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## Preemption of State Law Claims Involving Medical Devices: Why Increasing Liability for Manufacturers is a Perilous but Pivotal Proposition

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# Preemption of State Law Claims Involving Medical Devices: Why Increasing Liability for Manufacturers is a Perilous but Pivotal Proposition

## ABSTRACT

*A circuit split regarding the preemptive scope of the Medical Device Amendments of 1976 (MDA) has widened over the past several years. The split encompasses both the circumstances under which the MDA implicitly preempts state law claims and the scope of the MDA's express preemption provision. Manufacturers of medical devices regulated by the Food and Drug Administration (FDA) enjoyed many years of favorable rulings on the issue of federal preemption and deference to the primacy of FDA jurisdiction on monitoring or enforcement actions. However, the circuit split is reshaping the litigation landscape, and injured plaintiffs may rely on certain Circuit Court of Appeals' cases that have ruled against federal preemption to buttress new or existing product liability claims. Device manufacturers are also changing their approach to tackle the large number of impending lawsuits. This Note proposes resolving the circuit split by condensing the scope of federal preemption and further increasing liability for manufacturers to an unprecedented scale such that the tort regime substantially supplements federal agency enforcement.*

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Steven McCormick can no longer walk, relies on various medications to deal with persistent and excruciating pain, and lives in fear of developing cancer after being implanted with Infuse, a medical device manufactured and marketed by Medtronic.<sup>1</sup> Once a successful engineer for Lockheed Martin, Mr. McCormick’s misfortunes began nearly seventeen years ago when he experienced lower back pain, which slowly increased in severity until it became unbearable. Accordingly, he consulted with Dr. Michael Rosner, one of the best spine surgeons available.<sup>2</sup>

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1. See Statement of Claim at 9, McCormick v. Rosner, No. 2013.203 (Md. Health Care Alternative Dispute Resolution Office Apr. 23, 2013), available at <http://center.mdmalpracticeattorney.com/files/2014/02/SOC2013-203R.pdf>; Brief of Appellants at 9–10, McCormick v. Medtronic, Inc., 101 A.3d 467 (Md. Ct. Spec. App. Feb. 4, 2014) (No. 670), 2014 WL 2093919.

2. Michael K. Rosner, MD, FAANS, SOCIETY OF NEUROLOGICAL SURGEONS, <http://www.societyns.org/society/bio.aspx?memberid=145292/> (last visited Jan. 8, 2014); *Spines of Service Q&A*, SPINAL RESEARCH FOUND., <http://www.spinerf.org/learn/ask-expert-0/spines-service-qa> (last visited Jan. 8, 2014). Patients with chronic, intractable lower back pain often face the harsh reality that the prognosis for recovery with conservative, non-operative management alone is not good. See Gunnar B. J. Andersson et al., *Treatment of Intractable Discogenic Low Back Pain: A Systematic Review of Spinal Fusion and Intradiscal Electrothermal Therapy (IDET)*, 9 PAIN PHYSICIAN 237, 237 (2006). Consequently, such patients are confronted with a choice between living with persistent back pain and possible narcotic dependency or electing to consult a surgeon to potentially undergo operative management with a procedure such as spinal fusion. See *id.*

Thus, when Dr. Rosner recommended a common technique known as spinal fusion—a surgical procedure in which one or more vertebrae of the spine are “fused” together—Mr. McCormick had no reason to question this approach.<sup>3</sup> Dr. Rosner explained that he “intended to achieve fusion by using Infuse . . . a genetically engineered version of a naturally occurring protein that stimulates bone growth.”<sup>4</sup> Dr. Rosner described Infuse as the “latest and best technology” and assured Mr. McCormick that after the procedure, he would be “fit enough to parachute out of airplanes.”<sup>5</sup> What Dr. Rosner never disclosed to Mr. McCormick was that he was a paid consultant for Medtronic.<sup>6</sup>

During surgery, Dr. Rosner implanted Infuse in an “off-label” or unapproved manner.<sup>7</sup> Instead of getting better, Mr. McCormick’s back pain became progressively worse until he was forced to endure additional surgeries and go on disability.<sup>8</sup> Less than a year later, scans confirmed the presence of two nodules in his lungs.<sup>9</sup> Because it is now known that Infuse may be a cancer-causing agent,<sup>10</sup> Mr. McCormick must undergo regular tests to monitor the nodules and ensure that they do not become cancerous.<sup>11</sup>

3. “To achieve the fusion process, surgeons implant a graft—usually bone or bone-like material—around the vertebrae during surgery. Over the following months, a physiological mechanism similar to that which occurs when a fractured bone heals causes the graft to join, or ‘weld,’ the vertebrae together.” Brief of Appellants, *supra* note 1, at 5. While bone graft material was typically harvested from another part of the patient’s body, cost considerations, among other factors, compelled medical device manufacturers to artificially produce bone material for use in the procedure. *Id.* This produced bone-morphogenetic proteins (BMPs), which effectively promoted bone creation and remodeling and could thus serve as bone graft substitutes. See generally Erika H. J. Groeneveld & Elisabeth H. Burger, *Bone Morphogenetic Proteins in Human Bone Regeneration*, 142 EUR. J. ENDOCRINOLOGY 9 (2000).

4. Infuse is a recombinant BMP, which, in 2002, became the first BMP approved for clinical use in spinal fusion procedures. See Kevin S. Cahill et al., *Prevalence, Complications, and Hospital Charges Associated with Use of Bone-Morphogenetic Proteins in Spinal Fusion Procedures*, 302 JAMA 58, 58 (2009). Infuse consists of three components: an absorbable collagen sponge scaffold, a titanium threaded fusion cage, and rhBMP-2. *Coleman v. Medtronic, Inc.*, 167 Cal. Rptr. 3d 300, 304 (Cal. Ct. App. 2014). “During surgery, the doctor infuses the collagen sponge with liquid rhBMP-2 and inserts the sponge into the cage to both stabilize the spine and maintain spacing between the vertebrae during the fusion process.” *Id.*

5. Brief of Appellants, *supra* note 1, at 9. BMP use in spinal fusion procedures has increased exponentially since its introduction. Cahill et al., *supra* note 4, at 60. In the first year of clinical approval, BMP was used in less than 1 percent of all fusions. *Id.* Less than four years later, this had increased to nearly a quarter of all fusions. *Id.*

6. See Statement of Claim, *supra* note 1, at 7.

7. Brief of Appellants, *supra* note 1, at 9.

8. *Id.* at 9–10.

9. *Id.* at 10.

10. See, e.g., Nancy E. Epstein, *Basic Science and Spine Literature Document Bone Morphogenetic Protein Increases Cancer Risk*, 5 SURGICAL NEUROLOGY INT’L. 552, 552 (2014).

11. Brief of Appellants, *supra* note 1, at 10.

Mr. McCormick sued Dr. Rosner and Medtronic in Maryland state court to obtain compensation for his suffering.<sup>12</sup> Unfortunately, the circuit court dismissed all of Mr. McCormick's claims with prejudice and held that they were preempted by federal law.<sup>13</sup> However, the Maryland Court of Special Appeals reversed the lower court's ruling, holding that federal law does not preempt the claims and that Mr. McCormick should be allowed the opportunity to replead fraud with particularity.<sup>14</sup> Final resolution of the case is still pending, but like Steven McCormick, many patients continue to suffer both new and enduring complications from the use of Infuse.<sup>15</sup>

Generally, medical device manufacturers such as Medtronic are subject to an assortment of federal regulations pursuant to the Medical Device Amendments (MDA), which modified the Food, Drug, and Cosmetic Act (FDCA).<sup>16</sup> Because Congress granted enforcement authority to the Food and Drug Administration (FDA), civil plaintiffs are preempted from seeking to impose liability on device manufacturers in state court solely for violations of the FDCA.<sup>17</sup> However, whether state law claims that include allegations of FDCA violations can survive preemption—both express and implied—remains an open question. Previous rulings by the Supreme Court have outlined an extremely narrow “gap” through which state law claims can escape preemption,<sup>18</sup> but recent Circuit Court of Appeals' cases have created a circuit split that denies individuals like Steven McCormick basic justice for their suffering.

Part I of this Note will outline the MDA's classification of medical devices, the potentially laborious device approval process, and the Supreme Court cases that form the manufacturer-friendly foundation for federal preemption of state law claims. Part II will critique the different circuits' approaches to implied and express preemption. Part III will propose a resolution of the circuit split by expanding the extent of state law claims that can escape express and implied preemption. Immunizing medical device manufacturers from

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12. See *McCormick v. Medtronic, Inc.*, 101 A.3d 467, 476–77 (Md. Ct. Spec. App. 2014).

13. *Id.* at 477.

14. *Id.*

15. See, e.g., Jane Mundy, *Medtronic Infuse Bone Graft Leaves Young Father Disabled*, LAWYERSANDSETTLEMENTS.COM (Oct. 31, 2014, 8:00 AM), <http://www.lawyersandsettlements.com/articles/medtronic-infuse-bone-graft/interview-medtronic-lawsuit-bone-graft-14-20215.html>.

16. 21 U.S.C. § 360 (2012).

17. 21 U.S.C. § 335b(b)(1)(a) (2012) (describing the authority of the Secretary of Health and Human Services to enforce civil penalties for FDCA violations).

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

state law tort claims is economically inefficient. Rather, state law liability can complement federal agency enforcement.

## I. PREEMPTION OF STATE CLAIMS INVOLVING PMA-APPROVED MEDICAL DEVICES

### *A. Classes of Medical Devices Under the MDA*

Regulatory approval of the riskiest class of medical devices by the FDA typically involves a laborious premarket approval (PMA) process, but some manufacturers manage to escape via a less stringent 510(k) process. The FDA regulates medical devices pursuant to the FDCA,<sup>19</sup> which was modified by the MDA in 1976.<sup>20</sup> The MDA gave the FDA “new broad powers to regulate medical devices,”<sup>21</sup> and the statute divided devices into three classes. Class I devices present little or no risk to human health and safety and are subject to general controls such as manufacturing and labeling requirements.<sup>22</sup> Class II devices pose a slightly greater risk to human safety and are subject to general controls as well as special controls such as performance standards, post-market surveillance, and patient registries.<sup>23</sup>

A Class III device cannot provide a reasonable assurance of safety and effectiveness under Class I or II controls and is marketed as either a life-supporting device or one that causes an unreasonable risk of illness or injury.<sup>24</sup> As a result, a Class III device is subject to the rigorous PMA process.<sup>25</sup> However, some devices can obtain marketing clearance through a significantly less stringent 510(k) review process, which does not require any independent clinical

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19. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2012).

