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## Warning, This Decision Will Increase the Cost of Prescription Drugs: How the Supreme Court's Misapplication of Preemption Doctrine in *Wyeth v. Levine* Portends Devastating Consequences for Oklahoma

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## NOTES

### Warning, This Decision Will Increase the Cost of Prescription Drugs: How the Supreme Court's Misapplication of Preemption Doctrine in *Wyeth V. Levine* Portends Devastating Consequences for Oklahoma

#### *I. Introduction*

Critics called it a “major setback for business groups”<sup>1</sup> and a “cure worse than gangrene.”<sup>2</sup> Supporters said it was a “great day for . . . our Constitution.”<sup>3</sup> The Wall Street Journal opined that it was “the mother of all preemption cases.”<sup>4</sup> “It” is *Wyeth v. Levine*, perhaps the most important and hotly debated preemption case ever decided by the United States Supreme Court.<sup>5</sup> In *Wyeth*, the plaintiff, Diana Levine, brought an action under Vermont state law against drug manufacturer Wyeth Pharmaceuticals for failing to warn of dangers regarding the administration of the nausea medication Phenergan directly into a patient’s vein.<sup>6</sup> Wyeth defended on the grounds that Food and Drug Administration (FDA) labeling regulations preempted Levine’s claims.<sup>7</sup> Wyeth argued that it would have proved impossible to adhere to a state law duty to modify Phenergan’s warning label without violating federal law, and that judicial recognition of such state law claims would impede the objectives of Congress and the FDA in creating federal labeling regulations.<sup>8</sup> Finding for Levine, the Supreme Court held that FDA labeling requirements did not preempt the state law claims against Wyeth.<sup>9</sup> The Court found that Wyeth

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1. Adam Liptak, *No Legal Shield in Drug Labeling, Justices Rule*, N.Y. TIMES, March 5, 2009, at A1, available at <http://nytimes.com/2009/03/05/washington/05scotus.html>.

2. Jim Copeland & Paul Howard, Op-Ed., *Copeland/Howard: A ‘Cure’ Worse Than Gangrene*, WASH. TIMES, March 9, 2009, available at <http://www.washingtontimes.com/news/2009/mar/09/a-cure-worse-than-gangrene/print/>.

3. Press Release, Doug Kendall, President of Constitutional Accountability Ctr., Statement on Today’s Supreme Court Ruling in *Wyeth v. Levine* (March 4, 2009), available at [http://www.theconstitution.org/page\\_module.php?id=28&mid=15](http://www.theconstitution.org/page_module.php?id=28&mid=15).

4. *Wyeth v. Levine: The Mother of All Preemption Cases*, WALL ST. J. HEALTH BLOG (Sept. 19, 2008, 8:21 AM), <http://blogs.wsj.com/health/2008/09/19/wyeth-v-levine-the-mother-of-all-preemption-cases/>.

5. 129 S. Ct. 1187 (2009).

6. *Id.* at 1191-92.

7. *See id.* at 1193.

8. *Id.*

9. *Id.* at 1204.

could have complied with Vermont failure-to-warn law without violating its obligations under FDA regulations,<sup>10</sup> that Vermont's failure-to-warn laws did not obstruct the purposes and objectives of FDA drug labeling requirements,<sup>11</sup> and that the preamble to the 2006 FDA regulations—which asserted that state laws contrary to the regulations were preempted—did not merit deference.<sup>12</sup>

This note contends that the decision in *Wyeth v. Levine* is incorrect. The Supreme Court abandoned precedent by misapplying preemption doctrine. The Court erroneously applied the presumption against preemption, and its reasoning deviated drastically from prior case law. What is more, the Court ignored important economic and public policy considerations—namely, how subjecting pharmaceutical companies to liability under state failure-to-warn laws, despite their compliance with FDA labeling regulations, has the potential to dramatically increase prescription drug prices, which would prove especially troublesome for Oklahoma given its population demographics.

Part II of this note discusses the law before *Wyeth*, focusing on the FDA's regulatory framework for prescription drug labeling, evolution of the preemption doctrine, modern application of preemption doctrine by the Supreme Court, and Oklahoma's treatment of FDA labeling requirements vis-à-vis state law failure-to-warn claims. Part III provides an in-depth overview of the Supreme Court's decision in *Wyeth v. Levine*, highlighting the facts of the case, Justice Stevens' majority opinion, and Justice Alito's dissent. Part IV analyzes the Court's holding in *Wyeth*. Specifically, Part IV argues that the Court wrongly utilized the presumption against preemption, erroneously failed to conclude that state failure-to-warn claims upset the purposes and objectives of FDA drug regulations and thus are preempted by the doctrine of conflict preemption, and constructed an opinion that is inconsistent with its prior decision in *Geier v. American Honda Motor Co, Inc.* Part V explains how *Wyeth* is likely to cause a considerable increase in prescription drug prices and how such an increase would be exceedingly harmful to Oklahoma. Part V also outlines *Wyeth's* impact on Oklahoma tort practitioners, positing that the case will boost lawsuits against pharmaceutical companies premised on failure-to-warn theories, enhancing the Oklahoma tort bar's business. This note concludes in Part VI.

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10. *See id.* at 1200-01.

11. *See id.* at 1199.

12. *See id.* at 1201-02.

## II. *The Law Before Wyeth*

### A. *FDA Regulation of Prescription Drug Labeling*

The modern version of the FDA's regulatory scheme for prescription drug labeling originated with enactment of the Food, Drug, and Cosmetic Act of 1938 (FDCA), which was adopted by Congress to protect the public health and stop the sale of misbranded or adulterated drugs through enforcement of standards mandating purity and effectiveness.<sup>13</sup> Congress has expanded the FDCA over the past six decades and the primary regulation governing prescription drug labeling today is the New Drug Approval Process. This standard requires labels to contain the name of the drug and the manufacturer's place of business, "adequate directions for use, adequate warnings against dangerous use, and sufficient warnings against unsafe dosage."<sup>14</sup> In 2006, the FDA announced additional requirements for prescription drug labeling under the New Drug Approval process, which apply to all drugs approved after 2001.<sup>15</sup> The 2006 requirements introduced three changes: (1) addition of a "Highlights" section, which provides ready access to a drug's "most commonly referenced material;"<sup>16</sup> (2) reorganization of the graphical contents of labeling;<sup>17</sup> and (3) increased accessibility of warning and adverse reaction information.<sup>18</sup>

The FDA has described the New Drug Approval Process as "one of give-and-take with oversight by the FDA."<sup>19</sup> Under the New Drug Approval Process, the FDA approves proposed labeling following review of an application submitted to the FDA by the drug manufacturer.<sup>20</sup> The FDA investigates evidence submitted by the manufacturer, as well as other relevant information,<sup>21</sup> and the drug manufacturer and the FDA typically discuss the proposed labeling in detail, particularly as it relates to the warnings to be included.<sup>22</sup> Based on known scientific evidence, the FDA and the

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13. Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1100 (2007) (outlining requirements of the federal food and drug laws).

14. *See id.* at 1101-02.

15. *See id.* at 1106.

16. *Id.*

17. *See id.*

18. *See id.*

19. *See id.* at 1105.

20. *See id.* at 1104.

21. *Id.* (citing Brief for United States as Amicus Curiae Supporting Defendant-Appellant at 5, *Motus v. Pfizer Inc.*, 358 F.3d 659 (2004)(no. 02-55372), 2002 WL 32303084)(noting that the FDA does not explain what it means by "other relevant information").

