher, *Clear Evidence of Impossibility Preemption After* Wyeth v. Levine, 51 GONZ. L. REV. 439, 479 (2015).

95. *Compare* Robinson v. McNeil Consumer Healthcare, 615 F.3d 861, 869–70, 873 (7th Cir. 2010) (concluding there was "clear evidence" the FDA would have rejected a proposed warning change for Children's Motrin), *with Reckis*, 28 N.E.3d at 456–60 (reaching the opposite conclusion).

96. *See* Eric Lindenfeld, *Brand Name Preemption: The New Frontier in Pharmaceutical Product Liability Litigation*, 72 FOOD & DRUG L.J. 636, 636 (2017).

97. *See, e.g.*, Schedin v. Ortho-McNeil-Janssen Pharm., Inc., 808 F. Supp. 2d 1125, 1132 (D. Minn. 2011) ("[T]o trigger pre-emption, a brand-name manufacturer must show that the FDA would not have approved a proposed label change."), *aff'd in part, rev'd in part sub nom. In re* Levaquin Prods. Liab. Litig., 700 F.3d 1161 (8th Cir. 2012).

98. *See Dobbs*, 797 F. Supp. 2d at 1280 (holding that the defendant provided clear evidence that the FDA would have rejected a label change relating to increased suicide risk, despite the defendant having made no past attempts to add such warnings).

99. *See* Gallagher, *supra* note 94, at 465–68.

100. *Compare* S. Jersey Sanitation Co. v. Applied Underwriters Captive Risk Assurance Co., 840 F.3d 138, 143 (3d Cir. 2016) (holding that "preemption determinations are questions of law"), *with In re* Zofran (Ondansetron) Prods. Liab. Litig., 368 F. Supp. 3d 94, 120 (D. Mass. 2019) (holding that "preemption presents a question of fact").

101. 564 U.S. 604 (2011).

102. *See id.* at 609 (discussing failure-to-warn claims). *See generally* Mut. Pharm. Co. v. Bartlett, 570 U.S. 472 (2013) (extending *PLIVA*'s impossibility preemption analysis for generic manufacturers to design defect claims).

103. *See* Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S.C.).

104. *See id.* § 102, 98 Stat. 1592–93 (codified as amended at 21 U.S.C. § 355(j)(2)(A)); *PLIVA*, 564 U.S. at 613 (noting that generic drug manufacturers have a federal duty to copy brand name labels exactly).

because generic labels must be identical to their brand-name counterparts. Therefore, it is impossible for a generic manufacturer to unilaterally add or strengthen warnings without violating the FDCA.[105] While the Hatch-Waxman Act streamlined the process of generic drug approvals and has led to lower-cost drugs for consumers, the Supreme Court has "effectively immunized" generic drug manufacturers from state law liability.[106] Two years after *PLIVA*, the Court issued a similarly strong impossibility preemption ruling for a generic manufacturer in *Mutual Pharmaceutical Co. v. Bartlett*.[107]

Outside the context of generic drugs, however, it remains "exceedingly difficult to demonstrate that any consistent principle or explanatory variable emerges from the Supreme Court's products liability preemption jurisprudence."[108] This is especially problematic given the dramatic rise in federal product liability lawsuits against pharmaceutical manufacturers over the last several years. Between June 2018 and June 2019, 38,848 product liability lawsuits were filed against pharmaceutical companies in federal courts, almost tripling the amount of cases filed just five years ago.[109] Moreover, out of the sixty-seven pending products liability multidistrict litigation (MDL) proceedings today, twenty-three of them (over 34 percent) involve pharmaceuticals.[110] Persistent confusion among courts deciding these cases called for further Supreme Court intervention to clarify the preemption doctrine.

II. *MERCK SHARP & DOHME CORP. V. ALBRECHT*: AN END TO THE PREEMPTION MUDDLE?

In 2019, the Supreme Court revisited impossibility preemption in *Albrecht*.[111] *Albrecht* presented the Court with an opportunity to break its decade-long silence on how courts should interpret *Wyeth*'s clear evidence standard. Part II.A of this Note discusses the litigation leading up to the Supreme Court's decision. Part II.B examines Justice Breyer's majority opinion. Parts II.C and II.D explore Justice Thomas and Justice Alito's

105. *See generally Bartlett*, 570 U.S. 472; *PLIVA*, 564 U.S. 604.

106. *See* John C. P. Goldberg & Benjamin C. Zipursky, *The Supreme Court's Stealth Return to the Common Law of Torts*, 65 DEPAUL L. REV. 433, 454 (2016).

107. 570 U.S. 472 (2013).

108. Catherine M. Sharkey, *Products Liability Preemption: An Institutional Approach*, 76 GEO. WASH. L. REV. 449, 454 (2008).

109. *See Table C-2—U.S. District Courts–Civil Statistical Tables for the Federal Judiciary (June 30, 2019)*, U.S. CTS., https://www.uscourts.gov/statistics/table/c-2/statistical-tables-federal-judiciary/2019/06/30 [https://perma.cc/7QKY-5HUP] (last visited June 22, 2020); *see also Table C-2—U.S. District Courts–Civil Judicial Business (September 30, 2015)*, U.S. CTS., https://www.uscourts.gov/statistics/table/c-2/judicial-business/2015/09/30 [https://perma.cc/TRL9-QAGY] (last visited June 22, 2020) (stating that 13,939 product liability suits were commenced in 2014).

110. *See* U.S. JUD. PANEL ON MULTIDISTRICT LITIG., MDL STATISTICS REPORT—DISTRIBUTION OF PENDING MDL DOCKETS BY DISTRICT 1–4 (2019), https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDLs_by_District-November-19-2019.pdf [https://perma.cc/XV47-PA6J].

111. 139 S. Ct. 1668 (2019).

concurring opinions, which, as in *Wyeth*, illustrate the Justices' conflicting views on preemption and provide crucial insight for lower courts tasked with deciding preemption defenses. Finally, Part II.E identifies three interpretive issues arising from the *Albrecht* majority that must be resolved to ensure a uniform doctrine.

A. The Fosamax Litigation

Beginning in 2011, Merck Sharp & Dohme Corporation ("Merck") began to face what would ultimately become over a thousand lawsuits relating to Fosamax, its bisphosphonate osteoporosis drug for postmenopausal women.[112] Plaintiffs in these cases alleged that Fosamax caused them to suffer atypical femoral fractures and that Merck's FDA-approved Fosamax label failed to adequately warn of the risk of these fractures.[113] More than 260 of these cases are still pending in federal court today as part of an MDL.[114] A complete understanding of the *Albrecht* decision requires a review of the drug's label and the litigation leading up to the Supreme Court's decision.

1. The Evolution of the Fosamax Label

When the FDA approved Fosamax for the treatment of osteoporosis in postmenopausal women in 1995, it did not require Merck to include warnings about bone fractures.[115] However, letters, meeting minutes, and internal memoranda reveal that Merck knew as early as 1990 that continuous use of Fosamax could make bones susceptible to serious deficiencies and certain types of fractures.[116] Between 1990 and 2008, case studies and reports shared with Merck revealed a possible connection between bisphosphonate use and atypical femoral fractures.[117] A particularly striking example occurred in 2005, when Merck received a report from Dr. Joseph Lane, a renowned expert in metabolic bone disorders such as osteoporosis.[118] Dr. Lane's report stated that 100 percent of his patients who were prescribed Fosamax experienced atypical femoral fractures.[119] In fact, doctors at Lane's

112. The Fosamax lawsuits include two MDLs and a multicounty litigation (MCL). The second Fosamax MDL will be the focus of this Note. There were 269 active cases in this MDL as of July 16, 2020. U.S. JUD. PANEL ON MULTIDISTRICT LITIG., MDL STATISTICS REPORT—DISTRIBUTION OF PENDING MDL DOCKETS BY ACTIONS PENDING 1 (2020), https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_Actions_Pending-July-16-2020.pdf [https://perma.cc/4SD9-5CJP] [hereinafter JULY 2020 MDL STATISTICS REPORT].

113. *Albrecht*, 139 S. Ct. at 1675.

114. *See* JULY 2020 MDL STATISTICS REPORT, *supra* note 112, at 1.