20. Medical Device Amendments, 21 U.S.C. §§ 360–381 (2012).

21. *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1319 (3d Cir.1995), *cert. denied*, 516 U.S. 815 (1995).

22. 21 U.S.C. § 360c(a)(1)(A) (2012); *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, U.S. FOOD & DRUG ADMIN. (June 4, 2014) [hereinafter *FDA Marketing*], <http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ucm142523.htm> (“[Class I] devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Examples include enema kits and elastic bandages. 47% of medical devices fall under this category and 95% of these are exempt from the regulatory process.”).

23. 21 U.S.C. § 360c(a)(1)(B) (2012); *FDA Marketing*, *supra* note 22 (“Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs and some pregnancy test kits. 43% of medical devices fall under this category.”).

24. 21 U.S.C. § 360c(a)(1)(C) (2012); *FDA Marketing*, *supra* note 22 (“[Class III] devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Examples of Class III devices include implantable pacemakers and breast implants. 10% of medical devices fall under this category.”).

25. 21 U.S.C. § 360c(a)(1)(C) (2012).

testing if the device manufacturer can demonstrate that its product is “substantially equivalent” to an approved product—also known as a predicate device—already on the market.<sup>26</sup>

If a device does not qualify for clearance under the 510(k) process, the device must meet an extensive list of current good manufacturing practice (CGMP) requirements.<sup>27</sup> These requirements set forth a general quality system to ensure the safety and effectiveness of medical devices.<sup>28</sup> In addition, Class III devices may be subject to post-market requirements and regulations regarding labeling,<sup>29</sup> tracking,<sup>30</sup> post-market surveillance,<sup>31</sup> and traceability.<sup>32</sup>

26. See 21 U.S.C. § 360(o)(1)(A) (2012); 21 C.F.R. §§ 807.81, 807.87 (2015). The 510(k) clearance process has been repeatedly criticized as an ineffective means of establishing the safety and effectiveness of new devices. See Benjamin A. Goldberger, *The Evolution of Substantial Equivalence in FDA’s Premarket Review of Medical Devices*, 56 FOOD & DRUG L.J. 317, 331 (2001) (“Justice Stevens reasoned [in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493–94 (1996)] that even though FDA may examine a 510(k) with an eye toward safety and effectiveness, a finding of substantial equivalence is not a statement by FDA about the safety of a device. It is permission simply to market the device without going through the PMA process.”); Michael Van Buren, Note, *Closing the Loopholes in the Regulation of Medical Devices: The Need for Congress to Reevaluate Medical Device Regulation*, 17 HEALTH MATRIX 441, 460 (2007) (“[T]he relative speed of the 510(k) process, as compared to the PMA, increases the likelihood of defective products reaching the market . . . [Congress] should merely modify the 510(k) process and post-market processes as a means of ensuring greater device safety.”); INST. OF MED., MEDICAL DEVICES AND THE PUBLIC’S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 193 (July 2011) (“The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices . . . The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness as long as the standard for clearance is substantial equivalence . . .”). But see Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: The Right Approach for Most Medical Devices*, 69 Food & Drug L.J. 365, 393–94 (2014) (“Courts and commentators since *Lohr* (including the Supreme Court itself) have erred in uncritically extrapolating *Lohr* to the present day . . . [T]he 510(k) process has all or almost all of the attributes that the IOM [Institute of Medicine] Committee suggests should be incorporated in a premarket review system for moderate risk devices.”).

27. 21 U.S.C. § 360j(f) (2012); 21 C.F.R. §§ 820.1–820.250 (2015).

28. 21 C.F.R. § 820.1 (2015). Specifically, the FDA requires device manufacturers to adopt procedures and controls regarding (1) design control; (2) quality assurance programs; (3) adequate written cleaning procedures and schedules to meet manufacturing process specifications; (4) written manufacturing specifications and processing procedures; (5) process validation; (6) written procedures for finished device inspection to assure that device specifications have been met; and (7) corrective and preventive action. *Id.*; see 21 C.F.R. § 820.184 (2015).

29. 21 C.F.R. § 814.80 (2015).

30. 21 C.F.R. § 821.1 (2015).

31. *Id.*; see also 21 C.F.R. §§ 803.50(a), 822 (2015) (requiring manufacturers to report any post-approval information that reasonably suggests that the device (1) “[m]ay have caused or contributed to a death or serious injury” or (2) “[h]as malfunctioned” and that any recurring malfunction “would be likely to cause or contribute to a death or serious injury”).

32. *Id.*; see also § 820.65 (2015). The FDA is undertaking a new post-market device surveillance plan that involves labeling every implantable device with a standardized, traceable code, which will allow regulators and researchers to better track implants’ performance and note any safety issues that arise. See Josh Rising & Ben Moscovitch, *The Food and Drug*

As a result, the PMA process is laborious for device manufacturers. It requires a multi-volume application including reports of all studies and investigations of the device's safety and effectiveness previously published or that should reasonably be known.<sup>33</sup> In addition, the FDA may refer it to a panel of outside experts,<sup>34</sup> and may request additional data from the manufacturer,<sup>35</sup> before deciding whether to approve the application. Hence, it should come as no surprise that most device approval applications are filed under the significantly "weaker" 510(k) process, which raises concerns about the specifics underlying device approvals and the scope of device-related liability under state and federal law.

### *B. Implied Preemption of State Law Claims Under Buckman*

The Supreme Court has ruled that the MDA implicitly preempts certain state law claims, and that a presumption against preemption only applies in certain scenarios. The Supremacy Clause of the US Constitution<sup>36</sup> invalidates state laws that conflict with federal statutes and regulations.<sup>37</sup> The debate over whether courts should adopt a presumption for or against preemption<sup>38</sup> remains unresolved in the medical device context, but the Supreme Court has made certain pronouncements that shed light on the issue. Three cases in particular outline whether and when state law claims involving medical devices are federally preempted.<sup>39</sup>

In 2001, the Supreme Court held that the MDA implicitly preempted a state law fraud-against-the-FDA claim based on FDA rules about product approval.<sup>40</sup> *Buckman Co. v. Plaintiffs' Legal*

*Administration's Unique Device Identification System: Better Postmarket Data on the Safety and Effectiveness of Medical Devices*, 174 JAMA INTERN. MED. 1719, 1719 (Sept. 29, 2014).

33. 21 U.S.C. § 360e(c)(1) (2012).

34. 21 C.F.R. § 814.44(a) (2015).

35. 21 U.S.C. § 360e(c)(1)(H).

36. U.S. CONST., art. VI, cl. 2 ("[T]he Laws of the United States . . . shall be the supreme Law of the Land . . .").

37. See *Hillsborough Cty. v. Automated Med. Labs.*, 471 U.S. 707, 712–13 (1985).

38. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580 (2011) ("[T]he Supremacy Clause therefore suggests that federal law should be understood to impliedly repeal conflicting state law. Further, the provision suggests that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law."). *But see id.* at 2591 (Sotomayor, J., dissenting) ("For more than half a century, we have directed courts to presume that congressional action does *not* supersede 'the historic police powers of the States . . . unless that was the clear and manifest purpose of Congress.") (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("[W]e have long presumed that Congress does not cavalierly pre-empt state-law causes of action.").

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

40. See *Buckman*, 531 U.S. at 348.



*Committee* involved plaintiffs claiming injuries from the use of orthopedic bone screws.<sup>41</sup> The plaintiffs sued Buckman Company, a consulting company that had assisted the screws' manufacturer in bypassing the difficult PMA process for Class III medical devices and receiving 510(k) clearance.<sup>42</sup> The plaintiffs argued that Buckman made fraudulent representations to the FDA regarding the screws' intended use in order to receive this clearance, and asserted state tort claims characterized as fraud-on-the-FDA claims.<sup>43</sup>

The Court assumed that a presumption against preemption existed, but only in situations where the historic primacy of states in regulating matters of health and safety might raise federalism concerns.<sup>44</sup> Here, the Court did not believe fraud against federal agencies qualified as "a field which the States have traditionally occupied."<sup>45</sup> Instead, the situation before the Court involved an inherently federal relationship, and thus, the presumption against preemption did not apply.<sup>46</sup> Accordingly, the plaintiffs' claims conflicted with federal law—due to the federal statutory scheme empowering the FDA to deter and punish fraud against the agency<sup>47</sup>—and were implicitly preempted.<sup>48</sup>

The Court in *Buckman* focused on the importance of entrusting the FDA with exclusive authority to approve and enforce medical device regulations.<sup>49</sup> However, there remained the unaddressed fact that none of the agency's enforcement mechanisms includes a private right of action that would allow injured plaintiffs to be adequately compensated for injuries resulting from manufacturer non-compliance.<sup>50</sup> This is one of the underlying reasons why plaintiffs may seek redress under state law.

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41. *Id.* at 343.

42. *Id.* at 346.

43. *Id.* at 346–47.

44. *Id.* at 348 (citing *Lohr*, 518 U.S. at 485).

45. *Id.* at 347.

46. *Id.* at 347–48.

47. *See id.* at 350 (explaining that (1) allowing state-law fraud-on-the-FDA claims would conflict with the FDA's responsibility to monitor fraud, and (2) medical device manufacturers would face dramatically increased burdens—burdens not contemplated by Congress in enacting the FDCA and the MDA—if forced to comply with the FDA's detailed regime in the shadow of fifty state tort regimes).

48. *Id.* at 348. Because the Court found implied preemption, it did not express a view regarding whether the claims would also be subject to express preemption under the MDA's explicit preemption clause. *See id.* n.2.

49. *See id.* at 349–50.

50. Marcia Boumil, *FDA Approval of Drugs and Devices: Preemption of State Laws for "Parallel" Tort Claims*, 18 J. HEALTH CARE L. & POL'Y 1, 31 (2015).

