

# WYETH v. LEVINE: EXAMINING THE DOCTRINE OF IMPLIED PREEMPTION IN STATE- LAW TORT CLAIMS

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## I. INTRODUCTION

*Wyeth v. Levine* has been heralded “The Mother of all Preemption Cases”<sup>1</sup> and “the business case of the century.”<sup>2</sup> The significance of the decision transcends the individuals involved and could have substantial repercussions for both consumers and drug manufacturers.<sup>3</sup>

The tragic facts giving rise to this case began in April 2000, when respondent Diana Levine lost an arm to gangrene after the improper administration of Phenergan, an anti-nausea drug manufactured by Wyeth.<sup>4</sup> Levine sued Wyeth in a Vermont state court alleging negligence for failure to provide a warning label that strongly cautioned against, or even proscribed, certain methods of administering Phenergan.<sup>5</sup>

Wyeth’s defense to the suit was based on an implied preemption theory. Wyeth argued that the Food and Drug Administration’s (“FDA”) explicit approval of Phenergan’s warning label preempted

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1. Jacob Goldstein, *Wyeth v. Levine: The Mother of All Preemption Cases*, WALL ST. J., Sept. 19, 2008, <http://blogs.wsj.com/health/2008/09/19/wyeth-v-levine-the-mother-of-all-preemption-cases/>.

2. Alicia Mundy and Shirley S. Wang, *In Drug Case, Justices to Weigh Right to Sue*, WALL ST. J., Oct. 24, 2008, <http://online.wsj.com/article/SB122506300017470355.html>.

3. *See id.* (reporting that the decision could sharply limit an individual’s right to sue drug manufacturing companies for death or injury caused by medicine, resulting in billion-dollar savings for the pharmaceutical industry in litigation and settlement costs).

4. *Levine v. Wyeth*, 944 A.2d 179, 182 (Vt. 2006).

5. *Id.*

Levine's common law cause of action.<sup>6</sup> The jury found in favor of Levine and awarded her \$2.4 million in economic and \$5 million in non-economic damages.<sup>7</sup>

In October 2006, the Supreme Court of Vermont affirmed the lower court's decision, holding that Levine's claims were not preempted by the FDA's approval of the Phenergan label.<sup>8</sup> The United States Supreme Court granted Wyeth's petition for certiorari to decide whether FDA approval of prescription drug labels preempts state law product liability claims.<sup>9</sup>

## II. FACTS

### A. *Circumstances Giving Rise to Levine's Injury*

Diana Levine, a professional musician, habitually suffered from intense migraines accompanied by severe nausea.<sup>10</sup> On several occasions, Levine went to Northeast Washington County Community Health Center (Health Center) to treat her ailment.<sup>11</sup> Her typical treatment consisted of a dosage of Demerol for the migraine pain and a dosage of Phenergan for the nausea.<sup>12</sup>

The preferred method of administering Phenergan is through an intramuscular injection, but the drug can also be administered through an intravenous ("IV") injection.<sup>13</sup> The proffered benefit of intravenously administering Phenergan is more immediate nausea relief,<sup>14</sup> but there are also significant risks associated with IV administration, including a chance that arterial blood will be exposed to the drug.<sup>15</sup> Phenergan can cause severe tissue deterioration and lead to gangrene when exposed to arterial blood.<sup>16</sup> Because there is no

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6. *Id.* at 182–83.

7. *Id.* The original jury award was reduced to \$6.7 million.

8. *Id.* at 183.

9. Brief for the Respondent at *i*, *Wyeth v. Levine*, No. 06-1249 (U.S. Aug. 7, 2008).

10. Adam Liptak, *Drug Label, Maimed Patient and Crucial Test for Justices*, N.Y. TIMES, Sept. 19, 2008, available at <http://www.nytimes.com/2008/09/19/us/19scotus.html>.

11. *Id.*

12. *Id.*

13. Brief for the Respondent, *supra* note 9, at 9.

14. Petition for Writ of Certiorari at 2, *Wyeth v. Levine*, No. 06-1249 (U.S. Mar. 12, 2007).

15. Brief for the Respondent, *supra* note 9, at 10.

16. *Wyeth*, 944 A.2d at 183 n.1.

treatment that can reverse the onset of gangrene after exposure occurs, amputation of the affected appendage is invariably required.<sup>17</sup>

There are two procedures available for the intravenous administration of Phenergan: the “IV drip” procedure and the “IV push” procedure.<sup>18</sup> The IV-drip procedure allows gravity to pull the medication mixed with saline solution slowly into the patient’s veins through tubing attached to a hanging IV bag; the IV-push procedure directly forces the medicine into a patient’s vein using a syringe.<sup>19</sup> The IV-push procedure significantly increases the risk of arterial blood being exposed to Phenergan due to the likelihood of inadvertently puncturing an artery or piercing through a vein.<sup>20</sup>

In April 2000, Levine suffered from a migraine and nausea and went to the Health Center for her usual treatment.<sup>21</sup> Levine’s initial dose of Phenergan was administered through an intramuscular injection.<sup>22</sup> Unfortunately, her nausea did not subside and later that day she returned to the Health Center where a second dose of Phenergan was administered by an IV-push procedure.<sup>23</sup> According to trial testimony, the physician treating Levine did not understand the severe risks associated with the IV-push procedure.<sup>24</sup> The physician testified that he would have used the safer IV-drip method of intravenous administration had the warning been apparent on the drug’s label.<sup>25</sup>

The Phenergan administered through the IV-push procedure made contact with Levine’s arterial blood<sup>26</sup> and she suffered from a swift onset of gangrene that ultimately resulted in the amputation of her hand and forearm.<sup>27</sup> This tragically ended Levine’s career as a musician.

