

# A SHIFT IN THE PREEMPTION LANDSCAPE?

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## INTRODUCTION

Preemption is a doctrine that is experiencing something of a renaissance. Under the doctrine, state law tort claims may be barred where they conflict with federal law. The Supremacy Clause of the United States Constitution provides that federal law is “the supreme Law of the Land.”<sup>1</sup> Courts have interpreted this language as barring the application of state law where it is in “conflict” with federal law or “where it is ‘impossible for a private party to comply with both state and federal requirements.’”<sup>2</sup>

Manufacturers of pharmaceutical products frequently argue that state law tort claims alleging that the manufacturers failed to adequately warn of hazards associated with their products are preempted where the federal Food and Drug Administration (FDA)

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1. U.S. CONST. art. VI, cl. 2.  
2. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

has suggested that it would reject more stringent warnings.<sup>3</sup> Such arguments are often based on an extensive record before the FDA, including correspondence with the manufacturer discussing proposed labeling changes. In some instances, the agency may also issue public health alerts or press releases discussing potential health effects of a product. Accordingly, there may be a range in the strength of preemption arguments pursued by manufacturers, depending on the record before the FDA and the state of the science underlying the manufacturer's discussions with the agency.

In some cases, the preemption argument may be extremely powerful and clear cut. There are examples where the FDA has stated publicly that it would not approve additional warnings for a pharmaceutical product because they are not warranted and would actually be contrary to public health because they have the potential to discourage patients from taking beneficial medications.<sup>4</sup> As the FDA has recognized, overwarning can damage the public health, just as underwarning can.<sup>5</sup> Overwarning may discourage the public from

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3. The Federal Food, Drug, and Cosmetic Act generally restricts a manufacturer from changing the label of a pharmaceutical product without advance permission from the FDA. *See* 21 U.S.C. §§ 331(a), (c), 352 (2018); 21 C.F.R. § 314.70(a), (b) (2019). There are certain exceptions where the manufacturer may change the label in advance of FDA approval. *See, e.g.*, 21 C.F.R. § 314.70(c). Nonetheless, the FDA must ultimately approve any such changes. *See* 21 C.F.R. §§ 201.80(e), 314.70(c)(6)(iii) (2019).

4. In the *Incretin Mimetics* litigation, for example, the court confronted a record in which the FDA had stated publicly that the medications at issue, which were used to treat diabetes, were not associated with pancreatic cancer. *See In re Incretin-Based Therapies Prods. Liab. Litig.*, 142 F. Supp. 3d 1108, 1120–21 (S.D. Cal. 2015), *vacated*, 721 F. App'x 580 (9th Cir. 2017). The court granted summary judgment on preemption grounds, observing that “[t]he record establishes the FDA has specifically considered pancreatic cancer risk, commented publicly on the adequacy of drug labeling, and maintained its position that scientific evidence of a causal association between incretin mimetics and pancreatic cancer is indeterminate.” *Id.* at 1112. While the Ninth Circuit subsequently vacated and remanded so that the court could consider additional evidence, the case illustrates how, in certain instances, the FDA may not only take a position in correspondence with a manufacturer, but may also go further by publicly stating its position in a public health alert. *See In re Incretin-Based Therapies Prods. Liab. Litig.*, 721 F. App'x 580, 584 (9th Cir. 2017).

5. *See, e.g.*, Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008) (acknowledging that inappropriately crafted warnings “could discourage appropriate use of a beneficial drug”); Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,605–06 (Aug. 22, 2008) (observing that in crafting appropriate labeling, the FDA attempts to “prevent overwarning”).

using medications that would improve patients' medical conditions.<sup>6</sup> Likewise, overwarning may exaggerate the known risks of a pharmaceutical product, resulting in a flawed risk-benefit analysis for patients considering the medication.<sup>7</sup> Accordingly, the FDA has affirmatively encouraged patients to continue using medications where it has determined that allegations regarding potential health effects are unsupported and that no additional warnings are necessary.<sup>8</sup>

Where the FDA has issued such pronouncements affirmatively disclaiming the need for additional warnings, it is difficult for putative plaintiffs to argue that the FDA would approve the sort of warnings that plaintiffs maintain are necessary to provide an "adequate" warning to consumers. The regulatory record before the FDA largely answers the hypothetical question regarding whether the agency would approve warnings that plaintiffs argue are necessary.<sup>9</sup> In other cases, however, the record may be less clear. The FDA may have given only indications regarding its views, or the science itself may dictate that it is likely the FDA would reject additional warnings. Accordingly, there are many possible scenarios, depending upon the record presented to the court charged with deciding such questions.

Defendants have employed preemption arguments with success to dismiss large numbers of pharmaceutical product liability claims. Particularly in the generic pharmaceutical industry, defendants have utilized the fact that they are required by federal law to provide the same warnings as their branded pharmaceutical counterparts to win dismissal of claims alleging that their warnings were inadequate.<sup>10</sup> Courts have held that state law claims premised on the idea that generic manufacturers should have provided additional or different warnings are preempted by federal law.<sup>11</sup> While branded

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6. See Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. at 2851.

7. See *id.*

8. See sources cited *supra* note 4.

9. See sources cited *supra* note 4.

10. See *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) ("A manufacturer seeking generic drug approval . . . is responsible for ensuring that its warning label is the same as the brand name's."); *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 678 (5th Cir. 2014) ("[I]t follows that any state law tort claim that is based on a generic manufacturer's failure to update the labeling on its drug directly conflicts with this federal law requirement and is therefore preempted." (citing *Mensing*, 564 U.S. at 618)).

11. See *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013) ("[S]tate-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted

pharmaceutical manufacturers have been less successful in making preemption arguments, such arguments are gaining traction in this arena as well.<sup>12</sup> The record of a brand-name manufacturer's dealings with the FDA frequently provides grounds for the manufacturer to argue that it proposed additional warnings, but the FDA rejected

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by federal law under *PLIVA*."); *Mensing*, 564 U.S. at 618 (holding that defendant generic-drug manufacturer's state-law duty to provide a safer label conflicted with the federal-law duty to keep the label the same as its brand-name counterpart); *see also* Dolin v. GlaxoSmithKline LLC, 901 F.3d 803, 805 (7th Cir. 2018) ("The current state of federal law makes it virtually impossible to sue generic drug manufacturers on a state-law theory for failure to warn."); *Wagner v. Teva Pharm. USA, Inc.*, 840 F.3d 355, 358–59 (7th Cir. 2016) (preempting state tort claims related to generic manufacturer's failure to provide sufficient information, "regardless of how they are styled in [plaintiff's] complaint"); *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139–41 (8th Cir. 2014) (preempting consumer's failure to warn, design defect, and breach of implied warranty claims against generic manufacturer); *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 610–11 (5th Cir. 2014) (preempting consumer's failure-to-warn claims against generic manufacturers of metoclopramide); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150, 165 (3d Cir. 2014) (dismissing plaintiffs' claims where plaintiffs failed to show how generic manufacturers could have modified warranties without violating federal law); *Drager v. PLIVA USA, Inc.*, 741 F.3d 470, 473, 475 (4th Cir. 2014) (preempting consumer's claims for negligence, strict liability, breach of warranties, fraud and misrepresentation, and failure to warn); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 390–98 (6th Cir. 2013) (preempting consumer's failure-to-warn claims against generic manufacturers of metoclopramide); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013) (preempting consumer's failure-to-communicate claims); *Gaeta ex rel. A.G. v. Perrigo Pharm. Co.*, 469 F. App'x 556, 557 (9th Cir. 2012) (affirming summary judgment for defendant manufacturer in light of *Mensing*); Eric Lindenfeld, *Brand Name Preemption: The New Frontier in Pharmaceutical Product Liability Litigation*, 72 FOOD & DRUG L.J. 636, 636 (2017) ("Over the past six years, [the] Supreme Court has displayed an increased willingness to construe the Food, Drug and Cosmetic Act (FDCA) and federal preemption principles in a manner that immunizes manufacturers of generic drugs from product liability lawsuits.").

12. *See, e.g., Dolin*, 901 F.3d at 816 (holding that state law claims alleging failure to warn of risk of adult suicide with antidepressant use were preempted); *Cerveney v. Aventis, Inc.*, 855 F.3d 1091, 1099 (10th Cir. 2017) (holding that claims alleging failure to warn that a fertility drug could cause birth defects if taken before pregnancy were preempted); *Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 385 (6th Cir. 2017) (holding that state law failure-to-warn claims, alleging that antiepileptic drug caused birth defects, were preempted where manufacturer proposed, and the FDA rejected, warnings regarding the risk of cognitive development delay); *Christison v. Biogen Idec Inc.*, 199 F. Supp. 3d 1315, 1348 (D. Utah 2016) (claims alleging that a multiple sclerosis drug caused brain infection were preempted); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1280 (W.D. Okla. 2011) (claims alleging failure to warn of suicide risks with Effexor in patients of a certain age range were preempted).

them, rendering state law failure-to-warn claims preempted as a matter of law.

Nonetheless, some courts have gone out of their way to find reasons to deny preemption-based motions. In particular, courts have exhibited misplaced reliance on off-hand language in the Supreme Court's decision in *Wyeth v. Levine*.<sup>13</sup> *Wyeth* involved allegations that a drug used to treat nausea (Phenergan) caused a particularly harmful injury (gangrene), leading to amputation of the plaintiff's arm.<sup>14</sup> The defendant manufacturer argued, in part, that the claims were preempted because the FDA would not have approved a warning that covered this condition.<sup>15</sup> The Supreme Court ultimately sided with the plaintiff in rejecting the preemption defense based on the particular record before it.<sup>16</sup> Nonetheless, in doing so, the majority remarked that a record must manifest "clear evidence" that the FDA would have rejected more stringent or detailed warnings for the preemption defense to be successful.<sup>17</sup>

Some courts have construed this language to suggest that there is a requirement that evidence be "clear and convincing" in order to support a preemption defense warranting dismissal before trial.<sup>18</sup> These courts, in turn, have used this alleged standard to reject preemption arguments in circumstances where the record certainly warranted serious consideration.<sup>19</sup> Accordingly, what was originally tangential language in a split Supreme Court decision has become central for some courts addressing preemption questions.

