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The Contours of the Parallel Claim Exception: The Supreme Court's Opportunity to Define the Ill-Defined

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THE CONTOURS OF THE PARALLEL CLAIM EXCEPTION: THE SUPREME COURT'S OPPORTUNITY TO DEFINE THE ILL- DEFINED

*Jarett Sena**

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INTRODUCTION

In 2000, Richard Stengel had a SynchroMed EL Pump and Catheter manufactured by Medtronic implanted into his abdomen to deliver pain relief medication to his spine.¹ Five years later, Stengel began to experience ascending paralysis caused by a granuloma, or an inflammatory mass in his spine that formed at the tip of the catheter.²

1. *See Stengel v. Medtronic Inc.*, 704 F.3d 1224,1227 (9th Cir. 2013).

2. *Stengel v. Medtronic Inc.*, 676 F.3d 1159, 1161 (9th Cir. 2012), *reh’g en banc granted*, 686 F.3d 1121 (9th Cir. 2012), *and rev’d on reh’g en banc*, 704 F.3d 1224 (9th Cir. 2013).

Surgeons then removed the catheter and most of the granuloma, but it was not in time. The granuloma that formed at the catheter tip had rendered Stengel permanently paraplegic.³ Stengel has since died, allegedly from injuries he suffered in connection with the device.⁴

Richard Stengel is just one of the many people who have been injured by Class III medical devices. Class III medical devices are devices that either are used to sustain human life or present an unreasonable risk of injury.⁵ In 2009, the FDA issued over 160 Class I recalls of medical devices.⁶ Over the past year, over 500 medical-device related injuries and over 500 medical-device related deaths were reported to the FDA.⁷

Preemption externalizes the harms of medical devices from the manufacturers to the government and the public.⁸ In fact, the failures associated with Medtronic's Sprint Fidelis Leads could cost the government and the public up to \$1 billion dollars.⁹ A Sprint Fidelis Lead is a pacemaker lead that provides an electrical conduit between a pacemaker and heart, and thereby shocks the heart back into a normal rhythm when it detects an abnormality.¹⁰ After the Sprint Fidelis Lead was implanted into 150,000 patients, Medtronic issued a worldwide recall, and the FDA then issued a Class I recall due to the high failure rate associated with the leads.¹¹ Medtronic advised that the leads implanted into patients prior to the recall remain implanted

3. *See Stengel*, 704 F.3d at 1226.

4. Brief for the United States as Amicus Curiae at 4, *Stengel*, 704 F.3d 1224 (No. 12-1351).

5. 21 U.S.C. § 360c(a)(1)(C)(ii) (2012).

6. *See* H. DENNIS TOLLEY, EXAMINING THE SPRINT FIDELIS EFFECT ON MEDICARE COSTS 2 (2010). A Class I recall, the most serious type, is one in which there is a reasonable probability of serious health consequences or death. *See Background and Definitions*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/safety/recalls/ucm165546.htm> (last updated June 24, 2009). There also are adverse incidents associated with medical devices that have not been recalled or extensively litigated. For instance, the FDA has reported there have been twenty deaths and five hundred adverse events associated with Seprafilm, an adhesion barrier used to prevent post-surgical adhesions but there has yet to be a recall.

7. *SEE* FDA, *Maude- Manufacturer and User Facility Device Experience*, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/results.cfm>.

8. *See* David Chang, *Internalizing the External Costs of Medical Device Preemption*, 65 HASTINGS L.J. 283, 298 (2013).

9. *See* TOLLEY, *supra* note 6, at 19; Chang, *supra* note 8, at 302.

10. TOLLEY, *supra* note 6, at 3.

11. *Id.* A Sprint Fidelis Lead is a pacemaker lead that provides an electrical conduit between the pacemaker and the heart, which shocks the heart back into a normal rhythm if it detects an abnormality. Although for most leads there is a small rate of failure due to fracture, Sprint Fidelis leads have failed at higher rates than other leads. *Id.* at 2–3, 8.

because of the risks involved with surgically extracting the leads.¹² Instead of replacement, patients with the leads implanted are either closely monitored, or their leads are turned off, capped, and then replaced with another lead.¹³

Monitoring and replacing these leads impose significant health care costs.¹⁴ Because about eighty-five percent of the people who were implanted with Sprint Fidelis Leads were on Medicare, the Medicare program has paid millions of dollars in replacement and monitoring costs.¹⁵ If preemption did not exist—and manufacturers were forced to internalize these costs by facing potential lawsuits—Medtronic may have acted more quickly in addressing the defects in their leads.¹⁶ Quicker action by Medtronic could have saved the public millions, or perhaps even \$1 billion, in Medicare costs.¹⁷

In 2008, the Supreme Court in *Riegel v. Medtronic, Inc.* made it more difficult for plaintiffs to bring common law claims against manufacturers of Class III medical devices.¹⁸ The *Riegel* court essentially preempted common law claims in which the manufacturer complied with FDA's pre-market approval process.¹⁹ Plaintiffs, though, were not left without judicial recourse. The Court made clear that parallel claims or state-law claims premised on an FDA violation escape preemption.²⁰ However, the “contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined.”²¹ Consequently, lower courts have adopted conflicting interpretations of the parallel claim exception, especially in regards to two issues.²²

One issue that has plagued lower courts is whether a plaintiff must allege a violation of a generally applicable or a device-specific federal

12. *See id.* at 4.

13. *See id.*

14. *Id.* Making sure the leads do not fail “is a costly procedure, and each procedure carries the risk of complications or even death. Removing the defective lead is especially difficult because leads become imbedded into the surrounding tissue after they are positioned into the veins connecting to the heart.” *Id.*

15. TOLLEY *supra* note 6, at 2–3; Chang, *supra* note 8, at 301–02.

16. Chang, *supra* note 8.

17. *Id.* at 298.

18. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008). Under *Riegel*, a state law claim is expressly preempted if it imposes requirements that are “different from or in addition to” federal requirements. *Id.*

19. *See id.* at 332.

20. *See id.* at 328.

21. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010).

22. *See* Petition for a Writ of Certiorari at 9–11, *Medtronic, Inc. v. Stengel*, 134 S. Ct. 375 (2013) (No. 12-1351).

requirement to avoid express preemption.²³ While the Fifth, Sixth, Seventh, and Ninth Circuits have held that the federal requirement can be generally applicable, the Eighth and Eleventh Circuits have held that the requirement must be device-specific.²⁴

Another issue that has been divisive for lower courts is whether traditional state tort law claims are impliedly preempted by *Buckman Co. v. Plaintiffs' Legal Committee*.²⁵ The Sixth and Eighth Circuits have impliedly preempted state tort law claims premised on a FDA violation. By contrast, the Fifth, Seventh, and Ninth Circuits have held that such state law tort claims are not impliedly preempted.²⁶ For the lower federal courts to be divided over this issue of federal law is problematic, as it is in contravention of Congress's intent to create a uniform framework for regulating medical devices.²⁷

Stengel v. Medtronic, Inc. raised the very issues that have plagued lower courts, namely, whether a claim that a manufacturer failed to report adverse events fits within the parallel claim exception or is preempted, either expressly or impliedly.²⁸ The district court held that plaintiff's claims were expressly and impliedly preempted.²⁹ The Ninth Circuit affirmed, but then the full court reversed en banc.³⁰ Medtronic filed a petition for certiorari, arguing that the Supreme Court should clarify the contours of the parallel claim exception and overrule the Ninth Circuit's en banc decision.³¹ Recently, the Supreme Court denied Medtronic's petition for certiorari, and thus

23. *Id.* at 10.

24. *Id.*

25. *See id.* at 11; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that plaintiff's fraud on the FDA claim was impliedly preempted by the statutory scheme of the Food, Drug, and Cosmetic Act).

26. *Id.*

27. *See id.* at 19. Congress enacted a preemption provision in the Medical Device Amendments of the Food, Drug, and Cosmetic Act because states enacted varying laws in response to medical device failures in the mid-1970s such as the Dalkon Shield failures. *See* H.R. Rep. No. 94-853, at 45-46 (1976); Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691, 703-04 (1997).

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

29. *Stengel v. Medtronic, Inc.*, CV 10-318-TUC-RCC, 2010 WL 4483970 (D. Ariz. Nov. 9, 2010), *aff'd*, 676 F.3d 1159 (9th Cir. 2012), *reh'g en banc granted*, 686 F.3d 1121 (9th Cir. 2012), *rev'd en banc*, 704 F.3d 1224 (9th Cir. 2013).

30. *Stengel*, 704 F.3d at 1234; *Stengel v. Medtronic, Inc.*, 676 F.3d 1159, 1168 (9th Cir. 2012), *reh'g en banc granted*, 686 F.3d 1121 (9th Cir. 2012), *rev'd en banc*, 704 F.3d 1224 (9th Cir. 2013).

31. *See generally* Petition for a Writ of Certiorari, *supra* note 22, at 9-11.

the confusion surrounding the parallel claim exception continues.³² Although the Supreme Court's rationale for denial of certiorari is unclear, it could have been persuaded by the respondents' arguments that Medtronic did not properly raise an argument below, or that the Ninth Circuit's decision lacked finality.³³

This Note explores the split amongst the Circuits involving preemption of Class III medical devices and concludes that the Supreme Court should bridge the split in the near future. Part I provides a background on the FDA's statutory scheme and the Supreme Court's implied and express preemption doctrine in the context of medical devices. It also explores how claims that fit within the parallel claim exception avoid express or implied preemption. Part II of this Note explores the diverging interpretations to parallel claims that lower courts have adopted. Specifically, some courts have held that state law tort claims premised on an industry-wide violation are expressly or impliedly preempted, whereas others have held that such claims avoid preemption entirely. Part III outlines the arguments made in support and opposition of certiorari in *Stengel*. Finally, Part IV of this Note concludes that, based on sound public policy and precedent, traditional state law claims premised on violations of FDA regulations should survive both express and implied preemption.

I. THE FDA APPROVAL PROCESS AND THE PREEMPTION DOCTRINE

The Supreme Court decisions on preemption, as well as those of the lower courts, are based on their interpretations of The Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetics Act (FDCA). Accordingly, an understanding of the MDA's complex regulatory framework is crucial to understanding these court decisions.³⁴

32. See Michael Walsh, *The Preemption Pendulum: The Supreme Court Punts Stengel v. Medtronic*, STRASBURGER FOOD & DRUG L. BLOG, (June 24, 2012), <http://www.strasburger.com/preemption-pendulum-supreme-court-punts-stengel-v-medtronic/>.

33. See Respondents' Brief in Opposition at 7–9, 20–22, *Medtronic, Inc. v. Stengel*, 134 S. Ct. 375 (2013) (No. 12-1351).

34. J. David Prince, *The Puzzle of Parallel Claims, Preemption, and Pleading the Particulars*, 39 WM. MITCHELL L. REV. 1034, 1038–39 (2013).

A. The FDA Approval Process

The MDA divides medical devices into three categories.³⁵ Class I devices, such as bandages, do “not present an unreasonable risk of injury” and thus are subject to only general controls, such as labeling requirements.³⁶ Class II devices pose a greater risk than Class I devices, and are subject to special controls, such as performance standards and post-market surveillance measures.³⁷ Class III devices, such as implantable pacemaker pulse generators and heart valves, pose the greatest risk and are subject to extensive regulations.³⁸ A device is classified as Class III if it cannot be classified as a Class I or Class II device, and the device is (1) “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,” or (2) “presents a potential unreasonable risk of illness or injury.”³⁹

Class III medical devices must undergo a rigorous pre-market approval (PMA) process.⁴⁰ Manufacturers must submit the following to the FDA regarding Class III medical devices: (1) full reports of all studies that have been published or should reasonably be known by the manufacturer; (2) a full statement of the components, ingredients, and properties of the device; (3) a full description of the methods, facilities, and controls used for manufacturing, processing, and, when relevant, packing and installing the device; (4) samples or device components as requested by the FDA; and (5) a specimen of proposed labeling.⁴¹ The FDA then reviews all of this information and “weig[hs] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.”⁴² According to the Supreme Court, the FDA spends an average of 1200

35. 21 U.S.C. § 360c (2012).

36. *Id.* §360c(a)(1)(A); 21 C.F.R. § 880.6230, 880.5075 (2014); *see also* *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).

37. *See* 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. §§ 880.5860 (2014); 21 C.F.R. § 884.5460 (2014); *see also* *Riegel*, 552 U.S. at 317.

38. *See* 21 U.S.C. § 360c(a)(1)(C)(ii)(I)–(II); 21 C.F.R. § 870.3610 (2014); *see, e.g.*, *Riegel*, 552 U.S. at 317.

39. 21 U.S.C. § 360c(a)(1)(C)(ii); *Riegel*, 552 U.S. at 317.

40. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996); *see also* *Prince*, *supra* note 34, at 1039.

41. *See* 21 U.S.C. § 360e(c)(1); *see also* *Riegel*, 552 U.S. at 318. For the specific reporting rules required in PMA application, *see* 21 C.F.R. § 814.20 (2014).

42. 21 U.S.C. § 360c(a)(2)(C); *Riegel*, 552 U.S. at 318.

hours on each PMA submission.⁴³ After completing its review, the FDA can grant, deny, or condition approval on adherence to performance standards.⁴⁴ The FDA only approves the device if it finds that (a) there is a “reasonable assurance” of the device’s “safety and effectiveness,” and (b) the proposed labeling is neither false nor misleading.⁴⁵

The PMA process is a rigorous one, but there are three ways a device can avoid it. The first exception “grandfathers in” devices that are manufactured prior to the MDA’s effective date of May 28, 1976.⁴⁶ Devices manufactured prior to the MDA’s effective date can remain on the market until the FDA promulgates a regulation requiring pre-market approval.⁴⁷ The second exception allows for devices that are “substantially equivalent” to devices on the market prior to enactment of the MDA to go through an expedited § 510(k) process instead of PMA.⁴⁸ Most Class III devices enter the market through § 510(k) where they are reviewed by the FDA for equivalence but not for safety and effectiveness.⁴⁹ The third exception, known as the investigational device exemption (IDE), allows experts to use unapproved devices in research trials involving human subjects.⁵⁰

Once a device receives pre-market approval, it is still subject to regulatory constraints.⁵¹ After pre-market approval, the manufacturer cannot, without FDA permission: change the design, the manufacturing process, labeling, or any other attribute that would affect safety or effectiveness of the device.⁵² If a manufacturer wants to make such a change it must file, and the FDA must approve, a supplemental PMA.⁵³ The supplemental PMA application is

43. *Lohr*, 518 U.S. at 477. Before granting PMA approval, the FDA can also employ outside experts to review the information or request additional information from the manufacturer. 21 U.S.C. § 360e(c)(1)(G); 21 C.F.R. § 814.44(a) (2014).

44. *See* 21 U.S.C. § 360e; 21 C.F.R. § 861.1(b)(3) (2014); *see also Riegel*, 522 U.S. at 319.

45. 21 U.S.C. § 360e(d); *Riegel*, 522 U.S. at 318.

46. 21 U.S.C. § 360e(b)(1); *Riegel*, 522 U.S. at 317.

47. 21 U.S.C. §§ 360c(f)(1), 360e(b)(1).

48. 21 U.S.C. § 360c(f)(1)(A).

49. “Most new Class III devices enter the market through § 510(k). In 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices.” *Riegel*, 522 U.S. at 317 (citing PETER HUTT ET AL., FOOD AND DRUG LAW 992 (3d ed. 2007)).

50. *See* 21 U.S.C. § 360j(g).

51. *See Riegel*, 522 U.S. at 319.

52. 21 U.S.C. § 360e(d)(6)(A)(i); *see also Riegel*, 522 U.S. at 319.

53. 21 U.S.C. § 360e(d)(6)(A)(i).

“evaluated under largely the same criteria as an initial application.”⁵⁴ However, certain changes to a device’s label after pre-market approval do not require FDA approval.⁵⁵ For instance, the “changes being effected” regulation (CBE) allows a manufacturer to put in effect labeling changes:

- (i) that add or strengthen a contradiction warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association . . .
- (ii) that add or strengthen an instruction that is intended to enhance the safe use of the device . . .
- (iii) that delete misleading, false, or unsupported indications.⁵⁶

In addition to the pre-market approval requirements, a manufacturer must also comply with the MDA’s post-approval reporting requirements.⁵⁷ These reporting requirements compel a manufacturer to submit reports that include: (1) clinical investigations or scientific studies concerning the device, which is known or should be known by the manufacturer;⁵⁸ and (2) incidents in which a device “[m]ay have caused or contributed to a death or serious injury” or malfunctioned in a manner that “would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.”⁵⁹ Manufacturers must report death, serious injury, or malfunction to the FDA within thirty calendar days after the manufacturer “receive[s] or otherwise become[s] aware of information, from any source.”⁶⁰ The FDA can also obtain this post-approval information from other entities besides the manufacturer. For instance, the MDA requires physicians, hospitals, surgical facilities, and other health-service providers to report deaths or serious injury associated with a Class III medical device.⁶¹

54. *Riegel*, 552 U.S. at 319; see 21 C.F.R. § 814.39 (2014) (“[A]ll procedures and actions that apply to an application under § 814.20 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change.”).

55. Without FDA approval, a manufacturer may place into effect “i) labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association” or “ii) [l]abeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device.” 21 C.F.R. § 814.39(d)(2)(i)–(iii).

56. *Id.*

57. See generally 21 U.S.C. § 360i.

58. See 21 C.F.R. § 814.84 (2014).

59. 21 C.F.R. § 803.50 (2014).

60. *Id.*

61. 21 U.S.C. § 360i.

