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Products Liability—Conflict Preemption: The United States Supreme Court Denies Preemption Defense for Drug Manufacturers Using FDA-Approved Warning Labels

Charlotte J. Skar

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PRODUCTS LIABILITY—CONFLICT PREEMPTION:
THE UNITED STATES SUPREME COURT DENIES
PREEMPTION DEFENSE FOR DRUG MANUFACTURERS
USING FDA-APPROVED WARNING LABELS
Wyeth v. Levine, 129 S. Ct. 1187 (2009)

ABSTRACT

The United States Supreme Court held a plaintiff's defective warning claims were not preempted by federal law or the Federal Drug Administration (FDA) regulations. Part I of this article provides the factual background in which the plaintiff's arm was amputated after she was given an injection of Phenergan, a drug manufactured by Wyeth, and developed gangrene. The plaintiff brought defective warning claims against Wyeth in a Vermont state court. Wyeth's defense was that federal laws and regulations preempted the plaintiff's claims due to conflict preemption because, Wyeth argued, state tort suits would conflict with the purposes and objectives of federal laws and regulations, and state tort suits made it impossible to comply with both federal and state regulations. The jury returned verdicts against Wyeth, which were upheld by the U.S. Supreme Court. Part II gives a brief summary of the history of FDA regulations and preemption principles prior to *Wyeth v. Levine*. Part III analyzes the majority and minority opinions of the Supreme Court in *Wyeth v. Levine*. Finally, Part IV outlines the impact of the *Wyeth v. Levine* opinion on subsequent court opinions.

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I. FACTS

In 2006, the Vermont Supreme Court held Federal Drug Administration (FDA) label requirements were only minimum requirements, a drug manufacturer could create stronger warnings without prior FDA approval, and, consequently, a jury verdict finding a drug manufacturer liable on a failure to warn claim was not preempted.¹ The United States Supreme Court upheld the Vermont state court decision in *Wyeth v. Levine*,² holding FDA approval of the drug Phenergan's warning label did not preempt a state tort suit.³ Phenergan's manufacturer, Wyeth, previously submitted a revised label in 1988 in response to the FDA's request for different warnings concerning the risk of Phenergan, an irritant, coming into contact with arterial blood.⁴ The FDA did not respond to the proposed revisions about intra-arterial injections until 1996 and simply instructed Wyeth to "retain verbiage in current label."⁵ Wyeth argued, in *Wyeth v. Levine*, that FDA approval and the mandate to retain the warning label on Phenergan meant any state tort suit based on the adequacy of the warning label would be preempted and, therefore, dismissed.⁶ The argument was that preemption was implicated because the FDA found the warning safe and effective, but a jury verdict ultimately deemed the same label unreasonably dangerous.⁷

The plaintiff, Diana Levine, developed gangrene and suffered amputation of her right arm after she was given Phenergan for relief from nausea due to a migraine.⁸ Phenergan could be administered intra-muscularly or intravenously.⁹ The two intravenous methods included IV-drip and IV-push.¹⁰ IV-drip was a slower method, where the drug and saline solution were in a hanging bag and flowed through a catheter into the patient's

1. See generally *Levine v. Wyeth*, 2006 VT 107, 183 Vt. 76, 944 A.2d 179.

2. 129 S. Ct. 1187 (2009). The author will abbreviate the case as *Levine* because Wyeth has been a party in several cases cited in this article.

3. *Levine*, 129 S. Ct. at 1191.

4. *Id.*

5. *Id.* at 1192. The warning stated, "extreme care should be exercised to avoid" injection of Phenergan into arterial blood. *Levine*, 2006 VT 107, ¶ 4 n.1, 183 Vt. 76, 944 A.2d 179. The warning label further stated reports "suggest" gangrene would be likely if Phenergan came into contact with arterial blood. *Id.* Unintended arterial placement of the needle was "suspect" in these reports. *Id.* The warning label advised the preferable administration method was to inject Phenergan "through the tubing of an intravenous infusion set." *Id.*

6. Brief for Petitioner at 4, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

7. Brief for the United States as Amicus Curiae in Support of Petitioner at 19, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

8. *Levine*, 129 S. Ct. at 1191.

9. *Id.* Intramuscular administration is a direct injection into muscular tissue and does not include the risk of Phenergan coming into contact with arterial blood. WESTGROUP, AMERICAN JURISPRUDENCE PROOF OF FACTS 119 (3d ed. 2002).

10. *Levine*, 129 S. Ct. at 1191.

vein.¹¹ IV-push was a direct injection into the vein.¹² The risk of gangrene due to Phenergan's contact with arterial blood was always present and could not be eliminated during IV-push because the needle could either hit an artery, or Phenergan could escape into the vein.¹³ These risks were almost non-existent with the IV-drip method.¹⁴

Plaintiff Levine sued the drug manufacturer, Wyeth, under both negligence and strict liability theories in Vermont state court, claiming damages due to pain and suffering, medical expenses, and loss of livelihood as a professional musician.¹⁵ Wyeth filed a motion for summary judgment based on the preemption defense, arguing Wyeth was required to comply solely with the FDA-approved labeling.¹⁶ The Vermont Superior Court rejected Wyeth's motion and determined the FDA had not "specifically disallowed" any stronger language.¹⁷ The jury found Wyeth negligent, declared Phenergan a defective product because of its warning label, and awarded Levine \$7.4 million.¹⁸ The Vermont Supreme Court affirmed.¹⁹ The United States Supreme Court granted certiorari on the question of "whether the FDA's drug labeling judgments preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use" and affirmed the rulings and verdicts from the lower courts.²⁰

II. LEGAL BACKGROUND

Realizing the significance of the analysis and decision in *Wyeth v. Levine* requires an examination of the history of FDA regulation and conflict preemption. Pre-*Levine* confusion was created largely by evolving FDA regulations and changing FDA opinions.²¹ Preemption is clearly provided for in the Supremacy Clause.²² Preemption jurisprudence includes three levels of preemption: express preemption, field preemption, and

11. *Id.*

12. *Id.*

13. *Id.* at 1192.

14. *Id.* The solution will not flow into an artery or surrounding tissue if the catheter is not in a vein. *Id.*

15. *Id.* at 1191.

16. *Id.* at 1192.

17. *Id.*

18. *Id.* at 1193.

19. *Levine v. Wyeth*, 2006 VT 107, ¶ 5, 183 Vt. 76, 944 A.2d 179 (rejecting Wyeth's claim that the trial court failed in dismissing Levine's inadequate label claim on preemption grounds and also affirming the damages provisions).

20. *Levine*, 129 S. Ct. at 1193, 1204.

21. *See id.* at 1200-03.

22. U.S. CONST. art. VI, § 1, cl. 2.

implied conflict preemption.²³ Wyeth's defense in *Wyeth v. Levine* was that Levine's state claim was preempted by federal regulations because of conflict preemption.²⁴ Conflict preemption is controversial due to the uncertainty of Congressional intent in creating regulations, varying levels of authority granted to numerous federal agencies, and changing principles of important conflict preemption concepts.²⁵

A. FDA REGULATION EVOLUTION

Two federal bodies are responsible for the regulations at issue: (1) Congress is responsible for creating and amending the Federal Food, Drug, and Cosmetic Act (FDCA);²⁶ and (2) The Food and Drug Administration (FDA) is responsible for implementing regulations.²⁷ Prior to the FDA and the FDCA, state tort suits were the only protection afforded to consumers.²⁸ The FDA regulates a field involving health and safety—a position traditionally occupied by states—out of necessity for greater consumer safety.²⁹

1. *Objectives of the FDCA*

Congress created the FDCA in the 1930s due to the prevalence of unsafe drugs and fraudulent marketing of drugs.³⁰ The initial Act required manufacturers to submit new drug applications, reports, and proposed labels to the FDA in order to gain the requisite premarket approval of drugs and their labels.³¹ The FDA could reject a drug's entrance onto the market if the FDA determined a drug was not safe for use as labeled.³² In the original provisions of the FDCA, the FDA had to prove a drug was unsafe in order to keep that drug off the market.³³ In 1962, Congress shifted the burden of

23. *Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 713 (1985). Express preemption occurs when Congress expressly states a federal law preempts a state law. *Id.* Field preemption occurs where federal regulation is so extensive in an area of law there is no room left for state law in the same area. *Id.* Implied conflict preemption occurs where there is an actual conflict between federal and state law because it is physically impossible to comply with both or because "state law stands as an obstacle to the full purposes and objectives of Congress." *Id.*

24. *Levine*, 129 S. Ct. at 1193.

25. *See id.* at 1227 (Alito, J., dissenting) (stating the majority opinion "turned yesterday's dissent into today's majority opinion.")

26. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (1938).

27. *See generally Levine*, 129 S. Ct. at 1195-1204 (explaining the role of the FDA).

28. *Id.* at 1195.

29. *Id.* at 1194-95. Congress's first act was the Federal Food and Drugs Act of 1906, which prohibited the manufacturer and shipment of misbranded or tainted drugs and was meant to supplement state regulations and common law liability. *Id.* at 1195.

