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FRAUD-ON-THE-FDA & *BUCKMAN*—THE EVOLVING LAW OF FEDERAL PREEMPTION IN PRODUCTS LIABILITY LITIGATION

I. INTRODUCTION

Most manufacturers would believe that compliance with a federal regulation would preclude any chance of liability, especially when a plaintiff attempts to bring a state law claim. However, this has been an area of confusion in the products liability context. Courts normally hold that compliance with a federal regulation is only evidence of a manufacturer's due care.¹ Thus, the issue is whether a preemptive provision of a federal statute should override any or all state law claims brought by plaintiffs.

The United States Supreme Court has spoken on preemption in the products liability area beginning with its landmark decision *Cipollone v. Liggett Group, Inc.*² Subsequent decisions regarding automotive safety in *Freightliner Corp. v. Myrick*³ and *Geier v. American Honda Motor Co.*⁴ have failed to provide lower courts with constructive guidance. As was demonstrated in *Medtronic, Inc. v. Lohr*,⁵ the Supreme Court has struggled to interpret the preemptive provision of the Food, Drug, and Cosmetic Act⁶ as amended by the Medical Device Amendments.⁷ The latest Supreme Court decision, *Buckman Co. v. Plaintiffs' Legal Committee*,⁸ does not appear to shed much light on this preemptive confusion. The Court used implied preemption principles in its analysis and failed to clarify when express preemption would be appropriate.⁹ Consequently, the *Buckman* decision does not provide lower courts with much direction outside of fraud-on-the-FDA claims. The states appear to be interpreting the *Buckman* decision narrowly; thus, the Court's decision to preempt the fraud-on-the-FDA claims will not automatically apply to other state law claims.¹⁰

Part II of this Comment describes general federal preemption principles, and Part III details the Supreme Court's approach to determining whether federal preemption exists. Part IV introduces the Medical Device Amendments as well as the *Medtronic* decision and discusses the circuit court confusion that resulted from conflicting Supreme Court decisions. Part V introduces the *Buckman* decision, and

1. See DAVID G. OWEN ET AL., PRODUCTS LIABILITY AND SAFETY 390 (3d ed. 1996).

2. 505 U.S. 504 (1992).

3. 514 U.S. 280 (1995).

4. 529 U.S. 861 (2000).

5. 518 U.S. 470 (1996).

6. 21 U.S.C. §§ 301-95 (1994).

7. *Id.* § 360(k).

8. 531 U.S. 341 (2001).

9. See *infra* notes 134-37 and accompanying text.

10. See *infra* Part VII.A.

Part VI interprets that decision. Part VII reports the impact that *Buckman* has had on the lower courts as well as on the current preemption position.

II. BACKGROUND

A. Preemption Generally

Article VI of the United States Constitution states in part that:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority 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.¹¹

According to the Tenth Amendment, “[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.”¹² A state’s police power is a reserved power.¹³ Police powers allow states to regulate matters related to health and safety.¹⁴ Issues of preemption and federalism often arise when Congress legislates in areas covered by the states’ police powers. For example, Congress has increasingly legislated in the field of health care.¹⁵ Courts addressing these issues normally presume against preemption, and they also look to the language of the statute as well as to congressional intent for guidance.¹⁶

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

12. U.S. CONST. amend. X; *see also* *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 406 (1819) (Chief Justice Marshall stated that “[t]he government of the United States, then, though limited in its powers, is supreme; and its laws, when made in pursuance of the [C]onstitution, form the supreme law of the land.”).

13. *United States v. Morrison*, 529 U.S. 598, 618 n.8 (2000).

14. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996).

15. *Id.* (stating that “[d]espite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasingly significant role in the protection of the health of our people”).

16. *See* 2 DAVID G. OWEN ET AL., *MADDEN & OWEN ON PRODUCTS LIABILITY* § 28.1, at 884 (3d ed. 2000) (“A party advancing the defense of federal preemption must overcome an established presumption against federal preemption of state law.”) [hereinafter 2 *MADDEN & OWEN ON PRODUCTS LIABILITY*].

B. *Express and Implied Preemption Defined*

The federal government can preempt state common law, regulation, or statutory law through either a federal statute or regulation.¹⁷ Federal preemption is divided into two broad categories—express and implied.¹⁸ Express preemption is determined by looking solely to the express language of the statute, while implied preemption is analyzed by considering the statutory language as well as congressional intent.¹⁹

Implied preemption is further divided into two subcategories—field and conflict. Field preemption occurs when Congress enacts a specific statute with the intent that the statute will “effectively and functionally occupy the safety field.”²⁰ Problems occur when a state law or regulation purports to enter the field, and preemption may then be warranted.²¹ Conflict preemption arises when there is a direct conflict between federal and state law; in such a situation, federal law prevails.²²

C. *Statutes Raising Preemption Issues*

Preemption issues have arisen when several federal statutes that affect state regulation of health and safety have been enacted. Some federal statutes have caused preemption problems for several years, while newly enacted statutes and regulations pose new, novel problems to the courts. Examples of federal statutes that may trigger preemption include those regulating the following: tobacco labeling;²³ pesticide, herbicide, and rodenticide labeling;²⁴ motor vehicle safety;²⁵ medical devices;²⁶ boating;²⁷ and others.²⁸

17. 4 LOUIS R. FRUMER & MELVIN I. FRIEDMAN, PRODUCTS LIABILITY § 24.01[1], at 24-3 (2001) [hereinafter 4 FRUMER & FRIEDMAN].

18. See 2 MADDEN & OWEN ON PRODUCTS LIABILITY, *supra* note 16, §§ 28.1-2.

19. See *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); see also 2 MADDEN & OWEN ON PRODUCTS LIABILITY, *supra* note 16, § 28.1, at 883 (defining express preemption as “textual” and implied preemption as “contextual”).

20. 2 MADDEN & OWEN ON PRODUCTS LIABILITY, *supra* note 16, § 28.2, at 885.

21. *Id.*

22. *Cipollone*, 505 U.S. at 516.

23. Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334(a)-(b) (Supp. IV 1965); Public Health Cigarette Smoking Act of 1969, 15 U.S.C. § 1334(b) (1994).

24. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136v(b) (2000).

25. National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. § 1392(d) (1988) (current version at 49 U.S.C. § 30103(b) (1994)).

26. Medical Device Amendments of 1976, 21 U.S.C. § 360(k) (1994).

27. Federal Boat Safety Act of 1971 (FBSA), 46 U.S.C.A. § 4306 (West Supp. 2001).

28. See, e.g., Consumer Products Safety Act (CPSA), 15 U.S.C. § 2075(a) (1994); Federal Hazardous Substances Act (FHSA), 15 U.S.C. § 1261(b) (1994); Occupational Safety and Health Act of 1970 (OSHA), 29 U.S.C. § 667(a) (1994); Flammable Fabrics Act, 15 U.S.C. § 1203(a) (1994).

III. SUPREME COURT DEVELOPMENT

A. *Cipollone v. Liggett Group, Inc.*

In 1992, the Supreme Court decided *Cipollone v. Liggett Group, Inc.*,²⁹ a monumental decision within the area of products liability.³⁰ In *Cipollone*, the plaintiff brought an action against defendant tobacco manufacturers for (1) breach of an express warranty in advertising, (2) failure to warn consumers about smoking hazards, (3) fraudulent misrepresentation of the smoking hazards to consumers, and (4) conspiring to deprive the public of medical and scientific information regarding smoking.³¹ Defendants claimed that both the Federal Cigarette Labeling and Advertising Act³² and its successor, the Public Health Cigarette Smoking Act,³³ preempted petitioner's state law claims.³⁴ The Court held that the plaintiff's claims were only partially preempted and that federal law did not entirely protect the defendants from all claims.³⁵

The Court stated that "the pre-emptive scope of the 1965 Act and the 1969 Act [was] governed entirely by the express language in . . . each Act."³⁶ The Court rejected the petitioner's argument that the 1969 Act's preemption provision did not reach common law actions, stating that "the phrase '[n]o requirement or prohibition' sw[e]p[t] broadly and suggest[ed] no distinction between positive enactments and common law."³⁷ Ultimately, the Court concluded that the 1969 Act did not preempt all state common law claims; its preemptive provision was entitled to a "fair but narrow reading."³⁸

With respect to the 1969 Act, the Court held that the plaintiff's failure-to-warn claim was preempted because it relied on a state law "requirement or prohibition . . . with respect to . . . advertising or promotion," which was covered by the 1969 Act.³⁹ The Court further held that the breach-of-express-warranty claim

29. 505 U.S. 504 (1992).

30. 4 FRUMER & FRIEDMAN, *supra* note 17, § 24.02, at 24-12.

31. *Cipollone*, 505 U.S. at 508.

32. 15 U.S.C. §§ 1331-39 (Supp. IV 1965). The preemptive provision stated:

- (a) No statement relating to smoking and health, other than the statement required by . . . this title, shall be required on any cigarette package.
- (b) No statement relating to smoking and health shall be required in the advertising of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.