115. Brief for Respondents at 11, *Albrecht*, 139 S. Ct. 1668 (No. 17-290).

116. Joint Appendix (Volume I of II) at 100, *Albrecht*, 139 S. Ct. 1668 (No. 17-290).

117. *Id.* at 125–26.

118. Brief of Amici Curiae Joseph Lane, M.D., and Vincent Vigorita, M.D., in Support of Respondents at 2–3, *Albrecht*, 139 S. Ct. 1668 (No. 17-290) [hereinafter Lane and Vigorita Brief].

119. *Id.* at 18; *see also id.* at 3 (noting that no fewer than twenty-five patients taking Fosamax suffered from atypical femoral fractures).

hospital referred to these fractures as "Fosamax fractures."[120] Dr. Lane noted that his patients' injuries were not typical stress fractures and emphasized that his patients taking Fosamax were experiencing fractures that orthopedic physicians had not previously seen.[121]

Although Merck was aware of these studies and claimed to have kept the FDA informed of all relevant information,[122] it is unclear if Merck revealed the true nature of the problem to the agency.[123] Merck informed the FDA of studies concerning "stress fractures" but did not specify that the femoral fractures at issue were distinct from typical stress fractures.[124] In June 2008, the FDA alerted Merck that it was "aware of reports regarding" atypical femoral fractures in patients using bisphosphonates, citing several of the key articles written on the issue.[125] To address "concern[s] about this developing safety signal," the FDA requested that Merck submit its own investigative reports on the connection between Fosamax and femoral fracture risks.[126] After submitting its materials, Merck requested a PAS label change in 2008.[127] The proposed label change added mentions of fractures to both the "Warnings and Precautions" and "Adverse Reactions" sections of the Fosamax label.[128] Merck proposed referencing "'low-energy femoral shaft fracture[s]' in the Adverse Reactions section, and cross-referencing a longer discussion" of the fractures in the warnings and precautions section.[129] Under current federal regulations, warnings and precautions labels must describe "clinically significant adverse reactions," including any that are "serious even if infrequent."[130] Adverse reactions labels must describe "the overall adverse reaction profile of the drug based on the entire safety database," including a list of all "undesirable effect[s] reasonably associated with use of a drug."[131]

While the first sentence of Merck's proposed warning and precautions label stated, "[l]ow-energy fractures of the subtrochanteric and proximal femoral shaft have been reported in a small number of bisphosphonate-

120. *Id.* at 15.
121. *Id.*
122. *See* Brief for Petitioner at 8, *Albrecht*, 139 S. Ct. 1668 (No. 17-290) (noting that Merck brought the fracture considerations to the FDA's attention throughout the 1990s and that in "2008, Merck provided the FDA with a periodic safety update that included over 30 pages of information regarding these fractures").
123. Joint Appendix (Volume I of II), *supra* note 116, at 143 ("In my opinion, it appears that Merck was attempting to confound the true nature of the association between Fosamax and [atypical femoral fractures] by identifying numerous potential risk factors, very few of which were actually grounded in the available data.").
124. *See* Lane and Vigorita Brief, *supra* note 118, at 1 ("Stress fractures are radiographically and symptomatically different from atypical femur fractures associated with long-term use of Fosamax.").
125. Joint Appendix (Volume I of II), *supra* note 116, at 280–81.
126. *Id.* at 280.
127. Brief for Respondents, *supra* note 115, at 11.
128. *Id.* at 11–12.
129. Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1674 (2019).
130. 21 C.F.R. § 201.57(c)(6)(i) (2019).
131. *Id.* § 201.57(c)(7).

treated patients," the remainder of the proposed warning referred to the fractures as "stress fractures."[132] The proposed label also noted: "The number of reports of this condition is very low, and *stress fractures with similar clinical features* also have occurred in patients not treated with bisphosphonate."[133] According to Merck, it was "not possible . . . to establish whether treatment with [Fosamax] increase[d] the risk of [femoral fractures]," but Merck found it "important to include an appropriate statement about them in the product label" because of the temporal association between these fractures and bisphosphonate use.[134]

In 2009, the FDA sent Merck a "'Complete Response' letter," granting in part and denying in part Merck's application.[135] The FDA approved the addition of "'low energy femoral shaft and subtrochanteric fractures' to the Adverse Reactions section" because "'there is some basis to believe' Fosamax causes those fractures."[136] However, the FDA ultimately found that Merck's justification for elevating the warning to the warnings and precautions section was "inadequate," because "[d]iscussion of the risk factors for stress fractures is not warranted and is not adequately supported" by evidence.[137] The FDA offered Merck an opportunity to "resubmit" its application and to "fully address" the Fosamax deficiencies.[138] Instead, Merck withdrew its PAS application, added the approved femoral fracture language to the adverse reactions label through the CBE process, and did not resubmit its warnings and precautions label application or attempt to add further atypical femoral fracture language to the Fosamax label.[139]

In March 2010, the FDA announced it was working with an outside task force to gather information on the risk of femoral fractures because data submitted by Merck and other manufacturers did "not show[] a clear connection between bisphosphonate use and a risk of atypical subtrochanteric femur fractures."[140] In October 2010, based on the task force's report, the FDA required all bisphosphonate manufacturers to add the risk of atypical femoral fractures to the warnings and precautions sections of drugs' labels, because "these atypical fractures may be related to long-term . . . bisphosphonate use."[141] After this label change was mandated, hundreds of plaintiffs filed state law failure-to-warn suits claiming they were injured because of Merck's concealment of the Fosamax fracture risk between 1995 and 2010.[142]

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132. Brief for Respondents, *supra* note 115, at 12.
133. *Id.*
134. Joint Appendix (Volume II of II) at 478, *Albrecht*, 139 S. Ct. 1668 (No. 17-290).
135. Brief for Respondents, *supra* note 115, at 15.
136. *Id.* at 15–16 (quoting 21 C.F.R § 201.57(c)(7)).
137. *Id.* at 16.
138. Joint Appendix (Volume II of II), *supra* note 134, at 512.
139. Brief for Respondents, *supra* note 115, at 16.
140. Joint Appendix (Volume II of II), *supra* note 134, at 519.
141. Joint Appendix (Volume I of II), *supra* note 116, at 246–47.
142. *In re* Fosamax (Alendronate Sodium) Prods. Liab. Litig., 852 F.3d 268, 271 (3d. Cir. 2017) ("Beginning in 2010, hundreds of plaintiffs filed personal-injury suits against the drug manufacturer Merck Sharp & Dohme, alleging that the osteoporosis drug Fosamax caused

2. Procedural History

In 2011, the failure-to-warn actions against Merck involving atypical femoral fractures were consolidated as an MDL in the District of New Jersey and several cases were selected for trial.[143] Just as Wyeth had argued ten years earlier, Merck claimed that plaintiffs' state law failure-to-warn claims were preempted by FDA regulations.[144] Merck argued that the FDA's rejection of its PAS submission for an increased warning against "stress fractures" in the warning and precautions section of the Fosamax label demonstrated that the FDA would not have approved a label concerning atypical femoral fractures.[145]

The first bellwether trial involved Bernadette Glynn, a patient who took Fosamax from 2002 to 2009 and suffered from an atypical femoral fracture that required surgical repair in 2009.[146] Glynn claimed that her use of Fosamax caused this fracture.[147] To ensure that any and all facts relevant to preemption would appear on the record, the judge deferred a ruling on the preemption issue until after the jury made its decision.[148]

In June 2013, after considering the parties' additional briefing, evidence, arguments, and the trial record, the district court dismissed Glynn's claim based on federal preemption, holding that under *Wyeth*, clear evidence existed that "the FDA would not have approved a stronger warning to the Precautions section of the [Fosamax] label."[149] To show that no label change would have been accepted, the district court relied on: the FDA's rejection of the warnings Merck proposed for the warnings and precautions section of the Fosamax label, the FDA's response letter to Merck cautioning that stronger warnings could make Fosamax "misbranded," and the fact that the FDA never required Merck to submit new language or a different label change.[150] After the dismissal, Merck moved for an order to show cause why the claims of all other plaintiffs with injuries prior to the date of Glynn's injury should not also be dismissed pursuant to the court's preemption ruling.[151] The district court agreed and entered summary judgment for Merck.[152]

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them to suffer serious thigh bone fractures."), *vacated sub nom.* Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019).