This construction of the preemption standard has had significant consequences.<sup>20</sup> Preemption arguments frequently arise in large-scale litigation involving thousands of state law tort claims. Accordingly, whether a defendant may invoke the preemption defense to dispense with such claims before trial can have significant legal and economic

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13. 555 U.S. 555 (2009).

14. *Id.* at 559.

15. *Id.* at 572.

16. *Id.* at 581.

17. *Id.* at 571.

18. *See, e.g., In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 285–86 (3d Cir. 2017), *vacated*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019).

19. *See, e.g., id.*

20. *See* Michael P. Moreland, *Preemption as Inverse Negligence Per Se*, 88 NOTRE DAME L. REV. 1249, 1249 (2013) (observing that "[f]ederal preemption of state tort claims has been a controversial and frequently litigated issue over the past decade, arguably constituting the most important, if confusing, development in tort law over that period").

consequences.<sup>21</sup> As a result, preemption is an area of the law that has been the subject of significant focus and attention by various constituencies in recent years, including courts, commentators, litigants, and the business community at large, which views the doctrine as a potential check on out-of-control tort litigation.

The Supreme Court recently had an opportunity to address the preemption doctrine in *Merck Sharp & Dohme Corp. v. Albrecht*.<sup>22</sup> *Albrecht* involved allegations that a medication used to treat osteoporosis (Fosamax) was associated with atypical femur fractures.<sup>23</sup> Plaintiffs maintained that the product should have included a warning telling consumers of the potential risks.<sup>24</sup> In response, the manufacturer pointed to a record before the FDA that it argued showed that the agency would not have approved additional warnings for bone fractures at the time.<sup>25</sup> Indeed, the FDA arguably had considered the very issue in the litigation and had declined to require that the manufacturer provide additional warnings to consumers.

The trial court, which was presiding over hundreds of cases centralized in a multidistrict litigation (MDL) proceeding, ruled that the claims were preempted.<sup>26</sup> It found that the record showed that the manufacturer had presented the FDA with proposed language that would have warned of bone fractures, but that the FDA rejected the language as premature given the state of the existing science.<sup>27</sup>

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21. This is not the only area in which the Supreme Court's preemption decisions have had significant consequences for state law tort litigation. The Court has issued guidelines, for example, concerning when claims involving medical devices are preempted. *See, e.g.,* *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (finding that the Medical Device Amendments of 1976 preempt state requirements that are "different from, or in addition to" federal law requirements (quoting 21 U.S.C. § 360k(1) (2008))); *see also* *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496–97 (1996) (recognizing that the Medical Device Amendments of 1976 "do[] not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." (quoting 21 C.F.R. § 808.1(d)(2) (1995))). The Supreme Court has also provided guidance concerning when claims alleging fraud on the FDA are preempted. *See, e.g.,* *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that "fraud-on-the-FDA claims . . . are . . . impliedly pre-empted by[] federal law").

22. 139 S. Ct. 1668 (2019).

23. *Id.* at 1674.

24. *Id.* at 1672.

25. *See generally id.*

26. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 951 F. Supp. 2d 695, 705 (D.N.J. 2013), *vacated*, 852 F.3d 268, 302 (3d Cir. 2017).

27. *Id.* at 704.

However, the Third Circuit reversed.<sup>28</sup> The panel concluded that “clear and convincing” evidence was required to establish the preemption defense and that the manufacturer failed to meet that standard in the case before it.<sup>29</sup> In doing so, the court articulated a particularly rigorous version of the clear evidence standard, requiring that defendants submit evidence showing that it was “highly probable” that the FDA would reject additional warnings.<sup>30</sup> Moreover, the court concluded that it was appropriate for such questions to be submitted to a jury, rejecting the manufacturer’s assertion that such questions were primarily legal questions that should be resolved by judges alone.<sup>31</sup>

The Supreme Court granted certiorari, initiating proceedings that generated significant amicus interest.<sup>32</sup> The case raised an issue that was central to the preemption debate—whether a judge or a jury should decide preemption—which could have significant consequences in future litigation.<sup>33</sup> Moreover, it provided the potential that the Court might also elaborate on the standard used in deciding whether preemption applied. Accordingly, amicus parties filed multiple briefs in support of both the plaintiffs and the manufacturer. In addition, the Solicitor General intervened in the dispute, agreeing with the manufacturer that the claims were preempted because the FDA had concluded that no additional warning was warranted.<sup>34</sup>

The Supreme Court issued a decision that is sure to be the subject of debate in the coming years. On the issue before the Court, its decision was clear. The Court held that the preemption defense is primarily a question of law that must be decided by judges and not juries.<sup>35</sup> The Court reasoned that the preemption defense frequently involves the application of the law to facts that are not really in dispute.<sup>36</sup> Moreover, the Court determined that judges have greater

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28. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 302 (3d Cir. 2017), *vacated*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019).

29. *Id.* at 285–86.

30. *Id.* at 286.

31. *Id.* at 293.

32. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1676 (2019) (“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.”).

33. *See id.*

34. *See id.* at 1686 (Alito, J., concurring).

35. *Id.* at 1676 (majority opinion).

36. *Id.* at 1680.

institutional competence to decide the complex issues surrounding interpretation of agency decisionmaking in a statutory and regulatory context than juries.<sup>37</sup> Therefore, the Court concluded that judges—not juries—should decide such questions.<sup>38</sup>

However, in so ruling, the Court also discussed to some extent the standard for assessing the preemption defense.<sup>39</sup> As a threshold matter, the Court noted that the “clear evidence” standard could not be construed as a standard of proof, given that such issues were properly decided by judges as a matter of law.<sup>40</sup> Nonetheless, the Court suggested—in statements that Justice Alito noted arguably went beyond the scope of what the Court had agreed to decide<sup>41</sup>—that manufacturers invoking the defense must provide evidence that they fully informed the FDA regarding justifications for the warning that plaintiffs alleged was necessary and that the FDA nonetheless rejected changes to the labeling.<sup>42</sup> However, the exact scope of the Court’s ruling remains unclear, leaving the lower courts the task of applying the preemption standard to the varying records before them.

This Article examines the Court’s decision in *Albrecht*, its evolution from prior preemption law, and the likely consequences of the decision for future cases.<sup>43</sup>

Part I discusses the Supreme Court’s prior decision in *Wyeth v. Levine*<sup>44</sup> and the cases applying that decision. The language in the *Wyeth* decision, upon which some courts seized to impose an arbitrarily narrow view of the preemption doctrine, arguably was tangential to the decision and certainly not intended as imposing an ultra-strict standard for preemption. Nonetheless, misinterpretation of the decision led to inconsistent outcomes, creating a need for clarification of the preemption standard.

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37. *Id.*

38. *Id.* at 1679.

39. *See id.*

40. *Id.*

41. *Id.* at 1684 (Alito, J., concurring).

42. *Id.* at 1672 (majority opinion).

43. For a discussion of preemption more generally, and in particular the law governing preemption before *Albrecht*, see generally Stephen A. Gardbaum, *The Nature of Preemption*, 79 CORNELL L. REV. 767 (1994); Michael S. Greve et al., *Preemption in the Rehnquist and Roberts Courts: An Empirical Analysis*, 23 SUP. CT. ECON. REV. 353 (2015); Moreland, *supra* note 20; Caleb Nelson, *Preemption*, 86 VA. L. REV. 225 (2000).

44. 555 U.S. 555 (2009).

Part II discusses the *Albrecht* case<sup>45</sup> and its path to the Supreme Court. The disparate opinions rendered by the trial court and court of appeals illustrate the confusion introduced by the *Wyeth* decision.<sup>46</sup> The courts expressed conflicting views regarding the formulation of the standard and, more fundamentally, whether the standard contemplated that such questions could ultimately be submitted to a jury rather than being reserved for the courts.<sup>47</sup> While the Supreme Court made clear that such issues were reserved to judges rather than juries,<sup>48</sup> its statements regarding the appropriate standard remain less than clear.

Finally, Part III discusses the potential implications of the *Albrecht* decision for future cases. In many ways, *Albrecht* brings clarity regarding the principles to apply in assessing the preemption defense. No longer is there confusion regarding the proper decisionmaker for such questions. Nor is there any basis for asserting, after *Albrecht*, that the “clear evidence” standard is a standard of proof. Nonetheless, there is likely to be significant debate among the lower courts regarding what precisely is required to establish the preemption defense. As Justice Alito highlighted in his opinion concurring in the judgment, the only issue really before the Court, and the only issue it properly decided, was whether judges or juries would decide such questions.<sup>49</sup> Accordingly, the type of evidence that courts will consider and the standards for assessing that evidence remain to be determined. As Justice Alito noted, express statutory provisions indicate that preemption should apply where the FDA receives information regarding potential risks even if the FDA remains silent and takes *no* affirmative action expressing its disapproval of additional warnings.<sup>50</sup>

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45. 139 S. Ct. at 1676.

46. See Greve et al., *supra* note 43, at 354 (“[F]ederal preemption has remained a subject of intense scholarly debate and of a steady—and to virtually all observers, confusing—stream of Supreme Court decisions.” (internal citations omitted)); Keith N. Hylton, *An Economic Perspective on Preemption*, 53 B.C. L. REV. 203, 203 (2012) (“After decades of case law and commentary, preemption remains a controversial topic.” (internal citation omitted)); Lindenfeld, *supra* note 11, at 637 (“While the Supreme Court has issued some guidance in regard to brand name failure to warn claims, it has ultimately proven to be vague, unhelpful and yielding conflicting results in the courts.”).

