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FDA APPROVAL OF DRUGS AND DEVICES: PREEMPTION OF STATE LAWS FOR “PARALLEL” TORT CLAIMS

MARCIA BOUMIL*

I. INTRODUCTION

The U.S. Supreme Court’s important ruling in *Mutual Pharmaceutical Co., Inc. v. Bartlett*¹ concerns whether the Food and Drug Administration’s (“FDA”) approval of a generic drug insulates the drug manufacturer from liability under state tort laws from claims of injury due to an alleged “design defect.”² The Court previously ruled that FDA approval does not preempt state law claims based upon failure-to-warn, at least with respect to brand name products.³ In contrast, the Court previously ruled that the federal regulatory process leading to FDA approval of generic equivalents of brand drugs—and designation of the drug label—*does* preempt state law as to claims that challenge the warnings that accompany generic drugs.⁴ Thus, generic manufacturers are held immune from liability under state law for product liability, at least as to alleged failure-to-warn of adverse effects.⁵ This is primarily because generic drug manufacturers have no control over the drug label, which the FDA established in consultation with

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1. 133 S. Ct. 2466 (2013).

2. *See id.* at 2470 (holding that federal law preempts state design regarding generic drug adequacy of a warning in design-defect liability).

3. *See Wyeth v. Levine*, 555 U.S. 555, 581 (2009) (concluding that the plaintiff’s state law failure-to-warn claim was not preempted by defendant’s federal-law obligations and that Congress’ purpose was not obstructed).

4. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011) (holding that the federal drug regulations for generic drug manufacturers preempt the state-law claims that conflict with those regulations).

5. *See id.* (holding that where federal drug regulations directly conflict with a duty to warn imposed by state law, the state law will be preempted).

the brand manufacturer.⁶ In *Bartlett*, however, the issue was not failure-to-warn, but rather the design of the generic counterpart.⁷ Although the active ingredients are chemically equivalent, a generic is not an identical drug.⁸ The plaintiff in *Bartlett* alleged that the generic equivalent, also approved by the FDA, was flawed by a design-defect that made it unsafe for sale under state law.⁹

In each of these cases, the underlying issue has been whether the federal regulatory process leading to FDA approval of drugs and medical devices “preempt” state laws as to the safety issues addressed through the approval process. Thus, to summarize the applicable law prior to *Bartlett*, the Court had upheld failure-to-warn¹⁰ claims against the brand (preemption denied) but denied failure-to-warn¹¹ claims against the generic (preemption upheld); the Court has also denied device manufacturers’ liability for most product liability-related claims¹² (preemption upheld) pursuant to a specific statutory provision.¹³ By a vote of 5-4, *Bartlett* has now denied liability of generic manufacturers on the basis of design-defect.¹⁴ Following the Supreme Court opinion, however, the FDA set forth its agenda, which includes proposing a rule that would allow generic drug makers to revise their drug labels.¹⁵ If created and adopted, this rule

6. See *id.* at 2574–75 (stating that the FDA regulates warning labels).

7. See *Bartlett*, 133 S. Ct. at 2470 (explaining the design-defect cause of action against the generic manufacturer, and the inherent problems with such a cause of action).

8. See *Facts About Generic Drugs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm> (last updated Sept. 19, 2012) (noting the differences between generic and brand name drugs, which include variations in inactive chemical ingredients and rate of absorption).

9. See *Bartlett*, 133 S. Ct. at 2471–72 (referencing the plaintiff’s design-defect claim); see also *PLIVA*, 131 S. Ct. at 2572 (framing the question as whether or not the federal drug regulations preempt state law claims).

10. See *Wyeth v. Levine*, 555 U.S. 555, 581 (2009) (allowing the state failure-to-warn claim as supported by the history of co-existence between state and federal law and the FDA’s recognition of state law remedies).

11. See *PLIVA*, 131 S. Ct. at 2571 (holding that the federal regulations applicable to generic drug manufacturers preempt state law claims).

12. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (finding that manufacturer liability for state product liability claims are preempted to the extent that the state law requirements are different from, or in addition to the federal requirements).

13. See 21 U.S.C. § 360(k)(a)(1) (2012) (prohibiting the imposition of state law requirements different from, or in addition to federal law requirements); see also *Riegel*, 552 U.S. at 330 (noting that state law requirements are preempted to the extent that they are different from, or in addition to federal requirements).

14. See *Bartlett*, 133 S. Ct. at 2469, 2470 (holding that state law design-defect claims based on the adequacy of the warning label are preempted).

15. See Alexander Gaffney, *FDA Proposes Groundbreaking Overhaul of Generic Drug Labeling Regulation*, REG. AFF. PROF. SOC’Y (Nov. 11, 2013),

could again alter the landscape of liability for generic manufacturers.¹⁶ Further, the related issue (which is still unresolved by the high court and is the subject of a split among the circuit courts)¹⁷ is whether FDA approval of medical *devices* preempts *all* state law actions, thus insulating device manufacturers from product liability claims under all circumstances.¹⁸ This Article will address each of these issues, as well as the related issue of whether off-label use of FDA-approved medical devices give rise to liability.¹⁹

II. BACKGROUND

The FDA, pursuant to the Federal Food, Drug, and Cosmetic Act²⁰ (“FDCA”), is charged with the oversight of pharmaceutical and medical device production, sales, labeling, and marketing.²¹ Pursuant to the FDCA mandate, the FDA follows a rigorous approval process for new drugs and devices that requires each product to be tested for safety and, in the case of drugs, efficacy of each intended use.²² A New Drug Application (“NDA”) requires the manufacturer to submit reports of its clinical investigations,²³ non-clinical investigations to the extent relevant, and “any other data or information relevant to an evaluation of the safety and effectiveness of the

<http://www.raps.org/regulatoryDetail.aspx?id=9625#> (describing the agenda following the *Bartlett* decision as including a proposed rule for generic manufacturers to apply for a labeling change).

16. See Justin Hakes, *U.S. Chamber Decries FDA’s Proposed Rule on Generic Prescription Drug Labeling*, *BUS. WIRE* (Nov. 8, 2013), <http://www.businesswire.com/news/home/20131108005889/en/U.S.-Chamber-Decries-FDA%E2%80%99s-Proposed-Rule-Generic#.VBDI8PldWWY> (citing concerns that the proposed rule would allow a flood of litigation against generic drug manufacturers).

17. *Cf. Messner v. Medtronic, Inc.*, 975 N.Y.S.2d 367 (N.Y. Sup. Ct. 2013) (unpublished opinion) (explaining that the Supreme Court did not delineate what state parallel claims would survive preemption, and that the Fifth, Seventh, Ninth, and possibly Eighth Circuits, have allowed parallel state law causes of action for certain violations).

18. See *Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1084 (D. Or. 2013) (discussing the issue of whether or not all parallel state law claims are preempted by FDA approval of medical devices).

19. See *infra* Parts IV, V.

20. See 21 U.S.C. § 301 (2012).

21. See generally 21 U.S.C. § 393(a)–(b) (2012) (establishing the FDA’s mission as including the oversight of regulated products, including drugs and devices); see, e.g., *id.* § 355(b)(1)(B)–(F) (outlining the FDA’s oversight of new drug production, sales, and marketing); see also, e.g., *id.* § 360e(c)(1) (outlining the FDA’s oversight of new devices, including production, sales, and marketing).

22. See 21 U.S.C. § 355 (detailing the application process for new drugs); see also *Valley Drug Co. v. Geneva Pharms.*, 344 F.3d 1294, 1296 (11th Cir. 2003) (citing the inclusion of efficacy studies in new drug applications).

23. 21 U.S.C. § 355(b)(1)(A).

drug product . . . from any source.”²⁴ The FDA employs a standard stating that the drugs’ “probable therapeutic benefits must outweigh its risk of harm.”²⁵

The approval process for generic drugs follow a different path.²⁶ In order to expedite the approval of generic drugs, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act (“Hatch-Waxman”).²⁷ Hatch-Waxman encourages competition among generic manufacturers by allowing generic competitors to “piggyback” on FDA-approved drugs by means of an Abbreviated New Drug Application.²⁸ A generic competitor must demonstrate that its product is the chemical equivalent to the brand drug.²⁹ With respect to pharmaceuticals, once a product is deemed safe and effective for one or more uses, the manufacturer creates a drug label.³⁰

The function of the drug label is to inform prescribers and consumers through the publication of the established name of the drug, its ingredients, indications, directions for use, and summary of its adverse effects, contraindications, and effectiveness.³¹ If the manufacturer fails to provide a complete and accurate drug label, or if the manufacturer otherwise suggests that the drug may be prescribed or recommended for other uses not approved by the FDA, it is considered “misbranding,” and may subject the manufacturer to civil and criminal penalties.³² It is important to note that manufacturers of generic drugs are prohibited from altering the drug label.³³ Indeed, approval of the generic drug can be withdrawn if the label is changed, resulting in a “misbranding” of the drug.³⁴

24. 21 C.F.R. § 314.50(d)(5)(iv) (2013).

25. See *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 140 (2000) (describing the FDA’s cost benefit analysis involved in approving new drugs).

26. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013) (describing the approval process for generic drugs, generally).

27. See *id.* (recounting the adoption of the Hatch-Waxman Act).

28. See Joel Graham, Note, *The Legality of Hatch-Waxman Pharmaceutical Settlements: Is the Terazosin Test the Proper Prescription?* 84 WASH. U. L. REV. 429, 434 (2006) (describing how Hatch-Waxman encourages “piggybacking”).

29. See *Bartlett*, 133 S. Ct. at 2471 (describing the aspects of chemical equivalency mandated by Hatch-Waxman).

30. See 21 C.F.R. § 314.50 (2013) (describing the approval of a new drug based on the FDA’s safety determination, which also allows the manufacturer to finalize the proposed label).

31. See 21 U.S.C. § 352(a), (e), (n) (2012) (prescribing the factors that the drug label must meet in order to avoid being deemed misbranded).

32. See *id.* § 355(d) (outlining the classification of misbranding by the FDA).

33. See *Bartlett*, 133 S. Ct. at 2471 (noting that generic manufacturers are barred from changing the drug label).

34. See 21 C.F.R. § 314.150(b)(10) (2014) (explaining that approval can be withdrawn if the labeling for the drug product is “no longer consistent” with the listed drug that the abbreviated NDA refers to).

The FDA's authority, which does not cover the practice of medicine, does not, however, prevent physicians from prescribing approved drugs "off label"³⁵ (which means treating conditions not specifically approved by the FDA³⁶). Off-label use is common and, indeed, it is frequently even the standard of care.³⁷ As a result, the American Medical Association ("AMA") has consistently taken the position that "a physician may lawfully use an FDA-approved drug product or medical device for an unlabeled indication"³⁸

FDA approval of medical devices follows yet a different process. The FDCA, and specifically its Medical Device Amendments, classifies medical devices as Class I, Class II, or Class III, depending upon the potential risk or anticipated misuse or injury that may result from use of the drugs.³⁹ Class III devices are those marketed as life-supporting devices or any other device that may cause an unreasonable risk of illness or injury, and therefore require the greatest scrutiny.⁴⁰ While most Class I and II medical devices do not require FDA approval prior to marketing, Class III devices require substantial oversight and are subjected to a rigorous pre-marketing approval process conducted by the FDA before they may be sold.⁴¹

Despite the rigor of the FDA process, approved drugs and devices nevertheless sometimes cause injury. It is estimated that 10.2% of drugs approved by the FDA between 1975 and 1999 have either been assigned a

35. See *infra* note 37 and accompanying text. Thus, while the FDA prohibits a manufacturer from promoting a drug for an unapproved indication, once a drug is FDA-approved for at least one indication and is placed into interstate commerce, medical providers are free to prescribe it for any purpose, regardless of its labeling, subject only to professional standards. See *United States v. Caronia*, 703 F.3d 149, 152–53, (2d Cir. 2012). When a drug is used for a condition or in a manner that deviates from that described in the FDA-approved drug label, the use is considered "off-label." This includes use of the drug to treat a different medical condition or disease, as well as use in a dosage or route that deviates from that described in the approved label. See *infra* note 37 and accompanying text.

36. See Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 GEO. L.J. 2119, 2133 (2000) (noting that physicians are permitted to prescribe drugs for off-label uses); see also Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) About Off-label Drug Use*, 87 MAYO CLINIC PROC. 982, 983 (2006) (explaining that physicians frequently prescribe off-label drugs).

37. See Wittich et al., *supra* note 36 (explaining that physicians frequently prescribe off-label drugs).

38. Statement, Am. Soc'y of Hosp. Pharm., ASHP Statement on the Use of Medications for Unlabeled Uses (1992) (on file with author), available at <http://www.ashp.org/DocLibrary/BestPractices/FormStUnlabeled.aspx>.

39. See 21 C.F.R. § 860.3(c)(1)–(2) (2014) (defining what makes devices Class I, II, or III, differentiated by level of risk).

40. See § 860.3(c)(3) (defining Class III devices as those where the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential reasonable risk of illness or injury).

41. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–17 (2008) (explaining the different classes of devices); see also 21 U.S.C. § 860(a)(1)(A) (2012).

black box warning (denoting a severe safety risk), or have been withdrawn from the market entirely.⁴² In some cases, it was determined that the FDA was provided with inaccurate or incomplete data from the drug trials.⁴³ In other cases, either unanticipated side effects occurred, or known side effects occurred to an unanticipated number of patients.⁴⁴ In still other cases, the efficacy was less than expected or unacceptable in light of the risks.⁴⁵ Similar safety issues plague FDA-approved drugs that remain on the market, as more than 100,000 consumers are killed every year as a consequence of medical devices and pharmaceutical use.⁴⁶

The question has long been debated as to whether the federal regulatory process leading to FDA approval of drugs and devices “preempts” state law, thus foreclosing product liability actions that challenge drug safety and/or the reasonableness of their warnings.⁴⁷ While the FDA can withdraw approval of a dangerous drug or device—or issue other mandates—the law does not provide a private right of action to a consumer injured by an approved product.⁴⁸ The arguments in favor of FDA preemption are not without some appeal: the role of the FDA is to impose uniform standards for drug and medical device safety; without preemption, court decisions by individual states could undermine the FDA’s regulatory framework by potentially creating conflicting standards

42. See Daniel Kazhdan, *Other Developments in Intellectual Property: Wyeth and PLIVA: The Law of Inadequate Drug Labeling*, 27 BERKELEY TECH. L.J. 893, 904 (2012) (citing a 2002 study published in the *Journal of the American Medical Association* describing the statistics of serious warnings and market removals).

