

# MEDICAL DEVICES AND PREEMPTION: A DEFENSE OF PARALLEL CLAIMS BASED ON VIOLATIONS OF NON-DEVICE SPECIFIC FDA REGULATIONS

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*In Riegel v. Medtronic, Inc., the Supreme Court held that because the FDA imposes device-specific requirements on the most sophisticated medical devices, tort claims that would impose different or additional requirements on such devices are preempted. The Court created an exception to this preemption rule for claims that parallel federal requirements. However, it failed to define precisely what constitutes a parallel claim. Lower courts have split on whether claims based on violations of non-device specific, industry-wide federal regulations survive preemption. Several courts, including the Eighth Circuit, and at least one scholarly article, have concluded such claims are expressly and/or impliedly preempted. However, the Fifth and Seventh Circuits, and a handful of district courts, have taken a more liberal approach, holding that these claims should survive preemption. This Note explores the split and argues that the liberal approach is preferable for doctrinal and public-policy reasons.*

## INTRODUCTION

Courts and commentators have suggested that the Supreme Court's 2008 decision in *Riegel v. Medtronic, Inc.*<sup>1</sup> marked the end of litigation against manufacturers of Class III devices—the most dangerous medical devices regulated under the 1976 Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act (FDCA).<sup>2</sup>

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<sup>1</sup> 552 U.S. 312 (2008).

<sup>2</sup> Under the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (codified at 21 U.S.C. §§ 360c–360k (2006)), medical devices are classified according to the level of danger they pose. See 21 U.S.C. § 360c(a)(1)(A)–(C) (defining Class I devices as those that do not require special controls to ensure the device's safety and effectiveness, Class II devices as those that require special controls to ensure safety and effectiveness, and Class III devices as those that require premarket approval to ensure safety and effectiveness).

In *Riegel*, the Court held that because the FDA imposes rigorous design, manufacturing, and labeling requirements on Class III devices, tort claims that would impose requirements different from or additional to the FDA's requirements are preempted.<sup>3</sup> However, the Court was clear that consumers injured by medical devices could bring lawsuits based on claims that "parallel" the FDA's requirements.<sup>4</sup> But the Court failed to define precisely the concept of a parallel claim. This Note explores the scope of the parallel-claims exception to preemption.

The initial post-*Riegel* consensus appeared to be that plaintiffs would rarely, if ever, succeed in bringing such parallel claims. For example, in a student note, Malika Kanodia argued that *Riegel* "virtually ensures that medical device manufacturers enjoy legal immunity from injury claims involving products that have secured premarket approval from the FDA."<sup>5</sup> Similarly, James Beck concluded that after *Riegel*, the judicial understanding of preemption "is now established[:] There is extensive preemption of claims involving [premarket approval] devices."<sup>6</sup> Moreover, one federal judge described how "in the . . . months following *Riegel*, courts across the country have applied [the MDA] broadly, preempting all manner of claims."<sup>7</sup>

Concern about preemption of plaintiffs' claims is not just academic. These lawsuits involve sophisticated medical devices that are often necessary to the health and well-being of users. When these devices malfunction, they can produce extreme health problems, including discomfort, pain, and even death. For example, in a consolidated, multidistrict litigation involving hundreds of plaintiffs against the manufacturer of a defibrillator, one plaintiff described that each misfire of the defibrillator "felt like having a horse inside you trying to kick its way out of your chest."<sup>8</sup> The device allegedly misfired almost

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<sup>3</sup> *Riegel*, 552 U.S. at 312. There are two types of preemption: express and implied. Express preemption describes the explicit displacement of state laws by federal law, usually in the form of a statutory preemption provision. *Riegel* was an express preemption decision because it turned on the reach of the MDA's preemption provision. *Id.* at 316. For further discussion of express preemption, see *infra* Part I.A. Implied preemption describes the displacement of state law by federal law when there is no clear statutory command. For a discussion of implied preemption, see *infra* Part I.B.

<sup>4</sup> *Riegel*, 552 U.S. at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

<sup>5</sup> Malika Kanodia, Comment, *The Fate of the Injured Patient in the Wake of Riegel v. Medtronic: Should Congress Interject?*, 32 *HAMLIN L. REV.* 791, 794 (2009).

<sup>6</sup> James M. Beck, *Federal Preemption in FDA-Regulated Product-Liability Litigation: Where We Are and Where We Might Be Headed*, 32 *HAMLIN L. REV.* 657, 678 (2009).

<sup>7</sup> *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010).

<sup>8</sup> Sabrina Eaton, *Bill Would Allow Lawsuits for Faulty Medical Devices*, *CLEVELAND PLAIN DEALER*, May 12, 2009, at B1.

150 times in just a five-hour period.<sup>9</sup> The failure of Class III devices can also impose substantial and direct financial costs on users. For example, Stryker Howmedica's Trident—a replacement hip device—malfunctioned in dozens of users, and these malfunctions often required further surgery to correct.<sup>10</sup>

Even assuming that some claims against medical device manufacturers may be exaggerated, the fact that hundreds of lawsuits are routinely being preempted should give pause to those who favor a broad application of preemption following *Riegel*. If the manufacturer of a malfunctioning defibrillator negligently deviates from the FDA's manufacturing requirements, an injured user should receive redress for resulting injuries from that manufacturer. After all, providing compensation is one theoretical purpose of the tort system.<sup>11</sup>

The Supreme Court in *Riegel* assured plaintiffs that they could seek such compensation in the form of claims against manufacturers that are parallel to federal requirements. But the *Riegel* Court's description of parallel claims—the claims that survive preemption—was brief, vague, and consequently very difficult for subsequent courts to interpret.<sup>12</sup> In particular, the Court failed to address how its holding interacted with two different types of FDA regulations: device-specific requirements and non-device specific, or industry-wide, regulations.<sup>13</sup>

Every Class III device must conform to device-specific FDA requirements. Before manufacturers can introduce a Class III device

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<sup>9</sup> *Id.*

<sup>10</sup> *See, e.g.,* *Bausch v. Stryker Corp.*, 630 F.3d 546, 558–59 (7th Cir. 2010) (noting that the plaintiff underwent “revision” surgery, in which doctors removed the Trident and replaced it with a different device).

<sup>11</sup> For a discussion of the various roles that the tort system can play as well as a defense of the compensatory tort function, see generally MARK A. GEISTFELD, *TORT LAW: THE ESSENTIALS* (2008). Geistfeld writes that tort law “always” has been “conceptualized in compensatory terms” and that compensation is the “distinctive attribute of tort liability.” *Id.* at 87. The belief that tort law is primarily compensatory is contested, however. Many scholars argue that the proper province of tort law is deterrence. For an example of this view, see Richard A. Posner, *A Theory of Negligence*, 1 J. LEGAL STUD. 29 (1972). This Note does not endorse either a purely compensatory or a purely regulatory conception of tort remedies. It starts and ends with the premises that, at a doctrinal level, the availability of compensation informs whether tort claims are preempted, *see infra* notes 146–52 and accompanying text, and that, at a policy level, those who are injured by negligently manufactured or unreasonably dangerous products should receive redress.

<sup>12</sup> *See In re Medtronic, Inc.*, 623 F.3d at 1204 (“The contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined.”); *see also* Mark Herrmann, David Booth Alden & Bradley W. Harrison, *The Meaning of the Parallel Requirements Exception Under Lohr and Riegel*, 65 N.Y.U. ANN. SURV. AM. L. 545, 546–47 (2010) (noting that the “contours” of the parallel claims exception are “as-yet-undefined”).

<sup>13</sup> I use the terms “non-device specific” and “industry-wide” interchangeably throughout this Note.

onto the market, they must seek FDA approval.<sup>14</sup> This is an extraordinarily rigorous process that requires the FDA to spend over 1000 hours reviewing a manufacturer's "multivolume application," which often includes some or all of the following: reports of every study and investigation of the device, a statement describing component parts, samples of products, and descriptions of the methods used in production.<sup>15</sup> Through this premarket process, the FDA establishes device-specific requirements relating to design, manufacture, and labeling.<sup>16</sup> In *Riegel*, the Supreme Court held that the requirements imposed through this process preempt private tort suits.<sup>17</sup>

But medical devices also are governed by various industry-wide statutory provisions and FDA regulations. Most relevant to this Note are the FDA's Current Good Manufacturing Practices (CGMPs) for medical devices.<sup>18</sup> These regulations constitute an "umbrella" approach to regulation that "does not prescribe in detail how a manufacturer must produce a specific device."<sup>19</sup> Instead, the CGMPs require all manufacturers to "develop and follow procedures and fill in the details . . . for each type or family of devices."<sup>20</sup> For example, one regulation requires, among other things, manufacturers to "establish and maintain procedures to prevent contamination of equipment

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<sup>14</sup> 21 U.S.C. § 360e (2006). The MDA also allows a manufacturer to attempt to bypass this premarket process and "grandfather" devices onto the market if those devices are "substantially equivalent" to devices that were on the market before the MDA was adopted. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008) (describing the review process for "grandfathered" devices (quoting 21 U.S.C. § 360c(f)(1)(A))). This is called substantial equivalence approval. *Id.* President Obama recently issued an executive order directing federal agencies to streamline their regulations. Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011). In response, the FDA announced plans to make the substantial equivalence process more efficient. *FDA To Improve Most Common Review Path for Medical Devices*, FDA (Jan. 19, 2011), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm240418.htm>.

Further discussion of the distinctions between premarket approval and substantial equivalence approval are beyond the scope of this Note. Indeed, the details of substantial equivalence review are relevant to this Note only in that substantial equivalence is a less-exacting standard for FDA review and that in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Supreme Court held that requirements imposed on a device through substantial equivalence review do not have preemptive effect. Thus, I describe substantial equivalence here merely to offer background information about the FDA's review processes.

<sup>15</sup> *Riegel*, 552 U.S. at 317–18.

<sup>16</sup> See 21 U.S.C. § 360e (requiring a supplemental application for changes that affect the safety or effectiveness of approved devices).

