NOTES

RUNAWAY PREEMPTION: THE RECKLESS DOCTRINE OF *PLIVA* AND *MUTUAL PHARMACEUTICAL*

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I. INTRODUCTION

In March 2014, Gordon Johnston issued an urgent warning to members of Congress: the Food and Drug Administration was "[d]isregarding decades of regulatory stability" by proposing a new regulation that "raises patient safety concerns and threatens the system that created thousands of affordable options for consumers."[1] Johnston, himself a former deputy director at the FDA, was joined at a press briefing by economist Alex Brill, who estimated that the proposed regulation, if approved, would raise annual U.S. health care costs by $4 billion.[2]

Just what, exactly, was the FDA proposing to do? In the Agency's words, it sought to "clarify procedures" allowing drug manufacturers "to change . . . product labeling to reflect certain types of newly acquired information."[3] In plain English, the ultimate consequence of the rule would

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1. *GPhA to Congress: FDA Proposed Rule on Labeling Risks Widespread Confusion, Undermines Hatch-Waxman*, DRUG DISCOVERY & DEV. (Mar. 4, 2014), http://www.dddmag.com/news/2014/03/gpha-congress-fda-proposed-rule-labeling-risks-widespread-confusion-undermines-hatch-waxman.

2. *Id.*

3. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314,

be explicitly to permit generic drug manufacturers to update their labels with new safety warnings on a temporary basis, pending subsequent agency approval.[4] Under current regulations, brand-name drug manufacturers are already able to update their warning labels in a similar fashion.[5] However, the Agency has taken different positions over the years regarding whether generic drug manufacturers may update their labels.[6] The proposed rule, announced in November 2013, would eliminate the ambiguity by establishing parity between both types of drug manufacturers with respect to label updates.[7]

Although the FDA's proposed amendment may sound innocuous, it has attracted vehement opposition from the generic drug industry.[8] Five weeks after proposing the rule, the FDA announced that it was doubling the standard comment period because interested parties needed more time to prepare submissions.[9] Following the comment period, a lobbying organization for the generic drug industry threatened to sue the FDA if it attempted to implement the new rule.[10] The FDA prolonged uncertainty regarding the rule in November 2014 by announcing that it would delay publishing a finalized version until fall 2015.[11]

The generic drug industry and the Agency appear to be locked in a

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4. *Id.*

5. 21 C.F.R. § 314.70(c)(6)(iii) (2012).

6. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67,988.

7. *Id.* at 67,985.

8. Toni Clarke, *Generic Drugmakers Ramp Up Campaign Against FDA Label Proposal*, REUTERS (Feb. 28, 2014), http://www.reuters.com/article/2014/03/01/us-generics-labeling-idUSBREA2000M20140301. Johnston is now a consultant for the industry, *id.*, and the industry sponsored Brill's economic analysis, ALEX BRILL, MATRIX GLOBAL ADVISORS, FDA'S PROPOSED GENERIC DRUG LABELING RULE: AN ECONOMIC ASSESSMENT 10 (2014), *available at* http://www.matrixglobaladvisors.com/GenericLabelingRule.pdf. *See also* Tim Devaney, *Prescription Costs to Rise Under New FDA Rule?*, THE HILL (Feb. 26, 2014), http://thehill.com/regulation/pending-regs/199261-study-prescription-costs-to-rise-under-new-fda-rule (discussing Brill's economic analysis).

9. *FDA to Extend Comment Period on Proposed Rule on Safety Labeling Updates by Brand and Generic Drug Manufacturers*, FDA (Dec. 18, 2013), http://www.fda.gov/Drugs/NewsEvents/ucm379136.htm.

10. Alexander Gaffney, *Generic Drug Industry Threatens FDA with Lawsuit over Drug Labeling Proposal*, REG. AFF. PROFS. SOC'Y (Oct. 7, 2014), http://www.raps.org/Regulatory-Focus/News/2014/10/07/20497/Generic-Drug-Industry-Threatens-FDA-With-Lawsuit-Over-Drug-Labeling-Proposal.

11. Ed Silverman, *FDA Delays Final Rule on Allowing Generic Drug Makers to Update Labels*, WALL ST. J. (Nov. 18, 2014, 8:46 AM), http://blogs.wsj.com/pharmalot/2014/11/18/fda-delays-final-rule-on-allowing-generic-drug-makers-to-update-labels.

bizarre tug-of-war: the FDA is proposing to make it simpler for generic drug manufacturers to update warning labels, and the industry has responded with dire predictions about impending damage to the health care system. But the real issue at stake is the fallout of two recent Supreme Court cases that have drastically altered the landscape of pharmaceutical products liability.[12]

In *PLIVA, Inc. v. Mensing*[13] and *Mutual Pharmaceutical Co. v. Bartlett*,[14] the Court held 5-4 that generic drug manufacturers are not liable to patients in state courts for injuries caused by ineffective drug warning labels[15] or by "unreasonably dangerous" drugs.[16] There are no federal analogues to these common law causes of action, so patients who allege injuries caused by defective generic drug warning labels or drug designs are left without a remedy.[17] In other words, generic drug manufacturers are effectively immunized from these products liability claims.[18] Brand-name drug manufacturers, on the other hand, remain liable in state courts for claims based on product liability.[19] Recognizing the irrationality of this outcome, some commentators have suggested changing the law to abrogate generic manufacturer immunity.[20]

The state court liability claims asserted in *PLIVA* and *Mutual Pharmaceutical* raised questions implicating all dimensions of federal law—constitutional, statutory, and administrative. In both cases, patients claimed that prescription drugs produced by generic manufacturers severely harmed them. The patients in *PLIVA* alleged their injuries resulted

12. *See, e.g.*, Felicia Leborgne Nowels, *Current Preemption Issues in FDA Litigation: What's a Manufacturer to Do? Follow the Law—But Pay Close Attention to Future Changes in the Law*, *in* FOOD AND DRUG LITIGATION STRATEGIES: LEADING LAWYERS ON BUILDING STRONG DEFENSES AND ADAPTING TO EVOLVING FDA REGULATIONS 89, 97–99 (2013) (describing the issues raised by recent Supreme Court decisions).

13. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

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

15. *PLIVA*, 131 S. Ct. at 2581.

16. *Mut. Pharm.*, 133 S. Ct. at 2480.

17. *Id.* at 2485 (Sotomayor, J., dissenting).

18. *See* Nowels, *supra* note 12, at 90–91 (discussing generic drug manufacturers shielded from liability under state law).

19. *PLIVA*, 131 S. Ct. at 2581.

20. *See, e.g.*, Stacey B. Lee, PLIVA v. Mensing: *Generic Consumers' Unfortunate Hand*, 12 YALE J. HEALTH POL'Y L. & ETHICS 209, 258 (2012) ("[I]t is clear that, after *PLIVA*, some kind of change is necessary in order to ensure patient safety and the integrity of generic drug warnings."); Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 FORDHAM L. REV. 1835, 1875–79 (2013) (discussing proposals either to allow generic drug manufacturers to update their labels or to shift the authority and responsibility for label updates to the FDA).

from ineffective warning labels,[21] while the patient in *Mutual Pharmaceutical* claimed that the drug harmed her because it was defectively designed and "unreasonably dangerous."[22] In each case, the plaintiffs prevailed at the trial court level. On appeal to the Supreme Court, the manufacturers argued that the liability claims were preempted[23] by restrictive drug labeling rules promulgated by the FDA under the Federal Food, Drug, and Cosmetic Act[24] (FDCA). The Court applied a rule of preemption known as "physical impossibility" preemption.[25] It agreed with the manufacturers that it was "physically impossible" for them to comply simultaneously with both state law and federal regulations regarding drug label warnings. Therefore the state law (and the plaintiffs' claims) were preempted and unconstitutional. The FDA's proposed rule would undo the Court's holding by making it explicitly clear that generic manufacturers can update their drug labels. Based on the Court's logic, such a change is necessary to allow generic manufacturers to satisfy federal drug label regulations and state products liability laws simultaneously. Generic manufacturers, meanwhile, can retain the products liability immunity established in these cases by preserving the ambiguity of today's labeling regulations.

Justice Alito, writing for the Court in *Mutual Pharmaceutical*, described the holding as "a straightforward application of pre-emption law."[26] This Note will challenge the Court's "straightforward" application of impossibility preemption. *PLIVA* and *Mutual Pharmaceutical* rest on two propositions: first, that impossibility preemption arises whenever an actor cannot unilaterally comply with both state and federal law, and second, that common law damages are equivalent to statutory law for the sake of impossibility preemption analysis. These propositions are unsupported by preemption doctrine, and they have spawned a rule of runaway preemption that ignores the risk of over-preemption in a federal system of concurrent jurisdiction.

Part II provides an overview of preemption jurisprudence. Part III explains the development of impossibility preemption. Part IV considers

21. *PLIVA*, 131 S. Ct. at 2573.

22. *Mut. Pharm*., 133 S. Ct. at 2472–73, 2475–76.

23. *Id.*; *PLIVA*, 131 S. Ct. at 2573.

24. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399d (2012).

25. *Mut. Pharm.*, 133 S. Ct. at 2477; *PLIVA*, 131 S. Ct. at 2579.

26. *Mut. Pharm.*, 133 S. Ct. at 2480.

the special problem of common law preemption. Part V reviews the FDCA provisions and FDA regulations that provide the basis for the generic pharmaceutical industry. Part VI evaluates *PLIVA* and *Mutual Pharmaceutical*, arguing that both cases create undesirable modifications to impossibility preemption, which justify abandoning the doctrine in its current form. Finally, Part VII concludes.

II. THE FERTILE LANDSCAPE OF PREEMPTION JURISPRUDENCE

Preemption is the doctrine by which federal law is elevated above state law.[27] The federal government's power to preempt state authority is based on the Supremacy Clause,[28] which provides that the "Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[29] The supremacy of federal law has enabled uniform nationwide regulation of commercial markets, health and safety standards, and the environment.[30] Although the Supremacy Clause states clearly enough that Congress may invalidate state laws, it does not prescribe rules of interpretation to determine if and how a federal statute or regulation supersedes related state law. Thus, the Court's preemption jurisprudence supplies an analytical framework to resolve questions arising under the Supremacy Clause.[31]

The scope and application of preemption is central to the allocation of power between state and federal governments.[32] As Ernest Young has argued, the task of identifying the preemptive reach of federal laws has taken on heightened importance as the power of the federal government has expanded.[33] In particular, the Court's expansion of congressional authority

27. Christina E. Wells et al., *Preemption of Tort Lawsuits: The Regulatory Paradigm in the Roberts Court*, 40 STETSON L. REV. 793, 796 (2011).

28. *Id.*

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

30. Wells et al., *supra* note 27, at 796–97.

31. *See* Cipollone v. Liggett Grp., 505 U.S. 504, 516 (1992) (describing the Court's rules of preemption analysis as the starting point for "issues arising under the Supremacy Clause").

32. *See* San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 243 (1959) ("[D]ue regard for the presuppositions of our embracing federal system, including the principle of diffusion of power not as a matter of doctrinaire localism but as a promoter of democracy, has required us not to find withdrawal from the States of power to regulate where the activity regulated was a merely peripheral concern of [the relevant federal agency]."); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 241 (1947) ("[W]e have . . . the duty of judicially adjusting the interests of both the Nation and the State . . . ."); Wells et al., *supra* note 27, at 797 ("[P]reemption can upset the delicate balance of powers between federal and state governments.").

33. Ernest A. Young, *"The Ordinary Diet of the Law": The Presumption Against Preemption in the Roberts Court*, 2011 SUP. CT. REV. 253, 257–59.

under the Commerce Clause augmented the sphere of regulatory jurisdiction that is shared concurrently between the states and the federal government.[34] Within this sphere of concurrent authority, a frequent issue is not whether federal law *could* preempt concurrent state law under the Supremacy Clause, but whether Congress *intended* for a particular statute to do so.[35] State power is constricted to the extent that federal law preempts it.[36] The Court has protected the general police powers of the states by requiring a clear showing of congressional intent before finding preemption of state law.[37]

The Court has consistently identified four independently sufficient bases to support a finding of preemption.[38] These theories of preemption turn principally on whether Congress explicitly[39] or implicitly[40] intended to supersede state law, whether a state law "actually conflicts with federal law,"[41] and whether Congress intended to supersede state law even in the absence of an actual conflict.[42] Part II.A discusses express preemption. Part II.B introduces the three theories of implied preemption. One of these theories, impossibility preemption, is the subject of Part III.

34. *Id.* at 259.

35. *Id.* at 265.

36. *Id.* at 263.

37. *Id.* at 265.

38. *See, e.g.*, Hillsborough Cnty. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) (describing explicit and implicit preemption doctrines); Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 203–04 (1983) (same); Thomas W. Merrill, *Preemption and Institutional Choice*, 102 NW. U. L. REV. 727, 740 (2008) (same); Wells et al., *supra* note 27, at 797 (same).

39. *E.g.*, Geier v. Am. Honda Motor Co., 529 U.S. 861, 867 (2000) (analyzing an express preemption provision in the National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. § 1381 (1988)).

40. *E.g.*, *id.* at 881 (finding that a federal regulation preempted state law because it conflicted with the achievement of federal objectives, even though the relevant federal statute contained an express preemption clause that arguably did not call for preemption). A federal agency regulation may preempt state law just as a federal statute would, Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982), so long as the preemptive regulation is within the scope of authority delegated to the agency, *id.* at 159.

41. *Pac. Gas & Elec.*, 461 U.S. at 204.

42. *See, e.g.*, *Hillsborough Cnty.*, 471 U.S. at 714 (noting that implied field preemption doctrine "is, essentially, a question of ascertaining the intent underlying the federal scheme" in the course of the Court's evaluation of the preemptive effect of a federal regulation).

