

PRODUCTS LIABILITY—CONFLICT PREEMPTION:
REWRITING THE TEST FOR IMPOSSIBILITY: THE UNITED
STATES SUPREME COURT REMOVES THE PROTECTION OF
THE LAW FOR GENERIC DRUG RECIPIENTS
PLIVA, Inc. v. Mensing, 131 S. CT. 2567 (2011)

ABSTRACT

Originating in Minnesota District Court and Louisiana District Court, respondents in *PLIVA, Inc. v. Mensing* were drug recipients who argued the generic drug manufacturers of Reglan had a duty under state tort law to provide adequate warning labels detailing the risks associated with the medication. The United States Supreme Court held Food and Drug Administration (FDA) regulations imposed on generic drug manufacturers make it impossible for the generic manufacturers to comply with both state and federal law. Additional pertinent facts regarding this case are identified in Part I of this article. Part II details the extensive legal background surrounding both preemption and the FDA. Further, Part III describes the generic manufacturers' argument that they cannot unilaterally change their warning labels because of FDA regulations, in which the majority of the Court agreed. Thus, the respondent's claim was preempted by federal law. This 5-4 decision, overruling the Eighth and Fifth Circuit Court of Appeals, creates a new standard for the conflict preemption defense of impossibility and draws a dramatic distinction from the Supreme Court's previously decided conflict preemption case in 2009. Finally, Part IV analyzes the devastating nationwide impact of this opinion including the allowance of the protection of the law for those who receive name-brand prescription medications but denial of that protection to generic recipients. While some have characterized this decision as the decision that makes little sense, the Court contends generic drug recipients have simply been dealt an "unfortunate hand."

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I. FACTS

Gladys Mensing and Julie Demahy each began taking the generic version of Reglan, metoclopramide, in 2001 and 2002, respectively.¹ After taking the generic version for several years,² as provided by their pharmacists, each developed tardive dyskinesia.³ This severe neurological disorder develops in up to twenty-nine percent of patients who take metoclopramide for several years.⁴ In response, each individually brought suit against the manufacturer of the generic medication.⁵ The plaintiffs, Mensing and Demahy, argued the company, PLIVA, Inc., was liable under their respective state tort laws—Minnesota⁶ and Louisiana⁷—for failing to provide adequate warning labels.⁸

In both suits, the defendant, PLIVA, Inc., argued state tort claims were preempted by Food and Drug Administration regulations and federal statutes which mandated them to use the same “safety and efficacy labeling” as their name-brand equivalent.⁹ The Minnesota District Court agreed with the drug company’s arguments and granted summary judgment, but the Louisiana District Court held the tort claim was not preempted by federal law.¹⁰ The Eighth Circuit Court of Appeals disagreed, “declin[ing] to assume that Congress intended to shield from tort liability the manufacturers of the majority of the prescription drugs consumed in this

1. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2569 (2011).

2. *Id.* at 2572-73. The warning labels associated with Reglan and its generic counterpart has undergone changes since 1985 when the label was modified to mention tardive dyskinesia. *Id.* at 2572 (citing PHYSICIAN’S DESK REFERENCE 1635-36 (41st ed. 1987)). Most recent changes include a black box warning indicating “[t]reatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases.” *Id.* at 2573 (citing PHYSICIAN’S DESK REFERENCE 2902 (65th ed. 2011)).

3. *Id.* at 2573. Tardive Dyskinesia is defined as “involuntary movements of the facial muscles and tongue, often persistent, that develop as a late complication of some neuroleptic therapy, more likely with typical antipsychotic agents.” *STEDMAN’S MEDICAL DICTIONARY* 598 (28th ed. 2006).

4. *PLIVA, Inc.*, 131 S. Ct. at 2572 (citing *McNeil v. Wyeth*, 462 F.3d 364, 370 (5th Cir. 2006); Douglas Shaffer et al., *Tardive Dyskinesia Risks and Metoclopramide Use Before and After U.S. Market Withdrawal of Cisapride*, 44 J. AM. PHARMACISTS ASSN. 661, 663 (2004)).

5. *PLIVA, Inc.*, 131 S. Ct. at 2573.

6. *Id.* “[W]here the manufacturer . . . of a product has actual or constructive knowledge of danger to users, the . . . manufacturer has a duty to give warning of such dangers.” *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn. 1977).

7. *PLIVA, Inc.*, 131 S. Ct. at 2573. “[A] manufacturer’s duty to warn includes a duty to provide adequate instructions for safe use of a product.” *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 269-70 (5th Cir. 2002).

8. *PLIVA, Inc.*, 131 S. Ct. at 2573.

9. *Id.*

10. *Mensing v. Wyeth, Inc.*, No. 07-3919, 2008 WL 4724286, at *5 (D. Minn. Oct. 27, 2008); *Demahy v. Wyeth, Inc.*, 586 F. Supp. 2d 642, 662 (D. La. 2008).

country and leave injured parties like Mensing no legal remedy.”¹¹ In a similar fashion, the Fifth Circuit Court of Appeals articulated, “[t]here is no evidence sufficient for us to say that it was the ‘clear and manifest purpose’ of Congress to preempt state law, or to allow the FDA to do the same.”¹² Thus, the generic manufacturers appealed the decisions, which were heard as a consolidated lawsuit before the United States Supreme Court.¹³

II. LEGAL BACKGROUND

In order to understand how *PLIVA, Inc. v. Mensing*¹⁴ shapes both law and policy, one must study a variety of historical and legal factors. Those issues involve the current federal regulations concerning prescription drug certification, the constitutional basis of preemption, and the significant and binding precedent that shaped the *PLIVA, Inc.* decision. Together, current drug regulations, legal theories surrounding preemption, and precedential authority create a legal background referenced throughout the *PLIVA, Inc.* opinion.