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17. *Id.*

18. Brief for the Respondent, *supra* note 9, at 9.

19. *Id.* at 10.

20. *Id.* The proper functioning of the drip bag requires appropriate placement into a vein, allowing for mistakes to be corrected before the flow of the drug begins. Thus, the risk of inadvertent arterial exposure with the IV-drip procedure is much less than the risk associated with the IV-push procedure. *Id.*

21. *Wyeth*, 944 A.2d at 182.

22. *Id.*

23. *Id.*

24. Transcript of Oral Argument at 44, *Wyeth v. Levine*, No. 06-1249 (U.S. Nov. 3, 2008).

25. *Id.*

26. *Levine v. Wyeth*, 944 A.2d 179, 182 (Vt. 2006).

27. *Id.*

### B. *Evolution of the FDA's approval of Phenergan*

In 1955, the FDA initially evaluated and approved Phenergan along with directions that stated the drug could be safely administered through either intramuscular or intravenous injection.<sup>28</sup> Twelve years later, Wyeth discovered that exposure of Phenergan to arterial blood could cause gangrene and that IV administration of Phenergan increased the likelihood that such exposure would occur.<sup>29</sup> Wyeth reported this discovery to the FDA and in the following years Wyeth, often at the FDA's request, continually refined the Phenergan label with respect to the warning for IV administration.<sup>30</sup> Despite incessant modification to the Phenergan label, there is no evidence that Wyeth or the FDA considered the relative safety of the two methods of IV administration (IV-push as opposed to IV-drip) or thought to emphasize the heightened risk of, or even proscribe the use of, the IV-push procedure.<sup>31</sup>

In 1979, the FDA enacted new regulations specifying the format required for all prescription drug labels.<sup>32</sup> To comply with the new rules, Wyeth submitted a Supplemental New Drug Application with a revised label.<sup>33</sup> The new label was approved in 1998, after years of revision.<sup>34</sup> The Phenergan warning used in April 2000 was two pages long and stated in relevant part:

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28. Brief for Petitioner at 9, *Wyeth v. Levine*, No. 06-1249 (U.S. May 2008).

29. *Id.* at 12.

30. *Id.*

31. *Wyeth*, 944 A.2d at 188–89 (“Defendant has provided a number of letters exchanged by the FDA and defendant regarding Phenergan’s label, but these letters do not indicate the FDA’s opinion of the value of IV-push administration. Neither the letters nor any other evidence presented to the jury indicated that the FDA wished to preserve the use of IV-push as a method of administering Phenergan.”).

32. Brief for Petitioner, *supra* note 28, at 14.

33. *Id.* at 16.

34. *Id.* In 1987, the FDA recommended revisions pertaining to, among other things, the warning against inadvertent intra-arterial injection on the Phenergan label. In 1988, Wyeth incorporated the suggested changes as well as its own alterations and resubmitted the label to the FDA for final approval. The draft stated in relevant part:

INADVERTANT INTRA-ARTERIAL INJECTION: There are reports of necrosis leading to gangrene, requiring amputation, following injection of [Phenergan], usually in conjunction with other drugs; the intravenous route was intended in these cases, but arterial or partial arterial placement of the needle is now suspect . . .

There is no established treatment other than prevention:

- 1) Beware of the close proximity of arteries and veins at commonly used injection sites and consider the possibility of aberrant arteries.
- 2) When used intravenously, [Phenergan] should be given in a concentration no greater than 25 mg/ ml and a rate not to exceed 25mg/minute. Injection through a properly running intravenous infusion may enhance the possibility of detecting

INADVERTANT INTRA-ARTERIAL INJECTION: Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasations or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of (Phenergan), usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but perivascular extravasations or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs . . . .

When 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>35</sup>

Following her amputation, Levine sued Wyeth for failure to warn consumers of the potential dangers associated with the IV-push administration of Phenergan. Wyeth moved for summary judgment prior to trial and for judgment as a matter of law following the trial, both times asserting two arguments based on implied preemption: (1) that it was impossible for Wyeth to comply with both the FDA's labeling requirements and the demands of Vermont's common law; and (2) that liability in state courts for the use of FDA-approved labels presents an obstacle to the federal objectives of the Federal Drug and Cosmetics Act.<sup>36</sup> Both motions were denied and the jury found in favor of Levine.<sup>37</sup>

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arterial placement. In addition, this results in delivery of a lower concentration of any arteriolar irritant. *See* *Levine v. Wyeth*, 944 A.2d 179, 183 n.1 (Vt. 2006).

This draft was rejected by the FDA and the FDA told Wyeth to "retain the verbiage in the current label," pertaining to inadvertent intra-arterial injections. Brief for Petitioner, *supra* note 28, at 16. The FDA rejection was perhaps due to the view that the changes made were "non-substantive and rejected . . . for formatting reasons." Brief for Respondent, *supra* note 9, at 13. Wyeth once again reworked the Phenergan label and submitted it to the FDA on May 8, 1998, when it was finally approved. Brief for Petitioner, *supra* note 28, at 16. The FDA approval letter specified that the final printed label insert should be identical to the approved draft. *Id.*

35. *See Wyeth*, 944 A.2d at 183 n.1 (quoting the Phenergan label).

36. *Id.* at 183.

37. *Id.* at 182.

### III. LEGAL BACKGROUND

The Vermont Supreme Court's decision to uphold Levine's award was primarily predicated on the requirements of the preemption doctrine, the federal regulatory authority of the FDA, and the intersection of the FDA's authority and state common law.