30. *Id.*

31. *Id.*

32. *Id.*

33. *Id.*

proof regarding a drug's safety and effectiveness from the FDA to the manufacturer.³⁴ The manufacturer was required to prove the drug was safe for use according to the drug label and instructions.³⁵ Congress also added a "savings clause,"³⁶ whereby a state law would be invalidated if there was a "direct and positive conflict" with the FDCA.³⁷

The FDCA allows manufacturers to change a drug's label in two ways.³⁸ First, a drug manufacturer can file a supplemental application with the FDA and change the label upon FDA approval.³⁹ Second, a manufacturer can change a drug's label before gaining FDA approval if necessary to "add or strengthen a contraindication, warning, precaution, or adverse reaction . . ." or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product."⁴⁰ The second method is a result of "changes being effected" (CBE) regulations and may be done upon the manufacturer filing a supplemental application.⁴¹

2. *The FDA's Changing Opinion*

Along with implementing regulations created by Congress, federal agencies often create regulations or rules that have preemptive effect.⁴² Because an agency is uniquely qualified to evaluate the effect of regulations on state law, an agency's views are usually entitled to deference.⁴³ Prior to 2006, the FDA's official position was that state tort suits were meant to complement federal regulations in providing greater consumer safety.⁴⁴ In

34. *Id.*

35. *Id.*

36. See Brief of the Chamber of Commerce of the United States of America as Amicus Curiae in Support of Petitioner at 28, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) [hereinafter Brief of the Chamber of Commerce].

37. *Levine*, 129 S. Ct. at 1196.

38. *Id.*

39. 21 C.F.R. § 314.70(a) (2008). See also *Levine*, 129 S. Ct. at 1196.

40. 21 C.F.R. § 314.70(c) (2008). See also *Levine*, 129 S. Ct. at 1196.

41. 21 C.F.R. § 314.70(c) (2008). See also *Levine*, 129 S. Ct. at 1196.

42. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153-54 (1982) ("Federal regulations have no less pre-emptive effect than federal statutes" as long as the agency administrator does not exceed his or her authority or act contrary to congressional approval).

43. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996); *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001).

44. *Levine*, 129 S. Ct. at 1202-03; Brief of Amici Curiae Former FDA Commissioners Dr. Donald Kennedy and Dr. David A. Kessler in Support of Respondent at 2-4, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) [hereinafter Brief of Former FDA Commissioners] (stating state law enhanced consumer safety—the goal of federal regulation—because state tort suits brought information to light which was unknown to the FDA, state tort suits created an incentive to drug manufacturers to make risks known, and state tort suits provided compensation for victims which was not provided by federal law).

2006, the FDA declared, in a preamble to the FDCA, that the FDCA establishes both a floor and a ceiling on labeling requirements, so FDA approval of a label preempts state law or state common-law actions that conflict with or contradict its judgment.⁴⁵ The FDA's 2006 preamble also declared that state-law failure to warn claims threaten the FDA's role as an expert agency charged with the responsibility of evaluating and regulating drugs.⁴⁶ Whether the FDA was correct in stating its authority or whether it really only created minimal requirements was contested in *Levine* and in courts around the nation.⁴⁷

B. GENERAL PREEMPTION

Conflicts of law in the federal system are resolved through the Supremacy Clause of the United States Constitution, which declares federal law must remain supreme.⁴⁸ The existence of federal drug regulations raises the preemption question in state tort suits.⁴⁹ However, the preemption defense was rarely successful in blocking state common law personal injury and products liability claims until the U.S. Supreme Court's 1992 decision in *Cipollone v. Liggett Group, Inc.*⁵⁰ The preemption defense is premised on the assertion that a particular federal regulation forecloses an inconsistent state law regulation or state products liability judgment.⁵¹ The existence of preemption often depends upon the claim for relief.⁵²

Preemption analysis usually begins with "the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress."⁵³ Preemption defenses may be expressly provided for.⁵⁴ Preemption may

45. *Levine*, 129 S. Ct. at 1200. This floor and ceiling argument means the FDA's determinations were conclusive on both the minimum and the maximum warnings allowed on labels. Brief for Petitioner, *supra* note 6, at 11.

46. *Levine*, 129 S. Ct. at 1200.

47. Petition for Writ of Certiorari at 15-16, *Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

48. U.S. CONST. art. VI, § 1, cl. 2.

49. See LITIGATING TORT CASES § 60:30 (Roxanne Barton Conlin & Gregory S. Cusimano eds. 2003).

50. Brief for Petitioner at 15, *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504 (1992) (No. 90-1038). The Petitioner noted preemption of a state personal injury action, where federal law provided no alternative remedy, had never once been successful until the Third Circuit Court of Appeals ruled *Cipollone*'s claims were preempted. *Id.* at 4.

51. DAVID G. OWEN, JOHN E. MONTGOMERY & MARY J. DAVIS, PRODUCTS LIABILITY AND SAFETY 372 (Foundation Press 5th ed. 2007).

52. See *Levine*, 129 S. Ct. at 1194 (clarifying the difference between the jury's verdict that the warning was insufficient, rather than demanding a particular warning that eliminated IV-push altogether).

53. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

54. See *Cipollone*, 505 U.S. at 516-18.

also be implied in federal laws and regulations through field preemption or conflict preemption.⁵⁵ Wyeth argued the defense of implied conflict preemption in the Court.⁵⁶ Implied conflict preemption includes both an “impossibility” test⁵⁷ and a “purposes and objectives” test.⁵⁸ Both the impossibility and the purposes and objectives test depend upon a finding that federal and state laws actually conflict.⁵⁹

C. IMPLIED CONFLICT PREEMPTION

State law is impliedly preempted by federal law and regulations where state and federal law actually conflict, even if preemption was not expressly provided.⁶⁰ State law is “created” through jury verdicts because judgments essentially create a requirement for which a defendant must comply in order to escape liability, and so state tort suits may be preempted by federal regulations.⁶¹ Federal regulations created by agencies may have the same preemptive effect as congressional action if Congress has given the agency the authority to create regulations with preemptive force.⁶² Regulations preempt state law if they either make compliance with both federal regulations and state law impossible or if the state law stands as an obstacle to the purposes and objectives of Congress.⁶³

1. *Congressional Intent*

Congress’s purpose in enacting a statute or regulation is the “ultimate touchstone in every pre-emption case.”⁶⁴ Congressional intent is presumed

55. See *Rice*, 331 U.S. at 230-31. Field preemption occurs where a federal scheme is so pervasive in a particular area or field that a court may reasonably assume Congress did not intend to allow state law to supplement the federal laws in that field. *Id.* at 230. Wyeth, previously known as American Home Products, Inc., argued field preemption at the trial level, but conceded in the Vermont Supreme Court that field preemption did not exist in this case. *Levine v. Am. Home Products, Inc.*, No. 670-12-01, 2004 WL 5456809 (Vt. Super. July 30, 2004); *Levine*, 129 S. Ct. at 1192.

56. *Levine*, 129 S. Ct. at 1192.

57. See *Fid. Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

58. *Id.* (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 n.20 (1941)).

59. See *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000). The difference in the implied preemption approaches is not legally significant but is only a “terminological wedge.” *Id.*

60. *de la Cuesta*, 458 U.S. at 153.

61. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521-22 (1992). See also *Geier*, 529 U.S. at 882 (stating the Court’s preemption cases assume state tort judgments require compliance, so state tort judgments may actually conflict with federal laws or regulations).

62. *de la Cuesta*, 458 U.S. at 153-54.

63. *Id.* at 153.

64. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (citing *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). Contrarily, Justice Scalia wrote in the majority opinion in *Riegel v. Medtronic, Inc.*, “It is not our job to speculate upon congressional motives.” 128 S. Ct. 999, 1009 (2008).

to exist where Congress created a law that actually conflicts with state law or where Congress vested a federal agency with the authority to create regulations that conflict with state law.⁶⁵ The scope of any preemption provision depends upon the congressional purpose derived from statutory language, the statutory framework, and the structure and purpose of a statute.⁶⁶ A state jury verdict can conflict with federal regulation merely if it upsets congressional objectives.⁶⁷ The strength of a regulation is essential in an implied conflict preemption analysis.⁶⁸

2. *Federal Agency Authority*

One way Congress creates preemption of state law is through federal agencies and federal regulations.⁶⁹ Federal regulations have the same preemptive effect as federal statutes.⁷⁰ A federal agency does not need to make an express statement identifying a conflict in order for preemption to apply as long as there is an actual conflict.⁷¹ An agency's interpretation of a law's preemptive effect is given deference "when it [is clear] Congress delegated the authority to an agency to make rules carrying the force of law"⁷²

An example of an agency with the authority to promulgate regulations with the force of law can be found in *Geier v. American Honda Motor Co. Inc.*⁷³ In *Geier*, the Department of Transportation's interpretation of the regulations at issue was given great deference because Congress delegated the authority to the Department "to implement the statute; the subject matter [was] technical; and the relevant history and background [were] complex and extensive."⁷⁴ The agency was thus "uniquely qualified" to interpret the regulations and determine their preemptive effect.⁷⁵ Similarly, Congress expressly granted the FDA the authority to implement the provisions of the Medical Device Act and exempt state regulations from the Act's

65. *See de la Cuesta*, 458 U.S. at 153-54.

66. *Lohr*, 518 U.S. at 485-86.

67. *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 886 (2000).

68. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009) (citing *Geier*, 529 U.S. at 681, for the proposition that the Court "has recognized an agency regulation with the force of law can preempt conflicting state requirements").