A. EXPRESS PREEMPTION DOCTRINE

Congress may declare in the text of a statute that the federal law preempts state law.[43] Preemption clauses assert that state laws, or particular bodies of state law, are preempted by the federal statute.[44] Alternatively, savings clauses identify state laws that are insulated from preemption.[45] Statutes may contain a preemption clause, a savings clause, or both.[46] The effect of a preemption clause is determined by analyzing the statutory language of the provision and, if one exists, the relevant savings clause.[47] For example, in *Freightliner Corp. v. Myrick*,[48] a preemption clause provided that "[w]henever a Federal motor vehicle safety standard . . . *is in effect*, no State . . . shall have any authority either to establish, or to continue in effect, . . . any safety standard . . . not identical to the Federal standard."[49] A federal agency implemented, but then suspended, regulations requiring antilock brakes in trucks.[50] Two truck manufacturers argued that they could not be held liable in state court for failure to install antilock brakes because the statute expressly preempted state enforcement of safety standards that differed from federal standards.[51] They claimed the suspension of the antilock brakes requirement was a federal safety standard and therefore preempted any state standards requiring the brakes.[52] However, the express preemption clause did not apply because there was no federal regulation of antilock brakes "in effect."[53] Accordingly, the state standard was not preempted, even though the federal government suspended the requirement for antilock brakes.[54]

The statutory analysis required under express preemption raises several interpretive issues.[55] The presence of a preemption clause and a savings clause does not necessarily simplify preemption analysis. Despite

43. Merrill, *supra* note 38, at 738.
44. *Id.*
45. *Id.*
46. *Id.*
47. *See, e.g.*, Freightliner Corp. v. Myrick, 514 U.S. 280, 286–88 (1995) (holding that a state law claim was not preempted under a theory of express preemption because the preemption clause was conditioned on a federal regulation being "in effect," and a relevant regulation had not yet been adopted).
48. *Id.* at 280.
49. *Id.* at 284 (emphasis added).
50. *Id.* at 282–83.
51. *Id.* at 286.
52. *Id.*
53. *Id.*
54. *Id.*
55. Wells et al., *supra* note 27, at 798–99.

earlier precedent suggesting the contrary, the Court has held that congressional identification of preempted and nonpreempted state law is not exhaustive.[56] Thus, preemption or savings clauses do not foreclose the applicability of implied preemption doctrines.[57] Furthermore, preemption clauses commonly use imprecise language that makes the preemptive scope of statutes unclear,[58] an interpretive problem considered in more depth in Part IV.B.

B. IMPLIED PREEMPTION DOCTRINES

Under certain circumstances, the Court will imply preemptive intent in a federal law that does not explicitly address preemption. This is necessary to allow the federal government to achieve national legislative goals without interference from state law[59] under circumstances in which Congress has not enacted an express preemption clause.[60] As with preemption generally, implied preemption must mediate the tension between two opposing goals: facilitating the operation of national regulatory regimes and avoiding undue constriction of state authority. If federal laws were given preemptive effect only to the extent that statutory provisions so provided, Congress would need to exercise a degree of legislative clairvoyance to identify ex ante the myriad of ways that federal laws and state laws could overlap.[61] However, imbuing every federal law with implicit preemptive effect would severely constrict state power.[62] A central goal of implied preemption, therefore, is to establish a legal standard that identifies how much tension or conflict may permissibly exist between concurrent federal and state laws before the former impliedly

56. Geier v. Am. Honda Motor Co., 529 U.S. 861, 869 (2000). In an earlier case, the Court said that the presence of a preemption clause "implies" that Congress did not intend to preempt state law outside the scope of the clause. Cipollone v. Liggett Grp., 505 U.S. 504, 517 (1992).

57. *Geier*, 529 U.S. at 869.

58. Wells et al., *supra* note 27, at 799.

59. Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. REV. 967, 989 (2002).

60. *See, e.g.*, Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 388 (2000) (holding that a state act was preempted because it conflicted with "Congress's specific delegation to the President of flexible discretion" despite the fact that "the silence of Congress [regarding that state law was] ambiguous").

61. Young, *supra* note 33, at 272 (observing that it would "most likely be unmanageable [for Congress] to anticipate all the possible ways in which state law might undermine federal legislation").

62. *Id.* at 263–64. *See also id.* at 275 (observing that conflict preemption cases require the Court to balance "the degree of impedance to national purpose versus the value of state autonomy"); Davis, *supra* note 59, at 969 ("On a more basic level . . . preemption is about power and politics because it involves the fundamental balance of Congress's power in relation to the states.").

preempts the latter.[63]

There are two subcategories of implied preemption. First, a state law is impliedly preempted if it operates in a legislative field so "totally occupied" by federal law that it is reasonable to infer "Congress left no room for the States to supplement it."[64] This is referred to as "field preemption." Second, state law is preempted to the extent that it "actually conflicts with federal law."[65] This is referred to as "actual conflict preemption." An actual conflict exists when (1) the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"[66] or (2) it is impossible for a private party to comply simultaneously with applicable state and federal requirements.[67] These two instances of implied conflict preemption are referred to as "obstacle preemption" and "impossibility preemption," respectively.

In *Rice v. Santa Fe Elevator Corp.*,[68] the Court provided an enduring model of implied preemption analysis rooted in congressional intent.[69] At issue was whether a federal regime governing the storage and sale of grain preempted state regulation of those regulatory fields.[70] A grain dealer filed a complaint with the Illinois Commerce Commission against grain warehousemen, alleging violations of state regulations governing grain storage.[71] The warehousemen were licensed under the United States Warehouse Act,[72] which established a voluntary regulatory scheme that warehousemen could participate in by obtaining federal licenses.[73] The dealer's complaint, however, was based on violations of state laws regulating aspects of grain trading that were also regulated under the federal system. For example, state law required "just and reasonable" storage rates, while federal law obligated warehousemen to have rates approved by the Secretary of Agriculture.[74] The warehousemen argued the

63. Young, *supra* note 33, at 275–76.

64. Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 149, 153 (1982).

65. Hillsborough Cnty. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) ("Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law.").

66. Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995) (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

67. *Id.* at 281 (citing English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990)).

68. Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947).

69. Davis, *supra* note 59, at 979.

70. *Rice*, 331 U.S. at 235–36.

71. *Id.* at 220–21.

72. *Id.* at 220.

73. *Id.* at 233–34.

74. *Id.* at 224–25.

Illinois Commerce Commission did not have authority to regulate their conduct because the federal statutes preempted state laws regulating grain storage.[75] The dealer argued that the state regulations strengthened and supplemented federal law, and that the Commission could enforce them so long as they did not run counter to federal policy.[76]

The Court acknowledged that the grain dealer's theory of concurrent regulation was a "strong case" with "great plausibility."[77] However, "the special and peculiar history of the Warehouse Act" indicated that concurrent regulation would "thwart the federal policy" that Congress sought to implement.[78] The Court based its rejection of the concurrent regulation argument on an examination of the history of amendments to the Act[79] and the purposes of those amendments as explained in congressional committee reports.[80] The Act's legislative history and purpose showed that, by amending it, Congress eliminated the earlier system of concurrent regulation so as to achieve uniform business practices.[81] Therefore, the federal law governing warehouses wholly displaced state law, even where the two sources of law did not actually conflict.[82]

The implied preemption analysis in *Rice* illustrated a judicial "presumption against preemption" that favored state autonomy.[83] Importantly, the Court framed its implied preemption analysis with an assumption that overlapping state and federal laws generally operate concurrently: "Congress legislated here in a field which the States have traditionally occupied. So we start with the assumption that the historic

75. *Id.* at 222.

76. *Id.* at 231.

77. *Id.* at 232.

78. *Id.*

79. An earlier version of the Warehouse Act expressly provided that it was not to be construed so as to conflict with or limit state laws regulating warehousemen, and it required federal licensees to provide a bond to secure compliance with state and federal laws. *Id.* at 222–23. In amending the Act, Congress eliminated the language on state law conflicts and instead provided that the Secretary of Agriculture had exclusive power and jurisdiction over federal licensees. *Compare* Warehouse Act, ch. 313, § 29, 39 Stat. 486, 490 (1916) (disclaiming state conflicts), *with* Warehouse Act, ch. 366, § 29, 46 Stat. 1463, 1465 (1931) (amending section 29). *See also Rice*, 331 U.S. at 223–24 (describing the change). Congress also amended the bond requirement so that it secured compliance with federal law only. *Id.* at 224.

80. The Court quoted statements in Senate and House reports to the effect that the amendments would make the federal system independent of state law and would allow licensees to operate without interference from other agencies. *Rice*, 331 U.S. at 233–34.

81. *Id.* at 236.

82. *Id.*

83. Young, *supra* note 33, at 273, 275.

police powers of the States were not to be superseded by the Federal [Warehouse] Act unless that was the clear and manifest purpose of Congress."[84]

The complexity of the modern regulatory era has made it more difficult to ascertain congressional intent.[85] As one scholar observed, even *Rice*'s finding of implied field preemption was itself "based on a relatively weak showing" of congressional intent.[86]

The *Rice* presumption against preemption remains central to implied preemption analysis, at least in theory.[87] More recently, in *Geier v. American Honda Motor Co.*,[88] the Court found preemption based on the assumption that Congress would not intend to allow state law to operate where it significantly conflicted with federal objectives.[89] Arguably this makes the analysis more likely to preempt state law because preemption may result solely from a conflict with asserted federal objectives, even if the legislative history does not expressly show that Congress wished to displace concurrent state regulation.[90] *Geier* involved motor vehicle safety standards promulgated by the Department of Transportation pursuant to the National Traffic and Motor Vehicle Safety Act of 1966.[91] The Department sought to increase the inclusion and use of restraint systems in cars without incurring a public backlash or making cars too expensive.[92] It promulgated a regulation requiring 10 percent of cars manufactured after September 1, 1986 to include a passive restraint system, and it established a graduated scale ultimately requiring 100 percent of cars to include such a system by September 1, 1989.[93] The Department also allowed manufacturers to choose which system to use: automatic seatbelts, airbags, or a different technology.[94] It believed that the graduated requirement and the use of

84. *Rice*, 331 U.S. at 230 (citations omitted). *See also* Davis, *supra* note 59, at 979–80 (discussing the presumption against preemption as articulated in *Rice*).

85. *See* Young, *supra* note 33, at 270 (noting that ascertaining congressional intent has become more difficult).

86. *Id.* at 307.

87. *Id.*

88. Geier v. Am. Honda Motor Co., 529 U.S. 861 (2000).

89. *Id.* at 885. The assumption also applies to the interpretation of federal agency regulations, which was the issue in *Geier*. *Id.*

90. *See* Davis, *supra* note 59, at 1012–13 ("*Geier* represents a seismic shift in the Court's preemption doctrine. The Court has returned preemption doctrine to its early focus on federal exclusivity and turned away from any meaningful attempt at discerning congressional intent that has been 'the ultimate touchstone' of preemption analysis since the 1940s.").

91. *Geier*, 529 U.S. at 867.

92. *Id.* at 878–79.

93. *Id.* at 879.

94. *Id.*

varied systems would best promote safety, rather than a uniform requirement for airbags or seatbelts.[95] Alexis Geier was severely injured when she crashed her 1987 Honda into a tree, and she and her family sued Honda under state law for failing to design the car with an airbag.[96]

The Court relied on its conception of the national purpose furthered by federal law[97] rather than an examination into the Safety Act's history or purpose.[98] It extensively reviewed the history behind the Department's promulgation of the restraint system regulation[99] and concluded that the relevant federal objective was the gradual introduction of restraint systems.[100] Therefore, Geier's state law product liability claim was preempted because it would impose a uniform requirement for airbags.[101] In preemption parlance, Geier's liability claim under state law presented an actual conflict with federal law because finding Honda liable "would have stood as an obstacle" in the way of the Department's objective to phase-in restraint systems gradually.[102]

Implied preemption is rooted at least formalistically in congressional intent, but the analysis in *Geier* broadens the means by which the requisite intent can be inferred. Using regulatory history to infer intent attenuates the connection between political accountability and the exercise of preemption authority by partially transferring preemptive power from members of Congress to unelected regulators.[103] Furthermore, members of the Court may disagree about how to construe the relevant federal objective. As Justice Thomas wrote in a later opinion, the implied obstacle preemption analysis in *Geier* arguably allowed for a "freewheeling, extratextual, and broad evaluatio[n] of the 'purposes and objectives'" of the Department's regulation.[104]

95. *Id.* at 881.

96. *Id.* at 864–65.

97. Davis, *supra* note 59, at 1010.

98. *Id.* at 1008.

99. *Geier*, 529 U.S. at 875–81. Justice Stevens argued in dissent that there was no precedential support for finding implied conflict preemption based on "inferences from regulatory history and final commentary." *Id.* at 910–11 (Stevens, J., dissenting). Those sources "are even more malleable than legislative history." *Id.* at 911.

100. *Id.* at 881 (majority opinion).

101. *Id.*

102. *Id.*

103. *See id.* at 908 n.22 (Stevens, J., dissenting) (arguing that the *Rice* standard "reduces the risk that federal judges will draw too deeply on malleable and politically unaccountable sources such as regulatory history").

104. Williamson v. Mazda Motor of Am., Inc., 131 S. Ct. 1131, 1142 (2011) (Thomas, J.,

Rice and *Geier* are examples of implied field preemption and implied obstacle preemption, respectively.[105] Technically, the doctrines are distinct because the former leads to preemption whenever state law operates in a "field" dominated by a "federal interest," while the latter is premised on state law obstructing a federal objective.[106] The importance of this distinction is debatable since state laws that are preempted for operating in a field of dominant federal interest would also likely obstruct the federal government's objectives in regulating the field.[107] Both doctrines are sensitive to the intended reach of federal law by requiring courts either to identify the boundaries of a field dominated by federal regulation or to construe the ultimate objectives of federal law, before finding preemption of state law.

Implied impossibility preemption, the third and final variety of implied preemption doctrines, is distinct from field and obstacle preemption because it operates independently of congressional intent. Impossibility preemption is the subject of Part III.

III. THE DEVELOPMENT OF IMPOSSIBILITY PREEMPTION

A. THE FRUIT OF *FLORIDA LIME*

The roots of impossibility preemption are traceable to the trees and soil of Florida's avocado fields. In *Florida Lime & Avocado Growers, Inc. v. Paul*,[108] the Court analyzed a conflict between federal marketing regulations concerning the maturity of avocados and California law governing the same subject.[109] The Secretary of Agriculture regulated the maturity of avocados picked in South Florida pursuant to the Secretary's authority under the federal Agricultural Readjustment Act to set minimum maturity standards.[110] Under federal regulations, avocados qualified as

concurring) (quoting Wyeth v. Levine, 555 U.S. 555, 604 (2009) (Alito, J., dissenting)). *See also* Young, *supra* note 33, at 284–88 (discussing *Williamson* and *Geier*).

105. *See* Young, *supra* note 33, at 307 (characterizing *Rice* as an instance of field preemption). *But see* Davis, *supra* note 59, at 980 (suggesting *Rice* is distinct from earlier field preemption cases because it focused on the interaction between state law and federal objectives).

106. *E.g.*, Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982) (quoting Rice v. Santa Fe Elevator Corp, 331 U.S. 218, 230 (1947)).

107. *See* English v. Gen. Elec. Co., 496 U.S. 72, 79 n.5 (1990) ("Indeed, field pre-emption may be understood as a species of conflict pre-emption: [a] state law that falls within a pre-empted field conflicts with Congress' intent . . . to exclude state regulation.")

108. Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963).

109. *Id.* at 137–38.