43. See, e.g., *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 343 (2001) (explaining that the plaintiffs contend that the petitioner made fraudulent representations to the FDA in order to obtain approval).

44. See, e.g., *Feldman v. Lederle Lab.*, 592 A.2d 1176, 1179 (N.J.1991) (stating that the package contained no warning of the potential side effects of tooth discoloration).

45. See *Cooper Labs., Inc. v. Comm’r, Fed. Food & Drug Admin.*, 501 F.2d 772, 786 (D.C. Cir. 1974) (holding that the FDA’s rejection of a new drug was proper because evidence supporting the drug’s efficacy did not meet statutory standards).

46. See Jason Lazarou et al., *Incidence of Adverse Drug Reactions in Hospitalized Patients*, 279 JAMA 1200, 1202 (1998), available at <http://jama.jamanetwork.com/article.aspx?articleid=187436> (estimating that in 1994, approximately 106,000 deaths in the United States were due to an adverse drug reaction).

47. See Bryan G. Scott & Elizabeth K. Strickland, *Recent Developments in Federal Preemption of Pharmaceutical Drug and Medical Device Product Liability Claims*, THE DEFENDER, Fall 2009, at 22, available at <http://www.spilmanlaw.com/media%20content/media-content/documents/preemption-developments.pdf> (noting the debate over the past few years over the interplay between state tort laws, and federal regulation of pharmaceutical drugs and medical devices).

48. See *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995) (noting that Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA).

that intrude on the FDA's authority.⁴⁹ Fifty different state courts could establish conflicting standards to determine whether drugs approved by the FDA were safe and effective.⁵⁰ By vesting the FDA with exclusive enforcement authority, federal law would impose uniform standards to regulate the safety and efficacy of products, despite local rules.⁵¹ Federal law also serves to discourage lay juries from making independent determinations about safety.⁵² Presumably, exclusive FDA jurisdiction would also prevent litigants from bringing legal action based on claims that a certain product should not have gained FDA approval at all.⁵³

Of course, opponents of preemption also have a compelling argument: the FDCA does not include any private right of action.⁵⁴ In the absence of state tort laws, there would be no redress for plaintiffs who sustain severe injuries from unsafe pharmaceutical products.⁵⁵ In 2009, the U.S. Supreme Court, after considerable oral argument and review of the legislative history of the FDCA, determined that such a result was unacceptable.⁵⁶

Addressing the issue of brand liability, the Court issued a landmark opinion in the 2009 matter of *Wyeth v. Levine*.⁵⁷ In *Levine*, a Vermont woman brought a personal injury claim in state court after injecting the drug Phenergan.⁵⁸ The drug was manufactured by Wyeth Laboratories and is an antihistamine, which prevents against nausea.⁵⁹ Complications arose

49. *Wyeth v. Levine*, 555 U.S. 555, 612 (2009) (Alito, J., dissenting) (“[D]rug labeling by jury verdict undermines both our broader preemption jurisprudence and the broader workability of the federal drug-labeling regime.”).

50. *Id.* at 626 (explaining that without the FDA, consumers could suffer since juries in all 50 states would be free to contradict the FDA, and that the benefit of the FDA is the conveyance of warnings in one voice, rather than in 50 potentially conflicting ones).

51. See Jason C. Miller, Note, *When and How to Defer to the FDA: Learning from Michigan's Regulatory Compliance Defense*, 15 MICH. TELECOMM. & TECH. L. REV. 565, 566 (2009) (explaining that federal regulations preempting state tort laws avoid the asymmetry in the state tort systems).

52. *Id.* at 574 (explaining that giving FDA exclusive authority creates accountability not afforded to juries).

53. *Id.* at 579–80 (explaining that Michigan has excluded the evolving list of drugs as a basis for a liability action).

54. See *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010) (explaining that the Supreme Court has interpreted § 337(a) of the FDCA to mean that the federal government, and not private litigants, are authorized to file suit for noncompliance with medical provisions).

55. See Miller, *supra* note 51, at 569 (explaining that only private tort litigation can offer a remedy in the event that the FDA approves defective drugs).

56. *Wyeth v. Levine*, 555 U.S. 555, 581 (2009) (concluding that Congress has repeatedly declined to preempt state law, and that the FDA's recent position that state tort suits interfere with the statutory mandate is entitled to no weight).

57. *Id.*

58. *Id.* at 559.

59. *Id.* (noting that Phenergan is Wyeth's brand name for promethazine hydrochloride, an antihistamine used to treat nausea).

from the injection, which eventually led to the amputation of Ms. Levine's arm.⁶⁰ The plaintiff alleged that Wyeth had failed to include in its label a description of the potential arterial injuries that could result from a negligent injection of the drug.⁶¹ Wyeth defended on the basis that its label included FDA-required and approved warnings, and that such FDA approval preempted state law tort claims for failure-to-warn.⁶²

The *Levine* jury awarded damages after finding the label, despite approval by the FDA, to be insufficient under local tort law.⁶³ The Supreme Court of Vermont affirmed, concluding that FDA requirements "merely provide a floor, not a ceiling" for state regulation.⁶⁴ Thus, states are entitled to require more stringent measures for labeling drugs as long as they are not inconsistent with the FDA requirements.⁶⁵ The U.S. Supreme Court also affirmed, finding that state-law tort actions for failure-to-warn against a manufacturer of a brand drug are not preempted by the FDA approval process.⁶⁶

Wyeth v. Levine stands in sharp contrast to the U.S. Supreme Court's 2011 decision in *PLIVA, Inc. v. Mensing* ("PLIVA").⁶⁷ There, the Court was confronted with an alleged "failure to warn" claim where the plaintiff sued a generic drug manufacturer under state law for inadequately labeling its generic product.⁶⁸ The plaintiff in *PLIVA* alleged that she developed the (often irreversible) movement disorder, known as tardive dyskinesia,⁶⁹ as a result of taking PLIVA's metoclopramide (the generic form of Reglan)—a drug used to treat a digestive tract problem.⁷⁰ The plaintiff brought a state

60. *Id.* (explaining that the plaintiff, Levine, developed gangrene, and doctors amputated her right hand, and eventually her entire arm).

61. *See id.* at 559–60 (arguing that although a gangrene warning was included on Phenergan's label, the label should have included a warning against administering the drug via the higher-risk intravenous IV-push method, instead advising clinicians to use the safer IV-drip method of injection).

62. *Id.* at 560 (explaining that Wyeth argued that Levine's failure-to-warn claims were preempted by federal law).

63. *Id.* at 562.

64. *Id.* at 563.

65. *Id.* (concluding that as long as federal law and state law are not in conflict, then state law judgment is not preempted).

66. *Id.* at 581 (finding that state failure-to-warn cases do not obstruct federal regulation).

67. *Compare* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577–78 (2011) (noting that it was impossible for manufacturers to comply with both federal and state law, requiring state law to be preempted), *with* *Mensing v. Wyeth*, 588 F.3d 603, 614 (8th Cir. 2009) (finding *Mensing*'s claim can proceed and federal law requires such cases proceed), *and* *Demahy v. Actavis*, 593 F.3d 428, 449 (5th Cir. 2010) (noting that if Congress had intended to prevent state tort law cases, Congress would have clearly expressed that intent).

68. *PLIVA*, 131 S. Ct. at 2572.

69. *Id.*

70. *Id.* at 2572–73.

law failure-to-warn claim against the generic manufacturer, alleging that the warnings accompanying the drug failed to adequately warn consumers that prolonged use of metoclopramide could cause tardive dyskinesia.⁷¹

The case ultimately reached the U.S. Supreme Court, which denied the plaintiff's claim in a 5-4 ruling.⁷² The Court held that the FDA requirement that generic drugs be chemically equivalent to the brand product also prevents generic manufacturers from altering the FDA-approved label.⁷³ Thus, the *PLIVA* Court found that with respect to generic drugs, FDA regulations preempt state law and preclude failure-to-warn claims.⁷⁴ To hold otherwise would require generic manufacturers to do the impossible: comply with FDA labeling requirements, while also complying with various state laws by altering the label to impose stricter warnings in order to avoid allegations of failure-to-warn.⁷⁵

Levine also stands in contrast to the U.S. Supreme Court's 2008 opinion in *Riegel v. Medtronic, Inc.*,⁷⁶ a case that concerns whether FDA approval of medical *devices* insulates the manufacturer from state law product liability.⁷⁷ In *Riegel*, the plaintiffs represented a class in an action against the manufacturer of a balloon catheter, which allegedly ruptured while in the lead plaintiff's artery during the course of an angioplasty procedure.⁷⁸ The manufacturer of the balloon catheter had sought pre-marketing approval of the device by the FDA.⁷⁹ The FDA's protocol for approval of medical devices requires increasing scrutiny, depending upon the classification of the device.⁸⁰ The catheter at issue was a Class III medical device that required the highest level of FDA participation: pre-

71. *Id.* at 2570 (noting that the Plaintiffs argued that the manufacturers inadequately labeled the metoclopramide by failing to warn of the risks of long term use).

72. *Id.* at 2571, 2582.

73. *See id.* at 2580–81 (noting that any change to the drug would require the manufacturer to seek FDA approval).

74. *See id.* at 2581 (noting that because the pharmacist filled the prescription with the generic medication and not the brand-name, the state-tort claim was preempted).

75. *See* *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 37 (1st Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012), *and rev'd*, 133 S. Ct. 2466 (2013) (citing *PLIVA*, 131 S. Ct. at 2578 (2011) (“Generic drug manufacturers, unlike brand-name manufacturers, cannot unilaterally change their labels . . .”).

76. *See* 552 U.S. 312, 322 (2008) (noting that the Court has consistently held that FDA approval does not preempt state tort suits).

77. *Compare Riegel*, 552 U.S. at 345 (holding that 21 U.S.C. § 360(k)(a) does not preempt *Riegel*'s suit), *with* *Wyeth v. Levine*, 555 U.S. 555, 628 (holding that state law is preempted).

78. *See Riegel*, 552 U.S. at 320 (noting that *Riegel* alleged that the catheter's design, label, and manufacturing violated New York common law).

79. *Id.* (noting the Evergreen Balloon Catheter had received pre-marketing approval from the FDA).

80. *See id.* at 316–17 (noting that there are three classes, with Class III receiving the highest level of scrutiny).

marketing approval.⁸¹ The federal district court granted summary judgment to the defendant on the basis that pre-marketing approval had been granted,⁸² and the Second Circuit Court of Appeals thereafter affirmed.⁸³

After granting certiorari, the U.S. Supreme Court found that, with respect to *devices*, the FDCA—specifically including its Medical Device Amendments (“MDA”)⁸⁴—operates as the exclusive enforcement mechanism to establish the safety of medical devices approved, pursuant to the FDA’s rigorous regulations guiding Class III devices.⁸⁵ The MDA’s exclusivity provision that is applicable to medical devices (but not drugs) expressly “preempts” state laws, and a plaintiff injured by a medical device cannot look to state courts for compensation that would otherwise be available under tort theories such as negligence, failure-to-warn, or breach of warranty.⁸⁶

Although it might appear that the issue in the 2013 *Mutual Pharmaceutical Co., Inc. v. Bartlett*⁸⁷ case concerning the tort liability of a generic manufacturer would have been resolved by *PLIVA*, *Bartlett* presented the Court with an alternative theory of product liability.⁸⁸ The plaintiff in *Bartlett* alleged that the drug should not have been marketed, despite FDA approval.⁸⁹ The plaintiff’s arguments rested not on the basis of failure-to-warn, but on marketing a drug that the plaintiff claimed was unreasonably dangerous due to an alleged design-defect.⁹⁰ Neither *PLIVA* nor *Levine* had previously considered the state law tort liability of a generic manufacturer on the basis of design-defect.⁹¹

Before reviewing the *Bartlett* decision, as well as the pending cases on the related issue of medical device liability, it is important to define two forms of preemption that the courts distinguish: express preemption, and

81. *See id.* at 317–20 (noting that the catheter is a Class III device, which is the highest level of classification).

82. *See id.* at 320 (noting that the Evergreen Balloon Catheter received pre-marketing approval by the FDA).

83. *Id.* at 321 n.2 (noting that the Second Circuit Court affirmed the district court’s decision granting summary judgment).

84. Medical Device Amendments of 1976, 21 U.S.C. § 360 (2012).

85. *See Riegel*, 552 U.S. at 316 (stating that Congress passed the MDA, and included an express preemption provision).

86. *See id.* at 322–23 (noting that unlike general labeling duties, pre-marketing approval is specific to individual devices and is not an exemption from federal safety review); *see id.* at 324–25 (stating that the Court has consistently found federal statutes to preempt state tort claims).

87. 133 S. Ct. 2466 (2013).

88. *See id.* at 2478 (observing that the plaintiff advanced the stop-selling rationale).

89. *See id.* (noting that Bartlett argued the stop-selling rationale).

90. *See id.* at 2488 (observing that the design-defect claim is for an “unreasonably dangerous” product).

91. *See id.* at 2472, 2480 (noting that neither *Mensing* nor *Levine* had addressed this issue).

implied preemption. Express preemption occurs when a statute or case law explicitly provides for it.⁹² The MDA, for example, contains a specific (statutory) provision concerning the exclusivity of the MDA and Congress's (arguably) stated intent that they occupy the field to the exclusion of conflicting state laws.⁹³ So-called "implied preemption" occurs not from an explicit statutory pronouncement, but by implication when another federal statute or regulation occupies the field in such a way that its intended effect cannot be carried out if a conflicting state law is enforced.⁹⁴ In this context, it is alleged that the process for FDA approval of drugs implicitly preempts certain kinds of claims that give rise to state tort actions.⁹⁵ Specifically, those cases where a plaintiff alleges that a manufacturer made an incomplete or fraudulent representation to the FDA that led to its product's approval, and the product thereafter resulted in harm to the plaintiff (which constitutes a so-called "fraud on the FDA" claim).⁹⁶ The rationale is that the FDA regulatory process "occupies the field" on this issue, and that such claims should remain within the exclusive enforcement authority of the FDA:⁹⁷

the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.⁹⁸

The concept of "implied preemption" thus addresses the concern that the FDA might determine that certain mandated disclosures were complete or adequate, only to have lay juries in state courts second-guess such

92. See Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of a State Law Products Liability Claim*, 103 NW. U. L. REV. 437, 440 (2009) (defining express preemption as a statutory text that prohibits state-tort law claims).