143. *In re* Fosamax (Alendronate Sodium) Prods. Liab. Litig., 951 F. Supp. 2d 695, 697 (D.N.J. 2013), *vacated*, 852 F.3d 268 (3d Cir. 2017), *vacated sub nom. Albrecht*, 139 S. Ct. 1668.

144. *Id.* at 702.

145. *Id.* at 703.

146. *In re* Fosamax (Alendronate Sodium) Prods. Liab. Litig., No. 11-5304, 08-08, 2013 WL 1558697, at *2 (D.N.J. Apr. 11, 2013).

147. *Id.* at *7.

148. *In re* Fosamax (Alendronate Sodium): Prods. Liab. Litig., MDL No. 2243, No. 11-5304, 08-08, 2014 WL 1266994, at *5 (D.N.J. Mar. 26, 2014), *vacated*, 852 F.3d 268 (3d. Cir. 2017).

149. *See In re Fosamax*, 951 F. Supp. 2d at 700.

150. *Id.* at 703–04.

151. *See In re Fosamax*, 2014 WL 1266994, at *1.

152. *See id.* at *17.

Merck's victory was short-lived. Consumers of Fosamax appealed, and the Third Circuit vacated and remanded, holding that *Wyeth* required a heightened "clear and convincing" standard of proof[153] and that plaintiffs had "produced sufficient evidence for a reasonable jury to conclude that the FDA would have approved a properly-worded warning about the risk of thigh fractures—or at the very least, to conclude that the odds of FDA rejection were less than highly probable."[154] The Third Circuit also rejected Merck's claim that preemption questions should be decided by judges rather than juries.[155]

Merck petitioned the Supreme Court, "ask[ing] the Court to decide whether Merck's case and others like it 'must . . . go to a jury' to determine whether the FDA, in effect, has disapproved a state-law-required labeling change."[156] The Supreme Court granted certiorari.[157]

B. Justice Breyer's Opinion for the Court

The Supreme Court ruled 9-0 that the availability of the impossibility preemption defense is a question of law to be decided by the judge, not the jury.[158] In an opinion by Justice Breyer,[159] the Supreme Court promptly rejected the Third Circuit's analysis and remanded the case back to the Third Circuit.[160]

The decisive question before the Court was whether impossibility preemption defenses should be decided by judges as a matter of law.[161] The Court unanimously held that preemption is a question of law for judges to decide.[162] The Court reasoned that judges are "better equipped" than juries "to evaluate the nature and scope of an agency's determination" and "to interpret agency decisions in light of the governing statutory and regulatory context."[163] The Court also noted that deciding preemption questions as a matter of law would lead to "greater uniformity," which is especially important when questions involve "the scope and effect of federal agency

153. *In re* Fosamax (Alendronate Sodium) Prods. Liab. Litig., 852 F.3d 268, 285 (3d. Cir. 2017), *vacated sub nom.* Merck Sharpe & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019).
154. *Id.* at 271.
155. *Id.* at 290.
156. *See Albrecht*, 139 S. Ct. at 1676; *see also* Petition for Writ of Certiorari at 14, *Albrecht*, 139 S. Ct. 1668 (No. 17-290) ("This petition is the ideal vehicle in which to lay down a legal marker for when a failure-to-warn claim *is* properly preempted in the branded drug context, and thus revive the preemption defense that courts since [*Wyeth*] have narrowed virtually out of existence.").
157. Merck Sharpe & Dohme Corp. v. Albrecht, 138 S. Ct. 2705 (2018).
158. *Albrecht*, 139 S. Ct. at 1680–81.
159. Justices Ginsburg, Gorsuch, Sotomayor, and Thomas joined in the opinion. *Id.* at 1671.
160. *Id.* at 1680–81.
161. *Id.* at 1679–80.
162. *Id.* at 1679.
163. *Id.* at 1680.

action."[164] Justice Breyer noted that even if factual determinations need to be made, the "'better positioned' decisionmaker is the judge."[165]

As part of its analysis, the Court accepted the opportunity to "elaborate *Wyeth*'s requirements along the way."[166] Although this analysis was not directly connected to the question before the Court, and could be considered dicta, uncertainty surrounding the correct application of *Wyeth* was a major reason for the Court granting certiorari.[167] Therefore, Justice Breyer's analysis of *Wyeth* is a crucial part of the Court's opinion, and the framework Justice Breyer lays out must be followed by courts deciding future impossibility preemption defenses.

The Court noted that in cases comparable to *Wyeth*,

> "clear evidence" is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law, and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning.[168]

The Court stated that these conclusions "flow from . . . precedents on impossibility preemption and the . . . regulatory scheme that we reviewed in *Wyeth*."[169] The Court also clarified that this definition of clear evidence is not a heightened evidentiary standard but simply a requirement that the court consider "whether the relevant federal and state laws 'irreconcilably conflic[t].'"[170]

The Court also elaborated on *Wyeth*'s discussion of CBE regulations, noting that these regulations "permit[] drug manufacturers to change a label to 'reflect newly acquired information' if the changes 'add or strengthen a . . . warning' for which there is 'evidence of a causal association'" without prior FDA approval.[171] While the FDA can ultimately reject CBE submissions if manufacturers cannot show a change is based on reasonable evidence, CBE regulations permit changes in the interim. Thus, a manufacturer "will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both."[172]

Lastly, the Court noted that because the Supremacy Clause only gives "supreme" status to "the *Laws* of the United States,"[173] "pre-emption takes place 'only when and if [the agency] is acting within the scope of its congressionally delegated authority.'"[174] The Court provided several

164. *Id.*
165. *Id.* (quoting Markman v. Westview Instruments, Inc., 517 U.S. 370, 388 (1996)).
166. *Id.* at 1676.
167. *Id.* ("In light of differences and uncertainties among the courts of appeals and state supreme courts in respect to the application of *Wyeth*, we granted certiorari.").
168. *Id.* at 1672.
169. *Id.* at 1678.
170. *Id.* at 1679 (alteration in original) (quoting Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982)).
171. *Id.* (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A) (2019)).
172. *Id.*
173. *Id.* (quoting U.S. CONST. art. VI, cl. 2).
174. *Id.* (quoting New York v. FERC, 535 U.S. 1, 18 (2002)).

examples of actions that fall under this authority, including notice and comment rulemaking, formal rejection of a warning label that would have been adequate under state law, "or . . . other agency action carrying the force of law."[175]

Although Justice Breyer's opinion suggested that Merck's preemption defense failed because of the availability of CBE label changes, the Court did not answer the preemption question. Instead, Justice Breyer remanded the case to the Third Circuit to fully consider the clarified standards outlined in the opinion and to treat the preemption question as one of law rather than fact.[176] It is also possible that the Court remanded the case because it was not clear that enough Justices would reach the same conclusion about whether or not Merck's preemption defense could succeed. Although the judgment was unanimous, just as in *Wyeth*, the concurring opinions in *Albrecht* demonstrate enduring divides concerning how preemption principles apply in this context.[177]

C. Justice Thomas's Concurrence

Although he concurred in the judgment, Justice Thomas explained in a separate opinion that Merck's preemption defense should fail as a matter of law.[178] Justice Thomas remained skeptical of impossibility preemption as the best test for determining whether a conflict exists between state and federal law.[179] As in *Wyeth*, he relied on the "original meaning" of the Supremacy Clause to argue that preemption questions should be based on whether state and federal law are in "logical contradiction."[180] Nevertheless, Justice Thomas argued that Merck's defense failed under either evaluation.[181] Thomas found that state and federal law were not in logical contradiction because FDA approval does not shield a drug from being deemed unsafe by later federal action or the application of state law.[182] Justice Thomas also argued it was not impossible for Merck to comply with both state and federal law because "Merck point[ed] to no statute, regulation, or other agency action with the force of law that would have prohibited it from complying with its alleged state-law duties."[183] He went further than the majority and concluded that the FDA's 2009 response letter and other agency communications suggesting the FDA *would have* denied a future label change were insufficient to preempt plaintiffs' claims because "hypothetical agency action is not 'Law,'" and "Merck's belief that the FDA

175. *Id.*
176. *Id.* at 1680–81.
177. *See infra* Parts II.C, II.D.
178. *Albrecht*, 139 S. Ct. at 1681 (Thomas, J., concurring) ("[E]ven under our impossibility precedents, Merck's pre-emption defense fails.").
179. *Id.*
180. *Id.*
181. *Id.* at 1681–82.
182. *Id.*
183. *Id.* at 1683–84.