#### A. *The Doctrine of Preemption*

According to the United States Constitution, federal law is the "supreme Law of the Land."<sup>38</sup> This basic concept lays the foundational groundwork for the Supremacy Clause, which, according to the Supreme Court, embodies the notion that "state law that conflicts with federal law is 'without effect.'"<sup>39</sup> The preemption doctrine can be a defense to state law claims that conflict with federal law or federal objectives.<sup>40</sup> Out of respect for state sovereignty, there is a presumption against preemption.<sup>41</sup> This presumption is strengthened when the area of law at issue has a long history of state regulation.<sup>42</sup>

There are two general circumstances in which federal law preempts state law. First, Congress can explicitly preempt state law via statutory language or language in the legislative history.<sup>43</sup> Second, Congress can express its intent to control an entire field of regulation leaving states no option to supplement the federal regulation with additional requirements.<sup>44</sup>

Congressional intent to preempt state law can be discovered through an examination of the statute itself, the legislative history, and the pervasiveness of the federal regulations.<sup>45</sup> If a thorough

38. U.S. CONST. art. VI, cl. 2.

39. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

40. *E.g.*, *Riegel v. Medtronic Inc.*, 128 S. Ct. 999, 1001 (2008) (holding FDA's premarket approval process established federal regulations that preempted plaintiff's state law claims for negligence, strict liability, and implied warranty).

41. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("[B]ecause the states are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state law causes of action.").

42. *E.g.*, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005) (explaining that a long history of tort litigation against manufacturers of poisons added force to the presumption against preemption by the Federal Insecticide, Fungicide, and Rodenticide Act).

43. Beverly L. Jacklin, Annotation, *Federal pre-emption of state common-law products liability claims pertaining to drugs, medical devices, and other health-related items*, 98 A.L.R. FED. 124 (1990).

44. *Id.*

45. *Id.*

examination of the aforementioned items does not shed insight on congressional intent, the judiciary can consider the nature of the statutory scheme and the logistics of allowing both federal and state regulation.<sup>46</sup> If there is a national interest in uniformity, and dual regulation would detract from that uniformity, then congressional intent to preempt can be inferred.<sup>47</sup> Congressional intent to preempt can also be inferred when the state law stands as an obstacle to the accomplishment of congressional objectives.<sup>48</sup>

Only clear congressional intent to supersede state law can overcome the presumption against preemption.<sup>49</sup> But, congressional intent can be express or implied.<sup>50</sup> Without evidence of express preemption, implied preemption can prevail only if there is an actual conflict between federal and state law.<sup>51</sup> An actual conflict exists when “it is impossible for a private party to comply with both state and federal requirements, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”<sup>52</sup>

#### *B. Regulatory Authority of the FDA*

For much of the 19th century, states regulated domestically produced foods and drugs.<sup>53</sup> After several prominent disasters resulted from the inadequacy of these regulations, public support increased for federal regulation of the food and drug industry.<sup>54</sup> In response to the growing public demand, Congress passed the Food, Drug, and Cosmetic Act (“FDCA”) in 1938.<sup>55</sup> The FDCA provided for the Food and Drug Administration (“FDA”) as the regulatory agency in charge of evaluating and approving all drugs sold in the United

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46. *Id.*

47. *Id.*

48. *Id.*

49. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

50. *E.g.*, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (“In the absence of an express congressional command, state law is pre-empted if that law actually conflicts with federal law, or if federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.”) (internal citations and quotations omitted).

51. *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990).

52. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002).

53. John P. Swann, *FDA*, in *THE HISTORICAL GUIDE TO AMERICAN GOVERNMENT* (George Kurian, ed, 1998).

54. *Id.*

55. *Id.*

States.<sup>56</sup> The FDA is the only federal agency monitoring the safety, efficacy, and accessibility of drugs in the United States' market.<sup>57</sup> To do this, the FDA requires drug manufacturers to show that their drugs are "safe and effective" for approved uses and that the labeling is not "false or misleading."<sup>58</sup>

The FDA's approval process begins when the drug manufacturer submits a New Drug Application (NDA) for approval.<sup>59</sup> The FDA completes its evaluation according to the following criteria set forth in the FDCA: (1) whether test results establish that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling;" (2) whether there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling;" and (3) whether, "based on a fair evaluation of all material facts, such labeling is false or misleading."<sup>60</sup> If the statutory elements are satisfied, the FDA must approve the NDA;<sup>61</sup> though prior to the drug's distribution, the FDA requires a final label submission and can compel changes if necessary.<sup>62</sup>

The drug manufacturer is responsible for conducting the research and testing prior to the NDA's submission.<sup>63</sup> When testing a new drug, clinical trials are relatively small and focused on isolating variables concerning the disposition of the tested individuals.<sup>64</sup> Although these limitations are beneficial for testing the specific effects of the drug, they often fail to accurately demonstrate how the drug will work when prescribed to the diverse population at large.<sup>65</sup>

56. *Id.*

57. *See generally* 21 U.S.C.A. § 393(b) (West 2008); *see also* United States v. Sullivan 332 U.S. 689, 696 (1948) (stating the primary goal in enacting the FDCA was "to protect consumers from dangerous products").

58. Drug Amendments of 1962, Pub. L. No. 87-781, § 102(b), 76 Stat. 780, 781 (1962) (codified as amended at 21 U.S.C.A. § 355(b) (West 2006)).

59. 21 U.S.C.A. § 355(a)(West 2006).

60. 21 U.S.C.A. § 355(d).

61. *Id.*

62. 21 U.S.C.A. §355(b)(1)(F).

