

# THE MEANING OF THE PARALLEL REQUIREMENTS EXCEPTION UNDER *LOHR* AND *RIEGEL*

MARK HERRMANN, DAVID BOOTH ALDEN,  
AND BRADLEY W. HARRISON\*

## INTRODUCTION

In *Riegel v. Medtronic, Inc.*,<sup>1</sup> the Supreme Court held that federal law preempts most product liability claims against manufacturers for medical devices approved through the premarket approval (PMA) process.<sup>2</sup> The Court declared that 21 U.S.C. § 360k(a)—the express preemption provision added to the Federal Food, Drug, and Cosmetic Act (FDCA)<sup>3</sup> by the Medical Device Amendments of 1976 (MDA)<sup>4</sup>—bars state law claims that impose requirements “‘different from, or in addition to, any requirement applicable . . . to the device’ under federal law.”<sup>5</sup> Because the Riegels’ state law claims were based on supposed manufacturing, design, and warning defects that imposed such requirements, the Court held that they were preempted.<sup>6</sup>

But, *Riegel* went on to discuss a parallel requirements exception to the general rule of preemption. The Court said that § 360k(a) “does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties

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\* Mark Herrmann is a partner at Jones Day (Chicago, Illinois) and is the author of *THE CURMUDGEON’S GUIDE TO PRACTICING LAW* (2006), and is co-author of *STATEWIDE COORDINATED PROCEEDINGS: STATE COURT ANALOGUES TO THE FEDERAL MDL PROCESS* (2d ed. 2004). He co-hosts the Drug and Device Law Blog, <http://druganddevicelaw.blogspot.com>. From 1997 through 2007, he taught Complex Litigation on the adjunct faculty of Case Western Reserve University School of Law. David Booth Alden is a partner at Jones Day (Cleveland, Ohio), and Bradley W. Harrison is an associate at Jones Day (Cleveland, Ohio).

1. 552 U.S. 312 (2008).

2. *Id.* at 321–30. *Riegel* is discussed more fully below. See discussion *infra* Part II.D.

3. See The Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–99 (2006)).

4. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, 574 (1976) (codified at 21 U.S.C. § 360k(a)).

5. *Riegel*, 552 U.S. at 321 (quoting 21 U.S.C. § 360k(a)(1)).

6. *Id.* at 321–30.

in such a case ‘parallel,’ rather than add to, federal requirements.”<sup>7</sup> This parallel requirements exception is far from clear.

The Court created the exception twelve years earlier when it first considered the reach of the MDA’s express preemption provision in *Medtronic v. Lohr*.<sup>8</sup> The *Lohr* Court observed that: “Nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.”<sup>9</sup> And thus began the hotbed of current litigation involving devices approved through the PMA process.<sup>10</sup>

Given that the MDA’s express preemption provision affects (or may affect) most state law product liability claims concerning devices approved through the PMA process, the parallel requirements exception described in *Lohr* and *Riegel* is a critical issue in those cases. Unfortunately, although the Court has described the parallel requirements exception in cases where it did not apply, the Court has never addressed the exception’s contours or limits in a case in which it applied.<sup>11</sup> Moreover, commentators have focused much of their attention not on explaining how *Riegel* affected medical device cases, but rather on predicting what the case meant for two later prescription drug preemption cases that came before the Supreme Court—*Warner-Lambert Co. v. Kent*<sup>12</sup> and *Wyeth v. Levine*<sup>13</sup>—or ad-

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7. *Id.* at 330 (citing *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996)).

8. 518 U.S. 470, 495 (1996).

9. *Id.* at 495. In the concurring portion of her separate opinion, Justice O’Connor (concurring in part and dissenting in part), joined by three justices, added that she “agree[d] that the Lohrs’ claims are not pre-empted by §360k to the extent that they seek damages for Medtronic’s alleged violation of federal requirements.” *Id.* at 513 (O’Connor, J. concurring). Both *Lohr* and *Riegel* are discussed in greater detail below. See *infra* Part II.

10. Cases taking various approaches to the scope of the parallel requirements exception are discussed in Part III.B below.

11. See *Riegel*, 552 U.S. at 330 (“Although the Riegels now argue that their lawsuit raises parallel claims, they made no such contention in their briefs before the Second Circuit, nor did they raise this argument in their petition for certiorari. We decline to address that argument in the first instance here.”).

12. 552 U.S. 440 (2008) (per curiam) (a non-precedential opinion affirming, by an equally divided court, *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2006), which held that the fraud-on-the-FDA exception to Michigan’s immunity statute protecting drug manufacturers from liability in products was not preempted by federal law).

13. 129 S. Ct. 1187, 1204 (2009) (federal law did not preempt state law failure-to-warn claims relating to anti-nausea drug). This Article focuses exclusively on preemption in the context of medical devices approved through the PMA process. Preemption in the context of pharmaceuticals (where there is no express preemption provision), as discussed in *Wyeth*, is left for another day.

dressings preemption more generally.<sup>14</sup> Accordingly, the prevailing thought concerning *Riegel* is that most state law claims involving devices approved through the PMA process are preempted, but plaintiffs may pursue certain, as-yet-undefined, claims under the parallel requirements exception.<sup>15</sup>

Not surprisingly, in *Riegel*'s wake, plaintiffs attempt to cast their claims in light of the parallel requirements exception and seek to expand the limits of that exception. But “[l]ittle guidance is provided . . . in *Riegel* in assessing or determining the nature of parallel claims” that survive preemption.<sup>16</sup> Thus, lower courts have struggled to answer the ultimate question: Which state law claims survive preemption under the parallel requirements exception?

This Article attempts to answer that question. Part I briefly explains the FDCA, as amended by the MDA, and its regulation of medical devices. Part II examines the Supreme Court’s medical device preemption trilogy: *Medtronic, Inc. v. Lohr*,<sup>17</sup> *Buckman Co. v. Plaintiffs’ Legal Committee*,<sup>18</sup> and *Riegel v. Medtronic, Inc.*,<sup>19</sup> as well as *Bates v. Dow Agrosciences LLC*,<sup>20</sup> which discussed parallel requirements claims in relation to the federal pesticide labeling statute. Part III discusses the three major questions courts must address when faced with supposed parallel requirements claims, namely, whether (1) there was a federal violation; (2) the claims are truly parallel; and (3) punitive damages remedies for otherwise parallel claims conflict with federal law.

Significantly, many purported parallel requirements claims involve situations with no final adjudication of a proceeding initiated by the United States Food and Drug Administration (FDA) that a violation actually occurred. In those instances, the plaintiffs’ attempts to pass the threshold for establishing that a claim survives

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14. See, e.g., Richard A. Epstein, *The Case for Field Preemption of State Law in Drug Cases*, 103 NW. U. L. REV. 463 (2009); Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Product Liability Claims*, 103 NW. U. L. REV. 437 (2009).

15. See, e.g., Sharkey, *supra* note 14, at 450–51; see also *The Supreme Court 2007 Term—Leading Cases*, 122 HARV. L. REV. 405, 412, 414–15 (2008) (concluding that *Riegel*'s preemption likely protects only those manufacturers in compliance with FDA regulations).

16. *O’Shea v. Cordis Corp.*, No. 50-2006-CA-013019, 2008 WL 3139428, at \*3 (Fla. 4th Dist. Ct. App. May 19, 2008).

17. 518 U.S. 470 (1996).

18. 531 U.S. 341 (2001) (holding that fraud-on-the-FDA claims are impliedly preempted by the FDCA, as amended by the MDA).

19. 552 U.S. 312 (2008).

20. 544 U.S. 431 (2005).

express preemption (i.e., that the claim is based on a federal violation) implicate the concerns that led the *Buckman* Court to find implied preemption.<sup>21</sup> Ultimately, the Court's dicta in *Lohr* and *Riegel* outlining a parallel requirements exception to express preemption may have been much ado about very little, as few such claims should survive an implied preemption analysis.

## I. THE REGULATION OF MEDICAL DEVICES

Before the MDA was enacted in 1976, medical device manufacturers were subject to the varying laws and regulations of the fifty states.<sup>22</sup> Through the MDA, Congress unified and centralized the regulation of medical devices under the FDA.<sup>23</sup> To that end, Congress included an express preemption provision in the MDA; 21 U.S.C. § 360k(a):

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

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

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.<sup>24</sup>

The FDCA also provides that, with a limited exception for state enforcement of certain food-related statutes, all "proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."<sup>25</sup>

In addition to centralizing the regulation of medical devices, Congress sought to protect consumers from "increasingly complex

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21. See *Buckman*, 531 U.S. at 350–51. *Buckman* is discussed in Part II.B below.

22. See *Riegel*, 552 U.S. at 315–16 ("[Before the MDA was enacted in 1976,] [s]everal States adopted regulatory measures [relating to medical devices], including California, which in 1970 enacted a law requiring premarket approval of medical devices. Congress stepped in with the passage of the [MDA], which swept back some state obligations and imposed a regime of detailed federal oversight.") (citations omitted); Mark Herrmann & Geoffrey J. Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 FOOD & DRUG L.J. 1, 4 (1996).

23. See Herrmann & Ritts, *supra* note 22, at 4.

24. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 4(a)(9), 90 Stat. 539, 580 (1976) (codified at 21 U.S.C. § 360k(a)).

25. 21 U.S.C. § 337(a). Section 337(a) was not added to the FDCA by the MDA; instead, it was in the original FDCA. Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, § 307, 52 Stat. 1040, 1046 (1938).

devices which posed serious risk if inadequately tested or improperly designed or used,” without stifling medical innovation.<sup>26</sup> To assure adequate oversight, the MDA divides medical devices into three categories based on their presumed degree of risk. Class I devices do “not present a potential unreasonable risk of illness or injury” and are subject to only “general controls.”<sup>27</sup> Class II devices may involve a higher degree of risk and are subject to “special controls.”<sup>28</sup> Class III devices are those involving the highest potential risk and are for “use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health . . . .”<sup>29</sup> The FDA subjects Class III devices to its most rigorous scrutiny.

The MDA provides that manufacturers may not market Class III devices until they receive FDA approval through the PMA process.<sup>30</sup> There are two exceptions to this rule. First, devices sold before the passage of the MDA are grandfathered and may be marketed until the FDA promulgates a regulation requiring approval through the PMA process.<sup>31</sup> Second, new devices are exempt if the FDA finds them to be “substantially equivalent” to another exempt device.<sup>32</sup> This “substantial equivalen[ce]” determination is commonly referred to as the “510(k) notification process” based on the FDCA section requiring limited review before new devices may be

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26. S. REP. NO. 94-33, at 5 (1975), *as reprinted in* 1976 U.S.C.C.A.N. 1070, 1075.

27. 21 U.S.C. § 360c(a)(1)(A); 21 C.F.R. § 860.3(c)(1). “Examples of Class I devices include tongue depressors, arm slings, and hand-held surgical instruments.” Overview: FDA Regulation of Medical Devices (May 6, 2003), *available at* [http://www.qrasupport.com/FDA\\_MED\\_DEVICE.html](http://www.qrasupport.com/FDA_MED_DEVICE.html) (last visited Sept. 11, 2009) [hereinafter Overview: FDA Regulation of Medical Devices].

28. 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 860.3(c)(2). “Examples of Class II devices include physiologic monitors, x-ray systems, gas analyzers, pumps, and surgical drapes.” Overview: FDA Regulation of Medical Devices, *supra* note 27.

29. 21 U.S.C. § 360c(a)(1)(C)(ii); 21 C.F.R. § 860.3(c)(3). “Examples of Class III devices . . . are: replacement heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators.” Overview: FDA Regulation of Medical Devices, *supra* note 27.

30. 21 U.S.C. § 360e(a); *see also* 21 U.S.C. § 351(f).

31. 21 U.S.C. §§ 360c(f)(1), 360e(b)(1)(A).

