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WYETH V. LEVINE: WHAT DOES IT MEAN AND WHERE DO
PHARMACEUTICAL COMPANIES GO FROM HERE

Clay Landa*

I. INTRODUCTION

In the recent landmark decision in *Wyeth v. Levine*, the Supreme Court put drug manufacturers on notice that they can and should be liable for state tort claims for the harm their products cause regardless of Federal Drug Administration (“FDA”) approval of the drug’s use and warning labels.¹ The decision dispels recent efforts by pharmaceutical companies to claim that they have no greater duty to warn consumers of risks from their products above and beyond the FDA’s approved warnings.² Therefore, drug makers, under current statutes and regulations, continue to bear the responsibility for maintaining the safety of their products and for keeping their warning labels up to date or face paying the price for state tort claims.³ Drug makers may not claim that FDA approval of their drugs and warning labels, under the Federal Food, Drug, and Cosmetics Act (“FDCA”), preempts state tort claims for failure to warn of risks that caused harm.⁴

Absent a blanket federal preemption claim, drug makers find themselves back in a traditional products liability tort system. In this setting, drug makers must continue to follow the mandates of the FDCA and

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1. *Wyeth v. Levine*, 129 S. Ct. 1187, 1202, 1204 (2009).

2. *See id.* at 1199; Jonathan V. O’Steen & Van O’Steen, *The FDA Defense: Vioxx and the Argument Against Federal Preemption of State Claims for Injuries Resulting from Defective Drugs*, 48 ARIZ. L. REV. 67, 70 (2006) (noting that a finding of preemption would allow drug companies to skirt the common law duty to monitor their own products safety after approval).

3. *Wyeth*, 129 S. Ct. at 1197–98; Posting of Lyle Denniston to SCOTUSWiki, http://www.scotuswiki.com/index.php?title=Wyeth_v._Levine (last visited Jan. 15, 2010).

4. *Wyeth*, 129 S. Ct. at 1204.

corresponding regulations for drug approval and warning labels.⁵ However, since federal preemption will not apply, even if the FDA approves a warning for a specific hazard, the drug maker may be found liable in state courts for harm caused by that hazard.⁶ A warning, therefore, even though approved by the FDA, may not be enough if the state courts determine the warning was not strong enough.⁷

Without being able to point to one nationwide standard for warning labels and without specific state standards, drug makers would appear to be at the mercy of individual state court juries or judges to determine what warning was appropriate even though the FDA approved a specific warning label. The court system, however, only informs drug makers after the fact that the warning was not strong enough and does not provide clear, specific standards for compliance like FDA regulations.⁸ Wyeth argued this exact point before the Supreme Court and urged that allowing state tort claims when the FDA approved a specific label would thwart the regulatory system set up by Congress in the FDCA.⁹

Still, there are numerous avenues available for pharmaceutical companies to limit their liability and continue to produce and market drugs profitably. The Supreme Court's decision does not implicate or amend the required FDA approval of warning labels.¹⁰ Therefore, one approach for a drug maker, knowing of a potential hazard, would be to unilaterally strengthen their warning without prior FDA approval under current regulations to head off any state tort claims for failure to warn.¹¹ If the FDA ultimately determines not to approve the strengthened label, under explicit authority granted by Congress in the FDCA, drug makers have a strong argument that implicit conflict preemption now applies.¹² As another avenue, drug makers may include a potential warning amounting to a prohibition of the drug's use or method of delivery when seeking initial approval of the warning label.¹³ Again, if the FDA explicitly rejects such a

5. See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2006).

6. *Wyeth*, 129 S. Ct. at 1202.

7. *Id.* at 1201–02.

8. See W. Wylie Blair, *Implied Preemption of State Tort Law Claims Against Prescription Drug Manufacturers Based Upon FDA Approval*, 27 J. LEGAL MED. 289, 300 (2006) (arguing that state tort law actions are not a determination of a drug's risks and benefits founded on a centralized expert evaluation).

9. *Wyeth*, 129 S. Ct. at 1199.

10. *Id.* at 1198.

11. See 21 C.F.R. § 314.70(c) (2009).

12. See *Wyeth*, 129 S. Ct. at 1198 (stating that the Court will not hold it is impossible for drug manufacturer to comply with state tort claim and FDA labeling requirements absent clear evidence FDA would not have approved strengthened warning).

13. See 21 U.S.C. § 355(a)–(d) (2006) (mandating new drug application, FDA determination that drug is safe and effective as shown in the proposed labeling, and the format and contents of drug labels).

prohibitive warning, a drug maker may likely claim the FDA rejection preempts any state court requirement for the warning.¹⁴ In addition, drug makers may seek legislative action, both at the federal and state levels.¹⁵ In Congress, pharmaceutical companies could push for addition of an explicit preemption clause similar to one currently in the FDCA for medical devices.¹⁶ Finally, drug makers could take their case to state legislatures, seeking statutes that would not allow state tort claims for a failure to warn when the manufacturer complied with FDA regulations.¹⁷

Part II of this paper analyzes the history and background of federal preemption to give context to the current environment after *Wyeth*. Part III analyzes the Supreme Court's decision in *Wyeth*, holding that the FDCA and corresponding regulations do not preempt state tort claims.¹⁸ Finally, Part IV discusses and analyzes what drug makers may do now to continue to produce and market pharmaceuticals profitably while limiting their liability for state tort claims.