69. *de la Cuesta*, 458 U.S. at 153-54.

70. *Id.*

71. *Geier*, 529 U.S. at 884-85.

72. *See United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001) (discussing the *Chevron* deference).

73. 529 U.S. 861 (2000).

74. *Geier*, 529 U.S. at 883.

75. *Id.* (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996)).

preemptive effect.⁷⁶ The FDA was “require[d]” to assess the preemptive effect of the Act, and the Court’s opinion in *Lohr* was “informed” by the FDA’s determination.⁷⁷ However, the Court has also suggested that changing agency positions may be entitled to less deference.⁷⁸ Thus, it may be difficult to determine whether certain agencies have authority to create preemptive regulations or whether agency opinions may be ignored.

3. *Savings Clauses*

Another unclear area of pre-*Levine* conflict preemption jurisprudence involves the effectiveness of savings clauses.⁷⁹ Congress will sometimes draft federal safety statutes with a savings clause, which expresses in some manner the legislation is not intended to replace state tort suits, but instead “saves” them.⁸⁰ The purpose of a savings clause is to ensure an injured plaintiff has a private remedy under the law.⁸¹ However, a savings clause does not always preserve state tort remedies against an implied conflict preemption challenge.⁸²

For example, the Court in *Geier* determined the express preemption provision read with the savings clause required a narrow reading of the preemption clause so that a significant number of common law liability cases would be saved.⁸³ However, the savings clause did not bar the possibility that implied conflict preemption may block common law liability.⁸⁴ The savings clause did not suggest intent to save state tort causes of action that conflicted with federal regulations.⁸⁵ A savings clause may operate to save common law actions where federal regulation creates a floor or minimum requirement on manufacturers’ duties.⁸⁶ The regulations in *Geier* were not subject to the savings clause because saving common law suits would upset the purposes and objectives of federal regulations that constituted both a floor and a ceiling on what manufacturers could do.⁸⁷

76. *Lohr*, 518 U.S. at 495-96.

77. *Id.*

78. *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1009 (2008). The Court mentioned changing agency positions may be entitled to less deference in passing because it was clear in *Riegel* what the express preemption clause meant. *Id.*

79. *See Geier*, 529 U.S. at 869-74 (holding a savings clause ineffective).

80. OWEN, MONTGOMERY & DAVIS, *supra* note 51, at 373.

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

82. *See Geier*, 529 U.S. at 873-74.

83. *Id.* at 868. The clause stated compliance with a federal safety standard did not provide an exemption from common law liability. *Id.* (citing 15 U.S.C. § 1397(k) (1988)).

84. *Id.* at 869.

85. *Id.*

86. *Id.* at 870.

87. *Id.*

4. *Presumption Against Preemption*

The presumption against preemption was another uncertain piece of conflict preemption jurisprudence after the *Geier* decision because it went unmentioned.⁸⁸ Normally, both express and implied preemption analyses begin “with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”⁸⁹ The presumption against preemption applies with “particular force” where Congress acts in areas constituting the traditional police powers of health, safety, welfare, and morals.⁹⁰ Therefore, courts should avoid applying preemption if a piece of federal legislation has more than one possible meaning.⁹¹ Dissenting Justices often argue the presumption against preemption should only apply when determining whether preemption exists, but the U.S. Supreme Court has clearly stated the presumption applies when determining the scope of preemption as well.⁹² The presumption against preemption is intended to maintain the historic primacy of state regulations in health and safety concerns.⁹³

The United States Supreme Court clarified the conflict preemption doctrine in *Levine*, regarding agency authority, the presumption against preemption, and savings clauses.⁹⁴ The Court appears to have tightened conflict preemption tests, making them more difficult to plead. The Court’s decision will likely demand a detailed analysis of an agency’s history and authority before a state tort suit will be preempted in an area which the state has traditionally occupied.

III. ANALYSIS

In *Levine*, Justice Stevens delivered the opinion of the Court, in which Justices Kennedy, Souter, Ginsburg, and Breyer joined.⁹⁵ The majority

88. See Mary J. Davis, *On Preemption, Congressional Intent, and Conflict of Laws*, 66 U. PITT. L. REV. 181, 211 (2004) (discussing the Court’s opinion in *Geier*, which said the savings clause and the express preemption provision did not create a special burden on the defense of presumption, causing commentators to suggest the presumption was irrelevant). Wyeth argued in its Petition for a Writ of Certiorari the presumption does not apply when the area at issue has a history of significant federal presence. Petition for Writ of Certiorari, *supra* note 47, at 24.

89. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

90. *Altria Grp., Inc. v. Good*, 129 S. Ct. 538, 543 (2008) (citing *Medtronic v. Lohr*, 518 U.S. 470, 458 (1996)).

91. *Id.* (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005)).

92. *Lohr*, 518 U.S. at 485. See *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 545-46 (1992) (Scalia, J., concurring in judgment in part and dissenting in part).

93. *Lohr*, 518 U.S. at 485. State law may be preempted even if a federal law or regulation affects health or safety concerns. See, e.g., *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (holding the Medical Device Amendment (MDA) barred many state tort suits on medical devices).

94. *Wyeth v. Levine*, 129 S. Ct. 1187, 1194-1204 (2009).

95. *Id.* at 1190.

held Levine's claims were not preempted because it was not impossible for Wyeth to comply with both FDA regulations and the state verdict.⁹⁶ The majority also held preemption did not apply because Congress's objectives were to create greater consumer safety by the FDA regulations complementing state verdicts.⁹⁷ The majority reasoned that Congress provided a way for manufacturers to remain responsible for drug labels and that Congress did not grant the FDA authority to declare preemption on its own.⁹⁸ Justice Breyer joined the majority and filed a concurring opinion in *Levine*.⁹⁹ Justice Thomas also concurred in the judgment and filed an opinion.¹⁰⁰ Justice Alito dissented and filed an opinion, in which Chief Justice Roberts and Justice Scalia joined.¹⁰¹

A. MAJORITY OPINION

The existence of the implied preemption defense depends upon the claim for relief.¹⁰² The jury verdict found Wyeth negligent and Phenergan a defective product due to insufficient warnings and instructions.¹⁰³ Significantly, the jury found Wyeth had a duty to provide a sufficient warning but did not demand the warning be replaced by another warning.¹⁰⁴ The Court focused simply on whether an inadequate warning claim was preempted, rather than on whether a state could mandate a certain warning or proscribe certain uses.¹⁰⁵ A jury verdict mandating contraindication of the IV-push method, in spite of the FDA's decision that IV-push was safe, may have resulted in a different decision by the Court.¹⁰⁶ The majority opinion focused on the cornerstones of preemption, conflict preemption based upon impossibility, congressional purposes and objectives in enacting laws and regulations, and the continued importance of state tort suits in drug warning label safety.

96. *Id.* at 1199.

97. *Id.* at 1202-04.

98. *Id.* at 1197-98, 1201.

99. *Id.* at 1204 (Breyer, J., concurring).

100. *Id.* at 1204-17 (Thomas, J., concurring).

101. *Id.* at 1217-31 (Alito, J., dissenting).

102. *See id.* at 1194 (Levine's claim may have asked for a ruling that IV-push be prohibited, but the appealed verdict only found the label inadequate).

103. *Id.* at 1193.

104. *Id.* at 1194.

105. *Id.* Wyeth argued Levine's claim should be preempted because Levine apparently argued Phenergan's label should foreclose IV-push injection altogether before the trial court. Petition for Writ of Certiorari, *supra* note 47, at 2.

106. *See Levine*, 129 S. Ct. at 1194 (noting the FDA chose not to contraindicate IV-push administration, so a jury verdict mandating contraindication likely would directly conflict with the FDA's specific ruling).

1. *The Cornerstones of Preemption*

The Court's analysis began with the cornerstones of preemption: the supremacy of Congressional purpose and the presumption against preemption.¹⁰⁷ In *Levine*, the presumption against preemption applied because state tort suits have always been available for consumers injured by defective drugs.¹⁰⁸ Health and safety are traditionally state law issues, so the presumption against preemption applies to protect state interests from being "cavalierly" preempted by federal law.¹⁰⁹ The dissent argued the presumption against preemption did not apply in implied conflict preemption, but the majority of the Court made clear the presumption does apply in implied conflict preemption analyses.¹¹⁰ The mere existence of the FDCA was not enough to overcome the presumption against preemption.¹¹¹

The Congressional purpose in enacting and amending the FDCA has always been to protect consumers from harmful products and fraudulent marketing.¹¹² The Court determined the FDCA's provision that state law would only be invalidated upon a "direct and positive conflict" with the FDA was a savings clause.¹¹³ Congress increased the FDA's powers over time, but Congress also enacted the savings clause, and state tort suits continued.¹¹⁴ Congress consistently rejected enacting express preemption provisions, gave manufacturers the duty to prove their labels were adequate, and rejected a provision that would require the FDA to pre-approve all changes to drug labels.¹¹⁵ Congress also failed to provide remedies for injured consumers through the FDCA.¹¹⁶ The Court determined Congress did not provide a federal remedy because it intended state law to continue to provide remedies to injured consumers.¹¹⁷ The Court considered these factors as proof Congress never intended to remove the manufacturer's duty

107. *Id.* at 1194-95.