93. See *id.* (noting that the intent of the MDA was to preempt state tort cases that prevent production of devices that could help those in need).

94. See Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 NW. U. L. REV. 463, 464 (2009) (defining implied preemption as a conflict between federal and state statutes, where the intended effect of the federal statute cannot be carried out).

95. See *id.* at 470 (noting that the process of FDA approval still requires costly input for litigation).

96. See *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001); see, e.g., Michael P. Moreland, *Tort Reform by Regulation: FDA Prescription Drug Labeling Rules and Preemption of State Tort Claims*, 1 J. HEALTH & LIFE SCI. L. 39, 57 (2007) (noting that the suit claimed that the manufacturer lied to the FDA, and therefore was improperly given market clearance).

97. See *Buckman*, 531 U.S. at 352 (noting that there is clear evidence that Congress meant that the Medical Device Amendments of 1976 be enforced exclusively by the Federal Government).

98. *Id.* at 347.

disclosures and find them insufficient under local law.⁹⁹ In an undertaking where FDA approval is the gold standard, the argument is that manufacturers should not be held to satisfy the standards of the FDA's regulatory regime while also complying with every state's individual tort laws;¹⁰⁰ if manufacturers are brought to state court, then manufacturers would be subject to the unpredictability of countless jury verdicts rendered under a spectrum of different standards.¹⁰¹ This argument has largely been successful with respect to medical devices governed by the MDA, while it has largely been unsuccessful with respect to state law negligence and failure-to-warn claims as to FDA-approved brand drugs where there is no analogous statute to provide immunity.¹⁰²

III. MUTUAL PHARMACEUTICAL CO., INC. V. BARTLETT

A. *First Circuit Opinion*

In *Mutual Pharmaceutical Co., Inc. v. Bartlett*,¹⁰³ the plaintiff suffered pain in her shoulder, and to treat this pain, she was prescribed a generic form of the non-steroidal anti-inflammatory drug ("NSAID") known as Sulindac.¹⁰⁴ NSAIDs are known to cause two rare but serious hypersensitivity skin reactions that include necrosis of the skin and mucous membranes (toxic epidermal necrolysis),¹⁰⁵ and a somewhat less severe

99. *Id.* at 351 (holding that disclosures to the FDA may be deemed appropriate by the administration, but may be judged insufficient in a state court).

100. *Id.* at 350 (explaining that it will be impractical for manufacturers, and will increase the burden of manufacturers to comply with FDA's detailed regulatory regime and the 50 state tort regimes).

101. *See id.* (noting that manufacturers might be exposed to unpredictable civil liability, and may be discouraged from seeking FDA approval for their devices).

102. *Compare* *Wyeth v. Levine*, 555 U.S. 555, 574 (explaining that for drug products, Congress intended state rights of action to provide appropriate relief for injured consumers), *with* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580, 2581 (2011) (holding that a manufacturer cannot independently satisfy state duties for preemption purposes without the FDA's permission), *and* *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584 (2013) (concluding that compliance with federal and state duties was not possible, and impossibility preemption is inappropriate).

103. 133 S. Ct. 2466 (2013).

104. *Id.* at 2471. The FDA approved generic "sulindac" in 1978 under the brand name Clinoril, followed by several generic versions after patent expiration, including one that Mutual Pharmaceutical Co. would manufacture. *Id.* at 2471.

105. Toxic epidermal necrolysis is a rare but severe condition where the epidermis (upper layer of the skin) can separate from the skin. Thomas Harr & Lars E. French, *Toxic Epidermal*

related condition, Stevens-Johnson Syndrome.¹⁰⁶ When the Sulindac was prescribed to Ms. Bartlett in 2004, the label did warn of “severe skin reactions,” but did not specifically identify either toxic epidermal necrolysis or Stevens-Johnson Syndrome as a potential risk.¹⁰⁷ Both conditions, however, were listed on the package insert as potential adverse reactions, as was the possibility of death.¹⁰⁸

The First Circuit noted that the trial court found “overwhelming evidence” that Sulindac caused Ms. Bartlett to suffer Stevens-Johnson Syndrome/toxic epidermal necrosis (“SJS/TEN”), and that as a result, she was left permanently injured and horribly disfigured.¹⁰⁹ Bartlett’s lawsuit alleged that Sulindac had a defective design, and urged the court to find that Sulindac was unreasonably dangerous under the product liability standards that were in effect in Bartlett’s home state of New Hampshire.¹¹⁰ Mutual defended on the basis that claims of design-defect are preempted under federal law since the FDA requires the active ingredients in generic drugs to be chemically equivalent to those in the brand.¹¹¹ A jury found in favor of

Necrolysis and Stevens-Johnson Syndrome, ORPHANET J. RARE DISEASES (Dec. 16, 2010), available at <http://www.ojrd.com/content/5/1/39>.

106. *Id.* at 2471–72.

107. *Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 135, 142 (D.N.H. 2010) (explaining that Sulindac’s label listed “severe skin reactions” under its “Warnings” section, and Stevens-Johnson Syndrome and toxic epidermal necrolysis under its “Adverse Reactions” section), *aff’d*, 678 F.3d 30, 37 (1st Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012), and *rev’d*, 133 S. Ct. 2466 (2013).

108. *Id.* (noting that the label listed Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis as potential adverse reactions in its “Adverse Reactions” section). Subsequent to the plaintiff’s injury in 2005, the FDA completed a comprehensive review of NSAIDs and recommended that the label of all brand and generic forms be amended to specifically warn of toxic epidermal necrolysis. *Bartlett*, 133 S. Ct. at 2472.

109. *See Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 34 (1st Cir. 2012) (describing that Bartlett’s skin lesions involved 60–65% of her body), *cert. granted*, 133 S. Ct. 694 (2012), and *rev’d*, 133 S. Ct. 2466 (2013); *see also Bartlett*, 731 F. Supp. 2d at 142 (noting that Bartlett was in the hospital for three months, spending two months in a medically induced coma, and suffered permanent injuries, including blindness).

110. *See Bartlett*, 678 F.3d at 34 (stating that Bartlett brought claims for breach of warranty, fraud, negligence, design-defect, failure-to-warn, and manufacturing defect); *see also Bartlett*, 133 S. Ct. at 2471–72 (stating that NSAIDs, including Sulindac, were known in 2004 to potentially cause toxic epidermal necrolysis).

111. *Bartlett*, 678 F.3d at 37. *Bartlett* stands in contrast to prior lower court opinions that uniformly rejected the concept that the generic drug should not have been marketed at all. *See, e.g.*, *Moore v. Mylan, Inc.* 840 F. Supp. 2d 1337, 1352 n. 14 (N.D. Ga. 2012) (noting that any negligence claim is preempted because the plaintiff has not shown that there is a state law that asks the manufacturer to stop producing the drug when the FDA has granted authority to do so); *Coney v. Mylan Pharms., Inc.*, No. 6:11-cv-35, 2012 WL 170143, at *5 (S.D. Ga. Jan. 19, 2012) (explaining that if a state law prohibits a manufacturer from doing what federal law explicitly requires the manufacturer to do, it confers supremacy upon the state law); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.* (No. 11), No. 08-008 (GEB-LHG), 2011 WL 5903623, at *6 (D.N.J. Nov. 21, 2011) (holding that FDA statutory requirements preempts any conflicting tort duty arising under state law); *Lance v. Wyeth*, 4 A.3d 160 (Pa. Super. Ct. 2010) (declining to

the plaintiff and awarded her \$21.06 million dollars in compensatory damages.¹¹² The First Circuit Court of Appeals affirmed the jury verdict, and Mutual appealed to the U.S. Supreme Court.¹¹³

In pursuing her theory of a state-law design-defect on appeal to the First Circuit, Bartlett alleged that Sulindac's "risks outweighed its benefits[,] making it unreasonably dangerous to consumers, despite the [FDA] having never withdrawn its statutory 'safe and effective' designation that the original manufacturer had secured[,] and on which Mutual was entitled to piggyback."¹¹⁴ Mutual's appeal alleged that federal law forbids the generic drug from altering the label.¹¹⁵ The First Circuit acknowledged this basic *PLIVA* principle, but distinguished its finding on the basis that *Bartlett* purported that the drug had a design-defect that made it "unreasonably dangerous" under New Hampshire law.¹¹⁶ Thus, the First Circuit was not critical of the fact that the label did not warn the plaintiff of her injury; rather, the First Circuit concluded that the generic manufacturer had not foreseen the inherent danger of such injuries and opted not to market the product at all.¹¹⁷

The First Circuit's opinion in *Bartlett* represented a departure from a binding line of cases to the contrary, and *Bartlett*'s holding would require that generic manufacturers be liable for injuries caused by a product that the FDA did not deem to be unreasonably dangerous.¹¹⁸ The Solicitor General argued in his *amicus curiae* brief that the obligation to determine the risk,

impose on manufacturers a common law duty to recall a drug in the absence of a state statute or administrative mandate to recall a drug).

112. *Bartlett*, 678 F.3d at 43.

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

114. *Bartlett*, 678 F.3d at 34–35 (citations omitted).

115. *Id.* at 41.

116. *Id.* at 34–36 (noting that by trial date, Bartlett's remaining theory of design-defect was that Sulindac's risks outweighed its benefits).

117. *Id.* at 41 (stating that under the current law, the original manufacturer and not the generic manufacturer can alter the label); *see also Bartlett*, 133 S. Ct. at 2472 (explaining that in 2005, after Ms. Bartlett's injury, the FDA recommended changes to the warnings of all NSAIDs, including Sulindac, to specifically identify toxic epidermal necrolysis as an adverse side effect).

118. *Compare Bartlett*, 678 F.3d at 37 (explaining that the statute contains no general preemption provision, and that state law serves as a "complementary form of drug regulation"), *with Moore v. Mylan, Inc.*, 840 F. Supp. 2d 1337 (N.D. Ga. 2012) (concluding that because the manufacturer was prevented by federal law from changing labels to conform with a state law, the failure-to-warn claim is preempted), *and Coney v. Mylan Pharms., Inc.*, No. 6:11-cv-35, 2012 WL 170143 (S.D. Ga. Jan. 19, 2012) (holding that it would confer supremacy to state law if the manufacturer is prohibited by state law from doing what federal law requires it to do), *and In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.* (No. 11), No. 08-008 (GEB-LHG), 2011 WL 5903623 (D.N.J. Nov. 21, 2011) (stating that federal duty preempts plaintiff's claims), *and Lance v. Wyeth*, 4 A.3d 160 (Pa. Super. Ct. 2010) (declining to impose upon a drug manufacturer a common law duty to recall a drug, and stating that the FDA has the power to withdraw approval of prescription drugs).

benefit, and overall safety of drugs was within the exclusive purview of the FDA, and that neither generic nor brand manufacturers should make decisions about whether drugs were too risky for marketing.¹¹⁹ The Solicitor General urged the Court not to impose a duty on a manufacturer to recall a drug, either brand or generic, when it is deemed to have a design-defect.¹²⁰ To do so otherwise, he argued, would interfere directly with the authority of the FDA as final arbiter of the safety and effectiveness of approved drugs.¹²¹

The First Circuit also reviewed *Wyeth v. Levine*,¹²² where the U.S. Supreme Court found that state-law tort actions for failure-to-warn against a manufacturer of a brand drug are not preempted by the FDA approval process.¹²³ Of course, neither *Wyeth* nor *PLIVA* addressed the issue of whether consumers can bring claims alleging design-defect against drug manufacturers.¹²⁴ These cases are significant, however, in that the Supreme Court clearly treated brand and generic drugs differently with respect to product-liability claims based upon failure-to-warn.¹²⁵ In its 5-4 holding, the *PLIVA* Court concluded that generic drug manufacturers would be shielded from liability on the basis that they cannot alter the drug label.¹²⁶

It is notable that the First Circuit in *Bartlett* relied primarily on the Supreme Court's opinion in *Wyeth*, while the First Circuit largely sidestepped the decision in *PLIVA*.¹²⁷ *Bartlett* noted that although *Wyeth* is "technically limited to failure-to-warn claims, its logic applies to design defect claims as well."¹²⁸ Indeed, it opined that *PLIVA* "carved out an

119. Brief for Petitioner at 24, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (No. 12-142) (stating that Congress has vested the FDA with the responsibility to determine if a product is safe and effective prior to entering the interstate market).

120. *Id.* at 28 (arguing that it would be inconsistent with the FDCA to require a manufacturer to recall a product approved by the FDA if a jury under state tort law finds the product unsafe).

121. *Id.* (describing that such state-by-state considerations would undermine the FDA's drug-safety determinations).

122. 555 U.S. 555 (2009).

123. *Id.* at 581 (holding that the FDA's position that state tort suits interfere with its statutory mandate has no weight).

124. *Id.* at 558 (stating that the question was whether FDA approval provides a manufacturer with a complete defense to a state tort action); *see also* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2573 (2011) (explaining that the issue was whether the consumers' claims for failure to provide adequate labels are preempted by federal law).

125. *PLIVA*, 131 S. Ct. at 2574 (stating that a brand-name manufacturer is responsible for accuracy and adequacy of labels, while a generic manufacturer is responsible for ensuring that its warning label is the same as the brand name's label).

126. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 37 (1st Cir. 2012) (explaining that, unlike brand-name manufacturers, generic drug manufacturers cannot unilaterally change their labels), *cert. granted*, 133 S. Ct. 694 (2012), *and rev'd*, 133 S. Ct. 2466 (2013).

127. *Id.* at 30 (noting that *Wyeth* resolved the conflict against general preemption, while the Supreme Court has not extended *PLIVA*'s exception to design-defect claims).