110. *Id.* at 139.

mature only if they were picked after a predetermined harvest date.[111] On the other hand, California determined maturity based on oil content rather than harvest date.[112] California's law made the sale of avocados containing less than 8 percent oil by weight punishable by fine and imprisonment.[113] Some Florida avocados qualified as mature under the federal harvest date regulation before they attained 8 percent oil content.[114] Florida growers wishing to sell in California sued to enjoin enforcement of the California law, arguing that the federal harvest date regulation preempted California's oil content law.[115] The Court held that the regulation did not preempt the California law because (1) it was not "impossible" to comply with both rules,[116] (2) the state law did not conflict with federal objectives,[117] and (3) Congress did not intend to preempt state laws in the field of avocado farming.[118] To support the first holding, the Court articulated its frequently cited rule for implied impossibility preemption:[119] "[a] holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce."[120]

So phrased, the doctrine is appealing because of its decisiveness and simplicity. Once a party identifies multiple compliance obligations that are impossible to satisfy simultaneously, preemption is established and the judicial inquiry ends.

Given the significance accorded to impossibility preemption in *PLIVA* and *Mutual Pharmaceutical*, it is worth noting a few observations about *Florida Lime*. First, the Court did not choose its "physical impossibility" wording gratuitously. Rather, the opinion suggests that the test should be strictly applied.[121] There was no impossibility preemption in *Florida Lime*

111. *Id.*
112. *Id.* at 133–34
113. *Id.* at 134 n.1.
114. *Id.* at 140.
115. *Id.* at 134–35.
116. *Id.* at 143.
117. *Id.* at 146.
118. *Id.* at 152. *Florida Lime* is part of a buffet of cases from the High Court addressing preemption and foodstuffs. *See id.* at 134 (avocados); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 220 (1947) (grain); McDermott v. Wisconsin, 228 U.S. 115, 126–28 (1913) (corn syrup).
119. Caleb Nelson, *Preemption*, 86 VA. L. REV. 225, 228 n.15 (2000).
120. *Fla. Lime*, 373 U.S. at 142–43. The Court did not cite direct support for this proposition, instead directing the reader to compare its rule against rules from two other cases. *Id.* at 143.
121. *Cf.* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2485 (2013) (Sotomayor, J., dissenting)

because of a "suggestion" in the trial court that the Florida growers "might have avoided" documented rejections of avocados that had occurred under California law by leaving avocados on trees beyond the federal harvest date until they attained 8 percent oil content.[122] In other words, the growers failed to establish impossibility preemption because they could alter their harvesting schedules such that most avocados would satisfy both standards. The Court hypothesized that the impossibility doctrine *would* apply if the federal regulation prohibited harvesting avocados with more than 7 percent oil and California's 8 percent minimum requirement remained in effect.[123] This hypothesis suggests that the Court had a sort of Schrödinger's avocado[124] in mind—one that impossibly possessed both 7 percent and 8 percent oil content at the same time.

Second, the purported actual conflict in *Florida Lime* involved positive enactments—a regulation promulgated by the Secretary of Agriculture and a California statute. Under the hypothetical, every grower would be civilly and criminally liable to the State of California. The state statute would completely expel federally-compliant Florida avocados from California, essentially countermanding the hypothesized federal mandate that avocados must contain no more than 7 percent oil content at harvest.[125] The relevant California law was *not* a common law cause of action, such as one allowing consumers to sue growers for defective produce.

Third, both the state statute and federal regulation were intended primarily to implement a simple rule that would address a market coordination problem. Mature and immature avocados are indistinguishable from each other at retail, but mature avocados eventually ripen after purchase while immature ones remain unpalatable.[126] Before the statute was enacted, California consumers could not reliably distinguish good avocados grown by farmers who harvested a mature crop from bad

(describing impossibility preemption as "a demanding defense" (quoting Wyeth v. Levine, 555 U.S. 555, 573 (2009)).

122. *Fla. Lime*, 373 U.S. at 143.

123. *Id.* It follows from the hypothesis that compliance with the federal standard immunized the Florida growers from complying with rules with which it was impossible to comply. Generally, though, the Court was skeptical of the argument that federal compliance immunized the growers from "more demanding state regulations." *Id.* at 141.

124. *Cf.* Andrew Zimmerman Jones, *What is Schrodinger's Cat?*, ABOUT.COM, http://physics.about.com/od/quantumphysics/f/schroedcat.htm (last visited Apr. 17, 2015).

125. One statute countermanding another is the simplest and easiest scenario for preemption analysis; the supreme federal law prevails. *See* Young, *supra* note 33, at 272–73 (observing that preemption of state law would still be possible even if preemption doctrine were narrowed to apply only when a state statute countermanded a federal one).

126. *Fla. Lime*, 373 U.S. at 137.

avocados that other farmers harvested too early.[127] This uncertainty cheated consumers and depressed demand for avocados.[128] The Court reviewed the history of the Readjustment Act and found that Congress intended for the Secretary of Agriculture to implement rules that would improve marketability by coordinating harvesting.[129] The overlapping state and federal rules were each aimed at establishing a reasonable maturity criterion to which growers could reliably conform, rather than attempting to define the optimal avocado.[130]

The outcome of *Florida Lime* is somewhat surprising given the Court's relatively broad interpretation of congressional preemptive intent sixteen years earlier in *Rice.*[131] After all, the Secretary had clearly promulgated a rule in the "field" of avocado maturity and the California statute excluded at least some federally compliant avocados. The Court's reluctance to find preemption in *Florida Lime* demonstrates that impossibility is a strict standard, as later cases have confirmed.

B. SUBSEQUENT TREATMENT

The doctrine of impossibility preemption is rarely used.[132] Although *Florida Lime* only briefly discussed physical impossibility preemption,[133] the Court has routinely included the *Florida Lime* rule in its summary of preemption doctrines.[134] Despite frequently reciting the rule, the Court never applied it so as to preempt state law until it handed down *PLIVA*

127. *Id.*

128. *Id.* at 138.

129. *Id.* at 150.

130. Additionally, the differing standards did not stem from a concern about the appropriate balancing of public health concerns. *Id.* at 137 n.4 ("No health issue has been raised in this case.").

131. Davis, *supra* note 59, at 984.

132. Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1137–38 (2007); Young, *supra* note 33, at 289.

133. The entirety of the opinion devoted to impossibility preemption is six sentences long. *Fla. Lime*, 373 U.S. at 142–43.

134. *E.g.*, English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990) ("[T]he Court has found pre-emption where it is impossible for a private party to comply with both state and federal requirements . . . ." (citing *Fla. Lime*, 373 U.S. at 142–43)); Hillsborough Cnty. v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985) (exclusively citing *Florida Lime* as authority for impossibility preemption); Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 248 (1984) (same); Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190, 204 (1983) (same); Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982) (same).

See also PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2577 (2011) (citing Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)); Wyeth v. Levine, 555 U.S. 555, 563 (2009) (citing *Fid. Fed. Sav. & Loan*, 458 U.S. at 153); *Freightliner*, 514 U.S. at 287 (citing *English*, 496 U.S. at 78–79).

some forty-eight years after *Florida Lime*. In the intervening decades, the Court continued to strictly require a showing of physical impossibility.[135] The following two cases exemplify this trend.

In *Pacific Gas and Electric Co. v. State Energy Resource Conservation and Development Commission*,[136] two electricity companies argued that a California law imposing a moratorium on nuclear plant construction was preempted by federal regulations that expressly permitted construction.[137] Regulation of nuclear energy has historically been a federal monopoly.[138] The Nuclear Regulatory Commission ("NRC"), a federal agency, prescribed extensive regulations concerning the operation of nuclear plants and the handling of nuclear waste.[139] Congress charged the Agency with developing means to store and dispose of nuclear waste, and the Agency determined it was appropriate to license new reactors in light of the availability of waste disposal options.[140] However, California's moratorium forbid construction of new plants because a state agency determined existing disposal options were inadequate.[141] Despite the conflicting standards, the Court held that it was not impossible for the electricity companies to comply with both of them.[142] Since the NRC could only approve, rather than compel, nuclear plant construction, it was possible to comply with the Agency's disposal requirements and with California's moratorium.[143]

In *Silkwood v. Kerr-McGee Corp.*,[144] the Court considered whether a federal remedial scheme designed to regulate nuclear plants preempted a state law that allowed for a punitive damages recovery against a nuclear plant.[145] A federal statute vested the NRC with exclusive regulatory control over nuclear development safety.[146] The statute authorized the NRC to police compliance with federal nuclear safety standards by penalizing

135. *See* Young, *supra* note 33, at 273 (noting that cases before *PLIVA* confined impossibility preemption to situations in which "compliance with both federal and state [law] is a physical impossibility" (quoting *Fla. Lime*, 373 U.S. at 142–43)).

136. Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190 (1983).

137. *Id.* at 197–98, 217.

138. *Id.* at 206.

139. *Id.* at 217.

140. *Id.* at 218.

141. *Id.* at 197–98.

142. *Id.* at 219–20.

143. *Id.*

144. Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984).

145. *Id.* at 257.

146. *Id.* at 258.

violators.[147] A nuclear plant employee suffered injuries as a result of radioactive contamination, sued her employer under common law theories, and recovered compensatory damages.[148] She also recovered punitive damages because the jury found the contamination was caused by grossly negligent, reckless, or willful conduct.[149] The federal government argued that the punitive damages award impermissibly conflicted with the NRC enforcement regime, but the Court rejected the preemption challenge because "[p]aying both federal fines and . . . punitive damages for the same incident would not appear to be physically impossible."[150]

Arguably the Court could have found in these cases that it was "impossible" for plant operators to comply with the relevant federal waste disposal or federal safety regulations since state law imposed different standards. To some extent, *Pacific Gas* and *Silkwood* offered more compelling cases for finding impossibility. Recall that in *Florida Lime* the state law avoided preemption essentially because of a technicality, since it was possible for most avocados to satisfy both standards if the farmers planned appropriately. *Pacific Gas*, however, did not present an opportunity for the companies to take substantial advantage of federal compliance. Even so, the Court declined to rescue the power companies from California's moratorium. And in *Silkwood*, the nuclear company was obligated to pay punitive damages in state court even though it complied with the NRC's exclusive and extensive regulation of nuclear development safety.[151]

Silkwood is distinct from *Florida Lime* and *Pacific Gas* in one important respect: only *Silkwood* involved a common law damages claim, while the other two cases involved overlapping statutes and regulations. The significance of this distinction is the subject of Part IV.

147. *Id.* at 257.

148. *Id.* at 241–43, 245.

149. *Id.* at 245.

150. *Id.* at 257.

151. The NRC investigated the contamination incident and determined the company's only violation was failing to label two of the employee's post-contamination urine samples. *Id.* at 244. Some evidence at trial indicated the nuclear company may not have always complied with NRC standards, although it did not appear that potential noncompliance contributed to the employee's injuries. *Id.* at 243.

IV. THE INTERPRETIVE DILEMMA OF COMMON LAW PREEMPTION

One of the most vexing issues the Court has faced is whether a preemptive federal law preempts only positive enactments or both positive enactments and common law.[152] Positive enactments, that is statutes and regulations, prescribe rules governing conduct, while common law actions allow injured plaintiffs to seek compensation and also deter parties from engaging in tortious conduct that gives rise to liability.[153] Thus, common law causes of action are distinct from positive enactments because the former focuses on individualized compensation. However, each body of law may further regulatory objectives by either deterring or outlawing disfavored conduct.[154] Ascertaining preemption of common law is critically important when plaintiffs allege violations of common law duties by companies that are subject to federal regulations.[155] The Court has taken differing positions on common law preemption based on the text and history of the relevant federal statutes and regulations, as well as the scope of federal objectives.[156]

A. CASES INVOLVING IMPLIED PREEMPTION

In *San Diego Building Trades Council v. Garmon*,[157] the Court considered implied preemption of common law damages for the first time.[158] The issue was whether the National Labor Relations Act impliedly

152. *E.g.*, Michael P. Moreland, *Preemption as Inverse Negligence Per Se*, 88 NOTRE DAME L. REV. 1249, 1255–56 (2013) (explaining that under common law, a defendant drug manufacturer retains a choice between changing its labels or accepting damage awards against it as a business expense but does not have that choice under statutory and administrative regulations); Wells et al., *supra* note 27, at 802–17 (analyzing changes in the Court's handling of state tort lawsuits under preemption doctrines).

153. Wells et al., *supra* note 27, at 802–03.

154. *Id.*

155. *Compare Silkwood*, 464 U.S. at 256–58 (allowing a nuclear power plant employee to recover punitive damages in a common-law action because Congress did not intend to preempt such claims in enacting exclusive regulations of nuclear safety), *with* Am. Tel. & Tel. Co. v. Cent. Office Tel., Inc., 524 U.S. 214, 227–28 (1998) (disallowing a plaintiff's common law claims because to do otherwise "would be absolutely inconsistent with the provisions of" a preemptive federal statute).

156. *E.g.*, Goodyear Atomic Corp. v. Miller, 486 U.S. 174, 183–85 (1988) (analyzing the common law preemptive effect of a federal statute in light of "the statute's language and history"). *See also* Eric S. Almon, Comment, *Preemption of State Failure-to-Warn Claims After* Wyeth v. Levine*: The Regulatory Function of State Tort Law*, 45 U.S.F. L. REV. 215, 228–30 (2010) (comparing some of the Court's cases addressing preemption of failure-to-warn and products liability claims). *But see* Davis, *supra* note 59, at 1006–13 (concluding that after *Geier*, the Court's analysis of federal objectives is dispositive in implied preemption analysis, thus displacing the interpretive significance of preemption or savings clauses).