47. See *Albrecht*, 139 S. Ct. at 1668.

48. See *id.* at 1679.

49. *Id.* at 1684 (Alito, J., concurring).

50. *Id.*

I. THE SUPREME COURT'S DECISION IN *WYETH*

*Wyeth* was a case involving a particularly tragic set of facts.<sup>51</sup> The plaintiff was a professional musician who was injected with a medication used to treat nausea.<sup>52</sup> However, she developed gangrene and, as a result, her physicians had to amputate her forearm, causing significant pain and suffering and ending her career as a professional musician.<sup>53</sup>

The medication was injected using an “IV push” method instead of a “drip” method, and plaintiff argued not only that use of this method constituted malpractice on the part of the healthcare provider who performed the injection,<sup>54</sup> but also that the manufacturer should be liable for failing to adequately warn against this method of administration.<sup>55</sup> The medication, Phenergan, was particularly corrosive and could cause significant damage if it entered an artery rather than a vein.<sup>56</sup> Plaintiffs maintained that the IV push method of administration could result in the accidental introduction of the medication into a patient’s arteries.<sup>57</sup>

In response, the manufacturer argued that it provided warnings in the label indicating that IV push administration was, at a minimum, disfavored.<sup>58</sup> Among other things, the label warned against intra-arterial injection and advised that “[w]hen administering any irritant drug intravenously it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily.”<sup>59</sup>

The manufacturer further argued that the FDA would not have approved stronger or more detailed warnings regarding the IV push

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51. *Wyeth v. Levine*, 555 U.S. 555 (2009). For a discussion of the background of the *Wyeth* decision, see Douglas G. Smith, *Preemption After Wyeth v. Levine*, 70 OHIO ST. L.J. 1435, 1437–58 (2009).

52. *Wyeth*, 555 U.S. at 559.

53. *Id.*

54. *Id.* at 606 n.3 (Alito, J., dissenting). As the Court noted, the medical staff in plaintiff’s case made a variety of errors. Among other things, “[t]he record contain[ed] evidence that the physician assistant administered a greater dose than the label prescribed, that she may have inadvertently injected the drug into an artery rather than a vein, and that she continued to inject the drug after [plaintiff] Levine complained of pain.” *Id.* at 564 (majority opinion).

55. *Id.* at 560.

56. *Id.* at 559.

57. *Id.* at 560–61.

58. *Id.* at 561.

59. *Id.*

method.<sup>60</sup> The record showed that the FDA and the manufacturer had discussed additional warnings, but those warnings were not incorporated into the labeling.<sup>61</sup> The FDA suggested different warnings regarding the risk of arterial exposure, and the manufacturer submitted proposed language, but the FDA then rejected the warnings, telling the manufacturer that it should “[r]etain verbiage in [the] current label.”<sup>62</sup>

A Vermont state trial court denied the manufacturer’s pre-trial motion and allowed the case to proceed to trial, resulting in a finding of liability against the manufacturer.<sup>63</sup> Based on the record developed at trial, the trial court denied the manufacturer’s motion for judgment as a matter of law based on the preemption defense.<sup>64</sup> The trial court reasoned that the FDA gave only “passing attention” to the issue of IV-push administration, and therefore the record was insufficient to establish a preemption defense.<sup>65</sup>

The Vermont Supreme Court let the decision stand.<sup>66</sup> That court concluded that the FDA’s labeling requirements represented a “floor, not a ceiling, for state regulation.”<sup>67</sup> Accordingly, the court held that there was no conflict between the state law trial court ruling and federal law and thus no preemption defense.<sup>68</sup>

The Supreme Court issued a split decision, with a majority opinion written by Justice Stevens and joined by four other justices.<sup>69</sup> The Court agreed that the manufacturer failed to establish a preemption defense, concluding that the manufacturer could have provided additional or more detailed warnings that were consistent with FDA directions and which could have been approved by the FDA.<sup>70</sup> In doing so, the Court noted that, “absent clear evidence that the FDA would not have approved a change to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.”<sup>71</sup> It is this “clear evidence” language that subsequent

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60. *Id.* at 572.

61. *Id.* at 561–62.

62. *Id.*

63. *Id.* at 560–62.

64. *Id.*

65. *Id.* at 563.

66. *Levine v. Wyeth*, 944 A.2d 179, 197 (Vt. 2006).

67. *Id.* at 184.

68. *Id.* at 194.

69. *Wyeth*, 555 U.S. at 555.

70. *Id.* at 573.

71. *Id.* at 571.

courts, including the Third Circuit in *In re Fosamax*, latched onto to deny preemption claims that might otherwise be viable.<sup>72</sup>

Nonetheless, the various opinions the justices issued in *Wyeth* reflect disparate views regarding preemption as well as the record in the case.<sup>73</sup> For example, while Justice Breyer joined the majority, he also issued a concurring opinion noting that “it is . . . possible that state tort law will sometimes interfere with the FDA’s desire to create a drug label containing a specific set of cautions and instructions” and that “some have argued that state tort law can sometimes raise prices to the point where those who are sick are unable to obtain the drugs they need.”<sup>74</sup>

Justice Thomas wrote separately to concur in the judgment but spent most of his separate opinion attacking a particular aspect of the majority’s decision—specifically, what he described as “the majority’s implicit endorsement of far-reaching implied pre-emption doctrines.”<sup>75</sup> In particular, he objected to the Court’s “purposes and objectives” preemption jurisprudence under which the Court invalidated legislation where it conflicted with “broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law.”<sup>76</sup> Justice Thomas indicated that there should be some limits on the

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72. See Lindenfeld, *supra* note 11, at 641 (“Since the decision in *Levine*, courts have increasingly grappled with the clear evidence legal standard. The standard, which requires a court to determine the hypothetical answer to what FDA would have done, has confounded judges and commentators alike, and has spawned ‘a hodgepodge of judicial opinions that have reached varying results.’” (internal citations omitted)); see also *In re Fosamax* (Alendronate Sodium) Prods. Liab. Litig., 852 F.3d 268, 285–86 (3d Cir. 2017) (applying the clear evidence standard), *vacated*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019).

73. See *Wyeth*, 555 U.S. at 555.

74. *Id.* at 582 (Breyer, J., concurring) (citing Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, in *THE LIABILITY MAZE* 334, 335–36 (Peter W. Huber & Robert E. Litan eds., 1991)).

75. *Id.* at 583 (Thomas, J., concurring).

76. *Id.* As Justice Thomas further explained:

[T]here is no factual basis for the assumption underlying the Court’s “purposes and objectives” pre-emption jurisprudence that every policy seemingly consistent with federal statutory text has necessarily been authorized by Congress and warrants pre-emptive effect. Instead, our federal system in general, and the Supremacy Clause in particular, accords pre-emptive effect to only those policies that are actually authorized by and effectuated through the statutory text.

*Id.* at 602.

Court's preemption jurisprudence given the "federalist structure" embodied in the Constitution, which contemplated that the States would "retain substantial sovereign authority."<sup>77</sup>

Justice Thomas also noted potential inconsistencies in the Court's preemption jurisprudence, maintaining that the Court had "used different formulations of the standard to be used in deciding whether state and federal law conflict, and thus lead to pre-emption, under the 'impossibility' doctrine."<sup>78</sup> Specifically, he noted that some of the Court's cases had focused on whether there was a "direct" conflict, while others focused on "physical impossibility."<sup>79</sup> Without indicating a specific view on the correct standard, he concluded that the record before the Court indicated that the plaintiff's claims were not preempted.<sup>80</sup>

Justice Alito wrote a separate dissent, joined by Chief Justice Roberts and Justice Scalia, based largely on disputes regarding the contents of the record.<sup>81</sup> The majority opinion had concluded that "the labeling did not contain a specific warning about the risks of IV-push administration."<sup>82</sup> However, the dissent concluded that it was "demonstrably untrue that the FDA failed to consider (and strike a 'balance' between) the specific costs and benefits associated with IV push."<sup>83</sup> Justice Alito noted that the FDA had convened an advisory committee to look at, among other things, IV push and that the committee had "recommended an additional IV-push-specific warning for Phenergan's label."<sup>84</sup> In addition, in response to the committee's findings, the FDA directed that the manufacturer "make several changes to strengthen Phenergan's label, including the addition of uppercase warnings related to IV push."<sup>85</sup>

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77. *Id.* at 584–85. Justice Thomas further stated that, "[I]n order to protect the delicate balance of power mandated by the Constitution, the Supremacy Clause must operate only in accordance with its terms." *Id.* at 585.

78. *Id.* at 589 (internal citation omitted).

79. *Id.* at 589–90 (citing *Am. Tel. & Tel. Co. v. Cent. Office Tel., Inc.*, 524 U.S. 214, 227 (1998); *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)).

80. *Id.* at 591 ("[W]hatever the precise constitutional contours of implied pre-emption may be, I am satisfied that it does not operate against respondent's judgment below.").

81. *See id.* at 604–28 (Alito, J., dissenting).

82. *Id.* at 561 (majority opinion).

83. *Id.* at 612 (Alito, J., dissenting).

84. *Id.* at 613.

85. *Id.* at 613–14.