The FDA's surveillance system can generally be classified as passive because it requires manufacturers to do their own due diligence.⁶² However, the FDA does have a few affirmative obligations. First, the FDA is required to inspect domestic manufacturing facilities of Class III devices once every two years.⁶³ Second, the FDA has the authority to withdraw PMA based on newly reported or existing information, and the FDA must withdraw PMA if it determines that the device is unsafe or ineffective under the conditions of its labeling.⁶⁴ In addition, the FDA can order a label change based on newly acquired information;⁶⁵ if the FDA determines that the device poses an "unreasonable risk of substantial harm to the public," the FDA can require the manufacturer to notify affected individuals, or repair, replace, or refund the device.⁶⁶

B. The Preemption Doctrine

In addition to pre-approval and post-approval requirements, the MDA also contains a preemption provision. The preemption provision set forth in 21 U.S.C. § 360k(a) states that:

[N]o 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 [the FDCA].⁶⁷

The preemption doctrine is derived from the Supremacy Clause of the United States Constitution, which states that the "Laws of the United States . . . shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."⁶⁸ The Supreme Court has recognized that federal

62. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-09-370T, MEDICAL DEVICES SHORTCOMINGS IN FDA'S PREMARKET REVIEW, POSTMARKET SURVEILLANCE, AND INSPECTIONS OF DEVICE MANUFACTURING ESTABLISHMENTS 14 (2009), available at <http://www.gao.gov/assets/130/122801.pdf>.

63. 21 U.S.C. § 360(h).

64. *Id.* § 360e(e)(1); § 360h(e); see also *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319–20 (2008).

65. 21 U.S.C. § 360f(a)(2).

66. *Id.* § 360h(a)–(b).

67. *Id.* § 360k.

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

law can preempt state law either expressly or impliedly.⁶⁹ Express preemption occurs when the text of a federal statute clearly preempts state law.⁷⁰ Implied preemption occurs when Congress intended the federal statutory scheme to “occupy the field” (field preemption), or when state law conflicts with federal law (conflict preemption).⁷¹ The implied preemption analysis for medical device claims falls within the category of conflict preemption, of which there are two kinds.⁷² First, state law is impliedly preempted if it is physically impossible to comply with both state and federal law.⁷³ Second, state law is impliedly preempted if that state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”⁷⁴ The Supreme Court has analyzed claims involving medical devices under the doctrine of express preemption, as well as implied conflict/obstacle preemption.⁷⁵

There are three influential Supreme Court decisions on the preemption doctrine which involve medical device claims: *Medtronic, Inc. v. Lohr*,⁷⁶ *Buckman Co. v. Plaintiff’s Legal Committee*,⁷⁷ and *Riegel v. Medtronic, Inc.*⁷⁸ Due in large part to the last two decisions mentioned, preemption has become a major defense in the field of medical devices.⁷⁹ However, these decisions have also created a narrow gap, known as the parallel claim exception, through which state law claims can fit to avoid preemption.⁸⁰

69. See Jean Macchiaroli Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device “Parallel Claims”*, 9 J. HEALTH & BIOMEDICAL L. 159, 163 (2013).

70. See *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 241–42 (1947); see also Eggen, *supra* note 69, at 163–64.

71. Eggen, *supra* note 69, at 164.

72. *Id.*

73. “[T]he Court has found pre-emption where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce.” *Wyeth v. Levine*, 555 U.S. 555, 589 (2009); see also Eggen, *supra* note 69, at 164.

74. *Wyeth*, 555 U.S. at 589 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

75. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321–22 (2008) (undertaking an express preemption analysis); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001) (undertaking an implied conflict/ obstacle preemption analysis); see also Eggen, *supra* note 69, at 167.

76. 518 U.S. 470 (1996).

77. 531 U.S. 341.

78. 552 U.S. 312.

79. *Prince*, *supra* note 34, at 1038.

80. See generally, Eggen, *supra* note 69, at 160–61.

1. *The Supreme Court's Express Preemption Doctrine*

a. *Medtronic, Inc. v. Lohr*

The Supreme Court first addressed the scope of the MDA's preemption provision in *Lohr*.⁸¹ The Supreme Court, applying a presumption against preemption, ruled that Lohr's common law claims against a device approved through § 510(k) are not preempted.⁸² The presumption against preemption is used in a field traditionally occupied by the states.⁸³ In such a field, the Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."⁸⁴

In *Lohr*, Medtronic manufactured a Model 4011 pacemaker that was approved by the FDA through the expedited § 510(k) process requiring "substantial equivalence" to an already approved device.⁸⁵ In 1990, Lora Lohr's Model 4011 pacemaker failed, allegedly due to a defective lead.⁸⁶

Lohr and her husband sued under theories of negligence and strict liability.⁸⁷ The Court held that the Lohrs' claims were not preempted because § 510(k) approval did not amount to a federal requirement.⁸⁸ According to the Court, the § 510(k) process did not impose a federal requirement because the FDA had only made a determination of "substantial equivalence," not a determination of "safety and effectiveness."⁸⁹ "[S]ubstantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less effective than the earlier device."⁹⁰

Medtronic argued that the Lohrs' claims should be preempted because it complied with Current Good Manufacturing Practices (CGMPs), which impose generalized duties on all manufacturers of

81. Elliot Sheppard Tarloff, *Medical Devices and Preemption: A Defense of Parallel Claims Based on Violations of Non-Device Specific FDA Regulations*, 86 N.Y.U. L. Rev. 1196, 1203 (2011).

82. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 494 (1996).

83. *Id.* at 485.

84. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

85. *Lohr*, 518 U.S. at 480-81.

86. *Id.* at 481.

87. *Id.*

88. *Id.* at 502; *see also* Eggen, *supra* note 69, at 167.

89. *Lohr*, 518 U.S. at 493.

90. *Id.*

medical devices.⁹¹ The Court rejected Medtronic's argument and held that the generalized duties imposed by the CGMP are not specific enough to preempt the Lohrs' common law claims.⁹² Therefore, the Lohrs' state law claims regarding a device that went through § 510(k) were not preempted because there was no conflict with the FDA's rules relating to manufacturing and labeling.⁹³

b. Riegel v. Medtronic, Inc.

Twelve years later, the Supreme Court ruled that claims regarding medical devices that went through the full PMA have a preemptive effect. During a coronary angioplasty in 1996, Medtronic's Evergreen Balloon Catheter was inserted into Charles Riegel's artery to inflate the artery like a balloon in hopes of dilating it.⁹⁴ On the fifth inflation, the catheter burst, and as a result, Riegel suffered severe and permanent injuries.⁹⁵ Charles and his wife Donna sued in the Northern District of New York seeking compensatory damages.⁹⁶ They alleged that the catheter inserted into Riegel was designed, labeled, and manufactured in violation of New York common law.⁹⁷ In *Riegel*, the Supreme Court expressly preempted plaintiffs' common law claims involving an Evergreen Balloon Catheter, which went through the full PMA process.⁹⁸

In reaching the conclusion that the Riegels' state law claims were expressly preempted, the Court undertook a two step analysis.⁹⁹

91. *Id.* at 497–98. The CGMPs “govern the methods . . . for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices.” 21 C.F.R. § 820.1 (2014). The CGMPs were “established to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls.” *Facts About Current Good Manufacturing Practices (CGMPs)*, US FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm169105.htm> (last updated Oct. 24, 2014).

92. The generality of the CGMPs “make this quite unlike a case in which the Federal Government has weighed the competing interests.” CGMPs “reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.” *Lohr*, 518 U.S. at 501.

93. *See id.* at 501.

94. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008); Prince, *supra* note 34, at 1044.

95. *Riegel*, 552 U.S. at 320.

96. *Id.*

97. *Id.*

98. *Id.*

99. *See In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1151 (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010).

First, the Court had to determine whether the PMA imposed “requirements” of “safety and effectiveness” under the MDA. The Court held that PMA approval does impose “requirements” because, as the rigorous PMA process indicates, the FDA will only approve of a device if it “offers a reasonable assurance of safety and effectiveness.”¹⁰⁰ Second, the Court had to decide whether plaintiffs’ common law claims imposed requirements that were “different from or in addition to” the PMA requirements imposed under § 360k(a). The Court held that common law claims constitute “requirements” because the legal duty is imposed and the common law damages remedy is “a potent method of governing conduct and controlling policy.”¹⁰¹ The Court then concluded that the state law common law requirements are “different from or in addition to” those imposed by federal law.¹⁰² This is because a jury could weigh the risks and benefits of a device in a way that conflicts with the FDA decision made during PMA that the device was safe and effective.¹⁰³ For these reasons, the Riegels’ state law claims were expressly preempted by § 360k.

2. *The Parallel Claim Exception Carved Out in Riegel and Lohr*

Riegel effectively precluded many common law tort law claims. However, the *Riegel* court made clear that it was only preempting common law claims in which the manufacturer “violated state law tort duties notwithstanding *compliance* with the relevant federal requirements.”¹⁰⁴ The Supreme Court recognized in both *Riegel* and *Lohr* that claims premised on a *violation* of a federal requirement could survive preemption.¹⁰⁵ In *Lohr*, the Court said “nothing in § 360k denies [the state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.”¹⁰⁶ The *Riegel* Court reaffirmed this view when it said: “Section 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than

100. *Riegel*, 522 U.S. at 323. “Premarket approval . . . imposes ‘requirements’ under the MDA.” *Id.* at 322.

101. *Id.* at 324 (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521 (1992)).

102. *Id.* at 330.

103. *Id.* at 325.

104. *Id.* at 330 (emphasis added); *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010) (emphasis added).

105. *Riegel*, 522 U.S. at 330; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

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

add to, federal requirements.”¹⁰⁷ Hence, parallel claims—that is, state law claims premised on a violation of federal law—are not expressly preempted because such claims are not in conflict with federal requirements.¹⁰⁸

In a more recent decision involving generic drugs, the Supreme Court also seemed to leave the door open for parallel claims. In *Mutual Pharmaceutical Co. v. Bartlett*, the Court held that plaintiff’s design defect claim involving a generic drug was impliedly preempted due to the impossibility of complying with both state and federal law.¹⁰⁹ The Court found that plaintiff’s claim, which was premised on the theory that the manufacturer should have changed its labeling, conflicted with FDCA regulations prohibiting a generic drug manufacturer from unilaterally changing its labels.¹¹⁰ However, the Court did note that it was “not address[ing] state design-defect claims that parallel the federal misbranding statute.”¹¹¹ One claim that could fall within the parallel claim exception would be if the generic drug manufacturer violated the federal misbranding statute by failing to pull a dangerous drug from the market.¹¹²

B. Implied Preemption

Although a claim that falls within the parallel claim exception survives express preemption, such a claim may still be impliedly preempted.¹¹³ In 2001, the Supreme Court held in *Buckman* that plaintiff’s claims survived express preemption but failed to escape implied preemption.¹¹⁴ In *Buckman*, the Court looked beyond the text and used an implied conflict preemption analysis.¹¹⁵ Specifically, the *Buckman* court undertook an obstacle preemption analysis.¹¹⁶

107. *Riegel*, 552 U.S. at 330.

108. *See generally id.* at 312; *see also* Eggen, *supra* note 69, at 167.

109. 133 S. Ct. 2466, 2477.

110. *Id.* at 2473.

111. *Id.* at 2477 n.4.

112. *See id.*; *see also* Brian Wolfman & Anne King, *Mutual Pharmaceutical Co. v. Bartlett and Its Implications*, U.S. L. WK., Nov. 5, 2013, at 1, 8, *available at* <http://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=2306&context=facpub>.

113. “Thus, although [Riegel v.] Medtronic can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353 (2001).

114. *See id.* at 347–48.

115. Eggen, *supra* note 69, at 168 (citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

116. *See Buckman*, 531 U.S. at 350.

In *Buckman*, the FDA twice denied the manufacturer's § 510(k) application for use of a bone screw in spinal surgery.¹¹⁷ The manufacturer submitted a third application seeking approval for the bone screws for use in the long bones of the arms and legs.¹¹⁸ A regulatory consultant of the manufacturer represented to the FDA that the bone screws would only be used in long bone surgery.¹¹⁹ Thousands of plaintiffs sued the regulatory consultant alleging that the consultant, Buckman, made fraudulent representations to the FDA as to the intended use of the bone screws.¹²⁰

The Court treated the claims as within the parallel claim exception because “‘fraud on the FDA’ constitutes a violation of both federal and state law.”¹²¹ Nonetheless, the Court held that plaintiffs’ claims were impliedly preempted.¹²² As a threshold matter, the Court refused to apply the presumption against preemption because “policing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied.’”¹²³ The Court then held that the FDA has exclusive authority to enforce claims of fraud. It construed 21 U.S.C. § 337, which provides that enforcement of FDCA violations “shall be by and in the name of the United States,” as barring private action of plaintiff’s claims. The Court also explained that the § 510(k) approval process created a “comprehensive scheme for determining whether an applicant has demonstrated that a product is substantially equivalent to a predicate device”¹²⁴ First, the manufacturer must comply with FDA disclosure requirements such as submitting labeling and advertisements to the FDA.¹²⁵ Secondly, according to the Court, the FDA is given ample enforcement power to deter or punish fraud, including: the power to investigate fraud, seek injunctive relief and civil penalties, seize the device, and pursue criminal sanctions.¹²⁶

After determining that the FDA has ample authority to police fraud, the Court concluded that the “state law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police

117. *Id.* at 346.

118. *Id.*

119. *Id.*

120. *Id.* at 346–47.

121. *Id.* at 348; Eggen, *supra* note 69, at 169.

122. “[T]here is clear evidence here that Congress intended that the MDA be enforced exclusively by the Federal Government.” *Buckman*, 531 U.S. at 342.

123. *Id.* at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

124. *Id.* at 348.

125. *Id.* (citing 21 C.F.R. § 807.87(e)–(f) (2014)).

126. *Buckman*, 531 U.S. at 349; *see* 21 U.S.C. §§ 332, 333(a), 333(f)(1)(A), 334(a)(2)(D), 372 (2012).

fraud.”¹²⁷ The court gave several public policy reasons why there would be an inevitable conflict. First, complying with the FDA’s detailed regulatory scheme and the tort regimes of fifty states would be dramatically burdensome for the manufacturer.¹²⁸ Second, manufacturers may be deterred from applying for § 510(k) approval out of fear that they will be “exposed to unpredictable civil liability.”¹²⁹ Third, applicants worried that their disclosures will not be sufficient in state court, may submit a deluge of unnecessary information to the FDA, which would delay the “comparatively speedy § 510(k) process.”¹³⁰ Delays in § 510(k) approval would, in turn, impede competition among devices and delay the prescription of beneficial off-label uses.¹³¹

The question left open after *Buckman* is to what extent common law claims that parallel federal law are impliedly preempted.¹³² The *Buckman* court stated that some, but not all, parallel claims are impliedly preempted when it said, “although *Medtronic [v. Lohr]* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.”¹³³ According to the *Buckman* court, the difference between *Lohr*, in which the claims were not preempted, and *Buckman*, in which they were preempted, was the source of the cause of action.¹³⁴ In *Lohr*, the claim was based on traditional state law for failure to use reasonable care, whereas in *Buckman*, the Court found that the causes of action “exist solely by virtue of the FDCA disclosure requirements.”¹³⁵

C. The Narrow Gap

Together, *Riegel*, *Lohr*, and *Buckman*, “create a narrow gap through which a plaintiff’s state-law claim must fit through to escape express or implied preemption.”¹³⁶ The claim must allege a violation of a federal requirement to avoid express preemption under *Riegel*,

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

128. *Id.*

129. *Id.*

130. *Id.* at 351.

131. *Id.*

132. See *Eggen*, *supra* note 69, at 173; see also *Prince*, *supra* note 34, at 1071.

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

134. *Prince*, *supra* note 34, at 1071.

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

136. *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

but even if it does, it must then avoid the ambit of *Buckman*'s implied preemption doctrine.¹³⁷ However, the Supreme Court did not provide much guidance on what exactly fits through the narrow gap that they created through this triad of cases.¹³⁸ The result is that lower courts have not treated the narrow gap with consistency or uniformity.¹³⁹

This problem is exacerbated by the fact that judges often base their preemption decision off of extralegal factors such as their ideology, the court they sit on, and the residence of the litigants.¹⁴⁰ According to Professor Jean Eggen, courts have merged the distinct doctrines of express and implied preemption into a "unitary standard," such that it is now a matter of "policy and discretion," which standard courts choose to preempt plaintiff's claim.¹⁴¹ Supreme Court Justices Kennedy and Thomas have acknowledged that the preemption doctrine can result in a "freewheeling" judicial inquiry.¹⁴² Consequently, there is no uniform judicial inquiry of the preemption doctrine amongst the lower courts.

II. DIVERGING DOCTRINE IN THE WAKE OF *RIEGEL*

A. Genuine Equivalency

In the wake of *Riegel*, lower courts have differed on exactly which claims fit through this narrow gap to survive preemption. A threshold issue is what exactly constitutes a parallel claim. As established in *Bates v. Dow Agrosciences LLC* and *McMullen v. Medtronic, Inc.*, to

137. 27 MINN. PRAC., PRODUCTS LIABILITY LAW § 9.11.50 (2014).

138. The Eighth Circuit has said that "[t]he contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010).

139. Eggen, *supra* note 69, at 172.

140. According to a study conducted by Samuel Raymond, a New York University J.D. candidate, "litigants are better off when the case is decided in the state where they reside or have an office. When the plaintiff sues in a different state than their residence, they won just a single time. Plaintiffs won 27.2% of the cases where they sued in their home state court." Samuel Raymond, Note, *Judicial Politics and Medical Device Preemption After Riegel*, 5 N.Y.U. J.L. & LIBERTY 745, 765 (2010). In addition, Raymond's data shows "that Democratic-appointed judges [are] more than 3 times as likely to find 'no preemption' as Republican-appointed judges." *Id.*

141. Eggen, *supra* note 69, at 171–72; see also Jean Macchiaroli Eggen, *The Mature Product Preemption Doctrine: The Unitary Standard and the Paradox of Consumer Protection*, 60 CASE W. RES. L. REV. 95, 115, 133 (2009).