<sup>17</sup> *Riegel*, 552 U.S. at 330.

<sup>18</sup> 21 C.F.R. § 820 (2010).

<sup>19</sup> *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, FDA, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm#flexibility> (last updated Apr. 28, 2011).

<sup>20</sup> *Id.*

or product.”<sup>21</sup> A manufacturer could satisfy this requirement by developing one procedure for all of its devices. Thus, even though the procedure would not be device-specific, it would be legally binding.<sup>22</sup>

This Note addresses a question that has plagued courts after *Riegel*: whether claims based on violations of the FDA’s industry-wide regulations survive preemption in the context of specific devices.<sup>23</sup> In the post-*Riegel* world, plaintiffs face the two hurdles of express and implied preemption. First, courts have been skeptical that claims based on violations of these regulations qualify as parallel claims and thereby avoid express preemption. Second, courts have found that even if these claims are truly parallel, they are still impliedly preempted under another Supreme Court case: *Buckman Co. v. Plaintiffs’ Legal Committee*.<sup>24</sup> *Buckman* held that lawsuits based on violations of some, but not necessarily all, FDA regulations are preempted because they interfere with the FDA’s authority.<sup>25</sup>

Put simply, the *Riegel* Court did not address whether claims based on violations of FDA industry-wide regulations survive either express or implied preemption. Thus, trial courts have come to ad hoc judgments that leave plaintiffs frustrated, defendants anxious, and doctrine unsettled. As initial cases have reached the federal circuit courts sitting in diversity, a clear split has emerged. The Eighth Circuit held, in a consolidated litigation involving hundreds of claimants against the manufacturer of a defibrillator, that for a claim to survive preemption it must be based on a manufacturer’s alleged deviation from a premarket approval, device-specific requirement.<sup>26</sup> In contrast,

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<sup>21</sup> 21 C.F.R. § 820.70(e).

<sup>22</sup> The FDA has developed similar industry-wide reporting regulations. Manufacturers are required to report incidents in which the malfunction of a medical device may have been the cause of death or serious injury. *Id.* § 803. This regulation extends to all products, and thus it is not considered device specific. *See id.*

<sup>23</sup> To my knowledge, thus far, plaintiffs have tried to base parallel claims on violations of only two industry-wide FDA regulations: the CGMPs and the reporting regulation. My analysis could justify claims based on other industry-wide regulations. It is beyond the scope of this Note, however, to hypothesize which other regulations might be invoked by future plaintiffs for parallel claims.

<sup>24</sup> 531 U.S. 431 (2001); *see infra* Part II.A.2 (discussing implied preemption of parallel claims).

<sup>25</sup> *See* Catherine M. Sharkey, *The Fraud Caveat to Agency Preemption*, 102 Nw. U. L. REV. 841, 847–48 (2008) (discussing plausible readings of *Buckman*, including a “broad[ ]” interpretation and a narrow interpretation treating the case as “idiosyncratic”). The Supreme Court had a chance to clarify the scope of *Buckman* in *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008) (mem.) (per curiam), after granting certiorari to a case from the Second Circuit. However, because of Justice Roberts’ recusal, the Court split 4-4. *Id.* For further discussion of implied preemption under *Buckman*, *see infra* Part I.B.

<sup>26</sup> *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010). Throughout this Note, I refer to these lawsuits as the consolidated *Sprint Fidelis* litigation.

the Seventh Circuit held that claims based on violations of the FDA's industry-wide CGMPs survive preemption in *Bausch v. Stryker Corp.*<sup>27</sup> Less than a month later, the Fifth Circuit reached a similar holding with respect to parallel claims based on violations of the FDA's industry-wide reporting requirements in *Hughes v. Boston Scientific Corp.*<sup>28</sup>

This Note explores this circuit split. In Part I, I summarize the Supreme Court's recent preemption cases relevant to claims against manufacturers of Class III devices. These cases create considerable uncertainty with regard to the scope of both express and implied preemption. In Part II, I explore how courts have dealt with the question of whether claims based on violations of non-device specific regulations survive preemption. I discuss the restrictive approach to parallel claims adopted by the Eighth Circuit in the consolidated *Sprint Fidelis* litigation as well as the liberal approach adopted by the Seventh and Fifth Circuits. In Part III, I conclude that doctrinal and public policy arguments support the liberal approach. First, the liberal approach ensures that injured users receive compensation if they are so entitled. Second, it allows parallel claims to complement the FDA's enforcement actions by helping to detect violations, without interfering with the FDA's regulatory prerogatives.

## I

### THE SUPREME COURT'S PREEMPTION AND MEDICAL DEVICES DOCTRINE

Preemption is a federalism doctrine according to which federal laws displace overlapping or related state laws.<sup>29</sup> There are two forms of preemption: express and implied. Both forms implicate the viability of lawsuits against the manufacturers of medical devices.

Express preemption arises when a statutory provision explicitly displaces the application of different state laws.<sup>30</sup> By contrast, implied

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<sup>27</sup> 630 F.3d 546, 555 (7th Cir. 2010). *Bausch* was one of dozens of lawsuits brought against Stryker for its Trident device. In an unpublished opinion, the Sixth Circuit also has held that claims based on violations of the FDA's manufacturing regulations survive express and implied preemption. See *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440 (6th Cir. 2010).

<sup>28</sup> 631 F.3d 762, 771 (5th Cir. 2011).

<sup>29</sup> Preemption doctrine derives from the Supremacy Clause, which stipulates that "[t]his Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2.

<sup>30</sup> Express preemption provisions often are not precisely clear; thus, courts must interpret such provisions using the traditional tools of statutory interpretation. See Mary J. Davis, *The "New" Presumption Against Preemption*, 61 HASTINGS L.J. 1217, 1221 (2010)

preemption arises when federal law displaces state laws despite the fact that Congress has not explicitly authorized preemption. The Court is most likely to find implied preemption where it would be impossible for a regulated party to comply with both a state and federal rule, where a state rule frustrates the purpose of a federal rule, or where the federal government's occupation of a regulatory field is complete.<sup>31</sup> The primary test the Court employs is congressional intent,<sup>32</sup> and there is a strong presumption against implied preemption.<sup>33</sup>

Five recent Supreme Court decisions regarding preemption have dramatically altered the legal landscape for litigation against medical-device manufacturers: *Riegel, Cipollone v. Liggett Group, Inc.*,<sup>34</sup> *Medtronic, Inc. v. Lohr*,<sup>35</sup> *Bates v. Dow Agrosciences LLC*,<sup>36</sup> and *Buckman*. Because of these decisions, previously meritorious tort claims may no longer survive preemption.

### A. Express Preemption

As discussed above, the Court held in *Riegel* that the MDA<sup>37</sup> preempts lawsuits that impose requirements on medical device manufacturers that are additional to or different from the FDA's regulations.<sup>38</sup> *Riegel* was an express preemption decision because it was based on a statutory provision that explicitly invalidated state law.<sup>39</sup> The *Riegel* Court's holding that the MDA preempts nonparallel tort claims was the culmination of a line of cases dealing with preemption provisions that displaced "requirements."<sup>40</sup> A review of these deci-

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(describing a "variety of . . . tools" to interpret express preemption provisions including "an evaluation of the ordinary meaning of the terms of the statute, its structure, and its purpose as discerned through the legislative history").

<sup>31</sup> See *Wyeth v. Levine*, 129 S. Ct. 1187, 1208, 1213 n.4 (2009) (Thomas, J., concurring) (describing different forms of implied preemption).

<sup>32</sup> See *id.* at 1194 (describing intent as one of "two cornerstones of . . . pre-emption jurisprudence"); see also Davis, *supra* note 30, at 1221 (discussing the importance of intent to preemption analysis).

<sup>33</sup> See *Wyeth*, 129 S. Ct. at 1194–95 ("[W]e '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.'" (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996))); see also Davis, *supra* note 30, at 1223 (noting that under recent cases, Congress "has the final word" on preemption and has reinvigorated the presumption against preemption).

<sup>34</sup> 505 U.S. 504 (1992).

<sup>35</sup> 518 U.S. 470 (1996).

<sup>36</sup> 544 U.S. 431 (2005).

<sup>37</sup> 21 U.S.C. §§ 360c–360k (2006).

<sup>38</sup> 552 U.S. 312 (2008).

<sup>39</sup> See *supra* note 3 (noting that the Court relied on the MDA's preemption provision).

<sup>40</sup> Preemption provisions can be phrased in multiple ways, preempting state "laws," "statutes," "regulations," or "requirements." The MDA's preemption provision displaces

sions provides a context for understanding the reach of *Riegel* and its reaffirmation of the parallel-claims exception to preemption.

### 1. Requirements-Based Preemption Provisions

The MDA's preemption provision declares that "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 . . . which is different from, or in addition to, any requirement applicable under this chapter to the device."<sup>41</sup> Such a requirements-based preemption provision is not uncommon in public health statutes,<sup>42</sup> and it has always been clear that such provisions invalidate state positive law—for example, regulations and statutes. But *Riegel* went a step further, holding that such provisions also can preempt state tort claims that would impose requirements on defendants if the claims succeed.<sup>43</sup>

Prior to *Riegel*, the Court had hinted at, but never fully established, this proposition. The first case suggesting that a requirements-based preemption provision could displace tort claims was *Cipollone*.<sup>44</sup> In *Cipollone*, the plurality opinion stated that it was "difficult to say" whether or not common-law tort claims—which are based on the defendant's legal duty to the plaintiff—impose "requirements."<sup>45</sup> Thus, the plurality refused to read the relevant preemption provision as applying only to "positive enactments by legislatures and agencies."<sup>46</sup>

Only a few years after *Cipollone*, the Court first addressed the scope of the MDA's preemption provision in *Lohr*.<sup>47</sup> In *Lohr*, the plaintiffs brought an action alleging that the manufacturer had negligently designed a pacemaker. That pacemaker had been approved through the substantial equivalence process, which the Court described as "by no means comparable to the [more rigorous

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"requirements." 21 U.S.C. § 360k. I refer to provisions displacing requirements as requirements-based preemption provisions.