22. *See id.*

manufacturer then formulate labeling incorporating the appropriate warnings while attempting to avoid any statement of unsubstantiated risks that could deter use of the drug.<sup>23</sup> In the event that a pharmaceutical company does not complete the New Drug Approval process as outlined, the FDA can designate the drug misbranded and assess severe penalties against the company for selling it, including seizure of the drug from the market.<sup>24</sup>

The FDA has also established a process whereby drug manufacturers, in specific circumstances, can change existing labels to reflect newly acquired information without having to await approval of another application under the New Drug Approval process.<sup>25</sup> The “changes being effected” regulation provides that the holder of an approved application may commence distribution of the drug that is the subject of the proposed labeling change upon receipt by the FDA of a supplemental application if the proposed change is to, among other things, “add or strengthen a contraindication, warning, precaution, or adverse reaction.”<sup>26</sup>

#### *B. Evolution of Preemption Doctrine*

Preemption doctrine derives from the Supremacy Clause, found in Article IV of the United States Constitution.<sup>27</sup> The Supremacy Clause states:

This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, *shall be the supreme law of the land*; and the judges in every State shall be bound thereby, *any Thing in the Constitution or the laws of any State to the contrary notwithstanding*.<sup>28</sup>

Despite the Supremacy Clause’s command for broad federal authority, the Supreme Court has traditionally proved reluctant to find federal preemption of state laws due to respect for state sovereignty in our federalist system.<sup>29</sup>

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23. *See id.* at 1104-05.

24. *See id.* at 1101-02.

25. *See id.* at 1105.

26. *See* 21 C.F.R. § 314.70(c)(6)(iii)(A) (2008). The “changes being effected” regulation is particularly significant because it served as one basis for the *Wyeth* court’s conclusion that FDA drug labeling regulations did not preempt Levine’s state law action. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1197 (2009).

27. *See* Donald T. Bogan, *Protecting Patient Rights Despite ERISA: Will the Supreme Court Allow States to Regulated Managed Care?* 74 TUL. L. REV. 951, 960 (2000) (describing preemption analysis).

28. U.S. CONST. art. VI, cl. 2 (second emphasis added).

29. *See* Bogan, *supra* note 27, at 961.

Therefore, there is a presumption against preemption.<sup>30</sup> Courts will give federal law preemptive effect only when Congress displays a clear desire for preemption.<sup>31</sup>

The Court enumerated three categories of preemption in *Savage v. Jones*.<sup>32</sup> The first category is “express preemption, where Congress explicitly defines the extent to which its enactments preempt state law.”<sup>33</sup> The second category is field preemption.<sup>34</sup> Field preemption occurs when “state law attempts to regulate . . . a field that Congress intended the federal law exclusively to occupy.”<sup>35</sup> The final category of preemption is conflict preemption.<sup>36</sup> Conflict preemption arises when “it is impossible to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of” Congress’s purposes and objectives.<sup>37</sup>

### C. Modern Application of Preemption Doctrine by the Supreme Court

#### 1. *Geier v. American Honda Motor Co.*

In the 2000 case of *Geier v. American Honda Motor Co.*, the Supreme Court considered a lawsuit brought by an injured motorist against an automobile manufacturer under District of Columbia tort law.<sup>38</sup> The motorist argued that the manufacturer was negligent because it failed to design a driver’s side airbag in her vehicle, a 1987 Honda Accord.<sup>39</sup> In 1984, however, the Department of Transportation (DOT), “under the authority of the National Traffic and Motor Vehicle Safety Act of 1966,” had announced a Federal Motor Vehicle Safety Standard (FMVSS) “requiring auto manufacturers to equip some but not all of their 1987 vehicles with passive restraints,<sup>40</sup> which included airbags and automatic seatbelts.<sup>41</sup> The Court thus had to decide whether the safety standard issued by the DOT, which did not require

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30. *See Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (“Congress legislated here in field which the States have traditionally occupied. So we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act. . .”).

31. *See Retail Clerks Int’l Ass’n, Local 1625 v. Schermerhorn*, 375 U.S. 96, 103 (1963) (noting that “[t]he purpose of Congress is the ultimate touchstone” in every preemption case).

32. *See 225 U.S. 501* (1912) (holding that state law requiring manufacturer of medicinal feed to disclose ingredients was not preempted by federal law).

33. *Indus. Truck Ass’n v. Henry*, 125 F.3d 1305, 1309 (9th Cir. 1997).

34. *See id.*

35. *Id.*

36. *See id.*

37. *Id.*

38. 529 U.S. 861, 865 (2000).

39. *See id.* at 865.

40. *Id.* at 864-65.

41. *See id.* at 878.

automobile manufacturers to include airbags in all 1987 cars, preempted the motorist's state common-law tort claim.<sup>42</sup>

In a 5-4 decision,<sup>43</sup> the Court held that the 1984 FMVSS preempted the state law claim under the category of conflict preemption.<sup>44</sup> Writing for the Court, Justice Breyer found that the DOT had made clear its desire not to require inclusion of airbags in every 1987 automobile.<sup>45</sup> Rather, the DOT had determined that it could best promote safety by allowing manufacturers to choose from a range of different restraint devices (*e.g.*, automatic seatbelts and ignition interlock devices, as well as airbags).<sup>46</sup> The Court found that determination to be premised on several significant considerations, such as the belief that airbags could not make up for all of the dangers caused by unbuckled seatbelts, the intrusiveness of and public dislike for seatbelts and airbags, the danger that airbags pose to children and other out-of-position occupants in small cars, and the high cost of airbags compared to other restraint devices.<sup>47</sup> Because the motorist's state law action depended on a finding that the manufacturer was negligent in failing to install an airbag in the motorist's 1987 vehicle, the action—if successful—would create a new duty on automobile manufacturers who marketed their new vehicles in the District of Columbia to place airbags in all vehicles.<sup>48</sup> Therefore, the state law action “stood ‘as an obstacle to the accomplishment’” of the DOT's purposes and objectives in formulating the 1984 FMVSS—to achieve safety by permitting manufacturers to vary the types of restraint devices they placed in their automobiles.<sup>49</sup>

## 2. *Buckman Co. v. Plaintiffs' Legal Committee*

A year after it decided *Geier*, the Supreme Court heard another high-profile preemption case: *Buckman Co. v. Plaintiffs' Legal Committee*.<sup>50</sup> *Buckman* centered on a state law fraud claim.<sup>51</sup> The plaintiffs alleged to have suffered injuries from the implantation of orthopedic screws into their spines.<sup>52</sup> The plaintiffs contended that the consultant to the manufacturer of the screws had

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42. *Id.* at 865.

43. *See id.* at 863.

44. *See id.* at 886.

45. *Id.* at 863, 875.

46. *See id.* at 875-76.

47. *See id.* at 877-78.

48. *See id.* at 881.

49. *Id.* at 881-82 (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

50. 531 U.S. 341, 341 (2001).

51. *See id.* at 343.

52. *See id.*

obtained Food and Drug Administration (FDA) approval for the screws through misrepresentations to the FDA.<sup>53</sup>

The Court unanimously<sup>54</sup> concluded that “the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Medical Device Amendments of 1976 (MDA),” preempted the plaintiffs’ state fraud claim.<sup>55</sup> Like *Geier*, the Court decided *Buckman* on conflict preemption grounds.<sup>56</sup> The Court first stated that the presumption against preemption did not apply because “[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied.”<sup>57</sup> The Court noted secondly that the federal statutory scheme empowered “the FDA to punish and deter fraud against” its agency and that the FDA used this authority “to achieve a somewhat delicate balance of statutory objectives.”<sup>58</sup> In the Court’s view, permitting “fraud-on-the-FDA claims” to proceed under state tort law would disrupt this balance.<sup>59</sup> The Court emphasized that mandatory compliance with the FDA’s regulatory regime and the varying tort regimes of the fifty states would saddle manufacturers of medical devices with much greater burdens than Congress intended in passing the MDA.<sup>60</sup> The Court also stated its belief that enabling similar fraud claims to go forward would cause applicants to submit too much information to the FDA—thereby slowing the approval process and, in turn, impeding competition among manufacturers of medical devices.<sup>61</sup>

#### *D. Oklahoma’s Treatment of FDA Labeling Requirements and State Law Tort Claims*

Prior to the Supreme Court’s decision in *Wyeth*, a federal district court in Oklahoma weighed in on the issue of whether FDA labeling regulations preempt state law tort claims. In *Dobbs v. Wyeth Pharmaceuticals*, the United States District Court for the Western District of Oklahoma considered an action brought by the plaintiff against the defendant, Wyeth Pharmaceuticals, alleging that the plaintiff’s husband had committed suicide as a consequence of taking a prescription antidepressant drug manufactured by Wyeth.<sup>62</sup> The

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53. *See id.*

54. *See id.* at 342.