63. David A. Kessler and David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 471 (2008).

64. *Id.*

65. *See* Kessler and Vladeck, *supra* note 63, at 471-72 ("[M]ost clinical studies 'can detect drug-related injuries that occur at a rate of between one in 500 and one in 1,000. Yet if the drug is used by 200,000 people . . . a serious adverse event appearing in as few as one in 10,000 people is very significant, since it would occur 20 times. These rare reactions can be identified only after a drug has been widely used.") (quoting from William B. Schultz, *How to Improve Drug Safety*, WASH. POST, Dec. 2, 2004, at A35)



When manufacturers discover unanticipated or adverse effects associated with approved drugs, they are required to notify the FDA and update consumer warnings.<sup>66</sup> Because the FDA approval process can be time consuming, a drug manufacturer can bypass the FDA approval process and make label modifications on their own when faced with compelling public safety concerns.<sup>67</sup> In fact, drug manufacturers are statutorily required to alter a drug's label prior to FDA approval when necessary for the safe administration of the drug.<sup>68</sup> Statutory language allows drug manufacturers to bypass the approval process in order:

- (A) To add or strengthen a contraindication, warning, precaution, or adverse reaction;
- (B) To add or strengthen a statement about drug abuse, dependence, psychological effect or over dosage;
- (C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product . . . .<sup>69</sup>

If making a change prior to FDA approval, the drug manufacturer must immediately inform the FDA and send a Supplemental New Drug Application for a full review after-the-fact.<sup>70</sup>

### C. *Intersection of FDA Regulations and State Common Law*

When the FDCA was enacted in 1938, states had long-standing legal remedies for patients injured by defective or mislabeled drugs.<sup>71</sup> Relying on this tradition of state regulation, Congress did not provide an express preemption clause in the FDCA.<sup>72</sup> In the 1962 amendments to the FDCA, Congress explicitly stated its position on FDA approval and preemption: "Nothing in the amendments made by this Act to the

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66. 21 C.F.R. § 314.70(a) (2006).

67. 21 C.F.R. § 314.70(c)(6).

68. 21 C.F.R. § 201.57(c)(6)(i) ("labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug").

69. 21 C.F.R. § 314.70(c)(6)(iii)(A)–(C).

70. 21 C.F.R. § 314.70(c)(6).

71. Brief for Respondent, *supra* note 9, at 21.

72. *See* Kessler and Vladeck, *supra* note 63, at 462 ("No appellate court, before or after the advent of the FDA, has held that a state-law failure-to-warn claim for a prescription drug is preempted by federal law. And Congress has not acted to preempt or limit state damage actions, even though it has long been aware of tort litigation over drug products . . . ." (footnote omitted)).

Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law.”<sup>73</sup> The FDA resisted becoming involved in state tort litigation to preserve the incentive for drug manufacturers to discover and publicize unknown side-effects and risks.<sup>74</sup> This incentive enabled the agency to better protect public health.<sup>75</sup>

Taking into account the role of state failure-to-warn claims in promoting public safety and the statutory allowance for drug manufacturers to make changes without FDA approval, several courts, most notably in cases involving the drug Zolofit,<sup>76</sup> have held that state failure-to-warn claims are not in conflict with federal law.<sup>77</sup> Most of the opinions announcing this rule, however, are unpublished state or federal district court opinions so their precedential effect is minimal. In addition, at least a few courts have held that FDA approval does preempt state-law failure-to-warn claims.<sup>78</sup>

Recently, the FDA’s policy on preemption has changed.<sup>79</sup> In 2002, the FDA began filing amicus briefs in favor of drug manufacturers, asking courts to find that federal law preempted state law failure-to-warn claims.<sup>80</sup> The FDA’s new policy on preemption was formalized in

73. Drug Amendments of 1962 (Harris-Kefauver Act), Pub.L. No. 87-781, § 202, 76 Stat. 780, 793.

74. Kessler and Vladeck, *supra* note 63, at 463.

75. See *In re Kessler*, 100 F.3d 1015, 1016 (D.C. Cir. 1996) (state law actions make new evidence available to the FDA, which can be evaluated when deciding whether labeling changes are necessary); 21 C.F.R. § 20.1 (2006); Kessler and Vladeck, *supra* note 63, at 462–63.

76. Zolofit, or Sertaline HCI, is used to treat depression and certain anxiety disorders. *Needleman v. Pfizer, Inc.*, No. Civ.A. 3:03-CV-3074-N, 2004 WL 1773697 at \*1 (N.D. Tex. Aug. 6, 2004).

77. See, e.g., *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972 at \*1–\*3 (S.D. Ind. Jan. 28, 2002) (denying preemption for state failure-to-warn claim); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1018, 1032–44 (S.D. Ill. 2001) (denying preemption for state failure-to-warn claim); *Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723, 725 (Ga. Ct. App. 2003); *Bell v. Lollar*, 791 N.E.2d 849, 853–55 (Ind. Ct. App. 2003).

78. See *Needleman v. Pfizer, Inc.*, No. Civ.A. 3:03-CV-3074-N, 2004 WL 1773697 at \*1 (N.D. Tex. Aug. 6, 2004) (granting summary judgment to defendant based on conflict preemption because warning advocated by plaintiff would be misleading); *Ehilis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002) (granting summary judgment on the basis of conflict preemption after interpreting §314.70(c) to allow unapproved changes only temporarily and only in “limited circumstances”).