*C. Express Preemption of State Law Claims Under Riegel and Lohr*

After *Buckman*, it would take the Supreme Court seven years to address the MDA's preemption clause and rule that it expressly bars state law claims involving devices approved under the exhaustive, multi-step PMA process.<sup>51</sup> In particular, the MDA expressly preempts any state law requirement that adds to, or is different from, a safety or effectiveness requirement established under the MDA.<sup>52</sup>

In *Riegel v. Medtronic, Inc.*, plaintiffs sued Medtronic after a PMA-approved Class III cardiac catheter in the lead plaintiff's coronary artery ruptured and required emergency surgery.<sup>53</sup> The Court held that the MDA established a rigorous federal regulatory process for ensuring the safety of medical devices,<sup>54</sup> and the plain language of the MDA's preemption clause explicitly provided that no state may set requirements that differ from or add to the federal ones.<sup>55</sup>

*Riegel* differentiated and limited the earlier holding of *Medtronic, Inc. v. Lohr*,<sup>56</sup> in which preemption was not found for claims arising from alleged defects in a heart pacemaker lead cleared via the 510(k) "substantially equivalent" process.<sup>57</sup> Applying a presumption against preemption, the Court in *Lohr* held that the plaintiff's claims were not expressly preempted because the FDA had merely determined equivalency to a predicate device, rather than making a sufficient determination of safety and effectiveness.<sup>58</sup> In making this distinction, the Court strongly distinguished the "rigorous" PMA process from the "limited" nature of 510(k) review.<sup>59</sup>

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51. See *supra* Part I.A (explaining the details and steps of the PMA process).

52. 21 U.S.C. § 360k(a) (2012). An implementing regulation clarifies that state or local requirements are preempted only when (1) the FDA has established specific counterpart regulations, or (2) there are other specific requirements applicable to a particular device under the FDCA, thereby making any existing divergent state or local requirements applicable to the device different from, or in addition to, the specific FDA requirements. 21 C.F.R. § 808.1(d) (2015). The regulation also clarifies that Section 360k does not preempt state or local requirements that are equal to, or substantially identical to, requirements imposed by or under the [FDCA]. *Id.*

53. 552 U.S. 312, 320 (2008).

54. *Id.* at 323.

55. See *id.* at 324–25 (“[I]t is implausible that the MDA was meant to ‘grant greater power (to set state standards “different from, or in addition to,” federal standards) to a single state jury than to state officials acting through administrative or legislative lawmaking processes.’”).

56. 518 U.S. 470, 471 (1996).

57. See *id.*

58. *Id.* at 495.

59. *Id.* at 477–79.

## II. IMPOSING INCREASED LIABILITY ON MEDICAL DEVICE MANUFACTURERS MAY RESOLVE THE DEEPENING CIRCUIT SPLIT

While *Lohr* and *Riegel* fell on different sides of the line between two types of FDA review for medical devices, the Court acknowledged in both cases that some state law claims may survive MDA preemption. In *Lohr*, the Court correctly noted that “[n]othing 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.”<sup>60</sup> The Court echoed this observation in *Riegel*.<sup>61</sup>

Since *Riegel*, various circuit courts have addressed the issue of whether federal law preempts state law claims against medical device manufacturers that “parallel” federal requirements. Instead of narrowing the scope of *Buckman*’s implied preemption and *Riegel*’s express preemption, a circuit split has emerged regarding the narrow “gap” through which a plaintiff’s claims can escape both implied and express preemption. Three circuits have widened this gap, while other circuits have adhered to defendant-friendly precedents in favoring federal preemption or have thwarted plaintiffs by requiring them to plead a violation of a device-specific requirement. This Note proposes that the Supreme Court should enlarge the “no-preemption” gap to resolve the circuit split and eliminate any uncertainty regarding federal preemption.<sup>62</sup>

### *A. The Fifth, Seventh, and Ninth Circuits Correctly Ruled Against Federal Preemption and Eased Plaintiffs’ Pleading Burden*

The Fifth, Seventh, and Ninth Circuits have dramatically changed the outlook of medical device litigation by ruling against federal preemption.<sup>63</sup> In one case, the plaintiff alleged a violation of a state duty-to-warn law based on the manufacturer’s failure to comply with the FDA’s Class III device reporting regulations by not reporting the device’s previous injuries and malfunctions.<sup>64</sup> The Fifth Circuit

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60. *Id.* at 495 (emphasis added).

61. *Riegel*, 552 U.S. at 330 (“State requirements are pre-empted under the MDA only to the extent that they are ‘different from, or in addition to’ the requirements imposed by federal law. Thus, § 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.”) (citations omitted).

62. *See infra* Part III.

63. *See Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013), *cert. denied*, 134 S. Ct. 2839 (2014); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), *cert. denied*, 132 S. Ct. 498 (2011).

64. *See Hughes*, 631 F.3d at 765–66.

upheld the claim because it paralleled the federal requirements without imposing any additional requirements.<sup>65</sup> However, unsubstantiated allegations of an FDA regulatory violation are insufficient.<sup>66</sup> A plaintiff's claims are truly "parallel" when they identify specific FDA processes and procedures that were violated and caused the alleged injury.<sup>67</sup>

Under this reasoning, a medical device manufacturer is exposed to state liability whenever the manufacturer has violated analogous federal requirements.<sup>68</sup> This supports relaxing the plaintiffs' evidentiary burdens at the outset of a trial. Cases against medical device manufacturers should often progress to formal discovery, as such discovery is "necessary" for a plaintiff "to provide a detailed statement of the specific bases for her claim."<sup>69</sup> Appropriately, this rule would help plaintiffs defeat motions to

65. See *id.* at 771–72. In response to an argument by the defendant that only the FDA, not juries, should be allowed to determine non-compliance with federal requirements, the court held that neither a formal finding nor an enforcement action by the FDA was required to show a violation of such requirements. See *id.* at 772–73.

66. *Id.* at 773. The court noted that the plaintiff's allegations here were "not conclusory" as she "presented evidence that supports the view that [the defendant] violated the plain text of the [medical device reporting] regulations." *Id.* Compare *id.*, with *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (recognizing that injuries resulting from impurities in the manufacturing process could lead to a parallel claim; however, the complaint in question was "impermissibly conclusory and vague" as it did "not specify the manufacturing defect [or] a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury, nor d[id] the complaint tell [the court] how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process").

67. See *Bass v. Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012) ("In support of the allegations . . . , [the plaintiff] pleaded that [the defendant] initiated a recall on its [product], and that the recall 'included Plaintiff's specific hip device.' [The plaintiff] also alleged that the FDA sent a warning letter to [the defendant] five months before his surgery, which included a notice that [the defendant] failed to verify and implement changes . . .").

68. See *id.* at 510, 516 ("Under *Funk* and *Hughes*, [the plaintiff] has sufficiently pleaded parallel claims . . . to the extent that the claims are based upon manufacturing defects resulting from violations of federal regulations . . . The Court [in *Riegel*] explicitly stated 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."); *Hughes*, 631 F.3d at 767 ("*Riegel* and *Lohr* . . . make clear that a manufacturer is not protected from state tort liability when the claim is based on the manufacturer's violation of applicable federal requirements."); *Bausch*, 630 F.3d at 558 (concluding that the plaintiff's state law claims were neither expressly nor implicitly preempted as "federal law does not preempt parallel claims under state law based on a medical device manufacturer's violation of federal law").

69. *Bausch*, 630 F.3d at 558; see also *id.* at 554 ("[P]laintiffs [cannot] be expected to plead their claims with greater specificity without discovery to obtain access to confidential government and company documents.") (citing *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1209–14 (8th Cir. 2010) (Melloy, J., concurring in part and dissenting in part)).

dismiss based on federal preemption, which have been manufacturers' most potent weapon.<sup>70</sup>

A lower pleading standard is also supported by the fact that federal requirements are contained in PMA agreements that are nearly always confidential.<sup>71</sup> This confidentiality creates a problem for the injured plaintiff: to obtain discovery, the complaint must contain enough factual material to state a plausible claim.<sup>72</sup> However, all of the relevant factual material may be confidential and thereby out of reach.<sup>73</sup> The problem arises from the heightened pleading standards outlined by *Bell Atlantic Corp. v. Twombly*<sup>74</sup> and *Ashcroft v. Iqbal*,<sup>75</sup> and it leaves injured consumers uncompensated and device manufacturers under-deterred.<sup>76</sup> In the specific case of parallel claims against device manufacturers, these pleading standards have been described as a “grave,”<sup>77</sup> “astronomical,”<sup>78</sup> “insurmountable,”<sup>79</sup> and “virtually impossible” burden for plaintiffs.<sup>80</sup> In other words, “plaintiffs need the facts to get discovery, but they need discovery to

70. See MICHAEL K. BROWN ET AL., REED SMITH LLP, MEDICAL DEVICE PREEMPTION—IS THERE LIFE FOR PLAINTIFFS' CLAIMS AFTER *RIEGEL V. MEDTRONIC, INC?* (2012), available at [http://www.dri.org/DRI/course-materials/2012-DMD/pdfs/12\\_Brown.pdf](http://www.dri.org/DRI/course-materials/2012-DMD/pdfs/12_Brown.pdf) (“Federal preemption remains one of the most powerful defenses available to a medical device manufacturer facing a tort lawsuit involving a product approved by the FDA’s Premarket Approval (or PMA) process.”).

71. Cameron T. Norris, *Drugs, Devices, & Discovery: Using Fee-Shifting to Resolve the Twombly/Iqbal Problem for Parallel Claims Under the FDCA 1* (2014) (unpublished note), available at [http://www.americanbar.org/content/dam/aba/administrative/tips/lswc\\_cameronnorris.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/administrative/tips/lswc_cameronnorris.authcheckdam.pdf).

72. See Jonah B. Gelbach, *Locking the Doors to Discovery? Assessing the Effects of Twombly and Iqbal on Access to Discovery*, 121 YALE L.J. 2270, 2270 (2012) (“[E]mpirical results suggest that . . . *Twombly* and *Iqbal* have negatively affected plaintiffs in at least 15% to 21% of cases that faced Rule 12(b)(6) motions in the post-*Iqbal* data window.”); William M. Janssen, *Iqbal “Plausibility” in Pharmaceutical and Medical Device Litigation*, 71 LA. L. REV. 541, 541 (2011) (“In tandem, [*Twombly* and *Iqbal*] represent the Court’s resolve that speculation of wrongdoing will not be sufficient to unlock the doors to civil litigation in federal court. Instead, as *Iqbal* made firm, a plaintiff is now required to plead a claim that is factually “plausible” to avoid dismissal.”).

73. See 21 C.F.R. § 814.9 (2015).

74. 550 U.S. 544 (2007).