157. San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236 (1959).

158. Davis, *supra* note 132, at 1115.

preempted a state court from awarding damages to parties claiming injuries from unfair labor practices.[159] The plaintiffs' claim alleged tortious conduct that was arguably covered by the Act and thus subject to adjudication by the National Labor Relations Board.[160] The Board declined to adjudicate the dispute, so the plaintiffs sought relief in state court and prevailed.[161] Such an award would not be valid if the Act had removed the state court's jurisdiction to award common law damages.[162] The Supreme Court discussed the reasons why Congress created the Board, observing that "Congress evidently considered that centralized administration of specially designed procedures was necessary to obtain uniform application of its substantive rules and to avoid . . . conflicts likely to result from a variety of local procedures and attitudes toward[] labor controversies."[163] In light of this, the Board's jurisdiction was exclusive and preempted the state court's damages award.[164] This was true notwithstanding the fact that the award ostensibly served to compensate the plaintiffs, rather than to regulate labor relations.[165] As the Court put it, "remedies form an ingredient of any integrated scheme of regulation."[166] *Garmon* demonstrates that congressional intent is relevant to deciding the issue of implicit common law preemption.[167]

In *Silkwood v. Kerr-McGee Corp.*,[168] the Court distinguished *Garmon*[169] and held that a federal law did *not* preempt the authority of state courts to hold tortfeasors liable for compensatory and punitive damages.[170] At issue in *Silkwood* were amendments to the Atomic Energy Act, which provided that the federal Nuclear Regulatory Commission was to "retain exclusive regulatory authority" over the disposal of hazardous radioactive material.[171] A nuclear plant employee who suffered radiological injuries obtained compensatory and punitive damages from a nuclear plant operator

159. *San Diego Bldg. Trades Council*, 359 U.S. at 239.
160. *Id.* at 238.
161. *Id.* at 238–39.
162. *Id.*
163. *Id.* at 242–43 (quoting Garner v. Teamsters, Chauffeurs & Helpers Local Union No. 776, 346 U.S. 485, 490–91 (1953)).
164. *Id.* at 246.
165. *Id.* at 246–47.
166. *Id.* at 247.
167. *See* Davis, *supra* note 59, at 983 ("As the 1950s drew to a close, the Court . . . paid some attention to the requirement of clear evidence of congressional intent to preempt.").
168. Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984).
169. *Id.* at 249.
170. *Id.* at 258.
171. *Id.* at 250.

based on a tort claim in state court, which the operator challenged as preempted.[172] The Court reaffirmed an earlier holding that the Atomic Energy Act impliedly preempted the entire field of radiological safety aspects related to nuclear plant operations,[173] and it conceded that state court remedies were arguably within the preempted field "if there were nothing more."[174] Then the Court reviewed the subsequent history of amendments to other parts of the Atomic Energy Act, finding that statutory text and its accompanying Senate reports demonstrated an underlying assumption that state court remedies would remain in effect.[175] Additionally, the fact that Congress provided no federal remedies for employees injured at nuclear plants weighed against the Court finding implied preemption of all common law claims.[176]

The Court expressly rejected the argument that common law damages avoid federal preemption merely because they lack the force of positive regulatory enactments.[177] Instead, the Court concluded that common law damages are preempted only if there is a showing of "an irreconcilable conflict between the federal and state standards" or when the imposition of damages would frustrate federal objectives.[178] *Silkwood* thus reflected the Court's interest in assessing how Congress intended to account for the regulatory effect of common law claims.[179]

In *Wyeth vs. Levine*,[180] the Court considered implied preemption of common law damages in the context of the FDCA and held that such damages were not preempted.[181] Diana Levine suffered a severe reaction to

172. *Id.*

173. *Id.* at 249–50.

174. *Id.* at 250–51.

175. The Price-Anderson Act, Pub. L. No. 85-256, 71 Stat. 576 (1957) (codified as amended in scattered sections of 42 U.S.C.), amended the Atomic Energy Act and provided an indemnification scheme for nuclear power plants. *Silkwood*, 464 U.S. at 251. The Act was passed to allay the fears of nuclear plant operators that they could be bankrupted by lawsuits in state courts, although not of the type involved in *Silkwood*. *Id.* at 251–52 & n.12. A Senate Committee Report stated that the purpose of the Act was to create a cap on the amount of liability a plant could be subjected to in state courts, at which point the indemnification scheme would intervene. *Id.* at 252 (citing S. REP. NO. 85-296, at 9 (1957)). The Act was amended in 1966, and the Senate Report on the amendments declared that "[j]ust as the rights of persons who are injured are established by State law, the rights of defendants against whom liability is asserted are fixed by State law." *Id.* at 254 (quoting S. REP. NO. 89-1605, at 26 (1966)).

176. *Silkwood*, 464 U.S. at 251.

177. *Id.* at 256 ("We do not suggest that there could never be an instance in which the federal law would pre-empt the recovery of damages based on state law.").

178. *Id.*

179. Davis, *supra* note 59, at 993.

180. Wyeth v. Levine, 555 U.S. 555, 580–81 (2009).

181. Almon, *supra* note 156, at 232.

an antihistamine drug that necessitated the amputation of her arm.[182] A physician's assistant who injected the antihistamine into Levine's vein did not read a detailed drug label that cautioned professionals to use "extreme care"[183] when pushing an injection of the drug because it could inadvertently escape the vein and lead to the complications that harmed Levine.[184] Levine argued in state court that the drug was defectively designed because its warning label did not advise professionals to use a safer intravenous drip method, rather than the risky push injection method.[185] A jury agreed and awarded damages.[186]

Wyeth, the brand-name manufacturer of the drug, argued on appeal that the trial court's judgment was preempted because it sold the drug with the FDA-approved warning label, as required under FDA regulations.[187] In particular, Wyeth claimed that it was "impossible for it to discharge its state-law obligation to provide a stronger warning" label while simultaneously distributing the approved FDA warning label.[188] Leading up to *Wyeth*, circuit courts had accepted similar arguments from drug manufacturers and held that defective labeling claims in state court were preempted by the FDCA.[189] However, the Court rejected Wyeth's impossibility preemption argument because FDA regulations allowed manufacturers to issue updated warning labels with different language so long as the updated labels were subsequently sent to the Agency for review and approval.[190] *Wyeth* made it clear to drug manufacturers that no impossibility defense could be raised whenever the FDA regulations permitted changes to drug labels.[191] The Court also rejected Wyeth's argument that the state court judgment conflicted with federal objectives[192] because Congress neither provided a federal remedy for injured patients

182. *Wyeth*, 555 U.S. at 559–60.
183. *Id.* at 561–62.
184. *Id.* at 560 n.1.
185. *Id.* at 561–62.
186. *Id.* at 562.
187. *Id.* at 563–64.
188. *Id.* at 568–69.
189. Lee, *supra* note 20, at 228 & n.137.
190. *Wyeth*, 555 U.S. at 572–73.
191. Schwartz et al., *supra* note 20, at 1852–53. The Court's holding established that the FDA's rejection of a manufacturer's drug labeling change is a necessary condition to argue for impossibility preemption, but it did not indicate that such evidence would be sufficient for a finding of impossibility. *See Wyeth*, 555 U.S. at 571–72 ("[A]bsent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements. Wyeth has offered no such evidence.").
192. *Wyeth*, 555 U.S. at 580–81.

nor expressly preempted state law in the FDCA.[193]

Garmon, *Silkwood*, and *Wyeth* each raised the question of whether federal law impliedly preempted common law damages claims. Finding preemption under these circumstances, as the Court did in *Garmon*, significantly constricts the ability of state courts to provide relief for injured consumers and to incentivize corporations to treat employees safely and to sell safe products. This consequence weighs against preemption and in favor of carefully evaluating the intended reach of federal law. As the foregoing discussion demonstrates, the Court has resolved the issue by considering congressional intent in light of legislative and regulatory histories.

B. CASES INVOLVING EXPRESS PREEMPTION

Although express preemption clauses establish congressional intent to preempt, they often use ambiguous phrasing that makes the scope of preemption unclear.[194] This has led the Court to undertake sometimes excruciating textual analyses of statutory or regulatory language to ascertain the express preemption of common law claims, either in light of congressional intent or, arguably, in spite of it.[195]

In *Cipollone v. Liggett Group, Inc.*,[196] handed down in 1992 before *Wyeth*, the Court considered preemption of a common law products liability claim for the first time.[197] The son of a deceased smoker sued tobacco manufacturers, alleging, among other things, that they were liable for his mother's death because they failed to adequately warn consumers about the dangers of smoking.[198] The decedent began smoking in 1942 and died of lung cancer in 1984.[199] Congress enacted the Federal Cigarette Labeling and Advertising Act[200] in 1965, which required specifically-worded warnings on cigarette packages but barred requiring warnings in

193. *Id.* at 574–75.

194. Davis, *supra* note 59, at 997.

195. *See id.* at 1000 (discussing the Court's parsing of statutory language and analysis of legislative history in *Cipollone v. Liggett Group*, 505 U.S. 504 (1992)); *id.* at 1008–10 (describing the Court's analysis of ambiguous preemption and saving clauses in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), as based on "general judicially-determined frustration of national purposes" rather than congressional intent).

196. Cipollone v. Liggett Grp., 505 U.S. 504 (1992).

197. Davis, *supra* note 132, at 1120.

198. *Cipollone*, 505 U.S. at 509–10.

199. *Id.* at 508.

200. Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331–1340 (2012)).

advertisements.[201] The Act contained a preemption clause that provided "[n]o *statement* relating to smoking and health *shall be required* in the advertising of any cigarettes."[202] Congress amended the clause in 1969 to read "[n]o *requirement or prohibition* based on smoking and health *shall be imposed* under State law with respect to the advertising or promotion of any cigarettes."[203] The manufacturers argued that federal law preempted liability under state law for conduct occurring at any point after 1965.[204]

The Court splintered over the linguistic and legal significance of the differences between the 1965 and 1969 provisions. The majority opinion held that the 1965 provision preempted positive enactments related to cigarette advertising and packaging but not common law damages.[205] This was so because of the precise and narrow language that Congress chose.[206] There was no majority opinion regarding the preemptive scope of the 1969 provision. The plurality concluded the words "no requirement or prohibition"[207] sweep broadly, thereby preempting both positive enactments *and* common law.[208] A contrary textual interpretation would be inconsistent with "the general understanding of common-law damages actions," as typified by the *Garmon* Court's observation that state regulation of conduct occurs both through common law liability and positive enactments.[209]

In *Medtronic, Inc. v. Lohr*,[210] the Court relied on both textual analysis

201. 15 U.S.C. § 1331(2)(B); *Cipollone*, 505 U.S. at 514, 518.

202. *Cipollone*, 505 U.S. at 514 (quoting Pub. L. No. 89-92, § 5(a), 79 Stat. at 283 (amended 1969)) (emphasis added).

203. *Id.* at 515 (quoting Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 5(a), 84 Stat. 87, 88 (codified as amended at 15 U.S.C. § 1334(b) (2012))) (emphasis added).

204. *Id.* at 510.

205. *Id.* at 518–19.

206. *Id.* at 518.

207. 15 U.S.C. § 1334(b).

208. *Cipollone*, 505 U.S. at 521–23 (plurality opinion). A majority of the Court agreed with this conclusion. *See id.* at 548–49 (Scalia, J., dissenting) (agreeing with the plurality's conclusion that the language of the 1969 preemption provision covered both positive enactments and common law). Three Justices argued that neither the 1965 provision nor the modified 1969 provision preempted state common law damages claims. *Id.* at 534 (Blackmun, J., dissenting) ("[T]he modified language . . . no more 'clearly' or 'manifestly' exhibits an intent to pre-empt state common-law damages actions than did the language of . . . the 1965 Act.").

209. *Id.* at 521 (plurality opinion) (citing San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 247 (1959)). The *Garmon* Court found that a federal law preempted state common law because the history and purpose of the relevant federal statute demonstrated congressional intent to establish a national and uniform set of rules and procedures to adjudicate labor disputes. *See supra* notes 157–167 and accompanying text.

210. Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

and regulatory history to hold that an express preemption provision did not cover a common law damages claim.[211] Lora Lohr sued Medtronic, the manufacturer of her pacemaker, after she suffered a heart block attributable to a defective lead in the pacemaker.[212] She claimed Medtronic was liable under state law for defectively designing the pacemaker and for failing to adequately warn about the risk of failure.[213] A preemption clause in the Medical Device Act (MDA) provided, "[N]o State . . . may establish or [enforce] . . . any requirement . . . which is different from, or in addition to, any requirement applicable under [the MDA], and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]."[214]

Medtronic argued that common law standards relating to medical device manufacturing and labeling were preempted because Medtronic was required to comply with a series of generic "Good Manufacturing Practices" (GMP) promulgated by the FDA.[215] The Court identified several related FDA rules that narrowly construed the preemptive scope of MDA regulations.[216] Those regulations and the text of the MDA showed an "overarching concern that pre-emption only occur where a particular state requirement threatens to interfere with a specific federal interest."[217] Neither the generic GMP standards nor general common law duties to avoid foreseeable manufacturing dangers and to warn of risks were specific enough to constitute "requirements" as used in the preemption provision.[218] Lohr's common law claims did not avoid preemption *because* they were based on common law; rather, the claims were not preempted because they did not qualify as "different from, or in addition to, any requirement" and thus fell outside the scope of the express preemption clause.[219]

211. *Id.* at 482–86, 492–94; Moreland, *supra* note 152, at 1260; Almon, *supra* note 156, at 229.

212. *Lohr*, 518 U.S. at 481.

213. *Id.*

214. Medical Device Act, 21 U.S.C. § 360k(a)–(b) (2012); *Lohr*, 518 U.S. at 481–82.

215. *Lohr*, 518 U.S. at 483–84, 498–99.

216. *Id.* at 498–500.

217. *Id.* at 500.

218. *Id.* at 501–02.

219. 21 U.S.C. § 360k(a); *Lohr*, 518 U.S. at 502. In *Lohr*, the Court followed a rule from *Cipollone v. Liggett Group*, 505 U.S. 504 (1992), construing the presence of an express preemption provision as foreclosing the application of implied preemption doctrines. *Lohr*, 518 U.S. at 484–86; *Cipollone*, 505 U.S. at 517. Thus, once the Court established that the preemption provision did not apply to Lora Lohr's particular claims, that finding definitively resolved the question of preemption in the negative. *See Lohr*, 518 U.S. at 501–02 ("[N]one of the Lohrs' claims based on allegedly defective manufacturing or labeling are pre-empted by the MDA"). In later cases, the Court indicated that express preemption provisions do not exclude the operation of implied preemption doctrines. Davis, *supra* note 132, at 1001–02.

The Justices who signed Justice Stevens's majority opinion in *Lohr* appeared to fracture over the general reach of the express preemption clause. In a section of the opinion garnering only plurality support, Justice Stevens declined to address Lohr's broad assertion that common law duties could *never* qualify as a "requirement" under the statute.[220] Justice Breyer departed from Justice Stevens's opinion in this respect to address her argument.[221] In Justice Breyer's view, the statute's reference to a "requirement" could be read as covering tort claims in some circumstances,[222] but Lohr's claims were not preempted since the FDA's regulations demonstrated an intent not to preempt claims under the particular circumstances of her case.[223] Justice O'Connor, writing for three other Justices, extensively cited *Cipollone*'s observation that common law claims should not be treated differently from "requirements" imposed by positive enactments since both operate to regulate conduct.[224] She flatly concluded that the word "requirement" covered common law claims based on the statute's ordinary meaning and criticized the plurality's apparent hesitancy to do the same.[225] The *Cipollone* opinions and *Lohr* opinions thus presented competing theories about whether the Court should treat state statutes and state common law claims equivalently when applying the text of express preemption provisions.