142. *Wyeth v. Levine*, 555 U.S. 555, 604 (2009) (Thomas, J., concurring in the judgment); *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 459 (2005) (Thomas, J., concurring in part and dissenting in part); *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and dissenting in part).

fit within the parallel claim exception and thus avoid express preemption, plaintiff must show that the state and federal requirements are “genuinely equivalent.”¹⁴³ This means that a state law claim must be premised on a duty that is the same as the duty imposed by the FDCA.¹⁴⁴

For instance, in *Bates* the Supreme Court held that “a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA [the Federal Insecticide, Fungicide, and Rodenticide Act] in order to survive pre-emption.”¹⁴⁵ In *Bates*, Dow allegedly recommended the use of its pesticide in all soils even though Dow knew or should have known that the pesticide would stunt the growth of peanuts in soils with pH levels greater than 7.0.¹⁴⁶ Texas peanut farmers brought fraud and failure-to-warn claims against Dow.¹⁴⁷ The farmers’ fraud and failure-to-warn claims were parallel claims because they were premised on violations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) misbranding provisions.¹⁴⁸ The Court held that the common law duties plaintiff sought to impose were equivalent to the FIFRA’s requirements that a pesticide label not contain false or misleading statements or inadequate warnings. Although *Bates* involved FIFRA, the Court found that this “parallel requirements” reading of the statute “finds strong support in *Medtronic v. Lohr*.”¹⁴⁹

Although there is no Supreme Court case establishing the genuine equivalency standard for medical devices, the Seventh Circuit has applied *Bates* to the medical device context, and other circuits have followed suit.¹⁵⁰ In *McMullen*, the Seventh Circuit held that:

[I]n order for a state requirement to be parallel to a federal requirement . . . the plaintiff must show that the requirements are ‘genuinely equivalent.’ State and federal requirements are not

143. *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005).

144. *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 776 (D. Minn. 2009); *Prince*, *supra* note 34, at 1051.

145. 544 U.S. at 453.

146. *Id.* at 434–35.

147. *Id.* at 446.

148. *See id.* at 446–48. FIFRA’s misbranding provisions require that a pesticide label not contain false or misleading statements or inadequate instructions or warning. *Id.* at 447 (citing 7 U.S.C. §§ 136(q)(1)(A); (q)(1)(F)(G)).

149. *Id.* at 432.

150. *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005); *see also* *Wolicki-Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011).

genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.¹⁵¹

In other words, a state requirement is “different from or in addition to” when it is not genuinely equivalent to a federal requirement.¹⁵²

In contrast to *Bates*, the *McMullen* court held that the manufacturer’s alleged violation of a state requirement was *not* genuinely equivalent to the federal requirement allegedly violated.¹⁵³ Jack McMullen had two Medtronic Activa devices implanted in his brain to suppress tremors caused by his Parkinson’s disease.¹⁵⁴ In March 2001, McMullen underwent dental surgery that involved use of diathermy.¹⁵⁵ As a result of the diathermy, McMullen suffered severe brain damage. In January 2001, Medtronic knew of an anecdotal report where the use of diathermy on a person with an implanted Activa allegedly caused brain damage.¹⁵⁶ However, Medtronic did not strengthen its warning until May 2001.¹⁵⁷ McMullen and his wife brought a state law failure-to-warn claim, alleging that Medtronic violated its state and federal duty by failing to strengthen its warning between January and March 2001.¹⁵⁸

The Seventh Circuit held that the McMullens’ state law claim was not genuinely equivalent to any FDCA violation and thus was expressly preempted.¹⁵⁹ Under the FDCA, a manufacturer must obtain FDA approval to change warnings of an approved device but can temporarily amend its warnings pending FDA approval of the proposed changes.¹⁶⁰ The court understood these FDA regulations as allowing but not requiring the manufacturer to change its warnings

151. *McMullen*, 421 F.3d at 489 (citation omitted).

152. When “there are both state and federal requirements to this [same] effect, then the state requirements will not be different from, or in addition to, the federal requirements.” *Id.* at 488.

153. *Id.* at 490.

154. *Id.* at 484.

155. *Id.* at 485.

156. *Id.*

157. *Id.* at 485–86.

158. *Id.* at 486. Plaintiffs argue McMullen violated two federal regulations. “21 C.F.R. § 821.1, which requires manufacturers to track recipients of devices; and § 814.39, which permits manufacturers to enhance warnings pending approval of a proposed change to an earlier-approved warning.” *Id.* at 488–89.

159. *Id.* at 489. “Where a federal requirement permits a course of conduct and the state makes it obligatory, the state’s requirement is in addition to federal requirement and thus is preempted.”

160. *Id.*; see also 21 C.F.R. § 814.39 (2014).

upon learning of adverse events.¹⁶¹ In contrast to the FDCA, the state law duty would *require* the manufacturer to provide an additional warning between January and March 2001.¹⁶² Thus the court held that plaintiff's state law claim was expressly preempted because it was not genuinely equivalent to the FDCA violations alleged.¹⁶³

B. General or Device-Specific Requirement

Once it is established that the manufacturer violated a genuinely equivalent federal requirement, the question then becomes how specific that federal requirement must be. Whether the plaintiff must plead a violation of a generally applicable requirement or whether that federal requirement must be specific to the particular device in question has led to a split amongst the circuits.¹⁶⁴ The Fifth, Sixth, Seventh, and Ninth Circuits have held that a common law claim premised on a generally applicable requirement or industry-wide regulation survives preemption. In contrast, the Eighth and Eleventh Circuits have expressly preempted claims premised on an industry-wide regulation, and have instead demanded that the requirement be specific to the device in question.

Device-specific requirements are requirements set forth in the pre-market approval files.¹⁶⁵ For example, a device-specific requirement could be a manufacturer's representation in its PMA that each hip implant component be sterilized at a temperature of 800 degrees.¹⁶⁶ A federal requirement may also be more general, applying to the medical device industry as a whole. An example of such a generally applicable requirement is the Current Good Manufacturing Practices (CGMPs) set forth in the Quality System Regulation (QSR).¹⁶⁷ The CGMPs "govern the methods used in . . . the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished

161. *McMullen*, 421 F.3d at 489.

162. *Id.* at 490.

163. *Id.* at 489–90.

164. Prince, *supra* note 34, at 1054.

165. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206–07 (8th Cir. 2010).

166. *Bass v. Stryker Corp.*, 669 F.3d 501, 513 (5th Cir. 2012).

167. Prince, *supra* note 34, at 1054–55; *see also Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/qualitysystemsregulations> (last updated June 30, 2014).

devices.”¹⁶⁸ The CGMPs were “established to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls.”¹⁶⁹ Another example of a generally applicable requirement is the Medical Device Reporting requirements (MDRs), which require manufacturers to report to the FDA when they become aware of information that reasonably suggests that their device may have caused serious injuries or malfunctions.¹⁷⁰

How specific the requirement must be to survive preemption is so bound up with issues of pleading that it is hard to separate the two.¹⁷¹ Plaintiffs are now held to a heightened pleading standard due to the Supreme Court decisions of *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal*.¹⁷² Prior to *Twombly* and *Iqbal*, a plaintiff was held to a notice pleading standard, where his claims would not be dismissed under 12(b)(6) unless the plaintiff could “prove no set of facts in support of his claim which would entitle him to relief.”¹⁷³ However, in *Twombly* and *Iqbal*, the Supreme Court re-interpreted the pleading requirements of Rule 8 to require that the claim be “plausible on its face.”¹⁷⁴ These decisions raised the pleading standard from “possible” to “plausible.”¹⁷⁵ Plaintiffs can no longer rely on “labels and conclusions” or “formalistic recitations” to survive a 12(b)(6) motion to dismiss, but, rather, they must plead some facts that support their allegation.¹⁷⁶ Courts have relied on *Twombly* and *Iqbal*, in addition to *Riegel*, to dismiss parallel claims against medical devices.¹⁷⁷

168. 21 C.F.R. § 820.1 (2014); *see also Facts About Current Good Manufacturing Practices (CGMPs)*, *supra* note 91.

169. *Facts About Current Good Manufacturing Practices (CGMPs)*, *supra* note 91.

170. 21 C.F.R. § 803.50(a) (2014).

171. Eggen, *supra* note 69, at 174.

172. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007).

173. *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957), *abrogated by Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).

174. *Iqbal*, 556 U.S. at 663 (discussing Fed. R. Civ. P. 8); *Twombly*, 550 U.S. at 547 (discussing Fed. R. Civ. P. 8).

175. “[S]omething beyond the mere possibility of [a federal violation] must be alleged, lest a plaintiff with a largely groundless claim be allowed to take up the time of a number of other people.” Daniel W. Whitney, *Guide to Preemption of State-Law Claims Against Class III PMA Medical Devices*, 65 FOOD & DRUG L.J. 113, 124 (2010) (citing *Twombly*, 550 U.S. at 557–58).

176. *Iqbal*, 556 U.S. at 662; *Twombly*, 550 U.S. at 545.

177. Whitney, *supra* note 175, at 125.

Courts are divided on how specific a plaintiff must be in pleading claims against a Class III medical device manufacturer. The Eighth and Eleventh Circuits have held that only federal requirements that are specific to the device in question survive dismissal. In *In re Medtronic, Inc., Sprint Fidelis Leads Product Liability Litigation* (*Sprint Fidelis*), plaintiffs in a multidistrict litigation action alleged that leads, small wires connecting implantable cardiac defibrillators, were prone to fracture, causing patients to suffer unnecessary shocks.¹⁷⁸ The FDA ultimately issued a Class I recall of the leads, but at the time of the recall, over 150,000 leads were still implanted in patients.¹⁷⁹ Plaintiffs brought a manufacturing defect claim asserting that the welding technique used to affix the leads violated 21 U.S.C. § 351.¹⁸⁰ Section 351 states that a product is adulterated if not in conformity with the CGMPs.¹⁸¹

The District Court of Minnesota concluded that the “general allegations of failure to comply with the CGMPs . . . do not save these claims from preemption under § 360k because plaintiffs failed to identify any specific requirement in the PMA approval.”¹⁸² Given “[t]he flexibility inherent in the CGMPs and QSR,” plaintiff’s state law claim would impose requirements that are “different from, or in addition to” the CGMPs/QSR.¹⁸³ According to the court, plaintiff “cannot simply incant the magic words ‘[the defendant] violated FDA regulations’ to avoid preemption.”¹⁸⁴

On appeal, the plaintiffs argued that the district court’s application of *Twombly* held them to an impossible pleading standard because specific requirements in PMA approval are not accessible without discovery.¹⁸⁵ The Eighth Circuit rejected plaintiff’s argument and affirmed the district court, holding that the plaintiff “simply failed to

178. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1203 (8th Cir. 2010).

179. There is some dispute as to the number of leads that remain implanted in patients after the recall. Tolley estimates that 150,000 leads remain implanted, whereas the plaintiffs in the *Sprint Fidelis* Litigation allege that 257,000 leads remain implanted. Compare TOLLEY *supra* note 6, at 4, with *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1154 (D. Minn. 2009), *aff’d*, 623 F.3d 1200 (8th Cir. 2010), and Prince, *supra* note 34, at 1055.

180. *Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1206.

181. 21 U.S.C. § 351(h)(1) (2012).

182. *Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1206.

183. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d at 1158, *aff’d*, 623 F.3d 1200 (8th Cir. 2010).

184. *Id.*

185. *Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1206.

adequately plead that Medtronic violated a federal requirement specific to the FDA's PMA approval of this Class III device."¹⁸⁶

The Eleventh Circuit has aligned with the Eighth Circuit's position that the plaintiff must allege a device-specific requirement in the PMA. In *Wolicki-Gables v. Arrow International, Inc.*, an Arrow pump system was implanted into Linda Wolicki-Gables' back to deliver pain medication.¹⁸⁷ The connector of the pump was allegedly defective, resulting in Linda's partial paraplegia.¹⁸⁸ Linda and her husband brought manufacturing defect, design defect, and failure-to-warn claims premised on Arrow's failure to manufacture, design, and provide adequate warnings of the pump system in accordance with FDCA regulations.¹⁸⁹ The plaintiffs further contended that because the manufacturer destroyed the connector, they were entitled to a presumption that the connector was not manufactured in accordance with FDA regulations.¹⁹⁰ The Eleventh Circuit held that "to properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated."¹⁹¹ The court found that the complaint did not "set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged."¹⁹² According to the court, plaintiffs failed to properly allege parallel claims and therefore the claims were preempted.¹⁹³

Some district courts have issued similar rulings to those given by the Eleventh and Eighth Circuits. For instance, the Eastern District of New York took a stance akin to these Circuits in *Horowitz v. Stryker* and *Illaraza v. Medtronic, Inc.* In *Horowitz v. Stryker*, Stryker recalled some of its Trident hip implant systems due to dimensional anomalies of some of its component parts from 2006 to 2007.¹⁹⁴ In 2007, upon inspection of Stryker's manufacturing facilities, the FDA issued two warning letters stating that the Trident System was adulterated within the meaning of 21 U.S.C. § 351 because it

186. *Id.*

187. 634 F.3d 1296, 1297 (11th Cir. 2011).

188. *Id.* at 1298–99.

189. *Id.* at 1300.

190. *Id.*

191. *Id.* (quoting *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008))

192. *Id.* at 1302 (quoting *Illaraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009)).

193. *See id.* at 1303.

194. Plaintiff admitted that neither the Trident System nor the component parts implanted in her were included in any of the recalls. *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 275 (E.D.N.Y. 2009).

failed to comply with the CGMPs.¹⁹⁵ Plaintiff brought a manufacturing defect claim against Stryker premised on violations of the CGMPs.¹⁹⁶ The Eastern District held that “reliance on [defendants’ violations of] CGMPs and QSR . . . does not save these claims from preemption . . . [as such requirements] are simply too generic, standing alone, to serve as the basis for [her] manufacturing-defect claim[].”¹⁹⁷ In *Illaraza v. Medtronic, Inc.*, the plaintiff brought a manufacturing defect claim against Medtronic alleging that Medtronic’s pump and catheter, which fractured inside the plaintiff, violated the GGMPs.¹⁹⁸ The Eastern District held that CGMPs were left “intentionally vague and open-ended” so that the manufacturer can tailor the regulations to the safety and efficacy needs of their particular device.¹⁹⁹ Therefore:

[s]ince these regulations are open to a particular manufacturer’s interpretation, allowing them to serve as a basis for a claim would lead to differing safety requirements that might emanate from various lawsuits. This would necessarily result in the imposition of standards that are “different from, or in addition to” those imposed by the MDA—precisely the result that the MDA preemption provision seeks to prevent.²⁰⁰

The court in *Illaraza* similarly found plaintiff’s claims failed to withstand the pleading requirements of *Twombly* because plaintiff had “done nothing more tha[n] recite unsupported violations of

195. *Id.* at 276. The FDA defines a warning letter as:

[A] correspondence that notifies regulated industry about violations that FDA has documented during its inspections or investigations. Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act), its implementing regulations and other federal statutes. Warning Letters should only be issued for violations of regulatory significance, i.e., those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected. A Warning Letter is one of the Agency’s principal means of achieving prompt voluntary compliance with the Act.

U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL, EXHIBIT 4-1: PROCEDURES FOR CLEARING FDA WARNING LETTERS AND UNTITLED LETTERS (2012), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM176965.pdf>.

196. *Horowitz*, 613 F. Supp. 2d at 276.

197. *Id.* at 284 (citing *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1151 (D. Minn. 2009), *aff’d*, 623 F.3d 1200 (8th Cir. 2010)).

198. *See* 677 F. Supp. 2d 582, 583 (E.D.N.Y. 2009).

199. *See id.* at 588.

200. *Id.*

general regulations, and fail[ed] to tie such allegations to the injuries alleged.”²⁰¹

In all of the above-mentioned cases, the circuits or district courts seemed to take the view that plaintiff’s parallel claim must allege a violation of a specific requirement in the PMA to withstand *Riegel* and *Twombly*. The Fifth, Sixth, Seventh, and Ninth Circuits, however, have held that the plaintiff need not allege a device-specific requirement.²⁰² In the opinions of those Circuits, alleging that the manufacturer violated a generally applicable federal requirement is adequate at the pleading stage.²⁰³

In *Bausch v. Stryker Corp.*, the Seventh Circuit was faced with parallel claims against the same implant system as in *Horowitz*, and yet it held that the claims survived dismissal. Stryker’s Trident hip implant system was implanted in plaintiff’s body six days after the FDA issued a warning letter to Stryker stating that a component in the system was adulterated.²⁰⁴ Plaintiff alleged that the “Trident Acetabular Hip Systems were adulterated due to manufacturing methods that were not in conformity with industry and regulatory standards.”²⁰⁵ Stryker argued that plaintiff must allege a violation of a concrete, device-specific regulation, and thus plaintiff’s claims, premised on violations of the QSR and CGMPs, were too general to allow juries to enforce them.²⁰⁶ The Seventh Circuit said “we do not see a sound legal basis for defendants’ proposal to distinguish between general requirements and ‘concrete, device-specific’ requirements.”²⁰⁷ The court gave several reasons to support this conclusion. First, the distinction between general and specific requirements has no basis in the preemption provision of § 360(k).²⁰⁸ Second, it is difficult for a plaintiff to plead a device-specific requirement because most of the PMA specifications are not accessible without discovery.²⁰⁹ Third, a general/specific distinction

201. *Id.*

202. *See, e.g.*, Prince, *supra* note 34, at 1060.