75. 556 U.S. 662 (2009).

76. Norris, *supra* note 71, at 2.

77. Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Plaintiffs*, 35 S. ILL. U. L.J. 453, 454 (2011).

78. Malika Kanodia, *The Fate of the Injured Patient in the Wake of Riegel v. Medtronic: Should Congress Interject?*, 32 HAMLINE L. REV. 791, 827 (2009).

79. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1209 (8th Cir. 2010) (Melloy, J., concurring in part and dissenting in part).

80. Ashley A. Williams, *Surviving Medical Device Preemption Under 21 U.S.C. 360k: Clarifying Pleading Standards for Parallel Claims in the Wake of Twombly and Iqbal*, 9 SETON HALL CIRCUIT REV. 109, 130 (2013).

get the facts.”<sup>81</sup> It is thus sensible for courts to relax plaintiffs’ evidentiary burdens in medical device injury cases. Otherwise, plaintiffs may have no way of obtaining the information to prove the elements of their claims at the pleading stage.

The Ninth Circuit recently followed this line of reasoning in an *en banc* decision finding that state law failure-to-warn claims that parallel federal requirements are not expressly or implicitly preempted.<sup>82</sup> In *Stengel v. Medtronic, Inc.*, a Class III medical device’s risk of causing paralysis was not known at the time of PMA approval, but it became known to the manufacturer after approval but prior to the plaintiff’s injury.<sup>83</sup> However, the manufacturer failed to inform the FDA.<sup>84</sup> The plaintiffs claimed that the manufacturer was negligent under state law because it violated the federal MDA requirements to report adverse event information to the FDA.<sup>85</sup> The Ninth Circuit noted that *Riegel* expressly preserved claims alleging violation of state duties that “parallel,” rather than add to, federal requirements applicable to the device.<sup>86</sup> Specifically, a state law duty-to-warn “contemplates a warning to a third party such as the FDA,” and this is genuinely equivalent to the analogous federal duty under the MDA.<sup>87</sup>

While the court in *Stengel* did not rule on the claim’s merits, it found the claim based on a state duty-to-warn law could be distinguished from the PMA process at issue in *Buckman* because the state law duty paralleled a federal law duty under the MDA, as in *Lohr*.<sup>88</sup> The court further held that the claim was not implicitly

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81. Norris, *supra* note 71, at 11.

82. See *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013), *cert. denied*, 134 S. Ct. 2839 (2014).

83. *Id.* at 1227.

84. *Id.* at 1226; see 21 U.S.C. § 360i(a) (2012); 21 C.F.R. § 803.50(a) (2015) (“If you are a manufacturer, you must report . . . information . . . that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury, or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.”).

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

86. See *id.* at 1228 (“The rule that emerges from [*Lohr*, *Buckman*, and *Riegel*] is that the MDA does not preempt a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA.”).

87. *Id.* at 1233. Note that there is precedent to apply a genuine equivalence standard to determine parallelism. See, for example, *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005), in which the Seventh Circuit explained, “[i]n order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are ‘genuinely equivalent.’ State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.”

88. See *Stengel*, 704 F.3d at 1234 (Watford, J., concurring) (“[T]he [plaintiffs’] negligence claim is not expressly preempted because it seeks to hold Medtronic accountable only for failing

preempted given the crucial function of state law in “regulating the adequacy of post-sale warnings for products already on the market.”<sup>89</sup> In contrast to fraud against a federal agency, states have traditionally regulated post-sale warnings.<sup>90</sup> This fact triggers the presumption against preemption and creates another plaintiff-friendly ruling.<sup>91</sup> Not only does the Ninth Circuit’s ruling move away from preemption of parallel state law claims, it also demonstrates that the tort regime can serve a complementary role to the FDA’s regulation.

Admittedly, such rulings increase legal uncertainty for manufacturers involved in products liability cases. A manufacturer that complies with the FDA’s requirements would justifiably feel misled if it found itself liable under states’ laws. This is one reason why manufacturers of FDA-regulated medical devices enjoyed many years of favorable rulings. However, the Supreme Court recently declined to review *Stengel*,<sup>92</sup> indicating at least tacit approval of the reasoning. Thus, injured plaintiffs can rely on the Ninth Circuit’s reasoning to buttress new or existing product liability claims while manufacturers may be forced to change their approach in tackling the large number of potential lawsuits.

### *B. The Sixth and Eighth Circuits Stubbornly Cling to the Defendant-Friendly Rulings of Buckman and Riegel*

The Sixth and Eighth Circuits have found preemption even for state law claims of manufacturing defects based on a violation of a federal duty under the MDA.<sup>93</sup> Both circuits have ruled that post-sale failure-to-warn and failure-to-recall claims were expressly preempted by Section 360k under *Riegel* because they imposed requirements that were “different from” or “in addition to” federal requirements.<sup>94</sup>

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to do what federal law mandated—nothing more. The state law duty, as alleged by the [plaintiffs], is precisely parallel to the duties imposed by federal law.”)

89. *Id.* at 1235 (Watford, J., concurring).

90. *See* *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347 (2001).

91. *See id.*; *Stengel*, 704 F.3d at 1227.

92. *Stengel v. Medtronic, Inc.*, 134 S. Ct. 2839 (2014).

93. *See generally In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1203 (8th Cir. 2010); *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005), *cert. denied sub nom. Knisley v. Medtronic, Inc.*, 546 U.S. 935 (2005).

94. *See e.g., Sprint Fidelis*, 623 F.3d at 1205 (“The FDA’s PMA approval includes specific language for Class III device labels and warnings. Plaintiffs did not allege that Medtronic modified or failed to include FDA-approved warnings. Rather, they alleged that, by reason of state law, Medtronic was required to give additional warnings, precisely the type of state requirement that is ‘different from or in addition to’ the federal requirement and therefore preempted.” (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008))); *Cupek*, 405 F.3d at 424 (“Any claim, under state law . . . that Defendant failed to warn patients beyond warnings required by the FDA, or that Defendant failed to recall a product without first going through the

Similarly, a negligence per se claim for failing to comply with the FDA's conditions of approval was deemed to be a "disguised fraud-on-the-FDA claim" and thereby implicitly preempted under *Buckman*.<sup>95</sup>

Various circuits have also ruled diametrically on similar state law allegations of "failure to report." The Fifth and Ninth Circuits have determined that these claims are different from the fraud-on-the-FDA theory in *Buckman* and thus not implicitly preempted.<sup>96</sup> Conversely, the Eighth Circuit reached the same result as the Sixth Circuit but relied on different reasoning.<sup>97</sup> The Sixth and Eighth Circuits' adherence to the defendant-friendly rulings of *Buckman* and *Riegel* is misguided. *Riegel* "virtually ensure[d] that medical device manufacturers enjoy legal immunity from injury claims involving products that have secured premarket approval from the FDA."<sup>98</sup> Such unqualified immunity for manufacturers is improper in the medical device context; medical devices are inherently risky and no approval process can guarantee perfect safety.<sup>99</sup>

Similarly, the Court in *Buckman* implicitly preempted fraud-on-the-FDA claims; however, the Court's reasoning was based on policy instead of statute and is not readily applicable to parallel

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PMA supplement process would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA application and supplement process.").

95. *Cupek*, 405 F.3d at 424.

96. *See Stengel*, 704 F.3d at 1235 (Warford, J., concurring) ("In this case, Medtronic's failure to report was more than a mere misrepresentation to the FDA because it simultaneously misled the device's current and potential users, to whom Medtronic owed an independent duty under state law."). *Compare* *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 775 (5th Cir. 2011) ("[The plaintiffs] claim is not analogous to the 'fraud-on-the-FDA' theory in *Buckman*. The plaintiffs in *Buckman* were attempting to assert a freestanding federal cause of action based on violation of the FDA's regulations; the plaintiffs did not assert violation of a state tort duty. In contrast, [the plaintiff here] is asserting a [state] tort claim based on the underlying state duty to warn about the dangers or risks of product."), and *Stengel*, 704 F.3d at 1233 ("The [plaintiffs'] new claim specifically alleges, as a violation of [state] law, a failure to warn the FDA . . . we hold, under *Lohr*, *Buckman*, and *Riegel*, that this claim is not preempted, either expressly or impliedly, by the MDA."), with *Cupek*, 405 F.3d at 423 ("[C]ount IV [alleging Defendant's 'Negligence Per Se' in its 'failure to comply with the FDA's conditions of approval'] was preempted because it was, in essence, a disguised fraud on the FDA claim.").

97. *See In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1160–61 (D. Minn. 2009) ("[W]hat plaintiffs are . . . alleging is that Medtronic violated the FDCA by failing to inform the FDA in a timely fashion of adverse lead events. Such a claim necessarily fails, because no private right of action exists under the FDCA . . . Such claims are impliedly preempted by 21 U.S.C. § 337(a), which states that all proceedings for the enforcement or to restrain violations of the FDCA 'shall be by and in the name of the United States.' Hence, 'the FDCA leaves no doubt that it is the Federal Government rather than private litigants [which is] authorized to file suit for noncompliance with the medical device provisions.'").

98. *Kanodia*, *supra* note 78, at 794.

99. *See Riegel*, 552 U.S. at 337–38 (Ginsburg, J., dissenting).



claims based on violations of industry-wide FDA regulations.<sup>100</sup> Such parallel claims differ from fraud-on-the-agency claims in a number of ways: (1) they can rely on a “traditional state tort” rather than impermissibly depending on an implied cause of action under federal statute; (2) they serve a clearer compensatory purpose given their basis in tort law; and (3) they are more likely to complement the FDA’s enforcement actions without significant risk of disruption.<sup>101</sup> These differences would support the Ninth Circuit’s ruling against preemption of parallel state law claims.

The Court in *Riegel* preempted non-parallel claims to avoid unfairly burdening medical device manufacturers with “conflicting requirements based on inexpert determinations of safety and effectiveness.”<sup>102</sup> Industry-wide FDA regulations such as CGMPs differ as they allow manufacturers to control the flexibility of their manufacturing and production procedures.<sup>103</sup> Such regulations provide the opportunity for manufacturers to follow “precise and detailed manufacturing and production processes” from the outset, which should reduce the risk of legal liability.<sup>104</sup> In addition, the danger of parallel claims based on violations of industry-wide regulations producing fractured interpretations among federal district courts was addressed and subsequently dismissed by the Seventh Circuit.<sup>105</sup> The Seventh Circuit felt comfortable in relying on the federal appeals process, among other solutions, which “theoretically should push questions of federal law toward uniform interpretation and resolution.”<sup>106</sup>

Overall, the reasoning used by the Court in *Buckman* and *Riegel* to protect medical device manufacturers is unnecessary and harmful to consumers. Circuit courts that continue to rely on it to preempt parallel state law claims may be encroaching upon a basic principle of statutory interpretation—courts shall defer to any expressly manifested intent of Congress.<sup>107</sup> While further reducing

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100. Elliot S. 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, 1215 (2011).