32. 21 U.S.C. §§ 360c(f)(4), 360e(b)(1)(B).

sold.<sup>33</sup> Most Class III devices are approved under the 510(k) notification process.<sup>34</sup>

To obtain approval through the PMA process, the manufacturer must submit an application including, among other things: (1) full reports of all studies regarding the safety and effectiveness of the device that have been published or should reasonably be known to the manufacturer; (2) a full statement of the device's makeup and principle(s) of operation; (3) a description of the methods, facilities, and controls used for manufacturing; (4) samples or components of the device as requested by the FDA; and (5) a specimen of the proposed labeling.<sup>35</sup> The FDA may review these materials, employ outside experts to review them, and request any additional information it desires.<sup>36</sup> The FDA will approve the device only when it receives "reasonable assurance" that the product is safe and effective.<sup>37</sup> Once a manufacturer obtains PMA, it may market the device, but may not change the design, manufacture, label-

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33. In 1962, Congress added § 510 to the FDCA. *See* Drug Amendments of 1962, Pub. L. No. 87-781, § 302, 76 Stat. 780 (1962) (codified at 21 U.S.C. § 360c). In 1976, Congress added paragraph (k) to § 510 of the FDCA. *See* Medical Device Amendments of 1976, Pub. L. No. 94-295, § 4(a)(9), 90 Stat. 539, 580 (1976) (codified at 21 U.S.C. § 360(k)).

34. In *Riegel*, the Second Circuit noted that in 2005, approximately ninety-nine percent of newly-approved Class III devices were approved through the 510(k) process. *Riegel v. Medtronic*, 451 F.3d 104, 112 (2d Cir. 2006). In 2008, Professor Sharkey suggested that roughly ten percent of available Class III devices were approved through the PMA process. Sharkey, *supra* note 14, at 451. Regardless of the precise percentages, PMA-approved devices appear to be only a relatively small fraction of available medical devices.

35. 21 U.S.C. § 360e(c)(1).

36. 21 U.S.C. § 360e(c)(2), (d); 21 C.F.R. § 814.44(a).

37. 21 U.S.C. § 360e(d)(2).

[T]he safety and effectiveness of a device are to be determined—(A) with respect to the persons for whose use the device is represented or intended, (B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and (C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21 U.S.C. § 360c(a)(2).

[T]he effectiveness of a device is . . . to be determined . . . on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

21 U.S.C. § 360c(a)(3)(A).

ing, or other attributes that would affect the device's safety or effectiveness without FDA approval.<sup>38</sup>

After its initial approval, the FDA continually reviews its decisions and imposes stringent reporting requirements on the manufacturers including "continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use."<sup>39</sup> The FDA requires reports of adverse events from device user facilities,<sup>40</sup> manufacturers, and importers,<sup>41</sup> and it receives voluntary reports of adverse events from healthcare providers and patients.<sup>42</sup> The FDA also conducts on-site inspections of manufacturing facilities "to verify that the device[s are] being manufactured, stored, labeled, and shipped under approved conditions."<sup>43</sup>

The FDA has broad enforcement authority over medical devices. It may (1) restrict distribution of medical devices;<sup>44</sup> (2) issue warning letters to device manufacturers for suspected non-compliance with the FDCA;<sup>45</sup> (3) publish other public reports or disseminate information regarding medical devices or manufacturers;<sup>46</sup> (4) order corrective actions including notification, repair, modifications, adjustments, destruction, or additional device inspection;<sup>47</sup> (5) temporarily suspend approval "if [the] FDA determines that there is reasonable probability that continued distribution of the device would cause serious, adverse health consequences or death;"<sup>48</sup> (6) withdraw approval if the FDA determines that the device is no longer safe and effective or that "[a]ny postapproval requirement imposed by the PMA approval order or by regulation has not been met;"<sup>49</sup> and (7) order mandatory recalls "where FDA

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38. See 21 U.S.C. § 360e(d)(6)(A)(i).

39. 21 C.F.R. § 814.82(a)(2).

40. A "device user facility" is "a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office." 21 U.S.C. § 360i(b)(6)(A).

41. 21 U.S.C. § 360i(a)-(b), (e)-(f); 21 C.F.R. §§ 803.1-58, 814.84.

42. See U.S. DEP'T OF HEALTH & HUMAN SERVS. Form FDA 3500 (Medwatch Form for voluntary reporters, including healthcare professionals and patients), available at <http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/UCM082725.pdf>.

43. 21 C.F.R. § 814.82(b); see also 21 U.S.C. § 374.

44. 21 U.S.C. § 360j(e).

45. See FDA, *Regulatory Procedures Manual* § 4-1-1, at 4-2 (Mar. 2009), available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm> (last visited July 7, 2009).

46. 21 U.S.C. § 375.

47. 21 U.S.C. § 360h(a); 21 C.F.R. §§ 822.1-18 (2009).

48. 21 C.F.R. § 814.47(a)(2) (2009).

49. 21 C.F.R. § 814.46(a)(2) (2009).

finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death.”<sup>50</sup>

Under its own authority the agency may impose civil fines on manufacturers it finds to be noncompliant with the FDCA.<sup>51</sup> Further, the FDA may request that the Department of Justice pursue legal action against manufacturers to (1) seize medical devices that the FDA believes are adulterated or misbranded;<sup>52</sup> (2) enjoin a manufacturer from manufacturing or distributing medical devices;<sup>53</sup> or (3) institute criminal proceedings against a device manufacturer for engaging in a prohibited act.<sup>54</sup>

## II. THE MEDICAL DEVICE PREEMPTION TRILOGY AND *BATES*

Against the regulatory backdrop described above, the Supreme Court has addressed the preemptive effect of the FDCA on state law causes of action involving medical devices in three cases: *Medtronic, Inc. v. Lohr*, *Buckman Co. v. Plaintiffs’ Legal Committee*, and *Riegel v. Medtronic, Inc.* These decisions, along with *Bates v. Dow Agrosciences LLC*<sup>55</sup>—which addressed state law claims imposing parallel requirements in the context of the federal pesticide labeling statute<sup>56</sup>—provide the basis for evaluating the scope of state law claims that survive preemption by way of the parallel requirements exception.

### A. *Medtronic, Inc. v. Lohr*

In *Medtronic, Inc. v. Lohr*,<sup>57</sup> the Court considered the extent to which the MDA’s express preemption provision, § 360k(a), preempts state common law product liability claims relating to medical devices. In the case, Lora Lohr’s Medtronic heart pacemaker failed, allegedly because of a defective lead,<sup>58</sup> and she suffered “a ‘complete heart block’ that required emergency surgery” to replace

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50. 21 C.F.R. § 810.15 (2009).

51. 21 U.S.C. § 333(f) (2007).

52. 21 U.S.C. § 334 (2007).

53. 21 U.S.C. § 332 (2007).

54. See 21 U.S.C. §§ 331, 335, 351–52 (2007). For additional discussion on FDA enforcement authority, see JAMES M. BECK & ANTHONY VALE, *DRUG AND MEDICAL DEVICE PRODUCT LIABILITY DESKBOOK* § 4.01 (2009).

55. 544 U.S. 431 (2005).

56. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136–36y (2000).

57. 518 U.S. 470, 471 (1996).

58. Pacemakers consist of a generator and one or more leads, which are electrical wires that connect the generator to the heart. Based on information about

the pacemaker.<sup>59</sup> The lead in Ms. Lohr's original pacemaker had not gone through the PMA process but, instead, had been approved under the 510(k) notification process where the FDA found it to be "substantially equivalent" to devices already on the market when the MDA was enacted.<sup>60</sup>

Ms. Lohr and her husband brought a product liability action against Medtronic asserting Florida common law negligence and strict liability claims based on alleged manufacturing, warning, and design defects.<sup>61</sup> After the district court dismissed the action based on federal preemption, the Eleventh Circuit affirmed except with respect to the design defect claims, which it found were not preempted.<sup>62</sup>

The Supreme Court held that none of the claims before it on appeal were preempted.<sup>63</sup> The Court began by noting the "rigorous" PMA process for Class III devices.<sup>64</sup> The Court also noted, however, that "substantially equivalent" devices marketed under the 510(k) notification process were subjected to scrutiny that was "by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours."<sup>65</sup>

Because the 510(k) notification process allowed devices to be "marketed without running the gauntlet of the PMA process," the Court found that the MDA imposed no "requirements" on their design; instead, the statute merely "maintain[ed] the [pre-MDA] status quo with respect to the marketing of existing medical devices and their substantial equivalents."<sup>66</sup> Therefore, for lack of a conflicting federal requirement and based on the so-called "presump-

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the heart provided through the leads, the generator monitors and, when appropriate, stimulates the heart.

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

60. *Id.* at 480; *see* 21 U.S.C. §§ 360c(f)(4), 360e(b)(1)(B) (2007).

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

62. *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1350–52 (11th Cir. 1995).

63. There were opinions by (1) Justice Stevens (joined by Justices Ginsburg, Kennedy, and Souter); (2) Justice Breyer, concurring in part and concurring in the judgment; and (3) Justice O'Connor (joined by Chief Justice Rehnquist and Justices Scalia and Thomas), concurring in part and dissenting in part. Justice Stevens's opinion commanded a majority where joined by Justice Breyer's or Justice O'Connor's opinions and, otherwise, was a plurality opinion. *Lohr v. Medtronic, Inc.*, 518 U.S. 470 (1996).

64. *Id.* at 477.

65. *Id.* at 478–79 (citation omitted).

66. *Id.* at 494.

tion against preemption,<sup>67</sup> the Lohrs' design defect claims were not preempted.<sup>68</sup> Further, their manufacturing and warning defect claims survived preemption "because their generality leaves them outside the category of requirements that § 360(k) envisioned to be 'with respect to' specific devices such as pacemakers."<sup>69</sup>

Had the Court issued a narrow ruling on those grounds the controversy over parallel requirements might never have started. Instead, the Court expanded its reasoning, observing that "[n]othing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."<sup>70</sup> While state common law claims based on alleged violations of FDA regulations might include additional elements and, for that reason, "might be 'different from' the federal rules in a literal sense," they "do[ ] not amount to the additional or different 'requirement' that is necessary under the statute; rather, [the state law claim] merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law."<sup>71</sup> Indeed, all members of the Court agreed that parallel requirements claims survive preemption.<sup>72</sup>

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67. The "presumption against preemption" generally is traced to *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 334 (2008) (Ginsburg, J., dissenting); *Lohr*, 518 U.S. at 485. There, the plaintiffs alleged that Illinois grain warehouse regulations were preempted because they conflicted with federal regulations. The Court began its analysis by articulating what has become the "presumption against preemption;" namely, that, where "Congress legislate[s] . . . in a field which the States traditionally have occupied," the Court should "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice*, 331 U.S. at 230 (citations omitted). *Rice* said that "[t]he test" for conflict preemption purposes "is whether the matter on which the State asserts the right to act is in any way regulated by the Federal Act" and, applying that standard, found that most of the Illinois regulations at issue were preempted. *Id.* at 236.

68. *Lohr*, 518 U.S. at 492-94.

69. *Id.* at 502.

70. *Id.* at 495.

71. *Id.*

72. *Id.* (portion of Court's opinion authored by Justice Stevens and joined by Justices Kennedy, Souter, Ginsburg, and Breyer); *id.* at 513 (O'Connor, J., concurring in relevant part, joined by Chief Justice Rehnquist and Justices Scalia and Thomas) ("Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is 'different from, or in addition to,' requirements under federal law.").