In 2008, the Court revisited the same MDA preemption provision in *Riegel v. Medtronic, Inc.*[226] Charles Riegel developed a heart block after his doctor inserted a Medtronic catheter into his coronary artery.[227] He and his wife sued Medtronic, alleging that it was liable under state law for negligently designing, manufacturing, and labeling the catheter.[228] Riegel's catheter and Lohr's pacemaker were different in one crucial respect: only the catheter was determined to be safe and effective under the FDA's

220. *Lohr*, 518 U.S. at 502–03 (plurality opinion).

221. *Id.* at 503–04 (Breyer, J., concurring).

222. *Id.*

223. *Id.* at 507. Under Justice Breyer's theory, the statute's preemption language plausibly but ambiguously indicated congressional intent to preempt common law torts. *Id.* at 505–06. Therefore, recourse to the agency charged with implementing the statute was appropriate, and the FDA's narrow approach to preemption controlled. *See id.* at 506–07 ("At least in present circumstances, no law forces the FDA to make its requirements pre-emptive if it does not think it appropriate."). *See also* Moreland, *supra* note 152, at 1259–61 (analyzing Justice Breyer's concurrence in *Lohr*).

224. *Lohr*, 518 U.S. at 510–11 (O'Connor, J., concurring in part and dissenting in part).

225. *Id.* at 511–12.

226. Riegel v. Medtronic, Inc., 552 U.S. 312 (2008).

227. *Id.* at 320.

228. *Id.*

rigorous medical device premarket approval process (PMA),[229] which is similar to the approval process for new prescription drugs.[230] Once a device is approved under PMA, it must be manufactured "with almost no deviations" from the approved design.[231] By contrast, the pacemaker in *Lohr* qualified for an exemption from PMA because it was substantially equivalent to existing pacemakers.[232] Therefore, Medtronic was only obligated to follow the FDA's generic Good Manufacturing Practices when manufacturing the pacemaker, while it needed to adhere strictly to the specifications in the approved PMA application when manufacturing the catheter.[233]

First the Court concluded that the compliance obligations imposed on PMA device manufacturers were specific enough to qualify as "requirements" under the MDA's preemption provision.[234] Next the Court considered whether the Riegels' common law claims imposed, in the words of the statute, a "requirement . . . different from, or in addition to" the federal requirement.[235] This raised the same common law preemption issue that fractured the majority coalition in *Lohr*. Perhaps wishing to resolve the interpretive ambiguity unleashed in 1992 by the split opinions in *Cipollone*, the *Riegel* Court agreed on a clear interpretive rule: "Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent other indication, reference to a State's 'requirements' includes its common-law duties. . . . In the present case, there is nothing to contradict this normal meaning."[236] Accordingly, the MDA preempted the Riegels' common law claims.[237]

The Court's rule may overstate the conclusiveness of statutory interpretation in express preemption analysis.[238] Even so, after progressing

229. *Id.* at 322–23.

230. Almon, *supra* note 156, at 230.

231. *Riegel*, 552 U.S. at 323.

232. *Id.* at 322–23.

233. *Id.* at 323.

234. *Id.*

235. *Id.* at 328.

236. *Id.* at 324. Like some of the Justices in *Lohr*, the Court supported this proposition by quoting the plurality's analysis in *Cipollone v. Liggett Group*, 505 U.S. 504 (1992). *Riegel*, 552 U.S. at 324; Medtronic, Inc. v. Lohr, 518 U.S. 470, 504 (1996) (Breyer, J., concurring); *id.* at 510 (O'Connor, J., concurring in part and dissenting in part).

237. *See Riegel*, 552 U.S. at 330 (affirming dismissal of common law claims as preempted).

238. Michael Moreland has argued that the differing outcomes in *Lohr* and *Riegel* reflect the Court's sensitivity to congressional intent. Moreland, *supra* note 152, at 1284. Congress intended to preempt common law claims with respect to PMA devices but not with respect to devices only approved as substantially equivalent. *Id.* Statutory interpretation alone is "too often an under-determinative guide to resolving cases arising under express preemption." *Id.*

from *Cipollone* to *Riegel*, a majority of the Court agreed about how to interpret the word "requirements" when used in an express preemption provision. This rule of textual interpretation apparently resolved the question of whether common law claims should be treated as either compensatory laws capable of existing concurrently with overlapping federal law, or, as the Court held, regulatory laws that impermissibly conflict with federal prerogatives. The adoption of this interpretive rule is part and parcel of the Court's general skepticism towards the value of common law claims and unpredictable jury verdicts in light of modern federal regulatory agencies.[239]

V. FEDERAL REGULATION OF PRESCRIPTION DRUGS

As discussed in Part IV.A, the Court's approach to evaluating implied preemption of state common law claims has turned on the scope of federal objectives and statutory and regulatory histories. Furthermore, the Court's interpretive rule from *Riegel*, treating state common law the same way as statutes, does not readily extend to preemption issues under the FDCA because Congress did not include an express preemption clause in the FDCA. Therefore, familiarity with the background of the FDCA and the FDA is essential to evaluate the preemption issue raised in *PLIVA* and *Mutual Pharmaceutical*.

By 2009, the FDA was responsible for regulating the manufacture, sale, and labeling of eleven thousand prescription drugs.[240] Drug regulation necessarily involves trade-offs among conflicting goals of ensuring patient safety, reducing costs, and facilitating private development of new drug therapies. Even so, the overriding goal of federal regulation is to ensure that drugs are safe.[241] As the Court has concluded, the statutory and regulatory background of the FDCA does not reflect an intent to preempt state law tort claims or demonstrate a conflict between federal and state laws related to drug safety.

A. DEVELOPMENT OF THE MODERN REGIME

Although food and drug safety was traditionally the concern of state courts and legislatures, the flow of dangerous drugs across state lines was

239. *See* Davis, *supra* note 59, at 1015 (arguing after *Cipollone* and *Lohr*, but before *Riegel* was decided, that the Court's preemption jurisprudence reflected skepticism of jury damages).

240. Wyeth v. Levine, 555 U.S. 555, 578 (2009).

241. Lee, *supra* note 20, at 261.

serious enough to attract attention from Congress by the early twentieth century.[242] It established the FDA in 1906 to protect consumers from adulterated and misbranded food and drugs.[243] Although the 1906 Act provided an additional layer of consumer protection, it was not until the passage of the FDCA in 1938 that Congress began to require advanced FDA approval of drugs before they could be sold.[244] Thus, the FDCA brought about unprecedented federal oversight of public health.[245]

At first, the FDA preapproval requirement did not present much of an obstacle for drug manufacturers because the Agency lacked the resources and expertise to regulate drugs effectively.[246] However, Congress remedied this by amending the FDCA in 1962 to strengthen the preapproval requirement.[247] The 1962 Amendments overhauled the New Drug Application (NDA) process, which now requires drug manufacturers to demonstrate both the safety and effectiveness of proposed new drugs by undertaking a series of clinical trials.[248]

The NDA process continues to be the primary regulatory hurdle separating brand-name pharmaceutical companies from the prescription drug market. A new drug may not be sold in interstate commerce without the FDA's approval of an NDA for that drug.[249] An NDA applicant must provide the FDA with, among other things, pharmacological studies,[250] toxicology studies,[251] and analyses of controlled clinical studies relevant to each proposed use of the drug.[252] Ultimately, the manufacturer's data must demonstrate "substantial evidence of effectiveness"[253] and the manufacturer must explain how the benefits of using the drug outweigh its risks.[254] The FDA will approve an NDA unless the data is inadequate to establish the drug's safety, the NDA lacks "substantial evidence"

242. Matthew J. Clark, Note, *A Critical Analysis of* PLIVA, Inc. v. Mensing, 46 IND. L. REV. 173, 176 (2013).

243. Davis, *supra* note 132, at 1099–1100.

244. *Wyeth*, 555 U.S. at 566.

245. Danielle L. Steele, Comment, *The "Duty of Sameness" as a Shield—Generic Drug Manufacturers' Tort Liability and the Need for Label Independence After* PLIVA, Inc. v. Mensing, 43 SETON HALL L. REV. 441, 446 (2013).

246. Clark, *supra* note 242, at 177.

247. *Id.* at 177–78.

248. Gregory J. Feeney, Note, PLIVA, Inc. v. Mensing: *How Generic-Drug Manufacturers Avoided Liability for "Failure to Warn" Tort Claims*, 58 LOY. L. REV. 251, 256 (2012).

249. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a) (2012).

250. 21 C.F.R. § 314.50(d)(2)(i) (2012).

251. *Id.* § 314.50(d)(2)(ii).

252. *Id.* § 314.50(d)(5)(i).

253. *Id.* § 314.50(d)(5)(v).

254. *Id.* § 314.50(d)(5)(viii).

demonstrating effectiveness,[255] or certain other problems exist that preclude approval.[256]

Bringing a new drug to market is terrifically expensive. A study in 2003 found that, on average, it cost $802 million to research and develop a new drug for sale in the United States.[257] Another study in 2012 estimated the average cost at $1.2 billion.[258] The high cost of drug development reflects the reality that most experimental drugs do not make it beyond clinical trials.[259] The process of identifying a new compound, conducting preclinical and clinical trials, and obtaining FDA approval generally takes more than ten years.[260] Pharmaceutical companies undertake the investment risk of developing a new drug because their patent rights in any newly-approved drug allow them to exclude other companies from selling or manufacturing the drug for a limited time, typically eleven to twelve years.[261] The profits which flow from the patent exclusivity period are essential to supporting the development of new drugs.[262]

In addition to raising the costs of developing new drugs, the 1962 FDCA amendments also had the effect of discouraging the marketing of cheaper generic drugs.[263] Before 1962, generic drug sales were limited principally by the duration of patent terms on existing drugs. Once a drug's patent term expired, any manufacturer could seek FDA approval and sell a generic alternative.[264] The 1962 Amendments added a second limitation to generic drug entry because *all* drug manufacturers were subject to the

255. *Id.* §§ 314.105(a), 314.125(b)(3)–(5).

256. *Id.* § 314.125(b)(1)–(2), (6)–(18).

257. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003).

258. PHRMA, MEDICINES IN DEVELOPMENT: NEW DRUG APPROVALS IN 2011 2, (2012), *available at* http://www.phrma.org/sites/default/files/pdf/nda2011.pdf.

259. Joseph A. DiMasi, *Success Rates for New Drugs Entering Clinical Testing in the United States*, 58 CLINICAL PHARMACOLOGY & THERAPEUTICS 1, 1 (1995).

260. Henry Grabowski et al., *Returns on Research and Development for 1990s New Drug Introductions*, 20 PHARMACOECONOMICS 11, 14 (Supp. 3 2002).

261. Allison Stoddart, Note, *Missing After* Mensing*: A Remedy for Generic Drug Consumers*, 53 B.C. L. REV 1967, 1972 (2012). The effective length of the exclusivity period is affected in part by how long it takes for the FDA to approve a new drug for sale. *Id.*

262. Steele, *supra* note 245, at 449.

263. Laba Karki, *Review of FDA Law Related to Pharmaceuticals: The Hatch-Waxman Act, Regulatory Amendments and Implications for Drug Patent Enforcement*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 602, 607–08 (2005).

264. *See supra* note 246 and accompanying text (explaining that before 1962, it was easier to sell a drug that was not protected by a patent).

revamped NDA requirements for any drug not approved as of 1962.[265] Therefore, a manufacturer seeking to market a generic version of an off-patent post-1962 drug would need to undertake the same costly preclinical and clinical trials that the original manufacturer had completed under the newer NDA requirements, but the generic manufacturer would not receive the economic benefit of patent exclusivity.[266] Thus, by 1983, most of the bestselling brand-name drugs with expired patents did not face any competition from generic drug manufacturers[267] and generics accounted for only 13 percent of pharmaceutical sales.[268] One researcher found that of 150 post-1962 drugs that were off-patent by 1983, only 10 percent were available in the generic drug market.[269]

B. FACILITATING THE ENTRY OF POST-1962 GENERIC DRUGS

Congress established the framework for the modern generic drug industry in 1984 by passing the Drug Price Competition and Patent Term Restoration Act,[270] otherwise known as the Hatch-Waxman Amendments.[271] The Hatch-Waxman Amendments pursued the twin goals of (1) incentivizing the development of new drugs and (2) lowering the market price of off-patent drugs through generic competition.[272] First, the amendments extended the effective patent exclusivity terms of new drugs by restoring some of the time lost during the approval process.[273] Second, the amendments made it easier for generic drug companies to bring their drugs to market by establishing a new, simpler method of FDA premarket approval for off-patent post-1962 drugs.[274] A House Report zeroed in on the misaligned incentives created by the 1962 Amendments, finding that consumers were not benefitting from "savings on drugs approved after

265. Teresa J. Lechner-Fish, Comment, *The Hatch-Waxman System: Suffering a Plague of Bad Behavior*, 5 HOUS. BUS. & TAX L.J. 372, 387 (2005).

266. *Id.* at 384–85; Karki, *supra* note 263, at 607.

267. Garth Boehm et al., *Development of the Generic Drug Industry in the U.S. after the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 1, 2 (2013).

268. *Id.*

269. Lechner-Fish, *supra* note 265, at 381–82.

270. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355 (2012)).

271. Sarah Boehme, Note, *The Luck of the Draw: The Consequences of Being Prescribed a Generic Drug over a Brand Name Drug*, 32 MISS. C. L. REV. 145, 148 (2013).

272. Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 FOOD & DRUG L.J. 51, 69 (2003).

273. *Id.*

274. *Id.*

1962 because of the lack of an approval procedure" for generic drugs.[275]

The Hatch-Waxman Amendments added a subsection to the FDCA specifying a means of submitting an abbreviated new drug application (ANDA) to the FDA.[276] The ANDA process requires a prospective manufacturer to show that their drug contains the same active ingredients, warning label, and dosage strength as a previously-approved drug, so long as that drug is not protected by a valid patent.[277] Importantly, the ANDA process does not require an applicant to demonstrate the safety and effectiveness of the drug.[278] As the House Report put it, excusing ANDA applicants from undertaking new human clinical trials avoids "wasteful" retesting of drugs that have already been shown to be safe and effective as part of conventional new drug applications.[279]

By reducing barriers to entry, the Hatch-Waxman Amendments improved the availability of generic drugs and helped consumers realize significant savings on prescription drug costs.[280] According to recent studies sponsored by the generic drug industry, generic drugs accounted for 84 percent of prescriptions dispensed in 2012[281] and saved consumers an estimated $1.07 trillion from 2002 through 2011.[282]

C. LABELING REQUIREMENTS

Under general tort principles, drug manufacturers are exempt from strict liability for injuries, but they must adequately warn of the risks associated with their drugs.[283] Accordingly, the preparation of an effective warning label is a key part of the new drug application process.[284]

275. H.R. REP. NO. 98-857, at 17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650.

276. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585–92 (codified at 21 U.S.C. § 355 (2012)).