55. *Id.* at 344 (citations omitted).

56. *See id.* at 348.

57. *Id.* at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (internal quotation marks omitted)).

58. *Id.* at 348.

59. *Id.*

60. *See id.* at 350.

61. *See id.* at 351.

62. *Dobbs v. Wyeth Pharm.*, 530 F. Supp. 2d 1275, 1277 (W.D. Okla. 2008), *vacated* 606 F.3d 1269 (10th Cir. 2010).



plaintiff argued that the defendant was liable to her for damages under Oklahoma common law because it had failed to adequately warn that the drug her husband took, Effexor, could lead to suicidal thoughts and feelings.<sup>63</sup> The defendant filed a motion for partial summary judgment, arguing that FDA prescription-drug-labeling regulations preempted the plaintiff's claims.<sup>64</sup> Specifically, the defendant claimed that the FDA had concluded that scientific evidence did not support attaching a warning of suicide to Effexor, and therefore, it could not issue such a warning in order to comply with Oklahoma law, without violating federal law.<sup>65</sup> The plaintiff argued that the FDA regulations did not preempt Oklahoma law because the regulations permitted the defendant to change its label to include the suicide warning without FDA approval.<sup>66</sup>

The district court held that FDA prescription drug labeling regulations did in fact preempt Oklahoma tort law under the category of conflict preemption.<sup>67</sup>

The court focused its attention on two issues: (1) the history of the FDA's regulation of antidepressants, and (2) the FDA's position on preemption, as reflected by the preamble to its 2006 regulations.<sup>68</sup> Concerning the former, the *Dobbs* court found that the FDA had conclusively determined that warnings about the potential for suicide were unwarranted because scientific evidence did not support a strong enough connection between use of antidepressants and suicide.<sup>69</sup> The court based this finding on the writings of the FDA Psychopharmacological Drugs Advisory Committee, which convened for the express purpose of studying the potential link between antidepressant use and suicide, and had determined that no link existed.<sup>70</sup> The court also based its finding on numerous *amicus curiae* briefs filed by the FDA in other failure-to-warn cases stating that evidence did not show consumption of antidepressants was connected to suicide.<sup>71</sup> Accordingly, a state law determination that such a warning was necessary created a conflict "between federal and state law, and impose[d] inconsistent federal and state obligations."<sup>72</sup>

As to the FDA's position on preemption, the *Dobbs* court afforded significant weight to the FDA's judgment in the 2006 preamble that state

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63. *Id.* at 1277.

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.* at 1279-80, 1289-91.

68. *See id.* at 1280, 1285-86.

69. *Id.* at 1283-84.

70. *See id.* at 1282-83.

71. *Id.* at 1282-84.

72. *Id.* at 1289-90.

failure-to-warn claims conflicted with FDA regulations.<sup>73</sup> Citing *Chevron USA, Inc. v. Natural Resources Defense Council*,<sup>74</sup> the court rejected the plaintiff's argument that the FDA's change in position from 2000 (when the FDA stated on record that its regulations did not preempt state law failure-to-warn claims) meant the 2006 preamble was entitled to no deference.<sup>75</sup> Additionally, the *Dobbs* court was not persuaded by the conclusion of other courts that the 2006 preamble was "contrary to the regulations' imposition [on] drug manufacturers of a continuing duty to monitor the safety of their products . . . ."<sup>76</sup> The court stressed that manufacturers could still change their labels to reflect previously unknown or new risks, as opposed to risks the FDA had already analyzed.<sup>77</sup> Thus, the court found that the FDA's position on preemption, as reflected in the 2006 preamble, was reasonable, supported by law, and entitled to deference.<sup>78</sup>

### III. Wyeth v. Levine

#### A. Facts and Procedural History

On April 7, 2000, Diana Levine visited her local clinic to obtain treatment for a migraine headache.<sup>79</sup> Levine "received an intramuscular injection of Demerol for her headache and Phenergan," an antihistamine manufactured by Wyeth Pharmaceuticals, for nausea.<sup>80</sup> The treatment given to Levine did not provide her relief, so she returned later the same day to receive a second injection of both Demerol and Phenergan.<sup>81</sup> For Levine's second injection, the attending physician administered the drugs via the "IV-push" method, in which "the drug is injected directly into a patient's vein," rather than first

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73. *See id.* at 1289. In the 2006 preamble, the FDA stated "that state law claims concerning drug labeling 'conflict with and stand as an obstacle to the achievement of full objectives and purposes of Federal law.'" *Id.* (quoting 71 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, Fed. Reg. 3922, 3935 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601)).

74. *Dobbs*, 530 F. Supp. 2d at 1288 ("The fact that an agency has from time to time changed its interpretation . . . does not . . . lead us to conclude that no deference should be accorded to the agency's interpretation of the statute.") (quoting *Chevron USA Inc., v. Natural Res. Def. Council*, 467 U.S. 837, 863 (1984)).

75. *Id.* at 1287-88 ("Although the FDA's position regarding preemption since 2000 conflicts with its prior view, the change in position does not require this Court to disregard the FDA's current position.").

76. *Id.* at 1289.

77. *Id.*

78. *See id.* At 1288-89.

79. *Wyeth v. Levine*, 129 S. Ct. 1187, 1191 (2009).

80. *Id.*

81. *Id.*

being introduced into a saline solution bag and delivered to the vein through a catheter, the more common “IV-drip” method.<sup>82</sup> During the IV-push injection Phenergan escaped into Levine’s artery, where it encountered arterial blood.<sup>83</sup> Consequently, Levine developed gangrene, forcing doctors to amputate her entire right forearm.<sup>84</sup>

Levine incurred substantial medical expenses, pain and suffering, and the loss of her career as a professional musician, and she brought an action for damages against Wyeth.<sup>85</sup> Levine based her action on common law negligence and strict liability theories, alleging that Phenergan’s warning label “was defective because it [did not] instruct clinicians to use the IV-drip method” in favor of the IV-push method.<sup>86</sup> In response, Wyeth filed a motion for summary judgment.<sup>87</sup> Wyeth contended that federal law preempted Levine’s failure-to-warn claims on conflict preemption grounds.<sup>88</sup> The trial court found no merit in Wyeth’s conflict preemption argument and the trial proceeded.<sup>89</sup> Evidence presented during trial showed that the use of the IV-drip method in place of the IV-push method could virtually eliminate the risk of intra-arterial injection.<sup>90</sup> The record also contained “correspondence between Wyeth and the FDA discussing Phenergan’s label.”<sup>91</sup> “The FDA first approved injectable Phenergan in 1955. In 1973 and 1976, Wyeth submitted supplemental drug applications, which [the FDA] approved after proposing labeling changes.”<sup>92</sup> In 1981, after the FDA promulgated new guidance regarding labeling, Wyeth submitted a third supplemental application.<sup>93</sup> Throughout the subsequent seventeen years, Wyeth corresponded with the FDA intermittently concerning Phenergan’s label.<sup>94</sup> Notably, the FDA suggested different warnings relating

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82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.* at 1191-92. Phenergan’s warning label read, in pertinent part, as follows: “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 extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of Phenergan Injection, 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.” *Id.* at 1191 n.1.