would have eventually rejected a CBE application does not make an earlier CBE change impossible."[184]

D. Justice Alito's Concurrence

Justice Alito, joined by Chief Justice Roberts and Justice Kavanaugh, also concurred in the judgment, agreeing that impossibility preemption is a question of law.[185] However, unlike Justice Thomas, Justice Alito argued that Merck's preemption defense would likely *succeed* on remand.[186] Justice Alito worried that the majority provided a "skewed summary" of the law that would mislead lower courts deciding preemption defenses.[187] In particular, Justice Alito noted that a statutory provision enacted after the underlying events in *Wyeth* might impact the Third Circuit's preemption analysis on remand.[188] Under 21 U.S.C. § 355(o)(4)(A), the FDA has a duty to initiate a label change "[i]f the Secretary becomes aware of new information . . . that the Secretary determines should be included in the labeling of the drug."[189] Because the FDA has the burden to take action under these circumstances, FDA inaction may be sufficient to establish that it disapproved of additional warnings.[190] As Justice Alito noted, this mechanism does not "require the FDA to communicate to the relevant drug manufacturer that a label change is unwarranted; instead, the FDA could simply consider the new information and decide not to act."[191]

Justice Alito also noted that the majority made no mention of the possibility that the FDA would have accepted a PAS application instead of a CBE supplement where significant questions exist as to whether to modify existing labeling.[192] Justice Alito agreed with Justice Breyer that *Wyeth*'s use of the phrase "'clear evidence' was merely a rhetorical flourish" and did not espouse a heightened evidentiary standard.[193]

Lastly, Justice Alito's concurrence illustrates factual disputes among the Justices. Justice Alito criticized the majority's "one-sided account," noting that the FDA was aware of the atypical femoral fracture issue for years, regularly communicated with Merck about these risks, and studied all relevant information before instructing healthcare professionals and patients to continue using Fosamax.[194] Justice Alito noted that the FDA itself has taken the position that its "decision not to require a label change prior to [conducting its own analysis] reflected the FDA's 'determin[ation]' that a

184. *Id.* at 1683.
185. *Id.* at 1684 (Alito, J., concurring in the judgment).
186. *Id.* at 1684–85.
187. *Id.*
188. *Id.*
189. *Id.* at 1684.
190. *See generally* Douglas G. Smith, *A Shift in the Preemption Landscape?*, 87 TENN. L. REV. 213 (2019).
191. *Albrecht*, 139 S. Ct. at 1684 (Alito, J., concurring in the judgment).
192. *Id.* at 1685.
193. *Id.*
194. *Id.*

new warning" should not be added to the drug's label.[195] According to Justice Alito, state law failure-to-warn claims are preempted if the FDA "simply consider[ed] the new information and decid[ed] not to act"[196] because federal agencies are entitled to a "presumption" that they properly follow federal law.[197]

E. Interpretive Issues Raised by Justice Breyer's Framework

The three opinions in *Albrecht* highlight that, despite the Court's unanimous judgment, members of the Court hold divergent views on the powers of the administrative state and the role of judicial scrutiny in federal preemption cases.[198] While the majority chose not to answer the preemption question, Justice Thomas argued that Merck's impossibility preemption defense should fail as a matter of law,[199] and Justice Alito was convinced that Merck's preemption defense should succeed.[200] Lower courts tasked with applying the preemption framework outlined by Justice Breyer can use the concurring opinions to inform their analysis when determining whether defendant-manufacturers have satisfied *Wyeth*'s clear evidence requirement. When viewed collectively, the opinions in *Albrecht* and the preemption case law following *Wyeth* generate several questions about Justice Breyer's framework.

Three core interpretative issues arise from Justice Breyer's opinion. To succeed on an impossibility preemption defense, defendants must know: (1) what it means for a brand-name drug manufacturer to "fully inform[]"[201] the FDA, (2) what it means for federal and state law to "irreconcilably conflic[t],"[202] and (3) what agency actions are included in the FDA's "congressionally delegated authority."[203] Courts must agree on the answers to these questions in order to decide preemption defenses as a matter of law. This is no easy task. The fact that the Supreme Court remanded the case, rather than simply reinstating the district court's original holding, only highlights the difficulty of convergence on application. The Third Circuit recently remanded the case back to the district court, tasking the district court judge with deciding whether state law claims are preempted in the remaining Fosamax lawsuits.[204]

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195. *Id.*
196. *Id.* at 1684.
197. *See id.*; *see also* United States v. Chem. Found., Inc., 272 U.S. 1, 14–15 (1926) ("[I]n the absence of clear evidence to the contrary, courts presume that [federal agencies] have properly discharged their official duties.").
198. *See supra* Parts II.A–II.C.
199. *See Albrecht*, 139 S. Ct. at 1681–82 (Thomas, J., concurring).
200. *See id.* at 1684–85 (Alito, J., concurring in the judgment).
201. *Id.* at 1672 (majority opinion).
202. *Id.* at 1679.
203. *Id.*
204. Order, *In re*: Fosamax (Alendronate Sodium) Prods. Liab. Litig., Nos. 14-1900 et al., MDL No. 2243, at 1 (3d Cir. Nov. 25, 2019) [hereinafter Remand Order] ("[T]hese cases shall be remanded to the District Court . . . to determine in the first instance whether the plaintiffs'

III. HOW SHOULD LOWER COURTS IMPLEMENT JUSTICE BREYER'S FRAMEWORK?

Part III addresses the gaps left by Justice Breyer's clear evidence framework. Part III.A discusses what it means for a defendant-manufacturer to "fully inform[] the FDA of the justifications for the warning required by state law"[205] by looking at impossibility preemption jurisprudence since *Wyeth* and exploring the relationship between impossibility preemption and fraud-on-the-agency claims. Part III.B examines what it means for state and federal laws to irreconcilably conflict by analyzing how the adequacy of proposed label changes and the broad scope of the CBE regulation impact defendants' abilities to comply with both state and federal law. Finally, Part III.C explores the scope of the FDA's congressionally delegated authority by looking at which agency actions have been held to carry the force of law.

A. The Meaning of the "Fully Informed" Requirement

A major piece of Justice Breyer's definition of clear evidence is evidence that shows the court that the drug manufacturer *fully informed* the FDA of the reasons for the warning required by state law and that the FDA, in response to this information, informed the manufacturer that the FDA would not approve a change to the drug's label to include such a warning.[206]

1. Applicability of the Fully Informed Requirement

First, courts must decide when the duty to fully inform the FDA applies. The Supreme Court prefaced the clear evidence requirement with the language "in a case like *Wyeth*."[207] The Tenth Circuit has interpreted this language to mean that a drug manufacturer's duty to fully inform the FDA only applies to cases involving *Wyeth*'s particular circumstances.[208] Under this narrow view, defendants are only required to show clear evidence that the FDA was fully informed of justifications for warnings required by state law when a proposed label change is in dispute, as in *Wyeth* and *Albrecht*.[209] In *Cerveny v. Aventis*,[210] the Tenth Circuit held that the FDA's rejection of a citizen petition, rather than a proposed label change, did not require the defendant-manufacturer to show that it had fully informed the FDA under the clear evidence analysis and that, given this full information, the FDA would have rejected a unilateral label change, as in *Wyeth*.[211]

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state law claims are preempted by federal law under the standards described by the Supreme Court in its opinion.") .

205. *Albrecht*, 139 S. Ct. at 1678.

206. *Id.* at 1672.

207. *Id.* at 1678.

208. *See* Cerveny v. Aventis, Inc., 783 F. App'x 804, 808 n.9 (10th Cir. 2019) (noting that because "Aventis argues a different ground [than Wyeth] to show that the FDA would have rejected the Cervenys' proposed warning . . . Aventis is not left to show clear evidence that the FDA would have rejected any unilateral label change under the CBE regulation").

209. *See supra* Parts I–II.

210. 783 F. App'x 804 (10th Cir. 2019).

211. *See id.* at 808 n.9.