<sup>41</sup> *Id.*

<sup>42</sup> Other statutes with similar preemption provisions include the Public Health Cigarette Smoking Act, 15 U.S.C. § 1334(b) (2006), and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136v(b) (2006).

<sup>43</sup> *Riegel*, 552 U.S. 312.

<sup>44</sup> In *Cipollone*, the Court confronted the reach of the requirements-based preemption provision of the Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, § 2, 84 Stat. 87, 88 (1970) (codified at 15 U.S.C. § 1334(b) (2006)) ("No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.").

<sup>45</sup> *Cipollone*, 505 U.S. at 522 (plurality opinion).

<sup>46</sup> *Id.*

<sup>47</sup> 518 U.S. 470 (1996).

premarket approval process].”<sup>48</sup> The *Lohr* Court held that the requirements the FDA imposes through substantial equivalence approval are not preemptive.<sup>49</sup> Thus the plaintiffs’ claims were not preempted. However, in reaching this decision, a majority of the Justices also signaled acceptance of the conclusion that tort claims constitute genuine requirements and may be preempted by requirements-based preemption provisions.<sup>50</sup>

The next express preemption milestone was *Bates*, which addressed the preemptive reach of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)—a statute that also features a requirements-based preemption provision.<sup>51</sup> The *Bates* Court seemed to reverse course from the *Lohr* Court’s position that tort claims were requirements, explaining that “[a] requirement is a rule of law that must be obeyed,”<sup>52</sup> while “an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.”<sup>53</sup> Nevertheless, the majority still found that tort claims could be preempted. It described that FIFRA’s requirements-based provision could “pre-empt judge-made rules, as well as statutes and regulations.”<sup>54</sup>

Ultimately, the Court announced a bright-line rule regarding the reach of requirements-based preemption provisions in *Riegel*.<sup>55</sup> In *Riegel*, the plaintiffs brought negligence and strict liability actions against a manufacturer for injuries caused by a balloon catheter device. The *Riegel* Court returned to and elaborated on *Lohr*: State-law torts impose requirements just as positive-law enactments and regulations do.<sup>56</sup> The Court reached this conclusion because it reasoned that when plaintiffs win their tort suits, the resulting judgments impose design and manufacturing requirements on manufacturers. Moreover, these court-imposed requirements could conflict with the FDA’s premarket requirements. Thus, such claims are

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<sup>48</sup> *Id.* at 478–79; *see also id.* at 479 (describing the differences between substantial equivalence and premarket approval).

<sup>49</sup> *Id.* at 500–01 (finding that the generality of specifications under substantial equivalence approval made preemption inappropriate).

<sup>50</sup> In *Lohr*, the Court “fractured in an all but irreconcilable manner” over the preemption question. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1371 (11th Cir. 1999). But it was Justice Breyer’s concurrence that gave the Court its judgment, and his interpretation of “requirements” included common law actions, at least in some circumstances. *Davis*, *supra* note 30, at 1232 n.92.

<sup>51</sup> 544 U.S. 431 (2005).

<sup>52</sup> *Id.* at 445.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* at 443.

<sup>55</sup> 552 U.S. 312 (2008).

<sup>56</sup> *Id.* at 324.

preempted.<sup>57</sup> To distinguish *Lohr*, the Court emphasized that the FDA had approved the catheter in *Riegel* through the rigorous premarket approval process, whereas it had approved the pacemaker in *Lohr* through the less rigorous substantial equivalence process.<sup>58</sup> In *Riegel*, the Court found that the former process is preemptive; in *Lohr*, the Court had held that the latter is not.

## 2. *The Parallel Claims Exception*

Taken together, *Cipollone*, *Lohr*, *Bates*, and *Riegel* establish that requirements-based preemption provisions can displace tort lawsuits, which, like positive-law enactments, impose requirements on defendants. But the Supreme Court also has consistently acknowledged that even when statutes expressly preempt claims that deviate from federal requirements, plaintiffs can still bring claims that parallel federal requirements.<sup>59</sup> In *Riegel*, for example, Justice Scalia's majority opinion stated that the MDA's preemption provision did 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 [are] 'parallel.'"<sup>60</sup> However, the Court failed to define what constitutes a parallel claim.<sup>61</sup>

Specifically, *Riegel* failed to address two questions. First, the FDA imposes both industry-wide regulations and device-specific specifications.<sup>62</sup> *Riegel* did not say whether violations of any federal regulation can support a parallel claim or whether violations of only device-specific requirements can support such claims. Second, and perhaps more importantly, *Riegel* did not address whether truly parallel claims that survive express preemption also survive implied preemption under another Supreme Court case: *Buckman Co. v. Plaintiffs' Legal Committee*.<sup>63</sup>

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<sup>57</sup> *Id.* at 327–28.

<sup>58</sup> *Id.* at 322–23. For a summary of the two processes, see *supra* note 14 and accompanying text.

<sup>59</sup> See, e.g., *Riegel*, 552 U.S. at 330 (noting that 21 U.S.C. § 360k does not preempt parallel claims); *Bates*, 544 U.S. at 447–48 (describing parallel claims); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (similar).

<sup>60</sup> *Riegel*, 552 U.S. at 330.

<sup>61</sup> See *supra* note 12 and accompanying text (discussing *Riegel's* failure to define parallel claims).

<sup>62</sup> See *supra* notes 14–22 and accompanying text (describing device-specific premarket approval requirements and industry-wide regulations like the CGMPs and reporting requirements).

<sup>63</sup> 531 U.S. 341 (2001).

### B. Implied Preemption

In *Buckman*, thousands of plaintiffs brought individual tort claims to recover for spine injuries they sustained from using a particular type of orthopedic bone screw.<sup>64</sup> But their lawsuits were not against the manufacturer; instead, the plaintiffs sued a consultant to the manufacturer for helping the manufacturer commit fraud against the FDA in seeking approval of the device. The FDA had previously refused to approve the bone screw for use in spines. Based on the consultant's advice, the manufacturer represented to the FDA that the bone screws would be used only on long bones—legs and arms. Once the screws were on the market, however, doctors could use them for any bone, including the spine. Thus, the plaintiffs argued, the bone screws that caused their injuries never would have been on the market if the manufacturer had not committed fraud against the FDA.<sup>65</sup>

*Buckman* was an implied preemption case. In *Buckman*, the Court found that the FDA so completely occupied the relevant regulatory field that the plaintiffs' fraud-on-the-FDA claims were preempted: "[T]he federal statutory 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 . . . can be skewed by allowing fraud-on-the-FDA claims under state tort law."<sup>66</sup> Critical to the Court's holding was the fact that the plaintiffs were not bringing a traditional tort claim based on the manufacturer's violation of its duty of care to consumers. Instead, the plaintiffs' theory was that the manufacturer had violated its obligations to the FDA under the FDCA by lying about the intended use of the bone screw.<sup>67</sup>

Although *Buckman* was an implied preemption decision, it was also based, in part, on an interpretation of a provision of the FDCA which directs that "all . . . proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."<sup>68</sup> Based on this provision—and to protect the FDA's primacy in the field of device regulation—the *Buckman* Court rejected the plaintiffs' contention that "any violation of the FDCA will support a state-law claim."<sup>69</sup> However, the Court has never clarified which, if any, FDCA provisions and FDA regulations, if violated,

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<sup>64</sup> *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 818 (3d Cir. 1998), *rev'd sub nom. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

<sup>65</sup> *Buckman*, 531 U.S. at 341.

<sup>66</sup> *Id.* at 348.

<sup>67</sup> *Id.* at 346–47.

<sup>68</sup> 21 U.S.C. § 337(a) (2006).

<sup>69</sup> *Buckman*, 531 U.S. at 353.

could support a tort claim without interfering with the FDA's regulatory authority.<sup>70</sup>

To summarize the state of express and implied preemption after the Court's decision in *Riegel*, tort claims against medical-device manufacturers will be expressly preempted under the MDA as interpreted by *Riegel* if they are not parallel to federal requirements. But even if the state claims truly parallel federal regulations, they nonetheless may be impliedly preempted under *Buckman* if they interfere with the FDA's regulatory authority. In the next Part, I discuss how the ambiguities surrounding the definition of parallel claims under *Riegel* and the scope of implied preemption under *Buckman* have resulted in a circuit split regarding when plaintiffs' claims against medical-device manufacturers survive preemption.

## II

### THE LOWER COURTS' POLICING OF THE BOUNDARIES OF PARALLEL CLAIMS

Part II of this Note provides a survey of how various courts, including several of the federal circuits' courts of appeals, have resolved whether plaintiffs' claims based on violations of non-device specific FDA regulations survive preemption. Most of the early district court cases signaled a trend that these claims would not survive preemption. This restrictive approach to parallel claims is exemplified by the Eighth Circuit's decision in the consolidated *Sprint Fidelis* litigation. But an increasing number of courts, including the Seventh Circuit in *Bausch v. Stryker Corp.* and the Fifth Circuit in *Hughes v. Boston Scientific Corp.*, recognize that the Supreme Court's preemption decisions need not be read so restrictively and that violations of non-device specific regulations can underlie parallel claims.

#### A. *The Restrictive Approach: Violations of Industry-Wide FDA Regulations Cannot Underlie Parallel Claims*

The leading case for the proposition that violations of industry-wide FDA regulations cannot support parallel claims is the Eighth Circuit's decision in the consolidated *Sprint Fidelis* litigation.<sup>71</sup> Hundreds of plaintiffs brought state-law tort actions against a manufacturer alleging that it had failed to follow the CGMPs<sup>72</sup> when it used

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<sup>70</sup> See *supra* note 25 (discussing the difficulty in interpreting the breadth of *Buckman*).

<sup>71</sup> *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157–58 (D. Minn. 2009).

<sup>72</sup> 21 C.F.R. § 820 (2010).

a particular welding technique to manufacture its defibrillators.<sup>73</sup> The district court found these claims preempted. The court of appeals affirmed. In this section, I focus on the Eighth Circuit's opinion and similar district court decisions that take a restrictive approach to parallel claims.