*B. Buckman Co. v. Plaintiffs' Legal Committee*

Five years after *Lohr*, the Supreme Court revisited the issue of parallel requirements in *Buckman Co. v. Plaintiffs' Legal Committee*.<sup>73</sup> In the latter case, the plaintiffs alleged that their injuries resulted from purported defects in orthopedic bone screws implanted in their spines.<sup>74</sup> The FDA approved the screws under the 510(k) notification process when labeled for use in arm and leg bones but had not approved them when labeled for use in the spine.<sup>75</sup> The plaintiffs asserted state tort claims based on the manufacturers' supposed fraudulent representations to the FDA about the screws' intended use.<sup>76</sup> The district court dismissed the fraud-on-the-FDA claims based on federal preemption, and the Third Circuit reversed.<sup>77</sup>

The Supreme Court reversed the Third Circuit,<sup>78</sup> holding that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law."<sup>79</sup>

The conflict stem[med] from the fact that the federal regulatory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration c[ould] be skewed by allowing fraud-on-the-FDA claims under state tort law.<sup>80</sup>

The Court further explained:

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73. 531 U.S. 341 (2001).

74. *Id.* at 343.

75. *Id.* at 346.

76. *Id.* at 346–47. The named defendant in *Buckman* was a consulting company that assisted the device manufacturer in seeking 510(k) clearance from the FDA, not the device manufacturer itself. *Id.* at 343. The Court's decision, however, was not based in any manner on this fact. To the contrary, the Court noted that the 510(k) application, allegedly containing the fraudulent representations, was filed by the defendant and the manufacturer on the manufacturer's behalf. *Id.* at 346–47. Nowhere in the Court's opinion does it suggest that the outcome would have been different had the 510(k) application been filed solely by the manufacturer.

77. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817 (3d Cir. 1998), *rev'g* No. MDL 1014, 1997 WL 305257 (E.D. Pa. Mar. 28, 1997).

78. Chief Justice Rehnquist wrote the Court's opinion, which was joined by Justices O'Connor, Scalia, Kennedy, Souter, Ginsburg, and Breyer. Justice Stevens wrote an opinion concurring in the judgment, which Justice Thomas joined. *Buckman*, 531 U.S. at 342.

79. *Id.* at 531 U.S. at 348 (footnote omitted).

80. *Id.*

As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA. Would-be applicants may be discouraged from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability. In effect, then, fraud-on-the-FDA claims could cause the Administration's reporting requirements to deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine, see 21 U.S.C. § 396 (1994 ed., Supp. V), and even though off-label use is generally accepted.

Conversely, fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application.<sup>81</sup>

The holding in *Buckman* is clear: "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions."<sup>82</sup> The Court "express[ed] no view on whether these claims [we]re subject to express pre-emption under 21 U.S.C. § 360k."<sup>83</sup>

*Buckman* mentioned *Lohr*'s dictum regarding parallel requirements claims but did not discuss it in detail. Specifically, the Court rejected the *Buckman* plaintiffs' assertion that their fraud claims escaped preemption as "claims arising from violations of FDCA requirements."<sup>84</sup> The Court first noted that the *Lohr* plaintiffs' "claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements," and then observed that:

[The *Buckman* plaintiffs'] fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although [*Lohr*] can be read to allow certain state-law causes of actions that parallel

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81. *Id.* at 350–51 (footnote omitted).

82. *Id.* at 349 n.4.

83. *Id.* at 348 n.2.

84. *Id.* at 352 (citation omitted).

federal safety requirements, it does not . . . stand for the proposition that any violation of the FDCA will support a state-law claim.<sup>85</sup>

C. *Bates v. Dow Agrosciences LLC*

In the 2005 case of *Bates v. Dow Agrosciences LLC*,<sup>86</sup> the Court interpreted the scope of preemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).<sup>87</sup> In *Bates*, Texas farmers alleged that Dow's pesticide, Strongarm, destroyed their crops—due to the soil's high pH—and brought a range of state law damage claims against Dow.<sup>88</sup> The lower courts found those claims were preempted by FIFRA's express preemption provision, 7 U.S.C. § 136v(b).<sup>89</sup>

The Supreme Court vacated and remanded.<sup>90</sup> The Court found that state law claims imposing only parallel requirements survive express preemption under FIFRA's express preemption provision, which provides that States “shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.”<sup>91</sup> According to the Court, “[t]he imposition of state sanctions for violating state rules that merely duplicate federal requirements is . . . consistent with the text of” FIFRA's express preemption provision.<sup>92</sup>

The Court found that § 136v(b) did not preempt the *Bates* plaintiffs' design defect, negligent testing, manufacturing defect, and express warranty claims because § 136v(b) applies only to requirements relating to “labeling or packaging” and those claims “plainly d[id] not qualify as requirements for ‘labeling or packaging.’”<sup>93</sup> The *Bates* plaintiffs' fraud and negligent failure-to-warn claims did not escape preemption for that reason because they were

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85. *Id.* at 352–53.

86. 544 U.S. 431 (2005).

87. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136–36y (2000).

88. 544 U.S. at 435–36.

89. *See* *Dow Agrosciences, LLC v. Bates*, 205 F. Supp. 2d 623, 626 (N.D. Tex. 2002), *aff'd*, 332 F.3d 323 (5th Cir. 2003).

90. Justice Stevens wrote the Court's opinion, which was joined by Chief Justice Rehnquist and Justices O'Connor, Kennedy, Souter, Ginsburg, and Breyer, who also filed a concurring opinion. Justice Thomas filed an opinion concurring in the judgment in part and dissenting in part, and Justice Scalia joined that opinion.

91. 7 U.S.C. § 136v(b) (2006).

92. 544 U.S. at 442.

93. *Id.* at 444.

“premiered on common-law rules that qualify as ‘requirements for labeling or packaging.’”<sup>94</sup> As to those claims, the Court first observed that “§ 136v(b) prohibits only state-law labeling and packaging requirements that are ‘*in addition to or different from*’ the labeling and packaging requirements under FIFRA”<sup>95</sup> and then remanded for the lower courts to “decide in the first instance whether these particular common-law duties are equivalent to FIFRA’s misbranding standards.”<sup>96</sup>

Explaining this result, *Bates* first observed that its “‘parallel requirements’ reading of § 136v(b) . . . f[ound] strong support in” *Lohr*.<sup>97</sup> The Court also noted that unless parallel requirements claims survived express preemption under § 136v(b), there was no “plausible alternative interpretation of ‘in addition to or different from’ that would give that phrase meaning.”<sup>98</sup> The Court found that this result was consistent with the presumption against preemption.<sup>99</sup> Furthermore, *Bates* rejected the “greatly overstate[d] need for uniformity and centralization”<sup>100</sup> because, under FIFRA, “[s]tates may ban or restrict the uses of pesticides that EPA has approved; they may also register, subject to certain restrictions, pesticides for uses beyond those approved by EPA.”<sup>101</sup> Finally, *Bates* cautioned “that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive preemption” and “must also be measured against any relevant EPA regulations that give content to FIFRA’s misbranding standards.”<sup>102</sup>

However, the substantial differences between FIFRA on the one hand, and the FDCA and MDA on the other, limit *Bates*’s instructive value for interpreting the scope of preemption under the MDA. The scope of express preemption under FIFRA is limited to “labeling or packaging” requirements, whereas the MDA’s express preemption provision, 21 U.S.C. § 360k, applies more broadly to requirements “relat[ing] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.”<sup>103</sup> Further, the EPA’s review of pesticide labeling is substantially less extensive than the FDA’s review of PMA-approved de-

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94. *Id.* at 446.

95. *Id.* at 447 (emphasis in original).

96. *Id.*

97. *Id.*

98. *Id.* at 448.

99. *Id.* at 449.

100. *Id.* at 450.

101. *Id.* (citations omitted).

102. *Id.* at 453.

103. 21 U.S.C. § 360k(a)(2).

VICES, and FIFRA contemplates a substantially greater role for state regulation than the FDCA.<sup>104</sup> Nonetheless, *Bates* provides an extended discussion of why parallel requirements claims survive express preemption based on the presence of the words “in addition to or different from” in FIFRA’s § 136v(b) and, for that reason, provides insight into their meaning in the MDA’s § 360k(a).

D. *Riegel v. Medtronic, Inc.*

In 2008, the Court revisited the issue of express preemption under § 360k in *Riegel v. Medtronic, Inc.*<sup>105</sup> After Charles Riegel suffered a heart attack, his physician inserted a Medtronic balloon catheter into Mr. Riegel’s coronary artery, which was diffusely diseased and calcified.<sup>106</sup> The catheter was contraindicated for patients with diffusely diseased or calcified arteries.<sup>107</sup> Further, despite warnings against overinflation, the physician overinflated the catheter, which then burst.<sup>108</sup> Unlike the pacemaker lead at issue in *Lohr*, which the FDA had approved under the 510(k) notification process, the FDA had approved the catheter in *Riegel* under the “rigorous” PMA process.<sup>109</sup> Mr. Riegel and his wife filed suit against Medtronic asserting New York common law claims based on supposed manufacturing, warning, and design defects.<sup>110</sup> The district court dismissed the plaintiffs’ claims based on federal preemption, and the Second Circuit affirmed.<sup>111</sup>

The Supreme Court affirmed.<sup>112</sup> Initially, the Court found that the FDA’s approval through the PMA process, unlike approval

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104. See *Bates*, 544 U.S. at 440 (“EPA confirmed that it had ‘stopped evaluating pesticide efficacy for routine label approvals almost two decades ago’ . . . .”) (citation omitted); *id.* at 450 (outlining types of state regulation permitted under FIFRA); see also 7 U.S.C. § 136v(a) (“A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.”); *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1990) (saying FIFRA did not expressly or impliedly preempt local ordinance regulating pesticide use);

105. 552 U.S. 312 (2008).

106. *Id.* at 320–21.

107. *Id.*

108. *Id.*

109. *Id.*

110. *Id.*

111. *Riegel v. Medtronic, Inc.*, No. 99-CV-0649, 2003 U.S. Dist. LEXIS 27454 (N.D.N.Y. Dec. 2, 2003), *aff’d*, 451 F.3d 104 (2d Cir. 2006).

112. Justice Scalia wrote the Court’s opinion, which was joined by Chief Justice Roberts and Justices Kennedy, Souter, Thomas, Breyer, and Alito. Justice Stevens wrote an opinion concurring in part and concurring in the judgment, and Justice Ginsburg dissented. See *Riegel*, 552 U.S. at 314.

under the 510(k) notification process, “imposes [federal] ‘requirements’ under the MDA as [the Court] interpreted it in *Lohr*.”<sup>113</sup> Next, the Court concluded that the Riegels’ New York common law claims imposed requirements that were “different from, or in addition to, any [federal] requirement applicable . . . to the device.”<sup>114</sup> The Court “adhere[d] to” its conclusion in *Lohr* “that common-law causes of action for negligence and strict liability do impose ‘requirement[s]’ and would be pre-empted by federal requirements specific to a medical device. . . . Absent other indication, reference to a State’s ‘requirements’ includes its common-law duties.”<sup>115</sup>

Further, the Court rejected the plaintiffs’ contention that even if their claims imposed “requirements,” “general common-law duties are not requirements maintained ‘with respect to devices.’”<sup>116</sup> That was because the plaintiffs’ claims

depend[ed] upon New York’s ‘continu[ing] in effect’ general tort duties ‘with respect to’ Medtronic’s catheter. Nothing in the statutory text [of the MDA] suggest[ed] that the pre-empted state requirement must apply *only* to the relevant device, or only to medical devices and not to all products and all actions in general.<sup>117</sup>

Finally, *Riegel* reiterated *Lohr*’s parallel requirements exception: “[Section] 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”<sup>118</sup> Although the *Riegel* plaintiffs argued that they had asserted such parallel claims, the Court declined to address them because the plaintiffs had failed to raise them either before the Second Circuit or in their petition for certiorari.<sup>119</sup> Thus, *Riegel*, like *Lohr*, acknowledges (in dictum) the parallel requirements exception to the MDA’s express preemption provision but provides little guidance as to its meaning.<sup>120</sup>

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113. *Id.* at 321–23.

114. *Id.* at 323–30.

115. *Id.* at 323–25 (citing *Medtronic v. Lohr*, 518 U.S. 470, 512 (1996)).

116. *Id.* at 327.