Despite the Tenth Circuit's view, plaintiffs will likely argue that courts should adopt a broader understanding of "a case like *Wyeth*" to include situations where the FDA was "fully informed" by someone other than the defendant, such as by a third-party in a citizen petition.[212] That is exactly what the plaintiffs argued in *Cerveny*.[213] However, the Tenth Circuit's swift rejection of this "key difference" between *Cerveny* and *Wyeth* shows that courts may be predisposed to adopt a restricted understanding of what triggers the clear evidence requirement.[214] While this reading of the clear evidence framework will restrain the viability of state law failure-to-warn claims, neither *Albrecht* nor *Wyeth* involved a citizen's petition or other third-party method of informing the FDA, so it is unlikely that the Supreme Court intended the doctrine to extend outside of the proposed warning context.

2. Ways to Satisfy the Fully Informed Requirement

After establishing *when* defendants must fully inform the FDA, it must be decided *how* they can do so. As the Third Circuit noted, some courts "have decided preemption cases by simply treating the facts of *Wyeth* as a yardstick: if the evidence for FDA rejection in a given case is less compelling than the manufacturer's evidence in *Wyeth* . . . the manufacturer's preemption defense fails."[215] Other courts have "exhaustively survey[ed] the post-*Wyeth* case law and . . . test[ed] the facts of a particular case against prior decisions."[216] Because neither approach "clarifies or builds out"[217] the impossibility preemption doctrine, courts deciding impossibility preemption defenses must instead adopt a uniform understanding of what it means to "fully inform[] the FDA of the justifications for the warning required by state law."[218] Without such uniformity, Justice Breyer's framework cannot alert potential defendants of what to provide the FDA in order to avoid state law tort liability and cannot instruct lower court judges tasked with deciding preemption defenses as a matter of law. Prior Supreme Court jurisprudence and the concurring opinions in *Albrecht* offer important clues to address this inquiry.

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212. An FDA citizen petition is a vehicle for individuals and organizations to request that the FDA make changes to health policy, such as removing a drug from the market or altering a drug's label. *See* 21 U.S.C. § 355(q); *see also* Michelle Yearly, *Tenth Circuit Finally Shuts the Door Completely on* Cerveny, DRUG & DEVICE L. BLOG (Aug. 20, 2019), https://www.druganddevicelawblog.com/2019/08/tenth-circuit-finally-shuts-the-door-completely-on-cerevny.html [https://perma.cc/6E99-XBB3].

213. *Cerveny*, 783 F. App'x at 808 n.9 ("Specifically, [plaintiffs] contend that *Albrecht* 'dictates that only labeling changes *sought by the manufacturer* can lead to preemption,' and that '[the defendant] never sought the changes proposed by the [plaintiffs].'" (emphasis added) (quoting Letter from Adam S. Davis, Couns. for Plaintiffs/Appellants, to Elisabeth Shumaker, Clerk of U.S. Ct. of Appeals for the Tenth Cir. 1 (May 28, 2019))).

214. *Id.* ("We see nothing in *Wyeth* or *Albrecht* excluding Aventis from justifying preemption on this basis.").

215. *In re* Fosamax (Alendronate Sodium) Prods. Liab. Litig., 852 F.3d 268, 284 (3d. Cir. 2017), *vacated sub nom.* Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019).

216. *Id.*

217. *Id.*

218. *Albrecht*, 139 S. Ct. at 1678.

a. What Does Not Fully Inform the FDA?

Deciphering what fully informs the FDA requires analyzing what the Supreme Court and lower courts applying *Wyeth* and its progeny have determined falls short of this requirement. For example, in *Wyeth*, the Court held that Wyeth failed to fully inform the FDA because it failed to provide the agency with "an evaluation or analysis concerning the specific dangers posed by the IV-push method."[219] More recently, federal courts have found that the FDA's failure to mandate a warning does not show that the manufacturer fully informed the FDA because a manufacturer always remains responsible for the contents of its label.[220] Post-*Albrecht*, one state court has held that, in "misbranding avoidance" cases like *Wyeth*, defendants cannot claim they have fully informed the FDA unless they "have fully disclosed the need for the additional warning, only to be met with FDA refusal."[221]

The *Albrecht* concurrences provide further insight as to what does not satisfy this information requirement. Justice Thomas noted that Merck's preemption defense should fail as a matter of law because it offered "no statute, regulation, or other agency action with the force of law that would have prohibited it from complying with its alleged state-law duties."[222] Justice Alito, however, argued that the FDA's "extensive communication with Merck during the relevant period" demonstrated that the agency was fully informed of the risks of Fosamax and nonetheless determined that a label change was unnecessary until the FDA conducted its own analysis in 2010.[223]

On remand, the district court must resolve this factual dispute and decide whether Merck's correspondence provided the FDA with all relevant information about the justifications for state law warnings regarding atypical femoral fractures.

b. Does Evidence the FDA Previously Accepted Suffice?

Courts must also discern whether *Albrecht* enables plaintiffs to argue that evidence that the FDA previously accepted as adequate fails to fully inform the agency. This is especially relevant to Justice Gorsuch's "moral hazard" concern that brand-name drug manufacturers will attempt to "inform" the FDA by flooding the agency with so much information that it becomes

219. Wyeth v. Levine, 555 U.S. 555, 573 (2009).

220. *See* Mason v. Smithkline Beecham Corp., 596 F.3d 387, 396 (7th Cir. 2010) (holding that the FDA's inaction in failing to mandate a warning about a drug's risk of suicide does not show that defendant provided "clear evidence that the FDA would have rejected a label change warning about the risk of suicide by young adults").

221. A.Y. v. Janssen Pharm. Inc., 224 A.3d 1, 16–17 (Pa. Super. Ct. 2019) (holding that the defendant "did not make such a showing of full disclosure to the FDA during the relevant time").

222. *Albrecht*, 139 S. Ct. at 1683–84 (Thomas, J., concurring).

223. *Id.* at 1685 (Alito, J., concurring in the judgment).

impossible for agency officials to adequately understand a drug's risks.[224] Information accompanying proposed label changes should not contain false information or be crafted in the hopes that a proposed label will be rejected, thereby shielding manufacturers from future state law failure-to-warn claims.

In *Buckman Co. v. Plaintiffs' Legal Committee*,[225] the Supreme Court held that a private plaintiff's fraud claim predicated on a defendant's fraudulent violation of FDA reporting requirements was impliedly preempted by the FDCA because such claims "inevitably conflict with the FDA's responsibility to police fraud."[226] Armed with this holding, defendant-manufacturers have successfully argued that strict limitations on fraud-on-the-agency claims preclude plaintiffs from arguing that the FDA's basis for rejecting or accepting a label change was insufficient.[227] State law tort claims based on speculative arguments about what the FDA or a defendant-manufacturer could have done differently have also been held preempted.[228]

Applying *Buckman* broadly, some courts have held that *any* state law claims based on a defendant's communications with the FDA are preempted.[229] The district court in the Fosamax litigation adopted such a broad interpretation, holding that plaintiffs' claims that Merck intentionally withheld information related to atypical femoral fractures could not proceed.[230] Although the *Buckman* issue in the Fosamax litigation was not

224. *See* Transcript of Oral Argument, *supra* note 1, at 13.

225. 531 U.S. 341 (2001).

226. *Id.* at 350.

227. *See, e.g.*, D.W.K, Jr. v. Abbott Lab'ys, Inc. (*In re* Depakote), 87 F. Supp. 3d 916, 922 (S.D. Ill. 2015) (holding that plaintiff's claim that defendant "deliberately omitted" information from FDA submissions was "unavailing" to prevent preemption); *In re* Incretin Mimetics Prods. Liab. Litig., No. 13md2452, 2014 WL 4987877, at *2 (S.D. Cal. Oct. 6, 2014) ("[P]laintiffs' assertions that there are 'reasons to believe [pancreatic] cancers were not correctly reported and were under-reported' and that information was 'withheld by Defendants from the FDA' are fraud-on-the-FDA claims expressly preempted by *Buckman*."); *In re* Baycol Prods. Litig., 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007) (holding that "any evidence offered only to show that the FDA was misled or that evidence was intentionally concealed from the FDA would be excluded" under *Buckman*).