277. *Id.*

278. Lee, *supra* note 20, at 219.

279. H.R. REP. NO. 98-857, at 16, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649.

280. Sarah C. Duncan, Note, *Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change*, 13 VAND. J. ENT. & TECH. L. 185, 188 (2010).

281. MURRAY AITKEN & MICHAEL KLEINROCK, IMS INST. FOR HEALTHCARE INFORMATICS, DECLINING MEDICINE USE AND COSTS: FOR BETTER OR WORSE? A REVIEW OF THE USE OF MEDICINES IN THE UNITED STATES IN 2012, at 8 (2013), *available at* http://www.drugstorenews.com/sites/drugstorenews.com/files/US%20Medicines%202012.pdf.

282. *Generic Drugs Saved Consumers USD 193 Billion*, HOSPIMEDICA (Aug. 21, 2012), http://www.hospimedica.com/business/articles/294742171/generic_drugs_saved_consumers_usd_193_billion.html.

283. Wesley E. Weeks, Comment, *Picking Up the Tab for Your Competitors: Innovator Liability After* PLIVA, Inc. v. Mensing, 19 GEO. MASON L. REV. 1257, 1265 (2012).

284. Lee, *supra* note 20, at 215.

Brand-name and generic drug manufacturers are subject to different labeling requirements under the NDA and ANDA approval regimes.[285] In the case of a new drug, the manufacturer must submit proposed labeling with the NDA[286] and the FDA must reject the application if the label is "false or misleading in any particular."[287] Labeling approval for a new drug involves a years-long process during which the FDA and the applicant identify which risks should or should not be listed on a warning label based on scientific evidence regarding the drug's safety profile.[288] Generic manufacturers, however, need only show in an ANDA that their labeling will be "the same as the labeling approved for the" brand-name drug on which the generic drug is based.[289] This "duty of sameness" for generic drug labels is necessary because generic drug manufacturers usually do not have detailed clinical trial data on which to base a new or different safety label[290] and because the "central premise of the ANDA process[] [is] that generic drugs are . . . the therapeutic equivalent of" brand-name drugs.[291]

What suffices for an adequate warning label for a particular drug frequently changes over time.[292] This is because the small sample sizes of clinical trials are unlikely to detect every significant side effect that will arise in the general population.[293] FDA labeling regulations reflect the fact that, after approval, a drug's label may need to be updated when prolonged usage reveals additional risks.[294] The FDA has identified two textual sources which obligate manufacturers to update their labels. First, the FDCA broadly prohibits the sale of drugs that lack "adequate warnings against . . . unsafe dosage or methods or duration of administration or application."[295] Second, FDA regulations require all manufacturers to revise labels to warn of "clinically significant hazard[s] as soon as there is reasonable evidence of a causal association with a drug."[296]

285. Boehme, *supra* note 271, at 149.

286. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(1) (2012).

287. *Id.* § 355(d).

288. Lee, *supra* note 20, at 215.

289. 21 U.S.C. § 355(j)(2)(A)(v).

290. Lee, *supra* note 20, at 245–46.

291. *Id.* at 220.

292. Catherine D. DeAngelis & Phil B. Fontanarosa, *Prescription Drugs, Products Liability, and Preemption of Tort Litigation*, 300 J. AM. MED. ASS'N 1939, 1939–40 (2008).

293. *Id.*; Almon, *supra* note 156, at 235–36.

294. Lee, *supra* note 20, at 221.

295. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 352(f) (2012) (defining "misbranded" to include inadequate safety labeling); *id.* § 331(a) (prohibiting the introduction of "misbranded" drugs into interstate commerce).

296. 21 C.F.R. § 201.57(c)(6)(i) (2012); *id.* § 201.80(e). *See* Clark, *supra* note 242, at 190–92 (explaining regulatory history or revised label warnings).

The NDA and ANDA labeling rules reflect a sensible distinction. With an NDA, the manufacturer is bringing a wholly new drug to market and therefore bears the burden of demonstrating the adequacy of a proposed label based on clinical data. For several years following approval, the manufacturer enjoys an exclusive right to sell the drug and is also subject to an exclusive obligation to maintain the adequacy of the label based on any new data. After patent expiration, generic manufacturers enter the market and incorporate whatever brand-name label is in effect at the time the generic drug is approved for sale. However, complexity arises as time goes on. What might have been an adequate warning label when a generic drug was approved might no longer be adequate after several more years on the market. And although generic drug manufacturers do not conduct preapproval clinical trials, both generic and brand-name manufacturers are required to submit reports of post-approval adverse drug reactions to the FDA.[297]

The FDA regulations providing for updates to drug labels have been the subject of intense litigation.[298] The "flashpoint" in *PLIVA, Inc. v. Mensing* and in earlier cases is a regulation known as "changes being effected" (CBE).[299] The CBE process allows "the holder of an approved application" to add or strengthen warnings on an approved drug label by submitting a supplement to the FDA.[300] The manufacturer "may commence distribution of the [revised] drug product . . . upon receipt by the agency of [the] supplement."[301] Thus, a manufacturer does not need preapproval from the FDA to distribute drugs with updated labeling, although the FDA could order the manufacturer to stop selling the drug if it subsequently disapproves of the changes.[302] On its face, the language of the CBE regulation does not distinguish between brand-name or generic drug manufacturers. It refers only to "holder[s] of . . . approved application[s],"[303] while other regulations refer to "holder[s] of . . . *abbreviated new drug* application[s]"[304] or "holder[s]

297. Lee, *supra* note 20, at 216.

298. *See generally* Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466 (2013) (analyzing plaintiff's claim that a generic drug manufacturer failed to provide an adequate warning on its drug label); PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011) (same); Wyeth v. Levine, 555 U.S. 555 (2009) (same); Motus v. Pfizer, Inc., 358 F.3d 659 (9th Cir. 2004) (same).

299. Lee, *supra* note 20, at 224.

300. 21 C.F.R. § 314.70(c)(6), (c)(6)(iii), (c)(6)(iii)(A).

301. *Id.* § 314.70(c)(6).

302. *Id.* § 314.70(c)(7).

303. *Id.* § 314.70(c)(6).

304. *E.g.*, *id.* § 314.153(b)(6) (emphasis added).

of . . . approved application[s] *under section 505(b)* of the [FDCA],"[305] which is the subsection that establishes the NDA process. Nonetheless, the FDA has concluded that the CBE process is available to brand-name manufacturers but not to generic drug manufacturers.[306] This is so, according to the FDA, because a generic manufacturer's duty of sameness: if a generic manufacturer added a warning to its label, then the label would no longer be identical to the brand-name label.[307] The FDA has collectively interpreted the ANDA regulations, the CBE process, and the duty to maintain adequate labels as requiring generic manufacturers to notify the FDA if there is a need for new warnings. Under this scenario, if the FDA agreed with the generic manufacturer, the FDA would then work with the brand-name manufacturer to update its label and thus any generic drug labels based on it.[308] This was the FDA's suggested solution when it promulgated the final rules implementing the ANDA regime in 1992.[309] However, it never promulgated specific regulations clarifying this amorphous approach to generic drug label revisions.[310] Because of this failure, generic drug manufacturers seeking to update their labels face "an ill-defined process."[311]

D. TWO SYSTEMS OF DRUG SAFETY REGULATION

For most of its history, the FDA has recognized that federal regulations and state tort law "each provid[e] a significant, yet distinct, layer of consumer protection."[312] In other words, the FDA has traditionally understood tort lawsuits as complementing federal regulation of drug safety, rather than conflicting with it.[313] Tort lawsuits help bring forth safety data that might not otherwise be presented to the FDA.[314] The agency oversees the post-marketing surveillance of some eleven thousand

305. *E.g.*, *id.* § 314.52(a)(2) (emphasis added).

306. Clark, *supra* note 242, at 185.

307. *Id.* The FDA "may" seek to withdraw its approval of an ANDA if the generic drug's labeling "is no longer consistent with that for the [brand-name] drug referred to in the [ANDA]." 21 C.F.R. § 314.150(b)(10).

308. Clark, *supra* note 242, at 185.

309. Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992) (codified in scattered parts of 21 C.F.R.).

310. Lee, *supra* note 20, at 249.

311. *Id.*

312. Davis, *supra* note 132, at 1094.

313. Wyeth v. Levine, 555 U.S. 555, 580–81 (2009).

314. *See* David C. Vladeck, *FDA Preemption,* Wyeth*, Congress, and a Crystal Ball*, 32 HAMLINE L. REV. 707, 722 (2009) (noting that the Court will likely not "turn a blind eye" to tort litigation given that doing so may harm public health because the FDA does not have the resources to keep up with the safety data produced by drug companies).

prescription drugs,[315] but it lacks subpoena power and must rely on manufacturers to disclose data voluntarily.[316] Manufacturers have an incentive to downplay safety risks,[317] both during the approval process and for many years afterwards when additional risks may become apparent in the population at large. Furthermore, the agency is not equipped to be the sole regulator of post-marketing drug safety. A 2009 GAO report found that Agency staff lacked the funding, personnel, and data to monitor post-marketing drug safety effectively.[318] Only half of the Agency's safety-related positions were filled,[319] and its budget was about half the size necessary to fully track post-approval drug safety.[320]

One review of state lawsuits involving drug safety found that it was a "common theme" for manufacturers to delay reporting adverse safety data to the FDA and then to minimize the significance of worrisome data once it came to light.[321] For example, in a lawsuit against Bayer over deadly side effects caused by cerivastatin, internal documents showed the company had received adverse event reports showing heightened risks.[322] The company failed to process all of the event reports.[323] As one executive wrote in an internal memorandum, "If the FDA asks for bad news, we have to give, but if we don't have it, we can't give it to them."[324] In 2003 Bayer ended up settling claims related to cerivastatin for over $1 billion.[325] In another case, the manufacturer of olanzapine settled over eight thousand lawsuits for $690 million in 2005.[326] The plaintiffs claimed that the drug inadequately warned about the risk of weight gain and diabetes, prompting the FDA to require an updated safety label.[327] Litigation over Vioxx, an anti-inflammatory drug, uncovered internal documents showing that the

315. *Wyeth*, 555 U.S. at 578.

316. AS Kesselheim, *Permitting Product Liability Litigation for FDA-Approved Drugs and Devices Promotes Patient Safety*, 87 CLINICAL PHARMACOLOGY & THERAPEUTICS, 645, 646 (2010).

317. *Id.*

318. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-68, DRUG SAFETY: FDA HAS BEGUN EFFORTS TO ENHANCE POSTMARKET SAFETY, BUT ADDITIONAL ACTIONS ARE NEEDED 1 (2009), *available at* http://www.gao.gov/new.items/d1068.pdf.

319. *Id.* at 33–34.

320. *Id.* at 38.

321. Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. AM. MED. ASS'N 308, 309 (2007).

322. *Id.*

323. *Id.*

324. *Id.*

325. *Id.*

326. *Id.*

327. *Id.*

manufacturer sought to design clinical trials so as to mask the significance of dangerous cardiovascular side effects.[328]

The FDA's recognition of complementary state regulation has not been unbroken. In 2002, a former drug company lawyer who was serving as the FDA's general counsel argued in an amicus brief that the Agency's approval of a drug preempted the operation of state tort lawsuits.[329] This was consistent with the objectives of the George W. Bush administration, which aggressively pursued limitations on state tort liability in a number of industries.[330] Finding congressional support lacking, the administration turned instead to agency rulemaking and, in particular, interpretive regulatory preambles.[331] The FDA announced one of these preemptive preambles in 2006, asserting that tort lawsuits in state court frustrated the Agency's ability to pursue its drug safety objectives.[332] The Court rejected the Agency's attempt at preemption by preamble in the 2009 *Wyeth* decision, finding that the Agency's assertion improperly sought to "reverse[] the FDA's own longstanding position without providing a reasoned explanation, including any discussion of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence."[333]

The foregoing background sketches the regulatory landscape on which the Court decided *PLIVA* and *Mutual Pharmaceutical*. Two general propositions were settled when these cases reached the Court. First, the Hatch-Waxman Amendments successfully improved the widespread availability of cheaper generic drugs, as Congress intended, by relieving generic manufacturers from the onerous duty of establishing drug safety and effectiveness with clinical testing. Second, as the Court found in *Wyeth*, the availability of products liability claims in state courts ultimately helped improve the state of drug safety, consistent with the objectives of the FDCA and its accompanying FDA regulations. It is appropriate to analyze the Court's holdings and reasoning carefully in both of the cases with this background in mind.

328. Almon, *supra* note 156, at 238.

329. Davis, *supra* note 132, at 1094 & n.32, 1095.

330. Young, *supra* note 33, at 280. *See also* Almon, *supra* note 156, at 223 & n.57 (suggesting the Bush administration as a driving force in the FDA's changing stance on preemption).

331. Davis, *supra* note 132, at 1109–10.

332. *Id.*

333. Wyeth v. Levine, 555 U.S. 555, 576–77 (2009).

VI. IMPLIED IMPOSSIBILITY PREEMPTION IN *PLIVA* AND *MUTUAL PHARMACEUTICAL*

At the outset, it is important to note that *Wyeth* dealt with the overlap between *brand-name* drug labeling regulations and products liability claims. The former did not preempt the latter because it was possible for the manufacturer to update the drug label by submitting revisions to the FDA through the CBE process. *PLIVA* and *Mutual Pharmaceutical* involved a similar overlap of common law and FDA regulations, but the drugs at issue were approved under ANDA rather than NDA. The shift in regimes from NDA to ANDA proved to be decisive.[334] In both cases the Court distinguished *Wyeth* and held that common law claims were preempted.[335] In *PLIVA* the Court built on *Wyeth* dicta by holding that, for the purposes of impossibility analysis, actors are not obligated to alter their behavior so as to achieve dual compliance if doing so would require intervention by federal regulators.[336] In *Mutual Pharmaceutical*, the Court stated affirmatively what was implicit in *PLIVA*: under implied impossibility preemption, common law claims that overlap with federal regulations are treated the same way as overlapping state statutes.[337] Each of these points is developed below, followed by a critical evaluation of implied impossibility preemption in light of these modifications.

A. *PLIVA*

Gladys Mensing and Julie Demahy were prescribed Reglan, a drug frequently used to treat digestive tract problems.[338] Their pharmacists dispensed metoclopramide, the generic version of Reglan.[339] Each patient took the drug for several years and then developed tardive dyskinesia, which is a serious and commonly irreversible side effect associated with long-term metoclopramide use.[340] They asserted common law claims against the metoclopramide manufacturers, alleging the companies were liable because they should have (1) known there was a high risk of tardive dyskinesia associated with long-term use, (2) known the warning labels did

334. As Justice Thomas wrote in *PLIVA*, the Court "will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme." PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2582 (2011).

335. *Id.* at 2580–82; Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2479 (2013).