117. *Id.* at 328 (emphasis in original).

118. *Id.* at 330 (citations omitted).

119. *Id.*

120. *Riegel*, like *Lohr*, involved *only* express preemption under § 360k. Neither case discussed implied preemption, addressed in *Buckman*, which is based in substantial part on another FDCA section, 21 U.S.C. § 337.

### III. WHAT ARE THE PARALLEL REQUIREMENTS CLAIMS THAT ESCAPE PREEMPTION?

*Lohr* involved a device approved under the 510(k) notification process, which does not trigger preemption.<sup>121</sup> *Lohr* stated that “[n]othing in § 360k(a),” the MDA’s express preemption provision, “denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.”<sup>122</sup> In *Buckman*, there was no express preemption because the device had been approved through the 510(k) notification process.<sup>123</sup> The Court held, however, that the state law fraud-on-the-FDA claims at issue there were impliedly preempted.<sup>124</sup> *Bates*, although interpreting FIFRA and not the FDCA, reaffirmed *Lohr*’s parallel requirements approach to express preemption and found that the “in addition to or different from” language,<sup>125</sup> which closely tracks language in the MDA’s express preemption provision, required that approach. And *Riegel*—a case involving a PMA-approved device where the plaintiffs’ claims were preempted but no parallel claims were at issue—observed 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.”<sup>126</sup>

In short, state law claims paralleling federal requirements appear to survive express preemption under § 360k(a). But this conclusion has become established largely through dicta with little controlling authority outlining either what the un-preempted, surviving state law claims might be, or whether they survive in whole or only in part. Moreover, *Lohr* and *Riegel* said only that these hypothetical parallel claims were not *expressly* preempted.<sup>127</sup> They said nothing about the extent to which any such claims may be *impliedly* preempted. *Riegel*’s silence on this point, as well as its failure to cite or discuss the Court’s earlier decision in *Buckman*, is particularly puzzling.

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121. See discussion *supra* Part II.A.

122. *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996).

123. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 346 (2001).

124. *Id.* at 348.

125. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 448 (2005).

126. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (citations omitted).

127. Similarly, *Bates* addressed only express preemption under 7 U.S.C. § 136v(b).

From the cases discussed, it is possible to discern some general contours of a surviving, parallel requirements state law claim. First, there is little point in assessing whether claims relating to 510(k)-approved devices are “parallel” and survive express preemption given *Lohr*’s holding that, for 510(k) devices, there is no express preemption. Thus, the parallel requirements analysis should begin with claims relating to a PMA-approved device.

Second, the state law claim at issue must be one that both imposes requirements under the MDA and “relates to the safety or effectiveness of the device” or there would be no express preemption and, thus, no meaningful parallel requirements inquiry. Most state law claims based on theories of express warranty, affirmative misrepresentation, and implied warranty impose requirements and are preempted by § 360k(a) because they directly or indirectly challenge the adequacy of FDA-approved labeling or other federal requirements.<sup>128</sup> However, one could imagine claims unrelated “to the safety or effectiveness of [a] device,” for example, a claim based on representations relating to pricing.<sup>129</sup> Those claims are not suited to a parallel requirements inquiry.

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128. *E.g.*, *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008) (“[T]he better-reasoned approach would find plaintiff’s breach of express warranty claims based on the labeling of [the device at issue] preempted.”); *Lake v. Kardjian*, 874 N.Y.S.2d 751, 754 (Sup. Ct. 2008) (“[A] breach of express warranty claim based upon FDA approved statements in product labeling and advertising is preempted by the MDA.”). *But see* *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 839 (S.D. Ind. 2009) (finding that express warranty claims that “device implanted in [the plaintiff’s] hip failed to meet the promises of the [device’s] label and package inserts” were not preempted).

129. *See* *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997) (“Express warranties arise from the representations of the parties and are made as the basis of the bargain between them. A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA, and therefore we cannot say that such a cause of action is preempted.”); *Hofts*, 597 F. Supp. 2d at 839 (“Because express warranties ‘arise from the representations of the parties and are made as the basis of the bargain between them,’ a ‘state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA’ and therefore may not be preempted.”) (quoting *Mitchell*, 126 F.3d at 915); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 285–86 (E.D.N.Y. 2009) (finding “plaintiff’s breach of express warranty claim [to be] preempted to the extent that it is premised on FDA approved representations made by the manufacturer,” but finding that other express warranty claims failed because “[n]owhere in her amended complaint does plaintiff allege that she relied on defendants’ alleged representations” or “even describe how this representation was made”); *Huber v. Howmedica Osteonics Corp.*, No. 07-2400, 2008 U.S. Dist. LEXIS 106479, at \*8–11 (D.N.J. Dec. 21, 2008) (denying motion to dismiss express warranty claim for PMA-approved device). *See generally* *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 526

Third, the requirements imposed by the state law claim must parallel federal requirements or, conversely, cannot be “different from, or in addition to, any” MDA-imposed requirement “relat[ing] to the safety or effectiveness of the device or to any other matter included in [an MDA] requirement applicable to the device.”<sup>130</sup> This means that at a minimum, state law claims survive express preemption as parallel requirements claims only if they are premised on allegations that the device manufacturer *violated* federal requirements.

But, if a state law claim relates to a PMA-approved device and imposes requirements that relate to supposed violations of federal requirements, this does not end the inquiry. Courts also must decide whether (1) a federal requirement was violated; (2) the requirements the state law claim imposes truly parallel the federal requirement; and (3) all aspects of the claim survive preemption. The following subparts explore these issues.

#### A. Was A Federal Requirement Violated?

Following *Riegel*, plaintiffs’ attorneys routinely seek to avoid federal preemption by pleading a parallel requirements claim that alleges that the device manufacturer violated a federal requirement.<sup>131</sup> The evidence of the alleged violation can range anywhere from little more than the plaintiff’s allegation to a prior, final judicial or regulatory adjudication that the manufacturer violated the law.

##### 1. The Range of Possible Enforcement Actions

As the federal agency charged with enforcing the FDCA, the FDA brings, or recommends that the Department of Justice should bring, enforcement actions.<sup>132</sup> If the plaintiff’s claim is based on an instance in which the FDA had previously obtained a final judg-

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(1992) (Stevens, J., plurality) (finding express preemption provision in Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334, did not preempt state law express warranty claims because “a common-law remedy for a contractual commitment voluntarily undertaken should not be regarded as a ‘requirement . . . imposed *under State law*’ within the meaning of” that statute) (emphasis in original).

130. 21 U.S.C. § 360k(a).

131. Cases presenting alleged parallel requirements claims are discussed below in Part III.B.

132. 21 U.S.C. § 337(a) (“Except as provided in subsection (b) [relating to food products], all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.”); *see also* 21 U.S.C. §§ 332–334, 352, 355(e).

ment against the defendant manufacturer, the defendant may be effectively precluded from contesting whether a violation of the federal requirement occurred.<sup>133</sup> Conversely, if the defendant prevailed in a prior enforcement proceeding, the plaintiff may be similarly barred from arguing that a state law claim survives preemption based on a supposed violation of a federal requirement.<sup>134</sup>

But instances where federal enforcement proceedings have resulted in a final judgment are rare, and there are a range of intermediate possibilities. For example, a tort plaintiff might plead a violation of a federal requirement where the FDA had never identified or spoken about the supposed violation. In that event, there would be no evidence about whether the FDA believed a violation actually occurred.

Moving higher up on the enforcement continuum, the FDA could have sent the manufacturer an untitled letter, which raises alleged “violations that do not meet the threshold of regulatory significance for a Warning Letter.”<sup>135</sup> Or, the FDA could send the manufacturer a warning letter, which “is informal and advisory” and “communicates the agency’s position on a matter.”<sup>136</sup> As one court observed, however, even warning letters “merely establish a dialogue between the FDA [and the recipient] and do not necessarily lead to further sanctions.”<sup>137</sup> As another court noted, a warning letter is “a statement by the FDA . . . of what its position is on an issue, along with a threat of enforcement that does not arise to a promise to enforce,” but sending such a letter “standing alone, has no effect until and unless the FDA takes enforcement action.”<sup>138</sup>

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133. The manufacturer could also be legally precluded from contesting the violation based on issue preclusion. See RESTATEMENT (SECOND) OF JUDGMENTS §§ 39–62 (1980).

134. While a defendant that did not prevail in enforcement proceedings might, depending on the particular facts and the applicable law, be collaterally estopped from later contesting that a violation occurred, a plaintiff presumably would not have been a party to the FDA enforcement proceeding and, therefore, would not be collaterally estopped by a judgment for the defendant in the enforcement proceeding. But, even though collateral estoppel would not bar a plaintiff from claiming that the conduct at issue in the enforcement proceeding violated federal requirements, the fact that the defendant prevailed in those proceedings nonetheless should preclude such a claim.

135. FDA, REGULATORY PROCEDURES MANUAL § 4-2-1, at 4-26 (2009), available at [http://www.fda.gov/ora/compliance\\_ref/rpm/](http://www.fda.gov/ora/compliance_ref/rpm/).

136. *Id.* § 4-1-1, at 4-2.

137. *Prof'ls & Patients For Customized Care v. Shalala*, 847 F. Supp. 1359, 1365 (S.D. Tex. 1994) (citation omitted), *aff'd*, 56 F.3d 592 (5th Cir. 1995).

138. *Den-Mat Corp. v. FDA*, No. MJG-92-444, 1992 U.S. Dist. LEXIS 12233, at \*12 (D. Md. Aug. 17, 1992) (citation omitted); *accord* *Biotics Research Corp. v.*

Thus, neither an FDA untitled nor an FDA warning letter, by itself, establishes that a violation actually occurred. In response to such a letter the manufacturer may, for instance, prove to the FDA's satisfaction that there was no violation. Or, while not agreeing that a violation occurred, it may take any requested remedial actions to avoid the expense of contesting the issue or the perceived risks of prolonging a dispute with the manufacturer's primary regulator.

Even when more formal enforcement steps have been taken the FDA's determination that a violation occurred is not necessarily the last word.<sup>139</sup> The FDA could commence litigation accusing the manufacturer of having violated the FDCA, and the manufacturer could nonetheless win at trial. As the Supreme Court recently observed in *Wyeth v. Levine*, the FDCA's misbranding statute "contemplates that federal juries will resolve most misbranding claims" and, therefore, "the FDA's belief that a drug is misbranded is not conclusive."<sup>140</sup>

## 2. The Burdens Presented by Pursuing Non-Final Federal Violations in the Course of Adjudicating Whether State Law Claims Survive Preemption

In situations where FDA enforcement proceedings have not reached a final result that can be "imported" into the action in which the state law claim is asserted, there are likely questions about whether a violation of federal requirements in fact occurred and, if so, on what terms and to what extent the FDA would have pursued an enforcement action. To resolve the threshold "was there a violation" issue in the parallel requirements preemption in-

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Heckler, 710 F.2d 1375, 1378 (9th Cir. 1983) (saying warning letters "do not commit the FDA to enforcement action," and the recipient may not bring an action to challenge a Warning Letter); *see also* 21 C.F.R. § 10.85 (2009) ("A statement or advice given by an FDA employee . . . in writing . . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.").

139. For example, in *Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-1777, 2008 U.S. Dist. LEXIS 62131 (N.D. Tex. Aug. 13, 2008), the FDA had issued reports and warnings letters regarding violations of FDA current good manufacturing practices (CGMP) regulations and filed suit against the defendant's president and chief executive officer for violations of CGMP and premarket approval requirements. *Id.* at \*3-4.

140. 129 S. Ct. 1187, 1197 (2009); *see also* *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005) ("In criminal prosecutions for violations of FIFRA's provisions, *see* [7 U.S.C.] § 136l(b), juries necessarily pass on allegations of misbranding.").

quiry, the parties must litigate (without FDA involvement) the question of whether the manufacturer violated a federal requirement.<sup>141</sup> As *Buckman* recognized, doing that creates a raft of problems.