228. *See, e.g.*, Willis v. Abbott Lab'ys, No. 15-cv-00057, 2017 WL 5988215, at *8 (W.D. Ky. Dec. 1, 2017) ("[A]ny speculation as to what the FDA may have done had [the defendant-manufacturer] performed certain testing remains just that: speculation. Therefore, the Court rejects this argument."); Rheinfrank v. Abbott Lab'ys, Inc., 119 F. Supp. 3d 749, 767 (S.D. Ohio 2015) (dismissing plaintiff's argument that "if [the defendant-manufacturer] had funded or conducted studies that generated subsequently published data, those studies would have generated the same data sooner" and the FDA would not have rejected the warning they sought).

229. *See* Bader Farms, Inc. v. Monsanto Co., No. 16-CV-299, 2017 WL 633815, at *3 (E.D. Mo. Feb. 16, 2017) (noting that *Buckman* prevents "collateral attack[s] on the validity of [a federal agency's] decision"); *see also* James M. Beck, *"Fully Informing" the FDA*, DRUG & DEVICE L. BLOG (Sept. 26, 2019), https://www.druganddevicelawblog.com/2019/09/fully-informing-the-fda.html [https://perma.cc/TM3G-HA55].

230. *In re* Fosamax (Alendronate Sodium) Prods. Liab. Litig., MDL No. 2243, 08-08, 2014 WL 1266994, at *16–17 (D.N.J. Mar. 26, 2014) ("[W]hile Plaintiffs were able to find an expert to agree with their contention that Merck should have acted differently . . . Plaintiffs' contention appears to be a fraud-on-the-FDA theory which was rejected by the Supreme Court in *Buckman*."), *vacated*, 852 F.3d 268 (3d Cir. 2017), *reversed*, Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019).

questioned on appeal, the district court's extension of *Buckman* was problematically aggressive; a narrower view of *Buckman* should be adopted by lower courts deciding impossibility preemption questions where agency fraud is a concern. Construed narrowly, *Buckman* speaks only to circumstances in which a plaintiff raises a stand-alone, state-based claim of fraud-on-the-agency.[231] Several courts, including the Second Circuit, have adopted this limited understanding.[232] In *Desiano v. Warner-Lambert & Co.*,[233] a case that raises similar issues to those in *Albrecht*,[234] plaintiffs claimed they had evidence that Warner-Lambert, the defendant-manufacturer, engaged in intentional withholding and misrepresentation of important safety information about Rezulin, a diabetes drug.[235] Using *Buckman* as a shield, Warner-Lambert argued that plaintiffs' fraud-on-the-FDA claims were preempted.[236] While this deft argument succeeded at the district court level, Judge Guido Calabresi rejected the applicability of *Buckman* on appeal, holding that *Buckman* only applies to stand-alone fraud-on-the-agency claims.[237] Judge Calabresi noted that because the Rezulin case involved failure-to-warn claims traditionally regulated by the state, a presumption against preemption applies.[238] No such presumption applied in *Buckman*. Judge Calabresi also noted that the fraud-on-the-agency issue in *Desiano* served as an exception to a regulatory compliance defense under state law, whereas in *Buckman*, the fraud-on-the-agency issue was the cause of the entire action.[239] Warner-Lambert petitioned the Supreme Court.[240] However, in reaching a 4-4 decision (with Chief Justice Roberts recusing himself), the Court merely affirmed with no precedential effect.[241] A circuit

231. Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 NW. U. L. REV. 841, 845 (2008).

232. *See, e.g.*, Holley v. Gilead Scis., Inc., 379 F. Supp. 3d 809, 825 (N.D. Cal. 2019) ("[W]here 'failure-to-warn claims . . . [do] not arise solely by virtue' of federal law, there is no preemption under *Buckman* because 'there is no suggestion that Congress intended to displace traditional tort law by making all policing of medical labels and warnings the exclusive province of the FDA.'" (quoting McClellan v. I-Flow Corp., 776 F.3d 1035, 1040–41 (9th Cir. 2015) (alteration in original))); *In re* Zofran (Ondansetron) Prods. Liab. Litig., 368 F. Supp. 3d 94, 120 (D. Mass. 2019) ("It therefore appears that *Buckman* does not apply in the present circumstances.").

233. 467 F.3d 85 (2d Cir. 2006), *aff'd per curiam by an equally divided court sub nom.* Warner-Lambert Co. v. Kent, 552 U.S. 440 (2008).

234. Unlike in *Albrecht*, *Desiano* involved a state statute that expressly contained a fraud exception. *See Desiano*, 467 F.3d at 87.

235. *Id.* at 88.

236. *Id.* at 93. Defendants argued that under *Buckman*, the state's fraud exception to its regulatory compliance statute also had no teeth. *Id.* at 88.

237. *Id.* at 94–95.

238. *Id.* at 93–94.

239. *Id.* at 96; *see also* Benjamin C. Zipursky, Palsgraf*, Punitive Damages, and Preemption*, 125 HARV. L. REV. 1757 (2012) (containing an extensive theoretical defense of Judge Calabresi's *Desiano* opinion).

240. Petition for Writ of Certiorari at 13–23, Warner-Lambert Co. v. Kent, 552 U.S. 440 (2008) (No. 06-1498).

241. *See Warner-Lambert Co.*, 552 U.S. at 440 ("The judgment is affirmed by an equally divided Court.").

split on the issue remains,[242] and no clear pattern has emerged among lower courts.[243]

In his concurring opinion in *Buckman*, Justice Stevens advocated for a middle ground approach, arguing that fraud-on-the-agency claims should proceed "only when [they] are supported by an antecedent agency determination of fraud."[244] As torts scholar Professor Catherine Sharkey has argued, this approach best balances state and federal interests, allowing federal agencies and state tort law to work in tandem.[245] This approach also ensures that fraud-on-the-agency claims will be preempted only if they would "encroach upon," as opposed to "supplement and facilitate[] the federal enforcement scheme."[246]

The *Albrecht* majority and concurring opinions do not mention *Buckman* or fraud-on-the-agency concerns, which several commentators have flagged as a careless oversight.[247] These commentators claim that "any determination in a state-law-based case of whether the FDA was 'fully informed' about anything runs headlong into *Buckman*."[248] However, this is not the case. The Supreme Court omitted mention of *Buckman* because the agency fraud was no longer an issue in the case. The Court might also have avoided weighing in on *Buckman* because the Court was concerned that, as in *Warner-Lambert*, the politics of preemption would deadlock the Court, providing future litigants with no clear path forward.

Although the Court did not revisit the fraud issue, *Albrecht* cannot stand for the proposition that anything defendants submit to the FDA, even if fraudulent, can "fully inform" the agency under the clear evidence framework. Manufacturers cannot evade state law tort liability by inundating the FDA with information, armed with *Buckman* as a protection from any liability. This is exactly the "moral hazard" concern that Justice Gorsuch articulated during oral arguments.[249] To protect against such abuse, lower courts should adopt Judge Calabresi's narrow view of *Buckman*: a

242. *Compare* Garcia v. Wyeth-Ayerst Lab'ys, 385 F.3d 961, 966 (6th Cir. 2004) ("[T]he [fraud] exemptions are invalid as applied in some settings (e.g., when a plaintiff asks a state court to find bribery or fraud on the FDA) but not in others (e.g. claims based on federal findings of bribery or fraud on the FDA)."), *with Desiano*, 467 F.3d at 94–95 (disagreeing with *Garcia* in holding that *Buckman* did not preempt traditional state law tort claims that triggered the statute's fraud exemption).

243. *See* Zipursky, *supra* note 239, at 1791 (noting that courts' views on the applicability of *Buckman* "are all over the map").

244. *See* Sharkey, *supra* note 231, at 848.

245. *Id.* at 845.

246. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 354 (2001) (Stevens, J., concurring).

247. *See* Beck, *supra* note 229 ("Surprisingly, neither the majority nor any of the concurring opinions in *Albrecht* even mention *Buckman*—another sign that *Albrecht*'s dictum was not well thought out.").

248. *See* James M. Beck, *Reflections on* Albrecht—*What Preemption Being a "Legal Question" Might Mean*, DRUG & DEVICE L. BLOG (May 23, 2019), https://www.druganddevicelawblog.com/2019/05/reflections-on-albrecht-what-preemption-being-a-legal-question-might-mean.html [https://perma.cc/97NE-XDBN].