### 1. *Express Preemption*

The MDA's preemption provision expressly displaces any state requirements that are "different from, or in addition to" federal requirements.<sup>74</sup> Courts taking a restrictive approach to parallel claims have found that claims based on violations of industry-wide FDA regulations are expressly preempted for two reasons: First, such claims might subject manufacturers to different requirements, and/or, second, such claims might import too much state law into a federal domain.

First, some courts have held that if plaintiffs were able to base parallel claims on violations of non-device specific FDA regulations, then defendant medical-device manufacturers might indeed face different requirements because judges and juries in different lawsuits could easily interpret the same industry-wide regulation in different ways. For example, in the consolidated *Sprint Fidelis* litigation, the district court highlighted that the CGMPs are only a set of guidelines, to which every manufacturer must adhere by developing its own manufacturing procedures subject to approval by the FDA, and not precise requirements.<sup>75</sup> Because the CGMPs "are simply too generic," the court held that violations of the CGMPs could not be the basis for parallel claims.<sup>76</sup> The Eighth Circuit affirmed this logic, declaring that the "[p]laintiffs simply failed to adequately plead that Medtronic violated a federal requirement specific to the FDA's [premarket] approval of this Class III device."<sup>77</sup>

In another litigation involving claims premised on violation of the CGMPs, the district court further explained that the claims were preempted as nonparallel claims because "no regulation relied upon refers specifically to the medical device at issue here . . . [and thus] allowing them to serve as a basis for a claim would lead to differing

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<sup>73</sup> See *In re Medtronic, Inc.*, 592 F. Supp. 2d at 1157 (discussing plaintiffs' manufacturing-defect claims).

<sup>74</sup> 21 U.S.C. § 360k (2006).

<sup>75</sup> See *In re Medtronic, Inc.*, 592 F. Supp. 2d at 1157 ("The CGMPs and QSR require manufacturers to develop *their own* quality-system controls to ensure that medical devices are safe and effective for their intended use, and they are inherently flexible."); see also *supra* notes 18–22 and accompanying text (discussing CGMPs).

<sup>76</sup> *In re Medtronic, Inc.*, 592 F. Supp. 2d at 1157.

<sup>77</sup> *In re Medtronic, Inc.*, 623 F.3d 1200, 1207 (8th Cir. 2010).

safety requirements that might emanate from various lawsuits.”<sup>78</sup> Note that it was precisely this concern—that tort claims could subject manufacturers to conflicting requirements that motivated the Supreme Court in *Riegel*.<sup>79</sup>

Two district courts have found claims based on violations of industry-wide regulations to be expressly preempted for a second distinct reason. Every common law claim requires the plaintiff to prove the legal elements of his or her cause of action—such as duty and causation for a negligence claim or unreasonable danger for a strict liability claim. These two district courts held that because plaintiffs must prove these additional elements to win their lawsuits, such claims are preempted for imposing different or additional requirements on manufacturers.<sup>80</sup> According to this view, virtually all common law claims, even those based on violations of federal regulations, are preempted because “state law tort principles inevitably invade such a cause of action. . . . Once a state’s tort law becomes ingrained with the cause of action, it runs afoul of *Riegel*.”<sup>81</sup> Taken to its logical conclusion, this reasoning suggests that states may activate parallel claims only by statutorily authorizing damage awards for violations of FDA

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<sup>78</sup> *Ilaraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009). Several other district courts confronting claims based on violations of the CGMPs have reached a similar conclusion. *See, e.g.*, *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009) (preempting claims because the CGMPs are too general to serve as a basis for state tort claims); *Wolicki-Gables v. Arrow Int’l, Inc.*, 641 F. Supp. 2d 1270, 1288 (M.D. Fla. 2009) (same), *aff’d*, 634 F.3d 1296 (11th Cir. 2011). The Eleventh Circuit recently affirmed the *Wolicki-Gables* decision, tracking the Eighth Circuit in finding that claims based on non-device specific FDA regulations could not underlie parallel claims. *See Wolicki-Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (“A plaintiff must allege that ‘[the] defendant violated a particular federal specification referring to the device at issue.’” (alteration in original) (quoting *Ilaraza*, 677 F. Supp. 2d at 589)).

<sup>79</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) (“Indeed, one would think that tort law, applied by juries . . . is less deserving of preservation. . . . A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits . . .”).

<sup>80</sup> *See Hughes v. Bos. Scientific Corp.*, 669 F. Supp. 2d 701, 714 (S.D. Miss. 2009) (holding that state-law tort principles function as conflicting “requirements”), *aff’d in part, vacated in part*, 631 F.3d 762 (5th Cir. 2011) (reversing the district court on the express preemption issue); *Bausch v. Stryker Corp.*, No. 08 C 4248, 2008 WL 5157940, at \*4–5 (N.D. Ill. Dec. 9, 2008) (holding that negligence claims are based on common law and thereby function as a different requirement), *rev’d*, 630 F.3d 546, 563 (7th Cir. 2010). Both district courts were reversed on the preemption issue on appeal, and the theory that the common law elements of parallel claims require preemption of those claims does not appear to have much traction. Nonetheless, I discuss it because future courts facing parallel claims based on violations of industry-wide FDA regulations may be more receptive to the argument.

<sup>81</sup> *Hughes*, 669 F. Supp. 2d at 714.

requirements; claims pursuant to such a statute would not require plaintiffs to demonstrate additional legal elements.<sup>82</sup>

## 2. *Implied Preemption*

Even if claims based on violations of industry-wide FDA regulations do parallel federal requirements such that they are not expressly preempted, they may still be impliedly preempted under *Buckman*.<sup>83</sup> In *Buckman*, the Court held that the plaintiffs' fraud-on-the-FDA claims were impliedly preempted because they interfered with the FDA's regulatory authority.<sup>84</sup> Read broadly, *Buckman* stands for the proposition that any private action to enforce a violation of an FDA regulation is preempted. In post-*Riegel* litigations, a number of courts have reached precisely this conclusion.<sup>85</sup>

In the consolidated *Sprint Fidelis* litigation, for example, the district court explained that the FDCA and related FDA regulations do not create an implied cause of action by which the plaintiffs could bring their suit.<sup>86</sup> The court held further that "[p]laintiffs [could not] make an end run around this rule by recasting violations of the FDCA as violations of state common law" because such claims are impliedly preempted under *Buckman*.<sup>87</sup> Based on its reading of *Riegel* and *Buckman*, the district court concluded that virtually every claim against the manufacturer of a Class III medical device is preempted.<sup>88</sup> The only parallel claims that could survive implied and express pre-

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<sup>82</sup> See, e.g., *In re Medtronic, Inc.*, 592 F. Supp. 2d 1147, 1161 n.17 (D. Minn. 2009) ("[I]f a state were to pass a statute providing a remedy for a violation of the FDCA, a claim under such statute would not be preempted."); *Bausch*, 2008 WL 5157940, at \*4 (arguing that the only claim that survives *Riegel* "is a claim that is based on a state statutory enactment providing a damages remedy for violations of FDA regulations").

<sup>83</sup> 531 U.S. 341 (2001).

<sup>84</sup> For a description of the theory of fraud-on-the-agency liability and an analysis of the Court's implied preemption holding, see *supra* Part I.B.

<sup>85</sup> See, e.g., *In re Medtronic, Inc.*, 592 F. Supp. 2d at 1161 (arguing that after *Riegel* and *Buckman* "nearly all types of claims concerning FDA-approved medical devices are preempted"); *Wheeler v. DePuy Spine, Inc.*, 706 F. Supp. 2d 1264, 1269–70 n.4 (S.D. Fla. 2010) (asserting that "the Federal Government and not private litigants . . . are authorized to sue for noncompliance" with the MDA); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 659 (S.D. Tex. 2010) (relying on *Buckman* and *In re Medtronic, Inc.*, 592 F. Supp. 2d 1147, to find preemption of "private enforcement of FDCA regulations"); *Riley v. Cordis Corp.* 625 F. Supp. 2d 769, 776–77 (D. Minn. 2009) ("[E]nforcing the FDCA is exclusively the province of the federal government . . .").

<sup>86</sup> *In re Medtronic, Inc.*, 592 F. Supp. 2d at 1161 ("[N]o private right of action exists under the FDCA.").

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* (holding that *Buckman* and *Riegel* cause "nearly all types of claims concerning FDA-approved medical devices [to be] preempted").

emption would be claims either based on violations of device-specific requirements or authorized explicitly by a state.<sup>89</sup>

It is not clear how much of this reasoning the Eighth Circuit adopted in its treatment of the consolidated *Sprint Fidelis* litigation. The court cited *Buckman* for the proposition that parallel claims might be impliedly preempted for interfering with the FDA's regulatory authority,<sup>90</sup> but it did not explicitly affirm the district court's reasoning. Instead, it cited *another* district court's decision from within the Eighth Circuit for a similar—but arguably narrower—view of the combined weight of *Buckman* and *Riegel* (and thus a more liberal approach to parallel claims):

*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted . . .), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).<sup>91</sup>

In other words, rather than concluding that *any* claim alleging a violation of an industry-wide FDA regulation is impliedly preempted, as the *Sprint Fidelis* district court did, the circuit court allowed the possibility that traditional tort law claims predicated on such violations might survive implied preemption. However, this disclaimer notwithstanding, the court still found all of the *Sprint Fidelis* plaintiffs' claims either expressly or impliedly preempted.

### *B. The Liberal Approach: Violations of Industry-Wide FDA Regulations Can Underlie Parallel Claims*

After several initial setbacks, plaintiffs were more successful in pursuing claims based on violations of industry-wide FDA regulations. Indeed, plaintiffs have noticeably succeeded in avoiding preemption while bringing the same claims—based on violations of CGMPs and the reporting regulation—often against the same manufacturers that had defeated such claims on preemption grounds in earlier cases. There are two lead cases for the proposition that violations of industry-wide FDA regulations can support parallel claims: The Seventh Circuit's decision in *Bausch*<sup>92</sup> and the Fifth Circuit's decision in *Hughes*.<sup>93</sup>

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<sup>89</sup> *Id.* at 1161 n.17.