101. *See id.*

102. *Id.* at 1216–17.

103. *Id.* at 1217. *See also In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir. 2010) (explaining that CGMPs provide “general objectives for all device manufacturers” and can be applied to all medical devices).

104. *Sprint Fidelis*, 623 F.3d at 1206.

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

106. Tarloff, *supra* note 100, at 1217.

107. *See* Jamelle C. Sharpe, *Legislating Preemption*, 53 WM. & MARY L. REV. 163, 175 (2011). (“[W]hen preemption issues are framed for judicial resolution, the Supreme Court has steadfastly maintained that the inquiry is driven by whether Congress manifested some intent to

the scope of federal preemption may impede innovation and development of new devices, it appears “that the major concern of Congress in enacting the MDA was the protection of public health and safety from defective and dangerous devices.”<sup>108</sup> Minimizing the scope of federal preemption and allowing state tort liability to work in conjunction with the FDA’s enforcement scheme to solve medical device safety issues best serve this concern.<sup>109</sup>

*C. The Fourth, Eighth, and Eleventh Circuits Require Injured Plaintiffs to Impossibly Plead Violations of Device-Specific Requirements*

The Fourth, Eighth, and Eleventh Circuits have required plaintiffs to plead a violation of a device-specific requirement set forth in the PMA, rather than a general violation of federal regulations.<sup>110</sup> In other words, a state law claim is not “parallel” if the underlying claim is based on a generalized or industry-wide federal duty that applies to all medical devices, rather than to a device-specific federal requirement. In one case, the court held that imposing liability on manufacturers for violating a general federal requirement would be akin to enforcing a “heightened standard beyond that of the FDA—which is impermissible under *Riegel*.”<sup>111</sup>

A later case clarified that plaintiffs must set forth facts pointing to specific violations of PMA requirements.<sup>112</sup> Meeting the requirement involves providing factual details to substantiate the allegations.<sup>113</sup> A clear split exists on the level of specificity required for the allegedly violated requirement. The Fifth, Seventh, and Ninth

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displace state law with federal legislation.”); see also *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (“The purpose of Congress is the ultimate touchstone’ in every pre-emption case.” (quoting *Retail Clerks Int’l Ass’n v. Schermerhorn*, 375 U.S. 96, 103 (1963))).

108. Susan M. Mesner, *Medical Device Technology: Does Federal Regulation of This New Frontier Preempt the Consumer’s State Common Law Claims Arising from Injuries Relating to Defective Medical Devices?*, 7 J.L. & HEALTH 253, 294 (1993).

109. See *infra* Part III.

110. See *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012), cert. denied 133 S. Ct. 162 (2012); *Wolicki-Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296 (11th Cir. 2011); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010).

111. See *Walker*, 670 F.3d at 578.

112. *Wolicki-Gables*, 634 F.3d at 1301 (“Parallel claims must be specifically stated in the initial pleadings. A plaintiff must allege that [the] defendant violated a particular federal specification referring to the device at issue.” (citing *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009))).

113. *Id.* (“Plaintiffs cannot simply incant the magic words ‘[Appellees] violated FDA regulations’ in order to avoid preemption. . . . A plaintiff must allege that the defendant violated a particular federal specification referring to the device at issue.”) (citations omitted) (internal quotation marks omitted).

Circuits have held that the MDA does not expressly preempt state law claims based on alleged violations of federal regulations generally applicable to all medical devices.<sup>114</sup> But the Fourth, Eighth, and Eleventh Circuits' demand for plaintiffs to plead violations of device-specific requirements revives the dilemma of mandating plaintiffs to include facts in their pleadings that may not be accessible until discovery. Thus, under a proper application of *Twombly* and *Iqbal*, plaintiffs bringing parallel claims against Class III device manufacturers face an impossible pleading standard due to the confidentiality of PMA agreements.<sup>115</sup>

Courts should relax plaintiffs' pleading burdens in these cases. This suggestion may appear to contradict *Twombly*, in which the Court held that "some threshold of plausibility must be crossed *at the outset* before a . . . case should be permitted to go into its inevitably costly and protracted discovery phase."<sup>116</sup> However, allowing these claims to proceed to discovery is necessary to achieve Congress's primary goal of ensuring patient safety.<sup>117</sup> Resolution of the circuit split by expanding device manufacturer liability and reducing the scope of federal preemption of parallel state law claims is the first step in this direction.

#### *D. The Circuit Split Encapsulated*

Some courts and scholars have construed *Lohr* and *Riegel* expansively as holding that parallel claims are not preempted under any form of preemption.<sup>118</sup> Under that interpretation, *Buckman*—a

114. See *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013), *cert. denied*, 134 S. Ct. 2839 (2014) (holding that plaintiff's claims were not preempted despite being based on a general duty of reasonable care, which is violated by failure to warn the FDA); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) (holding that plaintiff's claim was not expressly preempted despite being based on the generally applicable federal requirement to submit adverse event reports to the FDA); *Bausch v. Stryker Corp.*, 630 F.3d 546, 554 (7th Cir. 2010) (holding that plaintiff's claims were not expressly preempted despite being based on alleged CGMP violations).

115. See *Norris*, *supra* note 71, at 15.

116. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (citation omitted) (emphasis added); see also *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009) ("Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.")

117. One possible solution is a "sliding scale," where the plaintiff's burden is "commensurate with the amount of information available . . ." See *Bausch*, 630 F.3d at 561. It has also been suggested that rigid application of *Twombly* is particularly inappropriate since all that would be required is "the grant of a request for focused discovery that will involve truly de minimis costs," which would not infringe upon "concerns for efficient case administration . . ." See *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1210 (8th Cir. 2010) (Melloy, J., concurring in part and dissenting in part).

118. See, e.g., *Stengel*, 704 F.3d at 1228, 1230; *Farm Raised Salmon Cases*, 175 P.3d 1170, 1181–82 (Cal. 2008), *cert. denied sub nom. Albertson's Inc. v. Kanter*, 555 U.S. 1097 (2009);

case where a parallel claim was preempted specifically by implied preemption—would appear to be of limited use or applicability. But this reading of *Lohr* and *Riegel* is incomplete. In *Buckman*, the Court cautioned that *Lohr* “did not . . . address . . . implied pre-emption. . . .”<sup>119</sup> Nor was implied preemption at issue in *Riegel*.<sup>120</sup> Instead, *Lohr* and *Riegel* outlined the contours of express preemption, while *Buckman* outlined the contours of implied preemption. Only all three cases, taken together, can provide an accurate view of the narrow “gap” through which a plaintiff’s state-law claim must fit in order to escape both express and implied preemption.<sup>121</sup>

The three cases suggest a two-step analysis: (1) the alleged conduct must violate the FDCA, and (2) the plaintiff must have a cause of action under state law independent of the FDCA.<sup>122</sup> However, whether specific claims fall into this gap is the issue underlying the circuit split that has emerged over the past several years.

Most recently, the Ninth Circuit aligned itself with the Fifth and Seventh Circuits in concluding that *Buckman* does not implicitly preempt state-law claims alleging a failure to report adverse events to the FDA.<sup>123</sup> These Circuits interpreted *Buckman* narrowly, finding that state law causes of action that refer to federal statutes and regulations as providing the basis for state law liability escape implied preemption because they remain based in traditional tort law.<sup>124</sup> In essence, these circuits widened the plaintiff-friendly gap between *Riegel* and *Buckman*.

This holding stands in stark contrast to the position taken by the Sixth and Eighth Circuits, which interpreted *Buckman* broadly to mean that a state law claim could survive implied preemption only if

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see also *Bass v. Stryker Corp.*, 669 F.3d 501, 514 (5th Cir. 2012) (interpreting *Riegel* as “unequivocally” precluding even implied preemption of “parallel” claims).

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

120. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 345 (2008) (Ginsburg, J., dissenting) (noting that respondent “relie[d] exclusively on §360k and [did] not argue [implied] preemption”).

121. See Jean M. Eggen, *Navigating Between Scylla and Charybdis: Preemption of Medical Device “Parallel Claims,”* 9 J. HEALTH & BIOMED. L. 159, 161 (2013) (“[T]he preemption doctrine has created ‘a narrow gap through which a plaintiff’s state-law claim must fit if it is to escape express or implied preemption’—the Scylla and Charybdis of Greek mythology, dual hazards that few sailors survived.” (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009))).

122. See *Sprint Fidelis*, 623 F.3d at 1204.

123. See *Stengel*, 704 F.3d at 1230; *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 775 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546, 556–58 (7th Cir. 2010).

124. See *Hughes*, 631 F.3d at 775 (“Because [the plaintiff] is asserting a recognized state tort claim, her claim is comparable to the tort claims in *Silkwood* and *Lohr* that *Buckman* recognized as surviving implied preemption.” (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 481 (1996); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984))); *Bausch*, 630 F.3d at 558 (holding that the plaintiff’s negligence claims were not implicitly preempted under *Buckman* because the plaintiffs were asserting breach of a recognized state-law duty).

it relied “on traditional state tort law which had predated the federal enactment in question.”<sup>125</sup> An equally sharp divide exists regarding express preemption, with the Fifth, Seventh, and Ninth Circuits sharply disagreeing with the Fourth, Eighth, and Eleventh Circuits about whether a tort plaintiff may successfully invoke the parallel claims exception when the federal requirement is a generalized federal duty, rather than one that is specific to the medical device at issue. However, a strict application of the *Twombly* and *Iqbal* pleading standards would render most, if not all, plaintiffs’ claims unable to progress past the pleading stage. Given the inherent risk involved with the continued use of most medical devices, combined with the Supreme Court’s refusal to resolve the circuit split, foreclosing plaintiffs’ options for redress at the pleading stage of lawsuits essentially blocks all paths to compensation. Instead, a more reasonable solution is to widen the plaintiff-friendly gap between *Riegel* and *Buckman* even further than the approach taken by the Fifth, Seventh, and Ninth Circuits.