As a result of these regulatory proceedings, Justice Alito noted that the label “addressed IV push in several passages.”<sup>86</sup> The label “warned of the risks of intra-arterial injection associated with ‘aspiration,’” “cautioned against the use of ‘syringes with rigid plungers” used in administering Phenergan through IV push, and warned that “inadvertent intra-arterial injection can result in gangrene of the affected extremity.”<sup>87</sup> Thus, “[w]hile Phenergan’s label very clearly authorized the use of IV push, it also made clear that IV push is the delivery method of last resort.”<sup>88</sup> The dissent concluded that this record was sufficient to establish the preemption defense: “Where the FDA determines, in accordance with its statutory mandate, that a drug is on balance ‘safe,’ our conflict pre-emption cases prohibit any State from countermanding that determination.”<sup>89</sup>

Finally, the dissent included some discussion regarding its skepticism about allowing juries to make decisions that are more properly within the purview of experts at the FDA: “By their very nature, juries are ill equipped to perform the FDA’s cost-benefit-balancing function.”<sup>90</sup> The dissent viewed the FDA as the superior decisionmaker regarding such questions because, among other things, the agency had “the benefit of the long view” and its decisions “consider the interests of all potential users of a drug.”<sup>91</sup> Moreover, failing to apply the preemption doctrine where the FDA had passed on such questions would risk the development of disparate rules applied among various states in an area in which uniformity is desirable: “[T]he FDA conveys its warnings with one voice, rather than whipsawing the medical community with 50 (or more) potentially conflicting ones.”<sup>92</sup>

## II. APPLICATION IN *ALBRECHT*

In the years following the *Wyeth* decision, there was significant turnover in the Court’s membership. Justice Stevens, who authored the majority opinion, as well as Justices Kennedy and Souter who

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86. *Id.* at 617.

87. *Id.* at 617–18.

88. *Id.* at 618.

89. *Id.* at 609.

90. *Id.* at 626.

91. *Id.*

92. *Id.*

joined it, subsequently vacated their positions.<sup>93</sup> Moreover, as time went on, there was arguably a divergence among the circuit courts in their interpretation of the *Wyeth* decision. While some courts seemed to go to great lengths to interpret *Wyeth* as imposing a particularly stringent standard for manufacturers seeking to invoke the preemption defense, other courts did not read much into *Wyeth*'s "clear evidence" language.<sup>94</sup> Accordingly, in the decade following *Wyeth*, the stage was set for a potential shift in the Court's preemption jurisprudence as new members were called upon to revisit the preemption doctrine.<sup>95</sup>

The Supreme Court ultimately revisited the issue of preemption in the context of state law pharmaceutical product liability claims in *Merck Sharp & Dohme v. Albrecht*.<sup>96</sup> Unlike *Wyeth*, the *Albrecht* decision arose in the context of an MDL proceeding involving hundreds of claims alleging that Merck's osteoporosis medication, Fosamax, was associated with atypical femur fractures.<sup>97</sup> While it may be somewhat counterintuitive that a medication used to treat osteoporosis might actually contribute to bone fractures, plaintiffs' theory was that, due to the mechanism of action, medications containing bisphosphonates could inhibit bone repair, leading to "microcracks" and subsequent fractures.<sup>98</sup> Plaintiffs theorized that such microcracks would ordinarily be repaired in the process of bone "resorption," in which bone is continuously broken down and replaced

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93. See *id.* at 555 (majority opinion); see also *Justices 1789 to Present*, SUP. CT. U.S., [https://www.supremecourt.gov/about/members\\_text.aspx](https://www.supremecourt.gov/about/members_text.aspx) (last visited Apr. 20, 2020) (showing court membership over time).

94. See, e.g., *In re Incretin-Based Therapies Prods. Liab. Litig.*, 142 F. Supp. 3d 1108, 1115 (S.D. Cal. 2015) (noting that *Levine* "does not define what constitutes clear evidence"), *vacated*, 721 F. App'x 580 (9th Cir. 2017); *Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 762 (S.D. Ohio 2015) (*Levine* "did not define the 'clear evidence' standard, nor did it suggest the level of proof required"); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1270 (W.D. Okla. 2011) (lower courts are left to determine what satisfies the "clear evidence" standard in each case).

95. See *Greve et al.*, *supra* note 43, at 378 (noting that "the Roberts Court has proven more hospitable to preemption claims—when measured by raw case outcomes—than either of the Rehnquist Courts").

96. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019).

97. See *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 them to suffer serious thigh bone fractures."), *vacated*, *Albrecht*, 139 S. Ct. at 1668.

98. *Id.* at 272.

with new bone cells.<sup>99</sup> Because the medication slowed down the resorption process in order to combat bone loss due to osteoporosis, plaintiffs maintained that Fosamax could interfere with the normal process of repair, leading ultimately to the accumulation of microcracks and subsequent stress fractures.<sup>100</sup> Accordingly, hundreds of plaintiffs filed suit, alleging that the manufacturer should be held liable because it failed to adequately warn of this risk associated with its product.<sup>101</sup>

While the trial court originally ruled that state law claims were preempted because the FDA had arguably rejected such warnings, the Third Circuit reversed.<sup>102</sup> In doing so, the Third Circuit interpreted the *Wyeth* language regarding “clear evidence” in a particularly idiosyncratic way, arguably misinterpreting the Supreme Court’s preemption standard and imposing unwarranted hurdles in front of defendants seeking to assert the preemption defense.<sup>103</sup>

#### A. *The MDL Court’s Ruling*

The preemption issue in *Albrecht* arose in a somewhat unusual procedural posture. In one of the hundreds of individual cases filed in the MDL, the defendant manufacturer sought summary judgment based on the preemption defense.<sup>104</sup> The trial court originally denied the motion on the ground that it believed that the motion should be considered after a more complete record was developed at trial.<sup>105</sup> In the ensuing trial proceeding, the manufacturer prevailed, obtaining a defense verdict based on the jury’s finding that there was no causal association between Fosamax and the plaintiff’s bone fracture.<sup>106</sup> The manufacturer then moved for judgment as a matter of law on the preemption defense, and even though the trial court had previously

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99. *Id.*

100. *Id.* As the court explained, “The standalone term ‘stress fracture’ typically connotes a fracture resulting from excessive loading of a normal bone, and is commonly seen in physically active individuals. A so-called ‘insufficiency stress fracture,’ by contrast, is a fracture caused by normal loading of poor-quality bone.” *Id.*

101. *Id.* at 271–72.

102. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 951 F. Supp. 2d 695, 700 (D.N.J. 2013), *vacated*, *Fosamax*, 852 F.3d at 302.

103. *See Fosamax*, 852 F.3d at 295–300.

104. *Fosamax*, 951 F. Supp. 2d at 700.

105. *Id.*

106. *See id.* at 701, 705.

denied the manufacturer's motion for summary judgment, the court granted the manufacturer's motion for judgment as a matter of law.<sup>107</sup>

The trial court concluded that there was "clear evidence that the FDA would not have approved a label change to the Precautions section of the Fosamax label."<sup>108</sup> In doing so, the court detailed an extensive record of communications between the manufacturer and the FDA, documenting that the agency had thoroughly considered the issue but had concluded that there was no basis for warnings suggesting that there was a causal relationship between Fosamax and atypical femur fractures.<sup>109</sup>

In June 2008, the FDA raised the issue when it sent manufacturers of products containing bisphosphonate (including Merck, the manufacturer of Fosamax) a request for information regarding the occurrence of atypical fractures in patients taking the medications.<sup>110</sup> The FDA noted that there had been reports regarding hip fractures in patients taking products containing bisphosphonate and accordingly that there was a "safety signal."<sup>111</sup>

The FDA reviewed the data it had collected from the manufacturers and concluded that it did not show an increase in the risk of atypical bone fractures.<sup>112</sup> Nonetheless, out of an abundance of caution, in September 2008, the manufacturer submitted a Prior Approval Supplement (PAS) to the FDA,<sup>113</sup> which suggested additional information to be included in the label regarding the

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107. *Id.* at 705.

108. *Id.* at 703.

109. *Id.* at 703–04.

110. *Id.* at 697. This was not the first time the issue had been raised. During the initial approval of Fosamax, there was discussion with the FDA regarding whether there was a theoretical possibility of bone fractures:

During Fosamax's development, Merck scientists and third-party researchers discussed the possibility that antiresorptive drugs could inhibit a bone's ability to repair microdamage, potentially leading to stress fractures. . . . Nonetheless, when the FDA approved Fosamax in 1995 for the treatment of osteoporosis in postmenopausal women, it did not require Merck to include a warning about bone fractures.

*In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 275 (3d Cir. 2017), *vacated*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). The Third Circuit concluded that, "Both Merck and the FDA have long been aware that antiresorptive drugs like Fosamax could theoretically increase the risk of atypical femoral fractures." *Id.* at 274.

111. *Fosamax*, 951 F. Supp. 2d at 697.

112. *Id.*

113. For a discussion of the PAS process, see 21 C.F.R. § 314.70(b) (2019).

occurrence of atypical fractures.<sup>114</sup> In particular, the manufacturer suggested that the occurrence of fractures be mentioned not only in the Adverse Reactions section of the label, but also in the Precautions section with the following warning:

Low-energy fractures of the subtrochanteric and proximal femoral shaft have been reported in a small number of bisphosphonate-treated [sic] patients. Some were stress fractures (also known as insufficiency fractures) occurring in the absence of trauma. Some patients experienced prodromal pain in the affected area, often associated with imaging features of stress fracture, weeks to months before a complete fracture occurred. 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 bisphosphonates. Patients with suspected stress fractures should be evaluated, including evaluation for known causes and risk factors (e.g., vitamin D deficiency, malabsorption, glucocorticoid use, previous stress fracture, lower extremity arthritis or fracture, extreme or increased exercise, diabetes mellitus, chronic alcohol abuse), and receive appropriate orthopaedic care. Interruption of bisphosphonate therapy in patients with stress fractures should be considered, pending evaluation of the patient, based on individual benefit risk/assessment.<sup>115</sup>

In April 2009, the FDA approved the additional language for the Adverse Reactions section but rejected the more detailed warnings that the manufacturer proposed for the Precautions section of the label.<sup>116</sup>

Underscoring that the agency did not believe further warnings were warranted, in May 2009, when the FDA sent a formal letter encapsulating its response to Merck's proposed language, the agency warned the manufacturer that Fosamax could "be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act" if the

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114. *Fosamax*, 951 F. Supp. 2d at 697–98.