128. *Id.* at 37.

exception to *Wyeth*, finding that the FDCA preempts failure-to-warn claims against generic drug manufacturers. . . . [because] the generic maker cannot alter the labeling”¹²⁹ According to the First Circuit, *Wyeth* established “a general no-preemption rule,”¹³⁰ and that if a generic drug company places a drug on the market, it incurs the potential for state law failure-to-warn and design-defect claims.¹³¹

Bartlett challenges the heart of the preemption issue: *PLIVA* and *Wyeth* were concerned that 50 different states would impose duties on a manufacturer, duties of which would be considered to be *in addition* to those duties imposed by the federal government.¹³² The appellate court in *Bartlett* specifically commented: “it is up to the Supreme Court to decide whether *PLIVA*’s exception is to be enlarged to include design-defect claims. Given the widespread use of generic drugs and the developing split in the lower courts, this issue needs a decisive answer from the only court that can supply it.”¹³³ Ms. Bartlett’s severe injuries provided a compelling example of the damage that can be caused by adverse side effects.¹³⁴

B. U.S. Supreme Court Opinion

1. The majority opinion

On June 24, 2013, the U.S. Supreme Court, by a vote of 5-4, found that state-law damage claims against a generic drug company alleging that design-defects (which are rooted in the inadequacy of the accompanying warnings) are preempted by federal law.¹³⁵ Noting that New Hampshire’s tort law requires drug manufacturers to ensure their drugs are not unreasonably unsafe, the Court concluded that drug safety must be evaluated on the basis of the chemical formulation and the content of the warnings.¹³⁶ Relying upon its own recent decision in *PLIVA, Inc. v. Mensing*, where the Court found that FDA regulations prohibit a generic

129. *Id.*

130. *Id.* at 38.

131. *See id.* at 37 (clarifying that effective warnings and design create safe drugs, and that all companies placing a drug on the market should be held to the same standard to ensure drug safety).

132. *Id.* (finding that the *Wyeth* rationale does not apply because generic drug manufacturers are legally prohibited from changing the label on drugs).

133. *Id.* at 38 (citations omitted).

134. *Id.* at 34 (noting that between 60–65% of the outer skin layer on Karen Bartlett’s body deteriorated, was burned, or became a wound, that she spent more than fifty days in Massachusetts General Hospital’s burn unit, and that she suffered from permanent near-blindness).

135. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2469–70 (2013).

136. *Id.* at 2470.

manufacturer from altering either the drugs' composition or label, the Court here concluded that the Supremacy Clause renders the New Hampshire law "without effect," and is effectively preempted since it would require a party to violate federal law.¹³⁷

For purposes of analysis, Justice Alito, writing for the majority and reversing the decision of the First Circuit, concluded that a solution that only gives drug manufacturers the option to remove a product from the market or pay for injuries is tantamount to "no solution" at all.¹³⁸ "under the Supremacy Clause, from which our pre-emption doctrine is derived, any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield."¹³⁹ The majority went on to conclude that even if there were no express preemption, New Hampshire law would be impliedly preempted because it is "impossible for a private party to comply with both state and federal requirements."¹⁴⁰ Of particular significance is the fact that the Court disavows any obligation to inquire into congressional intent as to whether preemption was a desired consequence of the regulations.¹⁴¹ Both Justice Breyer and Justice Sotomayor, who authored separate dissenting opinions, substantially relied upon evidence that the majority's conclusion was not consistent with FDA policy, despite the FDA's position as articulated in its *amicus curiae* brief.¹⁴²

The majority relied heavily on the language of New Hampshire's tort law.¹⁴³ New Hampshire requires manufacturers to ensure that their products are not unreasonably dangerous.¹⁴⁴ According to the majority, this can be

137. *Id.* at 2466, 2470, 2475–76 (noting that the generic drug would be a different drug if it were chemically changed, and that it would need its own NDA to be marketed across state lines); *cf. Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 584 (6th Cir. 2013) (denying impossibility preemption, as the defendant generic manufacturer could have updated its warning to match the updated warning of the brand).

138. *Bartlett*, 133 S. Ct. at 2470.

139. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) (citations omitted) (internal quotation marks omitted).

140. *Bartlett*, 133 S. Ct. at 2473 (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)).

141. *Id.* at 2480 (rationalizing that Congress's intent can be inferred even without an outright expression through outlined statutory duties, and that if federal law will not allow Mutual to act in response to the demands of the state, clearly preemption was a desired consequence).

142. *Id.* at 2481–82 (Breyer, J., dissenting) (arguing that weight should not be given to the FDA's views on preemption because it did not hold hearings, solicit the views of the public, failed to voice its opinion through regulations, and seems to not be able to make up its mind on the issue); *id.* at 2494 (Sotomayor, J., dissenting) (rejecting the notion that courts are to heed an agency's conclusion about whether a state law is preempted, especially when its analysis does not satisfy the "high threshold" to determine that a state law should be preempted when faced with a conflicting federal act).

143. *Id.* at 2473–77, 2479, 2480 (majority opinion).

144. New Hampshire law recognizes liability for design-defect when "the design of the product created a defective condition unreasonably dangerous to the user . . ." *Vautour v. Body Masters*

accomplished either by modifying the product design, or by adapting the warning label.¹⁴⁵ To assess whether a product is unreasonably dangerous, New Hampshire imposes a “‘risk-utility approach’ under which ‘a product is defective as designed if the magnitude of the danger outweighs the utility of the product.’”¹⁴⁶ In conducting that balancing test, New Hampshire examines three factors: (1) the desirability and usefulness of the product; (2) the ability of the manufacturer to reduce the risk without materially affecting the desirability and usefulness of the product (including the cost); and (3) the strength of the warnings to highlight hidden dangers from uses that can be foreseen.¹⁴⁷ Since redesign of Sulindac was not an option in *Bartlett*, the lower court’s inquiry focused on the ineffectiveness of warnings as evidence of a design-defect.¹⁴⁸

The trial court in *Bartlett* had devoted considerable attention to Sulindac’s label, even allowing into evidence a Comprehensive Review of NSAIDs that was completed by the FDA in 2005 (after the Plaintiff’s injury), as well as the FDA’s recommendation for a change of the label.¹⁴⁹ The change specifically included identifying toxic epidermal necrolysis as a possible adverse effect of both brand and generic NSAIDs.¹⁵⁰ Indeed, a specific jury instruction directed deliberations in which the jury would evaluate the drug label to assess whether it was unreasonably dangerous.¹⁵¹ The court pointedly instructed the jury that it “should find ‘a defect in design’ only if it found that ‘Sulindac was unreasonably dangerous and that a warning was not present and effective to avoid that unreasonable danger.’”¹⁵² The trial court, finding in favor of the plaintiff, based its ruling on the jury’s determination that an inadequate label made the product unreasonably dangerous pursuant to New Hampshire law.¹⁵³ Since it was clear to the majority that the jury verdict of “design defect” was directly

Sports Indus., Inc., 784 A.2d 1178, 1181 (N.H. 2001) (citation omitted). The assessment of “unreasonably dangerous” utilizes a “risk-utility” approach, wherein “a product is defective as designed if the magnitude of the danger outweighs the utility of the product.” *Id.* at 1182 (internal quotation marks omitted) (citation omitted).

145. *Bartlett*, 133 S. Ct. at 2474.

146. *Id.* at 2474 (quoting *Vautour*, 784 A.2d at 1182).

147. *Id.* at 2475.

148. *Id.* at 2475–76 (citing *Bartlett v. Mut. Pharm. Co.*, 678 F. 3d 30, 41 (1st Cir. (2012)) (noting that a product is more dangerous if not paired with an effective warning).

149. *See id.* at 2472 (citing *Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 135, 146–47 (D.N.H. 2010)) (highlighting the importance of changing the label in order to decrease its danger).

150. *Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 135, 146–47 (D.N.H. 2010).

151. *See Bartlett*, 133 S. Ct. at 2476 (presenting the jury with evidence sufficient to support a finding that the drug is unreasonably dangerous).

152. *Id.* (citation omitted).

153. *Id.*; *see also Bartlett*, 731 F. Supp. 2d at 151, 157 (disregarding the fact that generic companies cannot change drug labels pursuant to federal law).

premised upon a finding of an inadequate warning, the Court found that the case would fall clearly within the *PLIVA, Inc. v. Mensing* doctrine.¹⁵⁴

Summarizing its preemption rationale, the *Bartlett* majority concluded that when, as here, “federal law forbids an action that state law requires, the state law is ‘without effect.’”¹⁵⁵ This is what the majority identified as “impossibility pre-emption.”¹⁵⁶ With respect to *Bartlett*’s contention that Mutual could decline to market Sulindac or pay damages, the majority was unreceptive, rejecting out of hand what it called the “stop-selling rationale” as incompatible with principles of preemption.¹⁵⁷ The majority refused to construe the law as to hold that a party had a viable option to either cease its operation or accept liability: “Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be ‘all but meaningless.’”¹⁵⁸ Presumably, the Court rejected the solution suggested in the dissenting opinions because it would relegate a generic manufacturer to the status of a sitting duck, vulnerable to suits from any injured party and without recourse or ability to defend itself.

The majority and the dissenting opinions found agreement on a single point that may be significant to the future of preemption jurisprudence: Ms. *Bartlett*’s injuries were tragic and devastating, and all opinions would welcome, if not urge, Congress to resolve this preemption issue that has “vexed the Court—and produced widely divergent views.”¹⁵⁹ Because the FDCA “includes neither an express pre-emption clause (as in the vaccine context) (citations omitted) nor an express non-pre-emption clause (as in the over-the-counter drug context) (citation omitted) . . . [the Court] is left to divine Congress’ will . . . ”¹⁶⁰ and resort to interpretations of statutory and common law, about which there is fundamental disagreement.¹⁶¹

2. *The Breyer dissent*

154. *Bartlett*, 133 S. Ct. at 2476, 2478 (deciding that, like *PLIVA*, it is “impossible” for Mutual to satisfy state and federal labeling laws simultaneously when the only remedy is to withdraw from the market).

155. *Id.* at 2476–77 (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

156. *Id.* at 2477.

157. *Id.*

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

159. *Id.* at 2480, 2481 (Breyer, J., dissenting); *id.* at 2496 (Sotomayor, J., dissenting).

160. *Id.* at 2480 (Breyer, J., dissenting).

161. *See id.* at 2479 (majority opinion) (rejecting the dissent’s assertion that drug companies are not legally obligated to change the Sulindac label or design, and highlighting that in terms of common law duty and statutory law, a company can either comply, leave the market, or stay in the market and suffer the consequences of non-compliance).

Justice Breyer, joined by Justice Kagan, issued a brief but compelling dissent. Justice Breyer criticized the majority's conclusion that it was "impossible" to comply with both New Hampshire and federal law, which the majority found to be hopelessly in conflict.¹⁶² In Justice Breyer's view, Mutual had two options, consistent with state and federal law: (1) it could refuse to do business in New Hampshire,¹⁶³ or (2) it could incur damages under New Hampshire law that result from injuries to consumers.¹⁶⁴

Justice Breyer acknowledged that there was a divergence of opinion on the preemption issue, but in his view, "[w]here the Statute contains no clear pre-emption command, courts may infer that the administrative agency has a degree of leeway to determine the extent to which governing statutes, rules, [and] regulations . . . have pre-emptive effect."¹⁶⁵ Justice Breyer pointed out that although the FDA contributed an *amicus curiae* brief on the case, in developing its position, the FDA neither held hearings nor solicited opinions and arguments from the public.¹⁶⁶ The FDA also did not issue regulations—which it could have done.¹⁶⁷ Quoting *Bowen v. Georgetown Univ. Hospital*,¹⁶⁸ Justice Breyer commented that an "'agency litigating positions that are wholly unsupported by regulations, rulings, or administrative practice' are entitled to less than ordinary weight."¹⁶⁹ Justice Breyer also noted that, unlike *Medtronic, Inc. v. Lohr*, where preemption is addressed by statute, the FDCA contains no analogous general preemption provision with respect to drugs.¹⁷⁰ Indeed, Justice Breyer noted that in other contexts, the FDA has welcomed state tort law as a kind of "complementary form of drug regulation."¹⁷¹

3. *The Sotomayor dissent*

162. *Id.* at 2480–81 (Breyer, J., dissenting) (clarifying that compliance with federal and state law is not literally impossible, but that the federal objective may be frustrated if a company can only comply by withdrawing from the market or paying a sizable fee).

163. *Id.* at 2481.

164. *Id.* At oral argument, Justice Kagan commented: "the adequacy of the warning is really all over this case. There was expert testimony about the adequacy of the warning, there were jury instructions about the adequacy of the warning. . . . which does suggest that this is sort of within the four corners of *Mensing*." Transcript of Oral Argument at 30–31, *Bartlett*, 133 S. Ct. 2466 (No. 12–142).

165. *Bartlett*, 133 S. Ct. at 2481 (Breyer, J., dissenting).

166. *Id.* (noting that the FDA's views were not entitled to deference).

167. *Id.*

168. 488 U.S. 204 (1988).

169. *Bartlett*, 133 S. Ct. at 2481 (Breyer, J., dissenting) (alteration in original) (citation omitted) (quoting *Bowen*, 488 U.S. at 212–13).

170. *Id.* at 2482; see *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

171. *Bartlett*, 133 S. Ct. at 2482 (Breyer, J., dissenting) (quoting *Wyeth v. Levine*, 555 U.S. 555, 578) (2009)).