II. HISTORY AND BACKGROUND OF PREEMPTION

A. *Cipollone v. Liggett Group, Inc.* and the Intent and Purpose of Congress

In *Cipollone*, the Supreme Court laid down its touchstone analysis that the intent and purpose of Congress is the key to determine if federal preemption obviates a state failure to warn tort claim.¹⁹ In this case, the Court considered whether two federal cigarette labeling acts in 1965 and 1969 providing express preemption provisions sufficed to preempt state failure to warn claims.²⁰ The 1965 Act contained a vague preemption provision, providing that no other statement other than that required by the Act was required on any cigarette package.²¹ In 1969, Congress amended the labeling preemption provision to provide that no state could impose any requirement or prohibition concerning the advertising or promotion of any cigarette packages labeled in conformity with the Act.²²

including the risk information the label must contain).

14. See *Wyeth*, 129 S. Ct. at 1198.

15. See *infra* Part IV.C.

16. See 21 U.S.C. § 360k(a) (2006).

17. See *infra* notes 152–55 and accompanying text.

18. See *Wyeth*, 129 S. Ct. at 1204.

19. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516–20 (1992).

20. *Id.* at 514–15.

21. *Id.* at 514 (quoting Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, § 5, 79 Stat. 282, 283 (1965) (codified as amended at 15 U.S.C. §§ 1331–1341 (2006))).

22. *Id.* at 515 (quoting Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 5, 84 Stat.

As the two Acts contained express preemption provisions, the Court needed only to engage in standard statutory construction to determine the extent of the federal preemption and whether it was Congress' intent to preempt tort claims for failure to warn.²³ The Court found the 1969 amendments prohibiting any differing state requirements did preempt state tort claims, as the failure to warn would impose an additional duty or a requirement on a cigarette manufacturer.²⁴ As the 1965 Act did not prohibit any such requirements, this version of the Act did not preempt a state common law claim.²⁵ While *Cipollone* provided an exercise in statutory construction of an express provision, it also laid the cornerstone for implied conflict preemption through Justice Blackmun's concurrence.²⁶ Justice Blackmun agreed with the majority that the intent and purpose of Congress was the touchstone of any preemption analysis, but added that absent an express provision, the Court must resort to the principles of implied preemption to determine whether state law actually conflicts with federal law.²⁷ In essence, the Court must attempt to determine the intent of Congress to supplant a state law when Congress is silent.²⁸

B. *Geier v. American Honda Motor Co.* and Frustration of Purpose

In *Geier*, the plaintiff brought a claim against Honda, alleging that the manufacturer negligently designed the vehicle by not equipping it with a driver's side airbag.²⁹ Honda argued the Department of Transportation's Federal Motor Vehicle Safety Standard 208, which allowed car manufacturers to select from a range of safety features, preempted a state negligence claim as Honda complied with the minimum safety standard.³⁰ The question appeared to center on whether states could impose tort liability upon a car manufacturer who failed to exceed the federal standard.³¹

87, 88 (1970) (codified as amended at 15 U.S.C. § 1334 (2006)).

23. See Viet D. Dinh, *Reassessing the Law of Preemption*, 88 GEO. L.J. 2085, 2100 (2000) (noting that when Congress includes an express preemption clause, the work of the Court is limited and straightforward: "to interpret the express preemption clause and determine whether the state law at issue falls within the preemptive scope").

24. *Cipollone*, 505 U.S. at 522.

25. *Id.* at 519–20.

26. *Id.* at 532 (Blackmun, J., concurring).

27. *Id.*

28. *Id.*

29. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 865 (2000).

30. *Id.* at 881.

31. O'Steen & O'Steen, *supra* note 2, at 73–74.

The Court, however, as indicated by Justice Blackmun's concurrence in *Cipollone*, did not just ask whether the federal standard created a ceiling or a floor for safety regulations, but considered the purpose and intent of the Department of Transportation in creating the regulation.³² First, the Court interpreted the express preemption provision contained in the National Traffic and Motor Vehicle Safety Act,³³ providing that no state could establish a safety standard applicable to the same aspect of performance of a motor vehicle or equipment which is not identical to the federal standard.³⁴ Next, the Court considered the effect of the express preemption provision in light of a savings clause that compliance with a federal safety standard does not exempt any person from liability under common law.³⁵ The Court held that a reading of the preemption clause and savings clause together showed that Congress did not intend the Act or implementing regulations to preempt common law tort claims.³⁶

The Court's analysis did not end there, however. While Congress' intent may not have been to preempt tort actions, the Court considered the statute, specifically the safety standard approved by the Department of Transportation, under the doctrine of implied conflict preemption to consider whether a state tort action would frustrate the objectives of the Department even though Congress expressly stated preemption did not apply.³⁷ The Court determined that while the express provision did not preempt state law claims, the Department of Transportation intended to gradually introduce safety improvements over time.³⁸ Therefore, holding manufacturers liable for not exceeding the federal safety requirements under state tort law would frustrate this objective of gradual introduction, and thus, the federal safety standard preempted state tort claims.³⁹

C. *Sprietsma v. Mercury Marine*: Setting the Floor, Not the Ceiling for Actions

In *Sprietsma*, the plaintiff brought a common law tort claim against a boat manufacturer, alleging the propeller that injured her after falling overboard should have been equipped with a propeller guard.⁴⁰ As in *Geier*, the Court first interpreted an express preemption clause, stating that

32. *Geier*, 529 U.S. at 881.

33. 49 U.S.C. §§ 30101–30170 (2006).

34. *Geier*, 529 U.S. at 867 (quoting 15 U.S.C. § 1392(d) (1988) (repealed 1994)).

35. *Id.* at 868.

36. *Id.*

37. *Id.* at 870–86.

38. *Id.* at 874–75.