<sup>90</sup> See *In re Medtronic, Inc.*, 623 F.3d at 1204–05 (citing *Buckman* and deeming the issue of preemption of parallel claims “the crucial question on appeal”).

<sup>91</sup> *Id.* at 1204 (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

<sup>92</sup> 630 F.3d 546 (7th Cir. 2010).

<sup>93</sup> 631 F.3d 762 (5th Cir. 2011).

### 1. *Express Preemption*

In *Bausch*, the Seventh Circuit found that the fact that the plaintiffs' claims were based on violations of the CGMPs—i.e., requirements not tailored to a particular device—was not a reason to preempt them.<sup>94</sup> To the Seventh Circuit, the critical question was not whether the CGMPs are device-specific, but rather whether they are binding and enforceable against manufacturers. This question was easy for the court of appeals to resolve: “[F]ederal law is clear: for manufacturers of Class III medical devices,” even industry-wide regulations “are legally binding requirements.”<sup>95</sup> Further illustrating its concern with potential underenforcement of FDA regulations, the court explained that the CGMPs “are obviously vital to producing safe and effective medical devices.”<sup>96</sup> Preempting claims based on violations of the regulations would leave a large category of injured plaintiffs without an ability to vindicate their rights through the tort system, and this possibility motivated the Seventh Circuit to allow these claims to go forward.<sup>97</sup>

To the Seventh Circuit, the fact that industry-wide regulations allowed “some room for interpretation” and conceivably could be applied “more stringently than the FDA intended” did not trigger express preemption.<sup>98</sup> Indeed, the Seventh Circuit directly criticized the Eighth Circuit’s approach in the consolidated *Sprint Fidelis* litigation as “[trying] to stretch the Supreme Court’s decisions in this field beyond the boundaries that were made clear in [its] decisions.”<sup>99</sup> The Seventh Circuit had four reasons to oppose preemption. First, judges, rather than juries, ultimately define the content and meaning of the FDA’s industry-wide regulations for the purposes of tort claims

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<sup>94</sup> *Id.* at 555.

<sup>95</sup> *Id.*; see also *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App’x 436 (6th Cir. 2010). *Howard* was an unpublished Sixth Circuit decision, which, similar to *Bausch*, found that violations of a CGMPs regulation supported plaintiffs’ parallel claims. It held that the CGMP relied on by its plaintiff might be “incorporated” into the premarket approval process and was “not so vague as to be incapable of enforcement.” *Id.* at 440. Before *Bausch* and *Howard*, at least a handful of trial courts also found claims based on violations of the CGMPs were not expressly preempted. See *Prudhel v. Endologix, Inc.*, No. Civ. S-09-0661 LKK/KJM, 2009 WL 2045559, at \*6 (E.D. Cal. July 9, 2009) (“[S]tate law claims are not preempted if they parallel either specific or general FDA regulations.”); see also *Warren v. Howmedica Osteonics Corp.*, No. 4:10 CV 1346 DDN, 2010 WL 5093097 (E.D. Mo. Dec. 8, 2010) (upholding claims based on violations of CGMPs); *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 836–39 (S.D. Ind. 2009) (same).

<sup>96</sup> *Bausch*, 630 F.3d at 555.

<sup>97</sup> See *id.* (noting that preemption “would . . . leave injured patients without any remedy for a wide range of harmful violations of federal law”).

<sup>98</sup> *Id.* at 556.

<sup>99</sup> *Id.* at 549–50, 554 (criticizing the manufacturers’ preemption theory accepted by the Eighth Circuit in the consolidated *Sprint Fidelis* litigation).

against medical-device manufacturers. Second, interpreting the regulations is a question of federal law “subject to the usual processes for reconciling conflicting views”—i.e., review by the Supreme Court. Third, the distinction between general regulations and device-specific requirements is “slippery” and “less workable.” And fourth, such a distinction is not supported by the language of the preemption provision at issue.<sup>100</sup>

In *Hughes*,<sup>101</sup> the plaintiff brought a claim based on the manufacturer’s alleged violation of the FDA’s industry-wide reporting requirement. The defendant-manufacturer argued—and the district court agreed—that this claim was expressly preempted because the reporting requirement was an administrative regulation. To the district court, state tort claims could not be based on “administrative requirements[, which] lack independent substantive content.”<sup>102</sup> The Fifth Circuit reversed on this point—allowing the plaintiff’s claim to go forward—citing *Bausch* and the Sixth Circuit’s unpublished *Howard v. Sulzer Orthopedics, Inc.* decision approvingly for the proposition that claims based on violations of industry-wide regulations do not necessarily impose “different” requirements on manufacturers.<sup>103</sup>

Finally, both the Seventh and Fifth Circuits explicitly rejected the view, adopted by the district courts in their respective litigations, that virtually all purportedly parallel law claims are expressly preempted because plaintiffs must prove legal elements such as duty and causation.<sup>104</sup> The Seventh Circuit noted that such reasoning “overlooked the Supreme Court’s rejection in *Lohr* and *Riegel* of precisely that argument against common law claims.”<sup>105</sup> Both the Seventh and Fifth Circuits concluded that judicial determinations that a manufacturer owed a duty of care to consumers or that a manufacturing defect was the proximate cause of a consumer’s injury would not impose any additional requirements on the manufacturer.

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<sup>100</sup> *Id.*; see also *infra* notes 123–24 and accompanying text (discussing why these factors should push toward a uniform interpretation of the FDA’s requirements).

<sup>101</sup> *Hughes v. Bos. Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011).

<sup>102</sup> *Hughes v. Bos. Scientific Corp.*, 669 F. Supp. 2d 701, 713 (S.D. Miss. 2010).

<sup>103</sup> *Hughes*, 631 F.3d at 770 (describing *Bausch* as a “well-reasoned opinion” on the question of whether industry-wide regulations could underlie parallel claims).

<sup>104</sup> See *id.* at 772 (overruling the district court and finding that Supreme Court precedent allows the use of FDCA to establish state-law negligence per se); *Bausch v. Stryker Corp.*, 630 F.3d 546, 552–53 (7th Cir. 2010) (similar).

<sup>105</sup> *Bausch*, 630 F.3d at 552–53; accord *Hughes*, 631 F.3d at 772 (holding that the defendant’s optional state-law defense does not impose a different or additional requirement); *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 836–37 (S.D. Ind. 2009) (noting that such holdings would not impose different or additional requirements on a manufacturer).

## 2. Implied Preemption

The Fifth and Seventh Circuits also explored the argument that claims based on violations of non-device specific FDA regulations should be impliedly preempted under *Buckman*. Recall that, in *Buckman*, the Supreme Court preempted the plaintiff's fraud-on-the-FDA claims because they interfered with the FDA's regulatory purview.<sup>106</sup> To the Fifth and Seventh Circuits, the Court's reasoning in *Buckman* did not require preemption of the plaintiff's parallel claims. In *Bausch*, the Seventh Circuit explained that the claims at issue, "unlike those in *Buckman*, [were] tort law claims based on manufacturing defects, not fraud on a federal agency."<sup>107</sup> Similarly, in *Hughes*, the Fifth Circuit said that the plaintiff's claim, a parallel or traditional state tort claim, was "not analogous" to the claim in *Buckman* where the plaintiffs "attempt[ed] to assert a freestanding federal cause of action based on violation of the FDA's regulations."<sup>108</sup> The circuit court went on to explain that it did not make sense to invoke implied preemption with respect to claims that survive express preemption under *Riegel*—a decision that the Court announced several years after the *Buckman* decision.<sup>109</sup>

The Seventh Circuit in *Bausch* explained that two legal conclusions followed from the fact that the plaintiff's claims were traditional tort actions, and thus not analogous to the fraud-on-the-FDA claims at issue in *Buckman*. First, the fact that the FDCA does not create an implied cause of action became irrelevant because "the plaintiff claim[ed] breach of a well-recognized duty owed . . . under state law."<sup>110</sup> Second, the states' historic role in providing tort remedies bolstered the traditional presumption against implied preemption,<sup>111</sup> which requires a compelling justification for preemption of common law actions. Ultimately, the Seventh Circuit found no such justification.

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<sup>106</sup> See *supra* notes 66–70 and accompanying text (discussing the scope of *Buckman*). The Eighth Circuit invoked *Buckman* in the consolidated *Sprint Fidelis* litigation for the proposition that the plaintiffs' parallel claims based on violations of industry-wide FDA regulations similarly interfered with the FDA and had to be impliedly preempted. See *supra* Part II.A.2 (discussing the treatment of *Buckman* in the consolidated *Sprint Fidelis* litigation).

<sup>107</sup> *Bausch*, 630 F.3d at 557.

<sup>108</sup> *Hughes*, 631 F.3d at 775.

<sup>109</sup> *Id.* at 775–76.

<sup>110</sup> *Bausch*, 630 F.3d at 558.

<sup>111</sup> *Id.* at 557; see also *supra* note 33 (discussing the presumption against preemption).

## III

DOCTRINAL AND PUBLIC POLICY REASONS TO ADOPT A LIBERAL  
APPROACH TO CLAIMS BASED ON VIOLATIONS OF  
INDUSTRY-WIDE FDA REGULATIONS

As discussed in Part II, courts have moved in two directions on the question of whether claims based on violations of non-device specific FDA regulations survive preemption after *Riegel*. The conservative approach—exemplified by the consolidated *Sprint Fidelis* litigation—finds that such claims are expressly preempted as nonparallel and/or impliedly preempted as interfering with FDA enforcement.<sup>112</sup> *Bausch* and *Hughes* represent the liberal approach, which allows parallel claims to proceed. In this Part, I argue that the liberal approach is preferable.