203. *See id.* at 1060.

204. *Bausch v. Stryker Corp.*, 630 F.3d 546, 549 (7th Cir. 2010).

205. *Bausch v. Stryker Corp.*, No. 108CV04248, 2008 WL 4227478 (N.D. Ill. July 25, 2008).

206. *Bausch*, 630 F.3d at 554.

207. *Id.* at 555.

208. *Id.* at 556.

209. For plaintiff to plead a specific defect in the Trident that violated the FDA, “she would need access to the confidential materials in the premarket approval application setting forth the medical device’s specifications. This is *simply not possible without discovery.*” *Id.* at 560 (emphasis added); *see also* Ashley Abraham Williams, *Surviving Medical Device Preemption Under 21 U.S.C. 360k: Clarifying*

would “leave injured patients without any remedy for a wide range of harmful violations of federal law.”²¹⁰ Hence, the *Bausch* court, inapposite to the *Horowitz* court, found that a plaintiff’s claim should not be dismissed solely because it was based on a generally applicable requirement like the CGMPs.²¹¹

The Sixth Circuit in *Howard v. Sulzer Orthopedics Inc.* also held that a violation of a CGMP should withstand dismissal.²¹² In *Howard*, Sulzer allegedly used a manufacturing process that left lubricating machine oil on its knee implants, and as a result thousands of patients’ implants failed to bond with the bone.²¹³ Sulzer discovered the problem and voluntarily recalled 40,000 implants.²¹⁴ In a multi-district litigation proceeding, plaintiffs asserted a negligence per se theory under Ohio law.²¹⁵ The *Howard* court, contrary to the holding in *Sprint Fidelis*, where plaintiff did not identify a specific CGMP that was violated, cited a particular CGMP that “is not so vague as to be incapable of enforcement.”²¹⁶ In particular, the CGMP provided that “where manufacturing material is reasonably expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures . . . to ensure that it is removed or limited to an amount that does not adversely affect the device’s quality.”²¹⁷ The violation of this CGMP, which can be read as requiring Sulzer to remove the oil that the manufacturing process left behind, was sufficient to survive preemption.²¹⁸

Similarly, in *Hughes v. Boston Scientific Corp.*, the Fifth Circuit held that violations of the MDR, an industry-wide regulation like the CGMPs, withstood dismissal.²¹⁹ In *Hughes*, Boston Scientific manufactured a device that treated excess uterine bleeding by circulating hot saline solution into the uterus.²²⁰ Hot liquid leaked from plaintiff’s device, allegedly causing the plaintiff to suffer a

Pleading Standards for Parallel Claims in the Wake of Twombly and Iqbal, 9 SETON HALL CIRCUIT REV. 109, 121 (2013).

210. *Bausch*, 630 F.3d at 555.

211. *Id.*

212. 382 F. App’x 436, 440 (6th Cir. 2010).

213. *Id.* at 438.

214. *Id.*

215. *Id.*

216. *Id.*

217. *Id.*; see also 21 C.F.R. § 820.70(h) (2014).

218. *Howard*, 382 F. App’x at 440.

219. 631 F.3d 762, 769 (5th Cir. 2011).

220. *Id.* at 764.

second-degree burn.²²¹ Boston Scientific developed an algorithm for reporting burn injuries, where first-degree burns were never reported to the FDA and some, but not all, second-degree burns were reported.²²² Upon learning of these reporting practices, the FDA sent a warning letter to Boston Scientific to abandon the algorithm and begin reporting more burns.²²³ The plaintiff alleged that Boston Scientific, by failing to report these burns, violated the MDR, which requires manufacturers to report serious injuries and malfunctions to the FDA.²²⁴ The Fifth Circuit denied Boston Scientific's motion for summary judgment, holding that the plaintiff's state-law failure-to-warn claim premised on MDR violations was not preempted.²²⁵ The court stated "[a] factfinder could infer that a manufacturer's failure to provide this information as required by FDA regulations is a parallel violation of the state duty to provide reasonable and adequate information about a device's risks."²²⁶

About a year later, in *Bass v. Stryker Corp.*, the Fifth Circuit adhered to its decision in *Hughes* and held plaintiff's allegation of a generally applicable requirement avoids preemption.²²⁷ *Bass* involved claims alleging that Stryker's Trident system was adulterated in violation of the CGMPs.²²⁸ Specifically, the plaintiff alleged that excessive manufacturing residuals in the Shell component prevented bony ingrowth, which resulted in a loose shell, thereby causing pain in the plaintiff's hip.²²⁹ The Court held that:

[T]he key distinction between complaints that withstand a motion to dismiss and those that do not is not reliance on the CGMPs but rather . . . a manufacturing defect caused by a violation of federal regulations *and* allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury.²³⁰

The court in *Bass* found that plaintiff's claim pleaded sufficient facts including: warning letters issued by the FDA, a voluntary recall by Stryker, and an injury consistent with excessive residuals. Therefore the court held that the complaint met *Twombly's*

221. *Id.* at 765.

222. *Id.* at 766.

223. *Id.* at 767.

224. *See id.* at 766; *see also* 21 U.S.C. § 360i(a)(1) (2012); 21 C.F.R. § 803.50(a) (2014).

225. *See Hughes*, 631 F.3d at 769.

226. *Id.* at 771.

227. *See* 669 F.3d 501, 515 (5th Cir. 2012)

228. *See id.* at 510.

229. *See id.*

230. *Id.* at 511–12.

plausibility standard because it “specifie[d] with particularity what went wrong in the manufacturing process and cite[d] the relevant FDA manufacturing standards Stryker allegedly violated.”²³¹ The *Bass* court rejected Stryker’s argument that plaintiff’s claim should be expressly preempted because it was too vague to be enforced by a jury. The court reasoned that by the time the case was tried, the jury would have before it the PMA application that was approved by the FDA.²³²

The Ninth Circuit has taken the Fifth Circuit’s position that a violation of the generally applicable MDRs survives dismissal. In *Stengel v. Medtronic Inc.*, for instance, the Ninth Circuit held that the plaintiff’s claim alleging that Medtronic failed to report adverse events in violation of the MDR survives dismissal.²³³ In *Coleman v. Medtronic Inc.*, the California Court of Appeals followed the analysis of *Stengel*.²³⁴

In *Coleman*, plaintiff suffered painful complications after posterior lumbar interbody fusion surgery, a form of spinal surgery, allegedly because Infuse, a device designed to strengthen the spine of individuals with degenerated vertebral discs, was used during the procedure.²³⁵ The FDA had only approved Infuse for anterior fusion surgery, and thus using Infuse during posterior fusion surgery was considered an off-label use.²³⁶ The plaintiff brought a failure-to-warn claim based on Medtronic’s failure to report adverse events associated with Infuse in posterior fusion surgery.²³⁷ Medtronic reported to the FDA that there were no adverse events, but according to the plaintiff there were adverse events in twenty to seventy percent of posterior fusion cases where Infuse was employed.²³⁸ The court held that the plaintiff’s failure-to-warn claim, which relied upon industry-wide violations of the MDR, withstood dismissal.²³⁹ The plaintiff also asserted a manufacturing defect claim alleging that the

231. *Id.* at 510.

232. *Id.* at 512.

233. 704 F.3d 1224, 1233 (9th Cir. 2013).

234. 223 Cal. App. 4th 413 (Cal. Ct. App. 2014).

235. 167 Cal. Rptr. 3d 300, 304 (Cal. Ct. App. 2014), *review granted and opinion superseded sub nom.* *Coleman v. Medtronics*, 323 P.3d 1 (Cal. 2014).

236. Anterior Lumbar Interbody Fusion (Anterior Fusion), is a spinal fusion surgery where a surgical incision is made in the patient’s abdomen, compared to Posterior Lumbar Interbody Fusion (Posterior Fusion), where the incision is made in the patient’s back. *Id.* at 304–06.

237. *Id.* at 314.

238. *Id.* at 305.

239. *Id.* at 311.

plaintiff's Infuse device was defective because it failed to comply with the CGMPs.²⁴⁰ The California Court of Appeals held that pleading a violation of CGMP is sufficient to withstand dismissal because alleging a specific PMA requirement is not possible without discovery.²⁴¹

1. *Scope of Implied Preemption*

Not only do lower courts disagree about the scope of express preemption, but they also disagree about the scope of implied preemption. The Supreme Court in *Buckman* drew a distinction between the case at bar, where plaintiff's claims were impliedly preempted, and *Lohr*, where the plaintiff's claims were not.²⁴² In *Lohr*, the plaintiffs' claims survived preemption because they were based on traditional state law theories of negligence.²⁴³ By contrast, in *Buckman*, the plaintiffs' "fraud claims exist[ed] solely by virtue of the FDCA disclosure requirements."²⁴⁴ It is clear from *Buckman* that not all claims avoid implied preemption.²⁴⁵ What is less clear after *Buckman* is exactly which claims, other than fraud-on-the-FDA claims, if any, are impliedly preempted. The Sixth and Eighth Circuits have adopted an expansive view of *Buckman* to impliedly preempt traditional state law tort claims premised on FDA violations. By contrast, the Fifth, Seventh, and Ninth Circuits have limited *Buckman's* scope to fraud-on-the-FDA claims, thereby allowing traditional state law tort claims premised on FDA violations to avoid implied preemption.

In *Sprint Fidelis*, the Eighth Circuit held that the plaintiff's failure-to-warn claim, alleging that Medtronic did not accurately and timely submit adverse event reports in violation of the MDR, was impliedly preempted.²⁴⁶ The Court construed *Buckman* to require that "plaintiff must not be suing *because* the conduct violates the

240. *Id.* at 316.

241. *Id.* at 317.

242. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001).

243. *Medtronic, Inc. v. Lohrs*, 518 U.S. 470, 500–02 (2010); *See also Buckman*, 531 U.S. 352–53.

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

245. *Id.* ("Although Medtronic can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.")

246. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010).

FDCA.”²⁴⁷ The Court found that the claim that Medtronic did not provide the FDA with sufficient information is “simply an attempt by private parties to enforce the MDA claims foreclosed by § 337(a) as construed in *Buckman*.”²⁴⁸

The Sixth Circuit reached a similar conclusion in *Cupek v. Medtronic, Inc.*, when it impliedly preempted plaintiff’s negligence per se claim.²⁴⁹ In a negligence per se claim, the plaintiff relies on a violation of a statute or regulation to establish duty and breach in negligence.²⁵⁰ In *Cupek*, a pre-*Riegel* case, plaintiffs alleged a negligence per se claim against Medtronic’s pacemaker leads based on Medtronic’s failure to comply with the FDA’s conditions of approval.²⁵¹ The Sixth Circuit held that plaintiff’s claim was a “disguised fraud on the FDA claim” and therefore was impliedly preempted.²⁵²

Like the Sixth and Eighth Circuits, various district courts have expanded *Buckman* beyond fraud-on-the-FDA to impliedly preempt traditional state law tort claims. In *Lewkut v. Stryker Corp.*, the Southern District of Texas applied *Buckman* expansively to preempt Lewkut’s manufacturing defect claims.²⁵³ Lewkut alleged that Stryker’s hip implant system was adulterated in violation of 21 U.S.C. § 351(h) of the FDCA.²⁵⁴ To the extent that Lewkut alleged a parallel claim, the district court held that claim to be impliedly preempted because 21 U.S.C. § 337 “explicitly precludes private enforcement of federal laws regarding ‘adulterated’ devices.”²⁵⁵

Similarly, in *Wheeler v. DePuy Spine, Inc.*, the Southern District of Florida held that plaintiff’s negligence claim premised on violations of the FDCA was impliedly preempted.²⁵⁶ In *Wheeler*, the plaintiff suffered severe leg and back pain allegedly due to two implanted artificial discs.²⁵⁷ Plaintiff argued that DePuy violated the MDR by not accurately disclosing the number and extent of disc complications

247. *Id.* at 1204 (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

248. *Id.* at 1205.

249. 405 F.3d 421, 424 (6th Cir. 2005).

250. Eggen, *supra* note 69, at 189 (citing DAN B. DOBBS, THE LAW OF TORTS § 134, at 315 (2000)).

251. *Cupek*, 405 F.3d at 421.

252. *Id.* at 424.

253. 724 F. Supp. 2d 648, 660 (S.D. Tex. 2010).

254. *Id.* at 658; *see also* 21 U.S.C. § 351(h) (2012).

255. *Lewkut*, 724 F. Supp. 2d at 660.

256. 706 F. Supp. 2d 1264, 1270 (S.D. Fla. 2010).

257. *Id.* at 1266.

to the FDA.²⁵⁸ The court held that “[a]lthough Plaintiff states that he is not bringing a fraud-on-the-FDA claim, the claim described by Plaintiff appears to be such a claim, and as such it should be addressed to the FDA.”²⁵⁹ As in *Sprint Fidelis* and *Cupek*, although the plaintiffs in *Lewkut* and *Wheeler* asserted traditional state law causes of action, both courts saw these claims as disguised fraud-on-the-FDA claims.

As in *Wheeler* and *DePuy*, in *McClelland v. Medtronic, Inc.* the district court for the Middle District of Florida impliedly preempted the plaintiff’s traditional state law tort claim.²⁶⁰ In *McClelland*, Breanne McClelland allegedly died from a defect in Medtronic’s EnPulse Model E1DR21 pacemaker.²⁶¹ The plaintiff, decedent’s mother, alleged that prior to decedent’s death, Medtronic became aware that some of its pacemakers, including the E1DR21, were defective. Specifically, Medtronic knew that the E1DR21 was likely to “cause intense cardiac symptoms and fail[ure] to properly regulate cardiac rhythm.”²⁶² The plaintiff brought negligence per se and failure-to-warn claims premised on Medtronic’s failure to accurately and timely report E1DR21 incidents in violation of the FDCA. The district court stated:

[T]he [MDA] provides that all actions to enforce the FDA requirements “shall be by and in the name of the United States[.]” . . . In *Buckman*, the United States Supreme Court construed § 337(a) as impliedly preempting suits by private litigants “for noncompliance with the medical device provisions.” In other words, claims based upon FDCA disclosure requirements, rather than traditional state tort law are impliedly preempted.²⁶³

The *McClelland* court seemed to interpret *Buckman* very liberally to impliedly preempt all common law claims that are based on FDCA disclosure requirements.²⁶⁴ Accordingly, both *McClelland*’s negligence per se and failure-to-warn claims were impliedly preempted.

The Middle District of Florida explained that *McClelland*’s failure-to-warn claim was impliedly preempted because it was not based on

258. *Id.* at 1269–70; *see also* 21 C.F.R. § 814.3(1) (2014).

259. *Wheeler*, 706 F. Supp. 2d at 1270 n.4.

260. *McClelland v. Medtronic, Inc.*, No. 6:11-CV-1444-ORL-36KRS, 2012 WL 5077401, at *7 (M.D. Fla. Sept. 27, 2012).

261. After *McClelland*’s death, Medtronic issued a Class II Recall of many pacemakers including the E1DR21. *Id.* at *1.

262. *Id.*

263. *Id.* at *7 (internal citations omitted).

264. *See id.* at *5; *see also* Eggen, *supra* note 69, at 201.

common law, but rather based on Defendant's duty to warn pursuant to the FDCA and FDA regulations.²⁶⁵ The court did note that the plaintiff could have avoided implied preemption if she alleged that Medtronic breached a duty to the decedent instead of to the FDA.²⁶⁶ However, such an allegation would nonetheless be fatal because it would support express preemption.²⁶⁷ According to the court, a failure-to-warn claim premised on a manufacturer's duty to warn the patient or the patient's physician would be expressly preempted because such a duty is not "genuinely equivalent" to any FDA requirement.²⁶⁸ FDA regulations do not require manufacturers to warn individual doctors about the safety and effectiveness of a device.²⁶⁹ Thus, plaintiff's claim "would hold [the defendant] liable under state law without having violated an equivalent federal law" and therefore would be expressly preempted, even if not impliedly preempted.²⁷⁰

Another context in which district courts have expanded *Buckman* involves claims based on an off-label promotion theory. In *Riley v. Cordis Corp.*, the District Court of Minnesota concluded that plaintiff's failure-to-warn claim was impliedly preempted to the extent that it was based on an off-label promotion theory.²⁷¹ In *Riley*, Cordis manufactured a Cypher stent, a drug-coated stent that is implanted in a coronary artery to open up the artery and improve blood flow.²⁷² The plaintiff suffered a blood clot when the Cypher stent was implanted through direct stenting.²⁷³ Direct stenting occurs when the stent is implanted in an artery that has not previously been predilated with a balloon catheter.²⁷⁴ Since the FDA did not approve direct stenting of the Cypher stent, it constituted an off-label use.²⁷⁵ Plaintiff alleged that Cordis promoted the off-label use in a manner

265. *McClelland*, 2012 WL 5077401, at *5.

266. *Id.* at *7.

267. "To the extent Plaintiff's Amended Complaint is construed as alleging the breach of a duty to the Decedent and not the breach of a duty to the FDA, the principles outlined in *Buckman* are not implicated in this case. Though this fact is ultimately fatal to Plaintiff's claim, as it supports express preemption, it nonetheless falls outside of the realm of implied preemption." *Id.* at *7.

268. *Id.* at *6 *see also infra* Part II.A.

269. *McClelland*, 2012 WL 5077401, at *6.

270. *Id.*

271. 625 F. Supp. 2d 769, 783 (D. Minn. 2009).

272. *Id.* at 774.

273. *Id.* at 775.