Id. § 1334(a)-(b).

33. 15 U.S.C. §§ 1331-41 (1994). The new preemption provision under the 1969 Act stated that "(b) [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 the packages of which are labeled in conformity with the provisions of this Chapter." *Id.* § 1334(b).

34. *Cipollone*, 505 U.S. at 510.

35. *Id.* at 530-31.

36. *Id.* at 517.

37. *Id.* at 521 (quoting 15 U.S.C. § 1334(b) (1994)).

38. *Id.* at 523-24.

39. *Id.* at 524.

was not preempted because the claim arose from the manufacturer's statements or its voluntary undertakings in its advertisements rather than from any "impos[ition] under state law."⁴⁰ Additionally, the Court found that the first theory of the plaintiff's fraudulent misrepresentation claim, which alleged that the defendant's advertising neutralized the effect of federally mandated warning labels, was preempted by the 1969 Act.⁴¹ However, the Court held that the plaintiff's second misrepresentation theory—that the defendants made false statements and concealed material information—was not preempted because the theory rested on a state law duty not to deceive which did not arise from advertising or promotions.⁴² Finally, the Court held that the plaintiff's claim alleging a conspiracy by the defendants to misrepresent or to conceal material facts concerning the health hazards of smoking was not preempted because the conspiracy was not "based on smoking and health."⁴³

Before *Cipollone* was decided, it appeared that most courts rejected express preemption claims and relied on implied preemption in interpreting federal statutes.⁴⁴ However, as discussed above, the *Cipollone* Court used express preemption to determine whether state law claims were preempted.⁴⁵ Three years after *Cipollone*, the *Freightliner Corp. v. Myrick* decision put a new spin on the Supreme Court's recent decision.⁴⁶

B. Freightliner Corp. v. Myrick

Congress enacted the National Traffic and Motor Vehicle Safety Act of 1966⁴⁷ to prevent traffic accidents and injuries and drafted a preemption provision⁴⁸ and saving clause.⁴⁹ The plaintiffs in *Myrick* brought negligent design claims for the defendant's failure to install an antilock braking system in tractor-trailers.⁵⁰ The

40. *Cipollone*, 505 U.S. at 526-27.

41. *Id.* at 527.

42. *Id.* at 528-29.

43. *Id.* at 530.

44. OWEN ET AL., *supra* note 1, at 408.

45. See *supra* notes 36-43 and accompanying text.

46. *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995).

47. 15 U.S.C. §§ 1381-1431 (1988).

48. 15 U.S.C. § 1392(d) states:

Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to a Federal standard. Nothing in this section shall be construed as preventing any State from enforcing any safety standard which is identical to the Federal safety standard.

49. 15 U.S.C. § 1397(k) (1988) states that "[c]ompliance with any Federal motor vehicle safety standard issued under this subchapter does not exempt any person from any liability under common law."

50. *Myrick*, 514 U.S. at 282-83.

Court reasoned that because the National Highway Traffic Safety Administration suspended the regulation requiring certain stopping distances for trucks, the plaintiffs' claims could not be expressly preempted.⁵¹ In the alternative, the Court considered the defendant's implied preemption argument because it was reasonable to interpret *Cipollone* as approving the use of implied preemption in some circumstances.⁵² However, this argument failed because there was no federal statute to comply with; therefore, the plaintiffs' claims would not frustrate "federal objectives or purposes with respect to [braking] devices."⁵³

After *Cipollone*, it appeared that the Court was willing to preempt state law claims only if there was an express federal provision on point. *Myrick* changed this outlook dramatically. As one commentator stated, "[t]he unanimous decision in *Myrick*, it is seen, foreshadowed a potential reinvigoration of the doctrine of implied preemption."⁵⁴

C. *Geier v. American Honda Motor Co.*

In *Geier v. American Honda Motor Co.*,⁵⁵ the Court once again faced the National Traffic and Motor Vehicle Safety Act.⁵⁶ The Court adopted a three-part test for determining whether the plaintiff's claims were preempted: (1) "[did] the Act's express pre-emption provision pre-empt this lawsuit?"; (2) "[did] ordinary pre-emption principles nonetheless apply?"; and (3) "[did] this lawsuit actually conflict with [the Act's objectives], hence with the Act itself?"⁵⁷

As to the first prong of its test, the Court held that the savings clause would prevent preemption of the plaintiff's claims by forcing the preemptive provision to be read narrowly.⁵⁸ However, as to the Court's second prong, it concluded that "the savings clause (like the express pre-emption provision) [did] *not* bar the ordinary working of conflict pre-emption principles."⁵⁹ Regarding the last prong, the Court held that "[b]ecause the rule of law for which petitioners contend would have stood 'as an obstacle to the accomplishment and execution of' the important means-related federal objectives [of the Act], it was pre-empted."⁶⁰

51. *Id.* at 289.

52. *Id.* at 288 ("The fact that an express definition of the pre-emptive reach of a statute 'implies'—*i.e.*, supports a reasonable inference—that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied pre-emption.").

53. *Id.* at 289-90.

54. M. Stuart Madden, *Federal Preemption of Inconsistent State Safety Obligations*, 21 PACE L. REV. 103, 137 (2000).

55. 529 U.S. 861 (2000).

56. 15 U.S.C. §§ 1381-1431 (1988); *see supra* notes 47-48 and accompanying text.

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

58. *Id.* at 868. The savings clause stated that mere compliance with a federal safety standard would not exempt a defendant from liability under common law. *Id.* Thus, the clause "assumed that there [were] some . . . common-law liability cases to save." *Id.*

59. *Id.* at 869.

60. *Id.* at 881 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

Based on the Court's holding in *Geier*, the implied preemption doctrine appeared to be shifting away from the view taken in *Cipollone* and toward the view taken in *Myrick*.⁶¹ However, the task of interpreting the Medical Device Amendments and the accompanying preemptive provision harshly tested this trend.

IV. THE MEDICAL DEVICE AMENDMENTS AND THE FDA

A. *Background of the Medical Device Amendments*

In 1906, Congress enacted the Food and Drug Act to guard "against the manufacture or shipment in interstate commerce of any adulterated or misbranded food or drug."⁶² In 1938, the Act was expanded to "include misbranded or adulterated medical devices and cosmetics."⁶³ That same year, Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA),⁶⁴ which was amended in 1976 by the Medical Device Amendments (MDA).⁶⁵ The MDA was enacted specifically to provide for "the safety and effectiveness of medical devices intended for human use."⁶⁶ The enactment of the MDA was prompted by problems occurring with the "Dalkon Shield" and with other medical devices.⁶⁷ The FDCA provides an express provision governing preemption:

- (a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
 - (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.⁶⁸

61. Recall that in *Cipollone* the Court focused on an express preemption analysis under the Public Health Cigarette Smoking Act of 1969. See *supra* notes 36-38 and accompanying text. On the other hand, in *Myrick* the Court failed to find preemption, but hinted that even the presence of an express preemption clause will not "foreclose[] any possibility of implied preemption." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995).

62. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996).

63. *Id.*

64. 21 U.S.C. §§ 301-95 (1994).

65. Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C. (1994)).

66. 4 FRUMER & FRIEDMAN, *supra* note 17, § 24.05[4][b], at 24-59 (quoting 90 Stat. 539 (1976) (preamble)).

67. See *Medtronic*, 518 U.S. at 476 (discussing the Dalkon Shield and other medical devices that posed risks to the public, which prompted the Food and Drug Administration (FDA) to enact the MDA in 1976).

68. 21 U.S.C. § 360k(a) (1994).

Subsection (b) of the preemption provision contains an exemption from the general rule outlined in subsection (a):

- (b) Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
- (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
 - (2) the requirement—
 - (A) is required by compelling local conditions, and
 - (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.⁶⁹

The FDA, which has the power under the FDCA to approve medical devices before they are placed on the market,⁷⁰ has interpreted the FDCA and has provided limited exceptions to its preemption provision:

- (d) State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. There are other State or local requirements that affect devices that are not preempted by . . . the act because they are not “requirements applicable to a device” within the meaning of . . . the act.⁷¹

Under the MDA, the FDA has statutory procedures that it follows before it approves a medical device for public use. The FDA first divides medical devices into three categories—Class I, II, and III.⁷² Medical devices within Class I pose no unreasonable risk of illness or injury and are subject to minimal regulation by

69. *Id.* § 360k(b).

70. *See id.* § 360.

71. 21 C.F.R. § 808.1(d) (2001); *see supra* note 68 and accompanying text.

72. 21 U.S.C. § 360c(a) (1994).