39. *Id.* at 875.

40. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 55 (2002).

no state may enact a boat safety standard that is not identical with the federal regulations, and a savings clause, stating that compliance with federal regulations does not relieve a person from common or state law liability.⁴¹ Again, as in *Geier*, the Court rejected that the federal standard preempted all state tort claims and looked to whether implied conflict preemption obviated state claims.⁴² While the *Geier* Court found implied preemption applied, the Coast Guard's lack of enacting a safety regulation to require propeller guards in *Sprietsma* after a lengthy study did not preempt state tort actions.⁴³ The Coast Guard's failure to act indicated that the Coast Guard had not made a policy decision that propeller guards were unnecessary and that states should or could not impose more stringent safety measures.⁴⁴

D. Medical Device and Drug Cases: *Medtronic, Inc. v. Lohr* and *Riegel v. Medtronic, Inc.*

In *Lohr*, the Court considered whether federal laws and regulations preempted a state claim for a failed pacemaker and a failure to warn of the potential problem.⁴⁵ As in previously discussed cases, the medical device portion of the federal act contained an express preemption provision, prohibiting states from enacting any medical device requirements different from or in addition to federal standards.⁴⁶ While such a provision appeared to preempt state claims, the devil was once again in the details. Here, the FDA approved the device under a grandfather clause, allowing the device as substantially equivalent to a device in existence before passage of the amendments in 1976 and therefore subjecting it to a much less rigorous examination process.⁴⁷ The Court determined that the less stringent examination process did not impose specific design requirements and without such requirements, the federal standards could not preempt state regulation.⁴⁸ Similarly, FDA regulations concerning labels and warnings did not preempt state failure to warn claims because they were too general to be applicable to the specific device in question.⁴⁹ Finally, the Court affirmed that in all preemption cases, there is a presumption against preemption absent a clear congressional intent to supersede state law,

41. *Id.* at 58–59 (quoting 46 U.S.C. §§ 4306, 4311 (2006)).

42. *Id.* at 65.

43. *Id.* at 67.

44. *Id.* at 66–67.

45. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 481 (1996).

46. 21 U.S.C. § 360k(a) (2006).

47. *Lohr*, 518 U.S. at 478–80.

48. *Id.* at 497.

49. *Id.* at 501.

including state common law.⁵⁰

In *Riegel v. Medtronic, Inc.*, the Supreme Court again considered claims of negligence, labeling, and implied warranty against a manufacturer under the very same statutes as *Lohr*.⁵¹ Contrary to *Lohr*, the catheter in question here underwent a more rigorous pre-market approval process by the FDA.⁵² Therefore, the Court considered whether the pre-market approval process and FDA approval imposed federal requirements and then whether a state tort claim differed from those requirements.⁵³ If state common law claims imposed any differing requirement, federal standards must preempt state claims according to the express preemption provision in the Medical Device Amendments.⁵⁴ The rigorous pre-market approval process, which is specific to each device tested and approved by the FDA, imposed the type of requirements that were missing under the substantial equivalence test in *Lohr*.⁵⁵ Since the common law claim in question sought to require the catheter to be safer than the model approved by the FDA, a state tort action imposed a differing and heightened requirement.⁵⁶ The federal law thus preempted such a differing requirement.⁵⁷

Riegel was important not only for this statutory interpretation of the express preemption clause, but also for its discussion of the level of agency deference the Court should afford to the FDA's interpretation of the FDCA.⁵⁸ The Court specifically noted they did not have to rely on the FDA's position that preemption applies because the statute speaks for itself, but did agree with the dissent that only minimal deference under *Skidmore v. Swift & Co.* would apply.⁵⁹ Under *Skidmore*, the weight given to the agency's interpretation “depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.”⁶⁰ This consideration of agency deference provides keen insight into the Court's decision in *Wyeth v. Levine*, where there is no express preemption provision to guide the Court's

50. *Id.* at 485.

51. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320–21 (2008).

52. *Id.* at 317–20.

53. *Id.* at 321–22.

54. *Id.* at 316 (citing 21 U.S.C. § 360k(a) (2006)).

55. *Id.* at 322–23.

56. *Id.* at 324–25.

57. *Id.* at 330.

58. *Id.* at 326–27.

59. *Id.*

60. *Id.* at 338 n.8 (Ginsburg, J., dissenting) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

determination.⁶¹

III. *WYETH V. LEVINE*

A. Regulatory Scheme

A manufacturer, such as Wyeth, must submit a New Drug Application to the FDA for approval of all new pharmaceutical drugs, in this case Phenergan.⁶² The FDA must approve the drug unless the manufacturer fails to demonstrate that the drug is safe and effective, the drug will perform as represented, and the label is not false or misleading.⁶³ The FDA then mandates through regulations the format and content of drug labels, as well as the risk information the label must contain.⁶⁴ Once approved, normally any changes to the label and warnings must receive FDA approval before the manufacturer issues the altered label.⁶⁵ However, the FDA regulations also allow a manufacturer to distribute a drug with an altered label after submitting the change to the FDA, but prior to any FDA approval, if the changes “‘add or strengthen a contraindication, warning, precaution or adverse reaction’ or... ‘add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product.’”⁶⁶ Therefore, section 314.70(c) allows a drug manufacturer to strengthen the warnings given on a label without any FDA approval or regulation.⁶⁷

B. Phenergan’s Uses and Levine’s Circumstances

Under this regulatory scheme, the FDA approved a warning label submitted by Wyeth that provided when injecting the drug intravenously, health care workers should exercise extreme care to avoid intra-arterial injection.⁶⁸ Such intra-arterial injection could lead to pain, severe chemical irritation, severe spasms, and gangrene requiring amputation.⁶⁹ In addition, the warning indicated, “it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning

61. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1190 (2009).