Justice Sotomayor, with whom Justice Ginsburg joined, issued a separate and blistering dissent.¹⁷² For purposes of analysis, Justice Sotomayor's dissent divided the operative (preemption) provision into two major constituent parts: (a) the intent of Congress on the issue of preemption as gleaned from other FDA contexts;¹⁷³ and (b) the debate over the so-called "impossibility" preemption, specifically in contrast to her description of "obstacle" preemption.¹⁷⁴

On the issue of congressional intent, Justice Sotomayor initially notes the "conspicuous" absence of *Wyeth v. Levine*¹⁷⁵ from the majority opinion, even though *Levine* is clearly distinguishable on the basis of brand vs. generic liability.¹⁷⁶ Justice Sotomayor also points out that matters of health and safety, traditionally subject to a state's police powers, should not be "superseded by a Federal Act unless that was the clear and manifest purpose of Congress."¹⁷⁷

According to Justice Sotomayor, *Levine* supports the principle that "federal drug law and state common-law liability have long been understood to operate in tandem to promote consumer safety."¹⁷⁸ *Levine* acknowledged that even "as Congress 'enlarged the FDA powers,' it also 'took care to preserve state law.'"¹⁷⁹ More specifically, "Congress adopted a saving[s] clause providing that the amendments should not be construed to invalidate any provision of State Law absent 'a direct and positive conflict.'"¹⁸⁰ Finally, Justice Sotomayor emphasizes that the FDCA does not contain any provision that would evince intent to preempt the FDA regulations (brand or generic);¹⁸¹ indeed, if the FDA intended preemption, it would have said so—just as it did with respect to medical devices.¹⁸² Concluding her opinion with legislative history, Justice Sotomayor offered that the absence of a federal damages provision in the FDCA may, in fact,

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

173. *Id.* at 2483.

174. *Id.* at 2485.

175. 555 U.S. 555 (2009).

176. *Bartlett*, 133 S. Ct. at 2483–84 (citing *Wyeth*, 555 U.S. at 581) (holding that a state failure-to-warn claim regarding a brand-name drug did not warrant preemption by federal law, whereas *Mutual Pharm. Co.* focused on allowing generic drug preemption by federal law).

177. *Id.* at 2483 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

178. *Id.*

179. *Wyeth*, 555 U.S. at 567.

180. *Bartlett*, 133 S. Ct. at 2484 (Sotomayor, J., dissenting) (quoting Drug Amendments of 1962, 21 U.S.C. § 301 (2012)).

181. *Id.* at 2491–92 ("[Nothing in] federal law presupposes that drug manufacturers have a right to continue to sell a drug free from liability once it has been approved.").

182. Medical Device Amendments of 1976, 21 U.S.C. § 360(k)(2012) (including express exemption requirements for medical devices).

reflect Congress's expectation that state tort law *would* provide for monetary compensation to injured plaintiffs.¹⁸³

Turning to the issue of preemption on the basis of impossibility, Justice Sotomayor would require Mutual to demonstrate an "irreconcilable conflict" concerning the state and federal provisions before concluding there was a conflict.¹⁸⁴ When there is a genuine conflict, according to Justice Sotomayor, the inquiry into congressional intent is unnecessary, as the language of the statute would make the conclusion of preemption "inescapable."¹⁸⁵ Justice Sotomayor thus rejects the majority's "impossibility" argument, suggesting that a clear option in *Bartlett* was to simply compensate the small number of consumers who are injured.¹⁸⁶

Citing, as a starting point, a "presumption against pre-emption," Justice Sotomayor introduces the alternative concept of "obstacle pre-emption," which is not explained or defended by the majority.¹⁸⁷ As Justice Sotomayor describes, obstacle preemption applies when the state law "stands as an obstacle to the accomplishment of federal objectives."¹⁸⁸ Here, the FDA's policy was to approve Sulindac to be used for its intended purpose.¹⁸⁹ It was not to prevent consumers injured by the drug from receiving fair compensation.¹⁹⁰ Pursuant to this obstacle preemption rationale, state law would be preempted only if state failure-to-warn or design-defect statutes "stands as an obstacle to" making Sulindac available for consumer use.¹⁹¹ Justice Sotomayor concludes by acknowledging that Mutual's obstacle preemption defense presents a closer question, but that it would also fail, as it conflicts with "the purposes and objectives of the FDCA, as supplemented by the Hatch-Waxman Act."¹⁹²

Justice Sotomayor seemed to acknowledge that her position would be at least partially at odds with the Court's 2011 decision in *PLIVA, Inc. v.*

183. *Bartlett*, 555 S. Ct. at 2485 (Sotomayor, J., dissenting).

184. *Id.* (quoting *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984)).

185. *Id.* (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)).

186. *Id.* at 2489 (noting that Mutual could have complied with state requirements while also following federal law).

187. *Id.* at 2486, 2491.

188. *Id.* at 2491 (quoting *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (citation omitted)).

189. See George W. Evans & Arnold I. Friede, *The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis*, 58 FOOD & DRUG L.J. 365, 388 (2003) (explaining that the main function of the FDA is to ensure that new drugs are "safe and effective for their intended uses").

190. *Bartlett*, 133 S. Ct. at 2485 (Sotomayor, J., dissenting) (citing *Wyeth v. Levine*, 555 U.S. 555, 574–75, 574 n.7 (2009)).

191. See *id.* at 2491 (citing *Crosby*, 530 U.S. at 373).

192. *Id.* at 2493.

Mensing,¹⁹³ which she refers to as an “outlier.”¹⁹⁴ There, the Court found that there was “impossibility” preemption on the basis that a generic manufacturer could not offer product warnings that would conform to Minnesota’s duty-to-warn without altering the FDA-approved drug label. In Justice Sotomayor’s view, however, even *PLIVA* does not pre-ordain the *Bartlett* majority’s conclusion for the same reasons: the defendant could choose either not to market the product, or to compensate injured plaintiffs.¹⁹⁵

Returning to her policy rationale, Justice Sotomayor concludes her dissent by pointing out that Congress has not only spoken to the issue of state law preemption in other contexts, but that Congress has also responded “when it believes state tort law may compromise significant federal objectives.”¹⁹⁶ Justice Sotomayor points to state vaccination laws, also subject to pre-market approval, to illustrate her point.¹⁹⁷ Pursuant to early FDA vaccination policy, once the FDA approves the vaccine, compensation for vaccine-induced injuries was left to the states.¹⁹⁸ In 1986, Congress was concerned about an increase in state law tort litigation, and thus responded by enacting a National Childhood Vaccine Injury Act.¹⁹⁹ Among Congress’s provisions was a hallmark no-fault compensation scheme to compensate victims of vaccine-related injuries or death.²⁰⁰ According to Justice Sotomayor, Congress has thus demonstrated the willingness and ability to act when it believes that state tort law operates to the detriment of federal objectives.²⁰¹ By imposing preemption in *Bartlett* without congressional action, the Court leaves the intent of Congress unspoken, and leaves injured consumers without recourse.²⁰²

C. Analysis of *Bartlett* in Light of *PLIVA*

193. See *id.* at 2482–83 (recognizing that *PLIVA* expanded the scope of impossibility preemption to immunize generic drug manufacturers from state-law failure-to-warn claims).

194. *Id.* at 2486.

195. *Id.* at 2489 (discussing that New Hampshire did not require Mutual to do anything other than compensate consumers who were injured).

196. *Id.* at 2496.

197. *Id.* at 2495–96 (discussing how vaccine-related injuries were addressed largely by the states before the enactment of the National Childhood Vaccine Injury Act).

198. See *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068, 1072 (2011) (discussing the history of state run vaccine-induced injury compensation programs).

199. *Id.* at 1073.

200. *Id.* (discussing provisions within the National Childhood Vaccine Injury Act that establishes a no-fault compensation program, which allows a person injured by a vaccine to file a petition for compensation).

201. *Bartlett*, 133 S. Ct. at 2496 (Sotomayor, J., dissenting).

202. See *id.* (discussing the loss that *Bartlett* must bear due to preemption).

In this split decision, the 5-justice majority extended the logic of *PLIVA* to claims of design-defect.²⁰³ In *PLIVA*, the Court had previously found that failure-to-warn “defects” were preempted by the FDCA because of the FDCA’s prohibition on behalf of the generic in changing the brand’s label.²⁰⁴ The design of the label is part of the design of the drug, and the failure-to-warn is a failure of the label, which is a flaw of the drug itself.²⁰⁵ Thus, the majority did not note a viable distinction between a label’s failure-to-warn and a design-defect based upon the failed label.

Justice Sotomayor’s dissent, while thoughtful, requires that *PLIVA* be repudiated.²⁰⁶ There is no logic that would allow *PLIVA* to stand and for *Bartlett* to fail, and her sympathy for the case at hand doesn’t fix the gap in logic. It is doubtless why Justice Breyer declined to join, instead deciding to issue his own dissent that was short and pragmatic. Just because the FDA approved a product doesn’t end the inquiry; if the product was flawed (by design or by label) and a manufacturer chose to market it anyway, the manufacturer should be liable for damages.²⁰⁷

In many respects, the “impossibility” defense is at the heart of both *PLIVA* and *Bartlett*. It was “impossible” for the generic manufacturer to change the drug’s label.²⁰⁸ Failure to adjust the label to meet state law (New Hampshire, for *Bartlett*) was a violation of state tort principles.²⁰⁹ *Ergo*, there is a conflict between state and federal law, and the Supremacy Clause dictates that federal law preempts the incompatible state law.²¹⁰ The fact that the generic *might* have gone back to the FDA and requested a stronger label, or the fact that a stronger label specifically identifying the

203. *See id.* at 2478 (majority opinion) (citing *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011)) (explaining how the “stop-selling” argument affects the Court’s rationale).

204. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580–81 (2011).

205. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) (discussing product defect including defective labels); *see also* *Chatnam v. Pfizer, Inc.*, 960 F. Supp. 2d 641, 648 (S.D. Miss. 2013) (discussing the plaintiff’s claim that the drug’s “defect” is in the information, which did not accompany the drug, and determining that these allegations can only relate to the drug’s labeling and as such, are allegations that make up a failure-to-warn claim).

206. *Bartlett*, 133 S. Ct. at 2482 (Sotomayor, J., dissenting) (arguing that the majority incorrectly extended its holding in *Mensing*).

207. *Wyeth v. Levine*, 555 U.S. 555, 608 (2009) (discussing the manufacturer’s continuing obligations following FDA approval of a drug).

208. *Id.* at 2476–77 (discussing the majority’s holding that federal law prevents generic drug manufacturers from changing their labels, and that when federal law forbids an action, the state law is preempted).

209. *Id.* at 2475 (discussing the duty imposed on Mutual to strengthen labels based on the state’s design-defect cause of action).

210. *Id.* at 2470 (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)) (discussing the effect of the Supremacy Clause on state laws that require a private party to violate federal law).

type of injury suffered by Ms. Bartlett *was* later approved is legally without consequence; at the time of injury, neither had actually occurred.²¹¹

Having dismissed the idea that liability could be found on the basis of an ill-designed label, either directly or indirectly, the only remaining option for the *Bartlett* and *PLIVA* defendants would be to make a business judgment: what is the expected (liability) cost of marketing the product as is, and can the manufacturer charge a reasonable price in view of the expected liability? The majority rejected this “stop selling” option as “all but meaningless” for both *PLIVA* and *Bartlett*, concluding that if impossibility preemption were to have any meaning at all, it would not be to simply tell victims that there is no recourse in the law.²¹²

The Breyer dissent, rather than attempting to distinguish *PLIVA*,²¹³ quotes two former FDA commissioners, who stated that “the FDA has long believed that state tort litigation can ‘supplemen[t] the agency’s regulatory and enforcement activities’” in support of Justice Breyer’s conclusion that paying damages in the nature of strict liability is a viable option.²¹⁴ The majority and two dissenting opinions seem to agree that discerning the intent of Congress is key,²¹⁵ but disagree on what Congress would conclude.²¹⁶ All agree that *Wyeth v. Levine* reflects congressional intent that FDA regulation should be supplemented with state tort law, both as a check on the federal approval process and as a means of compensation.²¹⁷ The Breyer dissent would extend the logic to generics: “Tort suits can help fill the gaps in federal regulation by ‘serv[ing] as a catalyst’ to identify

211. See *Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 135, 144 (D.N.H. 2010) (explaining that the adequacy of warnings must be judged in light of the facts at the time of injury, without the benefit of hindsight).

212. *Bartlett*, 133 S. Ct. at 2477 (discussing the Court of Appeals’ reasoning that manufacturers could comply with federal- and state- law by stop-selling the product, which the Court found unsatisfactory); see also *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579 (2011) (explaining that the Supremacy Clause does not permit an approach to preemption, such as stop-selling, that renders conflict preemption all but meaningless).

213. At oral argument and in response to Justice Breyer, counsel for *Bartlett* argued that there was a distinction between *adequacy* of the warning (not argued) and efficacy of the warning (argued), which minimized the risk of Sulindac. Transcript of Oral Argument at 35–37, *Bartlett*, 133 S. Ct. 2466 (No. 12–142).

214. *Bartlett*, 133 S. Ct. at 2482 (Breyer, J., dissenting) (alteration in original) (quoting Brief for Donald Kennedy & David A. Kessler as Amici Curiae Supporting Respondents, *Bartlett*, 133 S. Ct. 2466 (No. 12–142)).

215. *Id.* at 2486 (Sotomayor, J., dissenting) (discussing the need for inquiry into congressional intent).

216. *Id.* at 2480 (majority opinion) (discussing the need for explicit resolution of the preemption question by Congress due to divergent views on the issue).

217. See 555 U.S. 555, 574–75 (2009) (discussing congressional silence on the issue of state tort law as evidence that Congress did not intend for FDA oversight to be the exclusive means of ensuring drug safety).

previously unknown dangers.”²¹⁸ The majority, however, noting the critical distinction between brand-name drugs and generics, denies that Congress intended for the logic of *Levine* to extend to generic counterparts.²¹⁹ The majority concludes that the jurisprudence of impossibility, coupled with absence of congressional activity following *PLIVA*, evinces the intent of Congress that brand and generics be treated differently.²²⁰ It may be on this point that Justices Breyer and Kagan, also dissenting, declined to join Sotomayor, as it is impossible to reconcile the logic of a different conclusion with *PLIVA*.