274. *Id.*

275. An "off-label" use is when a device is used for some other purpose than that which the FDA approved. *Id.* at 778.

that was not authorized by the FDCA.²⁷⁶ The court held the claim to be “impliedly preempted” under *Buckman*, because “promoting the off-label use of an FDA-approved medical device is not unlawful under ‘traditional state tort law which had predated the federal enactments in question[.]’”²⁷⁷

However, the *Riley* court did recognize that the plaintiff could have avoided implied preemption if Cordis (1) promoted the off-label use in a manner unauthorized by the FDCA, and (2) failed to include adequate warnings about the off-label use it was promoting.²⁷⁸ The first allegation would protect the claim from express preemption since it is premised on a violation of the FDCA.²⁷⁹ The second allegation would protect the claim from implied preemption because a duty to warn physicians or patients when an injury is reasonably foreseeable rests on traditional state law.²⁸⁰

Although the court granted leave to amend, it would be quite difficult for the plaintiff in *Riley* to prevail on this narrow theory.²⁸¹ The plaintiff’s claim would be expressly preempted if it solely alleged that manufacturer’s off-label promotion triggered a duty to warn about the off-label use. As the court explained, under the FDCA a “manufacturer could disseminate information about an off-label use of a device without triggering the duty to provide instructions or warnings about that off-label use.”²⁸² Therefore, the only way for plaintiff to prevail on this theory would be if the manufacturer changed the label while promoting off-label use.²⁸³ However, since there are strict limitations on a manufacturer’s ability to change its label post-approval, it likely will be difficult for plaintiff to amend the complaint and survive preemption.²⁸⁴

In *Caplinger v. Medtronic, Inc.*, the court also held plaintiff’s off-label promotion theory to be impliedly preempted.²⁸⁵ In *Caplinger*, the plaintiff suffered an injury after Medtronic’s Infuse device was

276. *Id.* at 783.

277. *Id.* (quoting *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353 (2001)).

278. *Id.* at 784.

279. *Id.*

280. *Id.*

281. *Id.* at 785; Eggen, *supra* note 69, at 188.

282. *Riley*, 625 F. Supp. 2d at 782 (citing 21 U.S.C. § 360aaa–6(b) (2006)).

283. *See id.*

284. *See* 21 U.S.C. § 360e(d)(6)(A)(i) (2012); 21 C.F.R. § 814.39(a) (2014); *Riley*, 625 F. Supp. 2d at 782 (citing 21 U.S.C. § 360aaa–6(b)); *see also* Eggen, *supra* note 69, at 188.

285. *See* 921 F. Supp. 2d 1206, 1219–20, 1224 (W.D. Okla. 2013).

used for posterior-approach lumbar spine fusion surgery to correct a degenerative disc condition.²⁸⁶ The use of Infuse during posterior fusion surgery was off-label because the FDA approved Infuse for anterior but not posterior surgery. The plaintiff brought a fraudulent misrepresentation claim and a negligence claim based on the theory that Medtronic promoted the off-label use of Infuse in posterior fusion surgery while downplaying its risks.²⁸⁷ The court held that both of these claims were impliedly preempted because promotion of off-label use is governed by the FDCA.²⁸⁸ The court concluded that “‘off-label use’ is a creature of the FDCA” and “is not a part of Oklahoma substantive law While plaintiff couches her claim as a state law negligence claim, this claim is, in substance, a claim for violating the FDCA and, thus, is clearly preempted under *Buckman* and § 337(a).”²⁸⁹

While these courts have interpreted *Buckman* broadly, other courts have limited *Buckman* to only fraud-on-the-FDA claims.²⁹⁰ The Fifth Circuit in *Hughes* held that the plaintiff’s failure-to-warn claim was not impliedly preempted.²⁹¹ As mentioned previously, *Hughes* involved Boston Scientific’s alleged failure to report serious burns associated with its uterine device in violation of the MDR requirement to report “serious injuries” and “malfunctions.”²⁹² The court held that the plaintiff’s claim is not analogous to *Buckman*, where “plaintiff did not assert a violation of a state tort duty,” because here, “Hughes is asserting a Mississippi tort claim based on the underlying state duty to warn about the dangers or risks of product [H]er claim is comparable to the tort claims in *Silkwood* and *Lohr* that *Buckman* recognized as surviving implied preemption.”²⁹³

The Seventh Circuit in *Bausch v. Stryker Corp.* reached a similar result as the Fifth Circuit. In *Bausch*, the Seventh Circuit held that

286. *Id.* at 1209.

287. *Id.* at 1221.

288. “To determine whether said conduct is improper would require reliance on the requirements of the FDCA. Further, even the concept of ‘off-label use’ is a creature of the FDCA, is defined by the FDCA, and is not a part of Oklahoma substantive law. While plaintiff couches her claim as a state law negligence claim, this claim is, in substance, a claim for violating the FDCA and, thus, is clearly preempted under *Buckman* and § 337(a).” *Id.* at 1219–20, 1224.

289. *Id.*

290. *See Prince, supra* note 34, at 1075.

291. *Hughes v. Bos. Scientific Corp.*, 631 F.3d 762, 776 (5th Cir. 2011); *see also* 21 U.S.C. § 360i(a)(1) (2012); 21 C.F.R. § 803.50(a) (2014).

292. *See supra* notes 219–26 and accompanying text.

293. *Hughes*, 631 F.3d at 775.

plaintiff's manufacturing defect claim, alleging that Stryker's hip implant system was adulterated in violation of the CGMPs, was not impliedly preempted.²⁹⁴ The Seventh Circuit rejected Stryker's argument that there is "no state tort duty to manufacture a product that is not adulterated."²⁹⁵ The court stated that "[w]hile there may not be a 'traditional state law' claim for an 'adulterated' product . . . the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers."²⁹⁶ This stands in direct contrast to *Lewkut*, where the court held that virtually the same claim was impliedly preempted.²⁹⁷

Like the Fifth and Seventh Circuits, the Ninth Circuit in *Stengel* has refused to extend *Buckman* to impliedly preempt traditional state law tort claims.²⁹⁸ After a catheter manufactured by Medtronic was implanted into Richard Stengel's abdomen, a granuloma formed at the catheter tip, rendering Stengel permanently paraplegic in 2005.²⁹⁹ The Stengels alleged that if Medtronic warned physicians that the catheter could cause a granuloma prior to Stengel's injury, Stengel's symptoms would have been diagnosed sooner, which in turn would have prevented his paralysis.³⁰⁰

The Stengels' failure-to-warn claim was premised on the theory that Medtronic breached its post-sale duty to report adverse events to the FDA.³⁰¹ The Stengels allege that Medtronic knew that a granuloma could form at the catheter tip prior to Stengel's injury, but failed to report that information to the FDA.³⁰² Particularly, according to the Stengels, FDA inspections in 2006 and 2007 revealed that Medtronic knew about the risks of a granuloma forming at the catheter tip.³⁰³ After the inspection, the FDA sent a warning letter to

294. See 630 F.3d 546, 558 (7th Cir. 2010).

295. *Id.* at 557.

296. *Id.*

297. Compare *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 660 (S.D. Tex. 2010) (holding that plaintiff's manufacturing defect claim alleging that the Trident hip implant system was adulterated in violation of the CGMPs was impliedly preempted), with *Bausch v. Stryker Corp.*, 630 F.3d 546, 556–57 (7th Cir. 2010) (holding that plaintiff's manufacturing defect claim alleging that the Trident hip implant system was adulterated in violation of the CGMPs was not impliedly preempted).

298. *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013).

299. *Id.* at 1227.

300. See Respondents' Brief in Opposition, *supra* note 33, at 6.

301. *Stengel*, 704 F.3d at 1232.

302. *Id.*

303. *Id.* at 1227.

Medtronic stating that Medtronic “misbranded” its device in violation of FDCA regulations.³⁰⁴

Before the en banc rehearing, the Ninth Circuit held that the Stengels’ failure-to-warn claim was impliedly preempted by *Buckman*.³⁰⁵ However, en banc, the full court reversed.³⁰⁶ The Ninth Circuit held that the plaintiffs’ failure to warn the FDA claim rested on traditional state law because “Arizona law contemplates a warning to a third party such as the FDA.”³⁰⁷ Under Arizona law, a manufacturer’s duty to a third party is satisfied if “there is ‘reasonable assurance that the information will reach those whose safety depends on their having it.’”³⁰⁸ In his concurrence, Judge Watford echoed the majority but put more of an emphasis on public policy objectives.³⁰⁹ Watford argued that “there is no question that state law has an important and legitimate role to play in regulating the adequacy of post-sale warnings for products already on the market.”³¹⁰

The California Court of Appeals affirmed *Stengel* in a recent case even though *Stengel* was not binding on the court.³¹¹ In *Coleman v. Medtronic, Inc.*, Medtronic allegedly failed to report adverse events associated with the off-label use of Infuse in posterior fusion surgery.³¹² Medtronic argued that plaintiff’s claim should be impliedly preempted because there is no duty to warn the FDA under state law, only a duty to warn physicians who then warn patients.³¹³ The court rejected Medtronic’s argument because a duty to warn the FDA is contemplated by California’s duty to “warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the

304. *Id.*

305. *Stengel v. Medtronic, Inc.*, 676 F.3d 1159, 1164 (9th Cir. 2012), *reh’g en banc granted*, 686 F.3d 1121 (9th Cir. 2012), *and rev’d on reh’g en banc*, 704 F.3d 1224 (9th Cir. 2013).

306. *Stengel*, 704 F.3d at 1234.

307. *Id.* at 1233.

308. *Id.* (quoting *Wilson v. U.S. Elevator Corp.*, 193 Ariz. 251, 972 P.2d 235, 237 (Ariz. Ct. App. 1998)).

309. *Stengel*, 704 F.3d at 1235 (Watford, J., concurring); *see also* Eggen, *supra* note 69, at 200.

310. *Stengel*, 704 F.3d at 1235 (Watford, J., concurring).

311. *Coleman v. Medtronic, Inc.*, 167 Cal. Rptr. 3d 300, 311 (Cal. Ct. App. 2014) (“We recognize, of course, that *Stengel III* is not binding on this court but it is persuasive authority that we elect to follow.”).

312. *Id.* at 314.

313. *Id.* at 312.

time of manufacture and distribution.”³¹⁴ The court further reasoned the “duty to warn should not be so narrowly defined as to exclude a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers.”³¹⁵ Hence, the court concluded that plaintiff’s failure-to-warn claim premised on violations of the MDR is not impliedly preempted.

The court similarly held that the plaintiff’s negligence per se claim, premised on Medtronic’s failure to report adverse events, was not impliedly preempted.³¹⁶ The court held that in actions involving negligence per se, the federal requirement is only used to establish the standard of care; the state law claim as a whole still very much relies on traditional state law.³¹⁷ The court stated “Coleman uses the negligence per se doctrine, well recognized in California tort law, to ensure that the state law duty he alleges directly parallels federal law; however, he is pursuing a remedy under state law, not federal law.”³¹⁸

Lastly, the Coleman court held that plaintiff’s alternative negligence per se theory, that Medtronic promoted the off-label use of posterior surgery in a manner unauthorized by the FDCA, was also not impliedly preempted.³¹⁹ The court held that plaintiff’s off-label promotion theory “is rooted in traditional state tort law and exists regardless of the FDCA and its regulations because the manufacturer of a medical device owes a duty of reasonable care to the consumer of such a device even in the absence of FDA regulations.”³²⁰

III. ARGUMENTS IN *STENDEL V. MEDTRONIC, INC.*

After the Ninth Circuit in *Stengel v. Medtronic, Inc.* ruled that plaintiffs’ failure-to-warn claim was not preempted either expressly or impliedly, Medtronic filed a petition for certiorari.³²¹ In its petition, Medtronic made two arguments as to why the Ninth Circuit’s decision should be reversed. First, it argued that the Stengels’ failure-to-warn claim should be expressly preempted because they have not alleged a federal requirement specific to the device in question.³²² Second, it

314. *Id.* at 311 (quoting *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 1002 (1991)).

315. *Id.* at 312.

316. *Id.* at 315.

317. *See id.* at 316.

318. *Id.*

319. *Id.* at 316.

320. *Id.*

321. *See generally* Petition for a Writ of Certiorari, *supra* note 22, at 8–9.

322. *See id.* at 18.

asserted that the Stengels' failure-to-warn claim should be impliedly preempted because it is not independent of the MDA requirements.³²³ In its brief in opposition, the Stengels argued that a state law claim premised on a generally applicable requirement such as the MDR should survive both express and implied preemption.³²⁴ The United States filed an amicus curiae brief that is generally in accord with the Stengels' position.³²⁵

Although the Supreme Court ultimately denied Medtronic's petition for certiorari,³²⁶ the arguments expressed in the *Stengel* briefs are well-crafted and will likely be used by plaintiffs and defendants in future cases. This is especially true now that the Supreme Court has allowed the circuit split on the contours of the parallel claim exception to continue. Further, this Note argues that the Supreme Court should bridge the divide amongst the circuits in a subsequent case, and predicts that the arguments that the Supreme Court will be presented with will be similar to the arguments made in *Stengel*.

A. The General/Device-Specific Argument in *Stengel*

1. *The Argument for a Circuit Split*

The Stengels' failure-to-warn claim relies on a violation of a generally applicable or industry-wide violation of the FDA's MDRs. Specifically, the claim relies on 21 U.S.C. § 360i(a) and 21 C.F.R. § 803.50(a), which require a manufacturer to report information that reasonably suggests that the device "may have caused or contributed to a death or serious injury."³²⁷ In its petition for certiorari, Medtronic argues that there is a circuit split on whether such a generally applicable requirement like the MDR survives express preemption.³²⁸ According to Medtronic, the Eighth and Eleventh Circuits have held that only claims premised on a violation of a device-specific requirement survive preemption.³²⁹ By contrast, the Fifth, Sixth, and Seventh Circuits have allowed generally applicable requirements to survive preemption.³³⁰

323. *Id.* at 22.

324. Respondents' Brief in Opposition, *supra* note 33, at 13, 18.

325. Brief for the United States as Amicus Curiae, *supra* note 4, at 13–14, 21–22.

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

327. 21 U.S.C. § 360i(a) (2012); 21 C.F.R. § 803.50(a) (2014); *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1226–27 (9th Cir. 2013).

328. Petition for a Writ of Certiorari, *supra* note 22, at 19.

329. *Id.*

330. *Id.*

2. *The Argument Against a Circuit Split*

The Stengels denied the existence of a circuit split. The Stengels argued that the Fifth, Sixth, and Seventh Circuits have held that a violation of a generally applicable requirement survives express preemption. However, according to the Stengels, the Eighth and Eleventh Circuits are consistent with the Fifth, Sixth, and Seventh Circuit opinions. The Stengels contended that in the Eighth and Eleventh Circuit opinions, *Sprint Fidelis* and *Wolicki-Gables*, the plaintiffs “failed to tie their particular claims to the violation of any [particular] federal requirement, either general or device-specific.”³³¹ Therefore, no circuit court opinion stands for the proposition that plaintiff must plead a device-specific federal requirement.³³²

The United States as amicus curiae agreed with the Stengels’ proposition that the circuits do not diverge on whether a requirement be general or device-specific.³³³ The United States contended that “[m]ost courts . . . have held that a state requirement is saved from express preemption if it parallels a federal requirement of any kind, be it device-specific or general.”³³⁴ According to the United States, although some courts have preempted claims premised on a generally applicable requirement, “the cases provide no explanation as to why that would be so, and they appear ultimately to rest on deficiencies in the plaintiff’s pleadings.”³³⁵

3. *The Argument for the General/Specific Distinction*

After Medtronic made the argument for a circuit split, it urged that a claim premised on a generally applicable federal requirement is expressly preempted because the federal requirement must be specific to the device in question.³³⁶ Medtronic relied on *Lohr* in support of its proposition—“this Court held in *Lohr* that generalized federal duties that apply to all medical devices are not federal ‘requirements’ within the meaning of § 360k(a).”³³⁷ According to Medtronic, the MDR is too generalized to be a federal requirement under § 360k because it applies to all medical devices.³³⁸ To fall

331. Respondents’ Brief in Opposition, *supra* note 33, at 10.

332. *Id.*

333. Brief for the United States as Amicus Curiae, *supra* note 4, at 16.

334. *Id.* at 17.

335. *Id.*

336. Petition for a Writ of Certiorari, *supra* note 22, at 30–32.

337. *Id.* at 31 (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501(1996)).

338. *Id.*

within the parallel claim exception, the violation of a federal requirement must run parallel to a violation of state law duty.³³⁹ Hence, under Medtronic's logic, plaintiff's state law claim premised on a generalized violation of a federal duty cannot fit within the parallel claim exception because a generalized federal duty is not a requirement under § 360k(a).³⁴⁰

Medtronic further claimed that the Ninth Circuit's decision to allow generally applicable requirements to escape preemption would "open the floodgates to potentially massive state-law liability imposed by lay juries asked to second-guess the FDA's expert regulatory oversight."³⁴¹ Medtronic seemed to take the position that a state law claim based on such a vague violation of the FDA regulations would afford the jury the discretion to second-guess the decisions of the FDA and thus impose state requirements "different from or in addition to" those imposed by the FDA.³⁴²

4. *The Argument Against a General/Specific Distinction*

The Stengels took the contrary position that "nothing in § 360k(a), *Lohr*, or *Riegel* demands that the requirement be specific to a particular device."³⁴³ According to the Stengels, the Supreme Court in *Lohr* "held, unanimously, that the *Lohr*'s labeling claims were not preempted . . . although the device was subject to *no* device-specific requirements at all."³⁴⁴ The Stengels also argued that in *Bates*, the Supreme Court held that plaintiff's claim survived preemption although there was no product-specific labeling requirement.³⁴⁵

The United States agreed with the conclusion reached by the Stengels and the Fifth, Sixth, Seventh, and Ninth Circuits, but for different reasons. According to the United States, the Court need not analyze whether a generally applicable requirement fits within the parallel claim exception because a generally applicable requirement has no preemptive effect to begin with.³⁴⁶ This is in contrast to the Stengels and the circuit courts, who assumed that all federal requirements, general or specific, have preemptive effect and thus must fit within the parallel claim exception to avoid express

339. *See supra* Part II.B.2.