108. *Id.* at 1195 n.3.

109. *Id.*

110. *Id.* The dissent noted the *Geier* Court "specifically rejected" the presumption against preemption. *Id.* at 1228. One commentator noted the *Levine* decision brought the "fabled" presumption "back in vogue." David G. Savage, *Business Downturn*, A.B.A. J., May 2009, at 21.

111. *Levine*, 129 S. Ct. at 1195 n.3.

112. *Id.* at 1195.

113. *Id.* at 1196. The opposing argument was that the "savings clause" was an attempt to preserve conflict preemption of state tort suits, not to save state tort suits from preemption. Brief of the Chamber of Commerce, *supra* note 36, at 28.

114. *Levine*, 129 S. Ct. at 1196.

115. *Id.* at 1196. The Court specifically noted Congress enacted an express preemption provision for medical devices but did not do the same for drugs. *Id.*

116. *Id.* at 1199. This "lack of federal remedy" assertion was argued and denied in *Cipollone*. See Brief for Petitioner, *supra* note 50, at 27.

117. *Levine*, 129 S. Ct. at 1199-1200.

to create and maintain safe labels.¹¹⁸ While keeping the cornerstones of preemption in mind, the Court turned to the conflict preemption tests: impossibility and congressional purposes and objectives.¹¹⁹

2. *Conflict Preemption Based Upon Impossibility*

The Court denied Wyeth's argument that Levine's claims were preempted because it was not impossible for Wyeth to comply with the FDA's requirements and Wyeth's manufacturer duties under state law.¹²⁰ The court declared that impossibility is a demanding defense.¹²¹ Wyeth argued it was impossible to comply with the state verdict because it could not change the warning without FDA approval of a supplemental application.¹²² However, the Court reasoned drug manufacturers retained their common law duties to warn, CBE regulations made it possible for Wyeth to comply with federal regulations and common law duties, and Wyeth would not have been guilty of "misbranding" if Wyeth made changes to make the label safer.¹²³

First, the Court determined the CBE regulations allowed Wyeth to "'add or strengthen a contraindication, warning, precaution, or adverse reaction' or to 'add or strengthen an instruction'" if it would make use of the product safer.¹²⁴ Wyeth could strengthen the label upon discovering newly acquired information consisting of new information of risks and data or new analyses of previously submitted data.¹²⁵ Wyeth could have changed Phenergan's label upon discovering the risk of gangrene from IV-push administration was more frequent or severe than previously known.¹²⁶ Wyeth had the ability and knowledge to make changes before FDA approval, as long as Wyeth filed a supplemental application with the FDA upon making any changes.¹²⁷

118. *Id.* at 1199.

119. *Id.* at 1196-1204.

120. *Id.* at 1196-97.

121. *Id.* at 1199.

122. *Id.* at 1196-97.

123. *Id.* at 1196-99.

124. *Id.* at 1196.

125. *Id.* at 1196-97 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2008)). A 2008 amendment allows a manufacturer to utilize the CBE method only if the new warning is based on "newly acquired information." *Id.* Though the CBE regulations were created after Levine's 2007 injury, the Court determined the "newly acquired information" amendment still gave Wyeth the ability to change Phenergan's warnings. *Id.* at 1197.

126. *Id.*

127. *Id.* at 1196.

Wyeth argued the CBE regulations did not allow Wyeth to change Phenergan's label.¹²⁸ Wyeth's argument was based on prior FDA consideration of the risks of IV-push administration.¹²⁹ Wyeth argued the FDA had adequate prior knowledge of the risks of gangrene due to IV-push administration, and the agency responded.¹³⁰ Therefore, according to Wyeth, any information Wyeth received of IV-push incidents was not "newly acquired."¹³¹ The Supreme Court disagreed and accepted Levine's prior incident evidence, indicating Wyeth could have done more to make Phenergan's label regarding the IV-push method safe.¹³² Wyeth "could have" analyzed subsequent incidents and added a stronger warning.¹³³ Therefore, it was not impossible for Wyeth to change Phenergan's label to make it safer regarding the risks of IV-push administration while still complying with the FDA's requirements.¹³⁴

Second, the Court also rejected Wyeth's contention that changing the label would have constituted misbranding or unauthorized distribution and, therefore, subjected it to liability.¹³⁵ Unauthorized distribution occurs where a new drug lacks an effective application with the FDA and is distributed.¹³⁶ Complying with the jury's verdict and making the warning stronger would not have made Phenergan a new drug without an effective FDA drug application.¹³⁷ Misbranding assumes the label is adequate and changes would make the label inadequate, however a stronger warning would have likely made Phenergan more adequate.¹³⁸ Further, the FDA does not have the authority to unilaterally determine a drug is misbranded.¹³⁹ The Court also found it difficult to believe the FDA would bring an action against Wyeth for making Phenergan's label safer under the CBE regulations.¹⁴⁰

128. *Id.*

129. Petition for Writ of Certiorari, *supra* note 47, at 6-8.

130. *Id.* at 7.

131. *Id.* at 6-8. *See also Levine*, 129 S. Ct. at 1199 (giving the history of the FDA's consideration on IV-push administration and citing the lower court's ruling that the label the FDA rejected was only different from, but not stronger than, the prior label).

132. *Levine*, 129 S. Ct. at 1197.

133. *Id.* The Court also disregarded Wyeth's argument the FDA still had to approve the changes eventually because eventual required approval did not make it impossible for the manufacturer to strengthen the label. *Id.*

134. *Id.* at 1196-97.

135. *Id.* at 1197.

136. *Id.*

137. *Id.*

138. *Id.*

139. *Id.* Federal juries determine whether a drug is misbranded. *Id.*

140. *Id.*

Finally, and perhaps most importantly, the Court made clear manufacturers are responsible for the adequacy of the initial warning label and remain responsible for the continuing adequacy of the label while a drug is on the market.¹⁴¹ Wyeth could not claim it did not have a duty to ensure the label was safe merely because the FDA determined the contents of the label were adequate before the drug made it to market.¹⁴² The Court examined the history of drug manufacturers' duties throughout the existence of the FDA and noted manufacturer duties were retained.¹⁴³ Ultimately, Wyeth had a duty to ensure Phenergan's label was safe, and Wyeth could not prove an adequate warning was impossible to achieve under both federal and state law due to the CBE regulations.¹⁴⁴ Beyond conflict preemption based on impossibility of compliance with both state and federal law, state tort suits may also be preempted where state suits conflict with congressional purposes and objectives in creating federal laws and regulations.¹⁴⁵

3. *Conflict Based on Congressional Purposes and Objectives*

Wyeth's preemption defense was also rejected under the purposes and objectives test because Congress was seeking to make drugs safer through the years, and state tort suits actually help achieve congressional goals.¹⁴⁶ Wyeth used the Court's analysis from *Geier*, arguing Congress's purpose was to grant the FDA complete authority in determining drug warning labels because it was an expert agency capable of striking a balance between competing objectives.¹⁴⁷ Wyeth's position, supported by the 2006 preamble to the FDCA, was that the FDCA creates both a floor and a ceiling on drug regulation and that the FDA's approval of a drug label was conclusive.¹⁴⁸

The Court rejected Wyeth's arguments, stating Congress never provided a federal remedy for consumers harmed by drugs, which could only mean Congress intended state tort law remedies to remain intact for injured consumers.¹⁴⁹ The Court noted Congress was aware of state tort suits when it created the FDCA and amended the Act throughout its existence.¹⁵⁰

141. *Id.* at 1197-98.

142. *Id.* at 1198. The Court recognized new risks are discovered over time and after drugs have already made it to the market. *Id.* at 1197.

143. *Id.* at 1198.

144. *Id.*

145. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

146. *Levine*, 129 S. Ct. at 1199.

147. *Id.* Brief for Petitioner, *supra* note 6, at 46.

148. *Levine*, 129 S. Ct. at 1199; Petition for Writ of Certiorari, *supra* note 47, at 3.

149. *Id.* at 1199-1200.

150. *Id.*

Congress created an express preemption clause regarding medical devices in the Medical Device Amendment (MDA) but did not do the same in the FDCA.¹⁵¹ Congress chose to remain silent on preemption even though Congress was aware of the “prevalence of state tort litigation,” which evidenced Congress’s intent for FDA regulations to be bolstered by state tort suits instead of displacing state suits.¹⁵²

The FDA is charged with determining whether a drug is safe and effective and whether the drug’s labels are adequate before the drug can go on the market, but it does not mean Congress’s purpose in creating the agency was also to remove the manufacturer’s common law duties.¹⁵³ Wyeth argued the FDA must have balanced the risks and benefits of Phenergan’s label proposals presented to it, and therefore state law would contradict FDA approval, as stated in the 2006 Preamble.¹⁵⁴ However, Congress did not provide the FDA with the authority to declare the preemptive effect of the FDCA, and Congress’s purpose was only to create a floor for regulations on which state verdicts could build.¹⁵⁵

The Court in the past has examined an agency’s views of preemption although the Court denied giving deference to an agency’s conclusions.¹⁵⁶ The Court unequivocally stated it still does its own conflict analysis and does not simply accept an agency’s conclusions.¹⁵⁷ Federal agency views may be given “weight” regarding the interplay between state tort law and agency regulations because agencies do have special knowledge and understanding of how the regulations actually work.¹⁵⁸ How much weight the Court gives these opinions depends on the thoroughness, consistency, and persuasiveness of the agency’s explanation.¹⁵⁹ The Court has given “substantial weight” to the FDA’s views on the preemptive effect of the MDA but the Court did not do the same in *Levine*.¹⁶⁰

151. *Id.* at 1200.