62. *Id.* at 1194–95 (citing 21 U.S.C. § 355 (2006)).

63. *Id.* at 1195; see 21 U.S.C. § 355(d) (2006).

64. *Wyeth*, 129 S. Ct. at 1196 (citing 21 U.S.C. § 355 (2006); 21 C.F.R. § 314.105(b) (2009)).

65. *Id.*

66. *Id.* (citing 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2009)).

67. *Id.*

68. *Id.* at 1192.

69. *Id.* at 1191 n.1.

satisfactorily.”⁷⁰ Therefore, the Phenergan label did not prohibit the use of direct intravenous injection or IV-push administration or indicate such a method should not be used.⁷¹

In April 2000, the plaintiff visited a local clinic complaining of nausea resulting from a migraine headache.⁷² Medical staff first administered the drug by intramuscular injection, which caused no harmful side effects.⁷³ The same day, when the nausea continued, medical staff directly injected Phenergan by the IV-push method rather than through tubing or intramuscular injection.⁷⁴ The medical staff inadvertently injected the drug into an artery resulting in severe damage, gangrene, and ultimately the amputation of Levine’s hand and forearm.⁷⁵

Levine brought a claim against Wyeth in Vermont Superior Court for negligence and failure to warn, arguing that the label should have prohibited IV push, as it was safer to use other available options.⁷⁶ Wyeth countered with three arguments: (1) the FDA’s approval of the drug label impliedly preempted state common law claims that the label was inadequate; (2) the FDA was aware of the dangers of IV push but did not prohibit its use so Wyeth could not prohibit its use; and (3) state common law claims penalizing drug companies for using FDA approved labels would pose an obstacle to the purpose of the FDA’s labeling regulations.⁷⁷

C. Holding and Analysis

1. Purpose and Intent of Congress and Presumption Against Preemption

Prior to analyzing Wyeth’s arguments that it would be impossible to comply with federal and state law and that state tort claims would obstruct the objectives and purposes of Congress, the Court set down two judicial cornerstones of preemption to guide the Court’s decision.⁷⁸ “First, ‘the purpose of Congress is the ultimate touchstone in every pre-emption case.’”⁷⁹ Second, in a preemption case where Congress has legislated in a field traditionally left to the states, the Court applies a presumption against

70. *Id.*

71. *Id.* at 1191–92 n.1.

72. *Id.* at 1191.

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.* at 1191–92.

77. *Id.* at 1192–93.

78. *Id.* at 1194.

79. *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

preemption because the “historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”⁸⁰

The history of the FDCA and the regulatory scheme dictated above indicate that Congress required the manufacturer to prove and maintain the safety and effectiveness of their drugs.⁸¹ Further, Congress took great care to ensure the continuation of state law in the face of federal legislation by inserting a savings clause in 1962, which detailed that a federal law would only preempt state law upon a direct and positive conflict with the FDCA.⁸² Notably, Congress enacted an express preemption provision for medical devices in 1976 but chose not to include a similar provision for prescription drugs.⁸³ Finally, after Levine’s lawsuit against Wyeth commenced, Congress again amended the FDCA to grant the FDA authority to require a drug maker to change a warning label based on information that becomes available after a drug’s initial approval; however, Congress specifically rejected a proposed provision to require FDA preapproval of any change to a label.⁸⁴

2. Complying with Both State and Federal Law is Not Impossible

Wyeth first contended that the FDA mandates the Company use the specific and identical label approved for the drug.⁸⁵ Further, Wyeth argued an amendment to the regulation, allowing a change to the warning label without FDA approval, simply reaffirmed the accepted interpretation of the regulation that a manufacturer may only strengthen a warning “to reflect newly acquired information.”⁸⁶ Therefore, Wyeth argued, this section mandates a strengthened warning only if new information has emerged that the FDA did not have when initially approving the warning label.⁸⁷ Without any such information presented in this case, Wyeth argued it was impossible for them to strengthen Phenergan’s label to comply with the state duty imposed by Vermont and comply with the FDA mandate.⁸⁸ If Wyeth had chosen to unilaterally strengthen their warning without any

80. *Id.* at 1194–95 (citing *Lohr*, 518 U.S. at 485).

81. *Id.* at 1195.

82. *Id.* at 1196.

83. *Id.* (citing 21 U.S.C. § 360k(a) (2006)).

84. *Id.* (citing Food and Drug Administration Amendments Act of 2007, § 901, Publ. L. No. 110-85, 121 Stat. 823, 922 (codified as amended at 21 U.S.C. § 555 (Supp. I 2009)); Prescription Drug User Fee Amendments of 2007, S. 1082, 110th Cong. § 208 (2007) (as passed by Senate, Apr. 10, 2007) (proposing new section 506D)).

85. *Id.* at 1196 (citing 21 U.S.C. § 355 (2006); 21 C.F.R. § 314.105(b) (2009)).

86. *Id.* (citing 21 C.F.R. § 314.70(c)(6)(iii) (2009)).