It is not unusual for the FDA to approve a generic drug, only to discover latent safety issues after it has been on the market.²²¹ Despite the FDA’s official position as articulated in its *amicus curiae* brief, former FDA commissioners Donald Kennedy and David Kessler support the imposition of state tort liability as a means of supplementing FDA efforts to ferret out unsafe products.²²² Kennedy and Kessler cite the agency’s lack of adequate resources to effectively police the drug market, which is part of the FDA’s core mission.²²³ Opponents speculate that some state tort laws would render the marketing of generics prohibitively expensive, which would be complicated by complex distribution systems that make it difficult to sell in some states but not others.²²⁴ It is doubtless that FDA preemption of state tort claims affects cost, and a change in the law would presumably result in a price increase for generic products.²²⁵

D. *The FDA Proposes New Labeling Requirements*

218. *Bartlett*, 133 S. Ct. at 2485 (Sotomayor, J., dissenting) (second alteration in original) (quoting *Bates v. Dow Argosciences LLC*, 544 U.S. 431, 451 (2005)).

219. *See id.* at 2480 (majority opinion) (explaining that a lack of a preemption clause leaves the Court to discern congressional intent from the FDCA).

220. *See id.* (discussing Congress’ lack of activity); *id.* at 2478 (discussing the impossibility issue).

221. Brief of Former FDA Commissioners Dr. Donald Kennedy and Dr. David Kellers as Amici Curiae Supporting Respondent at 8, *Bartlett*, 133 S. Ct. 2466 (No. 12-142) (discussing that FDA approval of a drug is not a guarantee that the drug will not cause serious adverse effects at a later date).

222. *Id.* at 6 (discussing the indispensable role that state tort litigation plays in achieving the congressional goal of the FDCA).

223. *Id.* at 12 (discussing the various conditions faced by the FDA that limit the agency’s ability to singlehandedly monitor all of the drugs available on the market).

224. Brief for Generic Pharmaceutical Association as Amicus Curiae In Support of Petitioner at 29–31, *Bartlett*, 133 S. Ct. 2466 (No. 12-142) (discussing the negative impact that state tort laws will have on the market for manufacturing generic drugs).

225. *Id.* (discussing the rise in generic drug prices as a result of state tort laws).

Just days after the Court's decision in *Bartlett*, the FDA released its most recent government agenda that includes new rules under consideration by various government agencies.²²⁶ Included in that agenda was the FDA's intent to raise the issue of a revision to its labeling requirements for generic drug makers.²²⁷ The FDA intends to publish a proposed rule that allows generic drug makers to make changes to product labels, independent of a brand-name manufacturer. This rule would empower generic companies to notify consumers about safety risks and concerns they become aware of, supporters say. In turn, it could potentially make generic drug makers liable in court for failing to do so.²²⁸

If, in fact, the FDA does consider and issue new rules revising its labeling requirements, such rules would be at odds with the position of the United States as *amicus curiae*, which supports Mutual's position against FDA preemption:

The Court need not decide whether the FDCA would preempt a "pure" design-defect claim that does not consider the adequacy of labeling. That issue is difficult and close, with several factors weighing in favor of finding no preemption. The government nevertheless concludes that the FDCA would preempt a pure design defect claim where, as here, the claim does not require the plaintiff to prove that the manufacturer knew or should have known of new and scientifically significant evidence that rendered the drug "misbranded" under federal law.²²⁹

A small point of agreement among the *Bartlett* parties, *amici*, and the Supreme Court is that the Court's latest ruling is to be narrowly drawn and construed, answering only the issue of whether a judgment based upon a design-defect claim against a generic manufacturer can stand.²³⁰ The

226. Thomas M. Burton, *FDA Rule to Expose Generic Drug Makers to Liability*, WALL ST. J. (July 3, 2013, 6:41 PM), <http://online.wsj.com/article/SB10001424127887324399404578584142169099794.html>.

227. *Id.*

228. *FDA to Allow Generic Drugmakers to Make Label Changes Independent of Innovators*, DRUG INDUSTRY DAILY, <http://www.fdanews.com/articles/156914-fda-to-allow-generic-drugmakers-to-make-label-changes-independent-of-innovators> (last visited Nov. 13, 2014).

229. Brief for the United States as Amicus Curiae Supporting Petitioner at 12, *Bartlett*, 133 S. Ct. 2466 (12-142).

230. *See Bartlett*, 133 S. Ct. 2466 (holding that *design-defect claims*, like New Hampshire's, that place a duty to alter composition or labeling for safety requirements conflict with federal law, and therefore cannot stand); Petition for Writ of Certiorari at 18, *Bartlett*, 133 S. Ct. 2466 (No. 12-142) (asserting that the Supreme Court is tasked with deciding whether precedent would be expanded to preempt state law design-defect claims); Brief of John and Tammy Gilbert et al. as

broader question of whether state tort liability should be employed as “a complementary form of drug regulation”²³¹ was saved for another day, and it appears that such a day will at least be scheduled for debate.

The stated purpose of the FDA’s proposed rules is to “create parity” between brand name drug manufacturers and generic manufacturers, allowing generics to alter the drug label to include information (including warnings) specific to the generic product.²³² In so doing, the presumption is that generic manufacturers would avoid the pitfalls and protections of *Bartlett* and *PLIVA*, assuming responsibility for their label, and thus the liability as well.²³³ Of course, the devil of the proposed change is in the details, and the FDA will also be cognizant of the costs and incentives involved with bringing generic products to market.²³⁴ Moreover, if the FDA’s goal is to “create parity,” then it can be expected that interested parties will raise the issue of parity between FDA-approved drugs and medical devices, particularly since there are a growing number of therapeutics where the distinction between drug and device is increasingly blurred.²³⁵

Amici Curiae in Support of Respondent at 22, *Bartlett*, 133 S. Ct. 2466 (No. 12-142) (stating that the Supreme Court has previously always held narrow circumscription of conflict preemption based on impossibility); Brief of the Council of State Governments as Amicus Curiae in Support of Respondent at 19–20, *Bartlett*, 133 S. Ct. 2466 (No. 12-142) (noting that unlike previous decisions involving failure-to-warn claims, the present case involved the issue of whether federal law preempts design-defect claims).

231. Brief for the United States, *supra* note 229, at 34 (quoting *Wyeth v. Levine*, 555 U.S. 555, 578 (2009)).

232. Burton, *supra* note 226.

233. See Toni Clark & Andrew Hay, *FDA Defends Generic Drug Label Proposal at U.S. House Hearing*, REUTERS (April 1, 2014, 6:58 PM), <http://www.reuters.com/article/2014/04/01/genericdrugs-idUSL1N0MT1IV20140401> (stating that the Supreme Court in 2011 ruled that manufacturers of generic drugs would not be liable for failure-to-warn against risk, and the FDA now would “unshackle” these manufacturers, exposing them to liability).

234. See Kurt R. Karst, *Generic Drug Labeling Preemption: The Flavor of the Day*, FDA LAW BLOG (March 10, 2014), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2014/03/generic-drug-labeling-preemption-the-flavor-of-the-day.html (noting that the FDA published a Preliminary Regulatory Impact Analysis addressing some cost concerns raised by lawmakers, and argued that the change would incentivize generic manufacturers to warn of safety risks).

235. See Lisa M. Mottes, *The Need For Federal Preemption of State Tort Claims in the Context of “New Drugs” and Premarket-Approved Medical Devices*, 41 SETON HALL L. REV. 723, 725 (2011) (stating that a call for safety has been initiated as a result of these cases and Congress has indicated there should be a uniform standard of no preemption). Consider, for example, nanomedicine—the application of nanotechnology to medicine—which enables the development of drug carriers that passively target tumors and deliver and dispense chemotherapeutics for cancer treatment. See Frederick A. Fielder & Glenn H. Reynolds, *Legal Problems of Nanotechnology: An Overview*, 3 S. CAL. INTERDISC. L.J. 593, 607–08 (1993-1994) (describing how nanotechnology-based treatments do not fit neatly into the Federal Food, Drug, and Cosmetic Act’s definitions of either “drug” or “device”); see also Jennifer H. Grossman & Scott E. McNeil,

IV. FDA PREEMPTION AND MEDICAL DEVICES

A. *Express Preemption: Riegel v. Medtronic, Inc.*

As discussed earlier, the U.S. Supreme Court treats drugs and medical devices differently with respect to federal preemption of state product liability laws.²³⁶ In the 2008 matter of *Riegel v. Medtronic, Inc.*,²³⁷ the Court found that the FDCA, including its Medical Device Amendments (“MDA”),²³⁸ provides the exclusive enforcement mechanism to establish the safety of medical devices “approved” by the FDA.²³⁹ Thus, the MDA arguably creates *express*²⁴⁰ preemption for medical devices by statute, rebutting the usual presumption against federal preemption of state law for matters involving consumer health and safety:

(a) General Rule

Except as provided in subsection (b) of this section, no State of political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is **different from, or in addition to**, any requirement under this chapter to the device, and

Nanotechnology in Cancer Medicine, 65 PHYSICS TODAY, Aug. 2012, at 38, 38 (Aug. 2012) (explaining how nanotechnology is applied to medicine to enable the development of drug carriers that passively target tumors and deliver and dispense chemotherapeutics for cancer treatment).

236. See *supra* Part I.

237. 552 U.S. 312 (2008).

238. Medical Device Amendments of 1976, 21 U.S.C. § 360(k) (2012).

239. See *Riegel*, 552 U.S. at 323–24 (stating that federal requirements specific to a medical device preempts common-law causes of action for negligence and strict liability (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 512 (1996))).

240. See *Indus. Truck. Ass’n v. Henry*, 125 F.3d 1305, 1309 (9th Cir. 1997) (explaining that in the past, federal courts have recognized three types of preemption: express, field, and conflict, the latter two categories being subcategories of implied preemption).

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.²⁴¹ (Emphasis added.)

Some courts have interpreted the phrase “different from, or in addition to” only in reference to the duty of care, precluding the imposition of a higher state-law duty, but allowing state-law damages to be “tacked on”;²⁴² other courts have interpreted it to preclude either a higher duty of care or additional (state law) damages.²⁴³

While acknowledging the important rationale for vesting the FDA with exclusive authority over the approval process for drugs and medical devices, there remains, of course, the other side to the story. The FDA is equipped with a broad range of enforcement mechanisms for noncompliance with the MDA.²⁴⁴ Once again, however, none of these enforcement mechanisms include a private right of action that would enable an injured plaintiff to be compensated for her injury.²⁴⁵ The resultant shield not only denies reasonable redress to an injured plaintiff, but it also negates an important incentive for manufacturers to address the dangers posed by the use of their devices. It also provides a disincentive for becoming forthcoming and transparent about known or reasonably anticipated risks.²⁴⁶

In *Riegel*, the plaintiffs brought a damages action under New York law alleging that the catheter that ruptured in the lead plaintiff’s coronary artery was inflated to a pressure that was higher than the Class III label indicated,

241. 21 U.S.C. § 360(k).

242. See, e.g., *Riegel*, 552 U.S. at 330 (holding that states are not prevented from providing a damages remedy on the basis of a violation of FDA regulations); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (holding that the MDA does not deny states the right to prove traditional damages remedy for violations of duties parallel to federal requirements); *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1248 (1997) (holding that a negligence claim for violating FDA regulations could be upheld because it did not impose greater requirements than the FDA itself imposed).

243. See, e.g., *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 28–29 (1st Cir. 1995) (holding that the language broadly preempts any state tort law, regardless of whether the manufacturer has in fact complied with the federal standard).

244. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 333–335c (2006) (listing penalties—criminal, civil, and regulatory—for noncompliance).

245. *Id.* (including criminal, civil, and regulatory penalties, but lacking a provision for a private right of action).

246. James W. Matthew et al., *New FDA Rule on Drug Labeling May Mean Increased Exposure and an Uncertain Path for Generic Pharmaceutical Manufacturers*, 81 DEF. COUNS. J. 306, 309 (2014) (quoting Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,988–89 (proposed Nov. 13, 2013)) (stating that generic drug manufacturers lack incentives to comply with FDA requirements and to maintain current safety information for their products).

which was approved by the FDA.²⁴⁷ The plaintiffs' state-law products liability action alleged that the catheter was defective.²⁴⁸ The Supreme Court in *Riegel* denied the claim, finding that the MDA expressly preempted the plaintiffs' state law claim because it would impose a standard of care that is greater than the safety requirements required by federal (FDA) regulations.²⁴⁹ The defendant argued that under such circumstances, the legislature, in enacting the MDA, believed that it would be counter-productive to require manufacturers to be beholden to multiple different state-specific tort law regimes, some of which imposed a duty greater than the FDA.²⁵⁰

The *Riegel* Court thus concluded, specifically pursuant to the MDA, that a product, having been approved by the FDA, could not be held to a state law standard that was "different from, or in addition to" the standard set forth under federal law.²⁵¹ In so holding, however, the Court expressly reaffirmed its 1996 holding in *Medtronic, Inc. v. Lohr*²⁵² that § 510 K of the MDA (which states that medical devices can be "cleared" pursuant to a less onerous approval standard for devices substantially equivalent to a pre-existing device) does not preclude "traditional damages remed[ies] for common law duties when those duties parallel federal requirements."²⁵³ The critical point is that the state law damages sought in *Lohr* (but not *Riegel*) were based upon a standard that was consistent with, and parallel to, the standards required under federal law.²⁵⁴

While *Riegel* found, pursuant to the MDA, that liability under state law for the alleged product defect would be denied, the issue continues to linger. In particular, several subsequent federal courts have attempted to parse the scope of "implied" preemption in deciding whether all state law claims are preempted, or just those that are "different from, or in addition to" those available under the federal law.²⁵⁵ *Riegel*, which spoke to *express*

247. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008) (stating that the plaintiffs, husband and wife, brought suit for injuries to the husband allegedly caused by a defective catheter).

248. *Id.*

249. *Id.* at 325.

250. Brief for Respondent at 42–43, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (No. 06-179) (arguing that Congress enacted a uniform federal regulatory framework to shield device manufacturers from conflicting regulatory requirements and from liability for devices that the FDA has found safe and effective).

251. *Riegel*, 552 U.S. at 325.

252. 518 U.S. 470 (1996).

253. *Id.* at 495.

254. *Id.* (asserting that nothing in § 360(k) denies Florida the ability to provide a damages remedy, even if it is literally different from the federal rules, as it is not an additional or different requirement and only serves to provide more incentive to comply with federal rules).