152. *Id.*

153. *Id.*

154. *Id.*

155. *Id.* at 1201. Commentators previously noted the FDA did have the authority to create preemptive regulations but had not done so. OWEN, MONTGOMERY & DAVIS, *supra* note 51, at 394.

156. *Levine*, 129 S. Ct. at 1201.

157. *Id.* at 1200-01. The Court’s statements on an agency’s authority to declare preemptive effects have been interpreted by some courts to mean an agency’s explanations, but not agency conclusions, may be given deference. *Barrientos v. 1801-1825 Morton LLC*, 583 F.3d 1197, 1214 (9th Cir. 2009).

158. *Levine*, 129 S. Ct. at 1201.

159. *Id.*

160. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996) (discussing the expertise of the FDA in determining the preemptive effect of the MDA and giving substantial weight to the FDA’s view of the MDA).

The Court rejected the FDA's 2006 preamble statements.¹⁶¹ First, the FDA's prior views were its regulations only created a floor and that state tort law could add to the regulations, providing greater consumer protection.¹⁶² In its proposed rulemaking in 2000, the FDA stated it would not make a rule implying state tort suits would be preempted.¹⁶³ However, the FDA proceeded to do the opposite in the 2006 preamble with a strong view its regulations preempted state law.¹⁶⁴ More importantly, the FDA's new position was contrary to congressional views and objectives already decided by the Court.¹⁶⁵ The FDA, therefore, did not have the necessary authority, nor did it have consistent opinions in order for the Court to give any weight to the FDA's statements.¹⁶⁶

4. *The State Tort Suit Advantage Over Federal Regulation*

The Court's decision in *Levine* favors state tort suits for protecting consumers. Prior to the 2006 preamble, the FDA considered state law tort suits to be "complementary" to drug regulations.¹⁶⁷ The Court supported state law tort remedies, noting product safety is increased when manufacturers are subject to state tort suits.¹⁶⁸ The Court supported its statements on the advantage of state tort suits with traditional products liability rationales, including increased safety incentives for manufacturers, remedies for injured plaintiffs, and increased consumer confidence.¹⁶⁹

Several amici briefs provided evidence of how overworked and understaffed the FDA is and enumerated many FDA "failures" in keeping unsafe products off the market.¹⁷⁰ Manufacturers who administer the studies on their drugs have greater access to study results and continue to receive information on the safety and effectiveness of drugs on the market;

161. *Levine*, 129 S. Ct. at 1201.

162. *Id.* at 1202.

163. *Id.*

164. *Id.* The Court called the FDA's adoption of preemption language in the preamble, after stating it would not adopt preemption, a procedural failure. *Id.*

165. *Id.* The Court stated Congress gave the FDA the authority to determine the preemptive effect of regulations in the MDA in 21 U.S.C. § 371(a), but it did not do the same through the FDA. *Id.*

166. *Id.* at 1201-02.

167. *Id.* See generally Brief of Former FDA Commissioners, *supra* note 44, at 7 (discussing the FDA's prior views on state tort suits and preemption).

168. *Levine*, 129 S. Ct. at 1202.

169. *Id.* at 1202-03.

170. See, e.g., Brief of DES Action as Amicus Curiae in Support of Respondent at 14, *Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249); Brief of Former FDA Commissioners, *supra* note 44, at 17, 23-24; Brief of New England Journal of Medicine Editors and Authors as Amici Curiae in Support of Respondent at 6-7, *Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249) [hereinafter Brief of New England Journal of Medicine Editors and Authors].

the FDA often relies on information from manufacturers.¹⁷¹ With 11,000 drugs on the market, the FDA does not have the resources to discover all the risks in drugs premarket or on-market.¹⁷² State tort suits uncover unknown drug hazards, motivate manufacturers to provide for greater safety, and compensate victims who otherwise would have no remedy.¹⁷³ The majority opinion ruled in favor of greater consumer remedies rather than out of concern for drug manufacturers.¹⁷⁴

The separate opinions, on the other hand, show conflict preemption issues are far from settled.¹⁷⁵ Justice Breyer highlighted areas where preemption may still exist.¹⁷⁶ Justice Thomas wrote a concurring opinion, in which he questioned the implied conflict preemption tests the Court uses—which he thinks “wander far” from what the U.S. Constitution requires—and declared the impossibility test too narrow and the purposes and objectives test too broad.¹⁷⁷ In his dissent, Justice Alito came to the opposite conclusion of the majority on many issues and would have ruled in the manner Justice Thomas fears.¹⁷⁸

B. JUSTICE BREYER’S CONCURRENCE

Justice Breyer concurred in the judgment and filed an opinion.¹⁷⁹ Justice Breyer stated state tort law did not conflict with a federal regulatory scheme in *Levine* but stressed FDA regulations may bear the force of law.¹⁸⁰ Justice Breyer noted state tort law may “interfere with the FDA’s desire to create a drug label containing a specific set of cautions and instructions.”¹⁸¹ Justice Breyer expressed the FDA should be allowed to determine when state torts suits are preempted based on Congressional purposes and objectives.¹⁸² Justice Breyer was also concerned about the rising prices of drugs if state tort suits were allowed to continue unabated, which was a popular argument from pro-business groups who wanted to

171. *Levine*, 129 S. Ct. at 1202; Brief of New England Journal of Medicine Editors and Authors, *supra* note 170, at 8, 10.

172. *Levine*, 129 S. Ct. at 1202 n.11. *See also* Altria Group, Inc. v. Good, 129 S. Ct. 538, 545 n.6 (2008) (discussing that overburdened agencies charged with regulating an “enormous amount of activity” should not be the exclusive source of regulation).

173. *Levine*, 129 S. Ct. at 1202.

174. *Id.*

175. *Id.* at 1204-31.

176. *Id.* at 1204 (Breyer, J., concurring).

177. *Id.* at 1205-09 (Thomas, J., concurring).

178. *Id.* at 1217-31 (Alito, J., dissenting).

179. *Id.* at 1190.

180. *Id.* at 1204 (Breyer, J., concurring).

181. *Id.*

182. *Id.* Justice Breyer failed to state why he thinks the FDA has this authority. *See id.*

take the burden of a common law duty off manufacturers.¹⁸³ Justice Breyer's concurrence focused on possibilities where preemption may still exist in suits similar to Levine's.

C. JUSTICE THOMAS'S CONCURRENCE IN THE JUDGMENT

Justice Thomas did not approve of the implied preemption tests the Court has crafted over the years.¹⁸⁴ First, Justice Thomas repeated and expanded upon his often-stated disagreement with the purposes and objectives conflict preemption jurisprudence.¹⁸⁵ Justice Thomas argued Congress's purposes and objectives were "potentially boundless" and that "musings . . . do not satisfy the Art. I, § 7 requirements for enactment of federal law."¹⁸⁶ Justice Thomas wrote "the purposes and objectives [of] pre-emption jurisprudence is inherently flawed" because it looks at the unwritten purposes and objectives of hundreds of individuals comprising Congress.¹⁸⁷ Justice Thomas would look to the law Congress actually makes, as the supremacy clause requires, rather than atextual notions or congressional inaction.¹⁸⁸

Justice Thomas also questioned the majority's adoption of the "physical impossibility" standard and asked for an explanation of why this is the precise standard.¹⁸⁹ Justice Thomas argued "[t]here could be instances where it is not 'physically impossible' to comply with both state and federal law, even when the state and federal laws give directly conflicting commands."¹⁹⁰ However, Justice Thomas did agree there was no direct conflict in Levine's case because there are no regulations stating an FDA-approved label must remain in force without ever being changed, although he said the majority opinion may lead to "freewheeling" evaluations.¹⁹¹ Justice Thomas's opinion noted the same conflict preemption cases may lead to different and even opposite conclusions.¹⁹² Justice Thomas stated he "can no longer assent to a doctrine that pre-empts state laws merely because they

183. *Id.* at 1204.

184. *Id.* at 1205.

185. *Id.* Justice Thomas wrote, "Under this approach, the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law." *Id.* Justice Thomas believes the tests the majority uses are inconsistent with the Constitution. *Id.*

186. *Id.* at 1207.

187. *Id.* at 1211.

188. *Id.*

189. *Id.* at 1209.

190. *Id.*

191. *Id.* at 1211, 1217.

192. *Id.* at 1213-15 (citing the use of *Geier* by the majority and the dissent).