336. *PLIVA*, 131 S. Ct. at 2580–82.

337. *Mut. Pharm.*, 133 S. Ct. at 2479.

338. *PLIVA*, 131 S. Ct. at 2572–73.

339. *Id.* at 2573.

340. *Id.*

not adequately warn of the risk, and, therefore, (3) used safer labels.[341] The manufacturers argued the claims were preempted because it was impossible to comply simultaneously with both state law and the FDA regulations requiring generic drugs to bear the same labels as the equivalent brand-name drugs.[342]

The Court first accepted the FDA's submission that the CBE process was unavailable to generic drug manufacturers.[343] Arguably, CBE was available to generic drug manufacturers.[344] But by agreeing with the FDA on this point, the Court found that generic manufacturers could not update their labels in the same manner as brand-name drug manufacturers, such as the one in *Wyeth*.[345]

Mensing and Demahy argued that, regardless of the dispute over CBE, the manufacturers were still obligated to comply with both the FDCA's general prohibition of misbranded drugs[346] and the FDA regulation[347] requiring manufacturers to revise labels to include warnings about serious hazards.[348] The manufacturers could have tried to avoid the CBE problem by alerting the FDA of the tardive dyskinesia hazard and requesting that the FDA work with the brand-name manufacturer to update Reglan's label.[349] Updating to a safer Reglan label would then require all the generic

341. *Id.* at 2574. Both patients pled state law product liability claims based on an objective knowledge standard; that is, they alleged that the manufacturers "knew or should have known" about the tardive dyskinesia risk and unsafe labeling. *Id.* at 2573–74.

342. *Id.* at 2573.

343. *Id.* at 2575–76.

344. The regulation establishing the CBE supplement process refers only to "changes to an approved application," without distinguishing between drug applications approved under the new drug application process and those approved under the abbreviated new drug application process. 21 C.F.R. § 314.70 (2012). Nonetheless, the FDA argued that CBE was available only to NDA holders because if an ANDA holder changed its drug label, the modified label would no longer be identical to the reference drug, which would be grounds for rejecting or withdrawing ANDA approval. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(4)(G) (2012); 21 C.F.R. §§ 314.94(a)(8)(iii), 314.150(b)(10). *See also PLIVA*, 131 S. Ct. at 2575 (citing 21 U.S.C. § 355(j)(4)(G)).

345. *PLIVA*, 131 S. Ct. at 2581 ("*Wyeth* is not to the contrary.").

346. *Id.* at 2576 (citing 21 U.S.C. § 352(f)(2) (2006)). The FDCA's operative provision prohibits, among other things, "[t]he receipt in interstate commerce of any . . . drug . . . that is . . . misbranded." Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(c) (2006). A drug is misbranded unless "its labeling bears . . . adequate warnings against . . . unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users." *Id.* § 352(f)(2). These standards are similar to, but not a verbatim recitation of, general duties recognized in common law products liability; that is, to sell products that are not unreasonably unsafe and that adequately warn of known risks.

347. *PLIVA*, 131 S. Ct. at 2576 (citing 21 C.F.R. § 201.57(e) (2006)).

348. The Court assumed but did not decide that these obligations existed. *Id.* at 2577.

349. *Id.* at 2578.

metoclopramide manufacturers to update their labels as well.[350] The manufacturers never attempted to do this[351] despite mounting evidence about the seriousness of the risk.[352]

Citing *Wyeth*, the Court framed the issue as "whether the private party could independently do under federal law what state law requires of it."[353] It concluded that the manufacturers could not independently change their labels without violating federal law[354] and that, while the FDA might have done something to update the label if the manufacturers had alerted it, the hypothesized sequence of events was too speculative to cure the impossibility of dual compliance.[355] The Court warily regarded the plaintiffs' proposed CBE workaround:

> Following Mensing and Demahy's argument to its logical conclusion, it is also *possible* that, by asking, the Manufacturers could have persuaded the FDA to rewrite its generic drug regulations entirely or talked Congress into amending the Hatch–Waxman Amendments. If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force.[356]

Therefore, the overlap between the common law claims and federal law presented a case of impossibility preemption,[357] and neither Mensing nor Demahy could sue the manufacturers for allegedly failing to adequately warn about the risk of tardive dyskinesia.

B. UNILATERAL ACTION

The Court in *PLIVA* found impossibility because the generic drug manufacturers could not act *unilaterally* to comply with federal regulations.

350. *Id.*

351. *Id.*

352. *Id.* at 2572. In 2009, several years after Gladys Mensing and Julie Demahy started taking metoclopramide, the FDA began requiring that metoclopramide labels include a "black box" warning urging that the drug not be used for more than twelve weeks. *Id.* at 2573.

353. *Id.* at 2579 (citing Wyeth v. Levine, 555 U.S. 555, 573 (2009)).

354. *Id.* at 2578.

355. *Id.* at 2579.

356. *Id.*

357. *See id.* at 2577 (finding impossibility); *id.* at 2580–81 (rejecting the argument that the showing of impossibility was challengeable because the manufacturers had alternative means to implement a safer label). The Court framed the plaintiffs' alternative label update argument as a challenge to the manufacturers' "federal affirmative defense of [impossibility] pre-emption" rather than an argument against a finding of impossibility. *Id.* at 2578. This phrasing distracts from the core issue, which was whether it was, in fact, "impossible" to update the label.

In other words, the Court ignored cooperative means of achieving dual compliance with federal regulations as part of its impossibility preemption analysis. Before *Wyeth*, unilaterality was not discussed in the Court's preemption jurisprudence. In *Wyeth*, unilaterality was part of the *manufacturer's* argument that the availability of the CBE process should be excluded from impossibility analysis.[358] The manufacturer argued that CBE did not mean what it said, and that even if it followed the procedure, it would still be unable to sell its drug with a new label unless and until the FDA took the further step of allowing a change to the underlying new drug application.[359] The Court rejected this interpretation of the CBE provision, finding that CBE did allow the brand-name manufacturer to market the updated drug label without FDA intervention.[360] In this respect, *Wyeth* and *PLIVA* are in agreement. However, the *PLIVA* Court construed *Wyeth*'s rejection of the argument to mean that unilaterality was, in fact, an integral part of impossibility analysis.[361] This does not logically follow from *Wyeth*. The *Wyeth* Court treated the availability of unilateral compliance as *sufficient* to avoid preemption, but crucially the *PLIVA* Court treated the same condition as *necessary* to avoid preemption.

Florida Lime did not discuss unilaterality of action because the issue was not raised.[362] And Justice Thomas was certainly correct in *PLIVA* when he observed that impossibility preemption would mean nothing if it were inapplicable whenever a party might ask Congress to change the law.[363] However, Justice Thomas carried this intuition breathtakingly far by disregarding the means by which the metoclopramide manufacturers might have brought about safer labeling.[364] He was skeptical of the convoluted steps that such a process would involve—first alerting the FDA, then waiting for the FDA to consult with the brand-name manufacturer, and then waiting for the resulting label updates (if any). In his words, such a process was "a Mouse Trap game."[365]

The complexity and ambiguity of the label updating regulations reflects the challenge of regulating a highly important and technical field

358. Wyeth v. Levine, 555 U.S. 555, 570 (2009).

359. *See id.* at 568–69 (discussing the manufacturer's argument regarding the CBE law and the Court's interpretation of the law).

360. *Id.* at 573.

361. *See PLIVA*, 131 S. Ct. at 2589 (Sotomayor, J., dissenting) (arguing the unilaterality requirement "has no basis in our precedents").

362. Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963).

363. *PLIVA*, 131 S. Ct. at 2578.

364. *Id.*

365. *Id.*

like prescription drugs. It does not reflect preemptive intent. As the *PLIVA* Court assumed, there is a duty on *all* manufacturers to not sell misbranded drugs. The operation of the FDCA hinges in part on this prohibition. The modern system of clinical trials and post-marketing surveillance has established minimum standards necessary to avoid the "misbranding" designation. Brand-name manufacturers and the FDA are cooperatively involved in writing drug labels and evaluating evidence of adverse reactions, both before and after marketing. In light of the ultimate goal of avoiding misbranded drugs, it is inexplicable that the particular sequence of actions necessary to comply with the FDCA should be given such totemic significance. Furthermore, it not clear that a generic manufacturer would "violate[] federal law"[366] by updating its label. If a generic drug label differs from the brand-name label, then the FDA "may" withdraw approval of the generic drug.[367] It is improbable that the FDA would seek to penalize a manufacturer for seeking to make its label safer.[368] And the FDCA outlaws the sale of *misbranded* drugs, not simply drugs with label discrepancies. All of this is not to say that it would be desirable for a generic drug manufacturer to update its label without seeking the FDA's blessing. However, by changing unilateral action from a sufficient condition to a necessary condition to avoid preemption, the Court contorted the "ill-defined process" of generic drug label updating into a *broadly preemptive* "ill-defined process."[369]

Florida Lime does not support such casual disregard for the workings of a complex regulatory regime.[370] There was no such thing as an avocado ripeness supplement or an abbreviated new avocado application. The overlapping rules in *Florida Lime* were intended merely to establish a simple way to facilitate market coordination by standardizing ripeness. Drug labeling, meanwhile, involves ongoing analysis of new drug hazards and cost-benefit evaluations of the value of additional warnings and the risks of overwarning.

Additionally, *Florida Lime* suggested a strict standard for "physical impossibility" that is not readily translatable to drug labeling. The labeling

366. *Id.*

367. *Id.* at 2575 (citing 21 C.F.R. § 314.150(b)(10) (2012)).

368. *See* Wyeth v. Levine, 555 U.S. 555, 570 (2009) ("[T]he very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept—neither Wyeth nor the United States has identified a case in which the FDA has done so.").

369. Lee, *supra* note 20, at 249.

370. *See supra* Part III.A.

conflict in *PLIVA* did not involve a "Schrödinger's label." It is not physically impossible for a drug label to satisfy state and federal law simultaneously in the way that it would be impossible for an avocado to possess both 7 percent and 8 percent oil content simultaneously. A label that satisfies both state products liability law and FDA regulations is, in fact, quite within the realm of reality. The real problem in *PLIVA* was that state law could impose liability for distributing an unsafe label sooner than the FDA might act to update the label. From a generic manufacturer's perspective, taking a cautious approach to CBE and product liability might require it to alter its behavior by waiting for an anticipated label revision before selling additional drugs. This would seem consistent with the Court's opinion in *Florida Lime*, which found there was no impossibility preemption because the farmers could leave the avocados on the trees longer until they satisfied both standards.[371]

In sum, this modification of the *Florida Lime* rule turns a blind eye to the messy and intricate realities of sophisticated drug regulation. It is an imprecise and heavy-handed answer to the vaporous problem of litigants evading preemption by pointing out that anyone might have "talked Congress into amending" federal law.[372]

C. *MUTUAL PHARMACEUTICAL*

The Court revisited *PLIVA* two years later in *Mutual Pharmaceutical*. The case involved a similar factual background. Karen L. Bartlett's doctor prescribed Clinoril for shoulder pain.[373] Bartlett's pharmacist filled the prescription with sulindac, the generic form of Clinoril.[374] After taking the drug, she developed toxic epidermal necrolysis, which lead to horrific disfiguration.[375] Most of her skin "deteriorated, . . . burned off, or [became] an open wound."[376] She sued the generic manufacturer, and a jury found it liable for selling a defectively designed product.[377] The manufacturer argued the defective design claim was preempted by the FDCA and by

371. Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 143 (1963). Admittedly it is a stretch to analogize *PLIVA* to *Florida Lime*, but there is no intervening precedent. Before *PLIVA*, the Court only recited the *Florida Lime* rule in passing, and it never reached a finding of impossibility preemption.

372. *PLIVA*, 131 S. Ct. at 2579.

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

374. *Id.*

375. *Id.*

376. *Id.*

377. *Id.*

FDA regulations.[378] Thus, unlike *PLIVA*, the challenged common law claim was based on a theory of defective design rather than failure-to-warn.[379] Bartlett argued that her defective design claim was not premised on a duty to revise the drug's labeling, which had defeated Mensing's and Demahy's claims.[380] However, the Court rejected Bartlett's attempt to distinguish *PLIVA*.[381]

The Court identified the manufacturer's "duties" under state law and federal law.[382] Under the relevant state law, juries evaluated product design based on (1) a product's usefulness to the public, (2) the manufacturer's ability to reduce risks without significantly affecting price or effectiveness, and (3) "the presence and efficacy of a warning to avoid an unreasonable risk of harm."[383] The Court identified what actions the manufacturer could have taken to comply with these state standards.[384] It could make the drug either more useful or less risky by changing its chemical design, or it could strengthen sulindac's warning to avoid an unreasonable risk of harm.[385] The Court found it was not legally possible for the manufacturer to change the drug's chemical design because federal law required generic drugs to use the same active ingredients as their brand-name counterparts.[386] Since redesign was impossible, the Court concluded that the design-defect claim effectively imposed a state law duty to strengthen sulindac's warnings.[387] The Court compared this with the generic manufacturer's "readily apparent" federal law duty to not change its drug label.[388] Therefore, Bartlett's design defect claim was preempted because it was "impossible"

378. *Id.*

379. *Id.* at 2478–79.

380. *Id.* at 2474.

381. *See id.* at 2575 (finding that the only way for the manufacturer to escape liability was to strengthen sulindac's label).

382. *Id.* at 2473–76 (state law duties); *id.* at 2476 (federal law duty).

383. *Id.* at 2475 (quoting Vautour v. Body Masters Sports Indus., Inc., 784 A.2d 1178, 1182 (N.H. 2001)).

384. *Id.*

385. *Id.*

386. *Id.* (citing 21 U.S.C. §§ 355(j)(2)(A)(ii)–(v), (8)(B) (2012); 21 C.F.R. § 320.1(c) (2012)). The code sections to which the Court cited require ANDA applications to contain information showing that, among other things, the new drug has the same active ingredients and dosage strength as an approved NDA drug. *Id.* at 2471 ("[T]he proposed generic drug must be chemically equivalent to the approved brand-name drug . . . [to be approved]."). The Court said it was also impossible to change the design of the drug because sulindac is a one-molecule drug incapable of being redesigned. *Id.* at 2475.

387. *Id.* at 2473, 2476.