#### *E. Effects of the Denial of Certiorari to Resolve the Circuit Split*

While *Stengel* most recently addressed the issue of federal preemption of state law claims, it has been argued that the issue of preemption can be avoided entirely in that case. Prior to the Supreme Court denying certiorari to review the *en banc* decision, the Court made a rare invitation for the Solicitor General to file a brief on the issue.<sup>126</sup> In his brief, the Solicitor General claimed that the Ninth Circuit *en banc* panel had used the wrong reasoning, but that the case was still not appropriate for Supreme Court review.<sup>127</sup> Specifically, he stated that the plaintiffs’ claim was neither expressly preempted by the MDA’s express preemption clause under *Riegel*, nor implicitly preempted by the *Buckman* holding regarding fraud-on-the-FDA claims.<sup>128</sup> Instead, the claim more closely resembled the claim against

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125. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 353 (2001); see *Sprint Fidelis*, 623 F.3d at 1205–06.

126. *Medtronic, Inc. v. Stengel*, 134 S. Ct. 375 (2013).

127. Brief for the United States as Amicus Curiae at 7, *Medtronic, Inc. v. Stengel*, 134 S. Ct. 375 (2013) (No. 12-1351).

128. See *id.* at 12 (“[H]ere, respondents attack petitioner’s conduct *after* its device received premarket approval (and after FDA approved any relevant supplemental application). That conduct . . . would have been governed not by the terms of the device’s premarket approval, but rather by FDA’s general regulations governing adverse-event reporting and labeling revision in light of new safety information. Accordingly, respondents’ failure-to-warn claim—whether styled as arising from petitioner’s failure to make adverse event reports to FDA or from its failure to make a revision to the device’s labeling—is not expressly preempted.”).

a brand-name prescription drug manufacturer that *Wyeth v. Levine* held was not implicitly preempted.<sup>129</sup>

The Solicitor General's novel argument departs from the analytic framework used by all other circuits in medical device preemption cases since *Riegel*<sup>130</sup> and disagrees with the notion that a state requirement is saved from express preemption if it parallels a federal requirement.<sup>131</sup> In fact, the Solicitor General trivializes the circuit split regarding the MDA's preemptive effect as "essentially academic" and argues that general federal requirements should be given no preemptive effect at all.<sup>132</sup> This is premised on the idea that Section 360k only has preemptive effect when a federal requirement is device-specific and relevant to the asserted state claim.<sup>133</sup>

However, there does not appear to be a sound legal basis for distinguishing between general requirements and device-specific requirements.<sup>134</sup> Not only would such a distinction leave injured plaintiffs without any remedy for a wide range of harmful violations of federal law, as stated above, but Section 360k explicitly applies preemption as a defense in cases in which states seek to impose on a manufacturer "any" requirement.<sup>135</sup> The provision does not apply preemptive effect only to device-specific requirements. Thus, the Solicitor General's reasoning regarding the Ninth Circuit's apparent improper interpretation of the preemptive effect of Section 360k and the emerging circuit split regarding this issue is as anemic as other circuits' arguments that plaintiffs must plead violations of device-specific requirements while still meeting the strict pleading standards of *Twombly* and *Iqbal*.

Instead, *Stengel* directly tackles the issue of federal preemption and prudently reverses the trend of defendant-friendly rulings premised on deference to the congressional grant of exclusive FDCA enforcement authority to the FDA.<sup>136</sup> The Supreme Court's recent

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129. See *id.* at 7 (referencing *Wyeth v. Levine*, 555 U.S. 555 (2009)).

130. See *id.* at 15 ("The courts of appeals, in every case since *Riegel* involving a device subject to premarket approval, have tacitly dispensed with the first step of a proper Section 360k(a) preemption analysis—i.e., asking whether FDA has established device-specific requirements on the same subject as the relevant state requirement.").

131. See *id.* at 17.

132. See *id.* at 17–18.

133. See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996) ("[I]n most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal 'requirement.'").

134. See *Bausch v. Stryker Corp.*, 630 F.3d 546, 555 (7th Cir. 2010), *cert. denied*, 132 S. Ct. 498 (2011).

135. See *id.*

136. See *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013), *cert. denied*, 134 S. Ct. 2839 (2014) (Watford, J., concurring); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 421 (6th Cir.

denial of certiorari to resolve the circuit split means that injured plaintiffs may rely on the *en banc* decision in *Stengel* to buttress new or existing product liability claims.

This is significant because there are currently thousands of claims, with thousands more unfiled, against some of the nation's largest manufacturers such as Medtronic. The large number of filed and unfiled cases exemplifies the inherently risky nature of the medical device industry and underscores the importance of expanding manufacturer liability. In addition, if medical device makers cannot accurately predict the protections they can expect against state law claims, manufacturers may decide to settle preemptively, which would reduce the aforementioned legal gridlock.<sup>137</sup> For example, in May 2014, Medtronic agreed to pay \$22 million to settle 950 claims involving the alleged off-label use of Infuse,<sup>138</sup> and the manufacturer announced plans to hold \$120 to \$140 million<sup>139</sup> in reserve to settle approximately 3,800 outstanding cases.<sup>140</sup>

Infuse, in particular, may be the medical device at the heart of the most prominently affected claims. The FDA approval for Infuse is specifically for its use in anterior fusion, a particular type of spinal fusion surgery in which the surgeon approaches the patient's spine from the front of the abdomen.<sup>141</sup> Thus, posterior fusion—in which the surgeon approaches the patient's spine from the patient's back—is considered an off-label use of Infuse. For various reasons, the off-label

2005), *cert. denied sub nom. Knisley v. Medtronic, Inc.*, 546 U.S. 935 (2005); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1203 (8th Cir. 2010).

137. There have been proposals to create a no-fault compensation scheme in order to restrict the number of state tort claims that could be filed against medical device manufacturers while also providing a means to immediately cover harmed patients' costs. See, e.g., David Chang, *Internalizing the External Costs of Medical Device Preemption*, 65 HASTINGS L.J. 283 (2013); Amalea Smirniotopoulos, *Bad Medicine: Prescription Drugs, Preemption, and the Potential for a No-Fault Fix*, 35 N.Y.U. REV. L. & SOC. CHANGE 793 (2012).

138. See Shezad Malik, *Shareholder Class-Action Lawsuit Over Medtronic BMP Infuse Proceeds*, THE LEGAL EXAMINER (Oct. 12, 2014, 4:58 PM), <http://fortworth.legalexaminer.com/defective-dangerous-products/shareholder-class-action-lawsuit-over-medtronic-bmp-infuse-proceeds/>; Press Release, Medtronic, Medtronic Agrees to Settle Certain INFUSE® Bone Graft Product Liability Cases (May 6, 2014), available at <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&id=1927406>.

139. It is possible that these amounts may not be considered significant for Medtronic, which had global revenues of approximately \$17 billion over the last fiscal year. See Press Release, Medtronic, Medtronic Reports Fourth Quarter and Fiscal Year 2014 Earnings (May 20, 2014), available at <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=1932575>.

140. Of the 3,800 additional claims stemming from implantation of a Medtronic Infuse bone graft, only approximately 1,200 have been filed to date. Jane Mundy, *Settlement Good News for Medtronic Infuse Bone Graft Victims*, LAWYERSANDSETTLEMENTS.COM (May 13, 2014 8:00 AM), <http://www.lawyersandsettlements.com/articles/medtronic-infuse-bone-graft/medtronic-lawsuit-bone-graft-16-19774.html#.VK4De3tChHM>.

141. *Coleman v. Medtronic, Inc.*, 167 Cal. Rptr. 3d 300, 304 (Cal. Ct. App. 2014).

use has become increasingly common since Infuse's clinical introduction and has caused a sharp rise in Infuse-related injuries.

For example, in *Coleman v. Medtronic*, plaintiffs alleged that Medtronic violated both state and federal laws by promoting the off-label use of Infuse while downplaying both the risk of complications and incidence of adverse events.<sup>142</sup> The Supreme Court recognized in *Buckman* that off-label use is not illegal or even disfavored under federal law.<sup>143</sup> Instead, it is an accepted and valuable part of the practice of medicine.<sup>144</sup> However, FDA regulations prohibit a device manufacturer from promoting the use of a device in a manner inconsistent with the premarket approval.<sup>145</sup>

Following the rationale of the Fifth, Seventh, and Ninth Circuits,<sup>146</sup> the state appellate court in *Coleman* held that the doctrines of express preemption and implied preemption did not preclude the plaintiff from bringing (1) a negligence per se claim based on Medtronic's alleged violation of a purported federal prohibition on the promotion of off-label uses,<sup>147</sup> and (2) a failure-to-warn claim or a negligence per se claim based on Medtronic's alleged failure to report adverse events to the FDA.<sup>148</sup> The court dismissed the plaintiff's failure-to-warn claim based on Medtronic's promotion of off-label use<sup>149</sup> for failing the *McMullen v. Medtronic, Inc.* genuine equivalence test.<sup>150</sup> However, other district courts have gone even further, relying on *Stengel* to hold that off-label promotion takes manufacturers

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142. See *id.* at 305–06.

143. See *id.* at 307 (“Nothing in the MDA prevents a doctor from using a medical device in an off-label manner.”); see also *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1218 n.3 (W.D. Okla. 2013) (“[O]ff-label usage of medical devices . . . is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.” (quoting *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001))).

144. See *Caplinger*, 921 F. Supp. 2d at 1218 n.3 (quoting *Buckman*, 531 U.S. at 350).

145. *Coleman*, 167 Cal. Rptr. 3d at 307.

146. See *id.* at 311–12 (“We conclude *Stengel III* provides the correct framework for analysis . . . We believe [the Eighth Circuit’s] broad interpretation of *Buckman* is unwarranted, as it would preempt almost any state law claim that references a federal requirement, even though the plaintiff is relying on state law, not federal law, to state a cause of action.”).

147. See *id.* at 316 (“[The plaintiff’s] negligence claim is premised on a state requirement that is parallel to the federal requirement to refrain from off-label marketing.”).

148. See *id.* at 312 (“We agree with [the plaintiff] that the duty to warn should not be so narrowly defined as to exclude a requirement to file adverse event reports with the FDA . . . construing this duty in that way creates a causation hurdle that plaintiffs would not otherwise face.”).