255. *Riegel*, 552 U.S. at 323, 330. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (dismissing a state law claim for failure to make a parallel claim); *Carrelo v. Advanced*

preemption, arguably left open the possibility that a tort claim could be brought under principles of *implied* preemption as to a state law that “parallels” federal law, which does not impose duties that are “different from, or in addition to” those available pursuant to federal law.²⁵⁶ In *Lohr*, Justice Breyer emphasized this point in his concurrence, noting that he did not “find any indication that either Congress or the FDA intended the relevant FDA regulations to occupy entirely any relevant field.”²⁵⁷ Latching onto this distinction, a number of cases have been brought in federal courts that interpreted *Riegel*, *Lohr*, and a third opinion, *Buckman Co. v. Plaintiffs’ Legal Committee*,²⁵⁸ regarding implied preemption.²⁵⁹

B. Implied Preemption: Buckman Co. v. Plaintiffs’ Legal Committee

In many respects, the preemption issue continues to surface because the *Riegel* Court, while clearly articulating the principles of “express” preemption of medical devices pursuant to § 360(k) of the MDA, left open the scope (and thus limits) of the so-called “implied” preemption.²⁶⁰ The U.S. Supreme Court in *Buckman Co. v. Plaintiffs’ Legal Committee* previously addressed this nuance in great detail,²⁶¹ but its interpretation has subsequently been disputed.²⁶²

In *Buckman*, the plaintiffs claimed that their injuries were a result of bone screws that had been used on their spines.²⁶³ They brought a civil action in federal court against Buckman Co., a consulting company that assisted the manufacturer of the screws in “navigating the federal regulatory

Neuromodulation Sys., Inc., 777 F. Supp. 2d 303 (D.P.R. 2011) (avoiding preemption by successfully pleading a failure-to-warn, a parallel claim); *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *5 (M.D.N.C. Aug. 5, 2009) (discussing cases upholding and denying preemption post-*Riegel*).

256. *Riegel*, 552 U.S. at 330 (holding that parallel claims cannot add to federal requirements and must be “premised” on FDA regulations).

257. *Lohr*, 518 U.S. at 508 (Breyer, J., concurring).

258. 531 U.S. 341 (2001).

259. See *infra* Part IV.C.

260. See *supra* notes 255–56 and accompanying text.

261. See 531 U.S. at 347–48 (holding that state law fraud on the FDA claims were impliedly preempted by federal law).

262. Compare *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 98 (2d Cir. 2006) (allowing parallel claims if the cause of action alleges a state claim other than fraud, by interpreting *Buckman*’s holding to limit claims which “solely” assign liability on the basis of fraud), with *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 966 (6th Cir. 2004) (upholding implied preemption “on the basis of state court findings of fraud,” but allowing the claim when a state “chooses to incorporate a federal standard into its law of torts . . . when the federal agency itself determines that fraud marred the regulatory-approval process”).

263. 531 U.S. at 344.

process for [those] devices.”²⁶⁴ The plaintiffs alleged that Buckman had made fraudulent representations to the FDA and that “but for” the false representations, they would not have been injured.²⁶⁵ The District Court for the Eastern District of Pennsylvania dismissed the plaintiffs’ so-called “fraud-on-the-FDA” claims on the ground that they were preempted by the MDA.²⁶⁶ A divided panel of the Third Circuit Court of Appeals reversed, concluding that there was no preemption.²⁶⁷ On appeal to the U.S. Supreme Court, the *Buckman* majority reversed the circuit panel, finding preemption on the basis that the claims under state law must “inevitably conflict” with the FDA’s obligation to police this type of fraud.²⁶⁸ Furthermore, allowing this type of claim could impose a chilling effect on the pre- and post-marketing information provided to the FDA, resulting in the FDA being hampered in its efforts to evaluate applications for approval.²⁶⁹ A concurring opinion emphasized the plaintiffs’ inability to establish the “but for” causation that they alleged.²⁷⁰

Among the current controversy within the circuits is the reach of *Buckman*’s implied preemption for claims of “fraud-on-the-FDA.” Specifically, the Fifth, Seventh, and Ninth Circuits²⁷¹ have since ruled that *Buckman* only preempts specific fraud-on-the-FDA claims where such claims interfere with the exclusive authority of the FDA to enforce matters pursuant to the FDCA.²⁷² Those that interpret *Buckman* to preempt all state court actions would preclude all traditional failure-to-warn and warranty claims when the alleged action violates a matter that the FDCA regulates.²⁷³ Those that interpret *Buckman* more narrowly find that so-called “parallel” state claims are not preempted.²⁷⁴ Parallel state claims are those that impose the same duties of care on the defendant—they merely add a state law damage action for failure to comply with the federal duty.²⁷⁵

264. *Id.*

265. *Id.* at 347.

266. *Id.*

267. *Id.*

268. *Id.* at 347, 350.

269. *Id.* at 349–51.

270. *Id.* at 354 (Stevens, J., concurring).

271. *See* Stengel v. Medtronic, Inc., 704 F.3d 1224 (9th Cir. 2013); Hughes v. Boston Scientific Corp., 631 F.3d 762 (5th Cir. 2011); Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010).

272. *See infra* Part IV.C.

273. *See infra* text accompanying notes 297–316 (discussing cases that held that state failure-to-warn claims are preempted by federal law).

274. *See infra* text accompanying notes 317–35 (discussing cases which narrowly interpreted *Buckman* and held that some parallel state claims are not preempted).

275. *Easterling v. Cardiac Pacemakers*, 986 F. Supp. 366, 371 (E.D. La. 1997) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)).

For example, a federal court in the Eastern District of Louisiana found as follows:

any claim based on the [federally regulated devices'] construction or composition, design, warnings, or express warranties would each specifically impose requirements different from or in addition to the FDA-approved requirements for the device.²⁷⁶

Such cases asserted state law tort theories such as failure-to-warn, manufacturing defects, breach of implied warranty, fraud, misrepresentation, etc.²⁷⁷ To date, several cases have reached the U.S. Court of Appeals and the legal conclusions are mixed.²⁷⁸ In light of the deep split of opinion among the circuit courts, the issue is poised to precipitate a definitive review by the U.S. Supreme Court.²⁷⁹

C. Analysis: Splitting the 5th, 6th, 7th, 8th, 9th, and 10th Circuits

One of the most recent cases to weigh in on the scope of implied preemption under *Riegel*, *Lohr*, and *Buckman* is a 2013 decision from the United States Court of Appeals for the Ninth Circuit in *Stengel v. Medtronic Inc.*²⁸⁰ In *Stengel*, the FDA had issued pre-marketing approval for implantable pain pumps and catheters that are used to deliver medication to a surgical site in the vicinity of the spinal cord.²⁸¹ Richard Stengel was a patient who had a Medtronic pump and catheter inserted, but soon thereafter

276. *Hinkel v. St. Jude Med., S.C., Inc.*, 869 F. Supp. 2d 739, 747 (E.D. La. 2012).

277. *See Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *5 (M.D.N.C. Aug. 5, 2009) (listing cases that have held preemption of state law claims).

278. *Compare Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1228–32 (9th Cir. 2013) (holding that the *Lohr*, *Buckman*, and *Riegel* Supreme Court decisions do not preempt parallel state claims), and *Howard v. Zimmer, Inc.*, 711 F.3d 1148 (10th Cir. 2013) (holding that a parallel fraud claim was properly raised), and *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011) (reversing a lower court decision, stating that the plaintiff successfully raised a parallel fraud claim not preempted by federal law), and *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) (holding that a state action based on an alleged violation of federal law is not preempted), with *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004) (holding that a state fraud on the FDA cause of action was preempted).

279. *See infra* Part IV.C.

280. 704 F.3d 1224 (9th Cir. 2013).

281. *Id.* at 1227.

lost strength and sensation in his legs.²⁸² Although testing was done to determine the cause, Stengel's treating physician did not timely seek or detect the presence of a granuloma that was ultimately determined to have caused Stengel's then-permanent paraplegia.²⁸³ Meanwhile, the FDA, in conducting a routine audit, discovered numerous unreported adverse events concerning this pump and catheter—including granulomas—and issued a "Warning Letter" to Medtronic, thus requiring Medtronic to distribute urgent warning letters to physicians who were using the products.²⁸⁴ Medtronic was subsequently also forced to issue supplemental warnings before the FDA eventually recalled the products.²⁸⁵

Stengel alleged that had his physician been timely notified by Medtronic of its post-marketing discovery of dangerous granulomas as required by the FDA, his physician would have tested for granuloma and Stengel's permanent injury would have been avoided.²⁸⁶ Medtronic countered that Stengel's lawsuit is exactly the type of state tort claim contemplated under *Riegel's* preemption doctrine: Arizona's damages provision would impose a legal standard that is "different from, or in addition to" the FDA's pre-marketing approval process of the pump and catheter, the very criteria set forth in *Riegel*.²⁸⁷

The unanimous *en banc* court in *Stengel*²⁸⁸ (overturning an earlier opinion of a 3-judge panel) examined *Riegel* and the MDA to conclude that "[s]tate requirements are preempted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law."²⁸⁹ Thus, the court interpreted these cases to allow "parallel" state damage claims that are neither different from nor in addition to those of the FDCA.²⁹⁰ The court relied substantially upon the Supreme Court's decision in *Medtronic, Inc. v. Lohr*,²⁹¹ which found that § 360(k) of the MDA does not preclude "traditional" common law tort remedies to the extent that they are not inconsistent with federal requirements.²⁹² The *Stengel* court found that there was enough ambiguity in the *Lohr, Buckman,*

282. *Id.*

283. *Stengel v. Medtronic Inc.*, 676 F.3d 1159, 1161 (9th Cir. 2013).

284. *Stengel*, 704 F.3d at 1227.

285. *Id.*

286. *Stengel*, 676 F.3d at 1161.

287. *Stengel*, 704 F.3d at 1226, 1230.

288. *Id.* at 1226. Initially, a three-judge panel of the Ninth Circuit Court of Appeals held (2-1) for Medtronic. *Stengel* was then granted a rehearing *en banc*, in which the court reversed and remanded the decision of the three-judge panel. *Id.*

289. *Stengel*, 704 F.3d at 1230 (quoting 21 U.S.C. § 360(k)(a)(1)).

290. *Id.* at 1226.

291. 518 U.S. 470 (1996).

292. *See id.* at 491 (explaining that a sweeping preemption of "traditional" common-law remedies was not intended by the legislature).

and *Riegel* precedent to avoid concluding that Congress and the FDA intended to “deprive the States of any role in protecting consumers from the dangers inherent in many medical devices.”²⁹³

Latching on to this distinction between express and implied preemption, the *en banc* Ninth Circuit allowed the plaintiff to bring his state-law “failure to warn” claims for injuries resulting from an FDA-approved medical device.²⁹⁴ The court specifically limited its reach to circumstances where state law does not impose safety requirements that are “different from, or in addition to” those required by the FDA.²⁹⁵ In so concluding, the *Stengel* court commented:

Given the ambiguities in the statute and the scope of the preclusion that would occur otherwise . . . we cannot accept Medtronic’s argument that . . . Congress clearly signaled its intent to deprive the States of any role in protecting consumers from the dangers inherent in many medical devices.²⁹⁶

On this preemption issue, *Stengel* stands substantially in unison with the MDA cases in the Fifth and Seventh circuits, which decided that parallel state-law claims are not preempted.²⁹⁷ In *Hughes v. Boston Scientific Corp.*,²⁹⁸ for example, the Fifth Circuit Court of Appeals concluded that Boston Scientific’s alleged negligent failure to report “serious injuries” and “malfunctions” of the device as required by the FDA (and deemed negligent under Mississippi state tort law) would not be preempted.²⁹⁹ The Fifth Circuit held similarly in *Bass v. Stryker*,³⁰⁰ stating that negligence claims premised upon failure-to-warn claims would be preempted, but not those based upon negligence in manufacturing.³⁰¹ Similarly, in *Bausch v. Stryker Corp.*,³⁰² the Seventh Circuit Court of Appeals decided that the alleged

293. *Stengel*, 704 F.3d at 123 (quoting *Lohr*, 518 U.S. at 489).

294. *Id.* at 1233–34.

295. *Id.* at 1233.

296. *Id.* (quoting *Lohr*, 518 U.S. at 489).

297. See *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006) (holding that the Louisiana statute went beyond scope of federal requirements, and related claims were preempted); *Chambers v. Osteonics Corp.*, 107 F.3d 1243, 1249 (7th Cir. 1997) (holding that the Indiana negligence claim was not preempted by the MDA).

298. 631 F.3d 762 (5th Cir. 2011).

299. *Id.* at 771.

300. 669 F.3d 501 (5th Cir. 2012).

301. *Id.* at 518.

302. 630 F.3d 546 (7th Cir. 2010).

defective manufacture of a device in violation of the MDA's manufacturing regulations would not be preempted.³⁰³

The Tenth Circuit Court of Appeals in *Howard v. Zimmer, Inc.*³⁰⁴ reached a similar conclusion despite a circuitous procedural route.³⁰⁵ *Howard*'s initial appeal occurred in the Sixth Circuit through multidistrict litigation, but eventually landed in the Tenth Circuit, which certified the preemption question to the Oklahoma Supreme Court.³⁰⁶ *Howard* involved a knee replacement (implant) that supposedly failed, and required removal due to the implant's inability to bond with the plaintiff's bone.³⁰⁷ The purported cause of the failure was an oily residue left on the device, which was in violation of the manufacturing standards required by the FDA.³⁰⁸ The plaintiff alleged that the violation of the manufacturing standard constituted negligence *per se*.³⁰⁹ Although the defendant urged that negligence *per se* cannot be predicated upon violation of a regulation (instead of a statute), the Oklahoma Supreme Court disagreed.³¹⁰ It established that (1) Oklahoma law does permit a private party (plaintiff) to assert a parallel claim for negligence *per se*, and (2) negligence *per se* can be based upon violation of a regulation when the enforcement of the regulation falls within the function of a governmental entity.³¹¹

In contrast to *Stengel, Hughes, Bausch, and Howard*, appellate courts in the Sixth and Eighth circuits issued opinions that were somewhat at odds with the narrow interpretation of their sister circuits.³¹² In *Garcia v. Wyeth-Ayerst Labs*,³¹³ the Sixth Circuit Court of Appeals determined that *Buckman* prohibits reliance on findings of the state court to establish that a defendant manufacturer misrepresented or withheld important safety data

303. *Id.* at 552.