87. *Id.* at 1192.

88. *Id.*

89. *See id.*

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

to the risk of arterial exposure in 1987.<sup>95</sup> In 1988, Wyeth submitted revised labeling containing the changes proposed by the FDA the previous year.<sup>96</sup> The FDA did not respond until 1996, when it told Wyeth to “[r]etain verbiage in current label.”<sup>97</sup> In 1998, the FDA approved Wyeth’s 1981 supplemental application.<sup>98</sup>

At conclusion of the trial, the jury found Wyeth negligent and that Phenergan was a defective product due to inadequate warnings.<sup>99</sup> The jury awarded Levine damages amounting to \$7,400,000.<sup>100</sup> Wyeth filed a motion for judgment as a matter of law.<sup>101</sup> The trial court denied Wyeth’s motion, dismissing its conflict preemption arguments.<sup>102</sup> The court found “no direct conflict between FDA regulations and Levine’s state law claims” because FDA regulations permit a manufacturer to strengthen its warnings on an interim basis without approval.<sup>103</sup> The trial court also concluded that allowing Levine’s state law claims to go forward would not impede the FDA’s purposes and objectives, as “the agency had paid no more than passing attention to” whether Phenergan should include a warning against using the IV-push method to administer the drug.<sup>104</sup> The Vermont Supreme Court affirmed the ruling of the trial court, holding “that the jury’s verdict did not conflict with the FDA’s labeling requirements for Phenergan because Wyeth could have warned against IV-push administration” in the absence of FDA approval.<sup>105</sup> Additionally, the Vermont Supreme Court held that “federal labeling requirements create a floor, not a ceiling, for state regulation.”<sup>106</sup>

#### *B. Justice Stevens’ Majority Opinion*

In a 6-3 decision, the United States Supreme Court affirmed the opinion of the Vermont Supreme Court, finding that FDA prescription drug labeling regulations did not preempt Diana Levine’s state failure-to-warn claims pertaining to Phenergan.<sup>107</sup>

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95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.* at 1193.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.*

107. *Wyeth v. Levine*, 129 S. Ct. 1187, 1196-97 (2009). Justice Thomas filed an opinion in which he concurred with the result reached by the majority but criticized the Court’s general

Regarding Wyeth's contention that it was impossible to comply with both state failure-to-warn requirements and its federal labeling duties,<sup>108</sup> the Court—agreeing with the trial court—found that the FDA's "changes being effected" (CBE)<sup>109</sup> regulation enabled Wyeth to change its label to comply with Vermont law without violating its obligations under the FDA labeling requirements.<sup>110</sup> The Court noted that, given the evidence presented showing at least twenty incidents prior to Levine's injury in which IV-push administration of Phenergan resulted in gangrene and an amputation, Wyeth could have—and should have—updated Phenergan's label to specifically warn against IV push administration of the drug on the basis that such evidence was "newly acquired information" under the CBE.<sup>111</sup>

Next, the Court rejected Wyeth's contention "that requiring it to comply with a state-law duty to provide a stronger warning about IV-push administration would obstruct the purposes and objectives of federal drug labeling" law and thereby trigger conflict preemption.<sup>112</sup> The Court took note of Congress's decision to omit an express preemption provision from the FDA regulations, writing:

If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's [Food and Drug Cosmetic Act] 70-year history. But despite its 1976 enactment of an express preemption provision for medical devices, Congress has not enacted such a provision for prescription drugs.<sup>113</sup>

The Court also dismissed Wyeth's claim that the preamble to the 2006 FDA regulations was entitled to preemptive force.<sup>114</sup> The preamble read, in part, "The FDCA establishes both a 'floor' and a 'ceiling' . . . FDA approval of labeling . . . preempts conflicting or contrary State law."<sup>115</sup> The Court listed three reasons the preamble did not have preemptive effect.<sup>116</sup> First, the Court

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approach to preemption cases. *Cf. id.* at 1204-17 (Thomas, J., concurring). Justice Breyer filed a concurring opinion emphasizing what he viewed as the narrow application of the majority opinion and cautioning against the potential economic effect of the majority opinion. *Cf. id.* at 1204 (Breyer, J., concurring). For purposes of this note, the aforementioned opinions will not be discussed further.

108. *Id.* at 1196 (majority opinion).

109. *Id.*

110. *See id.* at 1197.

111. *Id.* 1196-98.

112. *Id.* at 1199.

113. *Id.* at 1200.

114. *Id.* at 1203.

115. *Id.* at 1200.

116. *See id.* at 1201-03.

established that an agency regulation with the force of law could preempt conflicting state requirements.<sup>117</sup> Rather than it being an agency regulation with the force of law, the Court declared that the preamble was nothing more than a mere assertion by the FDA.<sup>118</sup> Second, the Court did not accord the preamble preemptive effect because the FDA finalized it “without offering states or other interested parties notice or opportunity for comment.”<sup>119</sup> The Court noted that the weight it accords to an agency’s explanation of a state law’s impact on the federal scheme depends on the explanation’s thoroughness, consistency, and persuasiveness, and that—in light of the procedural failure committed by the FDA in failing to provide opportunity for comment on the preamble—the agency’s views on state law were inherently suspect.<sup>120</sup> Third, the Court found the preamble plainly incongruent with the FDA’s long-held position that federal labeling standards did not preempt state tort law.<sup>121</sup> The Court highlighted the fact that, prior to Levine’s injury, the FDA had never so much as implied that state tort law was an obstacle to achievement of its goals.<sup>122</sup> Rather, the FDA had always categorized federal labeling standards as a minimum threshold “upon which States could build.”<sup>123</sup> Wading into a policy argument, the Court outlined the Court’s belief that state law had traditionally complimented, not obstructed, federal law in the field of prescription drug labeling by uncovering previously unknown drug hazards and incentivizing prompt disclosure of safety risks by drug manufacturers.<sup>124</sup>

Finally, the Court distinguished the case at bar from *Geier*.<sup>125</sup> In the majority’s judgment, *Geier* was entirely distinct from the case before the Court because the DOT in *Geier* had conducted formal rulemaking before adopting its regulation; the FDA had not.<sup>126</sup> Moreover, the FDA, unlike the DOT in *Geier*, had not engaged in a deliberative balancing of state law and federal

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117. *Id.* at 1200.

118. *See id.* at 1200-01 (“This Court has recognized that an agency regulation with the force of law can pre-empt conflicting state requirements. . . . We are faced with no such regulation in this case, but rather with an agency’s mere assertion that state law is an obstacle to achieving its statutory objectives.”).

119. *Id.* at 1201.

120. *Id.*

121. *Id.* at 1201-02.

122. *Id.*

123. *Id.* at 1202.

124. *Id.*

125. *See id.* at 1203 (“Wyeth and the dissent contend that the regulatory scheme in this case is nearly identical [to *Geier*], but as we have described, it is quite different.”).