87. *Id.*

88. *Id.*

newly acquired information that the FDA did not consider when approving the label, so the argument goes, they would violate federal law.⁸⁹

The Supreme Court determined that either under the new clarification in the regulation or as it stood at the time of Levine's injury, Wyeth could have complied with federal requirements and strengthened the warning to comply with Vermont's requirements.⁹⁰ Specifically, even under the new interpretation requiring "newly acquired information," Wyeth could have strengthened their warning based on a new analysis of existing data that Wyeth already submitted to the FDA.⁹¹ While Wyeth knew of the risks of Phenergan administered by IV push, a new analysis of this risk could have shown an adverse reaction of a different type, greater severity, or higher frequency that would constitute newly acquired information under the regulation.⁹² The record indicated at least twenty cases of gangrene and subsequent amputations from Phenergan injections, and therefore, Wyeth had ample opportunity to review this data to determine a greater risk and strengthen the warning as specifically allowed without FDA approval.⁹³

Further, strengthening the warning prior to FDA approval would not result in an unauthorized distribution of a drug or misbranding.⁹⁴ Unauthorized distribution only occurs when a manufacturer puts out a new drug.⁹⁵ Strengthening a label on an existing drug, under specific regulations that grant drug makers the authority to strengthen the label prior to FDA approval, does not make Phenergan a new drug.⁹⁶ In addition, misbranding does not occur simply because a manufacturer altered a label as allowed under regulations or else the regulation would have no meaning.⁹⁷

While the Supreme Court could have stopped there and held it was not impossible for Wyeth to comply with both state and federal law, the Court further stated that under the FDCA, drug manufacturers, and not the FDA, bear the primary responsibility for the safety of their products.⁹⁸ When the risk of gangrene and amputation became apparent to Wyeth, they had a duty to provide a warning that adequately detailed the risk, and federal

89. *Id.*

90. *Id.* at 1196–97.

91. *Id.* at 1197.

92. *Id.* (citing Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,607 (Aug. 22, 2008)).

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.* (citing 21 U.S.C. § 321(p)(1) (2006) (defining "new drug"); 21 C.F.R. § 310.3(h) (2009)).

97. *See id.*

98. *Id.* at 1197–98.

regulations specifically provided an avenue to provide this warning prior to FDA approval.⁹⁹ The Supreme Court further stated that they would not hold it was impossible to comply with both federal and state requirements without clear evidence that the FDA would have rejected the strengthened warning required by state law.¹⁰⁰ For Phenergan, the FDA did review evidence of the risks of IV push and approve a label that did specifically warn against the risks of improper administration.¹⁰¹ In this case, however, there was no evidence the FDA “gave more than passing attention to the issue,” the FDA made an affirmative decision to retain IV push, the FDA would have prohibited a strengthened warning, or that Wyeth submitted an extensive evaluation or analysis about the specific dangers from IV push.¹⁰² The Vermont courts required a strengthened warning, the FDA regulations allowed Wyeth to strengthen Phenergan’s warning, and Wyeth failed to present any evidence that the FDA would have prevented that warning.¹⁰³

3. State Tort Claims Do Not Obstruct the Purposes and Objectives of Congress to Regulate Drug Labels

Alternatively, Wyeth argued that FDA regulations are both the ceiling and floor for pharmaceutical warning labels such that FDA approval preempts any state tort claim concerning the drug’s warning, regardless of whether the FDA considered the risk at issue.¹⁰⁴ Further, Wyeth argued that since the FDA determines that a drug is safe and its warning adequate, the Court must presume that the FDA performed a “precise balancing of risks and benefits and... established a specific labeling standard that leaves no room for different state-law judgments.”¹⁰⁵

The Court strenuously dismissed these arguments. First, the entire history of Congressional action in passing and amending the FDCA indicates Congressional intent to continue to allow state tort claims in the face of federal legislation.¹⁰⁶ Further, throughout the seventy-year history of the FDCA, Congress never chose to include an express preemption provision for pharmaceutical drugs, while they did choose to do so for

99. *Id.* at 1198.

100. *Id.*

101. *See id.* at 1198 & n.5.

102. *Id.* at 1199.

103. *Id.*

104. *Id.*

105. *Id.* at 1200.

106. *Id.* at 1199; *see also id.* at 1199–1200 n.7 (stating that Congress did not provide a federal remedy for consumers in the 1938 statute specifically because witnesses testified that no such action was necessary since common law claims were already available under state law).

medical devices, over the counter medications, and cosmetics.¹⁰⁷ Where Congress is aware of state law that may potentially conflict with a federal interest and it chooses not to act, “the case for federal preemption is particularly weak”, especially in light of the presumption against preemption.¹⁰⁸

In spite of Congress’ apparent intent to remain silent, Wyeth argued the Court should rely on a recently enacted preamble to a 2006 FDA regulation, stating that the FDCA does act as a ceiling and a floor so that any approved FDA label preempts state tort claims.¹⁰⁹ The FDA preamble further stated that state tort claims threatened the FDA’s role to act as the expert evaluating and regulating drugs.¹¹⁰

While the Court has recognized that agency regulations carrying the force of law can preempt a state claim, the Court has only found so after conducting its own conflict determination by interpreting the state and federal law and has not relied solely on the agency’s determination of preemption.¹¹¹ Where Congress has not expressly delegated preemption authority to an agency, the Court may give some weight to an agency assertion of preemption.¹¹² However, the Court does not solely defer to the agency’s conclusion that preemption is appropriate, but instead gives some weight to the agency’s explanation of how the state claims will affect the federal regulatory scheme.¹¹³

In this case, the Court concluded the FDA’s preamble merited no deference.¹¹⁴ Specifically, the FDA enacted the preamble in 2006 without compliance with administrative law requirements for notice and comment and after the initial proposed rule explained there would be no preemption

107. *Id.* at 1200 (“Congress could have applied [the medical device] 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.” (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 326 (2008))); *id.* at 1200 n.8 (Congress preempted certain state requirements for over the counter medications and cosmetics, but stated “[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.” (quoting 21 U.S.C. §§ 379r(e), 379s(d) (2006))).