First, litigating the issue of whether there was a federal violation ignores § 337(a) of the FDCA, which provides that “all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.”<sup>142</sup> The Court noted in *Buckman* that “[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions,” and “[t]he FDA . . . has at its disposal a variety of enforcement options that allow it to take a measured response to suspected” FDCA violation.<sup>143</sup>

Having private tort plaintiffs rather than the FDA select which alleged violations to pursue undermines the FDA’s ability to “make

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141. Theoretically, courts could, based on the doctrine of primary jurisdiction, stay an action or dismiss it without prejudice pending the FDA’s resolution of whether violations occurred. Primary jurisdiction:

“[A]pplies where a claim is originally cognizable in the courts, and comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body.” The contours of primary jurisdiction are not fixed by a precise formula. Rather, the applicability of the doctrine in any given case depends on “whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application.” Among the reasons and purposes served are the promotion of consistency and uniformity within the areas of regulation and the use of agency expertise “in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion.”

When it is determined that primary jurisdiction to resolve an issue lies with an agency, a court otherwise having jurisdiction over the case may stay or dismiss the action pending the agency’s resolution of the question. The doctrine is to be “invoked sparingly, as it often results in added expense and delay.”

*Alpharma Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005) (citations omitted). Given the volume of claims relating to medical devices, the range of supposed FDCA violations alleged in those actions, and the fact that primary jurisdiction is to be “invoked sparingly,” it is unlikely that courts would routinely find that primary jurisdiction should be invoked in this context.

142. 21 U.S.C. § 337(a).

143. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 (2001); *see, e.g., Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (“[E]very federal court that has addressed the question has held that the FDCA does not create a private right of action to enforce or restrain violations of its provisions.” (quoting *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, 1997 WL 94237, at \*3 (D. Kan. Feb 26, 1997)); *see also* JAMES M. BECK & ANTHONY VALE, *DRUG AND MEDICAL DEVICE PRODUCT LIABILITY DESKBOOK* § 4.01 (2009).

a measured response” to suspected FDCA violations.<sup>144</sup> It also eliminates the resulting “flexibility [that] is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives.”<sup>145</sup> As with the state law fraud-on-the-FDA claims in *Buckman*, adjudicating FDCA violations in actions brought by private plaintiffs “inevitably conflict[s] with the FDA’s responsibility to police” manufacturers “consistently with the Administration’s judgment and objectives.”<sup>146</sup>

Second, tort plaintiffs would “prosecute” supposed FDCA violations in courts without the FDA’s direct involvement and without the benefit of the Agency’s substantial expertise. The FDA is the federal agency responsible for regulating medical devices; it defines and interprets the PMA requirements on which a state law claim must be based.<sup>147</sup> If private plaintiffs may, in effect, become prosecutors of supposed FDCA violations, the FDA will be glaringly absent from nearly all cases interpreting what its regulations mean.

Instead of having the true expert—the FDA—in the courtroom, trials will turn on the testimony of privately-retained experts. Experience and common sense suggest that in general, plaintiffs’ experts will testify that the requirements imposed by the FDA either compelled the device manufacturer to do something it allegedly did not do, or prohibited the manufacturer from doing something it allegedly did. The reverse is also true; defense experts generally testify that the FDA requirements allowed the manufacturers to do whatever they did or precluded them from doing what plaintiffs allege they should have done. In the end, juries will be left to choose between the parties’ retained experts’ competing (and sometimes extreme) opinions, and there is little reason to expect the resulting verdicts to reflect the FDA’s actual views.

Third, having juries rather than the FDA pass on alleged FDCA violations may create a systemic bias in favor of finding that the violations occurred and might result in over-deterrence. As *Riegel* explained, the FDA must, by statute,<sup>148</sup> “apply cost-benefit analysis,” while “[a] jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped the

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144. *Buckman*, 531 U.S. at 349.

145. *Id.*

146. *Id.* at 350.

147. See *Medtronic v. Lohr*, 518 U.S. 470, 496 (1996) (“[T]he FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the [FDCA] . . .”) (citation omitted).

148. 21 U.S.C. § 360c(a)(2)(C).

benefits are not represented in court.”<sup>149</sup> In *Warner-Lambert*, Justice Breyer made the same point during his questioning at oral argument:

Now, who would you rather have make the decision as to whether this drug is, on balance, going to save people or, on balance, going to hurt people? An expert agency, on the one hand, or 12 people pulled randomly for a jury role who see before them only the people whom the drug hurt and don't see those [other people] who need the drug to cure them?<sup>150</sup>

Juries also have been reported to suffer from substantial hindsight bias and according to some, reach decisions that have little relation to the scientific evidence presented.<sup>151</sup>

Thus, juries may see only the injured plaintiffs before them, not the systemic costs that may result from finding that the FDCA prohibits conduct. For that reason, juries may find violations based on conduct that the FDA would permit because that conduct is beneficial from a larger societal perspective. For example, fearing that judges or juries may conclude that legitimate and useful activities, such as advertising that apprises physicians about a product, nonetheless violate federal requirements, manufacturers might refrain from engaging in those activities.<sup>152</sup>

Fourth, having private litigants in effect prosecuting alleged FDCA violations creates substantial uncertainty. In many situations multiple plaintiffs sue a medical device manufacturer, which means there would be multiple fact-finders assessing a single alleged violation. There is no assurance that those fact-finders will (1) condemn only conduct that the FDA considers to violate federal requirements; (2) produce the results that an FDA enforcement action

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149. 552 U.S. 312, 325 (2008).

150. Transcript of Oral Argument at 30:22–31:3, *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006) (No. 06-1498), available at [http://www.supremecourt.us/oral\\_arguments/argument\\_transcripts/06-1498.pdf](http://www.supremecourt.us/oral_arguments/argument_transcripts/06-1498.pdf). *Warner-Lambert* is described *supra* note 12.

151. Reid Hastie & W. Kip Viscusi, *What Juries Can't Do Well: The Jury's Performance as a Risk Manager*, 40 ARIZ. L. REV. 901, 917 (1998) (“[T]he typical juror appears to be subject to a massive hindsight bias.”); Ross P. Laguzza, *Science Doesn't Matter: A Blasphemer's View of How To Win A Causation Battle*, 31 THE BRIEF 55, 55 (2002) (“[I]n most cases, [ ] scientific evidence has little bearing on jurors' decisions.”).

152. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (noting that, if private plaintiffs could pursue state law fraud-on-the-FDA claims, “[w]ould-be applicants may be discouraged from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer . . . to unpredictable civil liability”).

would; or (3) agree with one another—a concern that is absent when there is but a single enforcement authority.<sup>153</sup> Just as *Buckman* expressed concern that “fraud-on-the-FDA claims would . . . cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court,”<sup>154</sup> so too would private enforcement actions cause device manufacturers to fear that an unknown judge or jury would find fault with conduct the FDA would allow.<sup>155</sup>

For these reasons, the universe of claims that may survive express preemption under the parallel requirements exception for PMA-approved devices outlined in *Lohr* and *Riegel* should include only instances where there is a prior, final determination that a violation actually occurred. That is because establishing a necessary predicate to pursuing those claims—that there was a violation of a federal requirement—runs into the implied preemption principles articulated in *Buckman*.

Certainly the fact that there is an express preemption provision in a federal statute does not prohibit engaging in an implied preemption inquiry. Since *Freightliner Corp. v. Myrick*,<sup>156</sup> it has been clear that the fact that a statute has an express preemption provision does not bar the ordinary working of implied preemption principles.<sup>157</sup> And, as *Buckman* explained, there is “no presumption against pre-emption” when assessing whether a manufacturer violated a federal requirement because “the relationship between a

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153. Product liability cases involving medical devices are also dominated by complex questions of causation and the adequacy of particular warnings. The FDA’s absence in deciding these, and other, questions introduces additional risk of misinterpretation or misapplication of its requirements.

154. *Buckman*, 531 U.S. at 351.

155. In *Bates*, however, the Court dismissed this concern:

While it is true that properly instructed juries might on occasion reach contrary conclusions on a similar issue of misbranding, there is no reason to think such occurrences would be frequent or that they would result in difficulties beyond those regularly experienced by manufacturers of other products that everyday bear the risk of conflicting jury verdicts.

*Bates v. Dow Agrosiences LLC*, 544 U.S. 431, 452 (2005).

156. 514 U.S. 280 (1995).

157. *Id.* at 288. As the Court explained in *Freightliner*, “[t]he fact that an express definition of the pre-emptive reach of a statute “implies”—i.e., supports a reasonable inference—that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied preemption.” 514 U.S. at 288–89. Indeed, even the presence of a savings clause—a provision the FDCA does not contain for medical devices—“does not bar the ordinary working of conflict pre-emption principles.” *Geier v. Amen. Honda Motor Co.*, 529 U.S. 861, 869 (2000) (emphasis in original).

federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.”<sup>158</sup>

Thus, even if a plaintiff’s claims are premised on state law requirements that “parallel” federal requirements and, for that reason, survive express preemption under the dicta in *Lohr* and *Riegel*, those claims nonetheless are impliedly preempted under *Buckman* absent a prior, final determination that there was a violation of a federal requirement. In the real world this is a very significant limitation on the parallel requirements exception as comparatively few state law claims are based on prior, final determinations that a violation occurred.

### 3. A Hypothetical: Assume *Buckman* Involved a PMA-Approved Device

One way to demonstrate that *Buckman* and implied preemption limit the parallel requirements claims that survive express preemption under *Lohr* and *Riegel*’s dicta is to take the fraud-on-the-FDA claims at issue in *Buckman* and assess whether, if permitted to proceed, they would have imposed such “parallel requirements.” To do so, one must hypothesize that *Buckman* involved a PMA-approved device because there was no express preemption for the 510(k)-approved device at issue in *Buckman* and, therefore, no need to examine the parallel requirements exception.

These hypothetical fraud-on-the-FDA claims appear to be parallel requirements claims under *Lohr* and *Riegel*. They would “provide a traditional damages remedy for violations of common-law duties [that] parallel federal requirements;”<sup>159</sup> namely the federal requirements that require manufacturers to provide the FDA with truthful and complete data when seeking PMA approval.<sup>160</sup>

For purposes of assessing whether these fraud-on-the-FDA claims are impliedly preempted under *Buckman*, however, the underlying device’s method of approval is irrelevant. Notwithstanding the shift from a 510(k)-approved device (as in *Buckman*) to a PMA-approved device (as in our hypothetical), these claims create essentially the same problems that the *Buckman* plaintiffs’ claims created. As *Buckman* found, the federal enforcement scheme does not contemplate or permit private plaintiffs enforcing FDCA requirements when there is no underlying FDA enforcement action. Thus, al-

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158. *Buckman*, 531 U.S. at 347, 348.

159. *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996).

160. *See, e.g.*, 21 U.S.C. § 331(p) (2007) (prohibiting “the failure to provide any information required by” 21 U.S.C. § 360(j) or (k)).

though the hypothetical fraud-on-the-FDA claims would escape express preemption because they impose only state law requirements that “parallel” federal ones, these claims should be impliedly preempted under *Buckman*.

Not surprisingly, the *Buckman* plaintiffs argued that their claims imposed only parallel requirements and, therefore, survived preemption under *Lohr*'s dictum.<sup>161</sup> *Buckman* characterized this argument as one that both the *Buckman* and *Lohr* plaintiffs' claims arose from “violations of FDCA requirements,” and rejected it because the claims in *Lohr* “arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements,” while those in *Buckman* “exist[ed] solely by virtue of the FDCA disclosure requirements.”<sup>162</sup>

The *Buckman* plaintiffs, however, did not compare their claims to the *Lohr* plaintiffs' actual claims; instead, they compared them to the hypothetical claims that survive express preemption because they impose only parallel requirements as provided in *Lohr*'s dictum. The reason the *Lohr* plaintiffs' claims survived preemption was unrelated to the fact that they were based on common law obligations and not “solely” based on “violation[s] of the FDCA requirements.” Instead, the *Lohr* plaintiffs' claims escaped express preemption largely because the device at issue had been approved under the 510(k) notification process and, thus, there simply were no applicable federal requirements.