79. Kessler and Vladeck, *supra* note 63, at 463.

80. See *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litg.*, No. M: 05-1699 CRB, 2006 WL 2374742, at \*8 (N.D. Cal. Aug. 16, 2006) (observing the reversal in the FDA’s view on preemption); Amicus Brief for the United State in Support of the Defendant-Appellee and Cross-Appellant, and in Favor of Reversal of the District Court’s Order Denying Partial

the preamble of a 2006 FDA rule regarding drug labeling.<sup>81</sup> The agency now asserts that state law decisions in failure-to-warn cases impact the ability of the FDA to regulate drugs and to protect public health.<sup>82</sup> The FDA believes that state court decisions could force drug manufacturers to either add warnings that have not been approved by the FDA or to add warnings that have been specifically rejected by the FDA in order to avoid state liability.<sup>83</sup>

#### IV. HOLDING

In a 4-1 decision, the Vermont Supreme Court upheld Levine's failure-to-warn claim and the jury verdict in her favor.<sup>84</sup> Relying heavily on 21 C.F.R. §314.70(c) and interpreting it to "allow unilateral changes to drug labels whenever the manufacturer believes it will make the product safer," the majority found that there was not a direct conflict between the trial court's judgment and federal regulations.<sup>85</sup> Because drug manufacturers are authorized to make unilateral changes, Wyeth could have strengthened the warning on the Phenergan label, particularly regarding the risk associated with IV-push administration, but still complied with FDA regulations.<sup>86</sup> "While specific federal labeling requirements and state common law duties might otherwise leave drug manufacturers with conflicting obligations, § 314.70(c) allows manufacturers to avoid state claims without violating federal law."<sup>87</sup>

The majority insisted that 21 C.F.R. §314.70(c) not only allows, but indeed encourages drug manufacturers to add or strengthen warnings, and that the detrimental effects of state failure-to-warn claims provide incentive to take this action as soon as possible.<sup>88</sup> In this sense,

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Summary Judgment to Defendant-Appellee and Cross-Appellant at \*15, *Motus v. Pfizer*, 388 F.3d 659 (9th Cir. 2004) (Nos. 02-55372, 02-55498), 2002 WL 32303084.

81. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933-36 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (explaining the FDA's new policy on preemption in preamble to amendments).

82. Kessler and Vladeck, *supra* note 63, at 463.

83. *Id.*

84. *Levine v. Wyeth*, 944 A.2d 179, 182 (Vt. 2006).

85. *Id.* at 187.

86. See *id.* 188-89 (finding no evidence that the FDA's approval of the Phenergan label prevented Wyeth from changing the label to increase safety instructions).

87. *Id.* at 186.

88. *Id.*

the majority saw FDA labeling requirements as setting “a floor, but not a ceiling, for state regulation.”<sup>89</sup>

The majority found no evidence that the FDA’s rejection of the proposed label in 1988 was an explicit indication that the FDA carefully considered and subsequently decided the benefits to the IV-push administration outweighed the risks.<sup>90</sup> Thus, the FDA’s rejection did not constrain Wyeth from modifying its label regarding the IV-push administration method.<sup>91</sup> In rejecting preemption for state failure-to-warn claims, the Vermont Supreme Court not only demonstrated respect for the historical presumption against preemption, but also agreed with most other precedent on the issue.<sup>92</sup>

The majority also rejected Wyeth’s implied preemption argument because it did not find that the state claim interfered with the purpose of the FDCA.<sup>93</sup> The congressional purpose underlying the FDCA’s enactment and the FDA’s creation was to promote and protect public safety.<sup>94</sup> The majority determined that state law failure-to-warn claims share that purpose.<sup>95</sup> The court stated that “under any circumstances where it is possible to comply with both state law and the FDCA, the state law in question is consistent with the purposes and objections of Congress.”<sup>96</sup> Therefore, because Wyeth could comply with both state and federal law, Wyeth could not argue that compliance interfered with Congressional purpose.<sup>97</sup>

The Court acknowledged policy arguments both in favor of and against finding that state failure-to-warn claims conflict with congressional purpose.<sup>98</sup> Allowing state failure-to-warn claims could make beneficial drugs less available to consumers.<sup>99</sup> Curtailing these failure-to-warn claims, however, could leave consumers injured by harmful drugs without a legal remedy.<sup>100</sup> The majority found both

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89. *Id.* at 188.

90. *Id.* at 189.

91. *Id.*

92. *Id.* at 188.

93. *Id.* at 190.

94. *Id.*

95. *See id.* (looking to legislative history as evidence of Congress’s determination that “[m]any very helpful State laws are in effect; many such laws in some instances are even stronger than Federal laws for the protection of human health”).

96. *Id.* at 191.

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

policy arguments moot because the plain language of the 1962 Amendments indicates that Congress did not intend to interfere with state prerogatives unless there was a direct and insurmountable conflict.<sup>101</sup>

The Vermont Supreme Court refused to defer to the recent FDA pro-preemption position reflected in the “Supplementary Information” section of amendments to the FDA’s labeling requirements. According to the majority, deference is inappropriate because these amendments took effect in 2006, two years after this incident occurred.<sup>102</sup> In addition, deference to agency interpretation of a statute or amendment is required only if the statute or amendment is ambiguous.<sup>103</sup> The Court held that the statute was decidedly unambiguous, so deference to the agency interpretation was not required.<sup>104</sup>

## V. ANALYSIS

The strength of the Vermont Supreme Court’s decision lies in its consistency with Congress’s historical acceptance of state failure-to-warn claims.<sup>105</sup> State law failure-to-warn claims have provided an incentive for drug manufacturers to take responsibility for ensuring their product is safe.<sup>106</sup> Single-handedly regulating the drug market would be extremely difficult for the FDA alone; it is charged with an enormous task and has been severely under funded.<sup>107</sup> Although the FDA has an entire division devoted to monitoring drugs post-approval, according to a report by the Government Accountability Office, this division not only “lacks clear and effective processes for making decisions,” but also lacks clarity about its organizational role, struggles with management oversight, and is limited by data

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101. *Id.* at 190.