“general controls.”⁷³ Class II devices are potentially more harmful than Class I devices and thus are subject to “special-controls” regulations.⁷⁴ Finally, Class III devices “present[] a potential unreasonable risk of illness or injury” or are “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.”⁷⁵ Examples of Class III devices include hip and knee replacement components, intraocular lenses, and pacemakers.⁷⁶

Because of their increased risk, Class III medical devices require a premarket approval (PMA) process to provide “reasonable assurance of [their] safety and effectiveness.”⁷⁷ PMA requires the manufacturer of the device to submit information to the FDA regarding its safety.⁷⁸ However, there are three recognized exceptions to the vigorous and time-consuming PMA process. First, a “grandfathering” provision under the MDA allows devices manufactured prior to its enactment to remain on the market.⁷⁹ Second, in order to ensure a level playing field between grandfathered devices’ manufacturers and current medical devices’ manufacturers, the MDA provides that certain current devices that are “substantially equivalent” to pre-existing devices can speed through the PMA process via a § 510(k) notification.⁸⁰ This notification process is the typical way in which medical devices are approved.⁸¹ The third exception is based on the investigational device exemption (IDE), whereby a medical device may avoid the PMA process through human testing.⁸² According to the federal statute, investigational devices are exempted “to encourage, . . . to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use.”⁸³

B. *Interpreting the MDA—Medtronic, Inc. v. Lohr*

Medtronic, Inc. v. Lohr addressed the preemptive scope of the FDCA and the MDA. At the time the case was decided, there was confusion as to whether the FDCA’s preemptive provision trumped state common law claims.⁸⁴ The plaintiffs brought an action against the manufacturer of pacemaker leads, which had been pre-approved under § 510(k) of the FDCA, for negligent design and manufacture and

73. *Id.* § 360c(a)(1)(A).

74. *Id.* § 360c(a)(1)(B).

75. *Id.* § 360c(a)(1)(C).

76. 21 C.F.R. § 870.3610 (2001).

77. 21 U.S.C. § 360c(a)(1)(C).

78. *Id.*

79. *Id.* § 360e(b)(1)(A).

80. *Id.* § 360e(b)(1)(B).

81. 4 FRUMER & FRIEDMAN, *supra* note 17, § 24.05[4][d], at 24-67.

82. *Id.* (citing 21 U.S.C. § 360e(a)).

83. 2 MADDEN & OWEN ON PRODUCTS LIABILITY, *supra* note 16, § 28.7, at 918 (quoting 21 U.S.C. § 360j(g)).

84. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996).

for failure to warn of the pacemaker's dangers, as well as for strict liability.⁸⁵ The Supreme Court held that federal law did not preempt the plaintiff's claims.⁸⁶

The Court rejected Medtronic's argument that "any common-law cause of action is a 'requirement' which alters incentives and imposes duties 'different from, or in addition to,' the generic federal standards that the FDA has promulgated."⁸⁷ The Court distinguished *Cipollone*, where it had held that common law claims could be preempted,⁸⁸ stating that "[the Public Health Cigarette Smoking Act of 1969] did not sweep nearly as broadly as Medtronic would have us believe that [the MDA] does."⁸⁹ The MDA's legislative history indicated that the Act was directed at the risk of additional federal and state administrative regulation, rather than at the danger of pre-existing duties under common law.⁹⁰ Furthermore, the Court held that the plaintiff's design claim was not preempted because under the "substantially equivalent" standard, Congress intended only to level the playing field in competition, not to set safety and design requirements.⁹¹ The Court refused to believe that the preemptive provision of the FDCA would prevent a state from enacting additional or different "requirements" with respect to medical devices when these state requirements were stricter than the federal requirements.⁹² Ultimately, the Court concluded that state regulations, general in nature, were not preempted because they were not enacted to govern a specific medical device.⁹³

The *Medtronic* decision provided few answers to the then-existing preemptive confusion.⁹⁴ The plurality opinion failed to clarify the most essential issue governing preemption—whether state law claims can ever be preempted. Justice Stevens, writing for the plurality in *Medtronic*, concluded that state law claims were not a "requirement" under the MDA so as to invoke preemption.⁹⁵ Justice O'Connor and four other Justices felt that a state law claim was a "requirement" sufficient to be preempted by federal law.⁹⁶ Justice Breyer, while concurring in the judgment that the plaintiffs' claims were not preempted, nevertheless opined that a state claim could be classified as a "requirement," thus agreeing with O'Connor's reasoning.⁹⁷

Despite the shift in *Myrick* toward a possible implied preemption analysis, the *Medtronic* Court swung back toward the express preemption framework that was

85. *Id.* at 480-81.

86. *Id.* at 503.

87. *Id.* at 486-87; *see supra* note 68 and accompanying text.

88. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992).

89. *Medtronic*, 518 U.S. at 488.

90. *Id.* at 490.

91. *Id.* at 493-94; *see supra* note 80 and accompanying text.

92. *Medtronic*, 518 U.S. at 495.

93. *Id.* at 499-500.

94. *See* Madden, *supra* note 54, at 137.

95. *Medtronic*, 518 U.S. at 487-88.

96. *Id.* at 509.

97. *Id.* at 503-04.

established in *Cipollone*.⁹⁸ As a result, circuit courts would not fare well in their attempts to interpret the decision in *Medtronic*.

C. *Circuit Court Holdings on Preemption—Demonstrating the Confusion Created by the Supreme Court*

1. *Post-Cipollone v. Liggett Group, Inc.*

In *King v. Collagen Corp.*, the First Circuit Court of Appeals used *Cipollone* in its analysis, determining that an express preemption framework under the MDA was appropriate and that the plaintiff's claims were preempted.⁹⁹ In *Talbott v. C.R. Bard, Inc.*, the First Circuit again relied on *Cipollone* and followed *King* in holding that an express preemption analysis encompassed state law tort claims, both statutory and common law.¹⁰⁰ Furthermore, in *Stamps v. Collagen Corp.*, the Fifth Circuit employed a similar approach, holding that a lack of direct conflict between federal and state law did not prevent preemption because the court was required to conduct an express preemption analysis under *Cipollone* when there was a federal statute on point.¹⁰¹ In *Gile v. Optical Radiation Corp.*, the Third Circuit cited *Cipollone*, *King*, and *Stamps*, in ruling that the plaintiff's state law claims were expressly preempted under the MDA.¹⁰²

In *Kennedy v. Collagen Corp.*, the Ninth Circuit rejected the other Courts of Appeals' findings that the MDA's preemption provision swept broadly, instead holding that the statute should be read narrowly.¹⁰³ The court declared that "[s]tate common law is a law of general applicability"; therefore, under 21 C.F.R. § 808.1(d), which exempts laws not directed at specific devices from preemption, such claims should not be preempted.¹⁰⁴

98. See Madden, *supra* note 54, at 147 ("In *Medtronic*, the Court appeared to build on its analysis in *Cipollone*, focusing on express and not implied preemption analysis.").

99. *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir. 1993).

100. *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 27 (1st Cir. 1995). One defendant had pleaded guilty in an earlier criminal trial for fraud committed on the FDA, but the court held that there were no exceptions to the preemption clause, even when a manufacturer failed to comply with the MDA. *Id.* at 28.

101. *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1425 n.9 (5th Cir. 1993); see also *Reeves v. Acromed Corp.*, 44 F.3d 300, 304-05 (5th Cir. 1995) (holding that the plaintiff's failure-to-warn claim was preempted based on their holding in *Stamps v. Collagen Corp.*).

102. *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542, 545 (3d Cir. 1994); see also *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324-25 (3d Cir. 1995) (determining that the plaintiff's breach-of-implied-warranty claim was preempted while his breach-of-express-warranty claim was not because it was created by the parties and not by state law); *English v. Mentor Corp.*, 67 F.3d 477, 480 (3d Cir. 1995) (holding that under *Gile* and *Michael*, the plaintiffs' strict liability, negligence, and implied warranty claims were preempted, but their express warranty claim was not preempted under the MDA's express provisions).

103. *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1457 (9th Cir. 1995).

104. *Id.* at 1459; see *supra* note 71 and accompanying text.

2. *Post-Medtronic, Inc. v. Lohr*

Medtronic's plurality decision offered little hope that unified decisions would result. In *Mitchell v. Collagen Corp.*, the Seventh Circuit made a point to distinguish *Medtronic*, where the Supreme Court had held that the state common-law claims were not preempted by the MDA, and stated that "the *Medtronic* disposition must be read as acknowledging that at least some state-based common law causes of action" fall within the MDA's preemptive scope.¹⁰⁵

In stark contrast to the holding in *Mitchell*, in *Goodlin v. Medtronic, Inc.*, the Eleventh Circuit refused to preempt the plaintiff's state law claims.¹⁰⁶ Though it reached the same result as *Medtronic*, the court stated:

Despite the striking superficial similarity of the cases, the Supreme Court's disposition of [*Medtronic*] provides little more than a rudimentary analytical framework to guide our resolution of *Medtronic's* preemption claims in this case because . . . [*in Medtronic,*] the Court fractured in an all but irreconcilable manner over the extent to which section 360k(a) would ever preempt a general state common law tort claim.¹⁰⁷

In *Kemp v. Medtronic, Inc.*, the Sixth Circuit identified the split resulting from the decision in *Medtronic, Inc. v. Lohr*, stating that "[t]his appeal presents fractious issues which have sharply divided the various circuit courts which have considered them."¹⁰⁸ This reasoning received support from the Fifth Circuit, which chose to follow its own precedent and noted that "the Supreme Court's fractured ruling . . . does nothing to upset [the Fifth Circuit's] binding authority."¹⁰⁹

In sum, the decision in *Medtronic, Inc. v. Lohr* was creating grave confusion within the circuit courts. There was a clear dichotomy in the courts' interpretation of the preemptive provision of the MDA. The courts definitely needed proper direction.