Further, the reason the *Lohr* plaintiffs' claims survived preemption had nothing to do with parallel requirements. Indeed, those claims properly were never subjected to a parallel requirements inquiry. That inquiry addresses which claims survive express preemption—an issue that was irrelevant in *Lohr*—where there was no express preemption because the device at issue had been approved under the 510(k) notification process. As *Riegel* demonstrated, however, the *Lohr* plaintiffs' claims were not ones that, for a PMA-approved device where express preemption applies, could have survived preemption as claims imposing only parallel requirements. Putting aside the device's approval method, the *Lohr* plaintiffs' claims, like the *Riegel* plaintiffs' claims, were premised on supposed breaches of common law obligations *without* accompanying breaches of federal requirements.

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161. Brief for Respondent at 37–38, *Buckman*, 531 U.S. 341 (Oct. 23, 2000) (No. 98-1768), 2000 U.S. S. Ct. Briefs LEXIS 540, at \*37–38.

162. *Buckman*, 531 U.S. at 352–53 (citation omitted).

A more responsive answer to the *Buckman* plaintiffs' assertion that their fraud-on-the-FDA claims survived preemption because they imposed only parallel requirements under *Lohr*'s dictum might have been that, although possibly not expressly preempted, their claims were nonetheless impliedly preempted. For the reasons detailed at length in *Buckman*, even claims that survive express preemption by imposing only parallel requirements may nonetheless be impliedly preempted when, as in *Buckman*, they require private plaintiffs to usurp the FDA's role as the sole enforcer of the FDCA—a scenario unrelated to the approval method.<sup>163</sup>

*B. Does The State Law Claim Impose Requirements That "Parallel" Federal Requirements?*

A state law claim that purportedly escapes preemption under the parallel requirements exception faces a second hurdle: establishing that in fact, the state law claim *parallels* federal requirements. Under *Lohr*, mere similarity between the state and federal requirements is not enough; instead, parallel requirements claims escape express preemption because they "merely provide[ ] another reason for manufacturers to comply with *identical* existing 'requirements' under federal law."<sup>164</sup> This subpart details the extent to which each of the various types of supposedly "parallel" claims actually track a federal requirement.

1. Negligence Per Se Claims

The most directly parallel state law claim that a medical device plaintiff can assert is a negligence per se claim premised on a violation of an underlying federal requirement. As one court observed, "[a] claim of negligence per se simply adopts the standard of care imposed by a statute or regulation as the standard against which the defendant's conduct is evaluated."<sup>165</sup> Such claims should meet *Riegel*'s definition of a parallel state law claim: a claim "providing a damages remedy for claims premised on a violation of FDA regulations."<sup>166</sup>

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163. Along those lines, the Sixth Circuit found that a plaintiff's claims alleging failure to comply with FDA regulations amounted to "a disguised fraud on the FDA claim" and thus were preempted under *Buckman*. *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005).

164. *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996) (emphasis added).

165. *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1163 (D. Minn. 2009) (citing RESTATEMENT (SECOND) OF TORTS § 286 (1965)) (emphasis in original).

166. 552 U.S. 312, 330 (2008).

But negligence per se claims also may, for reasons discussed in Subpart III.A above, be impliedly preempted under *Buckman*. For example, the *Buckman* plaintiffs' "fraud-on-the-FDA" claims presumably could have been, for a PMA-approved device, recast as "failure-to-submit-the-required-information" negligence per se claims. Yet a court should still find claims recast in this manner to be impliedly preempted for the reasons detailed at length in *Buckman*. Indeed, the District of Minnesota recently held that broad-ranging negligence per se claims failed because, among other reasons, they were "impliedly preempted under 21 U.S.C. § 337(a) and *Buckman*."<sup>167</sup>

Negligence per se claims also may face other legal obstacles. Many states do not permit negligence per se claims where, as with the FDCA, the underlying statute or regulation does not permit a private right of action.<sup>168</sup> Most states have adopted some sort of legislative purpose limitation on the use of negligence per se.<sup>169</sup> As

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167. *In re Medtronic*, 592 F. Supp. 2d at 1163 n.19.

168. RESTATEMENT (SECOND) OF TORTS § 286, cmt. d (1965) (saying when "the legislature has indicated no intention that [a statutory provision] shall be so applied" in a tort suit, courts may "treat the provision as inapplicable"); *see also* RESTATEMENT (THIRD) OF TORTS, PRODUCTS LIABILITY § 4, comment *d* (1997) ("[P]urpose" is to be taken "into account in determining whether noncompliance . . . renders the product defective.").

169. Arkansas: *Branscumb v. Freeman*, 200 S.W.3d 411, 416–17 (Ark. 2004); Colorado: *Bittle v. Brunetti*, 750 P.2d 49, 58 (Colo. 1998); *Gerrity Oil & Gas Corp. v. Magness*, 946 P.2d 913, 930 (Colo. 1997); Connecticut: *Ward v. Greene*, 839 A.2d 1259, 1272 (Conn. 2004); *Gore v. People's Sav. Bank*, 665 A.2d 1341, 1351–52 (Conn. 1995); Florida: *White v. NCL America, Inc.*, No. 05-22030-CIV, 2006 WL 1042548, at \*5 (S.D. Fla. Mar. 8, 2006); *Labzda v. Purdue Pharm., L.P.*, 292 F. Supp. 2d 1326, 1355 (S.D. Fla. 2003); *Freehauf v. Sch. Bd. of Seminole County*, 623 So. 2d 761, 763 (Fla. Dist. Ct. App. 1993); Georgia: *Spivey v. Sellers*, 363 S.E.2d 856, 858 (Ga. Ct. App. 1987); Idaho: *O'Guin v. Bingham County*, 72 P.3d 849, 856 (Idaho 2003); Illinois: *Magna Trust Co. v. Ill. Cent. R.R.*, 728 N.E.2d 797, 805 (Ill. App. Ct. 2000); Kansas: *Alumbaugh v. Union Pac. R.R.*, 322 F.3d 520, 524–25 (8th Cir. 2003); *Bland v. Scott*, 112 P.3d 941, 947–48 (Kan. 2005); *Pullen v. West*, 92 P.3d 584, 593–94 (Kan. 2004); *OMI Holdings, Inc. v. Howell*, 918 P.2d 1274, 1296 (Kan. 1996); Kentucky: *T & M Jewelry, Inc. v. Hicks*, 189 S.W.3d 526, 530 (Ky. 2006); Massachusetts: *Swift v. United States*, 866 F.2d 507, 509 (1st Cir. 1989); Missouri: *Lowdermilk v. Vescovo Blg. & Realty Co.*, 91 S.W.3d 617, 629 (Mo. App. 2002); *Imperial Premium Fin. v. Northland Ins. Co.*, 861 S.W.2d 596, 599 (Mo. Ct. App. 1993); Nebraska: *Holmes v. Circo*, 244 N.W.2d 65, 69–70 (Neb. 1976); Nevada: *Texas Int'l Airlines, Inc. v. Bryan*, 857 F. Supp. 838, 848 (D. Nev. 1981); New Mexico: *F.D.I.C. v. Schuchmann*, 235 F.3d 1217, 1223 (10th Cir. 2000) (citing *Valdez v. Gillessen & Son, Inc.*, 734 P.2d 1258, 1261 (N.M. 1987)); *Ray v. Aztec Well Serv. Co.*, 748 F.2d 888, 890 (10th Cir. 1984) (finding liability because the plaintiff was in the class of people the legislature intended to protect and the injury was of the sort that the legislature intended to protect them from); *Jaramillo v. Fisher Controls Co.*, 698 P.2d 887, 892 (N.M. 1985); New York: *German v. Fed. Home Loan Mortgage Corp.*, 885 F. Supp. 537, 567 (S.D.N.Y. 1995); *Sheehy v. Big Flats*

the Tenth Circuit explained, “[w]here a statute creates legal duties and provides a particular means for their enforcement, *the designated remedy excludes all others.*”<sup>170</sup> Moreover, there are other state-imposed limitations that may prohibit a particular negligence per se claim relating to a medical device.<sup>171</sup> However, when negligence

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Cmty. Day, Inc., 541 N.E.2d 18, 21 (N.Y. 1989); Gain v. E. Reinforcing Serv., Inc., 603 N.Y.S.2d 189, 191 (App. Div. 1993); North Carolina: Hall v. Toreros, II, Inc., 626 S.E.2d 861, 867–69 (N.C. Ct. App. 2006), *review allowed*, 642 S.E.2d 248 (N.C. 2007); Williams v. City of Durham, 473 S.E.2d 665, 667 (N.C. Ct. App. 1996); Ohio: Hernandez v. Martin Chevrolet, Inc., 649 N.E.2d 1215, 1217 (Ohio 1995); Oklahoma: Gorton v. Mashburn, 995 P.2d 1114, 1117 (Okla. 1999); Oregon: Scovill v. City of Astoria, 921 P.2d 1312, 1316 (Or. 1996); Pennsylvania: Frederick L. v. Thomas, 578 F.2d 513, 517 n.8 (3d Cir. 1978); South Carolina: Hurst v. Sandy, 494 S.E.2d 847, 851 (S.C. App. 1997); Tennessee: Rains v. Bend of the River, 124 S.W.3d 580, 589–91 (Tenn. App. 2003); Utah: Rollins v. Petersen, 813 P.2d 1156, 1163–64 (Utah 1991); Wisconsin: Cooper v. Eagle River Mem’l Hosp., Inc., 270 F.3d 456, 460 (7th Cir. 2001); Chapman v. Mutual Ser. Cas. Ins. Co., 35 F. Supp. 2d 699, 705 (E.D. Wis. 1999).

170. Gammill v. United States, 727 F.2d 950, 953 n.3 (10th Cir. 1984) (emphasis added) (quoting Silverstein v. Sisters of Charity of Leavenworth, 559 P.2d 716, 718 (Colo. App. 1976)).

171. For example, several states do not allow negligence per se claims based on the violation of a regulation, as opposed to a statute. *See, e.g.*, LA. CIV. CODE ANN. art. 2317 (1997 & Supp. 2009); California Serv. Station & Auto. Repair Ass’n v. Am. Home Assurance Co., 73 Cal. Rptr. 2d 182, 188 (Cal. Ct. App. 1998); Murray v. Briggs, 569 So. 2d 476, 480 (Fla. Dist. Ct. App. 1990); Town of Kirklin v. Everman, 29 N.E.2d 206, 206–07 (Ind. 1940); Harwood v. Glacier Elec. Coop., 949 P.2d 651, 656 (Mont. 1997); Price v. Sinnott, 460 P.2d 837, 840 (Mont. 1969); McKinney v. H.M.K.G. & C., Inc., 123 S.W.3d 274, 280–81 (Mo. Ct. App. 2003); Elliott v. City of New York, 747 N.E.2d 760, 763–64 (N.Y. 2001); Chambers v. St. Mary’s Sch., 697 N.E.2d 198, 202–03 (Ohio 1998); Ridgecrest Retirement & Healthcare v. Urban, 135 S.W.3d 757, 763 (Tex. Ct. App. 2004). Moreover, negligence per se claims have been held improper where based upon the violation of FDA guidance, advisory, draft documents, or other pronouncement not having the force of law. *See* Flechsig v. United States, 991 F.2d 300, 304 (6th Cir. 1993); Jacobo v. United States, 853 F.2d 640, 641 (9th Cir. 1988); Gatter v. Nimmo, 672 F.2d 343, 347 (3d Cir. 1982); Smith v. Pulaski County, 501 S.E.2d 213, 214 (Ga. 1998); Schaeffer v. Stewart’s Plaza Pharmacy, Inc., 79 P.3d 922, 931–33 (Utah 2003); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 4 cmt. d (1997); RESTATEMENT (SECOND) OF TORTS §§ 288–288C (1965). Additionally, FDCA-based negligence per se claims have been rejected in cases where the standard allegedly imposed by the FDCA was held impermissibly vague. *See, e.g.*, Talley v. Danek Med., Inc., 179 F.3d 154, 161 (4th Cir. 1999); McNeil Pharm. v. Hawkins, 686 A.2d 567, 582 (D.C. Cir. 1996); Baraukas v. Danek Med., Inc., No. 97-613, 2000 WL 223508, at \*4 n.2 (M.D. N.C. Jan. 13, 2000); Shanks v. Upjohn Co., 835 P.2d 1189, 1200–01 (Alaska 1992); *In Re* Shigellosis Litig., 647 N.W.2d 1, 10–12 (Minn. Ct. App. 2002); Goodman v. Wenco Foods, Inc., 423 S.E.2d 444, 452 (N.C. 1992); Jones v. GMRI, Inc., 551 S.E.2d 867, 873 (N.C. Ct. App. 2001); Messer Griesheim Indus., Inc. v. Eastman Chem. Co., 194 S.W.3d 466, 483 (Tenn. Ct. App. 2005); King v. Danek Med., Inc., 37 S.W.3d 439, 458 (Tenn. Ct. App. 2000). For a thorough discussion of these, and other

per se claims are permitted on these facts—that is, an established violation of a federal requirement proximately caused the injury at issue—they do not suffer from being insufficiently “parallel” to a federal requirement.