340. Petition for a Writ of Certiorari, *supra* note 22, at 31.

341. *Id.* at 32 (citing *Lohr*, 518 U.S. at 501).

342. *See generally id.*

343. Respondents' Brief in Opposition, *supra* note 33, at 10.

344. *Id.* at 13 (emphasis in original).

345. *Id.*

346. Brief for the United States as Amicus Curiae, *supra* note 4, at 10–13.

preemption. The United States relied on *Lohr*, FDA regulations, and public policy objectives for its proposition that a generally applicable requirement has no preemptive effect whatsoever.³⁴⁷

B. The Implied Preemption Argument in *Stengel*

1. *The Argument for a Circuit Split*

As it does with express preemption, Medtronic argued that the Ninth Circuit's decision in *Stengel* deepens a split amongst the circuits as to whether the MDA impliedly preempts state law claims based on a manufacturer's failure to report adverse events to the FDA.³⁴⁸ While the Sixth Circuit in *Cupek* and the Eighth Circuit in *Sprint Fidelis* have impliedly preempted such claims, the Fifth Circuit in *Hughes* and the Ninth Circuit in *Stengel* have reached the opposite conclusion.³⁴⁹

2. *The Argument Against a Circuit Split*

The Stengels, on the other hand, denied the existence of a circuit split on whether state law failure-to-warn-the-FDA claims are impliedly preempted.³⁵⁰ They argued that “the cases cited by Medtronic do not reflect different approaches to preemption but rather different outcomes based on different pleadings.”³⁵¹ The Stengels contended that *Cupek* and *Sprint Fidelis* are consistent with the decisions of the Fifth, Seventh, and Ninth Circuits.³⁵² In *Cupek* and *Sprint Fidelis*, the plaintiff only alleged that the manufacturer breached a duty to the *government*, whereas in *Hughes* and *Stengel* the plaintiffs alleged that the manufacturer breached a duty to the *plaintiff*.³⁵³ In *Cupek* and *Sprint Fidelis*, the courts impliedly preempted plaintiffs' state law claims because they were disguised fraud on the FDA claims that were dependent upon the FDCA. They were dependent upon the FDCA because they would not have

347. *Id.*

348. Petition for a Writ of Certiorari, *supra* note 22, at 10.

349. See *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205–06 (8th Cir. 2010); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 423–24 (6th Cir. 2005). *But cf.* *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013); *Hughes v. Bos. Scientific Corp.*, 631 F.3d 762, 775–76 (5th Cir. 2011).

350. Respondents' Brief in Opposition, *supra* note 33, at 14.

351. *Id.* at 15.

352. See *id.*

353. *Id.* at 14–15.

been cognizable without an FDA violation.³⁵⁴ In contrast, the claims in *Stengel* and *Hughes* were not impliedly preempted because plaintiff alleged that the manufacturer violated a duty owed to the *plaintiff*.³⁵⁵ A claim premised on a duty owed to the plaintiff rests on traditional state law.³⁵⁶ The United States, as amicus curiae, also takes the Stengels' position that there is no circuit split as to whether state law tort claims are impliedly preempted.³⁵⁷

3. *The Argument for Implied Preemption*

Medtronic urged the Supreme Court to take the position of the Sixth and Eighth Circuits because they have interpreted *Buckman* "correctly," while the Fifth and Ninth Circuits have not.³⁵⁸ Medtronic read *Buckman* as holding that "the state law duty on which the claim is based must be independent of any duty imposed by the MDA."³⁵⁹ Medtronic explained that the Stengels' state law claim is not independent of any federal duty because there is no duty for manufacturers to submit information to the FDA under Arizona law.³⁶⁰ According to Medtronic, Arizona law only imposes a general duty to warn physicians and consumers; it does not impose a duty to warn the *federal government*.³⁶¹ Further, a state law duty requiring manufacturers to submit information to the federal government would "defy settled principles of federalism and sovereignty."³⁶² Therefore, since plaintiffs' state law claim is not independent of the federal duty alleged, their claim should be impliedly preempted as in *Buckman*.³⁶³

In addition, Medtronic argued that the Stengels' failure-to-warn claim should be impliedly preempted for public policy reasons because, as in *Buckman*, a failure-to-warn claim directly interferes with the regulatory scheme of the FDA.³⁶⁴ First, a state law violation would interfere with the FDA's authority to determine whether to withdraw approval when the manufacturer has failed to report

354. *See id.*

355. *See id.*

356. *See id.* at 14–16.

357. *See id.* at 22–23.

358. Petition for a Writ of Certiorari, *supra* note 22, at 22.

359. Reply Brief for Petitioner at 7, *Medtronic, Inc. v. Stengel*, 134 S. Ct. 375 (2013) (No. 12-1351).

360. Petition for a Writ of Certiorari, *supra* note 22, at 25.

361. *Id.*

362. *Id.*

363. *Id.*

364. *Id.* at 23–24.

adverse events.³⁶⁵ Second, complying with state law would increase the burdens on manufacturers and discourage them from seeking approval, or induce them to submit a deluge of adverse event reports that the FDA neither wants nor needs.³⁶⁶ Third, the causation inquiry under state tort law would burden the FDA.³⁶⁷ Medtronic claimed that causation can only be proven by establishing how the FDA would have responded if Medtronic submitted adverse event reports.³⁶⁸ Such an inquiry would “ensnare agency personnel in burdensome discovery and divert the agency from its regulatory mission.”³⁶⁹ Further, the causation inquiry would require a lay jury to determine what the FDA should have done if it had this information, which “would authorize lay juries to superintend the FDA’s decision-making.”³⁷⁰

4. *The Argument Against Implied Preemption*

The Stengels, on the other hand, argued that their claim that Medtronic breached its duty to report adverse events to the FDA is based on “an independent state law duty, not a duty that exists only under federal law.”³⁷¹ They relied on the third-party duty-to-warn doctrine to establish a state law duty that is independent of the FDCA. The Stengels argued that under Arizona law “a warning to a third party satisfies a manufacturer’s duty if, given the warning and relationship of the third party, there is a reasonable assurance that the information will reach those whose safety depends on their having it.”³⁷² In other words, Medtronic had a state law duty to warn the FDA, which in turn should have warned physicians, who in turn should have warned patients. The Stengels argued that Medtronic’s ultimate duty was to the plaintiff, and thus Medtronic breached that duty by failing to warn the FDA.³⁷³ According to the Stengels, then, their claim is different than Buckman’s claim, in which the

365. 21 U.S.C. § 360e(e)(1)(D)(i) (2012); Petition for a Writ of Certiorari, *supra* note 22, at 24.

366. Petition for a Writ of Certiorari, *supra* note 22, at 24.

367. *Id.* at 28–29.

368. *Id.*

369. Reply Brief for Petitioner, *supra* note 359, at 10.

370. *Id.*

371. Respondents’ Brief in Opposition, *supra* note 33, at 6.

372. *Id.* at 19; Stengel v. Medtronic Inc., 704 F.3d 1224, 1233 (9th Cir. 2013) (quoting Anguiano v. E.I. DuPont de Nemours & Co., 808 F. Supp. 719, 723 (D. Ariz. 1992), *aff’d*, 44 F.3d 806 (9th Cir. 1995)).

373. Respondents’ Brief in Opposition, *supra* note 33, at 19.

manufacturer only owed a duty to the *FDA* because here, Medtronic's ultimate duty was to the *plaintiff*.³⁷⁴

The Stengels also rejected Medtronic's argument that the state law claim would lead to second-guessing of FDA decision-making.³⁷⁵ They claimed that this case was unlike *Buckman*, where the jury would have to speculate on whether the FDA would have approved the drug in the absence of fraud, because "the FDA has already decided [through its warning letter] that Medtronic had not adequately complied with federal reporting requirements."³⁷⁶ In its reply brief, Medtronic made two points in response to the argument that the FDA already determined Medtronic failed to comply with the FDA. First, the warning letter does not constitute a final agency action and thus does not represent a decision by the FDA that Medtronic violated MDA requirements.³⁷⁷ Second, even if the FDA made a final determination that Medtronic violated the MDA, the state law claim would still invite a lay jury to "second-guess the FDA's carefully calibrated choice of remedy."³⁷⁸

The United States made a different argument as to why the Stengels' claim should not be impliedly preempted.³⁷⁹ In fact, the United States believed that the Stengels' reliance on the third-party duty-to-warn doctrine created a causation hurdle that may implicate *Buckman*.³⁸⁰ There is a causation hurdle under the third-party duty-to-warn theory because plaintiff must show that the manufacturer "should have reported adverse events to the FDA, which in turn would have warned physicians."³⁸¹ The United States believed that the "causation hurdle refers to the agency decision-making process and therefore may implicate *Buckman*."³⁸² However, according to the United States, the Stengels had a more natural theory of causation that did not implicate *Buckman*.³⁸³ This theory alleged that, upon learning of the adverse events associated with its catheter, Medtronic should have strengthened the warning of its device.³⁸⁴ The

374. *Id.*

375. *Id.* at 20.

376. *Id.*

377. Reply Brief for Petitioner, *supra* note 359, at 9.

378. *Id.*

379. Compare Respondents' Brief in Opposition, *supra* note 33, at 19, with Brief for the United States as Amicus Curiae, *supra* note 4, at 19.

380. Brief for the United States as Amicus Curiae, *supra* note 4, at 19.

381. *See id.*

382. *Id.*

383. *Id.*

384. *See id.*

CBE regulation allows a manufacturer to revise a device's labeling, without prior FDA approval.³⁸⁵ According to the United States, this CBE theory relies on traditional state law and thus avoids *Buckman* because it does not depend upon the FDA to warn doctors, but rather requires the manufacturer to warn doctors directly by revising its label.

In fact, the United States contended that a claim premised on the CBE process “would mirror the failure to warn claim against the prescription drug manufacturer that this Court held was not impliedly preempted in *Wyeth*.”³⁸⁶ In *Wyeth v. Levine*, plaintiff alleged that Wyeth failed to warn about the dangers of the “IV push method” in injecting the drug Phenergan.³⁸⁷ Wyeth argued that Levine's claim should be subject to implied conflict preemption/impossibility preemption because it is impossible for Wyeth to comply with state law requiring Wyeth to strengthen its warning and federal law, which prevents a manufacturer from changing its warning without FDA approval.³⁸⁸ The Supreme Court rejected Wyeth's argument because the CBE regulation allows a manufacturer to unilaterally strengthen its warning.³⁸⁹ Therefore, the Supreme Court found it is possible for manufacturers to comply with both state and federal law.³⁹⁰ Wyeth also made an obstacle preemption argument similar to that of *Buckman*, that strengthening its warning would “obstruct the purposes and objectives of federal drug labeling.”³⁹¹ The Supreme Court was also not persuaded by this argument.³⁹² The United States, as amicus curiae in *Stengel*, argued that, like in *Wyeth*, the Stengels'

385. See 21 C.F.R. § 314.70(c)(6)(iii) (2014); Brief for the United States as Amicus Curiae, *supra* note 4, at 2.

386. Brief for the United States as Amicus Curiae, *supra* note 4, at 20.

387. Phenergan can be injected through the “IV push method,” whereby the drug is directly injected into the patient's vein or through the “IV drip method,” whereby the drug is introduced into a saline solution and slowly descends into the vein through a catheter. The “IV push method” poses a greater risk than the “IV drip method.” Plaintiff argued that the manufacturer should have instructed to use the “IV drip method” instead of the “IV push method.” *Wyeth v. Levine*, 555 U.S. 555, 560 (2009).

388. *Id.* at 570.

389. “The CBE regulation permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA approved Phenergan's label does not establish that it would have prohibited such a change.” *Id.* at 573.

390. *Id.*

391. *Id.*

392. “Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling.” *Id.* at 581.

claim should not be preempted, because the CBE regulation also applies to medical devices.³⁹³

IV. WHY THE SUPREME COURT SHOULD HAVE ALLOWED STENGELS' CLAIM TO SURVIVE EXPRESS AND IMPLIED PREEMPTION

The Supreme Court was faced with an array of complex arguments on both the respondent and petitioner's side. This Note argues that the Supreme Court should have granted certiorari in *Stengel v. Medtronic* to clarify the confusion surrounding exactly which claims survive express and implied preemption. In the future, the circuit courts and the Supreme Court should adopt a liberal approach in allowing plaintiffs to plead violations of generally applicable requirements, but a conservative approach in applying *Buckman* to impliedly preempt state law tort claims.

A. Violations of Generally Applicable Federal Requirements Should Survive Preemption

1. *There Is a Circuit Split on Whether a Federal Requirement must Be Generally Applicable or Device-Specific*

The Supreme Court should have granted Medtronic's petition for certiorari because there is indeed a circuit split on whether the federal requirement must be device-specific or generally applicable. Although the Supreme Court skirted the issue by denying certiorari in *Stengel*, hopefully they will mend the circuit split in the near future. However, it must first be noted that the Stengels' argument—that there is not a circuit split, but rather that the different outcomes in the Eighth and Eleventh Circuits reflect problems of pleading—has some merit. In *Sprint Fidelis* and *Wolicki-Gables*, the two cases holding that a requirement be device-specific, the plaintiffs did not tie their injuries to *any* particular requirement, whether general or specific. In *Wolicki-Gables*, the plaintiffs did not cite a particular federal requirement that was violated; instead, they merely alleged that the manufacturer failed to reasonably design, manufacture, and provide adequate warnings of its pump system.³⁹⁴

The same can be said about *Sprint Fidelis*, to an extent. In *Sprint Fidelis*, the Eighth Circuit found plaintiff's manufacturing defect claim to allege that “state law entitles *every person* who has an

393. Brief for the United States as Amicus Curiae, *supra* note 4, at 20.

394. See *supra* notes 187–93 and accompanying text.

implanted Sprint Fidelis lead[] to damages . . . because all Sprint Fidelis leads have an unreasonably high risk of fracture failure.”³⁹⁵ Therefore, the problem with this claim is that, although pleaded as a parallel manufacturing defect claim, in actuality it amounts to a design defect claim.³⁹⁶ Design defect claims are almost always expressly preempted under *Riegel*.³⁹⁷ It is plausible that the court’s perception of the plaintiff’s claim as a design defect claim was due to her reliance on the generally applicable CGMPs. At the same time, it is also plausible that the court would not view plaintiff’s claim as a design defect claim if she were more concrete in tying her injury to the manufacturer’s violation of the CGMP.

In comparison to *Wolicki-Gables* and *Sprint Fidelis*, the pleadings presented in the Fifth, Sixth, and Seventh Circuits may have been stronger. As evidenced by *Bass*, *Howard*, and *Hughes*, the plaintiffs’ claims in these circuits may have survived preemption because the manufacturers’ violation of a generally applicable regulation was tied to plaintiff’s injury. First, in *Bass*, the complaint alleged that Stryker violated 21 C.F.R. §§ 820.20(a), 820.20(b)(2), and 820.70(e), which caused Bass to suffer from a loose Shell due to lack of bony ingrowth.³⁹⁸ Second, in *Howard*, the complaint alleged that Sulzer violated 21 C.F.R. § 820.70(h) by leaving oil on its machine, which thereby caused plaintiff’s knee implant to fail.³⁹⁹ Third, in *Hughes*, the complaint alleged that if Boston Scientific had complied with 21 C.F.R. § 803.50(a) and reported second-degree burns, the FDA would have taken action, thereby preventing plaintiff from suffering from such a burn.⁴⁰⁰

Although the pleadings in *Sprint Fidelis* and *Wolicki-Gables* may have been weaker than their counterparts, there are a number of district court pleadings that failed to survive preemption despite being as concrete as those in the Fifth, Sixth, and Seventh Circuits. For example, in *Ilaraza*, the Eastern District of New York dismissed

395. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1207 (8th Cir. 2010).

396. Prince, *supra* note 34, at 1056.

397. *Id.* (“Thus, as pleaded and argued, the manufacturing defect claims are not parallel, they are a frontal assault on the FDA’s decision to approve a PMA Supplement after weighing the product’s benefits against its inherent risks.”); see Whitney, *supra* note 175 at 127 (contending “that [a] design defect claim which challenges FDA’s findings concerning the safety of a device’s design imposes requirements that are different from, or in addition to, federal regulations and therefore is preempted”).

398. *Bass v. Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012).

399. *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App’x 436, 440 (6th Cir. 2010).

400. *Hughes v. Bos. Scientific Corp.*, 631 F.3d 762, 765 (5th Cir. 2011).

plaintiff's claims even though the plaintiff referenced particular CGMP violations.⁴⁰¹ Further, in *Parker v. Stryker*, the progeny of *Sprint Fidelis*, the District Court of Colorado dismissed plaintiff's parallel claims against Stryker's Trident hip implant system, even though plaintiff referenced particular CGMP violations and warning letters issued by the FDA which found Stryker violated the MDR and CGMPs.⁴⁰² The *Parker* decision is in conflict with that of Seventh Circuit in *Bausch* where plaintiff referenced the same CGMP violations and warning letters regarding the Trident System and yet survived dismissal.⁴⁰³

The Supreme Court also should have more closely considered the language in *Sprint Fidelis* and *Wolicki-Gables*, which clearly states that the plaintiff must allege a violation of a specific requirement in the device's PMA. In *Wolicki-Gables*, the Eleventh Circuit held that a plaintiff must point to "*specific PMA requirements* in the PMA approval."⁴⁰⁴ In *Sprint Fidelis*, the Eighth Circuit stated that "[p]laintiffs simply failed to adequately plead that Medtronic violated a federal requirement *specific to the FDA's PMA approval*."⁴⁰⁵ Further, although some courts have distinguished the different outcomes amongst the Circuits, others have more candidly recognized the divide.⁴⁰⁶ For these reasons, the divide amongst the lower courts is real, and the Supreme Court ought to bridge the divide. In bridging the divide, the Supreme Court should hold that a violation of a generally applicable requirement survives express preemption.