115. *Id.* at 698 (quoting Merck's Sept. 15, 2008 Prior Approval Supplement).

116. *Id.*

manufacturer included additional labeling changes before the FDA approved them.<sup>117</sup> The FDA explained its decision as follows:

We have completed the review of your [PAS] applications, as amended, and have determined that we cannot approve these applications in their present form. We have described below our reasons for this action and our recommendation to address this issue.

1. While the Division agrees that atypical and subtrochanteric fractures should be added to the **ADVERSE REACTIONS, Post-Marketing Experience** subsections of the [Fosamax] labels, your justification for the proposed **PRECAUTIONS** section language is inadequate. Identification of “stress fractures” may not be clearly related to the atypical subtrochanteric fractures that have been reported in the literature. Discussion of the risk factors for stress fractures is not warranted and is not adequately supported by the available literature and post-marketing adverse event reporting.<sup>118</sup>

As the FDA made clear, neither the published scientific literature it had reviewed, nor the post-marketing adverse event data reported to the agency warranted a change to the labeling to warn about the risk of stress fractures or atypical fractures in patients taking the medication.<sup>119</sup>

The FDA continued to examine the issue and released a series of public statements that addressed the concerns that had been raised regarding bone fractures.<sup>120</sup> In March 2010, the FDA published a Drug Safety Communication reporting the results of its analysis and stating that, “[a]t this point, the data that FDA has reviewed have not shown a clear connection between bisphosphate use and a risk of atypical subtrochanteric femur fractures.”<sup>121</sup> The FDA made clear

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117. *Id.*

118. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 277 (3d Cir. 2017) (quoting Letter from U.S. Food & Drug Admin. to Merck Sharp & Dohme (May 22, 2009)), *vacated*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019).

119. *See id.*

120. *Id.* at 287.

121. *Fosamax*, 951 F. Supp. 2d at 699 (quoting *FDA Drug Safety Communication*, U.S. FOOD & DRUG ADMIN. (Mar. 10, 2010), <https://www.fda.gov/drugs/postmarket->

that it was further examining the issue and that it was “working closely with outside experts, including members of the . . . American Society of Bone and Mineral Research Subtrochanteric Femoral Fracture Task Force, to gather [and analyze] additional information.”<sup>122</sup>

In September 2010, the American Society of Bone and Mineral Research (ASMBR) published a report that stated that there was an association between long-term bisphosphonate use and atypical femoral fractures.<sup>123</sup> However, the report concluded that the observed association had not been “proven to be causal.”<sup>124</sup>

In response to the report from the ASMBR Task Force, the FDA issued a second Drug Safety Communication largely repeating the Task Force’s findings.<sup>125</sup> The FDA agreed that, “[a]lthough it is not clear if bisphosphonates are the cause [of AFFs], these unusual femur fractures have been identified in patients taking these drugs.”<sup>126</sup> Nonetheless, the new ASMBR report appeared to move the needle somewhat in favor of additional warnings. The FDA noted that, based on the data the agency had assembled and reviewed, it was “considering” additional labeling revisions.<sup>127</sup>

In October 2010, the FDA issued its third Drug Safety Communication announcing additional labeling revisions.<sup>128</sup> The FDA indicated “that it would require all bisphosphonate manufacturers to add information on [atypical femoral fractures] to the Precautions section of [their] drug labels and [would] require a new Limitations of Use statement in the Indications and Usage section of the label.”<sup>129</sup> Thus, while the agency had previously rejected Merck’s proposed warnings in the Precautions section, after more than a year of data collection, study, and review, the FDA ultimately determined that

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drug-safety-information-patients-and-providers/fda-drug-safety-communication-ongoing-safety-review-oral-bisphosphonates-and-atypical).

122. *Id.*

123. *Id.* (citing Elizabeth Shane et al., *Atypical Subtrochanteric and Diaphyseal Femoral Fractures: Report of a Task Force of the American Society for Bone and Mineral Research*, 25 J. BONE & MIN. RES. 2267, 2269 (2010)).

124. *Id.*

125. *See id.*

126. *Id.*

127. *Id.*

128. *Id.* at 699–700.

129. *Id.* (citing *FDA Drug Safety Communication: Safety Update*, U.S. FOOD & DRUG ADMIN. (Mar. 13, 2010), <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-safety-update-osteoporosis-drugs-bisphosphonates-and-atypical>).

language should be added to this section as well. Nonetheless, this determination came only years after the agency's rejection of similar warnings and, even at this later date, the FDA noted that a causal relationship had not been established: "Although it is not clear if bisphosphonates are the cause, these unusual femur fractures have been predominately reported in patients taking bisphosphonates."<sup>130</sup>

As a result, and in response to the FDA directives, the manufacturer ultimately included the following warning in the Fosamax labeling:

Atypical, low-energy, or low trauma fractures of the femoral shaft have been reported in bisphosphonate-treated patients. . . . Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with bisphosphonates. Atypical femur fractures most commonly occur with minimal or no trauma to the affected area.<sup>131</sup>

The question before the trial court was whether claims by plaintiffs who had taken Fosamax and developed atypical fractures before the warnings were included in the Precautions section could bring their claims or whether their claims were preempted by federal law.<sup>132</sup>

The trial court agreed that the claims were preempted "because the FDA rejected Defendant's proposed label change," which was "clear evidence that the FDA would not have approved a stronger warning to the Precautions section of the label."<sup>133</sup> In doing so, the trial court rejected a variety of arguments the plaintiffs raised, including that the FDA's true reason for rejecting Merck's proposed labeling was that it used the phrase "stress fracture" rather than "atypical" fracture;<sup>134</sup> that the manufacturer could have implemented labeling changes unilaterally through a "Changes Being Effected"

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130. *Id.* at 700 (quoting *FDA Drug Safety Communication: Safety Update*, *supra* note 129).

131. *Id.*

132. *See id.*

133. *Id.*

134. *Id.* at 701, 704.

(CBE) supplement;<sup>135</sup> and that Merck had allegedly failed to provide the FDA with all relevant information regarding the label.<sup>136</sup>

The trial court reasoned that the record before the FDA showed that the agency had expressly rejected additional warnings to the Precautions section of the label when Merck submitted them: “The FDA’s rejection constitutes clear evidence that the FDA would not have approved a label change to the Precautions section of the label prior to [plaintiff’s] injury.”<sup>137</sup>

In rejecting plaintiff’s claim that the FDA action was based on the proposed label’s use of the phrase “stress fractures” rather than “atypical” fractures, the court noted that the FDA never came back to the manufacturer to ask it to submit new language.<sup>138</sup> Nor did plaintiff submit any direct evidence suggesting that the real reason for the FDA’s outright rejection of the proposed language in the Precautions section of the label was the use of the term “stress fracture.”<sup>139</sup>

Similarly, the trial court rejected plaintiff’s argument that the manufacturer could have submitted changes through a CBE supplement.<sup>140</sup> As the court noted, much like the PAS the manufacturer submitted but the FDA rejected, with a CBE supplement the “proposed change must be based on ‘reasonable evidence of’ an association between a hazard and the drug at issue.”<sup>141</sup> The court agreed that since the FDA rejected the manufacturer’s PAS, it would not have approved a CBE seeking to add the same language that it had rejected in the PAS.<sup>142</sup> Moreover, the court noted that using a CBE supplement to unilaterally add language to the product labeling would, as the FDA had suggested in correspondence with the manufacturer, render the product misbranded.<sup>143</sup>

Finally, the trial court concluded that the manufacturer had not failed to provide the FDA all the information it possessed on femur

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135. *Id.* at 701. Through a CBE supplement, the manufacturer may unilaterally change a drug label without prior FDA approval if there is “newly acquired information.” 21 C.F.R. § 314.70(c)(6)(iii) (2019). The FDA may then review and approve the supplement at a later time. *See id.*

136. *Fosamax*, 951 F. Supp. 2d at 701, 705.

137. *Id.* at 703.

138. *Id.* at 703–04.

139. *Id.* at 704.

140. *Id.* at 704–05.

141. *Id.* at 704 (quoting *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1271 (W.D. Okla. 2011)).

142. *Id.*

143. *Id.*

fractures, as the plaintiff alleged.<sup>144</sup> As the trial court noted, the record showed that the FDA was clearly in possession of information regarding the alleged link between bisphosphonate and atypical fractures.<sup>145</sup>

Having decided the issue in the context of an individual case, the trial court proceeded to put in place a procedure for applying its ruling to the hundreds of other cases that had been filed in the MDL. The court entered an order requiring all other plaintiffs in the MDL to show cause as to why their claims should not be dismissed pursuant to the court's preemption ruling and ultimately applied its preemption ruling to all claims in the MDL.<sup>146</sup>

While plaintiffs objected to this show cause procedure, the trial court rejected their objections.<sup>147</sup> As the court observed, it had repeatedly indicated to plaintiffs in the MDL that its ruling in the individual case would have a potential effect as to other plaintiffs in the MDL.<sup>148</sup> Moreover, through the show cause procedure, the court was effectively giving plaintiffs "another opportunity" to demonstrate that summary judgment was not warranted based on preemption.<sup>149</sup> The court likewise rejected plaintiffs' argument that there was some sort of "fraud" on the FDA through incomplete disclosure, noting that in *Buckman Co. v. Plaintiffs' Legal Committee*, the Supreme Court held that such claims regarding alleged fraud on the FDA would be preempted by federal statutory law that charged the FDA with policing submissions made to the agency.<sup>150</sup>

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144. *Id.* at 705.