108. *Id.* at 1200 (quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989)).

109. *Id.* (citing Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3,922, 3,934–35 (Jan. 24, 2006)).

110. *Id.* (citing Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3,935).

111. *Id.* at 1201.

112. *Id.*

113. *Id.* (“[W]e have given ‘some weight’ to an agency’s views about the impact of tort law on federal objectives when ‘the subject matter is technical[ly] and the relevant history and background are complex and extensive.’ Even in such cases, however, we have not deferred to an agency’s *conclusion* that state law is preempted.” (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000))).

114. *Id.*

or federalism effects.¹¹⁵ Again, while the Court could have stopped here, they chose to go further and state that the preamble was completely at odds with the long history of the FDA and with evidence of Congress' purpose.¹¹⁶

Further, the Court determined federal drug labeling requirements were not analogous to the regulatory scheme presented in *Geier*.¹¹⁷ In *Geier*, the Court found preemption based on its own analysis of the issues, finding that a state law claim requiring a specific vehicle safety device would pose an obstacle to the properly adopted federal scheme of phasing in safety devices.¹¹⁸ After undergoing this independent analysis, the *Geier* Court considered the agency's preemption conclusion only as further support for their holding.¹¹⁹ In *Wyeth*, the Court did not consider a regulation carrying the force of law, and even if it had, the long history of the FDCA and the FDA's position on state tort claims indicates that state tort claims do not pose an obstacle to federal drug labeling regulations.¹²⁰

IV. GOING FORWARD: PHARMACEUTICAL COMPANIES' REACTIONS

In the wake of this landmark decision, the pharmaceutical companies' worst fears seemed realized; instead of one regulatory compliance scheme, they would be subject to the whim of fifty states' court systems.¹²¹ An initial reading of the *Wyeth* decision would appear to put drug makers in a potentially hazardous position. They still need to comply with the FDCA and corresponding federal regulations to submit data about benefits and risks of a drug along with proposed warning labels.¹²² However, drug companies still have a duty to provide an adequate warning as judged by each individual state's judicial system, and the drug companies have no standards or guidelines to follow to determine what each individual state considers adequate warning.¹²³

115. *Id.*

116. *Id.*

117. *Id.* at 1203.

118. *Geier*, 529 U.S. at 874–75.

119. *Id.* at 875–77.

120. *Wyeth*, 129 S. Ct. at 1203–04.

121. Steve Forbes, *Supremely Destructive Stupidity*, FORBES, Apr. 13, 2009, at 13 (remarking that the Supreme Court's finding allowing state tort liability for federally approved drugs will lead to situations where drug makers must prepare for warning labels as judged by fifty states rather than one federally delegated authority).

122. See 21 U.S.C. § 355(a)–(d) (2006); 21 C.F.R. § 314.70 (2009).

123. See L. Gordon Crovitz, *Information Age: The Supreme Court and the Tyranny of Lawyers*, WALL ST. J., Mar. 9, 2009, at A17 (stating that every drug must carry fifty different warnings, one for each state, and even then, these warnings may be updated from time to time by local juries).

While many in the business community are lambasting this precarious position imposed on drug makers and potentially other businesses,¹²⁴ there are numerous options available for pharmaceutical companies to limit their liability, comply with both state and federal laws, and continue to market their products profitably.

A. Strengthened Warnings Without Prior Approval

As the Supreme Court noted, current FDA regulations allow a pharmaceutical company to unilaterally strengthen prescription medication warnings based upon newly acquired information without receiving prior FDA approval.¹²⁵ The “newly acquired information” does not have to be actual data of a risk that has surfaced since the approval of the drug.¹²⁶ Instead, a drug company may analyze existing data or information of greater risks or frequency of injuries and side effects to determine that the drug is causing harm.¹²⁷ In light of the Supreme Court’s strong language that drug companies carry the primary responsibility for post-approval monitoring of their drugs’ safety,¹²⁸ drug companies should consider themselves on notice to monitor this activity anyway.

Drug companies may choose to strengthen their warnings, even to the point of equaling a prohibition on the drug’s use or a specific method of delivery, and then submit this change to the FDA as required for approval.¹²⁹ As the FDA retains ultimate authority to review this change and either approve or reject the new labels use, the drug companies would have concrete evidence if sued in state torts to argue for preemption.¹³⁰ If the FDA denied the use of the strengthened warning and then an injured party sues the company in state court for failure to adequately warn, the drug company can rely on this denial as evidence that they could not provide a stronger warning under federal law.¹³¹ In such a case, the

124. *See id.*; Forbes *supra* note 121.

125. *Wyeth*, 129 S. Ct. at 1196–97.

126. *Id.* at 1197 (citing Supplemental Applications Proposing Labeling Changes for Approved Drug, Biologics, and Medical Devices, 73 Fed. Reg. 49, 603, 49, 604 (Aug. 22, 2008)).

127. *Id.* (citing Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. at 49,606–07).

128. *Id.* at 1197–98.

129. *See* 21 C.F.R. § 314.70(c) (2009).

130. *See Blair*, *supra* note 8, at 298–99 (noting that the FDA can make a drug manufacturer withdraw a strengthened label if the FDA does not think it is necessary).