249. *See* Transcript of Oral Argument, *supra* note 1, at 13.

presumption against preemption should apply to fraud-on-the-FDA claims that arise as exceptions to defenses to state law failure-to-warn claims. Alternatively, courts can adopt Justice Stevens's more moderate approach and hold that fraud-on-the-FDA claims in cases like *Albrecht* can only proceed if the FDA has previously established the existence of fraud.

3. Is Actual FDA Response Required?

Establishing how defendants can fully inform the FDA is only the first piece of the inquiry. Once a defendant shows it fully informed the FDA, Justice Breyer's framework requires that defendants show that "the FDA, in turn, informed the drug manufacturer that [it] would not approve changing the drug's label to include that warning."[250] This second prong raises questions about whether the FDA must actually notify defendants of a decision not to require a label or if FDA inaction can "inform" defendants of the FDA's determination that further warnings are unnecessary.

As Justice Alito noted in his concurring opinion, in certain scenarios, FDA inaction may signal the agency's determination that a label change is not required.[251] Under 21 U.S.C. § 355(o)(4)(A), if the secretary of health and human services discovers new information about a drug and determines that a label change is required based on this data, the FDA has a duty to unilaterally initiate a label change.[252] "The FDA's duty does not depend on whether the relevant drug manufacturer, as opposed to some other entity or individual, brought the new information to the FDA's attention."[253] However, if the secretary decides *not* to act on this new information about a drug, the FDA is not required to communicate to the relevant drug manufacturer that a label change is unwarranted; the agency can simply decide not to act.[254]

In a case like *Albrecht*, where a defendant-manufacturer has submitted a proposed label change and the secretary's unilateral actions under § 355(o)(4)(A) are not at issue, an actual FDA response is likely required to fully inform defendants that a proposed label was rejected. A state court in Connecticut recently addressed a defendant's argument that was based on Justice Alito's concurrence.[255] The defendant contended that "submission of data to the FDA, even after the injury in question, followed by FDA inaction demonstrates that the FDA would have rejected a proposed labeling change even if the [manufacturer] had submitted the information in time for a label change prior to the injury."[256] The court noted "[t]here is admittedly some

250. Merck Sharpe & Dohme Corp. v. Albrecht, 139 S. Ct. at 1668, 1678 (2019).
251. *Id.* at 1684 (Alito, J., concurring in the judgment).
252. *Id.*
253. *Id.*
254. *See* 21 U.S.C. § 355(o)(4)(A).
255. Roberto v. Boehringer Ingelheim Pharm., Inc., No. CPLHHDCV166068484S, 2019 WL 5068452, at *24 (Conn. Super. Ct. Sept. 11, 2019) (citing *Albrecht*, 139 S. Ct. at 1684 (Alito, J., concurring in the judgment)).
256. *Id.*

logic to this argument."[257] However, it ultimately rejected the argument and held that *Albrecht* required a showing of clear evidence "that the FDA actually informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning."[258] This case illustrates that lower courts are already using the *Albrecht* concurrences to inform their answers to impossibility preemption questions.

4. Summary

In sum, the fully informed requirement should be restricted to cases involving rejections of proposed label changes, rather than other third-party methods of informing the FDA. At a minimum, a defendant can satisfy this requirement if, after providing the FDA with an up-to-date analysis of the risk at issue, the FDA refused to accept the additional warning. While an actual FDA response might not be necessary in every case, when a defendant's proposed label change is at issue, an FDA response is likely necessary to ensure that a defendant is adequately informed of the FDA's decision. Courts should adopt a narrow or moderate view of *Buckman*. Further, defendants facing failure-to-warn claims cannot use *Buckman* as a broad shield from tort liability.

B. When Do State and Federal Laws Irreconcilably Conflict?

In addition to analyzing what fully informs the FDA, lower court judges deciding impossibility preemption questions must interpret what it means for state and federal laws to irreconcilably conflict.[259] Although the Supreme Court notes this is a "simpl[e] ask," in reality, it seems quite complex.[260]

In the context of proposed label changes, as in *Wyeth* and *Albrecht*, an analysis of irreconcilable conflict must begin by determining whether a defendant's proposed label provides an adequate description of a drug's risks. If the FDA rejects a brand-name drug manufacturer's label change because the agency determines the label is inadequate, a defendant-manufacturer cannot argue that this rejection makes it impossible to comply with both state and federal law. A proposed warning is adequate if it provides clear, comprehensive, and accurate information about a drug's risks and side effects.[261] As Professors John C. P. Goldberg and Benjamin C. Zipursky noted in their amicus brief to the Court, the "FDA's rejection of [Merck's] understated and muddled warning in no way indicates that the agency would have rejected a warning of the risk of atypical femoral fractures that was

257. *Id.*

258. *Id.* (quoting *Albrecht*, 139 S. Ct. at 1678).

259. Merck Sharpe & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1679 (2019) ("The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute" (quoting Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982))).

260. *Id.*

261. *See* Brief of Tort Law Professors John C. P. Goldberg and Benjamin C. Zipursky as Amici Curiae in Support of Respondents, *supra* note 21, at *14 ("Under state law, adequacy is a function of the accuracy and completeness of the information accompanying a product, as well as the prominence, clarity, and urgency with which that information is presented.").

adequate in the relevant dimensions."[262] In fact, the FDA invited Merck to resubmit an adequate proposed warnings and precautions label but Merck failed to do so.[263] Because there is a strong argument that Merck never presented the FDA with an *adequate* label concerning atypical femoral fractures, Merck cannot argue that the FDA's rejection of its 2008 proposed warnings and precautions label creates an irreconcilable conflict between state and federal law.[264] A key purpose of state failure-to-warn law is protection against inadequate labeling of drugs' dangerous side effects and risks.[265] Defendant-manufacturers cannot use impossibility preemption as a mechanism to avoid their state law duties.[266] The issue of inadequate labeling traces back to *Wyeth*.[267] In fact, the proposed warning rejected by the FDA in *Wyeth* was considerably stronger than the rejected "stress fractures" label at issue in *Albrecht*, highlighting the weakness of Merck's conflict argument.[268] "Evidence of a rejection of an adequate warning is the 'clear evidence' that was missing in [*Wyeth*], and is likewise missing in [*Albrecht*]."[269] Thus, the question becomes whether any warning that would have been adequate under state law would have been impermissible according to the FDA. If there are some clear and nuanced warnings that would have been permissible to the FDA and also would have been adequate under state law, there is no irreconcilable conflict.

Justice Breyer's framework in *Albrecht* also raises questions about whether the CBE label change process will preclude brand-name drug manufacturers from showing that state and federal law irreconcilably conflict.[270] Under CBE regulations, drug manufacturers can unilaterally change a drug's label if changing the label would add or strengthen a warning based on new information that shows a causal link between a drug and a risk or harm.[271] In *Wyeth*, the Court reasoned that because Wyeth made no attempt to make a label change through the CBE process, it failed to show it was impossible to change its product label under state law and still comply with federal law.[272] In *Albrecht*, "Merck conceded that the FDA's CBE regulation would have permitted [it] to try to change the label to add a

262. *Id.* at *3.
263. *See supra* Part II.A.1.
264. *See* Brief of Tort Law Professors John C. P. Goldberg and Benjamin C. Zipursky as Amici Curiae in Support of Respondents, *supra* note 21, at *3 (noting that "it was entirely possible for [Merck] to comply with both federal and state law by simply proposing or adding an adequate warning").
265. *See* Wyeth v. Levine, 555 U.S. 555, 574–75 (2009).
266. *Id.* at 575.
267. *Id.* at 572 ("[Wyeth] does not argue that it attempted to give the kind of warning required by the Vermont jury but was prohibited from doing so by the FDA.").
268. *Id.* at 562–63.
269. Brief of Tort Law Professors John C. P. Goldberg and Benjamin C. Zipursky as Amici Curiae in Support of Respondents, *supra* note 21, at *23 (emphasis omitted) (citation omitted).
270. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A) (2019).
271. *See* Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1673 (2019).
272. *Wyeth*, 555 U.S. at 572.

warning before [the FDA required it to do so in] 2010" but argued that the FDA would have rejected such a warning.[273]

While *Wyeth* and *Albrecht* demonstrate that the availability of the CBE label change process will severely weaken many impossibility preemption arguments, the CBE regulation does not destroy the impossibility preemption defense because the regulation cannot be applied in every case. As previously stated, label changes made in accordance with the CBE regulation can only be based on "newly acquired information," and the FDA has stated it will "not allow a change to labeling to add a warning in the absence of *reasonable evidence* of an association between the product and an adverse event."[274] Courts must also note that "the FDA contemplated that the CBE regulation would be used sparingly."[275] For example, one federal court applying *Albrecht* recently held that a single study performed on mice showing a drug's adverse effects fails to establish such reasonable evidence and cannot support a state law failure-to-warn claim arguing that a defendant-manufacturer should have attempted to add a CBE label change.[276] If plaintiffs cannot plausibly show that a defendant-manufacturer could have unilaterally changed its label, it will be much easier for defendants to show that failure-to-warn claims are preempted.[277]

Because CBE label changes are only available if certain new information becomes available, courts should not read *Wyeth* or *Albrecht* to require defendant-manufacturers to attempt unilateral label changes to show that compliance with state and federal law is impossible. Such a requirement runs headlong into Justice Gorsuch's concern that manufacturers will flood the FDA with inartful, confusing warnings in the hopes that the FDA will reject them.[278] Defendants cannot plan their own label rejections to show an irreconcilable conflict between state and federal law.