A. THE EXPANSION OF GENERIC DRUG CERTIFICATION

In 1906, state regulations and common law liability for “adulterated or misbranded drugs” were codified by federal statutes.¹⁵ In response to rising concerns regarding unsafe drugs and fraudulent marketing, Congress put forth another substantial step toward drug regulation by creating the Federal Food, Drug, and Cosmetic Act (FDCA).¹⁶ In 1962, the FDCA was considerably amended to require manufacturers of new drugs to prove they are safe, effective, and have accurate warning labels.¹⁷ The original modification by Congress included all types of drugs, regardless of their manufacturer.¹⁸

However, in 1984, the Hatch-Waxman Amendments, formally known as the Drug Price Competition and Patent Term Restoration Act, loosened

11. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612 (8th Cir. 2009).

12. *Demahy v. Actavis*, 593 F.3d 428, 449 (5th Cir. 2010).

13. *PLIVA, Inc.*, 131 S. Ct. at 2572.

14. 131 S. Ct. 2567 (2011).

15. *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 (2009); see Pure Food and Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (codified at 21 U.S.C. §§ 1-15 (1934)), repealed by Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 902, 52 Stat. 1040, 1059 (1938).

16. *Wyeth*, 129 S. Ct. at 1195. See generally Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

17. *PLIVA, Inc.*, 131 S. Ct. at 2574. These amendments are typically referenced as the Kefauver-Harris Amendments. Pub. L. No. 87-781, § 102, 76 Stat. 780, 781 (1962) (codified as amended in scattered sections of 21 U.S.C.). Current law still places a duty on the manufacturer of a name-brand drug to prove its safety and efficacy. 21 U.S.C. § 355(b)(1) (2006).

18. *PLIVA, Inc.*, 131 S. Ct. at 2574.

the standards required for certification of a “generic drug.”¹⁹ A generic drug, defined by the United States Supreme Court in 1983, refers to a “drug designed to be a copy of a reference listed drug (typically a brand-name drug), and thus identical in active ingredients, safety, and efficacy.”²⁰ The amendments allowed for drug certification after showing the generic drug is equivalent to drugs already approved and the warning labels are identical.²¹ Notably, the amendments encompassed no language expressly preempting state tort claims²² nor did they expressly preserve state tort claims through a savings clause.²³ While these laws have undergone additional revision in 2007,²⁴ the main events of *PLIVA, Inc.* took place prior to 2007.²⁵ Therefore, the applicable law in the decision does not include the 2007 Act.²⁶

B. INTERPRETING FEDERAL REGULATIONS

The paramount issue in *PLIVA, Inc.* involves whether the regulations of the FDA that apply to generic drug manufacturers preempt, or directly conflict with, state law claims.²⁷ The United States Supreme Court has routinely held federal regulations can have the same preemptive effect as federal statutes.²⁸ Traditionally, courts give deference to the view of an agency with regard to the impact of their regulations on state law.²⁹ Therefore, the FDA’s views are controlling unless plainly erroneous, inconsistent, or reflect unfair and uncertain judgment.³⁰ Recent United States Supreme Court precedent further articulated this standard by indicating while an agency’s interpretation of its regulations receive deference from the court, the agency’s conclusion regarding whether state law should be preempted does not receive the same deferential treatment.³¹

19. *Id.*

20. *Id.* (citing *United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55 (1983)).

21. 21 U.S.C. § 355(j)(2)(A).

22. *PLIVA, Inc.*, 131 S. Ct. at 2586 (Sotomayor, J., dissenting).

23. *Id.* at 2577 n.5 (majority opinion).

24. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended in scattered sections of 21 U.S.C.).

25. *PLIVA, Inc.*, 131 S. Ct. at 2574 n.1.

26. *Id.*

27. *Id.* at 2572.

28. *Fid. Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153-54 (1982).

29. *PLIVA, Inc.*, 131 S. Ct. at 2575 (citing *Auer v. Robbins*, 519 U.S. 452, 461-62 (1997)); *see United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996).

30. *PLIVA, Inc.*, 131 S. Ct. at 2575 (citing *Auer*, 519 U.S. at 461-62).

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

C. PREEMPTION: THE SUPREME LAW OF THE LAND

The origin of the preemption rule is in Article VI of the United States Constitution, the Supremacy Clause, which establishes federal law as the “supreme [l]aw of the [l]and.”³² Although the United States Supreme Court has recently heard multiple preemption cases, the preemption defense was historically unsuccessful until 1992.³³ While there are many types of preemption defenses, a court’s decision regarding them traditionally lies in the interpretation of non obstante³⁴ provisions.³⁵ In *PLIVA, Inc.*, the defense asserted by the manufacturing company involved a specific type of conflict preemption called impossibility.³⁶

1. *The Various Types of Preemption Defenses*

“[P]reemption entails far more than the idea that federal law prevails over state law in cases of conflict. Instead, preemption typically involves a decision to displace state law in some area in order to advance perceived federal policy goals.”³⁷ In making a decision to displace a set of laws, courts categorize preemption defenses by type: express preemption, field preemption, and conflict preemption.³⁸

First, “[e]xpress pre-emption requires explicit pre-emptive language.”³⁹ To qualify as express preemption, Congress must have enacted specific statutory language addressing the question of displaced federal laws.⁴⁰ However, if no express language exists to create an express preemption scenario, field or conflict preemption may still allow for the displacement of state law in support of public policy.⁴¹

Second, field preemption is determined by a “manifestation of congressional intent” to occupy an entire field of law, such that state regulation in that area is preempted.⁴² The final type of preemption,

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

33. *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 505 (1992) (indicating preemption is a valid defense in regards to a state personal injury action in which federal law prevented any legal remedy).

34. See discussion *infra* Part II.C.2.

35. *PLIVA, Inc.*, 131 S. Ct. at 2579-80.

36. *Id.* at 2577-80; see discussion *infra* Part II.C.1. (defining impossibility).

