

***MUTUAL PHARMACEUTICAL CO. V.
BARTLETT AND THE DEMISE OF
RECOVERY FOR CONSUMERS OF GENERIC
DRUGS***

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I. FACTS AND HOLDING

Mutual Pharmaceutical Co. v. Bartlett arose out of a patient’s tragic adverse reaction to a generic drug.¹ In 2004, Plaintiff, Karen Bartlett, received a prescription from her physician for the nonsteroidal anti-inflammatory drug (NSAID)

1. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2472 (2013).

Clinoril to treat shoulder pain.² Her pharmacist dispensed a generic form of the drug, Sulindac, manufactured by Defendant, Mutual Pharmaceutical Co. (Mutual).³ Bartlett suffered a rare but severe reaction to the drug, known as toxic epidermal necrolysis (TEN), resulting in the destruction of 60%–65% of the surface of her body, near blindness, and other significant physical disabilities requiring hospitalization for nearly two months—much of that time in a medically-induced coma.⁴ Bartlett required a feeding tube for a year and she remains unable to eat normally due to esophageal burns.⁵ Bartlett is unable to engage in sexual intercourse or perform aerobic activities due to vaginal and lung injuries.⁶ In addition, Bartlett has undergone twelve eye surgeries and will require many more.⁷

At the time Bartlett’s doctor prescribed Sulindac, the drug’s warning label did not specifically refer to TEN; rather, it warned of potential “severe skin reactions” and “[f]atalities.”⁸ The package insert accompanying the medication did, however, include TEN as a potential adverse reaction.⁹ In 2005, after a review of the risks and benefits of all approved NSAIDs, the Food and Drug Administration (FDA) recommended that the labeling of all NSAIDs be modified to specifically warn against TEN.¹⁰

In January 2008, Bartlett sued Mutual in New Hampshire state court under several theories, namely: breach of warranty, fraud, negligence, failure to provide adequate warnings, defective design, and defective manufacturing.¹¹ In September 2010, Mutual removed the case to federal court.¹² The District Court dismissed all of Bartlett’s claims, leaving only the design-defect claim to the jury.¹³ The jury found Mutual liable on the design-

2. Bartlett v. Mut. Pharm. Co., 678 F.3d 30, 34 (1st Cir. 2012), *rev’d*, 133 S. Ct. 2466 (2013).

3. *Id.*

4. *Id.* at 34, 43.

5. *Id.* at 43.

6. Bartlett v. Mut. Pharm. Co., 678 F.3d 30, 43 (1st Cir. 2012), *rev’d*, 133 S. Ct. 2466 (2013).

7. *Id.*

8. Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2472 (2013).

9. *Id.*

10. *Id.*

11. Bartlett v. Mut. Pharm. Co., 678 F.3d 30, 34 (1st Cir. 2012), *rev’d*, 133 S. Ct. 2466 (2013).

12. Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2472 (2013).

13. *Id.*

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defect claim and awarded Bartlett over \$21 million in damages.¹⁴ The First Circuit Court of Appeals upheld the verdict, leading Mutual to petition the Supreme Court for a writ of certiorari.¹⁵

The Supreme Court reversed the judgment of the First Circuit, finding that federal law preempted Bartlett's state law design-defect claim. The Supreme Court determined that under New Hampshire state law drug companies have a duty to either redesign an unreasonably dangerous drug or modify its warning label.¹⁶ Generic-drug manufacturers, however, are forbidden to take either action under FDA Regulations, which constrain them to adhere to specific design and labeling features of the drug's brand-name counterpart.¹⁷ In addition, the First Circuit accepted Mutual's claim that the simple chemical structure of the drug precluded its redesign because any change in its chemical structure would create a new drug that would require the filing of a New Drug Application (NDA) with the FDA.¹⁸ Submitting an NDA is an "onerous and lengthy" process that generic-drug manufacturers avoid by producing a generic version of an existing drug, subject to a much quicker and less costly approval process.¹⁹ The Supreme Court held that, because it would be impossible for Mutual and other similarly situated manufacturers to comply with both state and federal law, federal law preempted New Hampshire's warning-based design-defect cause of action with respect to FDA-approved drugs sold in interstate commerce.²⁰

II. BACKGROUND

This section will trace the legal framework relevant to this case. Section A discusses the history of federal regulation of drugs and drug labeling. Section B then examines federal preemption in the drug industry. Finally, Section C considers New Hampshire design-defect law as it applies to *Mutual Pharmaceutical Co. v. Bartlett*.

14. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2472 (2013).

15. *Id.*

16. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475 (2013).

17. *Id.*

18. *Id.* at 2470-71.

19. *Id.* at 2471 (citing Report to Congressional Requesters, Government Accountability Office, Nov. 2006, New Drug Development, 26 BIOTECHNOLOGY L. REP. 82, 94 (2007)).

20. *Id.* at 2477.

A. FEDERAL REGULATION OF DRUGS AND DRUG LABELING

Federal regulation of drugs and drug labeling began in 1906, when Congress enacted the Federal Food and Drugs Act, prohibiting the manufacture or interstate shipment of adulterated or misbranded drugs.²¹ Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA) in 1938,²² requiring manufacturers to submit a NDA, including reports of studies and proposed labeling information, for approval by the FDA before allowing a new drug to be distributed.²³ Initially, the Act required the FDA to “prove harm” to prevent a drug from entering the market.²⁴ However, in 1962, Congress amended the FDCA, which shifted the burden of proof to the drug manufacturer to demonstrate the drug’s safety and effectiveness for its intended dosage and use.²⁵ These amendments also included a savings clause providing that a state law “would only be invalidated upon a ‘direct and positive conflict’ with the FDCA.”²⁶ A 2007 amendment to the FDCA gave the FDA the authority to require a manufacturer to change a drug’s label to account for safety information that becomes available after a drug has already been approved.²⁷ However, the manufacturer remains under a continuing duty to update drug labeling as needed.²⁸ In most cases, the manufacturer must submit a supplemental application seeking approval of proposed changes to a drug’s label before they can be implemented.²⁹ However, the manufacturer may make certain types of changes to a label upon submission of its supplemental application without prior approval.³⁰

21. *Wyeth v. Levine*, 555 U.S. 555, 566 (2009). According to the current text of the statute, “A drug or device shall be deemed to be adulterated . . . [i]f it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium.” 21 U.S.C. § 351(b) (2012).

22. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (2012).

23. *Levine*, 555 U.S. at 566.

24. *Id.* at 567 (citing 21 U.S.C. § 102(d) (2006); 21 U.S.C. § 104(b) (2006); Federal Food, Drug, and Cosmetic Act Amendments, Pub. L. No. 87-781, 76 Stat. 780, 784 (1962)).

25. *Id.*; See Pub. L. No. 87-781, 76 Stat. 780 (1962).

26. *Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (quoting Federal Food, Drug, and Cosmetic Act Amendments, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962)).

27. *Id.*

28. *Id.* at 567-68.

29. *Id.* at 568.

30. 21 C.F.R. § 314.70(c)(6) (2014). Permitted changes include “(i) Addition to a

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (the Hatch–Waxman Amendments to the FDCA) to allow FDA approval of generic versions of approved drugs at a reduced cost and within a shorter time frame.³¹ Under the Hatch–Waxman Amendments, manufacturers may submit an Abbreviated New Drug Application demonstrating that the generic drug is bioequivalent to its name-brand counterpart and that the drug’s labeling is identical to that of the name-brand version.³²

The role of the FDA has changed in the years following the enactment of the FDCA. Its oversight and control over the drug industry has increased; however, drug manufacturers still bear the burden of ensuring the safety of their drugs. Generic drugs need not be chemically identical to their brand-name counterparts but must be bioequivalent and must contain the same warning labels. As exemplified by the instant case, state product liability claims regarding prescription drugs could potentially impose duties that conflict with these federal requirements.

B. FEDERAL PREEMPTION IN THE DRUG INDUSTRY

The Supremacy Clause of the United States Constitution states that federal law “shall be the supreme Law of the Land,” superseding any conflicting state laws.³³ When a law does not contain an express preemption provision, state law may be impliedly preempted if it is “impossible for a private party to comply with both state and federal requirements”³⁴ (impossibility preemption) or if it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress”³⁵ (obstacle preemption).

specification or changes in the methods or controls to provide increased assurance that the drug substance or drug product will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess; (ii) A change in the size and/or shape of a container for a nonsterile drug product . . . ; (iii) Changes in the labeling to reflect newly acquired information . . . ” *Id.*

31. *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 98 (Cal. Ct. App. 2008).

32. *Id.*; Bioequivalence means that the generic drug contains the same active ingredients, dosage, strength, and route of administration as the approved brand-name drug, though it need not be chemically identical. 21 U.S.C. § 355(2)(A) (2012).

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

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

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

Where a statute includes no express preemption provision, there is a dichotomy within the Court over whether a possible instance of obstacle preemption necessitates an investigation of federal objectives. One faction favors a more liberal reading of the federal law, relying on the presumption 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,”³⁶ which Congress generally demonstrates through extensive federal regulation of a certain area, through an Act pertaining to a field where the federal interest is clearly dominant, or through an action whose object bears the same purpose as the character of the obligations it imposes.³⁷ The Court has historically relied on such a presumption in its analysis of preemption questions.³⁸ The other camp, who constituted the majority in *Bartlett*, advocates a more conservative reading of the federal law, relying on the theory that the Supremacy Clause includes a *non obstante* provision discouraging attempts to harmonize federal and state laws where a potential conflict arises.³⁹ This group maintains that “federal law should be understood to impliedly repeal conflicting state law” without the need for an investigation of congressional purposes.⁴⁰ Where compliance with both federal and state law is impossible, however, “[a] holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design.”⁴¹

When a federal statute does not include language clarifying whether it is intended to preempt state law claims, courts may seek the opinion of the relevant federal agency to inform their decision on the question of preemption.⁴² The Medical Device Amendments specifically grant the FDA the power to issue an

36. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *see also* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2591 (2011) (Sotomayor, J., dissenting); *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2483 (2013) (Sotomayor, J., dissenting).

37. *Rice*, 331 U.S. at 230.

38. Matthew J. Clark, *A Critical Analysis of PLIVA, Inc. v. Mensing*, 46 IND. L. REV. 173, 196 (2013).

39. Matthew J. Clark, *A Critical Analysis of PLIVA, Inc. v. Mensing*, 46 IND. L. REV. 173, 196-97 (2013) (citing Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 241-42 (2000)).

40. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580 (2011); *see also* *Wyeth v. Levine*, 555 U.S. 555, 583 (2009) (Thomas, J., concurring).

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

42. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2481 (2013) (Breyer, J., dissenting).

advisory opinion on preemption upon request from “[a]ny State, political subdivision, or other interested person.”⁴³ Historically, the FDA has allowed state tort claims to prevail without comment on the issue of preemption.⁴⁴ The 1962 amendments to the FDCA included a savings clause stating that “the amendments should not be construed to invalidate any provision of state law absent a ‘direct and positive conflict.’”⁴⁵ Additionally, in 1976, Congress enacted a provision expressly preempting state products liability claims against the manufacturers of medical devices.⁴⁶ Congress has never, however, passed an equivalent provision for prescription drugs,⁴⁷ suggesting a different stance on state claims against drug manufacturers. Beginning in 2002, though, the FDA has filed amicus briefs expressing the view that FDA approval should preempt failure-to-warn claims in prescription drug cases, formalizing this recommendation in the preamble to a 2006 measure regulating the content and format of prescription drug labels.⁴⁸

In 2007, the Supreme Court decided not to heed the FDA’s recommendation that the FDCA preempt state tort suits against drug manufacturers because Congress had not given the agency permission to preempt state law itself⁴⁹ and because of the FDA’s inconsistent positions, in light of its having stated that the proposed rule would not preempt state law only six years earlier.⁵⁰ In *Wyeth v. Levine*, the Court held that a failure-to-warn claim against a brand-name drug manufacturer was not an obstacle to the accomplishment of Congress’s purposes under the

43. 21 C.F.R. § 808.5(a) (2014).