2. Generally Applicable Requirements Should Escape Preemption

Public policy and precedent dictate that violations of a generally applicable requirement escape preemption. There are two alternative

401. *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 586 (E.D.N.Y. 2009).

402. *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008).

403. *Bausch v. Stryker Corp.*, 630 F.3d 546, 556, 559 (7th Cir. 2010).

404. *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (emphasis added).

405. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1207 (8th Cir. 2010) (emphasis added).

406. *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440 (6th Cir. 2010) (holding "that the alleged violations in *Sprint Fidelis* were different from the ones here; and moreover the plaintiff there did not even identify a specific GMP that he thought had been violated"); *Bausch*, 630 F.3d at 554 (holding "the [*Sprint Fidelis*] case might well be distinguishable from our case based on the Medtronic Leads' plaintiffs' deliberate decision not to seek discovery and to assert claims for patients whose devices had not failed"). *But cf. Bausch*, *Bass v. Stryker Corp.*, 669 F.3d 501, 511–12 (5th Cir. 2012) (holding that "the circuits are not in complete agreement as to what constitutes a sufficient pleading with regard to a CGMP.")

holdings by the Supreme Court that would reach this end goal: (1) violations of generally applicable requirements have no preemptive effect whatsoever, or (2) violations of generally applicable requirements fall within the parallel claim exception. Admittedly, these are two divergent approaches that reach the same result of allowing Stengels' claims to avoid preemption. Fitting generally applicable requirements within the parallel claim exception is clearly the better of the two approaches. Affording generalized requirements no preemptive effect would reduce the parallel claim exception to a nullity.⁴⁰⁷ It would also reach the perverse result of making it easier for claims premised on a generally applicable requirement to avoid preemption than it would be for a device-specific requirement.⁴⁰⁸ Nonetheless, either approach is acceptable because it allows state law claims premised on the generally applicable MDRs or CGMPs to escape preemption. Allowing these generalized requirements to avoid preemption is not only consistent with *Lohr* and § 360k, but it is also necessary given the practical difficulties of alleging a device-specific requirement at the pleading stage.

a. Why Violations of Generally Applicable Requirements Should Have no Preemptive Effect

The United States' argument that generally applicable requirements have no preemptive effect because they are not federal requirements under § 360(k) does have support in *Lohr*. The *Lohr* court stated that "in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a *relevant* federal 'requirement.'"⁴⁰⁹ It would seem that "relevant" most likely means device-specific.⁴¹⁰ In addition, 21 C.F.R. § 808.1(d) provides that "[s]tate 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 [FDCA]."⁴¹¹ For these reasons, it is plausible that a regulation has to

407. See discussion *supra* Part III.A.3.

408. See *id.*

409. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996) (emphasis added).

410. In discussing the generality of the CGMPs, the *Lohr* Court stated that "the generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests *relevant* to the particular requirement in question. . . ." *Id.* at 501 (emphasis added).

411. Brief for the United States as Amicus Curiae, *supra* note 4, at 11.

be device-specific to have preemptive effect pursuant to *Lohr* and FDCA regulations.

Further, it can be argued that there would be minimal interference with the FDA decision-making process if a generally applicable requirement had no preemptive effect.⁴¹² Only a device-specific requirement in the PMA reflects the FDA's weighing of the risks and benefits of the device in question.⁴¹³ However, as explained in more detail below, a compelling argument can be made that a generally applicable requirement interferes with FDA regulatory objectives.⁴¹⁴ This is because the open-ended nature of a generally applicable requirement provides a jury greater discretion in interpreting the FDA's regulations.

b. Why Generally Applicable Requirements Should Fall Within the Parallel Claim Exception

Assuming *arguendo* that the Supreme Court rules that a generally applicable requirement has preemptive effect, preemption can still be avoided if the requirements fall within the parallel claim exception. However, Medtronic argues that only violations of a device-specific federal requirement fall within the parallel claim exception, whereas generally applicable requirements do not run parallel, and thus are expressly preempted.⁴¹⁵ Medtronic's distinction between specific and generally applicable requirements is misplaced.

Although *Lohr*, as mentioned above, suggests that there is a distinction between specific and general requirements, there is nothing in the text of § 360k to suggest a distinction.⁴¹⁶ Section 360k preempts a claim that imposes on a manufacturer “*any* requirement . . . which is different from, or in addition to, *any* requirement applicable under this chapter to the device.”⁴¹⁷ Because § 360k uses the broad phrase “*any* requirement,” generally applicable requirements should fall within its purview.⁴¹⁸ Further, there is nothing to suggest that generally applicable requirements are any less of a requirement than device-specific ones. First, the generally applicable CGMPs, QSRs, and MDRs refer to themselves as

412. *Id.*

413. *Id.*

414. *See infra* note 427 and accompanying text.

415. *See supra* note 336–40 and accompanying text.

416. *See supra*, note 343–44 and accompanying text.

417. 21 U.S.C. § 360k(a) (2012) (emphasis added).

418. *Id.*; *Bausch v. Stryker Corp.*, 630 F.3d 546, 555 (7th Cir. 2010).

requirements.⁴¹⁹ Second, generally applicable requirements are as legally binding as device-specific requirements.⁴²⁰ For instance, failure to comply with the QSRs, CGMPs, and MDRs can result in regulatory action.⁴²¹ Third, the differences between the two requirements are not intransigent, as generally applicable requirements can become device-specific requirements. As the Sixth Circuit noted in *Howard*, the CGMP standards can be incorporated into the PMA, which would transform them from industry-wide standards to device-specific requirements.⁴²² For these reasons, if device-specific regulations constitute requirements, then so should generally applicable ones. Therefore, if the Court fails to find that a generally applicable requirement has preemptive effect, it should at the very least find that a generally applicable requirement avoids preemption because it falls within the parallel claim exception.

Medtronic twisted *Lohr* into holding that a state law claim premised on a violation of a generally applicable requirement does not fall within the parallel claim exception.⁴²³ The *Lohr* court stated that the CGMPs “reflect important but entirely generic concerns about device regulation generally” and that a requirement must be “‘applicable to the device’ in question.”⁴²⁴ Medtronic argues that under *Lohr*, generally applicable regulations do not constitute requirements and thus cannot parallel state law.⁴²⁵ However, Medtronic’s argument should be rejected. If a generally applicable regulation is not a requirement under § 360k, it would be more consistent with *Lohr* if that requirement had no preemptive effect.⁴²⁶

419. 21 C.F.R. §§ 820.1; 803.50(a) (2014).

420. “[F]ederal law is clear: for manufacturers of Class III medical devices, the Quality System Regulations and Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements ‘under this chapter.’” *Bausch*, 630 F.3d at 555 (citing 21 C.F.R. § 820.1).

421. 21 C.F.R. § 820.1(c) (providing that “the failure to comply with any applicable provision in this part [of the regulations] renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.”); see also CCH Drug & Cosmetics L. Rep. ¶ 350,140 (Apr. 1, 1996), available at 1996 WL 34474338 (“Failure to comply with the MDR requirements is a prohibited act under the Food, Drug and Cosmetic Act (FD&C Act). Commission of a prohibited act may subject user facilities to injunction proceedings under Section 302 and criminal penalties under Section 303 of the FD&C Act.”).

422. *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App’x 436, 439 (6th Cir. 2010).

423. See Petition for a Writ of Certiorari, *supra* note 22, at 31.

424. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501 (1996); see also Petition for a Writ of Certiorari, *supra* note 22, at 31.

425. Petition for a Writ of Certiorari, *supra* note 22, at 31.

426. See *supra* notes 409–11 and accompanying text.

Medtronic's proposition would lead to the absurd result of treating generally applicable regulations as requirements to give them preemptive effect, but then treat them as if they were not requirements to avoid a parallel claim analysis. Such a result would further complicate an already very complicated preemption doctrine.

Medtronic's policy argument, that allowing claims premised on generally applicable requirements can lead to jury second-guessing of FDA decisions, has some merit, but that concern is ultimately overblown. Admittedly, compared to the extensive and detailed procedures specified in the PMA, the CGMPs and MDRs are vague and open-ended in order to give the manufacturer flexibility to implement best practices.⁴²⁷ However, the fear of jury second-guessing is likely overstated for several reasons. First, as the Court explained in *Bausch*, the meaning of FDA regulations is a matter of law for the judge, not the jury, to decide.⁴²⁸ Since judicial interpretation of FDA regulations is subject to the federal appeals process, the interpretation of FDA regulations should be relatively uniform.⁴²⁹ Second, a jury likely will be presented with a narrow question, such as whether the manufacturer submitted reports to the FDA when the device contributed to death or serious injury. This is a common sense question that would not superintend the FDA's scientific expertise. A jury would not have to conjure what is a serious injury because a "serious injury" is defined in the MDR.⁴³⁰ Third, as in *Hughes* and *Stengel*, presenting the jury with the FDA warning letters, which have already determined the manufacturer failed to comply with the MDR, will ensure that the jury does not find a violation beyond what the FDA found.⁴³¹

Putting precedent aside, a generally applicable requirement should also avoid express preemption due to the difficulty in alleging a device-specific requirement. Plaintiffs may not have the opportunity for discovery during the pleading stage.⁴³² As both the majority in

427. *Howard*, 382 F. App'x at 442 (Guy, J., dissenting).

428. *Bausch v. Stryker Corp.*, 630 F.3d 546, 556 (7th Cir. 2010).

429. *Id.*

430. MDR limits serious injuries to: "injury or illness that: (1) Is life-threatening, (2) Results in permanent impairment of a body function or permanent damage to a body structure, or (3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure." 21 C.F.R. § 803.3 (2014).

431. See Reply Brief for Petitioner, *supra* note 359, at 9.

432. Compare *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1207 (8th Cir. 2010) (dismissing plaintiff's complaint in part because plaintiff waived the opportunity for discovery), with *Bausch*, 630 F.3d at 561 (surviving dismissal at the complaint stage where plaintiff never had the opportunity

Bausch and the dissent in *Sprint Fidelis* note, it is virtually impossible for a plaintiff to plead a device-specific violation without discovery.⁴³³ To plead a device-specific violation, a plaintiff would need access to information contained within the PMA, but this information is generally proprietary and not obtainable without discovery.⁴³⁴ In the failure-to-warn context, alleging a device-specific violation would likely require access to mandatory adverse event reports or voluntary adverse event reports.⁴³⁵ Mandatory adverse event reports, which annually document the serious injuries or deaths associated with the manufacturer's device, may not even be discoverable at all.⁴³⁶ Although the consensus is that voluntary adverse event reports are discoverable, it is practically impossible for the plaintiff to access both types of adverse event reports without discovery.⁴³⁷

There are creative ways in which plaintiffs' attorneys can try to allege a device-specific requirement without discovery. Methods include Freedom of Information (FOIA) requests to obtain portions of the FDA's PMA files, post-market surveillance studies, and Establishment Inspection Reports (EIRs).⁴³⁸ Plaintiffs' lawyers can also obtain FDA advisory committee reports, public filings issued by the manufacturer, and information on suspected deaths, injuries, and malfunctions from the Manufacturer and User Facility Device Experience (MAUDE) database.⁴³⁹ Although these approaches are a cause for some optimism among plaintiff attorneys, obtaining PMA documents in discovery is still far more likely to yield information that the manufacturer violated a device-specific requirement.⁴⁴⁰

for discovery). *See also* *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008) (denying defendant's motion to stay discovery until after court rules on motion to dismiss).

433. *See Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1209 (contending that "[t]o apply *Twombly* rigidly without permitting discovery as to these [device-specific] documents effectively creates an impossible-to-achieve specificity requirement"); *see also Bausch*, 630 F.3d at 561.

434. *Bausch*, 630 F.3d at 561.

435. *See* Trevor K. Scheetz, Note, *Say What You Mean: The Discoverability of Medical Device Adverse Event Reports*, 2011 U. ILL. L. REV. 1095, 1097 (2011).

436. *See* 21 U.S.C. § 360i(b)(3) (2012); Scheetz, *supra* note 435, at 1124.

437. *See* Scheetz, *supra* note 435, at 1124.

438. EIRs "provide details regarding inspections of the manufacturer's facilities and outline observations of possible violations." Mitchell M. Breit et al., *Charting the Course in Medical Device Preemption*, TRIAL, Sept. 2013, at 28, 30.

439. The MAUDE database, an online database that monitors "suspected device-associated deaths, serious injuries, and malfunctions," is somewhat accessible to the public. *Id.* at 31.

440. *Id.* at 28.

For the aforementioned reasons, state law tort claims based on generally applicable federal requirements should not be expressly preempted. Generally applicable requirements should either have no preemptive effect at all, or at least fall into the parallel claim exception. Although either conclusion would be acceptable, fitting generally applicable requirements within the parallel claim exceptions makes more sense. First, holding that generalized requirements have no preemptive effect would reduce the parallel claim exception, that the Court spent time to carve out in *Lohr* and *Riegel*, and then tried to preserve in *Bartlett*, to a nullity.⁴⁴¹ This is because if generalized requirements had no preemptive effect, plaintiffs would sensibly try to avoid preemption entirely by pleading a violation of a generalized requirement rather than trying to fit their claims within the parallel claim exception.

Additionally, if a generalized requirement had no preemptive effect, it may be easier for plaintiff to avoid preemption by pleading a violation of a generalized requirement than it would be for plaintiff to plead a device-specific violation. A claim premised on a violation of a device-specific requirement would have to fit within the parallel claim exception, and thus undergo a genuine equivalency and implied preemption analysis.⁴⁴² However, if given no preemptive effect, a generally applicable requirement would evade the parallel claim analysis in its entirety. A more rigorous preemption analysis for violations of device-specific requirements, as opposed to generalized ones, is strange. A state law claim premised on a violation of a device-specific requirement may be less likely to impose different or additional requirements under § 360k. The FDA “weighed the competing interests relevant to the particular requirement in question” when it reviewed the device’s PMA application.⁴⁴³

441. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); see also *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 (2013). The Court recognized the parallel claim exception in all three of the these cases.

442. See *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1208 (8th Cir. 2010) (holding that plaintiff’s state law claim premised on the FDCA was impliedly preempted. Although this involved a generally applicable requirement, it is still possible that a device-specific requirement is impliedly preempted. However, this is unlikely because state law enforcement of device-specific requirements probably does not conflict with FDA objectives); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) (holding that the federal requirement and state requirement were expressly preempted because they were not genuinely equivalent. Although the federal requirement that was not equivalent here was the generally applicable CBE regulation, it is possible that a device-specific requirement could not run parallel to a state law duty).

443. *Lohr*, 518 U.S. at 501.

Therefore a jury award based on a manufacturer's failure to comply with device-specific PMA requirements probably would be less likely to diverge from the FDA's intentions than a violation of a generalized requirement.

Further, such a rule could encourage plaintiff's lawyers to rely on industry-wide standards like the CGMP or MDR in their pleadings, instead of trying to get their hands on more concrete, device-specific information. While a holding that generally applicable requirements have no preemptive effect gives greater leeway to generalized requirements than device-specific ones, recognizing the parallel claim exception properly treats both types of requirements with parity. For these reasons, the Supreme Court should conduct a parallel claim analysis and thus hold that a violation of the industry-wide MDR is not expressly preempted.

B. Traditional State Law Tort Claims Should Not Be Impliedly Preempted

1. There Is a Circuit Split on Whether State Law Tort Claims Are Impliedly Preempted

In its petition for certiorari in *Stengel*, Medtronic argued that the circuits are divided on whether state tort law claims are impliedly preempted under *Buckman*. According to Medtronic, while the Sixth and Eighth Circuits have impliedly preempted state tort law claims, the Fifth and Ninth Circuits have not.⁴⁴⁴ By contrast, the Stengels contended that the different outcomes can be explained by differences in pleading.⁴⁴⁵ They argued that, unlike Fifth and Ninth Circuit cases where the claims were premised on a state law duty owed to *plaintiff*, the claims in the Sixth and Eighth Circuit cases of *Cupek* and *Sprint Fidelis* were premised on a duty owed only to the *FDA*.⁴⁴⁶ There is a clear divide on the extent to which *Buckman* applies to state law tort claims. The Supreme Court should have granted certiorari in order to bridge the divide.