37. Thomas W. Merrill, *Preemption and Institutional Choice*, 102 Nw. U. L. REV. 727, 729 (2008).

38. *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 115 (1992); *Hillsborough Cnty., Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985).

39. *Gade*, 505 U.S. at 115 (quoting *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm’n*, 461 U.S. 190, 203 (1983)).

40. Merrill, *supra* note 37, at 729.

41. *PLIVA, Inc.*, 131 S. Ct. at 2577 & n.5.

42. *Gade*, 505 U.S. at 115 (citing *Pac. Gas & Elec. Co.*, 461 U.S. at 204).

conflict preemption, occurs when accomplishing both state and federal law is impossible, or when state law becomes an obstacle to the purposes and intentions of Congress.⁴³ While express preemption is the preferred preemption category for courts when settling disputes regarding conflicts of law, if a finding for express preemption cannot be found, courts seek to determine if either field or conflict preemption may serve as a valid defense.⁴⁴ In *PILVA, Inc.*, after eliminating the defense of implied preemption, the Court found conflict preemption existed.⁴⁵

2. *Non Obstante Provisions: Repealing State Laws*

In the eighteenth century, legislatures used non obstante provisions to indicate if a new statute should repeal any potentially conflicting laws.⁴⁶ However, current legislatures use non obstante provisions in a different manner than in the eighteenth century.⁴⁷ A current non obstante provision indicates a new statute may contradict prior law.⁴⁸ The provision also instructs the courts “not to apply the general presumption against implied repeals.”⁴⁹ Therefore, harmonizing conflicting laws has historically been a priority of courts in order to avoid implied repeals.⁵⁰

After considering the framer’s intent, the Court in *PLIVA, Inc.* determined the non obstante provision in the Supremacy Clause indicates federal law should be understood to “impliedly repeal conflicting state law.”⁵¹ The United States Supreme Court reached a similar conclusion in 2009, at which time it held a court should not interfere with federal law to accommodate a state law of inconsistent nature.⁵² Although the Court interprets the meaning of the non obstante provision in the Supremacy Clause in a similar manner in 2009 and 2011,⁵³ striking differences in the remainder of its preemption analysis exist.

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

44. *PLIVA, Inc.*, 131 S. Ct. at 2577 & n.5.

45. *Id.*

46. *Id.* at 2579 (citing Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 238-40 (2000)).

47. *Id.*

48. *Id.*

49. *Id.*

50. *PLIVA, Inc.*, 131 S. Ct. at 2580; *Doolittle v. Bryan*, 55 U.S. 563 (1853); *Ludlow’s Heirs v. Johnson*, 3 Ohio 553, 564 (1828); *Warder v. Arell*, 2 Va. 282, 296 (1796).

51. *PLIVA, Inc.*, 131 S. Ct. at 2580.

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

53. *PLIVA, Inc.*, 131 S. Ct. at 2580; *Wyeth*, 129 S. Ct. at 1187.

3. *Conflict Preemption: Impossible Compliance*

The primary function of the Supreme Court when analyzing a preemption issue is to determine whether state laws and regulations remain consistent with the goals of federal law.⁵⁴ In instances where state and federal law “directly conflict,” federal law must have priority.⁵⁵ Therefore, if a private party cannot possibly comply with both state and federal requirements, there is a federal law conflict that may give rise to the defense of impossibility.⁵⁶ The current test for impossibility used in both *PLIVA, Inc.* and *Wyeth v. Levine*⁵⁷ is “whether the private party could independently do under federal law what state law requires of it.”⁵⁸

D. INFLUENTIAL PRECEDENT: APPLICATION OF PREEMPTION

While a wealth of case law dealing with both warning labels and preemption defenses apply to the issues in *PLIVA, Inc.*, the United States Supreme Court relies heavily on two judicial opinions.⁵⁹ The first opinion, *Wyeth v. Levine*, was decided in 2009 by the United States Supreme Court.⁶⁰ Because the *Wyeth* decision also addresses federal preemption in the context of prescription drugs, it is frequently referenced in the *PLIVA, Inc.* decision.⁶¹

In *Wyeth*, a woman was prescribed and took an anti-nausea drug, Phenergan, for migraine treatment.⁶² However, her treatment resulted in gangrene and the amputation of her forearm.⁶³ The drug recipient argued the Phenergan label did not adequately warn her of the dangers associated with the medication.⁶⁴ Yet, in a 6-3 opinion, the Court held it was not impossible for the drug manufacturer of a name-brand drug to comply with both state and federal warning label laws.⁶⁵

54. *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992).

55. *PLIVA, Inc.*, 131 S. Ct. at 2577; *Wyeth*, 129 S. Ct. at 1205; *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372 (2000).

56. *PLIVA, Inc.*, 131 S. Ct. at 2577 (citing *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

57. 129 S. Ct. 1187 (2009).

58. *PLIVA, Inc.*, 131 S. Ct. at 2579. This test began to develop when the United States Supreme Court held in 2009 that no preemption defense existed where the defendant could “unilaterally” meet the requirements of state law. *Wyeth*, 129 S. Ct. at 1199.

59. *See, e.g., PLIVA, Inc.*, 131 S. Ct. at 2577; *Wyeth*, 129 S. Ct. at 1205.

60. *Wyeth*, 129 S. Ct. at 1187.

61. *See PLIVA, Inc.*, 131 S. Ct. at 2577.

62. *Wyeth*, 129 S. Ct. at 1191.

63. *Id.*

64. *Id.*

65. *Id.* at 1208.