44. David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure-To-Warn Claims*, 96 GEO. L.J. 461, 463 (2008).

45. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2484 (2013) (Sotomayor, J., dissenting) (quoting 21 U.S.C. § 202; Federal Food, Drug, and Cosmetic Act Amendments, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962)); see also *supra* Part II(A).

46. 21 U.S.C. § 360k(a) (2012) (stating that no State or political subdivision may establish any requirement relating to the safety of a medical device covered by the Act that differs from that established by the Act).

47. *Wyeth v. Levine*, 555 U.S. 555, 567 (2009) (citing 21 U.S.C. § 360k(a) (2006)).

48. Kessler & Vladeck, *supra* note 44, at 464; Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933-36 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601).

49. *Wyeth v. Levine*, 555 U.S. 555, 577 (2009).

50. Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, 65 Fed. Reg. 81,082, 81,103 (proposed Dec. 22, 2000) (to be codified at 21 C.F.R. pt. 201).

FDCA and therefore was not preempted.⁵¹ However, when injured consumers brought similar claims against a generic-drug manufacturer in *PLIVA, Inc. v. Mensing*, the Court reached a different result.⁵² In *Mensing*, the Court held that because FDA regulations require a generic drug's label to match that of the brand-name version, federal law preempted a failure-to-warn claim against the generic manufacturer under the doctrine of impossibility preemption.⁵³ The dissenting opinion, written by Justice Sotomayor and joined by Justices Ginsburg, Breyer, and Kagan, argued that Plaintiff's claim should not be preempted. The justices argued that, although a generic-drug manufacturer cannot independently modify its drug's label under federal law, taking the affirmative actions available to the manufacturer under federal law to induce a change in the label should bring it into compliance with its state law duty.⁵⁴ These actions might include initiating the "changes-being-effected" (CBE) process, writing "Dear Doctor" letters, and proposing a label change directly to the FDA.⁵⁵

The CBE regulation allows a drug manufacturer to update warning labels to increase safety without prior FDA approval provided that the manufacturer simultaneously file a supplemental application with the FDA.⁵⁶ In its amicus briefs, however, the FDA denied that a generic-drug manufacturer could lawfully engage in the CBE process except to update the generic drug's label to match its brand-name counterpart.⁵⁷ The majority accepted the FDA's interpretation of the CBE regulation with respect to generic-drug manufacturers.⁵⁸ The majority also deferred to the FDA's analysis that "Dear Doctor" letters⁵⁹ qualify as labeling and must be consistent with the drug's approved

51. *Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

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

53. *Id.*

54. *Id.* at 2585 (Sotomayor, J., dissenting).

55. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575 (2011).

56. *Id.*

57. *Id.*

58. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2575 (2011).

59. "DHCP letters are correspondence . . . intended to alert physicians . . . about important new or updated information regarding a human drug or biologic." U.S. DEPT OF HEALTH & HUMAN SERVS., ET AL., GUIDANCE FOR INDUSTRY AND FDA STAFF: DEAR HEALTH CARE PROVIDER LETTERS: IMPROVING COMMUNICATION OF IMPORTANT SAFETY INFORMATION (Jan. 2014), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM233769.pdf>.

labeling.⁶⁰ The dissent agreed that generic-drug manufacturers cannot fulfill their duty through the CBE process or Dear Doctor letters, but suggested that they may do so by reporting adverse reactions directly to the FDA.⁶¹ The majority rejected that theory because such changes could not be effected without third-party actions.⁶² That is, the FDA would have to mandate the proposed change and the brand-name counterpart would then have to implement it before it could be applied to the generic drug's label.⁶³ However, even brand-name drug manufacturers require the third-party action of FDA approval to make a permanent change to a drug label,⁶⁴ which has not deterred courts from holding them liable for state tort claims.⁶⁵ The majority's holding on this issue was misguided in its incongruity with the jurisprudence regarding brand-name drug manufacturers. In addition, the Court's decision resulted in disturbing policy concerns, discussed below.

Congress has never passed legislation to preempt claims against prescription drug manufacturers; however, it did enact such legislation regarding vaccines in 1986 when an increase in tort claims against their manufacturers threatened the stability of the market.⁶⁶ At the same time, the National Childhood Vaccine Injury Act (Vaccine Act) created a no-fault compensation program for those injured by vaccine side effects.⁶⁷

In sum, although the FDA has historically allowed state tort law to prevail without contention, it has changed its position in the last ten years. In amicus briefs and in the preamble for the 2006 amendments to its regulations, the FDA has expressed the view that its approval should preempt failure-to-warn claims against drug manufacturers. The Court has not adopted the agency's recommendations; however, it has held that failure-to-warn claims against generic-drug manufacturers are preempted while claims against brand-name manufacturers are not. Congress has yet to enact any legislation preempting tort claims

60. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2576 (2011).

61. *Id.* at 2584-85 (Sotomayor, J., dissenting).

62. *Id.* at 2578-79 (majority opinion).

63. *Id.*

64. 21 C.F.R. § 314.70(b)(2)(v)(A) (2014).

65. *See Wyeth v. Levine*, 555 U.S. 555, 571 (2009).

66. National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22(b)(1) (2012).

67. 42 U.S.C. § 300aa-10 (2012).

against drug manufacturers.

C. NEW HAMPSHIRE DESIGN-DEFECT LAW

Like many other states,⁶⁸ New Hampshire follows the strict liability approach to design defects set forth in the Restatement (Second) of Torts,⁶⁹ which stipulates that a manufacturer of a product is liable for a design defect if that product is “unreasonably dangerous.”⁷⁰ According to New Hampshire jurisprudence, this imposes upon the manufacturer a “duty to design his product reasonably safely for the uses which he can foresee.”⁷¹ New Hampshire law employs a “utility-risk” approach to determine whether a product is unreasonably dangerous, under which a jury must weigh the magnitude of the danger presented against the utility of the product.⁷² Some of the factors involved in the analysis include:

[T]he usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product’s effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.⁷³

If the jury determines that the risk of harm involved in using a product outweighs its benefit, the manufacturer will be held liable for a design defect.⁷⁴

III. THE SUPREME COURT’S DECISION

In *Mutual Pharmaceutical Co. v. Bartlett*, the United States Supreme Court addressed the general issue of whether federal law preempts state design defect claims against generic-drug manufacturers. The Court specifically focused on whether it was possible for drug manufacturers to comply with both the duties

68. Kristine Cordier Karnezis, Annotation, *Products liability: Modern Cases Determining Whether Product is Defectively Designed*, 96 A.L.R. 3d 22 § 3 (1979 & Cum. Supp.).

69. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013).

70. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

71. *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 847 (N.H. 1978).

72. *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001).

73. *Id.*

74. *Id.*

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imposed by state products liability law and those imposed by the FDCA.⁷⁵ In a 5–4 decision, the majority held that federal law preempts state products liability claims when the state law at issue imposes a duty on the manufacturer that conflicts with federal regulations.⁷⁶

The Court reached its decision by first considering the standard imposed by New Hampshire design defect law. The Court then discussed whether this duty conflicted with the standard imposed by federal law, ultimately concluding that it did. As a result, the Court determined that the FDCA preempted Bartlett’s claim in this case.

A. DID NEW HAMPSHIRE LAW IMPOSE A DUTY ON DEFENDANT?

Bartlett argued that Mutual’s drug was unreasonably dangerous because “[its] risks outweighed its benefits making it unreasonably dangerous to consumers.”⁷⁷ Although a jury agreed, the Court determined that the duty imposed on Mutual by such a standard conflicted with federal law.⁷⁸ Bartlett maintained that New Hampshire’s strict liability approach to products liability is “compensatory, not regulatory” and thus does not impose any duty on manufacturers.⁷⁹ Bartlett reasoned that the law does not punish a manufacturer for failing to satisfy a duty, such as the duty to avoid producing unreasonably dangerous products, but merely “redresses injuries.”⁸⁰ The Court refuted these assertions, finding that New Hampshire law requires manufacturers to ensure that their products are not “unreasonably dangerous.”⁸¹ To determine how manufacturers may accomplish this, the Court examined the three principal factors New Hampshire law employs to assess a product’s safety under its risk-utility approach to design defect claims:

[T]he usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product’s

75. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013).

76. *Id.*

77. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 34 (1st Cir. 2012), *rev’d*, 133 S. Ct. 2466 (2013).

78. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013).

79. Brief for Respondent at 19, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (No. 12-142), 2013 WL 602909, at *19.

80. *Id.*

81. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2474 (2013).

effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.⁸²

The Court determined that in order to increase the “usefulness” of a drug or reduce its “risk of danger,” addressing the first two factors, a manufacturer would generally be required to modify the drug’s design.⁸³ To satisfy the third factor, a manufacturer would have to strengthen the drug’s warnings, which would necessitate changing its labeling.⁸⁴

B. WAS IT IMPOSSIBLE FOR DEFENDANT TO COMPLY WITH BOTH STATE AND FEDERAL LAW?

The Court found that federal law preempted Bartlett’s claim because it was impossible for Mutual to comply with both its state-imposed duty to ensure that its drug was not unreasonably dangerous and its federally imposed duty not to modify the drug or its labeling.⁸⁵ The First Circuit acknowledged that Mutual could not legally redesign its drug and that the decision in *Mensing*, preempting failure-to-warn claims against generic-drug manufacturers, could extend to design defect claims as well.⁸⁶ However, the First Circuit determined that Mutual also had the option not to produce the drug at all.⁸⁷ The First Circuit relied on *Levine* for the proposition that the Supreme Court generally opposes preemption of state tort claims against drug manufacturers and noted that the Supreme Court had not yet explicitly extended its *Mensing* decision to design-defect claims.⁸⁸ The First Circuit also speculated that because Bartlett’s pharmacy removed her chance for a failure-to-warn claim under *Mensing* when it chose to dispense the generic form of Sulindac, the Supreme Court might be reluctant to deny her any avenue for relief by preempting the design-defect claim as well.⁸⁹ Contrary to the First Circuit’s conjectures, the Supreme Court rejected

82. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475 (2013) (quoting *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182 (N.H. 2001)).

83. *Id.*

84. *Id.*

85. *Id.* at 2475-76.

86. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 36-37 (1st Cir. 2012), *rev’d*, 133 S. Ct. 2466 (2013).

87. *Id.* at 37.

88. *Id.* at 38.

89. *Id.*

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Bartlett’s “stop-selling” argument, maintaining that exercising one’s option to stop acting had not defeated liability claims against an actor in prior cases.⁹⁰ According to the majority, allowing an actor to escape the impossibility of compliance with both state and federal law by ceasing to act would render impossibility preemption “all but meaningless” by negating its effects in virtually all instances where it might be implemented.⁹¹

C. JUSTICE BREYER’S DISSENT

In his dissent, Justice Breyer argued that compliance with both federal and state duties was not impossible for Mutual.⁹² Justice Breyer identified two actions that Mutual could take that, in his assessment, would not conflict with federal or state law: either refrain from doing business in the relevant state or pay the state penalty for failing to comply with the state law.⁹³ Justice Breyer further argued that although the views of the relevant government agency on the question of preemption may be informative, in this case the FDA’s position did not merit deference because the agency failed to hold hearings on the matter or solicit the opinions of the public and never solidified its views via regulations.⁹⁴ Justice Breyer disputed the majority’s analysis under impossibility preemption principles; however, he did not rule out the concept of preemption altogether.⁹⁵ Justice Breyer noted that although the FDCA does not include a general preemption clause, an obstacle preemption analysis might lead to the conclusion that the New Hampshire law poses an obstacle to fulfillment of the purposes of the FDCA.⁹⁶

D. JUSTICE SOTOMAYOR’S DISSENT

In her dissent, Justice Sotomayor reasoned that Bartlett’s design defect claim was distinct from her failure-to-warn claim—a theory rejected by the District Court of New Hampshire—and should not have been considered under failure-to-warn

90. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 (2013).

91. *Id.* (quoting *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579 (2011)).

92. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2480-81 (2013) (Breyer, J., dissenting).

93. *Id.* at 2481.