I consider first whether claims based on violations of industry-wide FDA regulations should be expressly preempted for imposing different or additional requirements. My answer to this question is purely doctrinal. Because of *Riegel*, if these claims do impose different or additional requirements on manufacturers, they are preempted regardless of what important purposes they could achieve. I then turn to whether these parallel claims should be impliedly preempted. The arguments for implied preemption are based on the Court's reasoning in *Buckman*. A close reading of *Buckman* reveals that the Court impliedly preempted fraud-on-the-FDA claims for public policy reasons that do not support the implied preemption of parallel claims based on violations of industry-wide FDA regulations. Specifically, these parallel claims differ from fraud-on-the-agency claims in three ways that militate against their implied preemption. First, they do not require an implied cause of action. Second, they serve a clear compensatory function. Third, they are likely to augment, rather than disrupt, the FDA's enforcement actions.

A. *Doctrinal Arguments Against Express Preemption*

The first argument for the express preemption of claims based on violations of industry-wide FDA regulations like CGMPs and the reporting regulation is that these regulations could be interpreted in different lawsuits as imposing different requirements on the same manufacturer. Such a possibility seems to require express preemption

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<sup>112</sup> See *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205–08 (8th Cir. 2010) (arguing that plaintiffs' tort claims are preempted); see also Herrmann, Alden & Harrison, *supra* note 12, at 565–76 (discussing a broad range of state torts that are expressly or impliedly preempted).

of claims based on violations of the regulation.<sup>113</sup> There is a strong argument, however, that courts should treat the CGMPs as device specific. True, CGMPs are phrased broadly as industry standards rather than specific requirements.<sup>114</sup> But individual manufacturers must provide specific details as to their own manufacturing processes for approval by the FDA.<sup>115</sup> Moreover, the Sixth Circuit suggested in its unpublished *Howard* decision that the premarket approval process “incorporate[s] the [C]GMP standards,” transforming industry-wide standards into specific requirements.<sup>116</sup> If courts were to treat the CGMPs as de facto device-specific requirements for individual devices, then plaintiffs’ lawsuits based on violations of the CGMPs would not necessarily subject a manufacturer to differing and conflicting requirements.

One might respond that because the CGMPs offer manufacturers flexibility to set their own standards, there is a risk that manufacturers will not adopt precise standards or procedures, and, consequently, juries might be able to impose varying requirements against the same manufacturer in different lawsuits.<sup>117</sup> For example, imagine that a manufacturer stated to the FDA that it would test a “representative sample” of devices to comply with the CGMPs.<sup>118</sup> One litigant might argue that the manufacturer negligently failed to comply with this requirement by not testing five percent of its products, whereas another plaintiff might claim that the manufacturer failed to comply by not testing ten percent of its products. If both lawsuits were successful, the manufacturer legitimately could complain that it faced truly different requirements.

Three responses to this hypothetical illustrate why claims based on violations of industry-wide FDA regulations should nevertheless survive express preemption. First, the reasoning underlying *Riegel*’s holding that nonparallel claims are preempted does not apply in this context. Under *Riegel*, nonparallel claims are preempted because they subject manufacturers to conflicting requirements based on expert

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<sup>113</sup> See *supra* Part II.A.1 (discussing lower courts’ theory of express preemption in parallel claims cases based on CGMPs).

<sup>114</sup> See *supra* notes 19–20 and accompanying text (describing CGMPs).

<sup>115</sup> *Id.*

<sup>116</sup> *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App’x 436, 440 (6th Cir. 2010).

<sup>117</sup> See *supra* notes 78–79 and accompanying text (describing some courts’ similar reasoning regarding parallel claims based on violations of the CGMPs).

<sup>118</sup> See 21 C.F.R. §§ 820.70, 820.72, 820.75 (2010) (establishing production and process controls for medical device manufacturers).

determinations of safety and effectiveness.<sup>119</sup> By contrast, the CGMPs allow each manufacturer *itself* to control how flexible its manufacturing and production procedures are.<sup>120</sup> Thus, a manufacturer could avoid litigation by adopting and following precise manufacturing and production processes.

Second, the Seventh Circuit in *Bausch* listed several factors that make it unlikely that multiple courts will divergently construe industry-wide regulations in different lawsuits. For example, the court explained that the meaning and content of FDA regulations is a matter of law to be addressed by a judge rather than a jury.<sup>121</sup> The Seventh Circuit likely offered this explanation to account for the Supreme Court's criticism in *Riegel* of jury verdicts as increasing the likelihood of manufacturers facing varying, uninformed, and unpredictable requirements.<sup>122</sup> The Seventh Circuit further noted that allowing parallel claims based on violations of industry-wide regulations was unlikely to produce variation because the interpretation of FDA regulations would be a matter of *federal* law—"subject to the usual processes for reconciling conflicting views."<sup>123</sup> In other words, the federal appeals process theoretically should push questions of federal law toward uniform interpretation and resolution.<sup>124</sup>

Third, courts can proactively address the concern that claims based on violations of the CGMPs could subject manufacturers to dif-

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<sup>119</sup> See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) (explaining that jury determinations of negligence or strict liability would impose requirements not based on cost-benefit analyses, unlike FDA determinations of manufacturer compliance).

<sup>120</sup> See *supra* notes 18–22 and accompanying text (discussing the CGMP umbrella approach and contrasting that approach to the FDA's device-specific requirements).

<sup>121</sup> *Bausch v. Stryker Corp.*, 630 F.3d 546, 556 (7th Cir. 2010) ("[T]he meaning of the FDA's requirements will present questions of law for the court to decide . . .").

<sup>122</sup> See *Riegel*, 552 U.S. at 312 ("[T]ort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. . . . A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.").

<sup>123</sup> *Bausch*, 630 F.3d at 556.

<sup>124</sup> See AM. LAW INST., *STUDY OF THE DIVISION OF JURISDICTION BETWEEN STATE AND FEDERAL COURTS* 165–68 (1969) (arguing that uniform application of federal law is more likely to occur through federal court adjudications because of greater experience with federal issues and more readily available oversight by federal appellate courts); Barry Friedman, *Under the Law of Federal Jurisdiction: Allocating Cases Between Federal and State Courts*, 104 COLUM. L. REV. 1211, 1221–22 (2004) ("Even if one were to make the strained assumption that federal interests are always protected in the state courts, litigation of numerous federal claims in state court nonetheless poses a large problem of disuniformity . . ."); Meredith Johnson Harbach, *Is the Family a Federal Question?*, 66 WASH. & LEE L. REV. 131, 185–86 (2009) (discussing five virtues of federal courts, including their tendency to produce uniform outcomes on issues of federal law); Burt Neuborne, *The Myth of Parity*, 90 HARV. L. REV. 1105, 1115–28 (1977) (discussing institutional and other advantages of federal courts in the context of civil rights litigation).

ferent requirements without a categorical bar on parallel claims. For example, courts could filter out problematic claims under the recently heightened pleadings standards. In other words, a court might not preempt a claim alleging only that a manufacturer was negligent for failing to follow the CGMPs, without any more detail, but nonetheless might dismiss the claim as merely conclusory under the requirements of *Bell Atlantic Corp. v. Twombly*.<sup>125</sup> Several post-*Riegel* courts have adopted this strategy of dismissing rather than preempting plaintiffs' claims.<sup>126</sup> Dismissing on a claim-by-claim basis because the plaintiff failed to allege sufficient facts is preferable to preempting all claims based on violations of industry-wide regulations, because the latter could set precedent that results in the unnecessary termination of otherwise meritorious tort claims.<sup>127</sup>

The other major argument for the express preemption of claims based on industry-wide FDA regulations is that such actions require demonstrating legal elements, like duty or unreasonable danger, which are technically additional to or different from the FDA's regulations.<sup>128</sup> But the Seventh and Fifth Circuits' rejection of this argument seems irrefutable: Common law elements are not requirements that manufacturers must meet.<sup>129</sup> That is, the fact that plaintiffs must demonstrate common law elements like duty or unreasonable danger does not change the technical specifications for devices. Moreover, as the Supreme Court explained in *Lohr*, although common law elements technically make the requirements imposed by a common law action "narrower" than the federal requirement, "in a literal

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<sup>125</sup> 550 U.S. 544, 555–56 (2007) (explaining that a complaint requires more than mere factual assertions to survive the pleading stage).

<sup>126</sup> The Fifth Circuit urged this distinction in its recent *Hughes* decision based on its view that "conclusory allegations of an FDA regulatory violation are impermissible." *Hughes v. Bos. Scientific Corp.*, 631 F.3d 762, 773 (5th Cir. 2011). However, the Fifth Circuit did not agree with the defendant's broader argument that "permitting the jury to determine whether [a manufacturer] violated the FDA's [industry-wide] reporting requirements would lead to the possible imposition of different or additional state requirements." *Id.* at 772. For a thorough discussion on pleading requirements for parallel claims, see Daniel W. Whitney, *Guide to Preemption of State-Law Claims Against Class III PMA Medical Devices*, 65 FOOD & DRUG L.J. 113, 123–26 (2010).

<sup>127</sup> See *infra* Part III.B.2–3 (discussing the compensatory and regulatory benefits of parallel claims based on violations of industry-wide FDA regulations).

<sup>128</sup> See *supra* Part II.A.1 (discussing preemption of common law claims because additional legal elements "invade" federal requirements).

<sup>129</sup> See *Hughes*, 631 F.3d at 772 (the defendant's reasonableness defense does not require additional or different requirements); *Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010) (using violations of FDA regulation to establish prima facie evidence of negligence does not impose requirements on the defendant manufacturers).

sense, such a difference . . . surely provide[s] a strange reason for finding pre-emption.”<sup>130</sup>

Perhaps there is a stronger argument that the state law legal elements of parallel claims require preemption of such claims because a court’s determination of an element, for example, the element of duty, in one litigation may affect the industry as a whole. However, this articulation of the argument is far afield from the reasoning in *Riegel*. There, the Court was not concerned about whether the law recognized a duty running from manufacturers to consumers. Instead, it was concerned that the manufacturers’ standard of care could vary from lawsuit to lawsuit.<sup>131</sup> Assuming that parallel claims based on violations of industry-wide FDA regulations are unlikely to impose different technical requirements on manufacturers, there is no reason why the demonstration of separate legal elements—even if such demonstrations could apply broadly across the industry—should result in preemption.