An additional influential case is *Rice v. Norman Williams Co.*⁶⁶ In *Rice*, the Supreme Court unanimously held the Sherman Act⁶⁷ did not invalidate California law regarding the sale of spirits.⁶⁸ In so holding, the Court articulated a concept referred to as “hypothetical impossibility.”⁶⁹ Hypothetical impossibility is frequently cited as a tenet of preemption analysis by many courts, including the Court in *PLIVA, Inc.*⁷⁰ Therefore, *Rice* pronounced a potential conflict does not demonstrate impossibility of following both state and federal law.⁷¹

III. ANALYSIS

The issue presented in *PLIVA, Inc.* depended upon “whether federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt, these state-law claims.”⁷² By means of a 5-4 decision, the Court held the generic drug manufacturers could not satisfy their state duties without the “federal government’s special permission and assistance.”⁷³ Therefore, state law may be preempted if a party cannot independently comply with both state and federal law.⁷⁴ The Court addressed two main arguments in support of its conclusion: (1) the generic drug manufacturers had avenues to change their warning labels, (2) and possibly conflicting federal laws should preempt state law.⁷⁵

A. THE MAJORITY OPINION

Justice Thomas authored the majority opinion in *PLIVA, Inc.*, in which Chief Justice Roberts, Justice Scalia, and Justice Alito joined in full and Justice Kennedy joined in part.⁷⁶ The majority opinion addressed the various methods the generic manufacturers could have used to change their warning labels. Additionally, the majority focused on the new standard for impossibility as conflict preemption and the impact this decision has on older preemption rulings.⁷⁷

66. 458 U.S. 654 (1982).

67. 15 U.S.C. § 1 (2006).

68. *Rice*, 458 U.S. at 661.

69. *Id.* at 659.

70. *See, e.g.*, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2587 (2011).

71. *Rice*, 458 U.S. at 659.

72. *PLIVA, Inc.*, 131 S. Ct. at 2572.

73. *Id.* at 2581.

74. *See id.*

75. *Id.* at 2570.

76. *Id.* at 2571.

77. *Id.* at 2570-71.

1. *Avenues for Changing Generic Drug Labels*

Mensing and Demahy argued preemption is an invalid defense because the generic drug manufacturers had the capacity to potentially change their warning labels.⁷⁸ The respondents argued three avenues existed to change the generic warning label including: (1) “changes being effected” (CBE), (2) “Dear Doctor” letters, and (3) FDA consent.⁷⁹

First, Mensing and Demahy argued an FDA-approved CBE process allows manufacturers like PLIVA, Inc. to alter their warning labels when needed.⁸⁰ Specifically, they advocated the process allows manufacturers who have already received FDA approval to strengthen or add precautions and warnings,⁸¹ and to add instructions about administration and dosage, which will facilitate safe use of the medication.⁸² However, the FDA contended a generic manufacturer may only change their drug labels “to match an updated brand-name label or to follow the FDA’s instructions.”⁸³ Additionally, the FDA interpreted CBE changes made unilaterally by a generic drug manufacturer to violate other FDA statutes and regulations.⁸⁴ Because the longstanding policy of the Court is to grant deference to an agency’s interpretation of its own regulations, the Court concluded, in a matter that corresponded with the FDA, that the generic manufacturers could not initiate the CBE process.⁸⁵

Second, the injured drug recipients argued the manufacturers could have sent additional warnings to physicians and other prescribing health care professionals through the use of “Dear Doctor” letters.⁸⁶ However, the FDA again received the Court’s deference with their opinion that such letters would qualify as labeling unapproved by the FDA.⁸⁷ The FDA further suggested such letters may mislead physicians to imply a difference in the therapeutic benefit of generic versus name-brand medications.⁸⁸

78. *Id.* at 2574.

79. *Id.* at 2575-77.

80. *Id.* at 2575. The CBE process has seen discussion throughout various cases with quickly changing analysis. *Gaeta v. Perrigo Pharmaceuticals Co.*, 630 F.3d 1225, 1231 (9th Cir. 2011); *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994).

81. 21 C.F.R. § 314.70(c)(6)(iii)(A) (2006).

82. *Id.* § 314.70(c)(6)(iii)(C).

83. *PLIVA, Inc.*, 131 S. Ct. at 2575.

84. *Id.* Other FDA regulations indicate a generic manufacturer’s approval and certification may be withdrawn if the label is no longer equivalent to the label of name-brand drugs. *See* 21 U.S.C. § 355(j)(4)(G) (2006); 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(1).

85. *PLIVA, Inc.*, 131 S. Ct. at 2575.

86. *Id.* at 2576.

87. *Id.* (citing 21 U.S.C. § 321(m); 21 CFR § 202.1(1)(2)).

88. *Id.* FDA regulations allow for the withdrawing approval of generic drugs if the labeling of the drug is “false or misleading in any particular.” 21 C.F.R. § 314.150(b)(3).

While this effect would violate the FDA's terms of certification for manufacturers, it would also be contrary to the FDA's goals and objectives.⁸⁹ Accordingly, the Court advised that federal law does not permit generic manufacturers to increase the strength of their warnings through "Dear Doctor" styled letters.⁹⁰

Third, the FDA asserted the generic manufacturers could have, and were legally required to, propose stronger warning labels if necessary to protect the health and safety of drug recipients.⁹¹ Additionally, if the FDA agreed with the generic manufacturer that a labeling change was appropriate, it would have cooperated with the name-brand manufacturer to create a new warning label for both drugs.⁹² However, PLIVA, Inc. argued that no duty of notification to the name-brand manufacturer exists on behalf of a generic drug company. They further contended no evidence exists of a generic drug manufacturer ever acting in a way that may be in accordance with any such duty.⁹³ Despite differing opinions regarding the legal duty to notify a manufacturer of unsafe products, the Court concluded "[b]ecause we ultimately find pre-emption even assuming such a duty existed, we do not resolve the matter."⁹⁴

2. *Possibly Preempt: Hypothetically Conflicting Laws*

After bearing consideration on the suggested avenues for changing prescription drug labels, the Court deciphered how the options of the generic drug manufacturers' impact their conflict preemption defense.⁹⁵ Initially, the Court clarified the type of preemption defense put forth by PLIVA, Inc. is that of conflict preemption.⁹⁶ While the Court explained "an express statement of preemption is always preferable, the absence of such a statement" should not lead to a finding for no express preemption, but instead to the possibility of conflict preemption.⁹⁷ Specifically, the Court narrowed the type of conflict preemption to that of impossibility.⁹⁸

89. *See PLIVA, Inc.*, 131 S. Ct. at 2576.