145. *Id.*

146. *In re Fosamax (Alendronate Sodium): Prods. Liab. Litig.*, No. 08-08(JAP)(LHG), 2014 WL 1266994, at \*10 (D.N.J. Mar. 26, 2014), *vacated*, 852 F.3d 268, 302 (3d Cir. 2017).

147. *Id.*

148. *Id.* at \*8.

149. *Id.* at \*10.

150. *Id.* at \*17 (citing *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 (2001)). The court also rejected plaintiffs' attempts to argue that their design defect claims were somehow exempt from the court's preemption ruling. *Id.* at \*14. As the court noted, the design defect claims amounted to failure-to-warn claims because the plaintiffs were not arguing that some different, non-defective design could have been utilized. *Id.* at \*13. Rather, the plaintiffs were saying that the labeling was inadequate or defective because there was not full disclosure of the risks associated with the product. *Id.*

*B. The Third Circuit's Rebuke*

The Third Circuit reversed the trial court, and in doing so offered its own gloss on the standard for preemption under the Supreme Court's decision in *Wyeth v. Levine*.<sup>151</sup> Latching onto the language in the Supreme Court's decision, the Third Circuit opined that "[t]he *Wyeth* 'clear evidence' standard is demanding and fact-sensitive."<sup>152</sup> The court reasoned that part of the preemption inquiry is determining whether the FDA would theoretically reject additional warnings that plaintiffs maintain were warranted.<sup>153</sup>

The court noted that what it labeled the "clear evidence standard" articulated in the *Wyeth* decision is "undefined"<sup>154</sup> and "is cryptic and open-ended, and lower courts have struggled to make it readily administrable."<sup>155</sup> According to the Third Circuit, "The *Wyeth* Court did not define the 'clear evidence' standard or explain how courts should apply it. The only guidance the Court offered was to call impossibility preemption a 'demanding defense.'"<sup>156</sup> The court then sought to fill this void by creating its own standard based on the language in the *Wyeth* decision.<sup>157</sup>

The Third Circuit interpreted this "standard" as a "standard of proof"<sup>158</sup> and concluded that it required a manufacturer to show that it is "highly probable" that additional or different labeling would be rejected by the FDA.<sup>159</sup> In calling the standard a "standard of proof," the court explained that "it specifies how *difficult* it will be for the manufacturer to convince the factfinder that the FDA would have rejected a proposed label change" and that "[t]he manufacturer must prove that the FDA would have rejected a warning not simply by a preponderance of the evidence, as in most civil cases, but by 'clear evidence.'"<sup>160</sup>

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151. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 302 (3d Cir. 2017), *vacated*, *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019).

152. *Id.* at 271.

153. *Id.*

154. *See id.* at 284.

155. *Id.* at 282.

156. *Id.* at 284.

157. *See id.*

158. *Id.* at 282, 284.

159. *Id.* at 295 ("Wyeth's 'clear evidence' standard of proof requires the manufacturer to prove that it is highly probable that the FDA would not have approved a change to the drug's label.").

160. *Id.* at 285.

In making this determination, the court made a related ruling that impacted its interpretation of the standard. The court ruled that it was permissible for juries to decide the preemption issue and that it was *not* an issue reserved solely for the court.<sup>161</sup> As a result, the court determined that the relevant inquiry was “whether a reasonable jury could find that the FDA would have approved the change.”<sup>162</sup>

The court therefore rejected Merck’s contention that the preemption issue was a pure question of law that only judges should decide and accepted plaintiffs’ contention that this was an issue that was, at a minimum, a mixed question of law and fact that juries could decide.<sup>163</sup> As the court noted, this distinction between questions of law and mixed questions of law and fact was “crucial in this case because it dictates the course of our summary judgment analysis.”<sup>164</sup> In particular, it dictated the standard that the court articulated, which focused on what “reasonable jurors” could determine based on the facts.<sup>165</sup>

The court reasoned that this issue involved questions of fact for several reasons. Among other things, the court noted that it entailed an “assessment of the probability of a future event”—whether the FDA would reject or accept additional or different warnings, weighing conflicting evidence, making inferences from the facts, and assessments regarding the motives and thought processes of FDA officials.<sup>166</sup> As a result, under the court’s ruling, “[a] state-law failure-

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161. *Id.* at 289. Other courts had suggested in contrast that “[t]he preemption decision is not evidence-based but is rather a question of law.” *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, 142 F. Supp. 3d 747, 755 (N.D. Ill. 2015) (quoting *Garza v. Wyeth LLC*, No. 2:12-CV-198, 2015 WL 364286, at \*4 (S.D. Tex. Jan. 27, 2015)).

162. *Fosamax*, 852 F.3d at 282.

163. *See id.* at 288. In support of their contention, plaintiffs pointed to cases like the Supreme Court’s decision in *Boyle v. United Technologies Corp.*, where the Court noted that questions regarding the government contractor defense could be submitted to a jury. *Id.* (citing 487 U.S. 500 (1988)).

164. *Id.* at 286.

165. *Id.*

166. *Id.* at 289–90; *see also id.* at 293 (“[W]e do not see any convincing prudential reasons to commit the *Wyeth* inquiry to a court rather than a jury.”). As the court explained:

We are instead trying to anticipate whether a reasonable juror, looking at all the evidence and trying to reconstruct a hypothetical event, could conclude that it is less than highly probable that the FDA would have rejected the change. And crucially for the Plaintiffs, we are drawing all reasonable inferences in their favor.

*Id.* at 297.

to-warn claim will only be preempted if a jury concludes it is highly probable that the FDA would not have approved a label change.”<sup>167</sup>

The court found that this standard was not satisfied because there was a disputed issue of fact regarding the reason that the FDA had rejected Merck’s proposed labeling.<sup>168</sup> Plaintiffs had argued that the FDA’s objection to Merck’s use of the word “stress fractures” in the proposed labeling could have been the reason for the FDA rejection of the labeling and not some broader concern that a warning regarding atypical fractures was not supported.<sup>169</sup> Basically, plaintiffs’ argument boiled down to a contention that “stress fractures” were not the same as “atypical femoral fractures” and that the FDA may have accepted the labeling if it had focused on atypical fractures, rather than using the term “stress fractures.”<sup>170</sup>

The Third Circuit agreed, concluding that “a reasonable jury could . . . conclude that the FDA rejected Merck’s proposed warning about femoral fractures in 2009 not because it denied the existence of a causal link between Fosamax and fractures, but because Merck repeatedly characterized the fractures at issue as ‘stress fractures.’”<sup>171</sup> The court characterized stress fractures as “minor fracture[s]” in contrast to the “atypical” femoral fractures that were at issue in the litigation, which it believed were more significant and serious fractures.<sup>172</sup>

### C. The Supreme Court Disagrees

The Supreme Court rejected the Third Circuit’s analysis.<sup>173</sup> As Justice Breyer made plain in his majority opinion in which five other Justices joined, “We here determine that this question of pre-emption

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167. *Id.* at 293. The court further explained that “[a] trial by jury would only be necessary in those cases where the evidence presented is more compelling than that in *Wyeth* but no ‘smoking gun’ rejection letter from the FDA is available.” *Id.* at 294.

168. *Id.* at 297.

169. *Id.*

170. *Id.* at 277. Among other things, the Third Circuit noted: “In rejecting Merck’s proposal, the FDA explained that ‘the term “stress fracture” was considered and not accepted. The Division believes that for most practitioners, the term “stress fracture” represents a minor fracture and this would contradict the seriousness of the atypical femoral fractures associated with bisphosphonate use.’” *Id.* at 279.

171. *Id.* at 298; *see also id.* at 300 (concluding that “[a] reasonable juror reviewing the evidence in this case could find it less than highly probable that FDA would” reject additional warnings).

172. *Id.* at 298–99.

173. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019).

is one for a judge to decide, not a jury.”<sup>174</sup> The Court cited multiple reasons for its decision.

First, the Court noted the “complexity” of the legal issues that must be resolved in deciding the preemption question: “The question often involves the use of legal skills to determine whether agency disapproval fits facts that are not in dispute.”<sup>175</sup> The Court concluded that judges would be “better equipped to evaluate the nature and scope of an agency’s determination” precisely because of their superior legal skills.<sup>176</sup> As the Court observed, “Judges are experienced in ‘[t]he construction of written instruments,’ such as those normally produced by a federal agency to memorialize its considered judgments.”<sup>177</sup> In addition, “judges are better suited than are juries to understand and to interpret agency decisions in light of the governing statutory and regulatory context.”<sup>178</sup>

Second, the Court maintained that committing the preemption question to judges would lead to “greater uniformity.”<sup>179</sup> Again, the Court’s skepticism of jury decisionmaking manifested itself in its comments on this consideration. In citing the need for uniformity, the Court seemed to assume that juries are prone to decisionmaking that is less than rational and not based on principles that would lead to consistent determinations from case to case. In contrast, the Court appeared to have greater confidence in the judiciary.<sup>180</sup> As a result, it believed that its decision would have positive practical consequences in that “greater uniformity is normally a virtue when a question requires a determination concerning the scope and effect of federal agency action.”<sup>181</sup>

Third, the Court indicated that, in its view, the preemption question would seldom turn on disputed facts, but rather was a primarily legal question.<sup>182</sup> The court acknowledged that “sometimes contested brute facts will prove relevant to a court’s legal

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174. *Id.* at 1672.

175. *Id.* at 1679–80.

176. *Id.* at 1680.

177. *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996)).

178. *Id.* (observing that “[t]o understand the question as a legal question for judges makes sense given the fact that judges are normally familiar with principles of administrative law”).

179. *Id.*

180. *See id.*

181. *Id.* (citing *Markman*, 517 U.S. at 390–91).