In sum, tort claims based on violations of industry-wide FDA regulations should not be expressly preempted under *Riegel*. Such a claim will rarely impose different requirements from the underlying regulation on a manufacturer, given that the claim’s substance will come from details that the manufacturer itself supplies to the FDA. Also, to the extent that courts have any latitude in interpreting regulatory requirements, they can avoid the problem of imposing differing standards without preempting plaintiffs’ claims. Over time, courts likely will push interpretation of industry-wide regulations toward uniformity and always may dismiss on a claim-by-claim basis to avoid subjecting manufacturers to conflicting requirements. Overall, tort claims do not inherently impose additional requirements; they merely require plaintiffs to prove additional legal elements, and the Supreme Court has explicitly held that the demonstration of legal elements does not require the preemption of claims.

### B. Policy Arguments Against Implied Preemption

In *Buckman*, the Supreme Court held that the plaintiffs’ fraud-on-the-FDA claims were impliedly preempted.<sup>132</sup> Several district courts and the Eighth Circuit Court of Appeals in *Sprint Fidelis*, cited *Buckman* to hold that some, if not most, parallel claims based on violations of general FDA regulations similarly must be impliedly pre-

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<sup>130</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996).

<sup>131</sup> See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) (noting that successive jury verdicts could disrupt the FDA’s cost-benefit analysis).

<sup>132</sup> *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001).

empted.<sup>133</sup> But few of these courts have explained why such parallel claims are analogous to the fraud-on-the-FDA claims in *Buckman*.

There are three reasons why courts should not interpret *Buckman* to require the implied preemption of parallel claims based on violations of FDA industry-wide regulations. First, parallel claims do not depend on an implied cause of action from the Federal FDCA as *Buckman*'s fraud-on-the-FDA claims did. Second, parallel claims based on violations of industry-wide FDA regulations serve a clearer compensatory function than fraud-on-the-FDA claims. Third, rather than interfering with the FDA's enforcement options, parallel claims based on violations of the FDA's industry-wide regulations should actually complement the FDA's enforcement decisions.

### 1. *Parallel Claims Do Not Depend on an Implied Cause of Action*

It is an established legal conclusion that the FDCA and attendant FDA regulations do not create an implied cause of action.<sup>134</sup> The *Buckman* Court extended this conclusion to preempt fraud-on-the-FDA claims. However, this reasoning arguably does not require preemption of parallel claims based on violations of industry-wide FDA regulations. In *Buckman*, "the fraud claims exist[ed] *solely* by virtue of the FDCA disclosure requirements."<sup>135</sup> The plaintiffs had no theory of liability other than that the defendant had violated the FDCA.<sup>136</sup> Thus, the Court found that their claims were preempted because they did not arise out of a "traditional state tort . . . which . . . predated the federal enactments" at issue.<sup>137</sup> But plaintiffs bringing claims based on violations of industry-wide FDA regulations like the CGMPs do have a theory of liability—negligence or strict liability, for example—that arises under state law. The only purpose the FDA regulation serves in the lawsuit is to serve as the standard of care.

In other words, courts that cite *Buckman* for the proposition that parallel claims are impliedly preempted overlook the distinction between the doctrine of implied causes of action and the doctrine of negligence per se. Both doctrines allow plaintiffs to recover damages

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<sup>133</sup> See *supra* Part II.A.2 (discussing how different courts have interpreted *Buckman* and *Riegel* to foreclose parallel claims). Admittedly, the Eighth Circuit appeared to read *Buckman* more narrowly, and, consequently, appeared to take a more liberal approach to parallel claims than the district court had taken.

<sup>134</sup> See, e.g., *Merrell Dow Pharm., Inc. v. Thompson*, 478 U.S. 804, 817 (1986) ("Congress has determined that there should be no private, federal cause of action for [a] violation [of the FDCA] . . .").

<sup>135</sup> *Buckman*, 531 U.S. at 353 (emphasis added).

<sup>136</sup> See *supra* Part I.B (discussing theory of liability and justifications for implied preemption in *Buckman*).

<sup>137</sup> *Buckman*, 531 U.S. at 353.

for violations of statutes or regulations that do not authorize a civil remedy. However, different tests govern the two doctrines.<sup>138</sup> The implied cause of action doctrine is “[m]ore narrow than negligence per se,” and “allows private claims only when Congress clearly so intended.”<sup>139</sup> But regulations can support negligence per se actions even if they do not create causes of action.<sup>140</sup>

One could respond that plaintiffs should not be able to “make an end run around th[e] rule [that the FDCA does not create a cause of action] by recasting violations of the FDCA as violations of state common law.”<sup>141</sup> But in *Merrell Dow Pharmaceuticals Inc. v. Thompson*, the Supreme Court strongly suggested that plaintiffs could make just that move.<sup>142</sup> In *Merrell Dow*, the Court did not require that states allow plaintiffs to incorporate FDA regulations into negligence claims, but it assumed that plaintiffs were allowed to do so.<sup>143</sup> Moreover, many states have held that FDA regulations can be incor-

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<sup>138</sup> See David G. Owen, *Proving Negligence in Modern Products Liability Litigation*, 36 ARIZ. ST. L.J. 1003, 1013 (2004) (“While the federal implication doctrine may be its cousin, negligence per se is an independent, substantive doctrine of state tort law applicable in both state courts and federal diversity actions . . .”).

<sup>139</sup> *Id.*; see also Pauline E. Calande, Note, *State Incorporation of Federal Law: A Response to the Demise of Implied Federal Rights of Action*, 94 YALE L.J. 1144, 1144 (1985) (“[E]ven when implied federal rights of action have been denied, states may often be able to provide a right of action to private plaintiffs by creating a parallel state law that incorporates federal law by reference.”).

<sup>140</sup> See Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 250 (2007) (describing that a majority of states allow negligence per se incorporation even when statutes do not create causes of action); see also *Lowe v. Gen. Motors Corp.*, 624 F.2d 1373, 1379 (5th Cir. 1980) (“The mere fact that the law which evidences negligence is Federal while the negligence action itself is brought under State common law does not mean that the state law claim metamorphoses into a private right of action . . .”); *Evraets v. Intermedics Intraocular, Inc.*, 34 Cal. Rptr. 2d 852, 859 n.6 (Ct. App. 1994) (“We perceive a difference between suing directly on the FDCA statutes and regulations and suing on a state law theory which incorporates the federal law as a standard of conduct.”).

<sup>141</sup> *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009).

<sup>142</sup> 478 U.S. 804 (1986). *Merrell Dow* was not a preemption case. The question presented to the Court was whether the incorporation of a federal standard into a state cause of action created federal question jurisdiction. In order to reach this question, the Court assumed that plaintiffs could incorporate statutory provisions from the FDCA into tort claims. See *id.* at 817 (“We conclude that a complaint alleging a violation of [the FDCA] as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim ‘arising under the Constitution, laws, or treaties of the United States.’” (quoting 28 U.S.C. § 1331 (2006))).

<sup>143</sup> See *id.*

porated into negligence per se actions, despite the fact that the FDCA does not itself create a cause of action.<sup>144</sup>

## 2. *Parallel Claims Serve an Important Compensatory Function*

Parallel claims based on violations of industry-wide FDA regulations are prototypical compensatory tort claims. Many medical-device users, through no fault of their own, suffer chronic and debilitating pain, sickness, and even death. They may incur huge financial losses because manufacturers negligently manufacture products and fail to report malfunctioning devices. The tort system strives to make such victims whole.<sup>145</sup> That the manufacturers' tortious conduct also violates federal law reinforces the fairness-based argument that these consumers deserve their day in court and their right to seek compensation.

Of course, one could counter that the fraud-on-the-FDA claims preempted in *Buckman* also serve a compensatory function. After all, in *Buckman*, the plaintiffs were medical-device users who had suffered injuries. However, the fact that they sought incidental compensation did not prevent the Court from holding that their claims were categorically noncompensatory. Instead, the Court held that the object of fraud-on-the-agency claims is “[p]olicing fraud against federal agencies[,] . . . hardly ‘a field which the States have traditionally occupied.’”<sup>146</sup> Moreover, fraud-on-the-agency claims intrude into the relationship between an agency and its industry—a field that is “inherently federal” because it “originates from, is governed by, and terminates according to federal law.”<sup>147</sup>

In contrast to fraud-on-the-FDA claims, parallel claims based on violations of industry-wide FDA regulations arguably are categorically compensatory. Indeed, *Buckman*'s treatment of a conflicting precedent, *Silkwood v. Kerr-McGee Corp.*,<sup>148</sup> supports this conclusion. In *Silkwood*, the plaintiff sought punitive damages after his daughter suffered contamination poisoning from a nuclear power plant.<sup>149</sup> The

<sup>144</sup> See, e.g., *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 932–33 (5th Cir. 2006) (allowing a state law negligence claim based on the defendant's failure to manufacture in accordance with federal law); *Stanton v. Astra Pharm. Prods., Inc.*, 718 F.2d 553, 563–64 (3d Cir. 1983) (same under Pennsylvania law); *Ezagui v. Dow Chem. Corp.*, 598 F.2d 727, 733 (2d Cir. 1979) (same under New York law); *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 461 (4th Cir. 1960) (same under Virginia law); *Valente v. Sofamor, S.N.C.*, 48 F. Supp. 2d 862, 876 (E.D. Wis. 1999) (same under Wisconsin law).

<sup>145</sup> See *supra* note 11 (discussing tort law's compensatory role).

<sup>146</sup> *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

<sup>147</sup> *Id.*

<sup>148</sup> 464 U.S. 238 (1984).