‘stan[d] as an obstacle’” to the purposes and objectives of Congress.¹⁹³ Justice Thomas believed the majority opinion gave “improperly broad preemptive effect to judicially manufactured policies[,]” but the dissent came to the opposite conclusion that the majority “undermine[d] . . . broader preemption jurisprudence and the broader workability of the federal drug-labeling regime.”¹⁹⁴

D. JUSTICE ALITO’S DISSENT

Chief Justice Roberts and Justice Scalia joined Justice Alito’s dissent.¹⁹⁵ The dissent began by stating Levine’s claim was simple medical malpractice and should not have constituted an insufficient warning claim against the manufacturer at all.¹⁹⁶ The dissent relied on the FDA’s judgments regarding the safety and effectiveness of drugs, regardless of whether the FDA’s decisions were wise.¹⁹⁷ Instead of applying the presumption against preemption, the dissent would have allowed a state tort suit here only if the FDCA expressly allowed it.¹⁹⁸ Likewise, the dissent said the FDA did set the floor and the ceiling on labeling requirements.¹⁹⁹ The dissent argued the FDA only set minimum standards if the FDCA expressly allowed, which was opposite of the majority’s decision that the FDA set minimum standards unless stated otherwise.²⁰⁰ The dissent read the clause, which the majority determined to be a savings clause, as merely recognizing the existence of conflict preemption, as in *Geier*.²⁰¹

The dissent argued the majority opinion in *Levine* turned “yesterday’s dissent into today’s majority opinion.”²⁰² The dissent compared the FDA to the Department of Transportation in *Geier* by declaring the FDA struck a

193. *Id.* at 1217.

194. *Id.* at 1217, 1222.

195. *Id.* at 1190. Interestingly, Chief Justice Roberts later recused himself in *Bruesewitz v. Wyeth*, 130 S. Ct. 1734 (2010), because he owned stock in Pfizer, Inc., and Pfizer acquired Wyeth in late 2009. Tony Mauro Comment to The BLT: The Blog of Legal Times, *Roberts Recuses in New Wyeth Case*, <http://legaltimes.typepad.com/blt/2010/03/roberts-recuses-in-wyeth-case.html> (Mar. 8, 2010, 13:06). Reportedly, Chief Justice Roberts did not recuse himself in *Wyeth v. Levine* because the merger had not yet taken place. *Id.* See also *Justice Robert’s Portfolio*, WASH. POST, Feb. 23, 2009, <http://www.washingtonpost.com/wpdyn/content/article/2009/02/22/AR2009022201649.html>.

196. *Levine*, 129 S. Ct. at 1217-18.

197. *Id.* at 1218.

198. *Id.* at 1219. Justice Alito also stated the presumption is irrelevant in conflict preemption analysis after *Geier* and questioned the “long-standing” nature of the presumption. *Id.* at 1228-29.

199. *Id.* at 1221.

200. *Id.*

201. *Id.*

202. *Id.* at 1227.

sensitive balance in its determinations, which should not be upset.²⁰³ Further, the dissent did not find a difference between the express preemption clause of the FDA and what it argued was the implied preemptive effect of the FDCA.²⁰⁴ Justice Alito further wrote the FDA's preamble did have the force of law because other FDA decisions have the force of law.²⁰⁵ In general, the dissent expressed great distaste for allowing jury verdicts where a federal agency regulates.²⁰⁶

The dissent argued juries are "ill-equipped" to determine the cost-benefit balance of warning label safety.²⁰⁷ The dissent stated the Court erred by concluding the FDA had not adequately considered the risks of IV-push.²⁰⁸ Further, the dissent read the jury verdict as requiring the manufacturer to contraindicate IV-push in disregard of the FDA's decision not to.²⁰⁹ The dissent disagreed with most of the jury's findings, noting Phenergan's label contained sufficient warnings against the very risk at issue.²¹⁰ Justice Alito's dissenting opinion determined state tort claims like Levine's could not coexist with the FDA's determinations because the FDA's original decision found Phenergan's label safe while the Vermont jury found Phenergan's label unsafe regarding the risks of IV-push administration.²¹¹

IV. IMPACT

The Court clarified points of contention in *Levine*. First, courts may use the absence of express preemption as evidence Congress did not intend for implied preemption to exist.²¹² The presumption against preemption is more important than it appeared to be after *Geier*.²¹³ The *Levine* Court was also more lenient than the *Geier* Court in reading statutory language as an effective savings.²¹⁴ The Court ensured the preemption defense will be difficult to plead where there is any available possibility of complying with both federal and state law.²¹⁵ The purposes and objectives test is not so

203. *Id.* at 1221, 1227.

204. *Id.*

205. *Id.* at 1228.

206. *Id.* at 1229-30.

207. *Id.* at 1229.

208. *Id.* at 1222.

209. *Id.*

210. *Id.* at 1226-27.

211. *Id.* at 1231.

212. *Id.* at 1200.

213. *Id.* at 1194-95.

214. *Compare id.* at 1196, with *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 868 (2000).

215. *Levine*, 129 S. Ct. at 1198-99.

broad because congressional silence was interpreted as Congress not intending preemption to exist and preemption not fitting with the purpose of the FDCA and FDA regulations.²¹⁶

The Court's decision in *Levine* also places a heavy burden on federal agencies desiring preemption of state tort suits.²¹⁷ Agencies must first be given the authority by Congress to declare the preemptive effect of regulations, and then agencies must actually create preemptive regulations with the force of law because mere opinions do not suffice.²¹⁸ An agency will not be presumed to have balanced the risks and benefits that create preemptive regulations.²¹⁹ Specifically for the FDA, the MDA and the FDCA have different preemptive effects, even though the FDA implements both acts.²²⁰ After *Levine*, conflict preemption analyses should require detailed and specific findings on all regulations and agencies.

The differing opinions in *Levine* show there are issues left to be settled. Three members of the Court still oppose the use of the presumption against preemption and would use a somewhat reverse presumption in favor of federal agencies.²²¹ Justice Thomas is adamantly opposed to the conflict preemption tests the Court uses and enumerated many weaknesses and uncertainties in conflict preemption principles.²²² The resulting uncertainties on conflict preemption tests, savings clauses, presumptions, and agency authority suggest each preemption claim will require an individualized and specific analysis in order to determine if preemption does in fact exist. The Court is still split on whether the FDA has the ability to create preemptive regulations.²²³ Further, the Court specifically did not answer whether a jury verdict mandating a particular warning would be preempted, as the *Levine* Court only said a verdict finding a label unsafe is not preempted.²²⁴ Subsequent cases have proven there are other resulting questions after *Wyeth v. Levine*.²²⁵

216. *Id.* at 1199-1200.

217. *Id.* at 1201-04.

218. *Id.* at 1200-01.

219. *Id.*

220. *Id.* at 1200 (noting the MDA has an express preemption provision, but the FDCA does not).

221. *See id.* at 1220 (Alito, J., dissenting) (stating that when the FDA determines a drug is safe, no state may countermand the FDA's determination).

222. *See id.* at 1209, 1211 (Thomas, J., concurring) (stating that "physical impossibility" may not be the best standard and that the purposes and objectives test is inherently flawed).

223. *See id.* at 1204 (Breyer, J., concurring); *id.* at 1228 (Alito, J., dissenting).

224. *Id.* at 1194.

225. *See infra* Part IV.A.

A. IMPACT ON SUBSEQUENT DECISIONS

The *Levine* decision has been called a “sea change” in preemption analysis.²²⁶ The Seventh Circuit Court of Appeals opined *Levine* restored conflict preemption to its pre-2001 form.²²⁷ A federal district court noted the Supreme Court had been moving away from finding conflict preemption based on alleged conflicts with purposes underlying federal regulations even before *Levine*.²²⁸ A state court determined the *Geier* decision has been specifically limited since *Levine* provides that conflict preemption based on agency regulation exists only where “there is an extensive contemporaneous history, and detailed agency explanations.”²²⁹ In particular, *Levine* contradicts several prior cases that gave preemptive effect to the FDCA’s preamble.²³⁰ *Wyeth v. Levine* has already resolved conflict preemption claims for several courts with suits based on similar facts and claims as *Levine*.²³¹ *Levine* answered important questions in the “tens of thousands of individual claims, and potentially millions of class actions claims” pending in federal and state courts where plaintiffs claimed FDA-approved labels were defective.²³² Further, the Supreme Court vacated judgment in *Colacicco v. Apotex, Inc.*,²³³ a preemption case similar to *Levine*, and remanded the case back to the Third Circuit Court of Appeals after *Levine*.²³⁴

Levine strengthened certain principles in conflict preemption jurisprudence. Courts have found a “renewed emphasis” on the presumption against preemption.²³⁵ Precedent not applying the presumption may be

226. *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 389 (7th Cir. 2010).

227. *Id.* at 391.

228. *Am. Ass’n of People with Disabilities v. Herrera*, 690 F. Supp. 2d 1183, 1207-08 (D.N.M. 2010). President Barack Obama issued a memorandum to federal agencies discouraging the creation of preemption. *See Tenuto v. Lederle Labs.*, No. 1134/81, 2010 WL 625223, at *7-8 (N.Y. Sup. Ct. Feb. 17, 2010).

229. *Morgan v. Ford Motor Co.*, 680 S.E.2d 77, 94 (W. Va. 2009).

230. *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 766 (Tex. App. 2009).

231. *Mason*, 596 F.3d at 396; *Schrock v. Wyeth, Inc.*, 601 F. Supp. 2d 1262, 1267 (W.D. Okla. 2009); *Aaron v. Wyeth*, No. 2:07cv927, 2010 WL 653984, at *5 (W.D. Pa. Feb. 19, 2010).