V. *BUCKMAN CO. V. PLAINTIFFS' LEGAL COMMITTEE*A. *Facts*

The facts of *Buckman Co. v. Plaintiffs' Legal Committee*¹¹⁰ developed as follows: Acromed Corporation was formed to develop an orthopedic device for

105. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 907, 910 (7th Cir. 1997); *see supra* note 86 and accompanying text.

106. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1382 (11th Cir. 1999).

107. *Id.* at 1371.

108. *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221 (6th Cir. 2000).

109. *See Martin v. Medtronic, Inc.*, 254 F.3d 573, 584-85 (5th Cir. 2001).

110. 531 U.S. 341 (2001).

implantation within the spine, formally termed the Variable Screw Placement Spinal Plate Fixation System.¹¹¹ The precise medical technology involved plates fixed with screws into the patients' spine to aid in spinal fusion.¹¹² Approximately one year after Acromed was formed, it initiated a relationship with the Buckman Company in order to achieve § 510(k) authorization.¹¹³ Following Buckman's initial representation to the FDA that the device was to be used in spinal fusion, the FDA informed Buckman on two separate occasions that there was no "substantial equivalence" to any currently-approved device, which would have allowed the companies to expedite the onerous premarket approval process.¹¹⁴ Subsequently, Buckman held a meeting with Acromed and the FDA and proceeded to submit separate premarket notifications for the plates and for the screws.¹¹⁵ The FDA subsequently approved the plates and screws as substantially equivalent to existing Class II medical devices which were used to repair the long bones of the arms and legs.¹¹⁶ However, "[t]he representations made by Buckman to the FDA were false and misleading" because Buckman never intended to use the plate and screws solely for fractures in the long bones, but also intended to implant them in the spine.¹¹⁷ Subsequently, the FDA determined that Buckman and Acromed committed fraud in obtaining approval for a substantially equivalent device.¹¹⁸

Following a television program describing the problems resulting from the implantation of pedicle screws, such as those manufactured by Acromed, thousands of plaintiffs filed complaints alleging injuries against hundreds of defendants; the complaints were subsequently consolidated.¹¹⁹ Plaintiffs' Legal Committee sued Acromed and Buckman, alleging state fraud-on-the-FDA claims.¹²⁰ The plaintiffs claimed the defendants made fraudulent representations to the FDA concerning the intended use of the screws and were therefore improperly given § 510(k) expedited premarket clearance.¹²¹ Additionally, the "[p]laintiffs further claim[ed] that such representations were at least a 'but for' cause of injuries that plaintiffs sustained from the implantation of these devices."¹²² The district court determined that the plaintiffs' claims were preempted by the FDCA, but the Third Circuit Court of Appeals reversed, concluding that neither express nor implied preemption applied.¹²³

111. Brief for Respondent at 6-7, *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768).

112. *Id.* at 7.

113. *Id.*; see *supra* note 80 and accompanying text.

114. Respondent's Brief at 7, *Buckman* (No. 98-1768).

115. *Id.* at 8.

116. *Id.* at 9.

117. *Id.*

118. *Id.* at 10.

119. Brief for Petitioner at 6, *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768).

120. *Buckman*, 531 U.S. at 346-47.

121. *Id.* at 343.

122. *Id.*

123. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 818-19 (3d Cir. 1998).

B. *Supreme Court Analysis*

The Supreme Court granted certiorari to resolve a split among the courts of appeals regarding the issue of whether the plaintiffs' state law claims were either expressly or impliedly preempted.¹²⁴ The Court reversed the Third Circuit's decision, holding that the state fraud-on-the-FDA claims conflicted with the FDCA and were therefore impliedly preempted.¹²⁵ In so holding, the Court stated that the preemption stemmed from the federal statutory scheme which gave the FDA the power to punish and deter fraud and which was used "to achieve a somewhat delicate balance of statutory objectives."¹²⁶ Thus, permitting the plaintiffs' claims would create an additional burden upon applicants for § 510(k) approvals because the state claims would "conflict with the FDA's responsibility to police fraud consistently with [its] judgment and objectives."¹²⁷ Also, allowing the state law claims would deter § 510(k) or "off-label" usage because applicants would fear exposure to civil liability.¹²⁸ Further, the Court determined that allowing the plaintiffs' claims would cause applicants to fear that their disclosures to the FDA would later be determined to be inadequate in state court, even if the FDA deemed the disclosures sufficient.¹²⁹ The Court distinguished *Medtronic* on the grounds that it was decided under an express preemption analysis which was applied to the manufacture of the device, while in the present case an implied preemption analysis was applied to a violation of FDCA requirements.¹³⁰

Justice Stevens, joined by Justice Thomas, wrote a concurring opinion.¹³¹ Stevens relied on the fact that the FDA had not reacted to the fraud-on-the-FDA claim by removing the device from the market, which implied that the claim could not be proved.¹³² However, Stevens felt that the Court's decision was harsh in not allowing any state tort claims for fraud even if the FDA had reacted to the claim; therefore, he concurred only in the judgment.¹³³

VI. DID *BUCKMAN* CLARIFY THE CONFUSION?

A. *Explanation of the Supreme Court Decision*

Buckman clarified *Medtronic* to the extent that it held that state law claims could be preempted. One oddity of the *Buckman* decision is that the Court ruled

124. *Buckman*, 531 U.S. at 347.

125. *Id.* at 348.

126. *Id.*

127. *Id.* at 350.

128. *Id.*

129. *Id.* at 351.

130. *Buckman*, 531 U.S. at 352.

131. *Id.* at 353-55.

132. *Id.* at 353.

133. *Id.* at 355.

unanimously, whereas in *Medtronic* it was harshly divided.¹³⁴ The Court also relied on implied preemption as opposed to the express preemption analysis it adopted in *Medtronic* and *Cipollone*.¹³⁵ Interestingly, the Court stated that the plaintiffs' fraud-on-the-FDA claims were impliedly preempted, but "express[ed] no view on whether the[] claims [were] subject to express pre-emption under 21 U.S.C. § 360k."¹³⁶ As one commentator opined, "[u]nfortunately, by applying implied rather than express preemption, the Court passed on an opportunity to clarify the fragmented [*Medtronic*] decision."¹³⁷

As amicus curiae, the United States seemed to influence the holding in *Buckman* substantially, and its arguments provide more insight into the Court's decision.¹³⁸ The United States' brief noted that both devices in *Buckman* and *Medtronic* were approved as substantially equivalent under § 510k, and it followed *Medtronic*'s reasoning in arguing that the plaintiffs' claims should be impliedly rather than expressly preempted.¹³⁹ Further, the United States argued that under *Medtronic*, the federal requirement had to be both "specific" and the state requirement "different from, or in addition to," that specific federal requirement for express preemption to be appropriate.¹⁴⁰ Because there were specific federal requirements for hearing aids, cables and leads, impact-resistant lenses, and devices containing natural rubber, the United States argued that the § 510k process, by contrast, was not specific because it applied to all medical devices generally.¹⁴¹

The United States argued that under implied conflict preemption principles, the plaintiffs' fraud-on-the-FDA claims were preempted.¹⁴² First, the United States differentiated *Medtronic* by arguing that in that case the plaintiffs' claims were related to the actual design of the device, while in *Buckman* the plaintiffs were challenging the way in which the FDA approved the device, which was an area of "preeminent federal concern."¹⁴³ The brief further stated that "[i]f federal regulatory agencies are to perform the important functions assigned to them by Congress, they must have the ability to decide, free from hindrances imposed by state law, how best to obtain the information they need and how to sanction those who fail to provide such information."¹⁴⁴ Additionally, the United States noted that

134. See *supra* notes 95-97 and accompanying text.

135. See Madden, *supra* note 54, at 147.

136. *Buckman*, 531 U.S. at 348 n.2.

137. Raymond M. Williams & Anita Jain, *Preemption of State "Fraud-on-the-FDA" Claims*, FOR THE DEF., June 2001, at 23, 25.

138. *Id.*

139. Brief of the United States as Amicus Curiae Supporting Petitioner at 9, *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768).

140. *Id.*

141. *Id.* at 12.

142. *Id.* at 16-17 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000)).

143. *Id.* at 17.