90. *Id.*

91. *Id.* The FDA provides that this duty of notification exists in 21 U.S.C. § 352(f)(2) and 21 C.F.R. § 201.57(e). *Id.* They attempt to persuade the Court that failure to notify the FDA of "unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users" results in a medication which is misbranded and therefore a violation of federal law. *Id.* (quoting 21 U.S.C. § 352(f)(2)).

92. *Id.*

93. *Id.* at 2577.

94. *Id.*

95. *See id.*

96. *See id.*

97. *Id.* at 2577 n.4.

98. *Id.* at 2577.

Mensing and Demahy argued that when a private manufacturer's capacity to comply with state law depends on endorsement and aid from the FDA, proving preemption requires the company to reveal the FDA would not have permitted compliance.⁹⁹ Asserting that the generic drug manufacturers of metoclopramide never attempted to even initiate the process of FDA approval, Mensing and Demahy argued *PLIVA, Inc.* did not meet its burden of proof.¹⁰⁰ The Court rejected their argument and held the question for impossibility "is whether the private party could independently do under federal law what state law requires of it."¹⁰¹

To support its conclusion, the Court looked to the non obstante provision of the Supremacy Clause within the United States Constitution.¹⁰² Specifically, it emphasized that to consider the actions of third and unrelated parties when determining preemption would be inconsistent with the non obstante provision.¹⁰³ This non obstante clause discourages analysis and speculation about the various ways third-party actions could potentially reconcile conflicting federal and state laws.¹⁰⁴ Therefore, the Court held when the "ordinary meaning" of a law stops a party from "independently" complying with both state and federal law, a preemption defense will succeed.¹⁰⁵

3. *Distinguishing Wyeth: Generic Drug Recipients Dealt an Unfortunate Hand*

In *Wyeth*, a name-brand manufacturing company responsible for injuries to recipients who did not receive adequate warning argued state tort claims were preempted by federal FDA laws.¹⁰⁶ The United States Supreme Court disagreed with the company in 2009, holding it was possible for the name-brand manufacturing company to comply with both laws.¹⁰⁷ The Court's rationale for this seemingly contradictory opinion in *PLIVA, Inc.* lies in the name-brand manufacturer's ability to complete CBE processes to strengthen their warning labels.¹⁰⁸ Because *Wyeth*, as a brand-name manufacturer, could unilaterally and independently strengthen their warning labels, it was not impossible for them to comply with both state

99. *Id.* at 2578-79.

100. *Id.* at 2579.

101. *Id.*

102. *Id.* at 2579-80 (citing U.S. CONST. art. VI, cl. 2).

103. *Id.* at 2580.

104. *Id.*

105. *Id.*

106. *Wyeth v. Levine*, 129 S. Ct. 1187, 1193-94 (2009).

107. *Id.* at 1204.

108. *PLIVA, Inc.*, 131 S. Ct. at 2581-82.

and federal laws.¹⁰⁹ The Court “acknowledge[d] the unfortunate hand” dealt to Mensing and Demahy, but explained it cannot unilaterally change FDA regulations.¹¹⁰ The Court suggested, ““it is not this Court’s task to decide whether the statutory scheme established by Congress is unusual or even bizarre.””¹¹¹

B. THE DISSENT: “THIS OUTCOME MAKES LITTLE SENSE”

Justice Sotomayor authored the dissent in *PLIVA, Inc.*, in which Justices Ginsburg, Breyer, and Kagan joined.¹¹² The disagreements surrounding the legal foundation of this case become evident throughout the dissent, beginning with the statement, “[t]he Court gets one thing right: [t]his outcome ‘makes little sense.’”¹¹³ Continuing its strong sentiments, the dissent further suggested that, as a result of the *PLIVA, Inc.* opinion, whether a drug recipient harmed by inadequate warning labels can receive the protection of the law now “turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug.”¹¹⁴ The dissent discussed the issues of congressional intent, the demanding requirements of an impossibility test, and the impact of *Wyeth*.¹¹⁵

1. *The Silence of Congress: What is Congressional Intent?*

The dissent contended when analyzing a preemption case, the role of the Court is to identify the clear and manifest purpose of Congress and give priority consideration to those purposes identified.¹¹⁶ While Congress has demonstrated a long-time interest in state tort litigation against drug manufacturers,¹¹⁷ the states have traditionally regulated health and safety matters.¹¹⁸ Therefore, in health and safety concerns, the Court considers the

109. *Id.* at 2581.

110. *Id.* at 2581-82.

111. *Id.* at 2582 (quoting *Cuomo v. Clearing House Ass’n, L.L.C.*, 129 S. Ct. 2710, 2733 (2009)).

112. *Id.* (Sotomayor, J., dissenting).

113. *Id.* at 2583.

114. *Id.*

115. *Id.* at 2583-93.

116. *Id.* at 2586. “[W]e start with the assumption that 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 [T]he purpose of Congress is the ultimate touchstone in every pre-emption case.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (internal quotations omitted).

117. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1196 (2009).