232. Petition for Writ of Certiorari, *supra* note 47, at 12-14. Footnote four of the Petition directed attention toward several class action suits with thousands of members. *Id.* at 14 n.4. *Wyeth* stated the individual suits were “too numerous to count.” *Id.*

233. 129 S. Ct. 1578 (2009).

234. *Colacicco*, 129 S. Ct. at 1578-79. The Third Circuit had previously determined the presumption against preemption applied with minimal force, the brand and generic drug claims were impliedly preempted, and the FDA’s preamble statements were entitled to deference. *Colacicco*, 521 F.3d 253, 285 (3d Cir. 2008). Further, the United States retracted its amicus brief for *Colacicco* after *Levine*. *Demahy v. Actavis, Inc.*, 593 F.3d 428, 443 (5th Cir. 2010).

235. *Am. Ass’n of People with Disabilities v. Herrera*, 690 F. Supp. 2d 1183, 1208 (D.N.M. 2010); *Chae v. SLM Corp.*, 593 F.3d 936, 944 (9th Cir. 2010) (applying the presumption, but still holding conflict preemption existed).

called into question.²³⁶ The presumption applies in any field where there is a history of state law regulation, even if there is also a history of federal regulation.²³⁷ Further, courts have applied the interpretation that disfavors preemption where there were two possible interpretations of the preemptive effect of regulations.²³⁸

Lower courts have relied on the Court's assertion that state tort suits and manufacturer duties remain important where federal regulations exist but federal remedies do not.²³⁹ The absence of a federal remedy for injured plaintiffs has served as evidence for courts that Congress did not intend a federal law or regulation to preempt state law or lawsuits.²⁴⁰ Additionally, some courts have determined the absence of express preemption provisions is further proof that Congress did not intend for implied preemption.²⁴¹ Those courts have specifically looked at an agency's explanation when examining the possible preemptive effect of regulations, but did not rely on agency conclusions on whether regulations have preemptive effect.²⁴² Agency positions on the preemptive effect of regulations seem entitled to "interpretational deference" only where clearly consistent with congressional intent and where the agency has not waived on its interpretation.²⁴³

Courts have also decided drug manufacturer defendants cannot prove implied preemption unless the defendants can prove through "clear evidence"²⁴⁴ the FDA would not have accepted stronger or better warnings.²⁴⁵

236. N.Y. SMSA Ltd. P'ship v. Town of Clarkstown, 603 F. Supp. 2d 715, 721 (S.D.N.Y. 2009).

237. *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 178 (1st Cir. 2009).

238. *Herrera*, 690 F. Supp. 2d at 1225; *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009).

239. *Aaron v. Wyeth*, No. 2:07cv927, 2010 WL 653984, at *5 (W.D. Pa. Feb. 19, 2010).

240. *Demahy v. Actavis, Inc.*, 593 F.3d 428, 435 (5th Cir. 2010); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612 (8th Cir. 2010) (stating Congress's purpose was not to shield manufacturers from tort liability for private parties without other remedy); *Dorsett v. Sandoz*, 699 F. Supp. 2d 1142, 1162 (C.D. Cal. 2010) (noting *Levine* shows the congressional purpose behind the FDCA was not to shield manufacturers from liability).

241. *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d at 174-75; *Holk*, 575 F.3d at 337. One court accepted Justice Thomas's concurring statements that congressional "musings" should not preempt state law under the Supremacy Clause of the Constitution. *Herrera*, 690 F. Supp. 2d at 1226.

242. *Barrientos v. 1801-1825 Morton LLC*, 583 F.3d 1197, 1214 (9th Cir. 2009).

243. *Chae v. SLM Corp.*, 593 F.3d 936, 950 (9th Cir. 2010).

244. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1198 (2009) (stating "absent clear evidence that the FDA would not have approved a change" the Court will not conclude it was impossible to comply with both federal and state requirements).

245. *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 395 (7th Cir. 2010); *Mensing*, 588 F.3d at 611; *see also Demahy*, 593 F.3d at 435 (stating mere "uncertainty about the FDA's response makes federal preemption less likely").

The clear evidence requirement has been called “demanding.”²⁴⁶ In one case, the clear evidence requirement was not met where the FDA examined data on risks but did not change a warning label because failure to act still did not prove the FDA clearly would have rejected stronger warnings.²⁴⁷ In another case, even where the FDA rejected some of the plaintiff’s suggested warnings, the plaintiff’s remaining claims were not preempted because the claims included other warnings not specifically rejected by the FDA.²⁴⁸ Likewise, the clear evidence requirement was held not met where the FDA rejected a warning but the manufacturer acquiesced and made no further attempt to ensure the warning label was safe.²⁴⁹ Defendant manufacturers can no longer claim state tort requirements are preempted just because a federal agency did not mandate a certain warning, because failure to mandate does not mean the warning clearly would have been rejected by a federal agency.²⁵⁰

The *Levine* decision has been applied to cases outside of drug manufacturing claims. The Federal Motor Vehicle Safety Standard (FMVSS) 208, which was at issue in *Geier*, where FMVSS 208 preempted a state lawsuit, was found not to preempt claims in a defective vehicle suit where the vehicle did not have side airbags.²⁵¹ The defendant claimed conflict preemption based on the purposes and objectives of FMVSS 208, but the court determined a suit on side impact airbags actually furthered the purposes and objectives of FMVSS 208.²⁵² The rationale behind *Geier* did not apply because FMVSS 208 did not contain a side airbag requirement.²⁵³ Further, the particular and specific scheme at issue in *Geier* relied on balancing the risks and benefits of airbags and the same scheme was not “in effect” for the alleged defective vehicle in this case.²⁵⁴ The district court

246. *Mason*, 596 F.3d at 393 (noting the FDA’s decision against using proposed warnings was not considered “clear evidence” the FDA would have rejected stronger warnings).

247. *Forst v. SmithKline Beecham Corp.*, 639 F. Supp. 2d 948, 954 (E.D.Wis. 2009) (observing the FDA did not prohibit all enhanced warnings, nor did it preclude changes of specific labeling elsewhere).

248. *See Lofton v. McNeil Consumer & Specialty Pharms.*, 682 F. Supp. 2d 662, 678 (N.D. Tex. 2010) (noting the plaintiffs’ claim would have been preempted if limited only to the failure to specifically warn of possible side effects of Motrin, but the plaintiffs’ claims included the failure to warn of the *symptoms* of side effects, and therefore preemption did not exist because the FDA had not rejected a warning on the symptoms).

249. *Aaron v. Wyeth*, No. 2:07cv927, 2010 WL 653984, at *6 (W.D. Pa. Feb. 19, 2010).

250. *Dorsett v. Sandoz*, 699 F. Supp. 2d 1142, 1156 (C.D. Cal. 2010).

251. *Durham v. County of Maui*, 696 F. Supp. 2d 1150, 1151 (D. Haw. 2010) (denying summary judgment for the defendant).

252. *Id.* at 1158.

253. *Id.*

254. *Id.*

determined FMVSS 208 set only minimum standards and applied the presumption against preemption.²⁵⁵

Geier was distinguished in another case where the plaintiff claimed the warnings in a vehicle's owner's manual regarding airbags were insufficient.²⁵⁶ There, the court determined FMVSS 208 established only the minimum standard for warnings on airbags.²⁵⁷ FMVSS 208 had a preemptive effect in *Geier* because manufacturers were given specific options and the plaintiff's suit in *Geier* would have "foreclosed" those options.²⁵⁸ An agency may require certain warnings, but if the agency does not forbid additional warnings, then a manufacturer may still have a duty under state law that may be enforced by a state court.²⁵⁹

The Court's rationale in *Levine* has been applied outside of products liability lawsuits, where a federal district court determined state law consumer protection statutes on advertising may complement federal law just as state common law duties may.²⁶⁰ An implied preemption defense was denied where the Federal Communication Commission (FCC) had extensive regulations but states also exercised police powers to regulate or prohibit telecommunications that harm citizens.²⁶¹ Another district court determined *Levine*'s provision that state law may be preempted by an agency regulation with the force of law applied to express preemption challenges as well.²⁶² The "demanding" physical impossibility test has been applied to deny a preemption defense by a national securities exchange registered with the Securities Exchange Commission (SEC) regarding claims based on an assault on the floor of the Philadelphia Stock Exchange.²⁶³

However, the *Levine* decision was not extended to a design defect claim where the plaintiff claimed the drug Redux was an "unreasonably dangerous drug for which no warning would have been adequate[.]" even though it had been approved by the FDA.²⁶⁴ The court distinguished *Levine* first because *Levine* was a failure to warn claim, and the present claim was

255. *Id.* at 1158-59, 61. FMVSS 208 set both a "floor and a ceiling" in *Geier* but not in *Durham*, which supports the conclusion that courts must make detailed and specific determinations regarding the preemptive effect of regulations. See *supra* Parts II.C.2, III.A.3.

256. *Cook v. Ford Motor Co.*, 913 N.E.2d 311, 324-25 (Ind. App. 2009).

257. *Id.* at 325.

258. *Id.* at 324.

259. *Id.* at 325.

260. See *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 370 (E.D.N.Y. 2010).

261. *Palmer v. Sprint Nextel Corp.*, 674 F. Supp. 2d 1224, 1231-32 (W.D. Wash. 2009).

262. *Rooney v. Philadelphia*, 623 F. Supp. 2d 644, 664 (E.D. Pa. 2009).