126. *Id.*

objectives in determining that state law was preempted.<sup>127</sup> Therefore, the rationale of *Geier* did not apply.<sup>128</sup>

### C. Justice Alito's Dissent

Justice Alito disagreed sharply with the majority opinion of Justice Stevens, filing a forceful dissent joined by Justices Roberts and Scalia.<sup>129</sup> The dissent began by criticizing the majority's emphasis on Congress's failure to include an express preemption provision in the FDCA, stating that "the ordinary principles of conflict pre-emption turn solely on whether a State has upset the regulatory balance struck by the federal agency."<sup>130</sup>

The dissent next argued that the rationale employed in *Geier* applied to the instant case.<sup>131</sup> The dissent posited that the FDA's oversight of Phenergan (spanning more than fifty years)<sup>132</sup> and decision not to mandate inclusion of a warning concerning IV-push administration on Phenergan's label was analogous to the regulatory balance struck by the DOT in formulating the restraint device regulation that was the subject of the *Geier* case.<sup>133</sup> Both regulations, Justice Alito wrote, were considered policy judgments.<sup>134</sup> Thus, the majority should have found that the FDA regulations preempted Levine's state law claims.<sup>135</sup>

The dissent took issue with the majority's analysis relating to the preemptive effect of the preamble to the 2006 FDA regulations.<sup>136</sup> The dissent pointed out that the *Geier* court had specifically rejected the majority's assertion that the preamble deserved no merit because the FDA had not conducted appropriate notice and comment rulemaking.<sup>137</sup> Further, the dissent

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127. *Id.*

128. *Id.*

129. *Id.* at 1218 (Alito, J., dissenting).

130. *Id.* at 1220.

131. *See id.* ("A faithful application of the Court's conflict preemption cases compels the conclusion that the FDA's 40-year-long effort to regulate the safety and efficacy of Phenergan preempts respondent's tort suit. Indeed, *that result follows directly from our conclusion in Geier* (emphasis added); *see also id.* at 1222 ("In its attempt to evade *Geier's* applicability to this case, the Court commits both factual and legal errors.").

132. *See id.* at 1222.

133. *See id.* at 1220-21.

134. *See id.* at 1218, 1221 ("Rather, the real issue is whether a state tort jury can countermand the *FDA's considered judgment that Phenergan's FDA-mandated warning label renders its intravenous (IV) use 'safe.'*") (emphasis added); *see also id.* at 1222 ("First, as a factual matter, it is demonstrably untrue that the FDA failed to consider (and strike a 'balance' between) the specific costs and benefits associated with IV push.").

135. *See id.* at 1221-22.

136. *See id.* at 1228.

137. *Id.* at 1227.

found the majority's distinction of *Geier* unpersuasive because the Department of Transportation's regulation in that case bore the force of law while the 2006 preamble did not.<sup>138</sup> The dissent opined that such a distinction was irrelevant, as the FDA regulations themselves bore the force of law.<sup>139</sup>

The dissent concluded by professing the belief that juries were ill-equipped to perform a cost-benefit analysis of the adequacy of prescription drug labels.<sup>140</sup> Instead, that analysis should have been left to the expertise of the FDA.<sup>141</sup>

#### IV. Wyeth's Legal Flaws

The Supreme Court's holding that FDA drug labeling regulations do not preempt state failure-to-warn lawsuits is incorrect in three important respects. First, the *Wyeth* majority erroneously relied on the presumption against preemption. Second, given the Court's reasoning in *Buckman Co. v. Plaintiff's Legal Committee*, the *Wyeth* majority should have found that FDA labeling requirements preempted Levine's state law action pursuant to the doctrine of conflict preemption—lawsuits like Levine's obstruct the purposes and objectives of the FDA. Instead, the Court focused heavily on Congress's decision to omit an express preemption clause from the original Food, Drug and Cosmetic Act (FDCA) and subsequent amendments thereto, confusing the distinction between express preemption and conflict preemption. Third, the Court's holding marks a significant departure from *Geier v. American Honda Motor Co.* As the dissent stated, the Court's reasoning in *Geier* should have compelled the *Wyeth* majority to honor the FDA's preemption views.

##### A. The Presumption Against Preemption Should Not Have Applied in *Wyeth*

The first flaw in the *Wyeth* decision is the Court's misplaced reliance on the presumption against federal preemption of state laws. The Supreme Court has established that there is a general presumption against federal preemption of state laws when Congress legislates "in a field which *the States have traditionally occupied*."<sup>142</sup> The states have regulated food and drugs since the United States' inception.<sup>143</sup> It is the federal government, however, and not the

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138. *See id.* at 1228.

139. *Id.*

140. *See id.* at 1229.

141. *See id.* at 1229-30.

142. *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996) (emphasis added) ("Because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly preempt state-law causes of action.").

143. *See Davis, supra* note 13, at 1100 ("The states had regulated the safety of food and



states, that has historically been the primary regulator of food and drugs sold in interstate commerce.<sup>144</sup>

“Federal regulation of food and drugs occurred as early as the mid-nineteenth century.”<sup>145</sup> In 1848, Congress passed the Drug Importation Act, which required the U.S. Customs Service Inspection to stop entry of adulterated drugs into the United States.<sup>146</sup> In 1906, Congress enacted the Pure Food and Drug Act.<sup>147</sup> The Pure Food and Drug Act prohibited “interstate commerce in misbranded and adulterated foods, drinks, and drugs.”<sup>148</sup> The states did not resist Congress’s exertion of federal power in passing the Pure Food and Drug Act, as one would expect if regulation of drugs sold in interstate commerce were a field the states had traditionally occupied. Rather, the states implored the federal government to engage in such regulation out of concern that they [the states] would prove unable to do so sufficiently.<sup>149</sup>

The Supreme Court confirmed the federal government’s predominance in regulating prescription drugs in interstate commerce with its ruling in *McDermott v. Wisconsin*.<sup>150</sup> In *McDermott*, the Court considered a Wisconsin state law barring all labeling of food or drugs not permitted by Wisconsin law.<sup>151</sup> Striking down the law, the Court held that it imposed too great a burden on interstate commerce and directly conflicted with the Pure Food and Drug Act of 1906.<sup>152</sup>

Phenergan’s manufacturer (Wyeth), like virtually all prescription drug manufacturers, sells the drug in interstate commerce. Considering the federal government’s primacy in regulating food and drugs in interstate commerce, the Court in *Wyeth* should not have applied the presumption against preemption to FDA prescription drug regulations. Had the presumption against preemption not applied in this case, it is likely the result would have mirrored that reached by the Court in *Buckman*, where—operating under an analytical

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drugs since the earliest days of the United States’ history.”).

144. *See id.*

145. *Id.* at 1099.

146. U.S. FOOD & DRUG ADMIN., Significant Dates in U.S. Food and Drug Law History, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm> (last visited on Nov. 8, 2009).

147. *Id.*

148. *Id.*

149. Davis, *supra* note 13, at 1100 (citing JAMES T. O’REILLY, FOOD AND DRUG ADMINISTRATION §§ 3:1-4 (2d ed. 2005)).

150. 228 U.S. 115 (1913).

151. *See* John Shaeffer, *Prescription Drug Advertising—Should States Regulate What is False and Misleading?*, 58 FOOD & DRUG L.J. 629, 634 (2003) (discussing *McDermott v. Wisconsin*).

152. *Id.*

framework presupposing no presumption against preemption—the Court found that the Medical Device Amendments to the FDCA preempted the plaintiffs’ fraud claims under state law.<sup>153</sup>

*B. An Obstruction of the FDA’s Purposes and Objectives: Why the Court Should Have Found Conflict Preemption Based on Buckman*

The second flaw in the Court’s decision is its failure to embrace *Buckman* and find that conflict preemption doctrine preempted Levine’s state law claims against Wyeth. It has long been the Supreme Court’s position that “conflict preemption occurs when state law stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress in enacting a federal law.”<sup>154</sup> Although there is no steadfast rule concerning when the Court will deem state law an impediment to Congress’s purposes and objectives in legislating, the rationale underlying the 2000 *Buckman* decision should have persuaded the Court in *Wyeth* to hold that state failure-to-warn actions impede Congress’s purposes and objectives in granting the FDA authority to promulgate labeling standards for prescription drugs.