388. *Id.* at 2476 (citing PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2577 (2011)).

for the manufacturer to comply with state and federal law.[389]

Justice Sotomayor argued in dissent that the design-defect cause of action did not require the manufacturer to act specifically in violation of federal law.[390] In her opinion, *PLIVA* was distinguishable because it was based on a state tort law that "required" manufacturers to strengthen drug labels if they knew of a drug's dangers.[391] The design claim in *Mutual Pharmaceutical*, however, was an incentive rather than a mandate.[392] In her view, the liability for injuries caused by defective designs encouraged manufacturers—but did not require them—to redesign potentially defective products.[393] Thus, sulindac's manufacturer was not required to do anything under state law other than compensate patients injured by an unreasonably dangerous drug.[394] Justice Alito, writing for the Court, criticized Justice Sotomayor's logic for relying on the "irrelevant" distinction between common law and positive enactments.[395] Justice Alito also dismissed an argument that the manufacturer could comply with both duties by simply choosing not to sell sulindac. Accepting that argument would make impossibility preemption "'all but meaningless.'"[396]

D. COMMON LAW EQUIVALENCE

The Court's implied preemption analysis in *Mutual Pharmaceutical* willfully fails to recognize the difference between common law claims and positive enactments. By treating both bodies of law as presumptively equivalent, the Court broke with precedent and created broad preemptive power where Congress did not so intend.

389. *Id.* at 2477.
390. *Id.* at 2488 (Sotomayor, J., dissenting).
391. *Id.* at 2489.
392. *Id.*
393. *Id.*
394. *Id.*
395. *Id.* at 2479 (majority opinion).
396. *Id.* at 2477. Justice Alito continued:

> The incoherence of the stop-selling theory becomes plain when viewed through the lens of our previous cases. In every instance in which the Court has found impossibility pre-emption, the "direct conflict" between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting.

Id. It is difficult to take Justice Alito's urgent defense of impossibility preemption seriously. He refers to "every instance" of impossibility preemption, which wrongly implies some degree of doctrinal prolificacy. Tellingly, Justice Alito cites "*PLIVA* [as] an obvious example" of a holding that would be reversed under the "stop-selling" theory, and then he proceeds without citing to any other cases. *Id.* at 2478. His opinion does not make it clear why it would be problematic if impossibility preemption were rendered "all but meaningless" given the token role that it has played in the Court's jurisprudence. *Id.* at 2477 (quoting PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2579 (2011)).

The assumed equivalence is apparent in how the Court frames its opinion. It first identified the state "duty." State law obligated manufacturers to compensate victims of defective products. Based on its interpretation of the applicable federal law, the Court reduced this to a duty to revise sulindac's label. Even accepting the Court's deductive logic, the label-change duty is still a common law obligation to compensate injured patients who sue the company and prove a defective design. Reducing the design defect claim to a label-change duty does not change the nature of the duty. Rather, phrasing the design claim as a label-change duty achieves rhetorical parity with the Court's application of *PLIVA*. The Court relied on *PLIVA* as clear evidence of a federal law "duty" to *not* change labels.[397] This allowed the Court to create an apples-to-apples, duty-to-duty comparison: state law required the manufacturer to change the label, but federal law required the manufacturer not to change the label. The state law effectively countermanded federal law. So framed, it would be difficult to find an easier case of impossibility preemption.

Justice Alito acknowledged that the significance of the distinction between statutes and common law judgments "has repeatedly vexed the Court."[398] At the end of his opinion, he articulated how the Court resolved the issue:

> FDCA's treatment of prescription drugs includes neither an express pre-emption clause . . . nor an express non-pre-emption clause . . . . In the absence of that sort of "explicit" expression of congressional intent, we are left to divine Congress' will from the duties the statute imposes. That federal law forbids Mutual to take actions required of it by state tort law evinces an intent to pre-empt.[399]

Justice Alito's characterization appropriately recognizes the interpretive difficulty of construing the preemptive scope of a statute that lacks a preemption clause. However, his rule takes a strange turn by purporting to "divine Congress' will from the duties the statute

397. This is a questionable reading of *PLIVA*. The Court did not articulate a duty not to change; instead, it accepted as true the FDA's conclusion that the CBE process was not available to generic manufacturers. As discussed above, the problem in *PLIVA* was that those manufacturers purportedly could not update their labels unilaterally without risking the FDA's revocation of ANDA approval. In other words, *PLIVA* identified an apparent gap in federal drug laws and regulations: all drug manufacturers are prohibited from selling misbranded drugs, but apparently only brand-name drug manufacturers had a regulatory process to update labels unilaterally. Rather than leave generic manufacturers to mind the gap, the Court freed them of responsibility to update their labels.

398. *Id.* at 2480.

399. *Id.* (citations omitted). It is curious that this rule statement should come at the end of the preemption analysis rather than at the beginning, seeing as it resolves a vexing threshold question.

imposes."[400] This assertion, for which he did not cite any authority, suggests that implied preemptive intent can be implied only on the face of the statutory language. Other implied preemption cases have not been so acontextual. In *Rice v. Santa Fe*, the Court evaluated congressional preemptive intent in part by reviewing legislative history, and although the Court ostensibly refrained from making such an inquiry in *Geier*, its preemption analysis was founded on the Court's conception of the relevant federal objectives at issue. Seeing as implied preemption is relevant only in cases where statutory language does not clearly address preemption, it is strange to take such a narrow approach to "divining" congressional intent.

Furthermore, Justice Alito's analysis assumes the very issue which it seeks to resolve. He argues that because the state and federal law requirements directly conflict, the requisite congressional preemptive intent is therefore established. This says nothing of whether the tort claim should be treated as a requirement that conflicts with federal regulatory objectives. In *Garmon*, the Court found that state law damages were preempted not just because they had the effect of imposing a regulatory requirement, but also because the legislative history showed Congress wished to exercise exclusive jurisdiction over labor claims by creating the National Labor Relations Board. Additionally, *Silkwood* established a high bar for finding implied preemption of state court damages, requiring the defendant to show "an irreconcilable conflict between the federal and state standards."[401] There was no irreconcilable conflict in *Silkwood* because the defendant could pay the damages judgment. By comparison, Justice Alito's analysis *starts* with the assumption that the products liability verdict constitutes a requirement, and therefore is preempted by any overlapping federal requirements. The fact that the generic drug manufacturer could pay damages to the injured patient and continue selling the drug is immaterial.

Justice Alito's confidence in characterizing the state law damages as preempted "requirements" seems explicable only by reference to the Court's apparent resolution of the issue in *Riegel*, in which the Court flatly stated that "requirements" include a state's common law duties. *Riegel*, however, announced a rule of statutory interpretation *with respect to express preemption clauses*. The holding is relevant for determining what a statute means when it speaks of preempting state "requirements"; it does not address how common law damages should be characterized for the purpose of implied preemption analysis.

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

Justice Alito's reasoning stands for two propositions: first, that implied preemption analysis is confined exclusively to the text of a federal statute without recourse to other interpretive aids; and second, that state law damages are *per se* requirements for the sake of implied preemption analysis. Justice Alito relied on these propositions in applying the *Florida Lime* rule, which provides "[a] holding of federal exclusion of state law is inescapable *and requires no inquiry into congressional design* where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce."[402]

Unlike the two other threads of implied preemption (obstacle preemption and field preemption), implied impossibility preemption does not require inquiry into congressional design. This may be appropriate when, as contemplated in the *Florida Lime* hypothetical, a federal statute and a state statute are directly at odds with each other. However, Justice Alito's propositions expand the mechanical and acontextual operation of implied impossibility preemption to encompass issues based on common law damages claims. This forecloses consideration of the relevant federal objectives and statutory and regulatory histories, leading to a form of implied preemption analysis that lacks an analytical component. In light of the unilateral action rule (which was incorporated into *Mutual Pharmaceutical*) and the common law equivalence rule, it is difficult to see any interpretive foundation supporting the doctrine of impossibility preemption in its current form. The interpretive tools that both facilitated and tempered the expansion of federal power under other preemption doctrines are notably absent from impossibility preemption, and the bizarre outcome of *PLIVA* and *Mutual Pharmaceutical* demonstrate the consequences of creating a broadly applicable rule of preemption that bears no connection to federal objectives, congressional intent, or regulatory and statutory histories.

E. IMPLIED PREEMPTION ON DRUGS

Impossibility preemption, as modified by *PLIVA* and *Mutual Pharmaceutical*, might better be described as "runaway preemption." Neither *PLIVA* nor *Mutual Pharmaceutical* purported to overrule *Wyeth*, so they did not undercut the Court's earlier finding that FDA regulations and state law have traditionally operated in complementary form. Rather, the Court distinguished *Wyeth* on the basis that it involved the NDA regime,

402. Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–43 (1963) (emphasis added).

while the other cases involved the ANDA regime. The crucial distinction from *Wyeth* was the ambiguity surrounding the CBE process (or lack thereof) for updating generic drug labels. The Court attached tremendous consequence to this apparent regulatory gap, for which the FDA had suggested a workaround by encouraging generic drug manufacturers to notify the Agency of hazards and wait for a label update from the name-brand manufacturer. Based largely on the CBE issue, the Court's finding of preemption created blanket products liability immunity for all generic drug manufacturers.

The consequences are significant. Immunity for generic drug manufacturers undercuts the FDA's objective of regulating drug safety. Most drugs consumed in the United States are generic drugs, and in many cases, generic drugs face no brand-name competition. This means that generic drug manufacturers may be the sole collectors of adverse drug event data for a particular drug, and therefore would become the best situated to identify and respond to latent drug hazards. Generic manufacturers will have no incentive to do so because they face no liability for harming patients, even if the manufacturer becomes aware of a latent risk, as happened in *PLIVA*.

Additionally, the issue of generic drug manufacturer liability was not addressed by the Hatch-Waxman Amendments. Congress was not responding to a perceived problem regarding the effect of state court judgments on drug safety or drug prices. Rather, the Hatch-Waxman Amendments sought to improve the availability of cheaper generic drugs by removing the need for generic manufacturers to undertake a costly and duplicative round of clinical testing. Otherwise, the ANDA process established by the Hatch-Waxman Amendments closely resembled the traditional NDA process; other than that, prospective generic drug manufacturers must show the FDA that their labels will copy the then-existing warning label of the relevant brand-name drug.

Finally, the *PLIVA* and *Mutual Pharmaceutical* holdings transformed the FDA into an accidental end-all-be-all drug safety regulator. Because of state law immunity, generic drug manufacturers are now answerable only to the Agency for safe labeling and drug designs. The FDA, meanwhile, is presently incapable of fulfilling the duties of being the sole regulator of drug safety. The Court, and not Congress, transformed the FDA into the singular vanguard of generic drug safety overnight.

VII. CONCLUSION

This Note started by observing the strange battle being waged by the FDA and generic drug manufacturers over a proposed rule that would simplify the process of updating generic drug warning labels. The impetus for the industry's wrangling is to preserve the windfall of products liability immunity conferred upon it by the Supreme Court. The FDA, meanwhile, is seeking to preserve the concurrent operation of state lawsuits by clarifying its "ill-defined process" for updating generic drug labels.

Next, this Note discussed the need for preemption doctrines in applying the language of the Supremacy Clause. Frequently the issue in preemption cases is not whether Congress *could* preempt state law; it is whether Congress *intended* to do so. Preemption issues involve important countervailing interests: federal law needs to be interpreted as preempting state law so as to achieve congressional objectives, but not so broadly preemptive that it needlessly constricts the operation of state law in spheres of concurrent state and federal regulatory authority.

The development of express and implied preemption doctrines reflect the ways in which the Court has balanced these interests. In *Rice*, the Court assumed that Congress did not intend to preempt traditional areas of state regulation, unless there was clear evidence to the contrary. In *Geier*, the Court canvassed the regulatory history of a federal motor vehicle safety standard to identify the federal objective, which then established the preemptive reach of the federal standard at issue. *Garmon* and *Silkwood* reached differing outcomes on the question of federal preemption of common law claims, but each case was based on an inquiry into congressional intent. *Cipollone*, *Lohr*, and *Riegel* showed that the Court struggled with the preemptive sweep of the word "requirements" when used in express preemption clauses and finally decided to construe it as covering both common law claims and positive enactments.

Next, this Note gave special consideration to implied impossibility preemption, which originated with the Court's preemption hypothetical in *Florida Lime* and was never applied to find preemption until *PLIVA*. *Florida Lime* is different from *PLIVA* in that it involved an overlap between federal law and a state statute, rather than a state court damages judgment. Furthermore, *Florida Lime* involved simple (albeit competing) rules designed to achieve market coordination easily. It did not involve the complexity and sophistication of drug safety regulation.

Before testing the Court's "straightforward" application of these

principles in *PLIVA* and *Mutual Pharmaceutical*, this Note summarized the history of the FDCA and the FDA. First, the primary goal of federal regulation of prescription drugs is to make sure that drugs are safe and effective. State court judgments have long operated concurrently with this objective, and they provide an additional check on drug safety in situations where manufacturers choose to hide or minimize damning safety data from the Agency. Second, Congress passed the Hatch-Waxman Amendments not to grant immunity to generic drug manufacturers, but rather to excuse them from the onerous and duplicative expense of retesting drugs that have already been approved.

The Court found the common law claims in *PLIVA* and *Mutual Pharmaceutical* to be preempted by FDA regulations, thereby freeing generic drug manufacturers (but not brand-name manufacturers) from liability in state courts for inadequate labels or unsafe designs. This outcome runs contrary to the purpose of the FDCA and the history of concurrent state regulation of drug safety. However, the Court effectively foreclosed recourse to the traditional sources of preemption analysis by applying a modified form of implied impossibility preemption.

First, the Court in *PLIVA* changed *Wyeth*'s reference to unilateral action from a sufficient condition to avoid preemption into a necessary condition to avoid preemption. This logical step lacks support in the *Florida Lime* hypothetical, disregards the FDA's proposed workaround for the label-updating gap, and imbued the agency's "ill-defined process" with preemptive effect.

Second, the Court's approach to the issue of common law equivalence in *Mutual Pharmaceutical* assumed, without analysis, that the patient's products liability judgment imposed a requirement akin to a state statute, meaning that any such judgment would be preempted by federal regulations. The Court's logic seems rooted in *Riegel*'s declaration of common law and statutory equivalence, even though *Riegel* involved an express preemption clause and *Mutual Pharmaceutical* did not. Assuming rather than analyzing common law equivalence artificially eliminates the Court's responsibility to inquire into the relevant statutory and regulatory background of federal law before finding preemption. Justice Alito's propositions, combined with the acontextual operation of traditional impossibility doctrine, led to runaway preemption of state laws which Congress did not intend to preempt and which the FDA long recognized as helpful in regulating drug safety.

Impossibility preemption is best suited for the narrow circumstances

under which it was hypothesized into existence: when a state statute or regulation conflicts with federal law so as to make dual compliance physically impossible, the conflict is clear enough to support a finding of implied preemption without recourse to congressional design. Neither *PLIVA* nor *Mutual Pharmaceutical* represent a "straightforward application" of preemption doctrines. Instead, the Court created a modified rule of impossibility preemption that sweeps broadly and unexpectedly, with far-reaching consequences for millions of patients who rely on generic drugs and expect them to be safely designed and adequately labeled.