94. *Id.*

95. *Id.*

96. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2481-82 (2013) (Breyer, J., dissenting).

analyses.⁹⁷ She also argued that federal law should not preempt Bartlett's design-defect claim and that the majority applied preemption principles improperly and misinterpreted New Hampshire law.⁹⁸ Justice Sotomayor pointed out that in the absence of "a direct conflict between two mutually incompatible legal requirements," the intentions of Congress must be considered, particularly in light of the presumption against preemption.⁹⁹ Here, she argued that federal drug law and state tort law have historically operated as complementary modes of promoting consumer safety and noted that FDA approval of a drug does not guarantee its safety.¹⁰⁰ To divine the intentions of Congress in enacting the FDCA, Justice Sotomayor noted the savings clause included in the 1962 amendments and highlighted the fact that Congress never adopted an express preemption clause for prescription drugs, even when it enacted one for medical devices.¹⁰¹ Justice Sotomayor referred to the limitations of preapproval drug testing in detecting adverse effects that are rare or have long latency periods and suggested that Congress never created a federal cause of action for injured consumers because it deemed state tort law adequate in providing consumers with the opportunity for relief.¹⁰² Considering the presumption against federal preemption together with her conclusion that Congress intended to protect consumer safety through passage of the FDCA, Justice Sotomayor disagreed with the Court's finding of federal preemption.¹⁰³

Additionally, Justice Sotomayor argued that New Hampshire products liability law does not require a manufacturer to take any action in response to a design-defect claim.¹⁰⁴ She referred to the Court's opinion in *Bates*, which rejected preemption of a design-defect claim that would likely motivate a label change.¹⁰⁵ She suggested that Bartlett's claim here would have a similar effect, providing Mutual with an incentive to change its drug's design or

97. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2482 (Sotomayor, J., dissenting).

98. *Id.* at 2483.

99. *Id.* at 2486.

100. *Id.* at 2483-84.

101. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2484 & n.2 (2013) (Sotomayor, J., dissenting).

102. *Id.* at 2484-85.

103. *Id.* at 2482-83.

104. *Id.* at 2488.

105. *Id.* (citing *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 444-46 (2005)).

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label without imposing an affirmative duty to act.¹⁰⁶ Justice Sotomayor distinguished this case from *Mensing*, where the applicable state tort law *required* modification of the drug's label.¹⁰⁷ She noted that under New Hampshire law, a manufacturer of a drug deemed unreasonably dangerous has various options including modifying the drug's design or label, removing the drug from the market, or paying compensation.¹⁰⁸

Further, Justice Sotomayor agreed with Justice Breyer that the Court should have considered obstacle preemption rather than impossibility preemption.¹⁰⁹ However, she argued that even that approach would not preempt Bartlett's claim, considering that the purpose of the FDCA was to protect the safety of consumers.¹¹⁰ She concluded that "state tort law generally complements the statute's safety goals," and therefore would not subvert Congress's intentions in enacting the FDCA.¹¹¹

Justice Sotomayor concluded her dissent by addressing the policy consequences of the Court's decision, noting that the FDCA's premarket approval process has served as a model for other products.¹¹² She stated that preempting design-defect litigation could have "serious consequences for product safety" because design-defect claims can identify product safety issues and "provid[e] incentives for manufacturers to remove dangerous products from the market promptly."¹¹³ Justice Sotomayor argued that by effectively providing immunity to manufacturers of products that require preapproval, the Court would force the public to rely on imperfect government agencies to recall unsafe products and leave injured consumers without a remedy.¹¹⁴ Accordingly, she indicated that Congress should make preemption decisions because it has the ability to enact alternative means for injured parties to secure compensation, as it did for those harmed by vaccines with passage of the Vaccine

106. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2489 (2013) (Sotomayor, J., dissenting).

107. *Id.* (citing *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2573-74, 2577-78 (2011)).

108. *Id.* at 2491.

109. *Id.* at 2492-93.

110. *Id.* at 2493-94.

111. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2493-94 (2013) (Sotomayor, J., dissenting).

112. *Id.* at 2495.

113. *Id.*

114. *Id.*

Act.¹¹⁵

IV. ANALYSIS

In considering whether federal law preempted Bartlett's claim due to impossibility, the majority and Justice Sotomayor's dissent disagreed on two major points: whether New Hampshire law imposed an affirmative duty on Mutual and whether the question of federal preemption requires consideration of Congress's intentions in enacting the relevant legislation. In her dissent, Justice Sotomayor suggested that the majority misinterpreted both New Hampshire state law and federal law in concluding that federal law preempted the claim.¹¹⁶ Although the Court correctly found that state law imposed a duty on Mutual, it erred in oversimplifying the nature of the duty. An examination of the duty reveals that Mutual could not have reasonably taken action to fulfill the state-imposed duty without violating federal law. Therefore, the Court correctly applied impossibility preemption. However, this result leads to unreasonable consequences that conflict with Congress's intent in enacting generic-drug law and leave generic-drug consumers without adequate remedies for their injuries.

Part A of this section discusses the Court's oversimplification of the duty imposed on the defendant. Part B considers the Court's application of impossibility preemption and concludes that the Court correctly applied this analysis, but that the analysis ultimately leads to unreasonable consequences. Part C predicts the implications of Bartlett on the drug manufacturing industry.

A. THE COURT OVERSIMPLIFIED THE DUTY NEW HAMPSHIRE LAW IMPOSED ON DEFENDANT

New Hampshire jurisprudence defines the state's position on the risk-utility test for an unreasonably dangerous product as a "multifaceted balancing process" in which many factors are considered and weighed against each other.¹¹⁷ New Hampshire has explicitly rejected the alternative design test endorsed by the Third Restatement of Torts, instead considering the availability

115. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2495-96 (2013) (Sotomayor, J., dissenting).

116. *Id.* at 2485.

117. *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 847 (N.H. 1978).

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of a reasonable alternative design as one of the many factors to be weighed in the risk-utility analysis.¹¹⁸ In her dissent, Justice Sotomayor suggested that a drug's warning label is simply another factor to be weighed in a risk-utility analysis and concluded that New Hampshire law does not impose a duty to redesign a defective product.¹¹⁹ In Justice Sotomayor's interpretation of New Hampshire law, the availability of an alternative design and the possibility that a warning could be strengthened may contribute to a conclusion that a product's design is unreasonably dangerous, but would not obligate the product's manufacturer to actually make changes that would improve its safety. Instead, she argued that "New Hampshire's design-defect claim creates an incentive for drug manufacturers to make changes" to the product,¹²⁰ and described the impetus for a manufacturer to make such changes as an "incidental regulatory effect"¹²¹ of exposure to liability rather than an affirmative duty.