144. *Id.* at 18.

the FDA has several methods of controlling fraud;¹⁴⁵ therefore, the brief concluded that state requirements governing fraud-on-the-FDA claims conflict with federal requirements because the FDA is best equipped to determine if it has been defrauded.¹⁴⁶ Allowing state fraud-on-the-FDA claims to stand, the United States contended, would result in nonuniformity between states in determining whether fraud has been committed; the remedies sought would differ, and there would be interference with the “FDA’s discretion to decide which of the statutorily prescribed remedies, if any, to pursue.”¹⁴⁷

The *Buckman* holding failed to specify whether preemption analysis differs based on the manner in which a device is appeared. Earlier circuit court decisions disagreed on this issue. In *Feldt v. Mentor Corp.* and *Reeves v. Acromed Corp.*, the Fifth Circuit held that the way in which the devices were approved was irrelevant to the preemption analysis.¹⁴⁸ Similarly, the Third Circuit held that MDA regulations were requirements, notwithstanding the manner in which the device was approved.¹⁴⁹ In *Becker v. Optical Radiation Corp.*, the Second Circuit also held that even though the FDA approved the device at issue as an “experimental device,” the plaintiffs’ claims were preempted.¹⁵⁰ However, in *Kennedy v. Collagen Corp.*, the Ninth Circuit adopted the minority position, holding that the PMA process was not specific enough to warrant preemption.¹⁵¹ Even subsequent to the *Medtronic* decision, the Sixth Circuit held that the experimental device requirements

145. See, e.g., 18 U.S.C. § 1001 (1994) (prohibiting fraudulent statements to federal agencies); 21 U.S.C. § 331(q)(2) (1994) (prohibiting fraudulent reports to the FDCA); *id.* § 372 (granting the FDA authority to investigate alleged fraud committed against it); *id.* § 332, 333(f)(1)(A), 334(a)(2)(D), 333(a) (granting the FDA various punitive powers); 21 C.F.R. § 10.30 (2001) (allowing any U.S. citizen to request that the FDA take action if the citizen believes that fraud has been committed against the FDA).

146. United States’ Brief at 21-24, *Buckman* (No. 98-1768).

147. *Id.* at 23-24.

148. *Feldt v. Mentor Corp.*, 61 F.3d 431, 435-36 (5th Cir. 1995); *Reeves v. Acromed Corp.*, 44 F.3d 300, 305 (5th Cir. 1995). Despite the device’s obtaining substantial equivalence, as opposed to undergoing full-scale PMA, the court in *Feldt* held that “[p]reemption does not depend on the route the product takes to the market, but on whether there are any specific federal requirements applicable to the device.” *Feldt*, 61 F.3d at 435-36.

149. See *English v. Mentor Corp.*, 67 F.3d 477, 483 (3d Cir. 1995) (holding that the “substantial equivalence” approval of the device did not change the analysis because general federal regulations have preemptive effect under *Stamps* and *King*, and “the mere fact that the FDA has promulgated regulations affecting groups of devices, rather than a specific type of device, should not alter whether or not there is preemption”); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir. 1995) (holding that specific FDA requirements for heart valves were not required to trigger preemption because the defendant’s heart valve was subject to “any requirement” under the MDA).

150. *Becker v. Optical Radiation Corp.*, 66 F.3d 18, 21 (2d Cir. 1995) (“While the FDA’s regulations impose no requirements concerning the design of [experimental devices], the FDA can hardly be expected to specify the safe and effective design of a device when it is still experimental. The point of the experiment is to find out *whether* the design is safe and effective.”).

151. *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1458 (9th Cir. 1995).

promulgated by the FDA were specific and thus had preemptive effect.¹⁵² Likewise, in *Mitchell v. Collagen Corp.*, the Seventh Circuit held that the PMA could qualify as a specific federal requirement.¹⁵³ Finally, *Goodlin v. Medtronic, Inc.* adopted the reasoning of *Kennedy* and held that the PMA process was not a specific federal requirement.¹⁵⁴

The Court in *Buckman* seemed to justify implied preemption based on the specific requirements the FDA imposes in the § 510k process, as well as on the FDA's power to detect and remedy fraud, both of which conflict with similar state requirements.¹⁵⁵ However, as the United States' amicus curiae brief pointed out, the § 510k process is not specific because it applies to all medical devices generally.¹⁵⁶ This reasoning would seem to apply regardless of which medical device approval process is used because both the PMA and experimental device approval processes apply to all medical devices generally.¹⁵⁷ *Medtronic* requires the imposition of a specific federal requirement to justify preemption.¹⁵⁸ Further, in *Kennedy*, the Ninth Circuit stated that "[t]he fact that the premarket approval process involves specific requirements must not be confused with the premarket approval requirement itself acting as a *specific* requirement."¹⁵⁹ The court went on to note that "[t]he potential for state common law to create an indirect regulatory effect is insufficient to alter the fact that state common law is a law of general applicability and therefore cannot qualify as a *specific* requirement which may be preempted by the MDA."¹⁶⁰ Similarly, in *Goodlin v. Medtronic, Inc.*, the Eleventh Circuit held that despite the fact the PMA process requires assurances as to safety and effectiveness, it does not constitute a requirement under the FDCA.¹⁶¹ After all, it is difficult to contend that the PMA or the investigational device exemption (IDE), which apply to all medical

152. *Martin v. Teletronics Pacing Sys., Inc.*, 105 F.3d 1090, 1098-1101 (6th Cir. 1997). Specifically, the court held that the plaintiff's manufacturing defect claim was preempted because the FDA had specific requirements for investigating the manufacturing of experimental devices prior to their being approved. *Id.* at 1099. The court further held that the plaintiff's design defect claim was preempted because under the FDA's investigational device exception (IDE) approval process, the "risks and benefits [of the device] were specifically reviewed and balanced in accordance with 21 C.F.R. § 812.30." *Id.* Additionally, the court preempted the plaintiff inadequate warning claim on the basis that experimental or investigational devices have specific labeling requirements, unlike those devices that are approved as "substantially equivalent." *Id.* at 1100. Finally, the court concluded that the plaintiff's express warranty claim was preempted because "[e]xpress representations made about investigational devices are subject to comprehensive FDA regulation." *Id.*

153. *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997) ("We agree that the PMA process, as opposed to the 'substantially equivalent' process at issue in *Medtronic*, can constitute the sort of specific federal regulation of a product that can have preemptive effect.").

154. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1376 (11th Cir. 1999).

155. *See supra* Part V.B.

156. Brief of the United States as Amicus Curiae Supporting Petitioner at 12, *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768).

157. *See supra* notes 78-83 and accompanying text.

158. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 486 (1996).

159. *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459 (9th Cir. 1995) (citation omitted).

160. *Id.*

161. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1375 (11th Cir. 1999).

devices generally, can be specific requirements.¹⁶² Therefore, express preemption is inappropriate. This reasoning comports with the FDA's interpretation under 21 C.F.R. § 808.1(d).¹⁶³

If there is no express preemption, then implied preemption, either field or conflict, is the only other way the state law claim can be preempted.¹⁶⁴ Some commentators have claimed that the Court's fragmented decision in *Medtronic* demonstrates that the PMA process would qualify as a specific requirement and would thus justify preemption.¹⁶⁵ However, *Medtronic* was hardly a one-sided decision, and the circuit court's indecisiveness demonstrates that the specific requirement debate is thriving.¹⁶⁶ One could argue that Chief Justice Rehnquist's statement in *Buckman* that "the § 510(k) process lacks the PMA review's rigor" implies that the PMA process is specific.¹⁶⁷ However, the Court conceded that the § 510(k) process does impose requirements despite its lack of rigor.¹⁶⁸ Thus, it is unpersuasive to argue that because the PMA approval process involves an abundance of requirements, such requirements are in fact specific to a particular medical device. Other courts have agreed that the PMA process is not a specific requirement that initiates federal preemption.¹⁶⁹

162. See *Goodlin*, 167 F.3d at 1377 ("We do not believe that requirements applicable to all devices that receive the FDA's approval via the PMA process satisfy the Court's demand for a specific requirement that applies to a particular device.").

163. Specifically, 21 C.F.R. § 808.1(d) orders preemption of state law "only when the [FDA] has established *specific counterpart regulations* or there are other *specific requirements* applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements." 21 C.F.R. § 808.1(d) (2001) (emphasis added); see also *Kennedy*, 67 F.3d at 1461 (Reinhardt, J., concurring) (stating that "§ 808.1 makes it clear that general state tort law is *not* preempted by the MDA").

164. See *supra* notes 18-22 and accompanying text.

165. See John D. Burnside, Comment, *Kennedy v. Collagen Corp.: Falling from the Medical Device Amendments' Federal Preemption Garden*, 28 ARIZ. ST. L.J. 949, 971 (1996) (supporting the holding in *Kennedy*, but conceding that the *Medtronic* decision suggests that the PMA process is a specific requirement); see also Juliann L. Safko, Note, *Massachusetts Sets Precedent for the First Circuit: The Premarket Approval Process of the Medical Device Amendment Preempts State Common Law Causes of Action*, 34 NEW. ENG. L. REV. 739, 757 (2000) ("[I]t is quite possible for the lower courts to infer that a device undergoing the PMA process would have preemptory effect over a state claim which involves a medical device that underwent the PMA process before being marketed.").