304. 718 F.3d 1209 (10th Cir. 2013).

305. *See* *Howard v. Zimmer, Inc.*, 299 P.3d 463, 466 (Okla. 2013) (describing the case as involving a "long and tortured litigation trail").

306. *Id.*

307. *Id.* at 465–66; *see also id.* at 466 n.6 (explaining that although "Zimmer, Inc." is the defendant in the case, the name "Sulzer" was used to describe the manufacturer throughout the litigation).

308. *Howard*, 299 P.3d at 466. The pre-marketing approval application for this Class III device required specific manufacturing procedures to "ensure that it is removed or limited to an amount that does not adversely affect the device's quality." 21 C.F.R. § 820.70(h) (2014).

309. *Howard*, 299 P.3d at 466.

310. *Id.* at 469, 472.

311. *Id.* at 471–73.

312. *See* *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013) (holding that the duty-to-warn claim was not preempted); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (holding that the failure-to-warn and manufacturer's instructions claims were preempted); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (holding that negligence *per se*, fraud, and failure-to-warn claims were preempted).

313. 385 F.3d 961 (6th Cir. 2004).

from the FDA.³¹⁴ Though not entirely on point, the Eighth Circuit Court of Appeals in *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*³¹⁵ characterized the claims under state law, which stated that the FDA was not provided with adequate information, and were “simply an attempt by private parties to enforce the MDA.”³¹⁶

Since early 2013, a number of lower courts,³¹⁷ several in the Ninth circuit,³¹⁸ and the Oklahoma Supreme Court³¹⁹ have followed the *Stengel* precedent.³²⁰ For example, the federal district court for the central district of California followed *Stengel* in the matter of *Simmons v. Boston Scientific Corp. et al.*³²¹ In *Simmons*, a defibrillator allegedly malfunctioned, causing injury to the plaintiff.³²² The defendants, of course, argued that the plaintiff’s claim was preempted under *Riegel* and the MDA.³²³ In an effort to overcome *Riegel* preemption, the plaintiff alleged that the defendants also violated parallel state law duties, including failure-to-warn, pursuant to the recent *Stengel* precedent.³²⁴ The district court recognized that in the absence of *Stengel*, *Riegel* preemption likely would have prevailed since the defendant argued it would be required to “give warnings to patients or physicians different from or broader than those required by FDA regulations.”³²⁵ Although the *Simmons* court recognized that the plaintiff’s claims might now prevail under *Stengel*, the plaintiffs ultimately failed anyway on procedural grounds.³²⁶

The split among the circuits concerning the scope of MDA preemption focuses squarely on the issue of whether both implied preemption under the

314. *Id.* at 966; *see also* *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005) (holding that a claim of negligence *per se* would be preempted under the MDA).

315. 623 F.3d 1200 (8th Cir. 2010).

316. *Id.* at 1205–06.

317. *See* *Messner v. Medtronic, Inc.*, 975 N.Y.S.2d 367 (N.Y. Sup. Ct. 2013) (unpublished opinion); *Burgos v. Satiety, Inc.*, No. 10-CV-2680 (MKB), 2013 U.S. Dist. LEXIS 31062, at *1 (E.D.N.Y., March 5, 2013).

318. *See* *Perez v. Nidek Co.*, 711 F.3d 1109 (9th Cir. 2013); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055 (D. Or. 2013); *Elliot v. Smith & Nephew, Inc.*, No. 112-CV-0070-EJL-MHW, 2013 U.S. Dist. LEXIS 59072, at *1 (D. Idaho, June 11, 2013).

319. *See* *Howard v. Zimmer, Inc.*, 299 P.3d 463 (Okla. 2013); *see also supra* notes 304–11 and accompanying text.

320. *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013).

321. No. CV 12-7962 PA (FFMx), 2013 U.S. Dist. LEXIS 45852, at *1 (C.D. Cal. Mar. 25, 2013).

322. *Id.* at *1–2.

323. *Id.* at *6–7.

324. *Id.* at *13–14.

325. *See id.* at *9–10 (explaining that *Stengel* allows state claims that are broader than those required by FDA if those state claims are based on the defendant’s failure-to-warn the FDA of the adverse health consequences of its medical device).

326. *Id.* at *14, *16.

rationale set forth in *Buckman*, (“this sort of litigation would exert an extraneous pull on the scheme established by Congress and is therefore preempted”³²⁷) and express preemption under *Riegel* (the FDA “may . . . approve devices that present great risks if they nonetheless offer great benefits in light of the available alternatives”³²⁸) leaves room for the “parallel” cause of action identified in *Stengel*, *Hughes*, and *Bausch*.³²⁹

Riley v. Cordis Corp.,³³⁰ a federal district court opinion from the district of Minnesota, provides a thoughtful interpretation of *Buckman*, *Lohr*, and *Riegel*, concluding that there is only a “narrow gap” of medical device cases that would survive MDA preemption.³³¹ Specifically, the court determined that “[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360(k)(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (since such a claim would be impliedly preempted under *Buckman*).”³³² So, for example, parallel state law claims that allege misrepresentation or nondisclosure (whether fraudulent or negligent) might fit through the *Riley* “narrow gap” since “the state-law claim is in substance . . . a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist.”³³³ Furthermore, *Riley* decided that state law claims “premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA” may survive preemption under *Buckman*.³³⁴ The courts in the *Hughes*, *Bausch*, and *Stengel* cases may have gone further, finding that so-called parallel state-law damage claims are not preempted, except to the extent that they clearly assert “fraud on the FDA.”³³⁵

V. MDA, PREEMPTION, AND OFF-LABEL USE OF MEDICAL DEVICES

327. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

328. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008).

329. See Jean M. Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device "Parallel Claims"*, 9 J. HEALTH & BIOMED. L. 159, 184–86, 208–09 (2013) (citing *Stengel*, *Hughes* and *Bausch* as examples of circuit court cases in which parallel manufacturing claims were not preempted).

330. 625 F. Supp. 2d 769 (D. Minn. 2009).

331. *Id.* at 777; see also Eggen, *supra* note 329, at 200 (“[S]ome courts have correctly inferred from *Lohr*, *Riegl*, and *Buckman* that all properly pleaded parallel claims, other than those narrowly asserting fraud on the FDA, survive express preemption . . .”).

332. *Riley*, 625 F. Supp. 2d at 777.

333. *Id.* (citing *Buckman*, 531 U.S. at 352–53).

334. *Id.*

335. See Eggen, *supra* note 329, at 184–85, 208–09 (citing *Hughes*, *Bausch*, and *Stengel* as examples of claims that would smoothly navigate the narrow gap and survive preemption).

A related issue that is yet unresolved is whether off-label uses of medical devices would survive MDA preemption.³³⁶ On the one hand, *Buckman* contemplated the burden that manufacturers face in seeking marketing approval each time a “reasonable” off-label use is contemplated,³³⁷ on the other hand, medical devices that are granted through pre-marketing approval (even on the basis of false, misleading, or incomplete information) for one use can do significant damage in the medical setting if used differently.³³⁸ With broad implied preemption, device manufacturers might be faced with an incentive to seek FDA approval for the most minimal contemplated use—and thereafter market the product for additional, perhaps largely untested, uses—with impunity.³³⁹

A recent example of an alleged off-label use of a medical device that a state court determined might fit through the MDA “implied preemption” window concerned use of products that included *INFUSE*—a genetically engineered protein that has been widely used in spinal surgeries—and is currently the subject of a congressional investigation.³⁴⁰ In *Cabana v. Stryker Biotech, LLC and Medtronic, Inc.*,³⁴¹ a state court action in California, the plaintiff, April Cabana, claimed that she initially suffered permanent, debilitating injuries in her spinal column as a result of two products (Calstrux and OP-I) manufactured by Stryker that were mixed together in a manner not approved by the FDA.³⁴² Cabana alleged that Stryker promoted use of the products off-label, knowing that doing so could result in harm.³⁴³ Stryker was subsequently indicted in federal court for illegal marketing of the products, and two of its sales managers pled guilty to off-label promotion.³⁴⁴ In a subsequent surgery to address her poor result, Cabana alleged that the surgeon used a Medtronic *INFUSE* bone

336. See *id.* at 172–73, 186 (explaining that off-label use of medical devices is another area in which lower courts have inconsistently analyzed parallel claims under the preemption doctrine).

337. *Buckman*, 531 U.S. at 350.

338. See Eggen, *supra* note 329, at 210 (explaining the factors to be considered in deciding whether to preempt claims that are based on a manufacturer’s misrepresentation or nondisclosure).

339. See *id.* at 203 (explaining that preemption rules that are broadly applied would shield device manufacturers from liability, and would remove the incentive to actively engage in post-marketing vigilance).

340. See Deena Beasley, *Medtronic Bone Graft has Limited Benefit, May Cause Harm: Reviews*, REUTERS, (June 18, 2013, 3:35 AM), <http://in.reuters.com/article/2013/06/17/us-medtronic-spine-graft-idINBRE95G14Z20130617> (stating that in 2011, *INFUSE*, Medtronic’s product, became the subject of a congressional investigation when Medtronic failed to disclose safety problems in the clinical trial data and over its off-label use).

341. No. BC465313, 2012 WL 3876245 (Cal. Super. Ct. Aug. 20, 2012).

342. *Id.*

343. *Id.*

344. *United States v. Stryker Biotech LLC*, Crim. No. 09-10330-GAO, 2010 WL 2900684 (D. Mass. July 21, 2010).

graft, also off-label, which failed to correct her condition.³⁴⁵ It was later reported in *The Spine Journal* that Medtronic failed to accurately report the side effects from the clinical trials, and that many of the investigators who worked on the studies had significant financial ties to Medtronic.³⁴⁶

Medtronic defended its action on the basis that Cabana's claim should be expressly preempted by the MDA since the devices received pre-marketing approval by the FDA.³⁴⁷ In refusing to dismiss the matter, the California trial court concluded that because it is alleged that defendants "promoted the use of its devices in violation of federal requirements. . . . *Riegel* is not authority that plaintiff's claims . . . are preempted here."³⁴⁸ In support of Cabana's claim that the *INFUSE* device was used off-label and therefore in violation of its FDA approval, Cabana offered evidence that Medtronic used a paid consultant to train her own physician in use of the bone graft for this off-label application.³⁴⁹ In 2012, Medtronic settled for \$85 million in a shareholder lawsuit, which alleged that Medtronic had failed to divulge that more than 85% of *INFUSE* sales were based upon off-label uses.³⁵⁰

VI. CONCLUSION: "PARALLEL" CLAIMS AS AN INTERIM MEASURE TOWARD PARITY FOR DRUGS AND DEVICES

In the context of medical devices, three U.S. Supreme Court cases³⁵¹ create the foundation for federal preemption under the FDCA, and specifically, the possibility of parallel state claims. These cases, because they are governed by the MDA, follow a different path from the Supreme Court cases that guide federal preemption in the context of FDA-approved drugs.³⁵² To summarize the issue as to medical devices, *Lohr* determined that the FDCA does not preempt "a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."³⁵³ *Buckman* supports the bringing of state law tort claims to the extent that a plaintiff "rel[ies] on traditional state tort law[.]" but rejects

345. *Cabana*, 2012 WL 3876245.

346. Beasley, *supra* note 340.

347. *Cabana*, 2012 WL 3876245.

348. *Id.*

349. *Id.*

350. Beasley, *supra* note 340.

351. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

352. See *Wyeth v. Levine*, 555 U.S. 555 (2009); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

353. *Lohr*, 518 U.S. at 495.

such claims if the FDCA provides “a critical element in [the] case.”³⁵⁴ In order to determine whether a state-law claim could prevail, Riegel provides the guidance, albeit in the context of drugs. There, the Court established a test for determining whether a state-law tort claim could proceed: it would ask whether state law imposes a safety requirement that is “different from, or in addition to” the federal requirement.³⁵⁵ This concept of a “parallel”³⁵⁶ claim now awaits more precise definition by the U.S. Supreme Court.

Until that time, the circuit courts in *Bausch*,³⁵⁷ *Hughes*,³⁵⁸ and, most recently, *Stengel*,³⁵⁹ can stand for the principle that it is yet unclear whether the FDCA actually intended to impose different tort rules for drugs and devices, particularly where state and federal law duties are parallel to one another. *Stengel*, in particular, refused to reach what would otherwise be the inevitable conclusion that Congress intended to “deprive the States of any role in protecting consumers from the dangers inherent in many medical devices.”³⁶⁰ The government argued as much in its *amicus curiae* brief in *Stengel*, wherein it explicitly challenged the Ninth Circuit Court of Appeals’ interpretation of parallel claims.³⁶¹ Curiously, however, at the same time, it also successfully took a position against certiorari in the U.S. Supreme Court where the issues might have been vetted and resolved. So while the MDA in recent years has largely shielded medical device manufacturers from liability pursuant to state tort law, it now appears that the climate is shifting, and it is only a matter of time before there is more activity in the circuit courts that lead to another case making its way to the U.S. Supreme Court. Until that time, *Stengel* provides compelling arguments, including the voice of the government, in favor of allowing state-law tort claims against manufacturers of medical devices.

354. *Buckman*, 531 U.S. at 353.

355. *Riegel*, 552 U.S. at 322.

356. *Id.* at 330.

357. 630 F.2d 546 (7th Cir. 2010).

358. 631 F.3d 762 (5th Cir. 2011).

359. 704 F.3d 1224 (9th Cir. 2013) (en banc), *cert. denied*, 134 S. Ct. 2839 (2014).

360. *Id.* at 1231 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 489 (1996)).

361. The government’s position as set forth in its *amicus curiae* brief arguing against the grant of certiorari is that there is no preemption by the MDA as to respondents’ claims that petitioner could have advised physicians of any new safety alerts by means of a CBE revision to the product’s label. See Brief for the United States as Amicus Curiae at 7, *Medtronic, Inc. v. Stengel*, 134 S. Ct. 2839 (2014) (No. 12-1351), 2014 WL 2111719, at *7.