Justice Sotomayor's assessment is sensible. Although liability for an unreasonably dangerous design indicates that a product's manufacturer breached its duty to "design his product reasonably safely for the uses which he can foresee,"¹²² such a finding does not place any affirmative mandates on the manufacturer to modify the design going forward. Liability imposes a monetary obligation on the manufacturer; however, the manufacturer may choose to continue to make the product with the defective design.¹²³ The risk of additional lawsuits may serve as an incentive to modify the product's design; however, in the absence of an injunction, the manufacturer is under no obligation to change the design.¹²⁴ For example, in the case of *In Re Ford Motor Co. E-350 Van Products Liability Litigation (No. II)*, a class of plaintiffs sought an injunction preventing the defendant from continuing to manufacture a van designed with a high center of gravity that resulted in an increased probability of rolling over,

118. *Vautour v. Body Masters Sports Indus., Inc.*, 784 A.2d 1178, 1182-84 (N.H. 2001).

119. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2488 (2013).

120. *Id.*

121. *Id.* (quoting *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-186 (1988)).

122. *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 847 (N.H. 1978).

123. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2491 (2013) (Sotomayor, J., dissenting).

124. *See Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 445 (2005).

even though a number of personal injury lawsuits had already been filed against the defendant due to rollovers.¹²⁵ The defendant automotive corporation chose to continue to produce vans with the unsafe design and was not forbidden to do so despite previous findings of liability.¹²⁶ However, state tort claims for damages have been construed in New Hampshire jurisprudence to impose a duty on defendants even if the defendant is not compelled to take action to fulfill that duty.¹²⁷ Therefore, under New Hampshire law, a finding that a product is unreasonably dangerous implies a duty to alter something about the product to render it reasonably safe for any foreseeable use.¹²⁸

If compliance with a state law duty would require violation of a federal law, a preemption analysis is necessary. In *Bartlett*, the Supreme Court reasoned that because federal law prevented Mutual from modifying the chemical structure of the drug under the FDCA and from altering the warning label following *Mensing*, it was impossible for Mutual to comply with its state law duty.¹²⁹ However, as Justice Sotomayor indicated, the drug's warning label is just one among many potential factors considered in determining whether a drug is unreasonably dangerous under New Hampshire law.¹³⁰ An adequate warning label would not necessarily protect the drug's manufacturer from liability.¹³¹ In fact, the trial court suggested a distinction between the issues of drug design and warning labels by dismissing Bartlett's failure-to-warn claim (but not the design-defect claim) and by instructing the jury not to consider Mutual's failure to alter the drug's warning label in its contemplation of the design-defect claim.¹³² In *Mensing*, the nature of the duty that the drug manufacturer breached under the failure-to-warn claim was clear: the duty to provide an adequate warning label.¹³³ The drug's warning label was the only factor in question and modifying the label was the only possible action that could have released the defendant from

125. *In Re Ford Motor Co. E-350 Van Prods. Liab. Litig.* (No. II), No. 03-4558, 2012 WL 379944, at *1 (D.N.J. Feb. 6, 2012).

126. *See, e.g., Pierson v. Ford Motor Co.*, No. C 06-6503 PJH, 2009 WL 2566950, at *1 (N.D. Cal. Aug. 18, 2009).

127. *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 847 (N.H. 1978).

128. *Id.*

129. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475 (2013).

130. *Id.* at 2488 (Sotomayor, J., dissenting).

131. *Id.*

132. *Id.* at 2490.

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

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liability.¹³⁴ In *Bartlett*, as the majority recognized, the nature of the duty was more complicated to discern because a number of factors must be considered and no single action would necessarily protect the manufacturer from liability.¹³⁵ Nevertheless, the Court identified only two potential actions that Mutual could have taken: chemically altering the drug itself or modifying its warning label.¹³⁶ Either of these actions would potentially have changed the drug's risk-utility balance. However, the former action would not have been physically possible due to the simple chemical structure of the drug and the prohibitions of the FDCA.¹³⁷ *Mensing* prohibited the latter action.¹³⁸

The dissents highlighted two alternative actions that Mutual could have taken: refrain from selling its drug in states that impose those obligations or pay a penalty for noncompliance with the law in those states.¹³⁹ These options seem to provide drug manufacturers with additional routes to remain in compliance with both state and federal law. However, neither of these actions would fulfill the New Hampshire duty to increase the drug's safety because neither action would affect its risk-utility profile. As the majority recognized, leaving the market is usually an option in a defective design suit; however, it has not prevented preemption in prior cases.¹⁴⁰ Furthermore, the dissents provided no examples of instances where a drug manufacturer has implemented either of the proposed alternatives.

Despite the absence of a potential course of action that would clearly change the drug's risk-utility profile without modifying either its chemical structure or warning label, the Supreme Court oversimplified Mutual's duty under New Hampshire law by limiting it to these two options. In *Mensing*, the Court found that although the defendant drug manufacturer might have been able to comply with its state law duty to strengthen its drugs' warnings if it had taken steps to petition the FDA, and the FDA had responded by mandating a label modification, the speculative possibility that such a series of events would take place was

134. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2573 (2011).

135. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2474 (2013).

136. *Id.* at 2475-76.

137. *Id.* at 2475.

138. *Id.* at 2476.

139. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2481 (2013) (Breyer, J., dissenting); *id.* at 2491 (Sotomayor, J., dissenting).