166. See 4 FRUMER & FRIEDMAN, *supra* note 17, § 24.05[4][e], at 24-73 to -79 (identifying the split between courts when determining whether federal preemption applies to investigational, substantially equivalent, or PMA-approved devices).

167. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

168. *Id.* at 348-49.

169. See 4 FRUMER & FRIEDMAN, *supra* note 17, § 24.05[4][e], at 24-79 (citing several state court decisions which have followed the reasoning of *Goodlin* and have found that the PMA process does not have preemptive effect).

B. Other Buckman Issues

A troubling aspect of the *Buckman* holding is that plaintiffs will be left with no recourse if their state law claims are preempted. Justice Stevens and Justice Thomas, concurring in the judgment, opined that under the Court's holding,

parties injured by fraudulent representations to federal agencies [will] have no remedy even if recognizing such a remedy would have no adverse consequences upon the operation or integrity of the regulatory process. [We] do not believe the reasons advanced in the Court's opinion support the conclusion that Congress intended such a harsh result.¹⁷⁰

In *Kennedy*, the Ninth Circuit likewise stated that

it is incredible to believe that Congress would, without comment, void all means of relief for those injured by illegal conduct. . . . [S]tate common law serves a different purpose than state regulation and is unlikely to have been the target of congressional attempts to promote the introduction of safe medical devices onto the market or even to curb dual regulation of the medical devices industry.¹⁷¹

In *Goodlin*, the Eleventh Circuit adopted similar reasoning to that of *Kennedy*.¹⁷² At least one court has held that an express warranty claim is not preempted because doing so would provide the plaintiff with no redress.¹⁷³ Commentators have agreed that preempting all of the plaintiffs' claims would not comport with congressional intent.¹⁷⁴ The *Buckman* holding does not appear to imply that state claims other than fraud-on-the-FDA will be preempted. *Buckman* did not rule on any claims related

170. *Buckman*, 531 U.S. at 355.

171. *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459 (9th Cir. 1995) (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)). The court further stated that "[p]remarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers." *Id.* at 1460.

172. See *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1378-79 (11th Cir. 1999) (identifying congressional intent for support in its argument that preempting state law claims would leave plaintiffs without any recourse).

173. *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1326 (3d Cir. 1995) ("The elimination of [express warranty] claims might result in the elimination of all legal remedies to the purchaser.").

174. See *Burnside*, *supra* note 165, at 964 (stating that "construing the MDA to eliminate compensatory remedies undercuts the MDA's consumer protection purpose"); see also Anne-Marie Dega, Comment, *The Battle over Medical Device Regulation: Do the Federal Medical Device Amendments Preempt State Tort Law Claims?*, 27 LOY. U. CHI. L.J. 615, 659-61 (1996) (arguing that leaving plaintiffs with no relief is against public policy because the remedies currently provided by the MDA are entirely insufficient).

to warning, manufacture, or design.¹⁷⁵ This dovetails with the position of the United States, whose amicus brief implied that state claims related to design should not be preempted.¹⁷⁶

There is also the issue of the saving clause found within the FDCA.¹⁷⁷ As the Court noted in *Buckman*, “neither an express pre-emption provision nor a saving clause ‘bar[s] the ordinary working of conflict pre-emption principles.’”¹⁷⁸ However, it is unclear whether the Court’s statement applies to devices approved under the PMA or where conflict preemption is not instituted. One commentator stated that “[the saving clause] proves to be important, as it reveals a clear statement by Congress regarding a medical device manufacturer’s potential liability under state law.”¹⁷⁹ Furthermore, “its existence lends additional support to the conclusion that Congress assumed device firms would remain civilly liable for device-related defects.”¹⁸⁰ Additional support that Congress did not intend to preempt all state law claims is evidenced through a federalism debate concerning whether Congress even considered preempting state law tort claims.¹⁸¹ This debate further bolsters the conclusion that the *Buckman* court did not intend to preempt all state law tort claims.

175. See *supra* note 125 and accompanying text.

176. See Brief of the United States as Amicus Curiae Supporting Petitioner at 12, *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768) (distinguishing *Medtronic* on the grounds that the *Buckman* case involved challenging the FDA’s approval process, while in *Medtronic*, the state claim was based on questioning the design of the device).

177. 21 U.S.C. § 360h(d) (1994) provides as follows:

Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

178. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 352 (2001) (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000)) (alteration in original).

179. *Dega*, *supra* note 174, at 653; see also *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1378-79 (11th Cir. 1999) (declaring that the presence of a saving clause expresses congressional intent not to preempt state law claims and thus to leave plaintiffs without any recourse).

180. Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691, 706 (1997); see also Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 929 (1994) (“[The saving clause] explicitly indicates that a company’s compliance with an FDA recall order will not bar tort claims brought against it.”).

181. See *Dega*, *supra* note 174, at 648-51, 655 (reasoning that Congress did not intend to include state common law claims within the MDA’s preemptive reach because Congress would have expressly said so instead of using ambiguous language, and noting that the MDA’s legislative history did not even address state tort law remedies); see also Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559, 607-10 (1997) (stating that in preserving federalism, “the Court has developed an interpretive guideline known as the ‘clear statement’ rule”; thus, before preemption can occur, the congressional intent must be entirely unambiguous).

C. A Critical Analysis of Buckman

The Supreme Court's reasoning in *Buckman* seems to comport with congressional intent regarding fraud-on-the-FDA claims.¹⁸² By using implied rather than expressed preemption, the Court arguably "dodged a bullet" with respect to the split created in *Medtronic*.¹⁸³ Additionally, the reasoning employed makes common sense and comports with decisions reached both post-*Cipollone* and post-*Medtronic*.¹⁸⁴ *Buckman* stated that "[e]very other court of appeals to consider whether preemption bars common-law actions raising agency-fraud claims implicating federal administrative activity has found preemption."¹⁸⁵ After *Buckman* was denied, many commentators agreed with its reasoning, stating that allowing such fraud-on-the-FDA claims would permit "second-guessing" of a federal agency.¹⁸⁶ The First Circuit's decision in *Talbott v. C.R. Bard, Inc.*, though controversial because the defendant admitted fraud but still prevailed on a preemption defense, nevertheless comports with *Buckman*.¹⁸⁷ *Talbott* demonstrates that even a claim which demonstrates egregious fraud-on-the-FDA will most likely be preempted.

Some commentators have opposed the *Buckman* decision, stating that it "could leave consumers out in the cold without any remedy."¹⁸⁸ Other commentators have opined that the decision may have deleterious effects on some states' tort reform laws because the states previously allowed fraud-on-the-FDA claims in exchange

182. See *Goodlin*, 167 F.3d at 1380-81 (opining that there is no legislative history which makes it plausible "to believe that Congress struck a . . . bargain—regulation in exchange for immunity from state tort suits—in the area of medical devices").

183. See *supra* notes 94-97 and accompanying text.

184. See *Mitchell v. Collagen Corp.*, 126 F.3d 902, 914 (7th Cir. 1997) (citing *Michael v. Shiley, Inc.* in support of preempting plaintiff's fraud-on-the-FDA claim); *Michael v. Shiley, Inc.*, 46 F.3d 1361, 1329 (3d Cir. 1995) (holding that plaintiff's fraud-on-the-FDA claim was preempted); *Reeves v. Acromed Corp.*, 44 F.3d 300, 306-07 (5th Cir. 1995) (refusing to create a fraud-on-the-FDA exception based on the holding in *King*, and opining that the FDA is more than equipped to deal with issues of fraud); see also *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 235 (6th Cir. 2000) (citing *Michael* and *Mitchell* for the proposition that the plaintiff's fraud-on-the-FDA claim was preempted because such a claim would create requirements that conflicted with federal law).

185. James V. Beck & John A. Valentine, *Challenging the Viability of FDCA-Based Causes of Action in the Tort Context: The Orthopedic Bone Screw Experience*, 55 FOOD & DRUG L.J. 389, 430 (2000).

186. See, e.g., Eric G. Lasker, *The Buck Stops Here: Product Liability Claims Involving FDA-Regulated Products*, U.S.L. WK. 2755, 2756 (2001) ("A jury is not guided by th[e] same balancing of regulatory objectives, and even if it were, it would not balance the objectives in the same way as the FDA.").

187. *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 28-30 (1st Cir. 1995) (holding that creating exceptions for noncompliance would disturb the uniformity in standards that Congress intended and that the FDA is best equipped to determine if violations of the MDA have occurred).

188. Rebecca Porter, *Supreme Court Rules That Suit for Fraud on Federal Agency Is Preempted*, TRIAL, Apr. 2001, at 17, 82.

for limiting other types of tort suits.¹⁸⁹ However, as previously discussed, fraud-on-the-FDA claims were preempted well before the decision in *Buckman* came along.¹⁹⁰ Additionally, the Court in *Buckman* said nothing about other state tort law claims being preempted, so the decision's effect on these other claims will be determined in the lower courts. Several courts have already addressed these issues.