Despite the Stengels' attempt to argue the contrary, the Fifth, Seventh, and Ninth Circuit decisions are irreconcilable with the Sixth and Eighth Circuit decisions, as well as with several district court

444. See Petition for a Writ of Certiorari, *supra* note 22, at 20.

445. See Respondents' Brief in Opposition, *supra* note 33, at 14–15.

446. See Petition for a Writ of Certiorari, *supra* note 22, at 25–26.

opinions.⁴⁴⁷ A brief comparison of these decisions reveals a clear divide. In *Sprint Fidelis*, *McClelland*, and *Wheeler*, the courts have impliedly preempted state law failure-to-warn claims premised on the manufacturer's failure to file adverse event reports.⁴⁴⁸ By contrast, in the Fifth and Ninth Circuit decisions of *Stengel* and *Hughes*, respectively, the courts held that state law failure-to-warn claims premised on the manufacturer's failure to file adverse event were not impliedly preempted.⁴⁴⁹ In *Lewkut*, the district court held that a state law tort claim premised on adulteration of the device was impliedly preempted, whereas the Seventh Circuit in *Bausch* held the exact opposite.⁴⁵⁰ In *Riley* and *Caplinger*, the district courts impliedly preempted state law tort claims based on an off-label promotion theory, while the California Court of Appeals in *Coleman* did not.⁴⁵¹

The differences in state law cannot explain these different outcomes. In all of the implied preemption cases, the state law tort duty that the plaintiffs sought to impose was virtually the same.⁴⁵² The Stengels argued that under Arizona law a manufacturer has as a duty to warn a third party when "there is 'reasonable assurance that the information will reach those whose safety depends upon their having it.'" ⁴⁵³ However, the third-party duty to warn is not unique to Arizona. The third-party duty principle was taken from a comment in the Second Restatement of Torts, and thus is a general proposition of tort law.⁴⁵⁴

What explains the different outcomes is not differences in law or pleading, but rather divergent judicial interpretations about *Buckman's* scope. The Sixth and Eighth Circuits interpreted

447. It is useful to look at district court opinions to determine how circuit courts would rule, given the scant number of circuit court opinions on implied preemption of Class III medical devices.

448. See, e.g., *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010); *McClelland v. Medtronic, Inc.*, No. 6:11-CV-1444-ORL-36 KRS, 2012 WL 5077401, at *5 (M.D. Fla. Sept. 27, 2012); *Wheeler v. DePuy Spine, Inc.*, 706 F. Supp. 2d 1264, 1270 (S.D. Fla. 2010).

449. See *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013); *Hughes v. Bos. Scientific Corp.*, 631 F.3d 762, 775 (5th Cir. 2011).

450. See *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 660 (S.D. Tex. 2010). *But cf.* *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010).

451. Compare *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1219–20 (W.D. Okla. 2013), and *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 783 (D. Minn. 2009), with *Coleman v. Medtronic, Inc.*, 167 Cal. Rptr. 3d 300, 316 (Cal. Ct. App. 2014).

452. See *supra* notes 294–97 and accompanying text (explaining the similarities of the duty imposed in *Bausch* and *Lewkut*, but conflicting outcomes).

453. See Respondents' Brief in Opposition, *supra* note 33, at 19.

454. See RESTATEMENT (SECOND) OF TORTS § 388 cmt. n (1965); Petition for a Writ of Certiorari, *supra* note 22, at 17.

Buckman to require that plaintiff's claim (1) must be based on traditional state tort law, and (2) "would not exist if the FDCA did not exist."⁴⁵⁵ According to Medtronic, though, the Fifth and Ninth Circuits have eschewed the second prong; they have held that plaintiff's claim passes *Buckman*'s test merely if it is based on traditional state law.⁴⁵⁶ However, the Ninth Circuit seems to be applying *Buckman*'s second prong. In the view of these courts, the state law tort claims they were presented with would exist if not for the FDCA.⁴⁵⁷ Whether the Ninth Circuit is applying the additional element or not, it is clear that the Ninth Circuit's, as well as the Fifth and Seventh Circuit's interpretations of *Buckman* diverge from those of the Sixth and Eighth Circuits. It could very well be that the different outcomes reflect different political attitudes towards preemption.⁴⁵⁸

2. *Traditional State Law Tort Claims Should Not Be Impliedly Preempted by Buckman*

The arguments that Medtronic and other manufacturers made as to why traditional state law tort claims should implicate *Buckman* are ultimately not compelling. One main argument is that if fraudulently misrepresenting information to the FDA is impliedly preempted by *Buckman*, then failing to report information to the FDA should also fall within its ambit. This is because both types of claims involve the failure to communicate properly with the FDA.⁴⁵⁹ Medtronic further argued that, like in *Buckman*, the plaintiff's claim is dependent upon the FDA requirements because informing the FDA is a "critical element" of the plaintiff's claim.⁴⁶⁰ According to Medtronic, Arizona common law does not impose a duty to warn the FDA, and thus the

455. See Petition for a Writ of Certiorari, *supra* note 22, at 17; Prince, *supra* note 34, at 1079.

456. See Petition for a Writ of Certiorari, *supra* note 22, at 11–12.

457. See Stengel v. Medtronic, Inc., 704 F.3d 1224, 1233 (9th Cir. 2013) (holding that plaintiff's claim "is a state-law claim that is independent of the FDA's pre-market approval process that was at issue in *Buckman*").

458. Raymond, *supra* note 140, at 765 (2010) ("Preemption cuts along clear ideological poles . . . Democratic-appointed [federal] judges were more than 3 times as likely to find 'no preemption' as Republican-appointed [federal] judges.").

459. See Petition for a Writ of Certiorari, *supra* note 22, at 20–21; see generally Coleman, v. Medtronic, Inc., 167 Cal. Rptr. 3d 300 (Cal. Ct. App. 2014), review granted and opinion superseded *sub nom.*, Coleman v. Medtronics, 323 P.3d 1 (Cal. 2014).

460. Petition for a Writ of Certiorari, *supra* note 22, at 23.

manufacturer's duty to warn the FDA would not exist if it were not for the FDA reporting requirements.⁴⁶¹

Medtronic's argument that plaintiff's failure-to-warn claim premised on a third party duty to warn is dependent upon the FDCA has validity. Under plaintiff's third-party duty-to-warn theory, the manufacturer has a duty to warn a third party like the FDA, who in turn will warn physicians and consumers.⁴⁶² However, the third-party duty doctrine does not specifically contemplate warning the FDA.⁴⁶³ The Ninth Circuit cites *Anguiano v. E.I. Du Pont De Nemours & Co.* in support of this proposition, but in that decision, a manufacturer had a duty to warn another manufacturer who incorporated the product of the first manufacturer.⁴⁶⁴ A state law duty for a manufacturer to warn a federal regulator has never been contemplated. Therefore, it cannot be said that the plaintiff's claim fully rests on traditional state law, independent of the FDCA.

Nonetheless, the plaintiff's claim based on the third-party duty-to-warn doctrine should avoid the ambit of *Buckman* because there is at least a semblance of a state law duty. Manufacturers have a duty to provide reasonable care, which includes warning those who can be foreseeably harmed.⁴⁶⁵

Further, it is hard to believe that the Supreme Court meant to extend *Buckman* as far as the Sixth and Eighth Circuits have taken it. The Supreme Court has recognized that in enacting the MDA, it was never Congress's intent to eliminate all state law claims. As the Supreme Court said in *Silkwood v. Kerr-McGee Corp.*, "it is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."⁴⁶⁶ However, impliedly preempting claims like that of the Stengels may do exactly that—remove means of judicial recourse. Impliedly preempting

461. *Id.* at 24.

462. *See supra* notes 372–73 and accompanying text.

463. *See supra* notes 360–362 and accompanying text.

464. *See* Stengel v. Medtronic Inc., 704 F.3d 1224, 1233 (9th Cir. 2013) (citing *Anguiano v. E.I. Du Pont De Nemours & Co.*, 44 F.3d 806, 811–12 (9th Cir. 1995)); *see also* Petition for a Writ of Certiorari, *supra* note 22, at 26.

465. *See* MacPherson v. Buick Motor Co., 217 N.Y. 382, 398 (1916) (holding that a manufacturer has a duty "either to exercise due care to warn users of the danger or to take reasonable care to prevent the article sold from proving dangerous when subjected only to customary usage").

466. 464 U.S. 238, 251 (1984); *see also* Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)) (holding that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements").

traditional state law tort claims, combined with the Supreme Court's express preemption decision in *Riegel*, would mean that nothing would fit through the narrow gap and survive preemption.⁴⁶⁷ Further, if all tort law claims were preempted, then it would render the distinction the Supreme Court made in *Riegel* and *Buckman* between express and implied preemption meaningless.

Another way plaintiffs could try to avoid the implied preemption thicket would be alleging that Medtronic breached its duty to warn physicians and patients. Such a claim obviously rests on traditional state tort law. *Buckman* would not be implicated because plaintiff would still have a theory of liability in the absence of the FDCA.⁴⁶⁸ However, as Judge Watford notes, alleging that a manufacturer breached its duty to warn doctors could be expressly preempted.⁴⁶⁹ This is because to fit within the parallel claim exception the state law duty alleged must be genuinely equivalent to a federal duty.⁴⁷⁰ The CBE regulation allows, but does not require, the manufacturer to strengthen its warnings.⁴⁷¹ There is no provision in the FDCA requiring the FDA to warn physicians; therefore, the imposition of a state law duty *requiring* that physicians be warned is not genuinely equivalent to the federal duty.⁴⁷² Regardless, a plaintiff could avoid express preemption by skirting the parallel claim exception. If the Court rules that a generally applicable requirement has no preemptive effect, then courts would not have to conduct a parallel claim analysis, which means that the genuine equivalency rule would not apply. Hence, a ruling that a generally applicable requirement has no preemptive effect would likely cause a plaintiff to avoid both express and implied preemption.

3. *Policy Arguments Against the Implied Preemption of Traditional State Law Tort Claims*

Although Medtronic looks to the public policy arguments in *Buckman* to impliedly preempt Stengel's failure-to-warn claim, these arguments have more force in the in fraud-on-the-FDA context than in the traditional tort law context. Fraud-on-the-FDA claims are

467. See Tarloff, *supra* note 81, at 1223.

468. In traditional state law tort claims the violation of the FDCA regulation is only needed to show breach. See *id.* at 1220.

469. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (Watford, J., concurring).

470. See *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005).

471. See *supra* notes 159–63, 383–93 and accompanying text.

472. See *Stengel*, 704 F.3d at 1234.

more likely to interfere with the regulatory objectives of the FDA than state law tort claims. The *Buckman* court's concerns that fraud-on-the-FDA claims would (1) interfere with FDA decision-making, (2) cause manufacturers to submit unnecessary information to the FDA, and (3) deter manufacturers from seeking § 510(k) approval, are not as legitimate in the failure-to-warn-context.

First, the *Buckman* court was concerned that jury verdicts regarding fraud-on-the-FDA claims could interfere with FDA decision-making. The United States as amicus curiae in *Stengel* expressed the same concern with regulatory interference in regards to the plaintiffs' third-party duty-to-warn theory.⁴⁷³ Under this theory, the plaintiff would have to prove that if the FDA received adverse event reports the FDA would have warned physicians. According to the United States, this causation inquiry could lead to jury second-guessing of the FDA decision-making process. However, the potential for a conflict between juries and the FDA is reduced in cases such as *Stengel* and *Hughes*, where FDA warning letters state that the manufacturer has not complied with the FDA.⁴⁷⁴

Second, the *Buckman* court held that fraud-on-the-FDA claims would create a "deluge of information that the Administration neither wants nor needs," which would hinder the FDA review process.⁴⁷⁵ The risk of a deluge of information is less likely to occur in the context of failure-to-warn-claims alleging that the manufacturer failed to report adverse events. Since these claims are based on the manufacturer's conduct *after* the device has been approved, it is hard to see how they will hinder the FDA pre-market approval process. Further, in *Stengel*, plaintiff's claim alleges that the manufacturer violated FDA regulations requiring it to report serious injury or death associated with its device. Reports on death and serious injuries are exactly the kind of information that the FDA does want or need.⁴⁷⁶ Third, *Buckman* held that fraud-on-the-FDA claims would deter manufacturers from applying for § 510(k) approval out of fear of civil liability. It is unlikely that failure-to-warn claims premised on a manufacturer's post-approval conduct would deter manufacturers from applying for PMA in the first place.

For these reasons, state-law tort claims do not interfere with the FDA's regulatory objectives in the same way as the claims in *Buckman*. Accordingly, courts should start with the presumption

473. Brief for the United States as Amicus Curiae, *supra* note 4, at 22.

474. See *supra* notes 376, 431 and accompanying text.

475. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 (2001).

476. See Tarloff, *supra* note 81, at 1227.

against preemption when conducting an implied preemption analysis. The presumption against preemption makes sense in the implied preemption context because the text is not clear enough to erase the presumption.⁴⁷⁷ Further, the presumption against preemption should apply to traditional-law tort claims because such claims historically have been in a field occupied by the states.⁴⁷⁸ State-law tort claims are different than the claims in *Buckman*, in which the Supreme Court refused to apply the presumption because “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied.’”⁴⁷⁹

Another reason to attach the presumption against preemption is the need for state-law claims to complement FDA enforcement actions.⁴⁸⁰ The FDA does not have the capacity to ensure that manufacturers are complying with FDA post-approval requirements on their own. In contrast to *Buckman*, where the court held that the FDA is amply equipped to police fraud, the FDA is far less equipped to enforce its post-approval reporting requirements. In fact, both GAO and FDA reports on post-market surveillance have found that the FDA’s ability “to understand the risks of adverse events related to the use of medical devices . . . is limited.”⁴⁸¹ Among the causes for the FDA’s limited post-market surveillance capacity is lack of time, as the FDA cannot review all the reports they receive.⁴⁸² Another constraint is that the passive medical device reporting system relies on the manufacturer to submit accurate and timely information.⁴⁸³ GAO found accurate and timely submissions do not always occur.⁴⁸⁴ Therefore, state-law tort claims are needed to make up for the deficiencies in the FDA post-market surveillance process.

CONCLUSION

Riegel made clear that state law claims that parallel federal requirements escape preemption.⁴⁸⁵ However, *Riegel* left uncertain

477. A presumption against preemption is “the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

478. *See supra* notes 83–49.

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

480. *See* Tarloff, *supra* note 81, at 1229.

481. U.S. GOV’T ACCOUNTABILITY OFFICE, *supra* note 62, at 14.

482. *See id.*

483. *See id.* at 14–15.

484. *See id.*

485. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

exactly which claims fall within the narrow gap, known as the parallel claim exception. In the wake of *Riegel*, lower courts have adopted conflicting interpretations of the contours of the narrow gap. While the Eighth and Eleventh Circuits have held that an industry-wide violation is expressly preempted under *Riegel*, the Fifth, Sixth, Seventh, and Ninth Circuits have allowed these claims to fit through the narrow gap. While the Sixth and Eighth Circuits have expanded *Buckman* to impliedly preempt state law tort claims, the Fifth, Seventh, and Ninth Circuits have again allowed these claims to fit through the narrow gap.

Stengel, the Ninth Circuit's en banc decision, in pending certiorari, had the opportunity to clarify the confusion surrounding the narrow gap. Unfortunately, the Supreme Court avoided the issue, thereby perpetuating the confusion. In a subsequent Class III medical device case involving parallel claims, the Supreme Court should grant certiorari because a parallel claim should not survive preemption in some circuits, but not in others. It is likely that the divide amongst the circuits will continue to widen, and it is only a matter of time before the Supreme Court will have to clarify the contours of the parallel claim doctrine. In clarifying the scope of the parallel claim doctrine, the Supreme Court should preserve a sufficiently sized gap for plaintiff's claims to avoid preemption. This is consistent with the Supreme Court precedent that has recognized that plaintiffs need some means of judicial recourse.⁴⁸⁶ Parallel claims are also needed to complement FDA oversight of medical devices, which is inadequate to enforce compliance with post-approval requirements by itself.

A violation of a generally applicable requirement such as the MDR should be sufficient to survive both express and implied preemption. To require plaintiff to plead a device-specific requirement to escape express preemption would unnecessarily narrow or maybe even eliminate the parallel claim exception. Once a plaintiff escapes express preemption by alleging a state law tort claim premised on a violation of an industry-wide requirement, he should not have to face the additional burden of proving his claim is not impliedly preempted. Implied preemption of state law tort claims would also essentially close the narrow gap left open for plaintiffs, in contravention of *Buckman* and *Riegel's* intent to keep the gap open. It should be recognized that constricting the gap, as the Eighth Circuit has done, is neither sound public policy nor supported by precedent.

486. See *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 266 (1984) (holding that "it is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct").

In the alternative, to ensure that plaintiffs still have a remedy, the Court could rule that generally applicable requirements such as the MDR have no preemptive effect. This ruling is supported by *Lohr*. If the MDR has no preemptive effect then plaintiff could prevail on the theory that the manufacturer should have strengthened its warnings pursuant to the CBE regulation. A claim premised on a CBE regulation should survive implied preemption because it is based on traditional state law. Further, the Supreme Court held in *Wyeth* that a claim premised on the CBE regulation survives implied preemption including both obstacle and conflict preemption.⁴⁸⁷

However, holding that a generally applicable requirement has no preemptive effect and then following *Wyeth's* implied preemption rationale in regards to medical devices would effectively eliminate the parallel claim exception that the Supreme Court has vigorously tried to preserve.⁴⁸⁸ Instead of looking to device-specific requirements in the PMA, plaintiffs would rely on vague and open-ended industry-wide requirements to escape dismissal. This probably was not the result the Supreme Court intended.⁴⁸⁹ Therefore, recognizing the parallel claim exception but widening it enough to provide means of judicial recourse seems to be the best option.

487. See *supra*, notes 386–92 and accompanying text.

488. See *Riegel*, 552 U.S. at 330; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); see also *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 (2013). The Court has recognized the parallel claim exception in each of these cases.

489. See *Riegel* 552 U.S. at 323–30. In *Riegel*, the Court, which held that a state law claim is preempted when a manufacturer complies with PMA requirements, expressed concern about state law tort claims imposing different or additional requirements under § 360k. For instance, the Court said “state tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.” *Id.* at 325. Hence, the Supreme Court would likely find that a ruling that all generally applicable regulations had no preemptive effect would similarly disrupt the federal scheme. This is because such a ruling would widen the door for plaintiffs who rely on violations of vague and open-ended standards.