118. *Lohr*, 518 U.S. at 485.

longstanding balance of power between Congress and the states in determining congressional intent.¹¹⁹

Given the traditional roles of state and federal government, the dissent recognized Congress has not used express language to preempt state tort law actions against generic or name-brand drug manufacturers.¹²⁰ Specifically, when Congress amended the FDCA in 1962, it took efforts to preserve state law.¹²¹ As additional proof of congressional intent in 1962, Congress had previously enacted an express preemption provision for medical devices,¹²² but did not include a similar provision in the Hatch-Waxman Amendments, which pertain to the issue in *PLIVA, Inc.*¹²³ Therefore, the dissent argued “Congress’ ‘silence on the issue . . . is powerful evidence that [it] did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.’”¹²⁴ Without congressional intent of superseding state law, the dissent believed the manufacturing company’s preemption defense was significantly weakened.¹²⁵

2. *Preemption: A Demanding Defense*

Additionally, the dissent noted the difficult burden proving impossibility as it “‘is a demanding defense.’”¹²⁶ As a traditional affirmative defense, a defendant bears the burden of proof¹²⁷ to illustrate the party cannot comply with both state and federal law.¹²⁸ Given this burden of proof, the dissent highlighted past preemption standards used by the United States Supreme Court bar the use of the preemption defense for hypothetical or potentially conflicting laws.¹²⁹ Therefore, the dissent suggested because the possibility of impossibility is not enough to warrant a preemption defense, the manufacturing company has at most demonstrated a hypothetical conflict and failed to meet its burden of proof.¹³⁰

119. See *PLIVA, Inc.*, 131 S. Ct. at 2586 (Sotomayor, J., dissenting).

120. *Id.*

121. *Id.*

122. 21 U.S.C. § 360k(a) (2006).

123. *PLIVA, Inc.*, 131 S. Ct. at 2586 (Sotomayor, J., dissenting).

124. *Id.* at 2586-87 (quoting *Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009)).

125. *Id.* at 2587.

126. *Id.* (quoting *Wyeth*, 129 S. Ct. at 1199).

127. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 255 (1984).

128. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963).

129. *PLIVA, Inc.*, 131 S. Ct. at 2587 (Sotomayor, J., dissenting); *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 110 (1992). “The existence of a hypothetical or potential conflict is insufficient to warrant” preemption. *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982).

130. *PLIVA, Inc.*, 131 S. Ct. at 2587-88 (Sotomayor, J., dissenting).

3. *Interpreting Wyeth: Overruled or Not?*

In addition to the dissent claiming that preemption was an invalid defense in *PLIVA, Inc.*, the dissent contended the majority incorrectly determined the current 2011 ruling does not impact the 2009 ruling in *Wyeth*.¹³¹ Instead, the dissent focused on the holding in *Wyeth*, which requires manufacturers show the FDA would not have approved a label change.¹³² In contrast, the dissenters reasoned the majority overrules *Wyeth* and does not require *PLIVA, Inc.* to meet the same standard of proof as name-brand manufacturing company in *Wyeth*.¹³³ Additionally, the dissent highlighted that it is possible for a generic drug manufacturing company to successfully utilize a preemption defense once they have proposed a warning label change to the FDA and that proposal has been denied.¹³⁴ These discrepancies led the dissent to conclude the majority “invents new principles of pre-emption law out of thin air to justify its dilution of the impossibility standard.”¹³⁵

IV. IMPACT

The decision of *PLIVA, Inc.* will undoubtedly affect future prescription drug recipients, the companies who produce those drugs, the prescribing physicians, the distributing pharmacists, and the discussion of FDA regulations in Congress.¹³⁶ Given that generic drugs account for seventy-five percent of the prescription drugs distributed in the United States, this decision impacts millions nationwide.¹³⁷ Unfortunately, the other millions of United States citizens who take generic drugs with inadequate warning labels will have no legal remedy or restitution.¹³⁸ An activist group, the Alliance for Justice notes, “What’s at stake? Keeping pharmaceutical companies honest about the potential danger their drugs pose.”¹³⁹

Aside from a sweeping change in a colossal portion of the nation’s health care, *PLIVA, Inc.* neglects to determine if generic drug manufacturers

131. *Id.* at 2582.

132. *Id.* at 2588.

133. *Id.*

134. *Id.* at 2588-89.

135. *Id.* at 2582.

136. *See id.* at 2572 (majority opinion) (holding those who receive generic medications cannot sue in tort for inadequate warning labels).

137. David W. Freeman, *Generic Drug Ruling May Effect Millions: What Did The Supreme Court Say*, CBS NEWS, http://www.cbsnews.com/8301-504763_162-20073825-10391704.html (last updated June 23, 2011).

138. *Id.*

139. *PLIVA, Inc. v Mensing*, ALLIANCE FOR JUSTICE, <http://www.afj.org/connect-with-the-issues/the-corporate-court/pliva-inc-v-mensing.html> (last visited Sept. 11, 2011).

have a duty to report dangers to the FDA.¹⁴⁰ Furthermore, the opinion creates a division in the protection of law provided to citizens, leaving those who receive generic drugs instead of name-brand drugs potentially injured with no legal solution.¹⁴¹ The majority also calls upon Congress to enact the changes that are necessary to avoid additional seemingly irrational decisions, unleashing a nationwide debate among politicians, corporations, and lobbyists.¹⁴² However, the impact of the decision extends beyond congressional politics and into the lives of North Dakota prescription drug recipients.¹⁴³

A. UNANSWERED QUESTIONS: GENERIC MANUFACTURER'S DUTY TO THE FDA

The issue remains unresolved with regard to a generic drug manufacturer's duty to warn the FDA that the labeling on their medications may not be strong enough or accurate.¹⁴⁴ While the potential duty is an important consideration for the safety of the millions of people who use prescription drugs every day, it also leaves the duty of the drug manufacturing companies ambiguous.¹⁴⁵ The American Association for Justice (AAJ) called the decision a "disastrous outcome for patient safety."¹⁴⁶ The AAJ continued that the Supreme Court decision eliminates any incentive for manufacturers of generic medications to verify the safety of their products.¹⁴⁷ In the view of the AAJ, less motivation to ensure the safety of generic products becomes especially relevant when ten extremely popular drugs are scheduled to be "coming off patent within the next few years."¹⁴⁸

Due to the Supreme Court's ambiguity, many individuals and organizations have begun advocating for clarification of the duty to report, including the consumer advocacy group Public Citizen.¹⁴⁹ Public Citizen

140. See *PLIVA, Inc.*, 131 S. Ct. at 2577.

141. See *id.* at 2583 (Sotomayor, J., dissenting).

142. *Id.* at 2582 (majority opinion).