2. Design Defect, Failure-To-Warn, Breach of Implied Warranty of Merchantability, and Other Labeling-Based Claims

At the other extreme from negligence per se claims, in terms of their “parallelism,” are design defect, failure-to-warn, breach of implied warranty of merchantability, and various labeling-based claims, including those crafted as claims for express warranty, affirmative misrepresentation, and breach of implied warranty of fitness for purpose.<sup>172</sup> Theoretically, one or more of these claims could be founded on an underlying violation of federal requirements if, for example, a device manufacturer did not use the FDA-approved design or labeling. However, those claims are rare in practice because manufacturers typically use the design and labeling the FDA approved.<sup>173</sup>

Traditional product liability claims are expressly preempted because the state law requirements they impose are “different from, or in addition to, any requirement” imposed by the FDCA.<sup>174</sup> As Justice Breyer observed in his concurrence in *Lohr*, “a federal MDA regulation [that] requires a 2-inch wire” in a device, preempts not only a state agency regulation that requires a 1-inch wire, but also “a state-law tort action that premises liability upon the defendant manufacturer’s failure to use a 1-inch wire (say, an award by a jury per-

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FDCA-based negligence per se claim issues, see JAMES M. BECK & ANTHONY VALE, DRUG AND MEDICAL DEVICE PRODUCT LIABILITY DESKBOOK § 4.02 (2009) and James M. Beck & John A. Valentine, *Challenging the Viability of FDCA-Based Causes of Action in the Tort Context: The Orthopedic Bone Screw Experience*, 55 FOOD & DRUG L. J. 389 (2000).

172. As noted previously *supra* note 129, it is conceivable that express warranty, affirmative misrepresentation, and implied warranty of fitness for purpose claims could be based on statements wholly unrelated to a medical device’s labeling. In that event, federal requirements might not be implicated and, for that reason, an express preemption analysis might not apply.

173. *Purcel v. Advanced Bionics Corp.*, No. 3:07-CV-1777, 2008 U.S. Dist. LEXIS 62131 (N.D. Tex. Aug. 13, 2008), may have involved such an instance. There, the plaintiffs alleged that the defendant’s implantable cochlear ear device was manufactured with a defective feed-through device the FDA had not approved that caused the device to be ineffective. *Id.* at \*5. Purcel found those plaintiffs’ strict liability and implied warranty of merchantability claims survived preemption as parallel requirements claims. *Id.* at \*7–8, \*11–12.

174. 21 U.S.C. § 360k(a)(1).

suaded by expert testimony that use of a more than 1-inch wire is negligent).<sup>175</sup>

These types of claims were at issue in *Riegel* where the Court affirmed the lower courts' preemption findings with respect to those plaintiffs' claims that relied on multiple legal theories—strict liability, negligence, and breach of implied warranty—and a wide range of supposed defects, including alleged defects in “design, testing, inspection, distribution, labeling, marketing, and sale” of the device.<sup>176</sup> Both before and after *Riegel*, courts have routinely dismissed these claims relating to PMA-approved devices routinely as expressly preempted because they plainly impose state law requirements that are “different from, or in addition to” federal requirements and, therefore, are not parallel claims.<sup>177</sup>

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175. *Medtronic v. Lohr*, 518 U.S. 470, 504 (1996) (Breyer, J., concurring in part and concurring in the judgment).

176. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320–21 (2008).

177. Some cases involve design defect claims. *See, e.g.*, *Gomez v. St. Jude Med. Daig Div., Inc.*, 442 F.3d 919, 930 (5th Cir. 2006); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009); *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1161–62 (D. Minn. 2009). Some involve failure-to-warn claims. *See, e.g.*, *Gomez*, 442 F.3d at 931; *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 490 (7th Cir. 2005); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 286–87 (E.D.N.Y. 2009); *In re Medtronic*, 592 F. Supp. 2d at 1159–61. Some involve implied warranty of merchantability claims. *See, e.g.*, *Mitchell v. Collagen Corp.*, 126 F.3d 902, 914–15 (7th Cir. 1997); *Horowitz*, 613 F. Supp. 2d at 284–85; *In re Medtronic*, 592 F. Supp. 2d at 1164. Some involve other labeling-based claims. *See, e.g.*, *Gomez*, 442 F.3d at 932 (express warranty claim based on representations in label, warnings, and instructions for use was preempted); *Bencomo v. Guidant Corp.*, No. 06-2473, 2009 U.S. Dist. LEXIS 55504, at \*16 (E.D. La. June 30, 2009) (holding that a breach of express warranty claim “when the representations at issue are approved by the FDA through the premarket approval process” was preempted); *Horowitz*, 613 F. Supp. 2d at 285 (“Plaintiff’s breach of express warranty claim is preempted to the extent that it is premised on FDA approved representations made by the manufacturer.”) (citation omitted); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008) (“Plaintiff’s express warranty claim would contradict the FDA’s determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements. Therefore, that claim is preempted by section 360k(a).”); *Lake v. Kardjian*, 874 N.Y.S.2d 751, 754 (Sup. Ct. 2008) (“[A] breach of express warranty claim based upon FDA approved statements in product labeling and advertising is preempted by the MDA . . .”).

*Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 839–40 (S.D. Ind. 2009), denied a motion to dismiss implied warranty of merchantability claims with respect to a PMA-approved device because, in 21 C.F.R. § 808.1, the MDA exempts from preemption regulations of general applicability, which the *Hofts* court found an implied warranty of merchantability claim to be. But *Hofts* did not address, much less distinguish, *Riegel*’s rejection of this interpretation of 21 C.F.R. § 808.1.

### 3. Manufacturing Defect Claims

Manufacturing defect claims lie between the extremes of state law negligence *per se* claims and common law claims asserting design and warnings defects. A claim that a plaintiff's injury was caused by a medical device that was manufactured improperly and in violation of a federal requirement seems like a prime candidate for being a non-preempted parallel claim. Some courts have held that these claims are indeed parallel and are not preempted, although some of those rulings were in the context of motions to dismiss where the factual record was undeveloped.<sup>178</sup>

But connecting a supposed manufacturing defect—typically, an isolated instance where the device was not manufactured in the way the manufacturer intended—to a violation of a federal requirement can be daunting, particularly because of prevailing standards regarding the specificity of pleading.<sup>179</sup> For example, in *In re Sprint Fidelis Leads Product Liability Litigation*,<sup>180</sup> the plaintiffs alleged a “manufacturing defect” based on supposedly inadequate welding techniques that purportedly did not comply with the FDA’s Current Good Manufacturing Practices (CGMP) and Quality System Regulation (QSR). In finding these claims insufficiently parallel to survive preemption, that court found that the applicable FDA regulations “serve only as ‘an umbrella quality system,’ providing ‘general objectives’ medical device manufacturers must seek to achieve.”<sup>181</sup> Because of the “flexibility inherent in the CGMPs and QSR,” the plaintiffs’ manufacturing defect claims were “not ‘parallel.’”<sup>182</sup> “In the absence of any specific requirement in the CGMPs/QSR that [the manufacturer] weld the . . . leads in a certain fashion, holding [the manufacturer] liable for such a welding ‘defect’ would impose requirements ‘different from, or in addition to’ those under federal law.”<sup>183</sup>

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*Riegel*, 552 U.S. at 328–29. *In re Medtronic*, relying on *Riegel*, rejected this interpretation of 21 C.F.R. § 808.1. 592 F. Supp. 2d at 1164.

178. *E.g.*, *Gomez*, 442 F.3d at 933 (where manufacturing defect claims had proceeded to jury trial, the court noted that “[t]he district judge properly limited [the plaintiff’s] negligence claim to a claim that the [device] used in her surgery was defectively manufactured because it did not comply with the FDA-approved specifications.”) (citation omitted); *Hofst*, 597 F. Supp. 2d at 836–37 (denying motion to dismiss).

179. See the discussion of recent Supreme Court decisions addressing pleading standards *infra* at text accompanying notes 189–91.

180. 592 F. Supp. 2d 1147 (D. Minn. 2009).

181. *Id.* at 1157.

182. *Id.* at 1158.

183. *Id.*

For example, in *Parker v. Stryker Corp.*,<sup>184</sup> the plaintiff “allege[d] that the [device] was defective because ‘the manufacturing processes for the device and certain of their [*sic*] components did not satisfy the [FDA’s] Pre-Market Approval standards for the devices.’”<sup>185</sup> In rejecting that claim, the court noted that, “[a]lthough such a claim appears to constitute the type of parallel claim the *Riegel* Court found to be outside the preemptive reach of section 360k, nowhere does plaintiff’s complaint provide any factual detail to substantiate that crucial allegation.”<sup>186</sup>

Similarly, the plaintiff in *Clark v. Medtronic, Inc.*<sup>187</sup> attempted to pursue a manufacturing defect claim relating to an implantable cardioverter-defibrillator (ICD) based on *res ipsa loquitur*, arguing that, because the device malfunctioned, it must have had a manufacturing defect. The court in *Clark* assumed without discussion that this claim survived preemption, but nonetheless rejected it because an “ICD is a complex device which ‘can fail for a variety of reasons, including medical complications, body rejection phenomena, allergic reaction, and surgical techniques, all of which occur without someone acting in a negligent manner.’”<sup>188</sup>

*In re Medtronic, Inc., Parker, and Clark* highlight the need for a plaintiff’s complaint to tie a manufacturing defect claim to supposed violations of specific federal requirements. These decisions are consistent with the Supreme Court’s recent focus in *Bell Atlantic Corp. v. Twombly*<sup>189</sup> and *Ashcroft v. Iqbal*<sup>190</sup> on the need for plaintiffs

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184. 584 F. Supp. 2d 1298 (D. Colo. 2008).

185. *Id.* at 1301–02 (citation omitted).

186. *Id.* at 1302. Other courts have reached the same conclusion with respect to attempts to assert manufacturing defect claims for the device at issue in *Parker*, an artificial replacement hip. *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 280–84 (E.D.N.Y. 2009); *Bausch v. Stryker Corp.*, No. 08 C 4248, 2008 U.S. Dist. LEXIS 99118, at \*6 (N.D. Ill. Dec. 9, 2008).

187. *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008).

188. *Id.* at 1094 (quoting *Mozes v. Medtronic, Inc.*, 14 F. Supp. 2d 1124, 1129 (D. Minn. 1998)).