In a unanimous opinion, which included all six members of the *Wyeth* majority, the *Buckman* Court held that the Medical Device Amendments (MDA) to the FDCA preempted a state law action against manufacturers of orthopedic screws which alleged that the manufacturers defrauded the FDA in gaining approval of the screws.<sup>155</sup> Chief among the *Buckman* Court’s reasons for rendering the aforementioned determination was its belief that Congress enacted the MDA intending to free medical device manufacturers from state tort regimes.<sup>156</sup> Allowing the state fraud claims to proceed would have abrogated Congress’s purpose for enacting the MDA and created greater burdens on medical device manufacturers than Congress foresaw, thus preventing the FDA from executing its responsibility to police fraud.<sup>157</sup> Furthermore, the Court believed subjecting medical device manufacturers to

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153. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001). The extent of the paradigm shift that occurs when the presumption against preemption is inapplicable is not entirely clear. It has been suggested by some, however, that—in the absence of the presumption against preemption—the Court broadens its definition of what constitutes “conflict” under the doctrine of conflict preemption. See Mary J. Davis, *The New Presumption Against Preemption* 61 HASTINGS L.J. 1217, 1252 (2010).

154. Susan D. Hall, *Preemption Analysis After Geier v. American Honda Motor Co.*, 90 KY. L.J. 251, 252 (2002) (quoting *Savage v. Jones*, 225 U.S. 501 (1912) (holding that federal law did not preempt a state law requiring manufacturers of medicinal feed to disclose ingredients)).

155. *Buckman*, 531 U.S. at 343–44. The *Wyeth* majority includes Justices Stevens, Kennedy, Souter, Ginsburg, Breyer, and Thomas. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1190 (2009).

156. *Buckman*, 531 U.S. at 352.

157. *Id.* at 350.

state tort regimes would cause manufacturers to submit more information to the FDA, which would slow the approval process and negatively affect competition in the medical device industry.<sup>158</sup>

The Court's rationale in *Buckman* is directly applicable to *Wyeth*. As in *Buckman*, there was evidence available to the *Wyeth* court indicating Congress did not contemplate that drug makers would be liable under state tort law after obtaining FDA approval of their labels.<sup>159</sup> In fact, the majority itself cited one piece of evidence supporting the conclusion that Congress desired to shield drug manufacturers from state tort liability: the first version of the FDCA provided a federal cause of action to persons injured by prescription drugs.<sup>160</sup> More persuasive is the extraordinary breadth of the FDA drug approval process.<sup>161</sup> Taking into account the FDA drug approval process's extensiveness, one has difficulty concluding that Congress contemplated a role for the states in judging drug safety after FDA approval.

Moreover, the Court contended in *Buckman* that medical device manufacturers would present the FDA with too much information if subjected to liability under state tort law, an assertion equally valid in the case of drug manufacturers. Like medical device manufacturers, drug manufacturers probably divulge even minimally supported safety information to the FDA during the approval process as a means of limiting future legal liability. Therefore, if concern over excessive information submission to the FDA was sufficient to find state law an impediment to federal objectives and purposes and trigger conflict preemption in *Buckman*, the same should have been true in *Wyeth*.

Rather than applying *Buckman's* analysis, however, the *Wyeth* court concentrated on the lack of an express preemption clause in the portion of the FDCA pertaining to drug regulation.<sup>162</sup> Keying on the absence of an express preemption clause in the FDCA was erroneous given the Court's prior statements on the doctrine of conflict preemption, a point Justice Alito articulated in his dissent.<sup>163</sup> By blurring the distinction between express and conflict preemption with unwarranted attention to the nonexistence of an

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158. *Id.* at 351.

159. *See Wyeth*, 129 S. Ct. at 1199-200 (citing H.R. 6110, 73d Cong., § 25 (1st Sess. 1933)).

160. *See id.*

161. *See discussion supra* Part II.A.

162. *See Wyeth*, 129 S. Ct. at 1200 ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history.")

163. *See id.* at 1220 (Alito, J., dissenting) ("[T]he ordinary principles of conflict pre-emption turn *solely* on whether a State has upset the regulatory balance struck by the federal agency." (emphasis added)); *see also* *Chicago & N. W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981).

express preemption provision in the FDCA, the *Wyeth* court not only improperly applied conflict preemption doctrine, but also essentially abrogated conflict preemption doctrine altogether. Henceforth, the Court can apply conflict preemption only if Congress explicitly declares state law a barrier to accomplishing its legislative objectives. Such a dismantling of conflict preemption doctrine indicates that the Court reached the wrong result.

*C. Driving Away From Precedent: Geier v. American Honda Motor Co. Inc. Should Have Compelled Deference to the 2006 FDA Preamble*

The final legal shortcoming of the Supreme Court's analysis in *Wyeth* is that the Court did not defer to the FDA's view on the preemptive force of its regulations, as reflected by the 2006 FDA preamble.<sup>164</sup> Honoring the FDA's views concerning the preemptive effect of its regulations is something the Court should have done in light of its decision in *Geier v. American Honda Motor Co., Inc.* In *Geier*, the Supreme Court declared that the Department of Transportation's (DOT) 1984 Federal Motor Vehicle Standard (FMVSS) preempted an injured motorist's defective design action against an automobile manufacturer under District of Columbia tort law.<sup>165</sup> The Court's ruling stemmed at least in part from its belief that the DOT's interpretation regarding the preemptive effect of the FVMSS was entitled to consideration given the extensive background of its investigation into the merits of automobile safety devices and the complexity involved in the issue.<sup>166</sup>

In working with Wyeth Pharmaceuticals to formulate a warning label for Phenergan, the FDA conducted an investigation as extensive—if not more so—than the DOT investigation of automobile safety devices in *Geier*. Justice Alito offered ample evidence supporting the aforementioned conclusion in his dissenting opinion in *Wyeth*. Justice Alito noted that “Phenergan’s warning label has been subject to the FDA’s strict regulatory oversight since the 1950’s” and that the FDA paid particular attention to the safety and effectiveness of IV-push administration as it related to Phenergan’s warning label.<sup>167</sup> The FDA, moreover, convened meetings with Wyeth specifically devoted to discussing Phenergan’s warning label and commissioned an

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164. In its 2006 preamble, the FDA stated that the FDCA “establishes both a ‘floor’ and a ‘ceiling’ . . . FDA approval of labeling . . . preempts conflicting or contrary State law.” *Wyeth*, 129 S. Ct. at 1200 (majority opinion).

165. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000). See discussion *supra* Part II.C.1. for an in-depth explanation of the 1984 Department of Transportation Motor Vehicle Safety Standard.

166. See *Geier*, 529 U.S. at 883.

167. *Wyeth*, 129 S. Ct. at 1222 (Alito, J., dissenting). For explanation of the IV-push method, see *supra* Part III.A.

advisory committee to study the inherent risks of Phenergan when injected via the IV-push method of intravenous drug administration.<sup>168</sup> Based on the study's findings and other research, the FDA instructed Wyeth to place a warning regarding IV-push on Phenergan's label.<sup>169</sup> The FDA did not, however, prohibit the IV-push method for administering Phenergan.<sup>170</sup>

Additionally, the complexity of prescription drug labeling is analogous to that of automobile safety devices. Both issues require specialized knowledge and expertise that Congress, state legislatures, the public, and juries are unlikely to possess. The DOT and FDA occupy a unique position from which to render considered judgments in the areas of automobile safety devices and prescription drug labeling, respectively.

The processes by which the DOT established regulations for automobile safety devices and the FDA decided the permissibility of IV-push administration of Phenergan are virtually indistinguishable. Thus, the *Wyeth* majority's refusal to give the FDA's statement that its guidelines preempted state law—as expressed in the 2006 FDA preamble—the same force it gave the DOT's preemption views in *Geier* was improper.