143. *Hoeven Launches the North Dakota Prescription Drug Guide*, FDA.GOV (Apr. 6, 2004), <http://www.fda.gov/ohrms/dockets/dockets/04n0115/04n-0115-ts00041-02.htm>. Since 2004, former North Dakota Governor John Hoeven has focused efforts to ensure citizens have information available regarding affordability of prescription medications, including generic options for medications. *Id.*

144. *PLIVA, Inc.*, 131 S. Ct. at 2577.

145. *Id.*

146. 2 FRANK C. WOODSIDE, III, DRUG PRODUCT LIABILITY § 14.04 (2011).

147. *Id.*

148. *Id.*

149. Pat Murphy, *Consumer Group Asks FDA to Revise Generic Drug Warnings*, LAWYERS WEEKLY USA, Sept. 12, 2011.

intends to persuade the FDA to authorize generic drug manufactures to edit or strengthen their warning label mechanisms.¹⁵⁰ As previously mentioned, some manufacturers currently have permission to use avenues to change their warning labels such as CBE and prior-approval-supplement procedures.¹⁵¹ Private Citizen recommends the FDA extend CBE or prior-approval-supplement procedure permissions to all manufacturers, name-brand and generic.¹⁵² In addition, the organization urges the FDA to further clarify a generic drug manufacturers' duty to report possible dangers associated with a medication not found on drug labeling.¹⁵³

B. THOSE WHO RECEIVE THE PROTECTION OF THE LAW

“It raises some eyebrows when the U.S. Supreme Court accepts review of a case, the principle issue of which has not divided the federal circuit Court of Appeals, and the U.S. Solicitor General recommends that the Court deny certiorari.”¹⁵⁴ Despite the questions regarding the Court's acceptance of this seemingly already decided case, the *PLIVA, Inc.* ruling creates a distinction between those who receive generic medications versus those who receive name-brand medications.¹⁵⁵ While the dissent suggests this distinction between name-brand and generic medications places the applicability of the law in the hands of a pharmacist,¹⁵⁶ others suggest the ruling creates a stronger dichotomy between those who can afford to pay for name-brand prescription medications and those who cannot.¹⁵⁷ “Mensing's attorneys said . . . [the] decision creates two different classes of patients—those who take name-brand drugs and those who take generics—and that generic users are now less safe.”¹⁵⁸

It has long been recognized that access to the justice system can be costly. Until this opinion, decades of United States Supreme Court opinions have intended to apply the law fairly to people regardless of their socioeconomic status. Arguably, this ruling forces society to return to a day where the law protects only one class of citizens.¹⁵⁹ While many

150. *Id.*

151. *Id.*

152. *Id.*

153. *Id.*

154. WOODSIDE, *supra* note 146, § 14.04.

155. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2582 (2011).

156. *Id.* at 2583 (Sotomayor, J., dissenting).

157. *See generally* Jeremy Herb, *Court Sides with Generic Drugmakers*, STAR TRIB., June 23, 2011 (explaining prescription drug recipients emerge into two groups, those who pay for name-brand prescriptions and those who receive generic prescriptions).

158. *Id.*

159. *See generally id.* (explaining future legal protection will only be available to the class of citizens receiving name-brand medications).

prescription drug recipients are aware of the potential savings associated with generic medications, few understand the use of generic drugs is encroaching upon their legal rights.¹⁶⁰

C. SAFETY IN THE HANDS OF CONGRESS

Although both the majority opinion and the dissent recognized the *PLIVA, Inc.* decision is unfair for the recipients of generic medications, both acknowledged the power to fix this unfair dichotomy lies in the hands of Congress.¹⁶¹ Accordingly, this opinion has sparked numerous interests in congressional representatives and the executive branch.¹⁶² Reuters reports “[t]he Obama administration supported the two women. It said the companies could have sought changes to the drug’s label.”¹⁶³ From a legislative standpoint, Representative Henry Waxman, ranking member of the House Energy and Commerce Committee, indicates he will strive to create the system Congress intended to originally establish through the Hatch-Waxman Amendments.¹⁶⁴ He contends “[c]onsumers need to have every confidence that generic drugs are the same as brand drugs.”¹⁶⁵

Without question, the actions taken by Congress in response to this decision will increase prescription drug safety¹⁶⁶ and impact future state tort litigation.¹⁶⁷ In 1982, when the FDA initially approved the policies allowing manufacturers to unilaterally change their warning labels, it is unlikely they accurately predicted the impact the 1984 Hatch-Waxman Amendments would have in the growth, demand, and popularity of generic drugs over the next thirty years.¹⁶⁸ Therefore, many are likely to see no reason why the FDA should not consider changing the current CBE policy

160. Tom Lamb, *Public Citizen Group Files FDA Petition To Fix Problems Exposed by Mensing Case Ruling*, DRUG INJURY WATCH (Sept. 8, 2011), <http://www.drug-injury.com/druginjurycom/2011/09/public-citizen-petition-fda-generic-drug-manufacturers-warnings-side-effects-mensing-supreme-court.html>.

161. *PLIVA, Inc.*, 131 S. Ct. at 2582.