102. *Id.* at 192–93.

103. *Id.* at 192.

104. *Id.* at 192–93.

105. *See* Drug Amendments of 1962 (Harris-Kefauver Act), Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (nothing in the statutes that govern the FDA indicate an express or implied intent to preempt state law actions); Kessler and Vladeck, *supra* note 63, at 462 (“No appellate court, before or after the advent of the FDA, has held that a state-law failure-to-warn claim for a prescription drug is preempted by federal law.”).

106. *See id.* at 463 (noting that drug companies have far greater resources than the FDA so drug companies need the incentive provided by state law tort actions in order to effectively use their resources to monitor drugs on the market and address safety concerns accordingly).

107. *See* Kessler and Vladeck, *supra* note 63, at 484 (describing how the FDA is “hamstrung” by resource and authority limitations).

constraints.<sup>108</sup> With only one hundred employees, this division must monitor over eleven thousand drugs on the market.<sup>109</sup> In contrast, the FDA's Office of New Drugs employs over one thousand employees to review only a few dozen new drug applications each year.<sup>110</sup> When comparing the small work force monitoring the continued use of approved drugs with the frequent discovery of new adverse reactions,<sup>111</sup> the need for state law to supplement the regulatory operations of the FDA becomes apparent.

An adverse judgment in a state failure-to-warn case does not negate the FDA's approval of a drug;<sup>112</sup> nor do state failure-to-warn claims force drug companies to revise labels: they simply force the companies to pay damages for injuries caused by a faulty label.<sup>113</sup> The fact that a company can perform a cost-benefit analysis and decide to keep its current label<sup>114</sup> bolsters the argument that compliance with both state and federal law is possible.<sup>115</sup> Of course, the underlying purpose of state law failure-to-warn actions is to provide incentive for drug manufacturers to improve labels to increase safety, but this is not a specifically required outcome of such an action.<sup>116</sup>

In order to make a valid claim for preemption, Wyeth must demonstrate a clear congressional intent to preempt state law.<sup>117</sup> Here, there is no evidence of that intent in the FDCA or in its amendments.<sup>118</sup> This is in stark contrast to similar legislation, for example the regulation of medical devices, where congress has

108. *Improvement Needed in FDA's Post-Market Decision-Making and Oversight Process*, HIGHLIGHTS OF GAO-06-402 (U.S. Gov't Accountability Office, Drug Safety), Mar. 2006, available at [www.gao.gov/cgi-bin/getrpt?GAO-06-402](http://www.gao.gov/cgi-bin/getrpt?GAO-06-402).

109. *Id.* at 485 (quoting statement from Dr. Bruce S. Psaty).

110. *Id.* (quoting statement from Dr. Bruce S. Psaty).

111. *Id.* at 466.

112. See 21 C.F.R. §§ 201.80(e), 314.80 (2008) (no mention of adverse state law judgments affecting FDA approval).

113. See Brief for the Respondent, *supra* note 9, at 36–37 (observing that state litigation may expose the dangers associated with new drugs and prompt revisions of labels but this is not required as a by-product of state action).

114. *Id.*

115. *Id.*

116. Brief for Former FDA Commissioners Dr. Donald Kenney and Dr. David A. Kessler as Amici Curiae in Support of Respondent at 10, *Wyeth v. Levine* (No. 06-1429) (Aug. 14, 2008).

117. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (assuming Congress does not “cavalierly pre-empt state law causes of action”).

118. See Drug Amendments of 1962 (Harris-Kefauver Act), Pub. L. No. 87-781, §202, 76 Stat. 780, 793 (“Nothing in the amendments . . . shall be construed as invalidating any provision of State law . . .”).

explicitly provided a preemption clause limiting state causes of action.<sup>119</sup>

The weakness in the Vermont Supreme Court's decision lies in the expansive interpretation of the scope of 21 C.F.R. § 314.70(c)(6). If the requirement that a drug manufacturer make a change prior to receiving FDA approval is dependent on the revelation of "new" information, then there is a valid argument for preemption as no *new* information became available here.<sup>120</sup> When the FDA approved Phenergan's label in 1998, it knew of the risks associated with the IV-push method of administration.<sup>121</sup> It even rejected a label that Wyeth claims<sup>122</sup> contained a stronger warning in reference to the IV-push method of administration.<sup>123</sup> Thus, changing the label would be an explicit contradiction of FDA instructions mandating that the label be identical to the draft submitted.<sup>124</sup>

In addition Wyeth argues that the regulatory process to approve new drugs is nearly identical to the process to approve medical devices, and because the Supreme Court recently upheld preemption for state-law claims directed at FDA approved medical devices,<sup>125</sup> preemption should also apply to state law claims directed at FDA approved drug labels.<sup>126</sup>

The Vermont Supreme Court's holding may also undermine the FDA's authority. The FDCA grants the FDA final authority on the content and format of drug labeling.<sup>127</sup> The review process for a drug label is quite rigorous and time intensive.<sup>128</sup> The FDA is required to make difficult balancing decisions weighing the benefits of a drug against its potential adverse affects.<sup>129</sup> When the FDA's experts determine that the benefits of a drug outweigh the risks, the FDA

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119. Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1009 (2008) ("Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.").