182. *Id.*

determination about the meaning and effect of an agency decision.”<sup>183</sup> Nonetheless, the Court did not believe that such factual determinations would be the driver of judges’ preemption decisions.<sup>184</sup> Moreover, it indicated that such factual questions were “subsumed within an already tightly circumscribed legal analysis.”<sup>185</sup>

In addition, the Court noted that in other contexts in which the Court had decided that questions were properly left for judges rather than juries, there likewise were “subsidiary factual disputes” that courts had to decide in order to decide the “broader legal question.”<sup>186</sup> These included, for example, the proper construction of patent claims and the voluntariness of criminal confessions, which the Court had already ruled were matters for judicial rather than jury decisionmaking.<sup>187</sup> “In those circumstances, ‘the fact/law distinctions at times has turned on a determination that, as a matter of the sound administration of justice, one judicial actor is better positioned than another to decide the issue in question.’”<sup>188</sup>

Having decided the question before it—whether judges or juries should decide the preemption issue—the Court then went on to discuss the “clear evidence” language from *Wyeth* that had caused such confusion among the lower courts, noting that the Court sought to “elaborate *Wyeth*’s requirements along the way.”<sup>189</sup> The majority made clear that, contrary to the Third Circuit’s view, the “clear evidence” language in *Wyeth* was not intended to impose a standard of proof.<sup>190</sup> This conclusion was consistent with, and indeed arguably dictated by, the Court’s determination that the preemption issue was one for judges and not juries:

We do not further define *Wyeth*’s use of the words “clear evidence” in terms of evidentiary standards, such as “preponderance of the evidence” or “clear and convincing evidence” and so forth, because . . . courts should treat the critical question not as a matter of

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183. *Id.*

184. *Id.*

185. *Id.*

186. *Id.* (quoting *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 327 (2015)).

187. *Id.* (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996)).

188. *Id.* (quoting *Markman*, 517 U.S. at 388).

189. *Id.* at 1676 (citing *Wyeth v. Levine*, 555 U.S. 555, 571 (2009)).

190. *Id.* at 1679.

fact for a jury but as a matter of law for the judge to decide.<sup>191</sup>

Because the preemption question was primarily an issue of law for judges to decide, construing the “clear evidence” language as an “evidentiary” standard would be inappropriate.<sup>192</sup> Rather, the only issue for the judge deciding such questions was whether “the relevant federal and state laws ‘irreconcilably conflic[t].’”<sup>193</sup>

The Court went on to elaborate that “clear evidence” was “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.”<sup>194</sup> The majority sought to tie these requirements to its prior decision in *Wyeth*, which was the source for the “clear evidence” rubric.<sup>195</sup> The Court noted that there were two reasons that the preemption argument “fell short” in *Wyeth*.<sup>196</sup> The first reason was that the manufacturer in *Wyeth* had not “supplied the FDA with an evaluation or analysis concerning the specific dangers’ that would have merited the warning.”<sup>197</sup> The second reason was that the manufacturer had not “attempted to give the kind of warning required by [state law] but was prohibited from doing so by the FDA.”<sup>198</sup> For these reasons, the Court held in *Wyeth* that the manufacturer had not demonstrated “that ‘it was impossible . . . to comply with both federal and state requirements.’”<sup>199</sup>

Having recounted the decisionmaking in *Wyeth*, Justice Breyer writing for the *Albrecht* majority observed that “[t]he underlying question for this type of impossibility pre-emption defense is whether federal law (including appropriate FDA actions) prohibited the drug

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191. *Id.*

192. *See id.*

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

194. *Id.* at 1672.

195. More generally, the Court sought to link its articulation of the standard to the Court’s prior impossibility preemption cases, asserting that its “conclusions flow from our precedents on impossibility pre-emption and the statutory and regulatory scheme that we reviewed in *Wyeth*.” *Id.* at 1678 (citing *Wyeth v. Levine*, 555 U.S. 555, 578 (2009)).

196. *Id.*

197. *Id.* (quoting *Wyeth*, 555 U.S. at 572–73).

198. *Id.* (quoting *Wyeth*, 555 U.S. at 572 n.5).

199. *Id.* (quoting *Wyeth*, 555 U.S. at 573).

manufacturer from adding any and all warnings to the drug label that would satisfy state law.”<sup>200</sup> The Court concluded that:

In a case like *Wyeth*, showing that federal law prohibited the drug manufacturer from adding a warning that would satisfy state law requires the drug manufacturer to show that it 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 changing the drug’s label to include that warning.<sup>201</sup>

The majority’s decision thus construed the “standard” as a very formalistic legal determination that judges could make without the need to delve extensively into disputed questions of fact.<sup>202</sup>

*Albrecht* thus arguably constitutes another step in the trend toward eroding jury power. Like the Court’s determinations that patent claim construction and the voluntariness of criminal convictions are matters for judges and not for juries to decide, the decision in *Albrecht* removes another area from the scope of jury decisionmaking. Moreover, at least in part, the rationale for doing so appears to be a deep skepticism on the part of the Court with respect to the rationality of jury decisionmaking. Particularly in a highly technical area such as agency decisionmaking regarding health and safety matters, the Court determined that judges would be superior decisionmakers as compared with juries given their familiarity with agency decisionmaking. *Albrecht* therefore stands in contrast to the approach taken by many lower courts, which viewed the preemption analysis as a highly fact-intensive matter that, in some circumstances at least, might be the appropriate subject of jury factfinding.

### III. THE FUTURE OF THE PREEMPTION DOCTRINE

The Supreme Court’s decision in *Albrecht* is likely to be the subject of ongoing debate within the federal judiciary charged with deciding preemption questions. Courts will continue to struggle with what precisely constitutes “clear evidence” sufficient to warrant application of the preemption doctrine. Moreover, the Court’s decision to leave the

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200. *Id.*

201. *Id.*

202. *See id.*

preemption issue to judges rather than juries may have significant consequences with respect to the strength of the preemption doctrine.

A. *The Likelihood of Pre-Trial Relief*

By committing preemption decisions to judges rather than juries, the Court has arguably paved the way for greater utilization of the preemption doctrine to bar cases before they go to trial. It is now clear that the Court views the preemption issue as one that is susceptible to decision as a “matter of law,” and in some ways *Albrecht* is an open invitation to trial judges to use their power to dispose of cases or entire groups of cases based on their own analysis of the record.

Moreover, the Court’s decision suggests that, in the Court’s view, the outcome of such decisionmaking will not turn significantly on factual disputes regarding the record. Part of the Court’s rationale in committing preemption questions to judges rather than juries was that the administrative record should be largely undisputed, and it is not likely that there will be significant factual disputes of the sort that are decided by juries.<sup>203</sup> Yet, the Court’s analysis arguably ignores the history of preemption litigation. Frequently, there are at least differences with respect to the factual record, if not significant disputes regarding the facts, that courts have cited in denying the preemption defense. That was certainly the case in *Fosamax* itself where the Third Circuit’s decision turned largely on a reading of the factual record that differed from that of the trial court.<sup>204</sup> While the trial court concluded that the manufacturer had submitted information regarding stress fractures, the plaintiffs maintained that the sort of “atypical fractures” that were at issue in the litigation were not fully discussed in the factual record.<sup>205</sup>

Indeed, the Justices in *Albrecht* themselves appeared to have some disagreement regarding the facts. For example, Justice Alito in his concurrence asserted that the majority had provided “a one-sided account” of the record before the FDA.<sup>206</sup> According to Justice Alito, the majority had ignored “extensive communication between Merck and the FDA” that he found extremely relevant to the preemption analysis.<sup>207</sup> Accordingly, his opinion sets forth a lengthy summary of

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203. *See id.*

204. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 271, 294 (3d Cir. 2017), *vacated*, *Albrecht*, 139 S. Ct. at 1668.

205. *See id.* at 272.

206. *Albrecht*, 139 S. Ct. at 1685 (Alito, J., concurring).

207. *Id.*

email correspondence between the manufacturer and the FDA, safety announcements made by the agency regarding the potential risks of fractures, and the work of a task force charged with examining the issue.<sup>208</sup> This factual record, he maintained, demonstrated that “for years the FDA was: aware of this issue, communicating with drug manufacturers, studying all relevant information, and instructing healthcare professionals and patients alike to continue to use Fosamax as directed.”<sup>209</sup>

Nonetheless, the Supreme Court’s decision assumes, if not directs trial courts to find, that preemption questions do not turn on significant disputes regarding the factual record. As such, *Albrecht* makes clear that the preemption issue is a quintessential legal issue that should be resolved at the pre-trial stage.<sup>210</sup> The indecision that some courts have exhibited in deciding preemption questions based on purported factual disputes is arguably at odds with the Supreme Court’s directive in *Albrecht*.<sup>211</sup> The trend within some courts of deciding preemption questions based on their own view of the factual record is likely to be de-emphasized as courts apply *Albrecht*. The Supreme Court has made clear that in its view such factual determinations should seldom, if ever, be an impediment to barring claims on preemption grounds.

### *B. Overwarning and the Preeminence of Agency Decisionmaking*

Concerns that insufficiently rigorous enforcement of the preemption doctrine will lead to overwarning are likely to persist. Underapplication of the preemption doctrine may lead manufacturers to seek to include warnings in product labeling that are not supported by science. Not only the Court in *Albrecht*, but the FDA also has recognized that there are potential problems with overwarning in pharmaceutical labeling: “Exaggeration of risk, or inclusion of speculative or hypothetical risks, could discourage appropriate use of a beneficial drug.”<sup>212</sup> Anyone who has taken the time to review the labeling for a pharmaceutical product can see that such labeling frequently includes a laundry list of conditions, many of which are not

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208. *See id.* at 1685–86.

209. *Id.* at 1686.

210. *See id.* at 1680 (majority opinion).

211. *See id.*

212. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008) [hereinafter Proposed Labeling Changes].

likely to occur with the medication and many of which may not be particularly serious.