149. See *id.* at 313 (“[W]e do not consider the state and federal requirements to be ‘genuinely equivalent.’ Federal regulations prevent device manufacturers from promoting off-label use of FDA-approved devices. Those requirements are substantively different than the requirements imposed by California common law in the failure to warn context.”).

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



outside the protection of the statutory scheme, including the protection afforded by preemption, for *all* state law claims.<sup>151</sup>

If the Ninth Circuit's decision remains in effect, the ability of medical device manufacturers to win dismissal of product liability claims on preemption will be considerably weakened, though not entirely eliminated.<sup>152</sup> Fearful manufacturers could point out that the Supreme Court, in upholding MDA preemption in *Riegel*, discerned from the congressional text that "the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations."<sup>153</sup>

Moreover, defining "parallel claims" as broadly as the Fifth, Seventh, and Ninth Circuits may have the negative effect of dragging the FDA into the middle of many lawsuits, thereby bringing about the interference with agency activities about which *Buckman* warned.<sup>154</sup> The protective shield of federal preemption prevents jurors from second-guessing the FDA's expert regulatory determinations. It also ensures that courts and juries do not get entangled in "the difficult task," assigned by Congress to the FDA, "of regulating the marketing and distribution of medical devices without intruding upon decisions" made by medical professionals with respect to beneficial and widespread off-label uses—decisions that, under Section 396, are

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151. See *Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977, 991–92 (D. Ariz. 2013) ("When the device is not being used in the manner the FDA pre-approved and the manufacturer is actually promoting such use, there is no law or policy basis on which to pre-empt the application of state law designed to provide that protection."). It is worth noting that the court in *Ramirez* emphasized that the loss of preemptive protection was largely attributable to Medtronic's active promotion of the off-label use of its device, and not the off-label use itself. See *id.* at 992 ("[W]hen the manufacturer has done nothing to . . . promote [the product's] use in an off-label manner, a claim based only [on] the manufacturer's knowledge of an off-label use appears to be preempted under § 360k . . . . The shield drops when the manufacturer violates federal law."). The court in *Ramirez* also followed the rationale of *Stengel* in finding the plaintiff's claims were not subject to implied preemption because they were not "wholly derivative" of federal law, like the claims at issue in *Buckman*. See *id.* at 994. But see *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1178 (C.D. Cal. 2013) ("[A]ny negligence claim based solely on illegal off-label promotion is impliedly preempted under *Buckman* . . . .").

152. See, e.g., *Pinsonneault v. St. Jude Med., Inc.*, 953 F. Supp. 2d 1006, 1011–12 (D. Minn. 2013) (holding that a state-law duty to warn consumers of the dangers of their products does not parallel a manufacturer's duty under federal regulations to inform the FDA of adverse events and dangers pertaining to their devices, as "it is not enough that a duty may be similar to or consistent with the federal duty to report; rather the duties must be identical or genuinely equivalent to survive preemption").

153. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 326 (2008).

154. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (holding that state-law fraud-on-the-FDA claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives" and also "dramatically increase the burdens" facing companies applying for approval to market new drugs).

“statutorily committed to the discretion of health care professionals.”<sup>155</sup>

Catherine M. Sharkey—a law professor at New York University School of Law and one of the nation’s leading authorities on federal preemption—suggests that the issue of encroachment on a “federal agency’s discretionary enforcement prerogative” is at the “new frontier” in medical device preemption.<sup>156</sup> However, Professor Sharkey argues that the solution is more federal agency involvement, not less.<sup>157</sup> She believes that private litigation should not become an available route for injured plaintiffs to undermine the FDA’s reasoned judgments.<sup>158</sup> But the only way for courts to close off this path is by soliciting input on the issue of federal preemption of parallel state law claims from the FDA itself.<sup>159</sup> Of course, it is possible that such agency-court partnerships would impose the very burden the Court in *Buckman* feared.<sup>160</sup> Professor Sharkey argues that the burden on the FDA from inquiries in tort suits would be modest at best, and such burden would be acceptable if a complementary role in liability cases may bring new risk evidence to the FDA’s attention.<sup>161</sup>

While Professor Sharkey advocates for greater FDA input when courts decide whether tort claims are “parallel” to federal requirements, she does not think that *Stengel* and courts following its reasoning have substantially expanded what was previously a narrow—and thus interpretively simple—gap between implied and express preemption.<sup>162</sup> However, courts’ recent decisions to deny dismissal of many state law claims against medical device manufacturers, with the series of Infuse injury cases involving Medtronic being a prominent example, would suggest otherwise.<sup>163</sup> A

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155. *Buckman*, 531 U.S. at 350; see also *Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (noting that Congress gave the FDA “complete discretion” to decide how and when to exercise the wide range of enforcement tools entrusted to it).

156. Catherine M. Sharkey, *Tort-Agency Partnerships in an Age of Preemption*, 15 THEORETICAL INQUIRIES IN L. 359, 359 (2014).

157. *See id.* at 362.

158. *Id.* at 375.

159. *Id.*

160. *See Buckman*, 531 U.S. at 351; *supra* note 154 and accompanying text.

161. *See Sharkey*, *supra* note 155, at 382–83.

162. *See id.* at 386 (describing plaintiffs’ hurdle in medical device liability cases as “thread[ing] the needle” of a two-sided preemption challenge”).

163. A federal district court in Minnesota has allowed a shareholder class-action lawsuit to proceed against Medtronic regarding Infuse. *See Malik*, *supra* note 138. A win by shareholders in the class-action lawsuit might result in additional actions filed by other patients injured as a result of surgical procedures involving Infuse. *See Jane Mundy, Medtronic Meddling Leads to Class-Action Lawsuit*, LAWYERSANDSETTLEMENTS.COM (Dec. 1, 2014, 8:00 AM), available at <http://www.lawyersandsettlements.com/articles/medtronic-infuse-bone-graft/interview-medtronic-lawsuit-bone-graft-15-20283.html>.

broader gap through which plaintiffs can escape federal preemption would support greater agency involvement, as Professor Sharkey argues, to help courts solve more difficult and complex liability cases that should more frequently progress beyond the pleading stage.<sup>164</sup> In fact, facilitating the progression of plaintiffs' meritorious suits against device manufacturers past the pleading stage is beneficial as private litigation brings an inflow of private capital from litigants and results in important information disclosures through the discovery process.<sup>165</sup> These features of private litigation have led many to describe the tort system as a critical "catalyst" for public enforcement.<sup>166</sup> Thus, as Professor Sharkey implies, state tort law must complement rather than undermine FDA regulation of medical devices by filling in gaps in the FDA's regulatory scheme.<sup>167</sup> This Note proposes that further reducing the scope of federal preemption of state law claims advances this goal.

### III. RESOLVING THE CIRCUIT SPLIT BY FURTHER FACILITATING ESCAPE FROM PREEMPTION

Preemption questions involve fundamental concerns over procedural justice for tort victims, state regulatory autonomy, and the optimal size of the federal administrative state.<sup>168</sup> A circuit split on the issue makes it difficult for courts to appropriately weigh these concerns, while simultaneously affecting the actions of both injured individuals and device manufacturers.<sup>169</sup> However, the interests of both parties are not analogous, and broad preemption of state law claims is economically inefficient and would provide inadequate redress for tort victims. Accordingly, the circuit split in question should be resolved by enlarging the gap between *Riegel* and *Buckman*

164. See *Bausch v. Stryker Corp.*, 630 F.3d 546, 554, 558 (7th Cir. 2010), *cert. denied*, 132 S. Ct. 498 (2011).

165. Tarloff, *supra* note 100, at 1225. While the FDA's knowledge of a device's possible risks is inherently limited because the FDA must rely on the manufacturer itself for the relevant information, the state tort system, through the discovery process, requires manufacturers to "disclose everything they know or reasonably should know" regarding the safety and efficacy of their products. See Lawrence O. Gostin, *The Deregulatory Effects of Preempting Tort Litigation: FDA Regulation of Medical Devices*, 299 JAMA 2313, 2315 (2008).

166. See *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005) ("Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of [the statutory regime]. . . . [T]ort suits can serve as a catalyst in this process . . .").

167. See generally Smirniotopoulos, *supra* note 137.

168. Jamelle C. Sharpe, *Toward (a) Faithful Agency in the Supreme Court's Preemption Jurisprudence*, 18 GEO. MASON L. REV. 367, 367 (2011).

169. See *supra*, Part II.E (providing examples of lower court decisions and party actions that have been influenced by the widening circuit split).

through which state law claims can escape express and implied preemption. Other than cases involving a violation of state law safety requirements that clearly conflict with federal requirements, all parallel state law claims should escape preemption at the pleading stage so that plaintiffs can gain access to discovery.

*A. Reasons against Immunizing Manufacturers from State Law Claims*

Courts' decisions to preempt state law claims involve consideration of regulatory efficiency and corrective justice.<sup>170</sup> Regulatory efficiency considerations involve determining: (1) whether it is ultimately more favorable to potential tort victims to preempt state law claims; or (2) whether the distributional effects, both positive and negative, of the preemption decision on various demographic or interest groups advance or impede predefined policy goals.<sup>171</sup> Similarly, corrective justice considerations examine whether the state remedial laws under which individuals, entities, or interest groups could obtain redress for private wrongs would be eliminated to serve some overriding federal purpose.<sup>172</sup> The assumption is that Congress would not intend to preempt state law claims if doing so would create a "remedial vacuum" unless there is a clear statement to the contrary.<sup>173</sup> In the device landscape created by the circuit split, the best solution with these two preemption factors in mind is reducing the immunization from state law claims enjoyed by manufacturers. The Fifth, Seventh, and Ninth Circuits have already moved in this direction,<sup>174</sup> and courts must push further forward.

Preempting claims against manufacturers has been likened to allowing manufacturers to 'externalize the harms produced by their

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170. See Sharpe, *supra* note 106, at 177–78.

171. See *id.* at 177; Sharpe, *supra* note 167, at 377.

172. See Sharpe, *supra* note 107, at 177; Sharpe, *supra* note 168, at 375–76 (“[Corrective justice] frequently manifests itself in arguments about whether Congress would intentionally preempt state tort laws without also providing allegedly injured parties an alternative means of redress.”).