263. See *Dooner v. DiDonato*, 971 A.2d 1187, 1200 (Pa. 2009).

264. *Longs v. Wyeth*, 621 F. Supp. 2d 504, 507-09 (N.D. Ohio 2009).

not.²⁶⁵ Further, *Levine* focused on the manufacturer's duties after a drug was on the market, and the present claims were based on the manufacturer's duties before market approval.²⁶⁶ The court upheld the order of summary judgment in favor of the drug manufacturer, Wyeth, because the plaintiff's design defect claims were based on pre-FDA approval duties, federal law preempted such claims, and the plaintiff neglected to provide evidence to refute the defendant's evidence that the drug label warnings were adequate as a matter of law.²⁶⁷

The Ninth Circuit Court of Appeals applied the presumption against preemption in a suit against Sallie Mae for fraudulent misrepresentations in billing statements and coupon books, but still held the claims were preempted.²⁶⁸ Conflict preemption existed where the relevant agency's position was "in harmony" with congressional intent, so the agency was entitled to deference.²⁶⁹ Further, the agency had no "dramatic change" in position regarding the preemptive effect of its regulations, so its opinion was not viewed with the same suspicion as the FDA's in *Levine*.²⁷⁰ The court still conducted an independent review in compliance with *Levine*, but the court ultimately agreed with the agency's interpretation and accorded deference to the agency's opinion.²⁷¹

Levine was followed with a split in the federal circuits regarding whether generic drug warning claims are preempted.²⁷² Some courts determined claims against generic drug manufacturers are still preempted, in part because those courts determined CBE regulations do not allow manufacturers to change warning labels without FDA approval.²⁷³ Other courts decided that after *Levine*, conflict preemption is not a defense for generic drug manufacturers.²⁷⁴ One court noted generic drugs "ride the

265. *Id.* at 509.

266. *Id.*

267. *Id.* at 506.

268. *See* *Chae v. SLM Corp.*, 593 F.3d 936, 950 (9th Cir. 2010).

269. *Id.*

270. *Id.*

271. *Id.*

272. *Stacel v. Tera Pharms., USA*, 620 F. Supp. 2d 899, 906 (N.D. Ill. 2009).

273. *Gaeta v. Perrigo Pharms. Co.*, 672 F. Supp. 2d 1017, 1020 (N.D. Cal. 2009). However, the Fifth Circuit Court of Appeals noted the FDA previously expressed in a footnote to the CBE regulations that generic drug manufacturers could not use CBE regulations, but the FDA has since removed the footnote. *Demahy v. Actavis, Inc.*, 593 F.3d 428, 443-44 (5th Cir. 2010).

274. *Demahy*, 593 F.3d at 436-49; *Bartlett v. Mutual Pharm. Co., Inc.*, 659 F. Supp. 2d 279, 305 (D.N.H. 2009); *Couick v. Wyeth, Inc.*, No. Civ.A.3:09CV210RJCD, 2009 WL 4670637, at *3 (W.D.N.C. Sep. 30, 2009); *Kellogg v. Wyeth*, 612 F. Supp. 2d 437, 441 (D. Vt. 2009); *Stacel*, 620 F. Supp. 2d at 906. *Levine* has also been applied to deny a conflict preemption defense for an over-the-counter drug manufacturer. *Valdes v. Optimist Club of Suniland, Inc.*, 27 So. 3d 689, 691 (Fla. Dist. Ct. App. 2009).

coattails” of brand name drugs.²⁷⁵ First, the federal regulations about generic drugs do not address post-FDA approval modifications to warnings.²⁷⁶ However, generic drug manufacturers must at least initiate label changes.²⁷⁷ Second, CBE regulations do not forbid generic drug manufacturers from changing warning labels if the changes are meant to make the drug safer.²⁷⁸ Third, *Levine* supports a conclusion that generic drug manufacturers have a duty to ensure warning labels remain safe because generic drug regulations specifically do not prohibit manufacturers from directly warning or requesting the FDA to warn doctors of newly discovered risks.²⁷⁹ Finally, the FDCA’s purposes and objectives, which the Court subscribed to in *Levine*, apply as much to generic drugs as they do to brand name drugs.²⁸⁰ After *Levine*, courts seem reluctant to rely on FDA opinions and prior amicus briefs that endorse preemption of claims against generic drug manufacturers.²⁸¹

B. IMPACT ON NORTH DAKOTA LAW

Wyeth v. Levine affirmed that manufacturers owe a duty under state laws to maintain the safety and effectiveness of their labels.²⁸² Although *Levine* provides opportunities for residents in every state to seek remedies despite the existence of federal regulations, North Dakota’s products liability law is not well-settled.²⁸³ Plaintiffs seeking recovery under North Dakota law must also overcome a rebuttable presumption against defects.²⁸⁴ The presumption a product is free from defects exists where warnings and instructions for a product are in conformity with government standards.²⁸⁵ Despite *Levine*, North Dakota law seems unfavorable to a plaintiff claiming a defective product due to warnings and instructions which have been approved by the FDA.

However, North Dakota suits may still implicate the *Levine* analysis. The pre-*Levine* confusion was exemplified in a federal case from the

275. *Munroe v. Barr Labs., Inc.*, 670 F. Supp. 2d 1299, 1302-03 (N.D. Fla. 2009).

276. *Demahy*, 593 F.3d at 436, 444.

277. *Id.* at 437-38; *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 608-09 (8th Cir. 2009).

278. *Demahy*, 593 F.3d at 440-41.

279. *Id.* at 444-45; *Mensing*, 588 F.3d at 608-09.

280. *Demahy*, 593 F.3d at 448-49.

281. *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142, 1154 (C.D. Cal. 2010).

282. *Wyeth v. Levine*, 129 S. Ct. 1187, 1197-98, 1202 (2009).

283. *See* N.D. CENT. CODE § 28-01.3-07(2) (1995) (providing the “problems with the current civil justice system” were codified along with the need for reform).

284. § 28-01.3-09.

285. *Id.*

District of North Dakota. The *Ehlis v. Shire Richwood, Inc.*²⁸⁶ decision agreed that the FDCA “‘smacks’ of preemption,” yet the law was not “cut and dried.”²⁸⁷ The district court ended its discussion by concluding it could not determine the MDA and the FDA were actually different or that preemption did not apply to the plaintiffs’ strict liability and negligence claims regarding the drug Adderall’s label.²⁸⁸ The court decided preemption might apply because the FDA dictated the contents of Adderall’s label, and the court found the manufacturer was prohibited from changing the label without the FDA’s approval.²⁸⁹ The court granted summary judgment in favor of the defendant manufacturer on the court’s shaky preemption stance, as well as other theories.²⁹⁰ *Levine* and changes in the FDCA do not support the court’s reasoning, and the *Ehlis* decision should not be cited as precedent because the court found no difference between the FDCA and the MDA, and the court did not recognize the manufacturer’s duty to amend defective warning labels.²⁹¹ However, the *Ehlis* plaintiff’s proposed “black box” warning, a particular warning surrounded by a black box on the label, may still be preempted after *Levine* because the FDA may have already rejected that particular warning.²⁹²

V. CONCLUSION

In *Levine*, the United States Supreme Court toughened the implied conflict preemption test in areas of the law traditionally regulated by states by applying the presumption against preemption.²⁹³ The Court reiterated congressional purpose is still the ultimate touchstone in finding conflict preemption.²⁹⁴ An impossibility defense under conflict preemption is difficult to assert because it must be absolutely impossible for a defendant to have complied with both the federal and state regulations in order to claim

286. 233 F. Supp. 2d 1189 (D.N.D. 2002). The father of a five-week-old girl killed the infant after taking the drug Adderall. *Ehlis*, F. Supp. 2d at 1190. He alleged Adderall caused psychosis and sued the drug manufacturer in part because the drug’s warning label did not warn about this effect. *Id.* at 1190-91.

287. *Id.* at 1197.

288. *Id.* at 1198.

289. *Id.*

290. *Id.* The court granted summary judgment because of the learned intermediary doctrine. *Id.*

291. *See generally Levine*, 129 S. Ct. 1187 (2009) (making extremely detailed findings and rejecting similar preemption claims).

292. *See id.* at 1194 (declining to answer whether a verdict mandating a particular warning was preempted—though it should be noted the plaintiff *Levine* did originally request a specific warning).

293. *See supra* Part III.A.1.

294. *Id.*

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the defense.²⁹⁵ The mere presence of the FDA and the FDCA do not prove Congress's purposes and objectives were to vest a federal agency with exclusive authority over the safety and effectiveness of drug labels.²⁹⁶ Ultimately, drug manufacturers retain responsibility to ensure their labels are safe and effective, and merely using an FDA-approved label may be insufficient to provide a conflict preemption defense.²⁹⁷ Congress intended the FDA's regulations to be supplemented by state tort suits rather than be preemptive of such suits.²⁹⁸ Finally, the FDA cannot unilaterally declare state tort suits are preempted.²⁹⁹

*Charlotte J. Skar**

295. *See supra* Part III.A.2.

296. *See supra* Part III.A.3.

297. *Id.*

298. *See supra* Part III.A.4.

299. *Id.*

*2010 J.D. with distinction from the University of North Dakota School of Law. Thank you to Paul LeBel for inspiring this article.