162. *Key Congressman Urges Actions on High Court’s Mensing Ruling*, 28 GENERIC LINE, no. 17, Aug. 31, 2011, available at LexisNexis; James Vicini, *Supreme Court Rejects Generic Drugs Labeling Suits*, REUTERS, June 23, 2011, <http://www.reuters.com/article/2011/06/23/us-genericdrugs-labeling-warning-idUSTRE75M3RT20110623> (last updated June 23, 2011).

163. Vicini, *supra* note 162.

164. *Key Congressman Urges Actions on High Court’s Mensing Ruling*, *supra* note 162.

165. *Id.*

166. *See generally* Ben Moscovitch, *FDA Regulatory Changes Sought To Reverse Generic Labeling Ruling*, 17 FDA WEEK, no. 35, Sept. 2, 2011 (explaining current CBE standards, enacted in 1982, ineffectively address modern prescription medication concerns).

167. *See generally* *Attorneys Discuss State of Litigation Surrounding Zolofit & SSRIs*, TORTS AND PERSONAL INJURY LAW COMMUNITY BLOG, Aug. 24, 2011, available at LexisNexis (explaining many attorneys involved in potential litigation of Zolofit and other medications based their strategy and timing decisions on the *PLIVA, Inc.* decision).

168. *Id.*

to allow generic manufacturers the same privileges as name-brand manufacturers.¹⁶⁹ If, in the future, Congress loosens the requirements for the FDA's CBE policy, the application of *PLIVA, Inc.* in future tort cases will decrease significantly.¹⁷⁰ Specifically, all manufacturers will fall into the *Wyeth* holding, which disallows preemption, rather than the *PLIVA, Inc.* holding for granting impossibility to only generic manufacturers.¹⁷¹ Until then, attorneys nationwide looking to initiate massive products liability cases will likely file suit against name-brand producers, but they may wait, refrain, or decline filing suit against possibly preempted generic manufacturers.¹⁷²

D. NORTH DAKOTA DRUG RECIPIENTS

The safety and efficacy of prescription drugs impacts all recipients, including those in the Midwest.¹⁷³ In particular, North Dakota citizens utilize a higher volume of prescription drugs than the national average.¹⁷⁴ Accordingly, the North Dakota law currently views products liability as a rapidly expanding area of law, which will require frequent treatment from the courts and the legislature.¹⁷⁵ Prior to *PLIVA, Inc.*, North Dakota law addressing products liability preemption was governed by the Eighth Circuit's ruling, which did not distinguish name-brand and generic manufacturers.¹⁷⁶ Therefore, current North Dakota statutes define a manufacturer without drawing a distinction between those who produce name-brand versus generic drugs.¹⁷⁷ In response to *PLIVA, Inc.*, North

169. *Id.*

170. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1208 (2009) (Thomas, J., concurring); *see also PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011) (holding the current CBE policy makes it impossible for *PLIVA, Inc.* to change their warning labels).

171. *See Wyeth*, 129 S. Ct. at 1208 (Thomas, J., concurring); *see also PLIVA, Inc.*, 131 S. Ct. at 2572.

172. *Attorneys Discuss State of Litigation Surrounding Zoloft & SSRIs*, *supra* note 167 (explaining the state of litigation surrounding drugs which may cause psychological disorders which are produced in a name-brand and generic version).

173. *See, e.g.*, AARP KNOWLEDGE MANAGEMENT, STATE HEALTH CARE BRIEF (June 2009), available at http://assets.aarp.org/rgcenter/health/state_hcb_09_nd.pdf. "In 2005, about [fifty-seven percent] of prescriptions for North Dakota residents were filed with generics." *Id.*

174. *Id.*

175. *See* N.D. CENT. CODE § 28-01.3-07(2) (1995). "In recent years it has become increasingly evident that there are still serious problems with the current civil justice system. As a result, there is an urgent need for additional legislation to establish clear and predictable rules with respect to certain matters relating to products liability actions." *Id.*

176. *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612 (8th Cir. 2009).

177. N.D. CENT. CODE § 28-01.3-01(1).

"Manufacturer" means a person or entity who designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or a component part of a product prior to the sale of the product to a user or consumer. The term includes any seller of a product who is

Dakota's legislature will likely define what constitutes a generic manufacturer.¹⁷⁸ Supporting the likelihood of this projected change, North Dakota legislative committees, such as the Health Care Reform Review Committee, are currently addressing a variety of health concerns related to North Dakota citizens and will continue these discussions until 2013.¹⁷⁹

In addition to changes with regard to products liability analysis, North Dakota courts will begin to construe their conflict preemption analysis with regard to the defense of impossibility in compliance with *PLIVA, Inc.*¹⁸⁰ While the North Dakota Supreme Court has recently decided a federal preemption case,¹⁸¹ they must now consider how the "ordinary meaning" of a law stops a party from "independently" complying with both state and federal law.¹⁸²

V. CONCLUSION

In *PLIVA, Inc.*, the United States Supreme Court held federal FDA regulations preempted state tort law regarding the warning labels produced by generic drug manufacturers.¹⁸³ With this ruling, the Court rewrites an important test for impossibility, a type of conflict preemption. While the impacts of the changes in this test remain uncertain, for now, those generic drug recipients who have been injured because of inadequate warning labels have been dealt an "unfortunate hand" by the United States Supreme Court.

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owned in whole or significant part by the manufacturer or who owns, in whole or significant part, the manufacturer.

Id.

178. *See id.*

179. *See, e.g.*, N.D. LEGISLATIVE MGMT., MINUTES OF THE HEALTH CARE REFORM REVIEW COMMITTEE 1-2 (June 14, 2011), available at <http://www.legis.nd.gov/assembly/62-2011/interim-info/minutes/hc061411minutes.pdf>.

180. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011).

181. *State v. Hager*, 2010 ND 217, ¶¶ 12, 24, 790 N.W.2d 745, 750, 754.

182. *PLIVA, Inc.*, 131 S. Ct. at 2580.

183. *Id.* at 2582.

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