173. See Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B.U. L. REV. 559, 617 (1997); see also *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 337 (2008) (Ginsburg, J., dissenting) (“The MDA’s failure to create any federal compensatory remedy for such consumers further suggests that Congress did not intend broadly to preempt state common-law suits . . . . It is ‘difficult to believe that Congress would, without comment, remove all means of judicial recourse’ for large numbers of consumers injured by defective medical devices.” (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984))).

174. See *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013), *cert. denied*, 134 S. Ct. 2839 (2014); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), *cert. denied*, 132 S. Ct. 498 (2011).

devices to the government and public.<sup>175</sup> This is harmful, as externalities borne by those that did not produce them distort the true costs and use of resources.<sup>176</sup> In the medical device context, permitting medical device manufacturers to externalize harms fosters poor corporate behavior and does not compel companies to act swiftly and appropriately when their products harm consumers.<sup>177</sup> In essence, broad preemption removes any economic incentive for manufacturers to be principled corporate citizens because they do not suffer any consequences if they fail to act in a responsible manner.<sup>178</sup> Instead, manufacturers should bear the costs; internalization of externalities is tort law's way of preventing or deterring harmful actions.<sup>179</sup> As a specific example, the Eighth Circuit's finding of broad preemption of state law claims<sup>180</sup> externalized the costs of the injuries to Medicare.<sup>181</sup> Estimates indicate that this directly resulted in Medicare paying up to one billion dollars in additional claims.<sup>182</sup> Had Medtronic been forced to internalize the potential costs of its product's defects in that case, Medtronic would have been compelled to act much more quickly to address the problem, saving hundreds of millions of dollars and preventing thousands of unnecessary injuries.<sup>183</sup> Externalizing the costs of defective devices onto the government, and ultimately the tort victims themselves, is a clear example of economic inefficiency.

Preemption is also harmful to tort victims, as state law tort suits can uncover unknown hazards associated with medical devices and incentivize manufacturers to divulge safety risks promptly.<sup>184</sup> This is especially true given the large number of medical devices that receive approval under the significantly less stringent 510(k) process.<sup>185</sup> Manufacturers have much greater access to information

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175. See Chang, *supra* note 137, at 299.

176. See *id.*

177. See *id.* at 300.

178. See *id.*

179. Israel Gilead, *Tort Law and Internalization: The Gap Between Private Loss and Social Cost*, 17 INT'L REV. L. & ECON. 589, 589 (1997).

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

181. H. DENNIS TOLLEY, EXAMINING THE SPRINT FIDELIS EFFECT ON MEDICARE COSTS 2 (2010), available at [http://www.rheingoldlaw.com/blog/2010-4-7\\_Tolley%20Report\\_Final.pdf](http://www.rheingoldlaw.com/blog/2010-4-7_Tolley%20Report_Final.pdf).

182. *Id.*

183. Chang, *supra* note 137, at 304.

184. *Wyeth v. Levine*, 555 U.S. 555, 579 (2009).

185. FDA approval, no matter how rigorous or extensive, does not give blanket immunity to manufacturers from liability for injuries caused by faulty or excessively risky devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 337–38 (2008) (Ginsburg, J., dissenting) (“FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify

about their products, particularly in the post-marketing phase as new risks emerge.<sup>186</sup>

In addition, recent history suggests that the FDA does not have adequate time, capacity, or resources to monitor manufacturers to ensure that their post-market conduct complies with safety requirements; to perform the necessary cost-benefit analysis to determine when enforcement actions are appropriate; or to pursue legal actions against manufacturers when doing so would be efficient.<sup>187</sup> The FDA's limited resources exacerbate the problem, despite an ever-growing mission of regulating and protecting the public from an increasing number of medical devices.<sup>188</sup> Parallel claims based on violations of the FDA's industry-wide regulations can complement the FDA's efforts in all of these endeavors. In particular, tort litigation "can help uncover previously unavailable data on adverse effects, questionable practices by manufacturers, and flaws in regulatory systems."<sup>189</sup> Moreover, increased accountability under state tort law deters risky device designs and encourages continued research and testing of devices on the market.

Some have argued that tort law may in fact over-deter manufacturers by dissuading them from developing beneficial devices.<sup>190</sup> Because tort claims focus on the harm suffered by a particular patient, rather than the benefits received by others, they may not produce efficient results.<sup>191</sup> Tort law also cannot help patients who are denied access to a valuable medical device due to such over-deterrence.<sup>192</sup> However, while tort law does not provide a perfect regulatory system, it is a necessary supplement to the equally imperfect oversight by the FDA.<sup>193</sup> As it currently stands, the FDA cannot adequately identify the risks associated with devices before they are on the market, nor can it effectively monitor and regulate

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potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection.").

186. *Wyeth*, 555 U.S. at 578–79.

187. Tarloff, *supra* note 100, at 1224.

188. See INST. OF MED., *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* 193 (2007), available at [http://www.nap.edu/openbook.php?record\\_id=11750&page=193](http://www.nap.edu/openbook.php?record_id=11750&page=193) ("The [FDA] lacks the resources needed to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future.").

189. See Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 JAMA 308, 308 (2007).

190. Smirniotopoulos, *supra* note 137, at 818.

191. *Id.*

192. *Id.*

193. *Id.* at 819.

those products once they are in widespread use.<sup>194</sup> Accordingly, the most efficient regulatory regime is one that provides deterrence, corrective compensation, and incentives for manufacturers to disclose pre- and post-market safety information by creating the threat of substantial monetary damages and reputational costs in cases of non-compliance or misconduct.<sup>195</sup> Such a regime must entail a greater threat of litigation against manufacturers as a significant complement to continued agency oversight.

### *B. Reducing Preemption and Increasing Tort Liability*

Imposing liability for meritorious parallel state law claims serves a clear compensatory function and complements, rather than interferes with, the FDA's monitoring actions and enforcement decisions.<sup>196</sup> Like Steven McCormick, many medical device users suffer chronic and debilitating pain, injuries, and even death through no fault of their own. Such victims often incur huge financial losses because manufacturers negligently manufactured products and failed to report malfunctioning devices. The state law tort system may be needed to make such victims whole.<sup>197</sup> That the manufacturers' tortious conduct also violates federal and state laws reinforces the argument that injured consumers deserve an opportunity for corrective justice and their right to seek compensation.<sup>198</sup> Parallel claims, in particular, are based on a traditional duty of care arising under state law. The most damning part of such claims is that the manufacturer failed to satisfy its obligation to its consumers—as opposed to its obligation to a federal agency—and, as such, falls under the purview of a traditional state law theory of liability.<sup>199</sup>

Without further expanding the no-preemption gap, some injured plaintiffs may still be denied compensation because their tort suits are blocked and because the FDA is not empowered to ensure that injured victims of improperly manufactured devices receive

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194. In fact, we may be “substantially dependent on the tort system to provide the educational function of revealing massive cover-ups of health information . . . or occasional efforts to conceal risk information from regulatory agencies like the FDA . . . .” Robert Rabin, *Regulatory Compliance as a Defense to Products Liability*, 88 GEO. L.J. 2049, 2069 (2000).

195. See Smirniotopoulos, *supra* note 137, at 814.

196. See Tarloff, *supra* note 100, at 1220.

197. See *id.* at 1222.

198. For a discussion of the various roles that the tort system can play as well as a delineation and defense of the compensatory function of tort law, see generally Mark A. Geistfeld, *The Principle of Misalignment: Duty, Damages, and the Nature of Tort Liability*, 121 YALE L.J. 142 (2011); Mark A. Geistfeld, *Negligence, Compensation, and the Coherence of Tort Law*, 91 GEO. L.J. 585 (2003).

199. See Tarloff, *supra* note 100, at 1223.

damages. In addition, plaintiffs' claims based on violations of non-device-specific regulations that should survive preemption fall within the traditional domains of state authority to provide compensation for injured citizens and to promote public health and safety.<sup>200</sup> Moreover, the advantages of the state law tort system and the dangers associated with medical devices have spurred many members of Congress to push for a uniform standard of no preemption for premarket-approved devices.<sup>201</sup> Thus, a move towards decreased preemption and increased tort liability fulfills tort law's natural compensatory function and ensures effective deterrence without federal encroachment on a traditional area of state law authority.<sup>202</sup>

#### IV. CONCLUSION

A circuit split encompassing both the circumstances under which the MDA implicitly preempts state law claims and the scope of the MDA's express preemption provision has deepened over the past several years. This circuit split is reshaping the medical device litigation landscape, and device manufacturers have changed their approach to tackle the large number of impending lawsuits in light of federal circuit court decisions ruling against federal preemption of so-called "parallel" state law claims. While agency regulation of medical devices was previously adequate to ensure consumer safety, the inevitable increase in mobile healthcare and consumer access, among other considerations, requires supplementation to the regulatory scheme.<sup>203</sup> Thus, the circuit split should be resolved by condensing the scope of federal preemption and further increasing liability for manufacturers to an unprecedented scale such that the

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200. See *id.* at 1230.

201. Lisa M. Mottes, *The Need for Federal Preemption of State Tort Claims in the Context of "New Drugs" and Premarket-Approved Medical Devices*, 41 SETON HALL L. REV. 723, 725 (2011).

202. See generally Pamela H. Bucy, *Private Justice*, 76 S. CAL. L. REV. 1, 54–62 (2002) (discussing the benefits of allowing private parties to assist in regulation via litigation, emphasizing their advantages in detection and gathering information). Note that the FDA alone may not do an adequate job deterring dangerous behavior by device manufacturers, since the FDA, like all agencies, is subject to capture by the industries that it regulates. See Smirniotopoulos, *supra* note 137, at 808–09 (stating that the FDA is particularly vulnerable to manufacturer influence and agency capture, which can hinder effective regulatory decision-making by biasing the agency toward decisions that benefit manufacturers). "Capture, in turn, leads to lax regulations and weak enforcement by an agency." Norris, *supra* note 71, at 16.

203. In particular, mobile devices such as smartphones and tablets have provided a new medium for medical devices—one that provides direct consumer access to medical tools—and technology is threatening to outpace the regulatory environment. See Vincent J. Roth, *The mHealth Conundrum: Smartphones & Mobile Medical Apps—How Much FDA Medical Device Regulation is Required?*, 15 N.C. J.L. & TECH. 359, 361 (2014).



state law tort regime substantially supplements agency enforcement. This would fulfill state tort law's natural compensatory function and efficiently fill in any gaps in the overall regulatory scheme.

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