189. 550 U.S. 544 (2007). *Twombly* affirmed the dismissal of a complaint alleging antitrust conspiracy claims, observing that “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.” *Id.* at 555 (citations omitted).

190. 129 S. Ct. 1937 (2009). In *Iqbal*, a Pakistani Muslim who had been arrested in connection with the investigation into the September 11, 2001, terrorist attacks filed a *Bivens* action against federal officials. The trial court denied the federal officials’ motion to dismiss based on qualified immunity, and the Second Circuit affirmed. In reversing, the *Iqbal* Court observed that “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do

to provide a non-speculative factual basis for claims in their complaints. The decisions rejected *Conley v. Gibson*'s permissive pleading standard, which allowed claims to proceed "unless it appear[ed] beyond doubt that the plaintiff c[ould] prove no set of facts . . . which would entitle him to relief."<sup>191</sup> In short, manufacturing defect claims may, at least in theory, "parallel" federal requirements. But connecting the supposed device's alleged manufacturing defect to a concrete violation of an actual federal requirement often may be an insurmountable hurdle for plaintiffs to overcome.

### C. Preemption and Punitive Damages

*Lohr* and *Riegel* stated, respectively, that § 360k(a) does not bar plaintiffs from pursuing a "traditional damages remedy" or a "damages remedy for claims premised on a violation of FDA regulations."<sup>192</sup> As Justice O'Connor's concurrence in *Lohr* explained:

Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is "different from, or in addition to," requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.<sup>193</sup>

But what if, even though the federal and state duties arguably parallel one another, other aspects of the state law claim conflict

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not suffice" and that "Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Id.* at 1949–50 (citation omitted). Further, *Iqbal* made clear that *Twombly* is not limited to antitrust actions; instead, the "decision in *Twombly* expounded the pleading standard for 'all civil actions' . . ." *Id.* at 1953 (citation omitted).

191. *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957). *Twombly* found that: this phrase is best forgotten as an incomplete, negative gloss on an accepted pleading standard: once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint. *Conley*, then, described the breadth of opportunity to prove what an adequate complaint claims, not the minimum standard of adequate pleading to govern a complaint's survival.

550 U.S. at 563 (citations and footnote omitted).

192. *Medtronic v. Lohr*, 518 U.S. 470, 495 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

193. 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part) (emphasis in original); see also *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447–48 (2005) (quoting this portion of Justice O'Connor's opinion in *Lohr* with approval).

with provisions contained in the FDCA's enforcement scheme? Punitive damages are a particularly potent method of governing conduct and, as the Supreme Court stated in *Exxon Shipping Co. v. Baker*,<sup>194</sup> "the consensus today is that punitives are aimed not at compensation but principally at retribution and deterring harmful conduct."<sup>195</sup> In that sense, a punitive damages remedy is an enforcement action. For that reason, punitive damages may not merely "impose[e] different or additional remedies" for violating federal requirements but may instead constitute "different or additional requirements." Further, state law punitive damages awards that exceed the FDCA's express limitations on federal civil penalties may expressly or implicitly conflict with federal law.

These are relatively uncharted waters in the context of medical devices. There do not appear to be any decisions considering whether, for claims that survive express preemption under *Lohr* and *Riegel* because they impose only parallel requirements, accompanying punitive damages demands are, for other reasons, either expressly or impliedly preempted. Nonetheless, as explained below, awarding punitive damages in connection with state law parallel requirements claims may run afoul of federal law.

First, Congress created a detailed federal enforcement scheme for the FDCA that includes civil penalties, criminal penalties, seizure, and injunctive relief,<sup>196</sup> but not punitive damage awards to private plaintiffs. Furthermore, Congress has stated that enforcing the FDCA is an exclusively federal task: "[A]ll . . . proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."<sup>197</sup> Superimposing state law punitive damage remedies "aimed at deterrence and retribution" on top of the federal enforcement scheme lacking those remedies necessarily readjusts Congress's calculus regarding the appropriate penalties for violating federal law.<sup>198</sup> Accordingly, state law punitive

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194. 128 S. Ct. 2605 (2008).

195. *Id.* at 2621 (footnote omitted).

196. 21 U.S.C. §§ 331–34 (2007).

197. 21 U.S.C. § 337(a) (emphasis added).

198. In *Baker*, the Supreme Court rejected Exxon's claim that, in light of the federal enforcement scheme established in the Clean Water Act, 33 U.S.C. § 1251–1387 (CWA), substantial awards of punitive damages to persons whose property was damaged by the Exxon Valdez oil spill were preempted. 128 S. Ct. at 2618–19. But the CWA is substantially different from the MDA and the FDCA. Specifically, (1) the CWA has no express preemption provision analogous to the MDA's § 360k(a) and the FDCA's § 337(a); (2) the CWA has a broad savings provision, 33 U.S.C. § 1321(o), that *Baker* found relegated Exxon to the "untenable claim that the CWA somehow preempts punitive damages, but not compensatory

damage claims, even if they are imposed for violating federal requirements, may be (1) expressly preempted by (i) § 360k(a) because they impose additional state requirements that do not “parallel” federal ones, or (ii) § 337(a) because they are state-based enforcement actions; and (2) impliedly preempted because, by increasing the penalties for violating federal law above what Congress intended, they conflict with the federal enforcement scheme.<sup>199</sup>

Second, in the context most analogous to punitive damage awards in civil litigation—civil penalties under the FDCA—Congress has stated that the FDA *must* be involved and consider specified factors when assessing those civil penalties for violations of federal device requirements. The civil penalty provision provides:

*[T]he Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.*<sup>200</sup>

In a civil action between a private plaintiff and a medical device manufacturer, the FDA is not present to make any of these determinations. Accordingly, such awards may conflict with § 333(f)(5) and may thus be preempted.

Third, the FCDA’s civil penalty provisions for devices set maximums that limit the total penalties that may be imposed.<sup>201</sup> As the Supreme Court observed in *Baker*, “a penalty should be reasonably predictable in its severity, so that even Justice Holmes’s ‘bad man’ can look ahead with some ability to know what the stakes are in choosing one course of action or another.”<sup>202</sup> Section 333(f)(1)(A) provides that “any person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty in an amount *not to exceed* \$15,000 for each such violation, and *not to exceed* \$1,000,000 for all such violations adjudicated in a

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damages” when “nothing in the statutory text points to fragmenting the recovery scheme this way,” 128 S. Ct. at 2619; and (3) there does not appear to be authority under the CWA that, as *Buckman* found for the FDCA, it was important to preserve a federal agency’s “enforcement options that allow it to make a measured response to suspected” violations. *Buckman v. Plaintiff’s Legal Comm.*, 531 U.S. 341, 349 (2001).

199. To the extent that there is express preemption of punitive damage awards under 21 U.S.C. § 337(a) or implied conflict preemption, then such preemption would not be limited to litigation relating to parallel requirements claims or to PMA-approved devices and, instead, would apply more broadly.

200. 21 U.S.C. § 333(f)(5)(B) (2007) (emphasis added).

201. 21 U.S.C. § 333(f)(1)(A), (B) (2007).

202. *Baker*, 128 S. Ct. at 2627.

single proceeding.”<sup>203</sup> If a court in which such a parallel requirements claim is pending permits a punitive damages award on that claim of more than \$15,000 per violation or a total of \$1 million, that exceeds § 333(f)(1)(A)’s cap.<sup>204</sup> As the Supreme Court explained in *BMW of North America, Inc. v. Gore*,<sup>205</sup> courts “should ‘accord ‘substantial deference’ to legislative judgments’” that are reflected in statutory civil and criminal penalties when considering “‘appropriate sanctions for the conduct at issue.’”<sup>206</sup>

Finally, § 333(f) provides that, for some violations, civil penalties may not be awarded in certain circumstances.<sup>207</sup> Specifically, § 333(f)(1)(B) provides that, for certain types of violations, the civil penalty provision does not apply if (1) there was not “a significant or knowing departure from such requirements” or “a risk to public health;”<sup>208</sup> (2) the violation was a “minor violation[ ]” if the defendant demonstrates “substantial compliance;”<sup>209</sup> and (3) when the violation related to “one or more devices which are not defective.”<sup>210</sup> Significantly, the first item limits penalties for violations of

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203. 21 U.S.C. § 333(f)(1)(A) (2007) (emphasis added).

204. Also, shifting from the currently-prevailing paradigm of the FDA as the sole enforcement authority to one where multiple private plaintiffs may pursue “parallel claims” would mean that there could be many more “single proceeding[s]” and, therefore, much greater potential exposure.

205. 517 U.S. 559 (1996). In *Gore*, the Supreme Court found that a state law punitive damages award was excessive and violated the Due Process Clause.

206. *Id.* at 583 (quoting *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 301 (1989) (O’Connor, J., concurring in part and dissenting in part)). In the context of assessing whether punitive awards are excessive, *State Farm Mut. Ins. Co. v. Campbell*, 538 U.S. 408, 428 (2003), also recognized the importance of “disparit[ies] between . . . punitive damages award[s] and the ‘civil penalties authorized or imposed in comparable cases.’” (Citation omitted). Punitive damage awards for state-claims imposing parallel requirements would, of course, be subject to federal and state due process limitations and, in some instances, additional common law and statutory limitations.

207. 21 U.S.C. § 333(f)(1)(B) (2007).

208. 21 U.S.C. § 333(f)(1)(B)(i) (2007) (which applies to violations of FDA regulations implementing (1) the records and reporting requirements established by § 360i(a), including adverse event reporting; and (2) the good manufacturing practices requirements in § 360j(f)).

209. 21 U.S.C. § 333(f)(1)(B)(ii) (2007) (which applies to “minor violations” when the violator “demonstrates substantial compliance” for violations of (1) 21 U.S.C. § 360i(e), which relates to device tracking; or (2) § 360i(g), which relates to reporting removals and corrections).

210. 21 U.S.C. § 333(f)(1)(B)(iii) (2007) (which applies to devices that are adulterated because they were “prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health” in violation of 21 U.S.C. § 351(a)(2)(A)).

“good manufacturing practices requirements,”<sup>211</sup> a basis that medical device plaintiffs frequently allege as the grounds for supposed parallel requirements claims.<sup>212</sup> If a jury assessing punitive damages relating to a state law claim that parallels federal good manufacturing requirements is not required to assess whether there was “a significant and knowing departure from [those] requirements” or “a risk to public health,” then the state law damages remedy may impose requirements that go beyond federal requirements, and § 333(f)(1)(B)(i)’s “safe harbor” is nullified. Furthermore, even if the jury does make those assessments, there is no guarantee that the jury’s determinations will track what the FDA’s decisions would have been.

#### IV. CONCLUSION

Courts assessing whether state law claims asserted by product liability plaintiffs against medical device manufacturers escape express preemption under § 360k(a) should focus on whether (1) a federal requirement was violated; (2) the requirements imposed by the plaintiff’s state law claims actually parallel federal requirements; and (3) punitive damages remedies appended to those claims survive preemption. As to the first question, absent a prior, final determination that the manufacturer actually violated a federal requirement, establishing this predicate for avoiding express preemption implicates the concerns that led the Court in *Buckman* to find there was implied preemption; namely, the specter of private plaintiffs usurping the FDA’s ability “to achieve a somewhat delicate balance of statutory objectives” in enforcing the FDCA.<sup>213</sup> With respect to the second question, most courts have found that only negligence per se and manufacturing defect claims parallel federal requirements. And those claims often suffer from other infirmities, including plaintiffs’ inability to sufficiently tie their claims to supposed violations of federal requirements. As to the final question, even if a state law claim imposes only parallel requirements for violating a federal requirement, an accompanying punitive damage award may be either expressly or impliedly preempted, although courts have yet to grapple with those issues.

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211. 21 U.S.C. § 360j(f).

212. *E.g.*, *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282–84 (E.D.N.Y. 2009); *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157–58 (D. Minn. 2009).

213. *Buckman v. Plaintiff’s Legal Comm.*, 531 U.S. 341, 348 (2001).