131. *See id.* at 299 (“If FDA does not allow a drug manufacturer to warn the public of potential dangers posed by a product, yet the manufacturer still is held liable for failure to warn under a state tort claim, it is impossible for the manufacturer to comply with both state and federal requirements. It is difficult to ascertain how FDA’s regulation could have been considered to do anything but preempt the field.”); Dinh, *supra* note 23, at 2102 (stating that conflict preemption can be found, regardless if Congress appeared silent on the issue, if a state law actually conflicts with a federal law).

company would have evidence of exactly what the Supreme Court in *Wyeth* stated was lacking to find preemption—it would be impossible to comply with both federal and state law.¹³²

B. Submission of a Prohibition Warning and Greater Evidence of Risk

Along the same lines as unilaterally strengthening warnings of drugs already approved, pharmaceutical companies could submit numerous proposed warnings with a new drug application along with greater evidence of all risks and benefits associated with the drug's use. The drug makers bear the ultimate responsibility for the safety of their own products,¹³³ but the FDA continues to shoulder the role as the expert federal agency charged with weighing the benefits and risks of a drug, along with proposed warning labels, before approving the drug's use and warning label.¹³⁴ The *Wyeth* Court decision against preemption mainly relied on the fact that the FDA did not make an affirmative decision to allow IV-push administration, did not consider a prohibition of this use or strengthened warning, and did not consider extensive evidence of the risks and benefits of the method.¹³⁵

Therefore, a pharmaceutical company may submit extensive evidence of a risk inherent in a drug along with several proposed warning labels, even one amounting to a prohibition on a specific use for the drug or a delivery method. Because the FDA is responsible for reviewing all of this information and the proposed warning labels, the FDA will be forced to choose an appropriate label if the FDA approves the drug. As with the strengthened warnings for approved drugs detailed above, the drug maker can point to the FDA's explicit refusal to allow a strengthened warning to illustrate it would be impossible to comply with the FDA requirements and state law.¹³⁶

Further, if the expert agency charged with regulating drug use and warning labels truly considers a wide possibility of proposed warnings as well as extensive evidence of the drug's risks and benefits, a pharmaceutical company may argue the decision of the FDA falls under *Geier* and not

132. *See Wyeth*, 129 S. Ct. at 1198 (holding that without clear evidence that the FDA would have rejected the strengthened warning, the Court would not find preemption due to the impossibility to comply with both federal and state law).

133. *Id.* at 1197–98.

134. *See* 21 U.S.C. § 355(a)–(d) (2006); 21 C.F.R. § 314.70 (2009).

135. *See Wyeth*, 129 S. Ct. at 1198–99.

136. *See id.* at 1198 (holding that without clear evidence that the FDA would have rejected the strengthened warning, the Court would not find preemption due to the impossibility to comply with both federal and state law); Blair, *supra* note 8, at 299 (stating that express rejection of a proposed warning by the FDA should preempt a state tort claim requiring the same warning).

Wyeth.¹³⁷ The Supreme Court specifically held that *Geier* did not apply to the warning label for Phenergan primarily because there was no extensive record indicating the FDA's balancing of risks and benefits of heightened warnings.¹³⁸ While the *Wyeth* Court also recognized the federal agency's rule in *Geier* was worthy of some level of deference because they conducted a formal rulemaking, the holding shows the Court is more likely to find preemption when the agency record reveals "the factors the agency had weighed and the balance it had struck..."¹³⁹ Therefore, even after *Wyeth*, a drug manufacturer may still successfully argue that implied preemption applies to negate a state tort claim.¹⁴⁰ If the drug manufacturer can point to specific evidence where the FDA did consider the risks and benefits of a certain label and required another label, then a state tort claim requiring more may very well frustrate the purposes and objectives of Congress.¹⁴¹

The courts may soon test this argument as the Supreme Court recently remanded a drug warning preemption case where the Third Circuit found preemption of state tort claims.¹⁴² In *Colacicco*, the Third Circuit deferred to the FDA's preamble asserting preemption, failed to apply a strong presumption against preemption, and failed to recognize that drug manufacturers maintain responsibility for drug safety through their ability to update warnings prior to FDA approval under FDA regulations.¹⁴³ These ruling are inconsistent with the Supreme Court's decision and may very well change the outcome of the case in *Colacicco*.¹⁴⁴ However, such a result is not a foregone conclusion. In *Colacicco*, the Third Circuit specifically distinguished the facts and decision of the Vermont Supreme Court in *Wyeth*.¹⁴⁵ The Third Circuit based its finding of preemption

137. See Posting of Anthony J. Sebok to FindLaw.com, <http://writ.news.findlaw.com/sebok/20090317.html> (Mar. 17, 2009) (stating that implicit preemption because a state law frustrates the objectives and purposes of federal law may occur when the FDA has considered the background reasons for allowing or disallowing a warning and made a decision on which label to require).

138. See *Wyeth*, 129 S. Ct. at 1203.

139. *Id.*

140. See Sebok, *supra* note 137 (arguing that a showing of the background reasons for a rejection may provide a record of the balancing of risks and benefits to show a heightened warning would frustrate the purpose of the FDA when a state may require what the FDA specifically rejected).

141. See *Wyeth*, 129 S. Ct. at 1203–04.

142. *Colacicco v. Apotex, Inc.*, 129 S. Ct. 1578, 1578–79 (2009) (remanding case to the Third Circuit for further consideration in light of *Wyeth*).

143. See *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 264–68, 275–76 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009).