Justice Thomas's concurrence should also inform courts' understanding of what demonstrates an irreconcilable conflict.[279] In both *Wyeth* and *Albrecht*, Justice Thomas argued that evidence from the founding era shows that state and federal law directly conflict when they are in logical contradiction, even if compliance with both laws is possible.[280] In *Albrecht*, Justice Thomas

273. *Albrecht*, 139 S. Ct. at 1675.

274. Supplemental Application Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008) (to be codified at 21 C.F.R. pts. 314, 601, and 814) (emphasis added) (quoting FOOD & DRUG ADMIN., PUBLIC AVAILABILITY OF LABELING CHANGES IN "CHANGES BEING EFFECTED SUPPLEMENTS" 2 n.4 (2006), https://www.fda.gov/media/71848/download [https://perma.cc/RK67-7PF9]).

275. McGrath v. Bayer HealthCare Pharm. Inc., 393 F. Supp. 3d 161, 170 (E.D.N.Y. 2019).

276. *Id.*

277. *See* Goodell v. Bayer Healthcare Pharm. Inc., No. 18-cv-10694, 2019 WL 4771136, at *4 (D. Mass. Sept. 30, 2019) ("Without factual allegations that Bayer had new information in this time period such that it could have or should have amended the label pursuant to the CBE regulation, the complaint is barred as preempted.").

278. *See* Transcript of Oral Argument, *supra* note 1, at 13.

279. *See* Merck Sharp & Dohme v. Albrecht, 139 S. Ct. 1668, 1681–84 (2019) (Thomas, J., concurring).

280. *Id.* at 1681; Wyeth v. Levine, 555 U.S. 555, 590 (2009) (Thomas, J., concurring in the judgment).

noted 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."[281] In a recent concurrence to a denial of certiorari, Justice Gorsuch also noted that "[a]t the time of the founding, [the Supremacy] Clause would have been understood to pre-empt state law only if the law logically contradicted the 'Constitution,' [or] the 'Laws of the United States.'"[282] This opinion shows that the idiosyncratic "logical contradiction" method may be gaining support among the bench as future preemption cases reach the Supreme Court.

In sum, the FDA's rejection of an inadequate label change does not create an irreconcilable conflict between state and federal law. Additionally, while the availability of the CBE regulation weakens the impossibility preemption defense, the limited applicability of CBE label changes restricts courts' ability to require these label changes to demonstrate an irreconcilable conflict. In addition to an impossibility preemption analysis, courts should conduct a "logical contradiction" analysis because this method is supported by at least two Justices.

C. What Actions Are Within the Scope of the FDA's Congressionally Delegated Authority?

The final question raised by Justice Breyer's *Albrecht* framework relates to the Court's statement that only agency actions "taken pursuant to the FDA's *congressionally delegated authority*" can determine the answer to preemption questions.[283] The answer to this question is especially relevant to the future of the Fosamax litigation. In its order remanding the case back to the district court, the Third Circuit specifically instructed the court to "determine the effect of the FDA's Complete Response Letter and other communications with Merck on the issue of whether such agency actions are sufficient to give rise to preemption."[284]

While Justice Breyer cautioned that "[t]he question of disapproval 'method' [was] not . . . before [the Court]," he noted that, "[f]ederal law permits the FDA to communicate its disapproval of a warning by means of notice-and-comment rulemaking setting forth labeling standards; by formally rejecting a warning label that would have been adequate under state law; or with *other agency action carrying the force of law*."[285] To properly decide impossibility preemption questions, lower courts must adopt a common understanding of these other agency actions.

First, courts should establish what agency actions do *not* carry the force of law. In *Wyeth*, the Court held that the FDA's 2006 preamble declaring that

281. *Albrecht*, 139 S. Ct. at 1681 (quoting *Wyeth*, 555 U.S. at 590).

282. Lipschultz v. Charter Advanced Servs. (MN), LLC, 140 S. Ct. 6, 7 (2019) (Mem.) (quoting Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 260 (2000)).

283. *Albrecht*, 139 S. Ct. at 1679 (emphasis added).

284. Remand Order, *supra* note 204, at 1.

285. *Albrecht*, 139 S. Ct. at 1679 (emphasis added) (citations omitted).

state law failure-to-warn claims threaten the role of the FDA did not carry the force of law because "Congress has not authorized the FDA to pre-empt state law directly."[286]

The *Albrecht* concurring opinions provide little consensus on this point. Justice Thomas advocated for an even narrower position, noting that only *final* agency actions carry the force of law.[287] Unlike the majority opinion, Justice Thomas did not consider the FDA's 2009 response letter to Merck's stress fracture warning to carry the force of law because response letters have "no implication as to the ultimate approvability of [an] application."[288] Justice Thomas also noted that "neither agency musings nor hypothetical future rejections constitute pre-emptive 'Laws.'"[289] Conversely, Justice Alito argued that in several scenarios, FDA *inaction* may carry the force of law, such as when the secretary of health and human services chooses not to act on newly acquired information under § 355(o)(4)(A).[290] Justice Alito also noted the relevance of the FDA's informal communications with Merck leading up to the required label change in 2010.[291] Recognizing all FDA contacts with defendant-manufacturers as relevant to the preemption analysis gives the FDA much latitude to preempt state law claims. One federal court recently noted that public informal communications between the FDA and drug manufacturers should receive such judicial notice.[292] While confusion and controversy remain regarding what specific agency actions have preemptive effect, one trend is clear: *Albrecht* continues the Supreme Court's trend of shifting institutional power away from the courts and into the hands of federal agencies.[293]

CONCLUSION

As products liability suits against pharmaceutical companies continue to rise, federal preemption in the prescription drug context is likely to remain a hotly litigated issue. The Supreme Court's renewed interest in the federal preemption doctrine marks an important step forward in clarifying the procedure for deciding impossibility preemption defenses. It is now clear that judges, rather than juries, must decide impossibility preemption questions as a matter of law. However, divides among the Justices as to how these questions should be answered remain. While Justice Breyer's framework in the Court's recent *Albrecht* decision contains several interpretive gaps, it is nonetheless illuminating for lower courts trying to

286. Wyeth v. Levine, 555 U.S. 555, 575–76 (2009).
287. *Albrecht*, 139 S. Ct. at 1683 (Thomas, J., concurring).
288. *Id.* (emphasis omitted).
289. *Id.* at 1682 (quoting U.S. CONST. art. VI, cl. 2).
290. *Id.* at 1684 (Alito, J., concurring in the judgment).
291. *Id.* at 1686.
292. *See* Bowling v. Johnson & Johnson, No. 17-cv-3982, 2018 WL 1587598, at *4 (S.D.N.Y. Mar. 28, 2018) (holding that "because . . . FDA . . . warning letters are publicly available evidence of agency actions, the Court deems it proper to take judicial notice of them").
293. Catherine M. Sharkey, *Inside Agency Preemption*, 110 MICH. L. REV. 521, 595 (2012).

frame impossibility preemption questions. The concurring opinions in *Albrecht* and the case law since 2009 help to fill the gaps left by the majority opinion and are instructive for courts ruling on these defenses.