140. *Id.* at 2478 (majority opinion).

insufficient to make compliance with both state and federal standards possible.¹⁴¹

Here, the questionable prospect that Mutual might alter its drug's risk-utility profile sufficiently to satisfy a jury that the drug is not unreasonably dangerous by altering its chemical structure or warning label similarly fails to provide adequate support for equating the duty to produce a drug that is not unreasonably dangerous with a duty to modify its structure or label. First, such modification would not guarantee compliance with the state standard. Second, there could be alternative methods, not discussed in the *Bartlett* case, for a manufacturer of a drug deemed unreasonably dangerous to alter the drug's risk-utility profile without changing its chemical composition or its warning label. For example, gaining FDA approval for the drug to treat a serious illness that no other drug has effectively treated could increase a drug's utility adequately to offset the risk without requiring any actual change to the drug or its label. A finding that avoiding certain foods or chemicals while taking the drug drastically reduced its risk of harm would also change the drug's risk-utility profile without modifying the drug itself (although additional warnings would probably be warranted). These examples illustrate the complexity of the duty imposed by New Hampshire law and the imprudence of reducing it to a binary standard, though neither of the suggested paradigms would be feasible for Mutual in this case.

In conclusion, New Hampshire law imposed a duty on Mutual to design a safe product. Although Mutual's only viable courses of action to fulfill that duty were forbidden by federal law, it is not clear that either of those actions would necessarily have altered the drug's risk-utility profile sufficiently to render it reasonably safe. In addition, a drug's risk-utility profile could theoretically be modified to improve the drug's safety without taking either course of action. Therefore, although New Hampshire imposed an affirmative duty on manufacturers to design a safe product, the duty cannot be simplified to a binary standard of modifying either the drug's design or its warning label.

141. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579 (2011).

**B. THE COURT CORRECTLY APPLIED IMPOSSIBILITY
PREEMPTION, BUT WITH UNREASONABLE RESULTS.**

In the absence of an express preemption clause, federal preemption of a state tort claim depends upon “whether there is an irreconcilable conflict between the federal and state standards or whether the imposition of a state standard in a damages action would frustrate the objectives of the federal law.”¹⁴² The state standard here involved designing a drug that was not unreasonably dangerous. Federal law forbade the only actions Mutual could have taken to bring its product into compliance with that standard. Therefore, under a theory of federal preemption that fails to account for Congress’s purpose in enacting the federal law, the Court correctly found that federal law preempted Bartlett’s claim due to impossibility of compliance with the competing federal and state standards.

While the Supreme Court’s reduction of the state-imposed duty to a modification of the drug’s chemical structure or warning label was an oversimplification, those were the only two available courses of action that could potentially change the drug’s risk-utility profile. As the Court discussed, changing the drug’s chemical composition could increase its “usefulness” or reduce its “risk of danger.”¹⁴³ Strengthening its warning could “avoid an unreasonable risk of harm from a foreseeable use.”¹⁴⁴ Both of these actions might, but would not necessarily, render the drug reasonably safe from a jury’s perspective. The two alternative actions proposed by the dissents, to refrain from selling the drug in New Hampshire or to pay a fine for failing to comply with the state law duty, would not alter the drug’s risk-utility profile and hence would not bring Mutual into compliance with its state law duty. Compliance with that duty would, in this case, require an action that is forbidden by federal law. Therefore, the Court was correct in finding that it was impossible for Mutual to comply with both state and federal standards. The law requires that federal law preempt state law where such a conflict arises,¹⁴⁵ so the Court was also correct in holding that federal law preempted Bartlett’s claim here.

142. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 239 (1984).

143. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475 (2013).

144. *Id.*

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

The Court's finding that federal law preempted Bartlett's claim due to Mutual's inability to modify its drug's design or warning label, though correct, seems unreasonable. Consider the case of a product whose concept itself is unreasonably dangerous, barring the possibility of improving its risk-utility ratio by modifying its design or warning label. In such a case, it would be impossible for the manufacturer to comply with the state law duty the Court identified in its decision (the duty to increase the safety of the product in question). Should it make a difference that in the hypothetical case, compliance is impossible due to the nature of the product, whereas in *Bartlett*, compliance was impossible due to federal law? Although the mechanism for impossibility differs, the result is the same. Should the hypothetical product manufacturer be allowed to escape liability for harm caused by its unreasonably dangerous product simply because it could not have designed the product more safely?

Because Mutual could not have complied with the duty imposed by state law without violating federal law, the doctrine of impossibility preemption obligated the Supreme Court to hold that federal law preempted Bartlett's claim. If the Court had not previously ruled in *Mensing* that impossibility preemption bars failure-to-warn claims against generic-drug manufacturers,¹⁴⁶ the outcome here would have been very different. Although Mutual still would not have been able to alter the drug's chemical composition, Mutual might have been able to comply with the state law duty to design a drug that was not unreasonably dangerous for a foreseeable use by modifying Sulindac's warning label. As compliance with both federal and state standards would not have been impossible, the preemption question would have rested on whether the duty imposed by Bartlett's claim posed an obstacle to the fulfillment of Congress's purposes in enacting the FDCA. This would have allowed for a much stronger argument against preemption. In cases where state law may pose an obstacle to the fulfillment of Congressional purposes, the Supreme Court has historically accepted the presumption against preemption.¹⁴⁷ An analysis of Congress's intentions in enacting the FDCA and its Hatch–Waxman Amendments would have revealed a consumer-oriented goal of safely making prescription drugs available to the public at a reduced cost.¹⁴⁸ The Court

146. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581-82 (2011).

147. *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 449 (2005).

148. *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 98 (Cal. Ct. App. 2008).

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would not likely find that New Hampshire's product liability law posed any obstacle to the fulfillment of that goal. However, Mutual still could have argued that holding generic-drug manufacturers liable for harm caused by their drugs would pose an obstacle to those purposes by inducing manufacturers to increase costs to offset liability. Instead, the Court negated the need for any analysis of Congressional intent, leaving Congress with the burden of amending the FDCA or enacting new legislation to resolve any issues that were not explicitly addressed in the statute.