VII. POST-BUCKMAN

A. Lower Court Treatment of *Buckman*

After analyzing *Buckman*, it is difficult to determine whether state law claims other than fraud-on-the-FDA claims will be preempted, especially when they are related to design, manufacturing, warnings, or labeling. Some scholars have opined that claims based on improper labeling may also be preempted because they “would require a jury to second-guess a specific regulatory determination in which the FDA dictated the conduct alleged to be tortious.”¹⁹¹ Recent case law demonstrates how lower courts are handling this issue.

Globetti v. Sandoz Pharmaceutical Corp. presents a good example of how lower courts are applying the *Buckman* decision to other state tort claims.¹⁹² In *Globetti*, the defendant attempted to use the holding in *Buckman* to argue that all of the plaintiff's claims involved communications with the FDA and thus were preempted.¹⁹³ The district court reasoned that the *Buckman* decision involved only “fraud-on-the agency” and thus did not preclude the assertion of theories of liability.¹⁹⁴ The court stated that “[a]lthough *Buckman* precludes a plaintiff from seeking damages because the defendant lied to the FDA, it is something completely different to contend that plaintiff is precluded from seeking damages for injuries due to lies to her.”¹⁹⁵ Additionally, the court held that *Buckman* did not preempt the plaintiff's failure-to-warn claims:

In the case before the court, plaintiff's claims also do not arise “solely from the violation of the FDCA requirements.” Defendant owed separate duties beyond simply full and fair disclosure to the FDA, duties not to market a defective and unreasonably dangerous product, not to misrepresent or suppress the facts

189. *Id.* at 82 (quoting Arnold Levin, plaintiffs' attorney, for the proposition that some “tort reform” statutes may be invalid”); see also Mary A. Zedran, *Select Recent Court Decisions*, 27 AM. J.L. & MED. 351, 352 (2001) (“This ruling could also have the unintended consequence of invalidating tort-reform laws in several states.”).

190. See *supra* note 184 and accompanying text.

191. Lasker, *supra* note 186, at 2756.

192. *Globetti v. Sandoz Pharm. Corp.*, No. CV98-TMP-2649-S, 2001 U.S. Dist. LEXIS 2391 (N.D. Ala. Mar. 5, 2001).

193. *Id.* at *2-3.

194. *Id.* at *3-4.

195. *Id.* at *4-5.

needed by *physicians and consumers* to assess the safety of the product, and to adequately warn of known risks associated with it. These duties existed irrespective of the FDCA. Thus, while plaintiff cannot recover simply because defendant defrauded a federal agency, nothing in *Buckman* suggests that she cannot recover where the misrepresentations or suppression were directed *at her* (through her physician) or when the warning given (even though FDA approved) inadequately disclosed the hazards of the product.¹⁹⁶

Finally, the court cited *Goodlin v. Medtronic, Inc.* for the proposition that state common law claims are not preempted by the FDCA or the MDA.¹⁹⁷ Therefore, the *Buckman* decision did not preclude all state law claims, and it appears to be strictly complied with as related to fraud-on-the-FDA claims only.

In *Dawson v. Ciba-Geigy Corp.*, the plaintiffs filed a class action complaint against the manufacturer of the drug Ritalin for allegedly creating a market for the drug while downplaying its risks.¹⁹⁸ The court found that the plaintiffs' complaint did not rest solely on federal law, and thus the plaintiffs' claims were "traditional state law tort and fraud claims."¹⁹⁹ The court did not imply preemption as the Supreme Court had done in *Buckman* because in this case, the plaintiffs' complaint did not rest on fraud on the FDA, but rather on fraud committed by the defendants on the public.²⁰⁰ The court stated that "*Buckman* thus clarified that traditional state tort law claims (even those which parallel FDCA requirements) are not necessarily preempted by the FDCA and are not necessarily the same as 'fraud on the FDA' type claims."²⁰¹ Further, the court noted that a violation of the FDCA was not a necessary element of the plaintiffs' claims, which relied on traditional state law tort and fraud principles.²⁰² Thus, *Dawson* circumscribed *Buckman*'s preemptive scope.

In *Flynn v. American Home Products Corp.*, the plaintiff suffered a leaky heart valve after using a diet drug, "fen-phen," and she sought relief based on fraudulent misrepresentation, negligent misrepresentation, and under Minnesota's consumer protection statutes.²⁰³ According to the plaintiff, the defendant-manufacturer failed to comply with FDA regulations that required disclosure of adverse drug experiences.²⁰⁴ The Minnesota court, confronting the issue for the first time, applied *Buckman* in holding that the existence of state law tort claims conflicted with the

196. *Id.* at *6.

197. *Id.* at *7; *see supra* note 172 and accompanying text.

198. *Dawson v. Ciba-Geigy Corp.*, No. 00-6162, 2001 U.S. Dist. LEXIS 6869, at *3 (D.N.J. May 23, 2001).

199. *Id.* at *11.

200. *Id.* at *20.

201. *Id.* at *21 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001)).

202. *Id.*

203. *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 345 (Minn. Ct. App. 2001).

204. *Id.*

FDA's authority to consistently police fraud.²⁰⁵ The court stated that "the *Buckman* Court's observation that 50 state-law causes of action for violation of the FDA's detailed regulations would increase the burdens placed on applicants for FDA approval applies to drug manufacturers as well as to medical-device manufacturers."²⁰⁶ The court also noted that the state claims, including the fraudulent misrepresentation claim, would fail under Minnesota law if there were no preemption, reasoning that there was no fiduciary duty or intent that the plaintiffs rely on the representations.²⁰⁷

It appears that lower courts are currently in agreement that *Buckman* did not preclude all state law tort claims, but that it will be strictly complied with when fraud-on-the-FDA claims are advanced.²⁰⁸ Other courts interpreting medical preemption clauses related to the FDA have reached results similar to those previously discussed.²⁰⁹ Moreover, still other courts have looked to *Buckman* for guidance when considering claims not related to medical devices or the FDA.²¹⁰

205. *Id.* at 347, 349.

206. *Id.* at 349.

207. *Id.* at 349-50.

208. *See, e.g.,* Caraker v. Sandoz Pharms. Corp., No. 96-CV-4113-JPG, 2001 U.S. Dist. LEXIS 15568, at *55 (S.D. Ill. Sept. 4, 2001) (stating that "*Buckman*'s specific holding, narrowly read, is not controlling" in the pharmaceutical context as to warning claims).

209. *See, e.g.,* Gebhardt v. Mentor Corp., No. 00-15279, 2001 U.S. App. LEXIS 17223, at *5 n.1 (9th Cir. Aug. 1, 2001) (Plaintiff brought a fraud-on-the-FDA claim on appeal, but conceded that under *Buckman*, the fraud claim was not valid.); Cooper v. Smith & Nephew, Inc., No. 00-2556, 2001 U.S. App. LEXIS 15408, at *21 n.3 (4th Cir. July 9, 2001) (relying on *Buckman* and rejecting the plaintiff's fraud-on-the-FDA claim); Fitzgerald v. Smith & Nephew, Inc., No. 00-1145, 2001 U.S. App. LEXIS 12853, at *10 n.3 (4th Cir. June 12, 2001) (Plaintiff alleged that the defendant committed fraud-on-the-FDA but conceded that the decision in *Buckman* precluded her claim.); Andrx Pharms., Inc. v. Biovail Corp., No. 01-6194-CIV-DIMITROULEAS, 2001 U.S. Dist. LEXIS 16904, at *18 (S.D. Fla. Sept. 19, 2001) (holding that plaintiffs' claims for "deceptive and unfair practices," "tortious interference," and "negligence per se" were preempted under the FDCA and *Buckman*); Caraker, 2001 U.S. Dist. LEXIS 15568, at *35-36 (using implied preemption and *Buckman* to hold that plaintiffs' failure-to-warn claims were not preempted).

210. *See, e.g.,* Green v. Fund Asset Mgmt., L.P., 245 F.3d 214, 223 n.7 (3d Cir. 2001) (distinguishing *Buckman* in determining that the plaintiffs were not alleging fraud-on-the-agency claims, but rather were asserting "violations of state and federal securities laws"); Morgan v. Brush Wellman, Inc., No. 3:94-CV-369, 2001 U.S. Dist. LEXIS 14072, at *47-48 (E.D. Tenn. Sept. 4, 2001) (relying on *Buckman* when analogizing between the FDA's balancing of objectives in determining fraud against the agency and "the [Department of Energy's] . . . balanc[ing of] policy objectives including economics and national security needs"); *In re* Bridgestone/Firestone, Inc., Nos. IP 00-9373-CB-S, MDL 1373, 2001 WL 876385, at *9 (S.D. Ind. July 27, 2001) (citing *Buckman* for support in holding that plaintiffs' product recall claim was preempted under the Motor Vehicle Safety Act because plaintiffs cannot rely on express preemption provisions or saving clauses); McCall v. Pacificare of California, Inc., 21 P.3d 1189, 1199 n.9 (Cal. 2001) (discussing the Medicare Act and stating that "[t]o the extent the [plaintiffs'] complaint alleges fraud on the [Health Care Financing Administration], defendants may, on remand, assert it is preempted under the rule in *Buckman*"); Sprietsma v. Mercury Marine, No. 89492, 2001 Ill. LEXIS 1039, at *15-16 (Ill. Aug. 16, 2001) (citing *Buckman* for the proposition that the court would not rule out implied preemption under the Federal Boat Safety Act).