144. See *Colacicco*, 129 S. Ct. at 1578–79.

145. See *Colacicco*, 521 F.3d at 271–72 n.17 (stating the Vermont Supreme Court found no evidence that the FDA intended to prohibit defendant from strengthening the warning and therefore it was not impossible for *Wyeth* to comply with both federal and state requirements but that the facts in *Colacicco* are different).

mainly on the extensive record of the drugs' benefits and risks considered by the FDA, including the risk at issue in the case.¹⁴⁶ Preemption applied, like in *Geier*, because the FDA made an affirmative decision that the science did not support a warning such as that sought by the plaintiffs in the case.¹⁴⁷ If the Third Circuit still makes such a finding on remand and the Supreme Court does not hear and alter the outcome of the case, pharmaceutical companies still have an avenue to pursue preemption claims.¹⁴⁸

C. Seeking Legislative Changes

Rather than seek additional preemption decisions from the courts, which will be hard pressed to issue such findings after *Wyeth*, the easiest path may very well be to seek legislative action. A clear message from Congress to preempt state tort claims for pharmaceutical drugs in light of the Supreme Court's holding will completely reverse the decision. Further, as the current Congress may very well be disinclined to seek such an action, the drug companies may seek legislative remedies on the state level.

Congress has seen fit to include an express preemption provision for medical devices in the FDCA.¹⁴⁹ The Supreme Court upheld this express preemption provision in *Reigel v. Medtronic* specifically because the medical device at issue had undergone an extensive pre-market approval process by the FDA.¹⁵⁰ Congress may be leery to add a similar provision under the current circumstances of the FDA approval process and safety-monitoring regime for fear the FDA cannot adequately ensure the safety of prescription drugs.¹⁵¹

Alternatively, drug companies could seek redress from individual state legislatures to enact their own federal preemption statutes. Such statutes could take many forms such as a statute allowing complete immunity from state tort claims and liability when the FDA approved the drug and its

146. *Id.* at 271–72.

147. *Id.*

148. See Sebok, *supra* note 137 (noting that if pharmaceutical companies submit the scientific work as in *Colacicco*, then *Wyeth* may have produced a good result).

149. 21 U.S.C. § 360k(a) (2006).

150. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315–23 (2008).

151. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 & n.11 (2009) (noting that “the FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge” and citing three recent studies stating the FDA was not in a position to meet its current or emerging regulatory responsibilities); O’Steen & O’Steen, *supra* note 2, at 85–86 (remarking that approximately half of the FDA’s drug evaluation budget comes from fees paid by the pharmaceutical companies in return for expedited approval of drugs, a system that provides an incentive for the FDA to rush drugs to the market without undertaking thorough studies to determine the risks of drugs).

label.¹⁵² While this type of statute provides the greatest protection for pharmaceutical companies, it allows no avenue for injured parties to seek redress when even the Supreme Court has acknowledged the FDA cannot guarantee drug safety.¹⁵³ Prescription drug companies could seek weaker state protections, such as those in place in Texas and New Jersey, where compliance with FDA regulations for warning labels provides a rebuttable presumption of the drug's safety.¹⁵⁴ Finally, other states, such as Utah and Oregon, at least attempt to limit liability by barring punitive damages for drug manufacturers whose drugs and warnings comply with current FDA regulations.¹⁵⁵

V. CONCLUSION

After *Wyeth v. Levine*, one thing is clear: pharmaceutical companies are responsible for the safety of their own products and potentially liable in state courts for any injuries their products may cause.¹⁵⁶ While drug makers have pushed recently for a broad ruling that FDA approval of the drug's use and warning labels preempts any state tort claims, the Supreme Court resoundingly dispelled this argument.¹⁵⁷ While many in the business community lambasted the Supreme Court's decision for the effects it might cause on the business community,¹⁵⁸ the truth of the matter may not be as catastrophic as initially thought. Within the ruling itself, there may still be room for a finding of preemption if a pharmaceutical company can show that the FDA considered and affirmatively rejected a strengthened warning.¹⁵⁹ In addition, an extensive record of the FDA's consideration of the risks and benefits of a drug, including the specific risk associated with an injury, may allow a finding of preemption.¹⁶⁰ These two approaches to limiting liability may spur pharmaceutical companies to do exactly what the Supreme Court wanted—closely monitor their own products, continue to inform the FDA about risks and benefits, and allow the expert federal

152. See, e.g., MICH. COMP. LAWS § 600.2946(5) (2000) (stating that a drug is not defective or unreasonably dangerous in a product liability action if the FDA approved the drug and its label for use and the drug and label were in compliance with FDA regulations at the time the manufacturer sold the drug).

153. See *Wyeth*, 129 S. Ct. at 1202 & n.11.

154. See TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (Vernon 2005); N.J. STAT. ANN. § 2A:58C-4 (West 2000).

155. See OR. REV. STAT. § 30.927 (2009); UTAH CODE ANN. § 78B-8-203 (Repl. Vol. 2008).

156. See *Wyeth*, 129 S. Ct. at 1202–04.

157. See *id.* at 1203–04.

158. Crovitz, *supra* note 123; Forbes, *supra* note 121.

159. See *supra* Part IV. B.

160. See *supra* Part IV.B.

agency to make a final determination.¹⁶¹ Alternatively, drug manufacturers may attempt legislative remedies to immunize themselves from liability, such as an express preemption clause in the FDCA similar to the existing clause for medical devices.¹⁶² As this option may not gain much traction with the current Congress, pharmaceutical companies may instead seek state legislation that inoculates them from liability based upon FDA approval for their drugs.¹⁶³ One thing is clear after *Wyeth v. Levine*, pharmaceutical companies will have to do more work to limit their liability from any harm their products may cause.

161. *See Wyeth*, 129 S. Ct. 1197–98.

162. *See supra* note 149 and accompanying text.

163. *See supra* notes 152–55 and accompanying text.