### V. *The Implications of Wyeth v. Levine for Oklahoma*

The Supreme Court's decision in *Wyeth v. Levine* presents two major implications for Oklahoma. First, *Wyeth* will lead to an increase in prescription drug prices. Oklahoma's senior citizen population, in comparison to the national average, is proportionately larger than most other states, and many of those seniors are either uninsured or ineligible for government programs that subsidize prescription drug purchases.<sup>171</sup> Therefore, any increase in the cost of prescription drugs will affect Oklahoma more than most states. Second, the Supreme Court's ruling in *Wyeth* will prove greatly beneficial to Oklahoma tort practitioners by making it easier to litigate successfully against pharmaceutical companies.

#### A. *Wyeth v. Levine Will Increase Prescription Drug Prices*

##### 1. *Litigation Hinders Pharmaceutical Development*

Litigation encumbers pharmaceutical development, which, in turn, causes an asymmetry between supply and demand—triggering a rise in the cost of prescription drugs. Litigation hinders pharmaceutical development in two

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168. *Wyeth*, 129 S. Ct. at 1222.

169. *Id.* at 1225.

170. *See id.* (“While Phenergan’s label very clearly authorized the use of IV push . . .”).

171. *See infra* Part V.A.4.

primary ways. First, litigation forces pharmaceutical companies to expend capital they would otherwise devote to research and development on legal services.<sup>172</sup> The drug industry spends sizable sums hiring in-house and outside counsel to offer legal advice and defend lawsuits initiated by consumers.<sup>173</sup> Further, drug companies must carry liability insurance policies or, alternatively, self-insure if they deem premiums charged by insurers to be excessive.<sup>174</sup> Secondly, litigation discourages pharmaceutical development because of its inherent unpredictability.<sup>175</sup> Like all businesses, drug companies must balance risk and reward in determining whether to bring their product to market, and product liability entails present and future risks that, while virtually impossible to quantify, could lead to the company's financial ruin.<sup>176</sup>

*2. A Comparison of the U.S. and Canadian Liability Systems Shows That Litigation Results in Higher Prescription Drug Prices*

Comparing the U.S. and Canadian liability systems illustrates that litigation directly correlates with higher prescription drug costs. Though the U.S. and Canada each model their liability system on English common law, the respective systems have important differences.<sup>177</sup> Most importantly, the U.S. has adopted strict products liability while Canada relies solely on a negligence standard.<sup>178</sup> Other distinctions include the advent of market share liability in the U.S., limited rights of appeal for Canadian litigants compared to their U.S. counterparts, and fewer punitive damages awards in Canada than in the U.S.<sup>179</sup>

A 1992 study by the U.S. General Accounting Office (GAO) discovered large price differences for the same drugs sold in both the U.S. and Canada.<sup>180</sup> A sample of 121 commonly prescribed drugs sold in both the U.S. and Canada

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172. See Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION*, 334, 335-36 (Peter W. Hubert & Robert E. Litan eds., 1991).

173. *Id.*

174. *Id.* at 337.

175. *Id.*

176. *Id.*

177. Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 *J.L. & ECON.* 203, 206 (1997) (discussing how the United States liability system has drifted considerably from the common law heritage it shares with the Canadian system).

178. *Id.* at 206-07.

179. *Id.* at 207-08. Market share liability is a theory of damages whereby each defendant manufacturer of a drug pays a percentage of the plaintiff's damages equal to their share of the market, if the court cannot determine which manufacturer is responsible for making the drug causing the injury.

180. *Id.* at 204.

found that the median price was about forty-three percent higher in the U.S. than in Canada.<sup>181</sup> Criticism of the GAO study was widespread, as some experts believed the study's methodology was biased in favor of finding higher prices in the U.S.<sup>182</sup> But a study by Professor Richard L. Manning of Brigham Young University in the *Journal of Law and Economics* confirms the GAO study's conclusion that prescription drug prices are lower in Canada, and proves that the disparity results from the differing liability systems.<sup>183</sup>

Professor Manning's study calculated drug prices based on four variables: manufacturing and marketing costs, the regulatory environment in which the company sells its products, the liability environment which prevails in the market, and the structure of the market for each product.<sup>184</sup> Manning incorporated the effects of the liability environment prevailing in the market by measuring four risks: litigation history, vaccine liability cost, controlled substances designation, and risk assessment surveys of health professionals.<sup>185</sup> The results indicated that, when accounting for the effects of all four variables, the price differential between Canada and the United States amounted to "a mean difference of 69.7 percent and a median difference of 43.6 percent."<sup>186</sup> Removing the liability cost variable, however, resulted in a reduction of the mean price differential to 35.5 percent and a reduction of the median difference to 32.6 percent.<sup>187</sup> Manning's study found that the proportion of cases won by plaintiffs had a particularly substantial effect on price difference,<sup>188</sup> which is notable given that *Wyeth* will enhance plaintiffs' chances of prevailing over drug companies in products liability cases by preventing drug companies from proffering preemption defenses based on FDA labeling requirements.

### 3. *The Story of Bendectin: A Practical Example*

Bendectin, a drug prescribed to alleviate nausea and vomiting accompanying pregnancy,<sup>189</sup> is a practical example of litigation's effect on innovation, drug prices, and—ultimately—availability of the drug itself. First introduced to the U.S. market in 1956, Bendectin achieved great success; by the time its manufacturer withdrew Bendectin from the market, it was sold in

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181. *Id.*

182. *Id.*

183. *See id.*

184. *Id.* at 209.

185. *Id.* at 217-22.

186. *Id.* at 206.

187. *Id.*

188. *Id.* at 223.

189. Lasagna, *supra* note 172, at 337.

twenty-two countries and used by around twenty-five percent of pregnant women in America.<sup>190</sup> Epidemiological research into Bendectin's effect on birth defects produced mixed results.<sup>191</sup> The FDA also investigated Bendectin, determining that "this drug has been the most carefully studied of all drugs which could be used to treat the nausea and vomiting of pregnancy. There is no evidence that any other drug is safer in treating [this condition]."<sup>192</sup> Yet many suits came to trial, and although Merrell (Bendectin's manufacturer) won the great majority of them, the company pulled Bendectin from the market citing unsustainable legal costs.<sup>193</sup> Consequently, pregnant women lost the only prescription drug then available for treating nausea and vomiting.<sup>194</sup>

*4. Overdose: How an Increase in Prescription Drug Costs is Especially Problematic for Oklahoma*

Due to Oklahoma's population demographics and other economic factors, the prescription drug cost increases *Wyeth v. Levine* portends will prove exceedingly harmful to the state. Senior citizens, who invariably utilize prescription drugs more than adults and children, make up a significant portion of Oklahoma's population.<sup>195</sup> According to the AARP, thirteen percent of Oklahoma's population is age sixty-five or older.<sup>196</sup> This figure places Oklahoma ahead of thirty states in terms of percentage of the population over sixty-five years old.<sup>197</sup> Eighteen percent of Oklahoma's population is between the ages of fifty and sixty-four.<sup>198</sup>

Oklahoma also has a high number of individuals lacking health insurance coverage, especially among the elderly.<sup>199</sup> In 2007, 94,551 Oklahomans between the ages of fifty and sixty-four were uninsured.<sup>200</sup> Moreover, thirty percent of Oklahoma's seniors in 2007 were not eligible for the Medicare Part D Low Income Subsidy—meaning they had to pay the full cost of their

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190. *Id.* at 338.

191. *Id.* at 339.

192. *Id.* at 340.

193. *Id.*

194. *Id.*

195. See AARP, WHY HEALTH CARE REFORM IN OKLAHOMA 1 (2009), available at [http://assets.aarp.org/rgcenter/health/state\\_hcb\\_09\\_ok.pdf](http://assets.aarp.org/rgcenter/health/state_hcb_09_ok.pdf).