120. Brief for the United States as Amicus Curiae at 9, Wyeth v. Levine, No. 06-1249 (U.S. Dec. 21, 2007).

121. Wyeth v. Levine, 944 A.2d 179, 183 (Vt. 2006).

122. The trial court interpreted the proposed changes to be non-substantive and immaterial. *Wyeth*, 944 A.2d at 189.

123. *Supra* note 34; Brief for the United States as Amicus Curiae, *supra* note 120, at 25.

124. *Id.*

125. Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1008 (2008).

126. Brief for the Petitioner, *supra* note 28, at 31.

127. 21 U.S.C.A. § 355 (West 2006).

128. Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996).

129. Brief for the United States as Amicus Curiae, *supra* note 120, at 8.

approves the drug.<sup>130</sup> Allowing state failure-to-warn claims despite FDA approval actually conflicts with the FDA's determination that the drug, as labeled, was safe and effective.<sup>131</sup>

For Phenergan, the FDA found that the benefits of allowing intravenous administration of Phenergan outweighed the risks.<sup>132</sup> The experts for Wyeth testified that "extreme nausea can cause a patient to lose fluid quickly, which leads to dehydration, a serious medical condition" and that "[a] doctor, confronted with a patient in dire need of relief from nausea, could reasonably decide that benefits of IV-push administration would warrant taking its increased risk."<sup>133</sup> The IV-push administration of Phenergan allows the drug to take effect within five minutes.<sup>134</sup> The IV-drip administration requires several more minutes in order to take effect and the intramuscular injection can take even longer.<sup>135</sup>

Allowing state juries to take the balancing role away from the FDA interferes with the purpose of the FDA as a federal regulatory agency.<sup>136</sup> When juries are confronted with horrific facts relating to one individual's experience with a drug, they often fail to consider the beneficial aspects of the drug and the thousands of patients who have benefited from its use.<sup>137</sup> Jury members are not likely to find that a warning label provided sufficient information concerning risks when the victim of a horrible accident is sitting before them.<sup>138</sup>

When threatened with extraordinary damages from jury verdicts, drug manufacturers are more likely to limit methods of administration or discontinue drugs with potentially harmful side-effects, despite knowing that the method of administration or the drug itself will benefit the majority of users.<sup>139</sup> Limiting administration options and pulling drugs poses a great harm to the public by decreasing availability of advantageous treatments.<sup>140</sup> Congressional

130. Petition for a Writ of Certiorari, *supra* note 14, at 3.

131. Brief for the United States as Amicus Curiae, *supra* note 120, at \*8.

132. *Id.* at 40.

133. Petition for Writ of Certiorari, *supra* note 14, at 8.

134. *Id.*

135. *Id.*

136. Brief for Petitioner, *supra* note 28, at 46.

137. *Riegel v. Medtronic Inc.*, 128 S. Ct. 999, 1008 (2008).

138. Brief for the Petitioner, *supra* note 28, at 46.

139. *Id.*

140. *See id.* (arguing that the FDA's responsibility extends past protecting public safety to promoting public health, and part of promoting public health involves making decisions to keep beneficial, yet risky, drugs available).



intent as outlined in the FDCA was not only to have a regulatory agency that increased the safety and effectiveness of the drugs sold in the United States, but also to have that agency ensure consumer accessibility to those drugs.<sup>141</sup> Allowing state court verdicts to limit the ability of drug manufactures to keep drugs on the market limits the FDA's ability to ensure consumer accessibility to beneficial treatment options.

## VI. ORAL ARGUMENT

This ruling is not likely to be the sweeping victory in favor of preemption for which most big pharmaceutical manufacturers are hoping.<sup>142</sup> Levine's arguments traced the historical regulation of pharmaceuticals by the FDA and demonstrated that Congress has consistently recognized state tort action.<sup>143</sup> The absence of an express congressional intent to preempt state claims supports Levine's argument that the federal regulations simply provide a minimum level of protection that states can supplement.<sup>144</sup> In addition, the purpose of the FDA's regulatory authority is to protect public safety.<sup>145</sup> As this is, in part, the purpose of state tort law as well, the two are not in conflict.<sup>146</sup>

Levine pointed out that there is no statutory evidence to support Wyeth's argument that labeling changes under 21 C.F.R § 314.70(c)(6)(2006) must be "new."<sup>147</sup> Rather, drug manufacturers must alter labels when they are aware of a significant risk, new or old, that is not adequately specified in the label.<sup>148</sup> In this case, Wyeth was not certain that the FDA had performed a risk-benefit analysis pertaining specifically to the IV-push method of administration, which detracted

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141. See generally 21 U.S.C.A. § 393(b) (West 2008) (stating the purpose of the FDA is to promote safety, effectiveness, and accessibility of drugs sold in the US market).

142. See Tony Mauro, *High Court Appears Torn Over Drug Labeling Case*, LEGAL TIMES, Nov. 4, 2008, available at <http://www.law.com/jsp/articles.jsp?id=1202425751725> (quoting legal expert's belief that a ruling in favor of federal preemption can be expected in this case because there was no evidence that Wyeth withheld information from the FDA).

143. See Brief for the Respondent, *supra* note 9, at 30-31 ("Nothing in the FDCA's history suggests that Congress either viewed state-law claims intended to promote public safety and compensate injured patients as conflicting with the federal scheme or intended to allow FDA [approval] to immunize drug manufacturers from such claims.").

144. *Id.* at 32.

145. *Id.* at 46.

146. *Id.* at 50.

147. *Id.* at 32.