One theme arguably underlying the Supreme Court's decision in *Albrecht* is the Court's concern with committing preemption questions to juries precisely because juries may be more likely to believe that manufacturers should be held liable where they failed to include warnings in the labeling, even where such warnings were not supported by the existing science. Precautions accompanying pharmaceutical labeling should be based on sound science, and Congress arguably established a preeminent role for the FDA in deciding such scientific questions under the statutory framework.<sup>213</sup> Allowing juries to second-guess such agency decisionmaking appears to be a significant concern at the forefront of the Supreme Court's reasoning in issuing the *Albrecht* decision.<sup>214</sup>

As the Supreme Court recognized in *Albrecht*, allowing juries to decide questions that are within agency competence can have a variety of adverse consequences.<sup>215</sup> The FDA has recognized, for example, that it is important to include only scientifically supported information in a pharmaceutical's labeling: "[L]abeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to lose its significance."<sup>216</sup> Allowing lay juries to decide that additional warnings that the agency has deemed scientifically unsupported should be included in the labeling could have significant adverse public health consequences. The message for the judiciary charged with deciding preemption questions is that labeling must be based on sound science and that, where experts at the FDA conclude that warnings would be counterproductive or are not scientifically justified, those determinations should stand and should not be second-guessed in state law tort litigation.<sup>217</sup>

### C. *The "Method" by Which Preemption Is Accomplished*

One issue that the Court in *Albrecht* specifically left open was the type of FDA action that may trigger the preemption analysis. The Court noted that, under federal law, the FDA can communicate its

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213. See *Albrecht*, 139 S. Ct. at 1679.

214. See *id.* at 1680.

215. See *id.*

216. Proposed Labeling Changes, 73 Fed. Reg. at 2851.

217. See Moreland, *supra* note 20, at 1255 ("A recurring question in the preemption debate is whether permitting judges and juries to second-guess federal administrative safety determinations undermines the federal safety regime.").

“disapproval of a warning” through notice and comment rulemaking.<sup>218</sup> However, as the majority further acknowledged, there are other means by which the FDA could potentially reject a warning short of such notice and comment rulemaking.<sup>219</sup> The Court noted that it was not addressing the full panoply of potential mechanisms by which the FDA could express its conclusions: “The question of disapproval ‘method’ is not now before us.”<sup>220</sup> The majority noted only that, in order for preemption to apply, the FDA must be acting “within the scope of the authority Congress has lawfully delegated.”<sup>221</sup>

In his opinion concurring in the judgment, Justice Alito raised one such disapproval mechanism that he maintained was specifically codified in the statutes governing the FDA.<sup>222</sup> Under this mechanism, the FDA need take no affirmative action to express its disapproval—its inaction alone would be sufficient to establish that it disapproved of additional warnings because federal law places the burden on the FDA to take affirmative action under certain circumstances.<sup>223</sup>

Specifically, Justice Alito observed that “[u]nder 21 U.S.C. § 355(o)(4)(A), . . . Congress has imposed on the FDA a duty to initiate a label change ‘[i]f the Secretary becomes aware of new information, including any new safety information . . . that the Secretary determines should be included in the labeling of the drug.’”<sup>224</sup> The implication of this statutory provision is that the FDA could make determinations that would have preemptive effect simply by not acting in the face of submitted information: “[I]f the FDA declines to require a label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified.”<sup>225</sup> As Justice Alito noted, § 355(o)(4)(A) 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.”<sup>226</sup>

Moreover, as Justice Alito observed, under the plain language of this statute, “[t]he FDA’s duty does not depend on whether the relevant drug manufacturer, as opposed to some other entity or

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218. *Albrecht*, 139 S. Ct. at 1679.

219. *See id.*

220. *Id.*

221. *Id.*

222. *Id.* at 1684 (Alito, J., concurring).

223. *See id.*

224. *Id.* (quoting 21 U.S.C. § 355(o)(4)(A) (2018)).

225. *Id.* (citation omitted).

226. *Id.*

individual, brought the new information to the FDA's attention."<sup>227</sup> Accordingly, preemption could apply in situations where the record of FDA activity is thin. All that would be required would be to show that the FDA had information regarding a potential risk from any source and yet did not take any action to require manufacturers to address the potential risk through additional warnings.<sup>228</sup> Justice Alito specifically encouraged the court of appeals to address the effect of this statute on remand.<sup>229</sup>

#### D. The "Clear Evidence" Standard

More broadly, the standard for determining whether preemption applies is likely to be the subject of continuing debate within the lower courts. While the majority in *Albrecht* addressed some aspects of the standard, it by no means provided a thorough specification, much less sought to apply the standard to the facts of the case. Instead, the Court remanded the case to the lower court to decide the preemption question in the first instance.<sup>230</sup>

Moreover, technically the only issue properly before the Court was whether a judge or jury should decide the preemption question.<sup>231</sup> As Justice Alito observed in his opinion concurring in the judgment, "the only question" that the Court actually decided was whether preemption was "a question of law to be decided by the courts, not a question of fact."<sup>232</sup> In Justice Alito's view, the majority's musings regarding the "clear evidence" standard are no more than that, and moreover constitute a "skewed summary" that could be "misleading on remand."<sup>233</sup>

Indeed, Justice Alito went so far as to characterize the majority's decision as recognizing that the "clear evidence" language from *Wyeth* was "merely a rhetorical flourish."<sup>234</sup> As Justice Alito observed, the majority opinion plainly held that "[s]tandards of proof, such as preponderance of the evidence and clear and convincing evidence, have no place in the resolution of this question of law."<sup>235</sup>

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227. *Id.*

228. *See id.*

229. *Id.* at 1685.

230. *See id.* at 1680–81 (majority opinion).

231. *See id.* at 1679.

232. *Id.* at 1684 (Alito, J., concurring).

233. *Id.*

234. *Id.* at 1685.

235. *Id.*

Justice Alito further criticized the majority for “refus[ing] to acknowledge” that there is more than one way in which a drug manufacturer could attempt to alter pharmaceutical labeling.<sup>236</sup> In addition to the Changes Being Effected (CBE) regulation that permits a manufacturer to change its labeling without pre-approval from the FDA, Justice Alito noted that manufacturers could submit a Prior Approval Supplement (PAS) to propose labeling changes, as the manufacturer did in *Albrecht*.<sup>237</sup> As the trial court observed, the FDA’s rejection of such changes proposed in a PAS could also have preemptive effect.<sup>238</sup> Accordingly, there is likely to be further debate regarding a range of aspects of the standard for imposing preemption.

#### *E. Implications for the FDA*

Finally, to the extent there is a lack of clarity regarding the standard for establishing preemption after *Albrecht*, it is likely that the FDA will see an uptick in the number of requests from manufacturers proposing additional warnings in their labeling. One thing that is clear from *Albrecht* is that if a manufacturer proposes, and the FDA rejects, an additional warning, any state law claims based on the lack of such a warning will be preempted by federal law.<sup>239</sup> Thus, out of an abundance of caution, manufacturers may exhibit a bias toward submitting proposed labeling changes in order to establish a record that indisputably will be sufficient to establish the preemption defense under *Albrecht*.

This is not necessarily a positive development. To the extent manufacturers submit proposed warnings that are less than justified by the underlying science, the FDA will be forced to expend time and resources examining proposed warnings that probably should not have been submitted in the first place. Such work may take away from the important work that the FDA undertakes in other areas to ensure that pharmaceutical products are both safe and effective and that accurate information is provided to patients as new developments occur.

This dynamic may also impose unnecessary costs on manufacturers, who will have an incentive to anticipate issues that may develop into litigation and to submit proposed warnings with

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236. *Id.*

237. *Id.* (citing 21 C.F.R. § 314.70(b) (2018)).

238. *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 951 F. Supp. 2d 695, 705 (D.N.J. 2013), *vacated*, 852 F.3d 268, 302 (3d Cir. 2017).

239. *See Albrecht*, 139 S. Ct. at 1679.

respect to such issues to the FDA. Some of this work may be justified. However, there undoubtedly will be situations where manufacturers expend resources providing submissions to the FDA where no additional warnings are likely warranted. Again, this phenomenon will not only impose direct costs on manufacturers, but may also drain resources that could otherwise be used to ensure and monitor the safety and efficacy of their products.

#### CONCLUSION

Debate over the preemption doctrine is likely to continue. While the Supreme Court's decision in *Albrecht* resolved some issues, such as which decisionmaker is charged with deciding whether preemption applies, the Court's decision leaves many questions unanswered.<sup>240</sup> Central among these is the standard for preemption, including what types of FDA action are sufficient to establish the defense. The fact that the preemption issue frequently arises in large-scale, high-stakes litigation is only likely to intensify the debate within the lower courts, given that such dispositive issues will be hotly contested among litigants.

As the courts struggle to apply *Albrecht*, it will be interesting to see how they address the tension between the Court's ruling that the preemption question is primarily a question of law and the frequently fact-intensive arguments regarding the administrative record that have framed preemption litigation to date. As noted above, the Supreme Court's characterization of the standard is a rebuke to some lower courts' (including the Third Circuit's) prior characterization of the standard as "fact-sensitive" and arguably represents a further erosion of the power of the jury in our civil justice system.<sup>241</sup> Similarly, courts are likely to continue to express different views as to the types of FDA action that are sufficient to support the preemption defense. As the majority recognized in *Albrecht*, there is a range of agency action authorized by statute that could have preemptive effect.<sup>242</sup> Nonetheless, *Albrecht* stands as a strong directive from the Court that, where FDA action has been taken that is inconsistent with state law tort claims, elimination of such claims as a matter of law is required.

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240. See generally *id.*

241. See *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 271 (3d Cir. 2017), *vacated*, *Albrecht*, 139 S. Ct. at 1668.

242. See *Albrecht*, 139 S. Ct. at 1680.