196. *Id.*

197. U.S. CENSUS BUREAU, RANKING OF STATES BY PROJECTED PERCENT OF POPULATION AGE 65 AND OVER: 2000, 2010, 2030 (2004), <http://www.census.gov/population/www/projections/projectionsagesex.html>.

198. AARP, *supra* note 195, at 1.

199. See *id.*

200. *Id.*



prescription medications for at least part of the year.<sup>201</sup> By comparison, twenty-three percent of Florida's seniors, nineteen percent of Arizona's seniors, and twenty-seven of Utah's seniors were ineligible for the Medicare Part D Low Income Subsidy in 2007.<sup>202</sup>

In sum, Oklahoma's demographic realities mean an increase in prescription drug costs generated by *Wyeth* will disproportionately affect the state. Due to greater incidences of illness and disease, senior citizens' consumption of prescription drugs far exceeds prescription drug consumption among other population groups.<sup>203</sup> Not only does Oklahoma's senior citizen population surpass that of most states, but also the number of seniors in Oklahoma who are ineligible for prescription drug subsidies under Medicare is greater than in traditional retirement destinations such as Florida and Arizona.<sup>204</sup> Therefore, the *Wyeth* case should be of particular concern to Oklahomans already struggling to pay for prescription drugs.

#### *B. Wyeth v. Levine Will Benefit Oklahoma Tort Practitioners*

*Wyeth v. Levine* will affect Oklahoma in a second, noteworthy way: by enabling plaintiffs to sue drug manufacturers post-FDA approval, *Wyeth* will encourage the proliferation of failure-to-warn claims, which will in turn encourage the proliferation of Oklahoma tort practitioners' business.

Prior to the Supreme Court's decision in *Wyeth*, injured consumers could not bring actions against pharmaceutical companies in Oklahoma for inadequate warnings on FDA-approved drugs; an Oklahoma federal court had held that FDA labeling requirements preempted failure-to-warn claims brought pursuant to Oklahoma state law.<sup>205</sup> With the Supreme Court's ruling in *Wyeth v. Levine*, however, Oklahoma plaintiffs are now much more likely to achieve

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201. JACK HOADLEY ET AL., THE KAISER FAMILY FOUND., THE MEDICARE PART D COVERAGE GAP: COSTS AND CONSEQUENCES IN 2007 6 (2008), available at <http://www.kff.org/medicare/upload/7811.pdf>. That amounts to about 66,550 people who had to pay 100% percent of their prescription drug costs. THE KAISER FAMILY FOUND., STATE HEALTH FACTS (2007), <http://www.statehealthfacts.kff.org/comparetable.jsp?ind=3>.

202. HOADLEY ET AL., *supra* note 201, at 6.

203. A study by the Centers for Disease Control and Prevention found that eighty-seven percent of Americans over the age of sixty-five surveyed from 2001-2004 reported using prescription drugs in the past month. Only sixty-six percent of 45-65 year-olds and thirty-eight percent of 18-44 year-olds said they had used prescription drugs in the past month. CTRS. FOR DISEASE CONTROL & PREVENTION, PRESCRIPTION DRUG USE IN THE PAST MONTH BY AGE, SEX, RACE AND HISPANIC ORIGIN: UNITED STATES, 1988-1994 AND 2001-2004 1 (2008), available at <http://www.cdc.gov/nchs/data/hus/08.pdf#098>.

204. See HOADLEY ET AL., *supra* note 201, at 6.

205. See *Dobbs v. Wyeth Pharm.*, 530 F. Supp. 2d 1275 (W.D. Okla. 2008). See *supra* Part II.D. for a detailed summary of the case's holding.

positive outcomes in suits against drug companies because drug companies will be hard-pressed to argue that federal law preempts state failure-to-warn claims.<sup>206</sup>

Scholars and attorneys agree that the increased likelihood of success by plaintiffs whose claims FDA regulations would have previously preempted has shifted incentives in favor of trial lawyers. “Some trial lawyers who have been hesitant to bring claims against pharmaceutical companies are now going to be more willing to do so,” Benjamin C. Zipursky, professor of law at Fordham Law School in New York City and visiting professor at Harvard Law School, states.<sup>207</sup> Referring to *Wyeth*, corporate defense attorney John Beisner echoed the sentiments of Professor Zipursky, saying, “We’re going to see a substantial uptick in the number of cases filed.”<sup>208</sup>

Indeed, the weeks immediately following the Supreme Court’s *Wyeth* decision saw judges in state and federal courts around the country permit upwards of 250 previously stayed lawsuits to move forward.<sup>209</sup> Moreover, recent data suggests that jurors are becoming more sympathetic to plaintiffs in product liability cases.<sup>210</sup> Last year, the five most lucrative product liability verdicts rose fifty-two percent, with Pfizer—perhaps the best-known pharmaceutical company in America—losing verdicts of \$78 million and \$34 million.<sup>211</sup> “It’s a reflection of the fact that Main Street is hurting,” said Tobias Millrood, attorney for the plaintiffs in the \$34 million case against Pfizer.<sup>212</sup> “In this climate [alluding to the recent financial collapse and economic downturn], there’s a strong identification with the little man,” said Millrood.<sup>213</sup>

All told, *Wyeth v. Levine* is a positive development for Oklahoma’s tort bar. Bound by *Wyeth*, Oklahoma courts must now reject preemption defenses they previously allowed to block state failure-to-warn claims against pharmaceutical companies. Accordingly, Oklahoma tort practitioners can henceforth successfully try cases they would not have even taken before

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206. See *supra* Part III.B for a thorough discussion of the Supreme Court’s holding in *Wyeth v. Levine*.

207. Amanda Gardner, *Supreme Court Rejects Limits on Drug-Injury Lawsuits*, U.S. NEWS & WORLD REPORT, Mar. 4, 2009, <http://www.usnews.com/health-news/managing-your-healthcare/policy/articles/2009/03/04/supreme-court-rejects-limits-on-drug-injury.html>.

208. Margaret Cronin Fisk, *Jurors Turned Against Companies in 2009 Product-Defect Cases*, BLOOMBERG, Jan. 7, 2010, <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=awwb48m7sQQ>.

209. *Id.*

210. See *id.* (stating five of the fifty largest verdicts were claims involving defective products).

211. *Id.*

212. *Id.*

213. *Id.*

*Wyeth*. Combined with a growing sensibility favoring product liability plaintiffs in the wake of the worst recession since the Great Depression, the ability to sue drug companies for failure to warn despite compliance with FDA regulations means *Wyeth v. Levine* will serve as a boon to Oklahoma's tort practitioners. Nonetheless, a victory for the tort bar is not a victory for the average Oklahoma citizen. That *Wyeth* will enable tort lawyers to grow their practices excuses neither the Supreme Court's flawed legal reasoning nor the growth in prescription drug prices the decision will doubtless produce.

#### VI. Conclusion

*Wyeth v. Levine* is among the most consequential preemption cases of our time, which makes the Supreme Court's failure to reach the proper result very troubling. The Court misconstrued preemption doctrine, deviating from well-established principles and avoiding the direct applicability of recent case law. Perhaps more worrisome was the Court's inability to grasp the economic implications of its decision. Without the shield of FDA approval, drug manufacturers will face a barrage of state tort lawsuits—and the result will be climbing prices for prescription medications. While the rise in litigation is welcome news for Oklahoma trial lawyers, it has the potential to be catastrophic for the state's many seniors—who already struggle to afford the medicines vital to their health. The Supreme Court should revisit *Wyeth v. Levine* and overturn its wrongheaded decision at the first opportunity—restoring the FDA to its position as the rightful arbiter of drug safety by ruling that FDA regulations preempt contrary state lawsuits. Because the fact is, *Wyeth v. Levine* is a dose of bad medicine Oklahoma cannot afford.

*Tyler R. Barrett*