Interestingly, the same four Supreme Court justices—Breyer, Ginsburg, Sotomayor, and Kagan—comprised the dissents in both *Bartlett* and *Mensing*. Their opinions in both cases arose out of similar policy concerns, particularly the inability of those harmed by generic drugs to recover for their injuries, decreased incentives for generic-drug manufacturers to monitor and report risks associated with their drugs, and the discrepancy in liability of generic and brand-name manufacturers.¹⁴⁹ If the majority had taken these serious policy concerns into account rather than focusing on a strict, conservative reading of the FDCA, it might have reached a different conclusion. The sole dissenting opinion in *Mensing* involved a strong argument against preemption, suggesting that the question of whether a generic-drug manufacturer fulfilled its state law obligation to provide adequate warnings on its drug labels should be left to the finder of fact based on the available steps it had taken to improve its labeling.¹⁵⁰ The dissents in *Bartlett* are less compelling because the alternative avenues proposed for Mutual to comply with its state law duties without violating federal law would not actually meet the state-imposed obligation of altering the drug's risk-utility profile to increase its safety. In *Bartlett*, the dissenting justices strived for a result that would protect design-defect plaintiffs from the unforgiving situation in which the *Mensing* decision left failure-to-warn plaintiffs.

The Supreme Court's decision to preempt failure-to-warn claims in *Mensing* left *Bartlett* with no recourse for her devastating injuries but to attempt a design-defect claim arguing

149. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2592-93 (2011) (Sotomayor, J., dissenting).

150. *Id.* at 2589.

that Mutual could have satisfied its state law duty while remaining in compliance with the FDCA. Although Bartlett's arguments were not generally consistent with the jurisprudence, the Court had never before categorically rejected the viability of such a claim. With its decision in *Bartlett*, the Supreme Court has effectively denied victims of injury caused by generic drugs any chance for recovery. The future implications of this decision, discussed below, illustrate how the Court's decision to extend federal preemption of state tort claims against generic-drug manufacturers to design-defect claims presents obstacles to the Congressional objectives of the FDCA.

C. FUTURE IMPLICATIONS OF *BARTLETT*

Although the Court decided this case correctly based on applicable law, the decision will have several harmful implications. First, persons injured as a result of design defects in generic drugs will have no remedy. Second, generic-drug manufacturers will have no incentive to remove harmful drugs from the market until compelled to do so by the FDA—a complex and potentially lengthy process that may leave multitudes of consumers vulnerable to a drug's harmful effects in the interim. Third, generic-drug manufacturers will have no incentive to monitor and report harmful side effects of their drugs, further hampering the FDA's regulation of these drugs.

The Court's decision effectively leaves patients injured by generic drugs without remedy. Federal law does not preempt similar claims against brand-name drug manufacturers;¹⁵¹ however, in many cases, consumers do not have the ability to choose a brand-name drug rather than a generic one. Some states mandate that pharmacists dispense the generic version unless otherwise specified by the patient's physician.¹⁵² The price of the drug or the patient's insurance company may also prohibit the patient from selecting the brand-name version.¹⁵³ As a result of this ruling, like Bartlett, most patients harmed by a design defect in a generic drug will have no legal remedies available for their injuries.

This elimination of tort liability for generic-drug manufacturers will also expose the public to a greater risk of

151. *E.g.*, *Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

152. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2592 (Sotomayor, J., dissenting).

153. *Id.*

harm. Typically, successful damages claims against a drug manufacturer provide a strong incentive for the manufacturer to remove the drug from the market or at least modify it to avoid future liability.¹⁵⁴ Without the risk of liability, generic-drug manufacturers will have no incentive to modify or remove a drug that has caused injury until it has caused harm to a large enough portion of its consumers to either impact its sales or prompt the FDA to require the drug's modification or removal from the market. The FDA tends to issue such mandates only after receiving a significant number of reports of adverse reactions, and in the past, litigation has informed the FDA's decisions in some cases.¹⁵⁵ Without tort claims as a source of information about adverse drug effects, it will likely take longer for the FDA to collect adequate data, leaving more consumers exposed to the risk of injury in the meantime.

The Court's decision will also remove generic-drug manufacturers' incentives to report adverse reactions to the FDA. The law requires drug manufacturers to submit reports of adverse reactions to the FDA.¹⁵⁶ Nevertheless, most adverse reactions go unreported.¹⁵⁷ Without tort liability as a motivating factor, generic-drug manufacturers will be even less inclined to monitor and report adverse reactions to their drugs.

Congress could intervene in two ways to restore some recourse to the patient injured by generic drugs in the future: pass an amendment to the generic-drug legislation including an express non-preemption clause or set up a no-fault compensation program for those injured by generic drugs, similar to the one established for those injured by vaccinations. Adding a non-preemption clause to the legislation would explicitly demonstrate

154. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2488 (2013) (Sotomayor, J., dissenting).

155. Kessler & Vladeck, *supra* note 44, at 477.

156. 21 C.F.R. § 314.80(b) (West, Westlaw through June 12, 2014; 79 FR 33835).

157. Kessler & Vladeck, *supra* note 44, at 490 (citing *Reauthorization of the Prescription Drug User Fee Act: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 107th Cong. 49 (2002) (statement of Rep. Henry A. Waxman)). Two possible reasons for the underreporting of adverse reactions include the difficulty physicians face in determining whether the event is associated with use of the drug or a symptom of the underlying illness and the challenge of causally linking the event with the drug when the event is one that commonly occurs in the general population, such as heart attack. See Christopher R. Page, Comment, *These Statements Have Not Been Approved by the FDA: Improving the Postapproval Regulation of Prescription Drugs*, 88 OR. L. REV. 1189, 1199-1200 (2009).

Congress's intention to allow state tort claims against generic-drug manufacturers despite the regulations in the FDCA. This action would reinstate tort liability for generic-drug manufacturers and offer a remedy to injured patients like Bartlett through the court system. Alternatively, a no-fault compensation program would continue to protect generic-drug manufacturers from liability and would limit the potential recovery for injured consumers. Unlike Bartlett, however, these consumers would receive some compensation for their injuries.

The future implications of the Court's decision are alarming. It is ironic that although Congress sought to benefit the public by making affordable drugs more widely available, the Supreme Court's decision in *Bartlett* will shield drug companies from liability for the public's increased exposure to risk created by the prevalence of those drugs. Of course, there are risks associated with taking any medication, generic or not; and by increasing the public's access to these drugs, Congress also increased its potential exposure to adverse drug reactions. However, there is no indication in the history of generic-drug legislation that Congress intended to leave victims of such harm without recourse. While the Court's decision may have applied the law correctly, the direction generic-drug law has taken with *Mensing* and now *Bartlett* fails to serve the interests of Congress or the American public.

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