B. *The Current Preemption Position*

As previously discussed, the Supreme Court has shifted between an express preemption approach and an implied preemption approach.²¹¹ One commentator concluded that the “consequence of the Supreme Court’s failure to harmonize *Cipollone* and *Geier* will be a bumper crop of conflicting decisions brought about by the inability of courts to determine in a consistent way whether the polar magnetic field of express preemption clauses, or that of savings clauses, is the stronger.”²¹² However, the *Buckman* Court quoted *Geier* for the proposition that express preemption and saving clauses will not bar an implied preemption analysis.²¹³ Thus, it appears that the Supreme Court is teetering toward implied preemption.²¹⁴

In *Caraker v. Sandoz Pharmaceuticals Corp.*, an inadequate warnings claim was brought against a pharmaceutical company, and the court ruled out express preemption because Congress did not provide a preemption provision for pharmaceuticals under the FDCA²¹⁵. In the court’s opinion, congress’ failure to provide such a provision was “some evidence against congressional intent to scrap almost the entire scheme for state law products liability cases based on failure to warn.”²¹⁶ Additionally, the court reasoned that the presumption against preemption applied because the giving of “warnings as to the risks of ingesting dangerous prescription drugs” was an area of state concern.²¹⁷

However, one must not lose sight of each specific federal statute and the different avenues each court can use to interpret the statute’s express preemptive provision, provided there even is such a provision. Two Supreme Court decisions rendered subsequent to *Buckman* illustrate this point²¹⁸. Even though these cases are not products liability actions, the Court utilizes the same analysis to determine whether state claims will be preempted. In *Lorillard Tobacco Co. v. Reilly*, the Court considered a claim brought by cigarette manufacturers, cigar manufacturers and retailers, and manufacturers of smokeless tobacco products against the Attorney General of Massachusetts alleging that regulations restricting retail sales transactions, promotion, and labeling of tobacco products were preempted.²¹⁹ The Court’s analysis of the express language of the Federal Cigarette Labeling and

211. *See supra* Part III.

212. *See* Madden, *supra* note 54, at 158.

213. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. at 341, 352 (2001) (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000)).

214. *See* OWEN ET AL., *supra* note 1, at 71 (“Post-*Geier* cases seem to be embracing the implied preemption analysis employed there.”).

215. *Caraker v. Sandoz Pharms. Corp.*, No. 96-CV-4113-JPG, 2001 U.S. LEXIS 15568, at *42-43 (S.D. Ill. Sept. 4, 2001).

216. *Id.* at *43.

217. *Id.* at *57 (citing *Buckman*, 531 U.S. at 348).

218. *Lorillard Tobacco Co. v. Reilly*, 121 S. Ct. 2404 (2001); *Egelhoff v. Egelhoff Breiner*, 532 U.S. 141 (2001).

219. *Lorillard Tobacco Co.*, 121 S. Ct. at 2410-12.

Advertising Act²²⁰ and of congressional intent was almost identical to the analysis used in *Cipollone*.²²¹ The Court held that the state regulations were preempted because they targeted cigarette advertising, but conceded that “[s]tates remain free to enact generally applicable zoning regulations, and to regulate conduct with respect to cigarette use and sales.”²²² Further, the Court stated that “Congress preempted state cigarette advertising regulations like the Attorney General’s because they would upset federal legislative choices to require specific warnings and to impose the ban on cigarette advertising in electronic media in order to address concerns about smoking and health.”²²³

In *Egelhoff v. Egelhoff Breiner*,²²⁴ the Court considered preemption with respect to the Employee Retirement Income Security Act (ERISA).²²⁵ The Court held that the plaintiffs’ claims were impliedly preempted because the state statute at issue concerned areas of ERISA, reasoning that uniformity among the states would be impossible “if plans [were] subject to different legal obligations in different States.”²²⁶ The Court conceded that family law is typically an area of state concern, thus creating a presumption against preemption, but held “that presumption [could] be overcome where, as here, Congress ha[d] made clear its desire for preemption.”²²⁷

Based on the most recent Supreme Court decisions and on those preceding them, it is difficult to determine exactly where federal preemption exists post-*Buckman*. As evidenced by *Buckman* and *Geier*, implied preemption is very much alive.²²⁸ However, as demonstrated in *Lorillard Tobacco Co.* and *Egelhoff*, the Court is willing to expressly preempt state statutes or regulations that conflict with federal statutes.²²⁹ Congressional intent and the history underlying the enactment of the statute or regulation are paramount in an express preemption analysis, especially when attempting to determine whether Congress intended to provide plaintiffs with no recourse in the products liability context.²³⁰ Because Congress did not choose the same express language for each preemptive statute and because it had different motivations for enacting each statute, a thorough analysis of each preemptive provision is required. Similarly, when a saving clause exists, as in *Geier*, the courts must determine whether the clause will bar an express preemption analysis and will

220. See *supra* note 32 and accompanying text.

221. *Lorillard Tobacco Co.*, 121 S. Ct. at 2414-17; see *supra* Part III.A.

222. *Lorillard Tobacco Co.*, 121 S. Ct. at 2419. The state regulations at issue set “restrictions on outdoor advertising, point-of-sale advertising, retail sales transactions, transactions by mail, promotions, sampling of products, and labels for cigars.” *Id.* at 2410-11.

223. *Id.* at 2419.

224. 532 U.S. 141 (2001). *Egelhoff* involved a dispute over a state statute that allegedly eliminated the defendant as a beneficiary of an insurance policy. *Id.* at 144.

225. See 29 U.S.C. § 1144(a) (1994) (stating that ERISA “shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan”).

226. *Egelhoff*, 532 U.S. at 148.

227. *Id.* at 151.

228. See *supra* Parts III.C, V.

229. See *supra* notes 219-27 and accompanying text.

230. See *supra* Part VI.B.

instead leave at most the possibility of implied preemption.²³¹ As evinced in *Buckman*, the type of claim alleged is also important when determining whether to use an express or implied preemption analysis and whether a presumption against preemption exists.²³² In sum, the patchwork Supreme Court decisions appear to require a case-by-case analysis to determine whether express or implied preemption principles apply to a particular state law claim in relation to a particular federal statute or regulation.

VIII. CONCLUSION

Federal preemption is a difficult issue because of the delicate balance that has been struck between federal and state powers, especially when related to areas where states have traditionally governed, such as health and safety. The Supreme Court has provided some insight and much confusion for analyzing preemption within the products liability context, beginning with *Cipollone* and continuing with its recent decision in *Buckman*. The Court's decisions have created a split within the circuit courts that have endeavored to determine whether federal preemption principles differ for medical devices that are approved as substantially equivalent, as investigational devices, or as PMA devices.²³³

In *Buckman*, the Court shed a fraction of light on this confusion. *Buckman* essentially applied an implied preemption analysis in determining that the plaintiffs' fraud-on-the-FDA claims were preempted. This decision comported with previous circuit courts' decisions.²³⁴ However, the debate as to whether PMA devices were specific requirements sufficient to trigger preemption was not clarified. Combining the reasoning of the courts in *Goodlin* and *Kennedy* with both congressional and regulatory intent suggests that the PMA does not qualify as a specific requirement under the FDCA.²³⁵ It does not seem likely that Congress intended to provide plaintiffs with no recourse for their injuries. Lower courts grappling with *Buckman* have strictly construed its holding in determining that state law claims other than fraud-on-the-FDA will not be preempted.²³⁶ Therefore, at best, *Buckman* clarifies only claims related to fraud-on-the-FDA, and we must wait for yet another Supreme Court decision or for congressional action to illuminate the ongoing confusion that underlies federal preemption. The Supreme Court may soon get another chance.²³⁷

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231. See *supra* notes 58-59 and accompanying text.

232. See *supra* notes 143-47 and accompanying text.

233. See *supra* notes 148-54 and accompanying text.

234. See *supra* note 184 and accompanying text.

235. See *supra* notes 151, 154 and accompanying text.

236. See *supra* Part VII.A.

237. See *Motorboats: U.S. Supreme Court Asked to Settle Propeller Guard Preemption Question*, BNA PROD. LIAB. DAILY, Dec. 13, 2001, available at WL 12/13/2001 PLD d3.

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