148. *Id.*

from the argument that the FDA's preference for the use of a specific label indicated that the IV-push method could not be proscribed or more strongly cautioned against.<sup>149</sup> Despite this reasoning, discussion at the Oral Argument indicated that the Supreme Court is not likely to read § 314.70(c)(6) quite as expansively as the Vermont Supreme Court.<sup>150</sup>

Wyeth has the momentum of the Supreme Court's recent decision in *Reigel v. Medtronic, Inc.*,<sup>151</sup> supporting the push for preemption. Although *Reigel* involved regulations that included an express preemption clause, the eight to one decision stressed the importance of the FDA's authority to balance benefits and risks of proposed medical devices.<sup>152</sup> In addition, though it is unclear whether the FDA specifically considered the risks and benefits of the IV-push procedure (as opposed to intravenous administration in general), there is a valid argument that the risk could have been considered and resolved in favor of preserving the IV-push method of administration for the benefit of more immediate nausea relief.<sup>153</sup>

If the United States Supreme Court overturns the Vermont Supreme Court's decision, the holding is likely to be extremely narrow and focus on two primary facts: first, the fact that the FDA had all of the relevant information and, second, the fact that Wyeth provided four specific references to the dangers of intravenous administration on the Phenergan label. Even though these specific references failed to clearly distinguish between the IV-push and the IV-drip methods of intravenous administration, and even though it seems the FDA failed to properly analyze the risks and benefits of each method of administration individually, there was no indication that Wyeth misrepresented facts to the FDA.

Questions from the Supreme Court Justices at the Oral Argument tended to focus specifically on what information was submitted to,

149. See Brief of Former FDA Commissioners Kennedy and Kessler, *supra* note 116, at 14-15 (finding Wyeth's argument fails because few, if any, cases show that the FDA resists when companies try to strengthen warning labels).

150. See Transcript of Oral Argument at 32-41, *Wyeth v. Levine*, No. 06-1249 (U.S. Nov. 3, 2008) (noting the Justices' tendency to construe the requirement in 21 C.F.R. § 314(c)(6) as being triggered by the revelation of "new" information).

151. *Riegel v. Medtronic Inc.*, 128 S. Ct. 999 (2008).

152. *Id.* at 1008.

153. See Mauro, *supra* note 142 (noting how Scalia and several other Justices seemed persuaded that Wyeth acted properly and according to FDA procedure in notifying the FDA of the risk and should not be punished for the FDA's error in judgment).

and reviewed by, the FDA.<sup>154</sup> Evidently, the Court was trying to determine whether the FDA balanced the risks and benefits of the IV-push procedure independent from the IV-drip method of intravenous administration.<sup>155</sup> Some Justices, most prominently Justice Ginsberg, refused to accept that the FDA could properly perform the balancing procedure and decide that the benefits of the IV-push procedure outweighed the risk.<sup>156</sup>

Because there was no evidence that Wyeth attempted to withhold information and because Wyeth followed the FDA's reporting requirements, the Court will likely rule in favor of Wyeth based on a narrowly construed implied preemption theory. The Court will likely find that an actual conflict between state and federal law was present under the circumstances because the state law provided an obstacle to the accomplishment of Congressional objectives. Congress intended for the FDA to have the authority to make careful balancing decisions regarding the safety, effectiveness, and accessibility of drugs in the US market.<sup>157</sup> So long as the FDA was equipped with the appropriate information to make such a decision, its authority should not be usurped by state court decisions. As Justice Scalia indicated in the Oral Argument, it appears in this instance that Wyeth complied with the applicable statutory requirements, thus either the FDA or the physician who improperly administered the Phenergan should be responsible for the injury.<sup>158</sup>

In spite of the potentially favorable holding, the recent election of a democratic President along with a majority of democrats in Congress could soon set efforts in motion to combat any preemption decisions granted by the Court.<sup>159</sup> Several key democratic figures, including Senator Henry Waxman, the Chairman of the House of Representatives Committee on Oversight and Government Reform, have expressed grave concern over the FDA's new policy on

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154. Transcript of Oral Argument at 1–17, *Wyeth v. Levine*, No. 06-1249 (U.S. Nov. 3, 2008).

155. *See id.* at 5 (“[T]he FDA was aware of the IV use and a certain risk. But did it ever discreetly consider the IV-push versus the IV administered the usual way by a drip bag?”).

156. *Id.* at 7 (“[T]he risk of gangrene and amputation is there. No matter what benefit there was, how could the benefit outweigh that substantial risk.”).

157. *See generally* 21 U.S.C.A. § 393(b) (West 2008) (stating the purpose of the FDA is to promote safety, effectiveness, and accessibility of drugs sold in the U.S. market).

158. Transcript of Oral Argument at 28–29, *Wyeth v. Levine*, No. 06-1249 (U.S. Nov. 3, 2008).

159. Tony Mauro, *War Over Wyeth*, LEGAL TIMES, Dec. 29, 2008, available at <http://www.law.com/jsp/dc/PubArticleDC.jsp?id=1202426836486>.

preemption.<sup>160</sup> An October 2008 report prepared for Senator Waxman quoted veteran FDA officials stating the agency's new regulations on preemption were based on "gross misstatements" that were "naïve to what actually occurs in practice."<sup>161</sup> With a democratic majority in Washington, it is likely that the movement to combat the FDA's new policy on preemption, along with any protections granted to pharmaceutical companies by the Supreme Court in this decision, will only gain momentum.

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160. STAFF OF H. COMM. ON OVERSIGHT AND GOV. REFORM at 3, 110TH CONG., MAJ. STAFF REPORT ON FDA CAREER STAFF OBJECTED TO AGENCY PREEMPTION POLICIES (Comm. Print Oct. 2008).

161. *Id.*