<sup>149</sup> *Id.* at 241–43.

defendant argued that the damages should be impliedly preempted for interfering with the Nuclear Regulatory Commission's relationship with its industry.<sup>150</sup> The Court rejected this argument and upheld the damages.<sup>151</sup> *Buckman* distinguished *Silkwood*, rather than overturning it, noting that, unlike fraud-on-the-FDA claims, the claim at issue in *Silkwood*, "was . . . based . . . on traditional state tort law principles of the duty of care."<sup>152</sup> Parallel claims, like the tort claim in *Silkwood*, also are based on the traditional duty of care. They arise under state law and are grounded in traditional state law theories of liability. Moreover, the gravamen of such claims is that the manufacturer failed to satisfy its obligation to its consumers—as opposed to its obligation to a federal agency.

The argument that parallel claims serve a clearer compensatory function than fraud-on-the-FDA claims is more than just a policy argument. It also suggests that parallel claims should be entitled to protection by the doctrinal presumption against preemption. The Court has explained its hesitancy to preempt tort claims when doing so would leave injured victims without any avenue for compensation. For example, the Court in *Lohr* expressed its doubt that the FDA's arsenal of tools—"recall, replace, or refund"—was of any help to injured plaintiffs given that those "remed[ies do] not extend to recovery for compensatory damages."<sup>153</sup> Moreover, in *Silkwood*, the Court explained that "in light of Congress' failure to provide any federal remedy for persons injured . . . [i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."<sup>154</sup> It similarly should be difficult to believe that Congress intended to leave consumers injured by devices manufactured in violation of federal regulations without any compensatory remedy, and Congress's intent is the touchstone for preemption.<sup>155</sup> Thus, courts should presume that these claims are not impliedly preempted.

Even if the presumption against preemption attaches, it still is only a presumption. There might be compelling reasons to find preemption of parallel claims based on violations of general FDA regulations. Based on the Court's reasoning in *Buckman*, the most serious

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<sup>150</sup> *Id.* at 245.

<sup>151</sup> *Id.* at 248–58.

<sup>152</sup> *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001).

<sup>153</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 n.7 (1996).

<sup>154</sup> *Silkwood*, 464 U.S. at 251.

<sup>155</sup> See *supra* note 32 and accompanying text (stressing the centrality of congressional intent).

risk is that parallel claims interfere with the FDA's enforcement monopoly.<sup>156</sup> In the next section, I address this concern.

### 3. *Parallel Claims Complement the FDA's Enforcement Actions*

Recent history suggests that the FDA does not have adequate time, capacity, or resources to monitor manufacturers to ensure that their postmarket conduct complies with safety requirements;<sup>157</sup> to perform the necessary cost-benefit analysis to determine when enforcement actions are appropriate;<sup>158</sup> or to pursue legal actions against manufacturers when doing so would be efficient.<sup>159</sup> Parallel claims based on violations of the FDA's industry-wide regulations can complement the FDA's efforts in all of these endeavors.

Consider the scope of the problem confronting the FDA. Any of the many medical-device manufacturers could violate an industry-wide regulation at any time, in any facility. In 1989, the Comptroller of the General Accountability Office was already concerned about the FDA's ability to monitor medical-device manufacturers given that "[m]ore than 1,700 different types of medical devices are available in the United States today, millions of Americans come into contact with them, and these devices represent an industry of more than \$14 billion annually."<sup>160</sup> Today, this problem is even more pronounced, since "[t]he FDA now regulates products that amount to one-quarter of the

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<sup>156</sup> See Calande, *supra* note 139, at 1157 ("If the creation of private remedies through state incorporation . . . impair[s] the operation of a comprehensive federal regulatory scheme, such state action would be barred under the doctrine of federal preemption.").

<sup>157</sup> See *Medical Devices: The Public Health at Risk: Hearing Before the Subcomm. on Health & the Env't of the H. Comm. on Energy & Commerce*, 101st Cong 35 (1989) (statement of Charles A. Bowsher, Comptroller General, General Accounting Office) [hereinafter Bowsher] (discussing the FDA's "relatively cursory review" of an overwhelming number of medical devices); David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts To Preempt Failure-To-Warn Claims*, 96 GEO. L.J. 461, 465 (2008) (arguing that preemption's unspoken assumption of FDA watchfulness is silly because the FDA is unable to handle postmarket review of thousands of drugs).

<sup>158</sup> See Bowsher, *supra* note 155, at 37 ("For postmarket surveillance to work, information about device problems must be promptly and accurately transmitted to FDA, the Agency must be able to analyze the data and identify the problems, and there must be a systematic process by which FDA decides upon the appropriate level of action. . . . [W]e found several weaknesses in these three areas.").

<sup>159</sup> See, e.g., SPECIAL INVESTIGATIONS DIV., MINORITY STAFF OF H. COMM. ON GOV'T REFORM, 109TH CONG., PRESCRIPTION FOR HARM: THE DECLINE IN FDA ENFORCEMENT ACTIVITY i (2006), available at <http://bit.ly/qnY7eu>. ("[T]here has been a precipitous drop in FDA enforcement actions over the last five years. In some cases, FDA headquarters rejected the enforcement recommendations of FDA field offices despite findings by agency inspectors that violations led to multiple deaths or serious injuries. . . . [T]here is a growing laxity in FDA's surveillance and enforcement procedures, a dangerous decline in regulatory vigilance, and an obvious unwillingness to move forward even on claims from its own field offices." (internal quotation marks omitted)).

<sup>160</sup> Bowsher, *supra* note 155, at 34.

consumer spending in the United States[, b]ut it has only 9,000 employees nationwide.”<sup>161</sup>

The problem of industry size is compounded by the FDA’s inability to develop efficient methods for collecting information on postmarket performance.<sup>162</sup> Its failure may be partially attributed to its consistent budgetary pressures, which make postmarket monitoring difficult.<sup>163</sup> The FDA’s postmarket difficulties also may be partially due to political pressure and the growing influence of industry representatives on the agency’s decision making.<sup>164</sup> The Obama administration has taken steps to make the FDA more proactive, streamlined, and efficient. However, many of these changes deal with premarket activity rather than postmarket monitoring.<sup>165</sup> And even with a larger budget and more political support, the FDA will remain “a small ‘David’ facing dozens of ‘Goliaths.’”<sup>166</sup>

Given these circumstances, parallel claims based on violations of FDA industry-wide requirements, far from interfering with the FDA’s enforcement decision making, should strengthen the FDA’s position. Private litigation against manufacturers brings an inflow of private capital from litigants<sup>167</sup> and results in information disclosures through the discovery process.<sup>168</sup> These features of private litigation have led

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<sup>161</sup> Kessler & Vladeck, *supra* note 155, at 484–85 (2008).

<sup>162</sup> See Bowsher, *supra* note 155, at 35 (“[W]ithin the FDA’s postmarket surveillance systems we also discovered . . . there was a severe shortage of information about the nature and scope of problems associated with the devices once they had become available in the marketplace and began to be used.”); see also THOMAS O. MCGARITY, *THE PREEMPTION WAR: WHEN FEDERAL BUREAUCRACIES TRUMP LOCAL JURIES* 190 (2008) (noting that manufacturers can “manipulate agency assessments” because the FDA relies on manufacturers to report information).

<sup>163</sup> MCGARITY, *supra* note 160, at 197–98 (“The agency has never devoted more than a small fraction of its available resources to the postmarketing surveillance program. . . . [R]esource shortages plague [the] FDA’s postmarketing surveillance efforts with respect to medical devices.”).

<sup>164</sup> This Note does not take a position on whether the FDA has been “captured.” See, e.g., *id.* at 186 (defining “capture” theory as “the possibility that regulatory agencies over time become ‘captured’ by the very entities that they are supposed to be regulating”). One can reject the idea of capture and still accept that the FDA has insufficient monitoring or enforcement resources.

<sup>165</sup> See *supra* note 14 (discussing a new Executive Order streamlining substantial equivalence approval).

<sup>166</sup> Kessler & Vladeck, *supra* note 155, at 495.

<sup>167</sup> See, e.g., MCGARITY, *supra* note 160, at 198 (“Lawyers for the victims of accidents resulting from violations of agency regulations . . . can supplement scarce agency enforcement resources both by uncovering fraud and violations and by providing a strong additional incentive to comply with regulatory requirements.”).

<sup>168</sup> See, e.g., Kessler & Vladeck, *supra* note 155, at 492 (“The information-gathering tools lawyers have in litigation are . . . more extensive than the FDA’s. Indeed, the FDCA does not give the FDA the most important tool trial lawyers have—the right to subpoena relevant information from any source.”); Robert L. Rabin, *Poking Holes in the Fabric of*

many to describe the tort system as a critical “catalyst” for public enforcement.<sup>169</sup> Consider the example of litigation against manufacturers of silicone breast implants. While many continue to question the merits of those lawsuits, no one seriously disputes that the litigation forced manufacturers to reveal information that they had previously concealed from the FDA.<sup>170</sup>

Of course, the plaintiffs in *Buckman* similarly argued that fraud-on-the-FDA claims complement the FDA’s enforcement actions.<sup>171</sup> Yet the Court still held that these claims are impliedly preempted because they interfere with the FDA’s overall ability to “achieve a somewhat delicate balance of statutory objectives.”<sup>172</sup> There are three ways in which fraud-on-the-agency claims disrupt the FDA’s enforcement prerogatives. Exploring each reveals that parallel claims based on violations of industry-wide FDA regulations are potentially less disruptive than fraud-on-the-agency claims.

First, the *Buckman* Court rejected fraud-on-the-FDA claims in part because it found that such claims create an incentive for manufacturers to submit excessive information to the FDA in order to avoid liability.<sup>173</sup> The Court was concerned that this “deluge of information that the Administration neither wants nor needs” would hamper the FDA’s review process and potentially delay the introduction of safe devices to the market.<sup>174</sup>

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*Tort: A Comment*, 56 DEPAUL L. REV. 293, 302 (2007) (“Pretrial discovery has frequently unearthed both industry and regulatory agency practices that might otherwise never have seen the light of day.”).

<sup>169</sup> *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005) (“Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of [the statutory regime]. . . . [T]ort suits can serve as a catalyst in this process . . . .”); see also Sharkey, *supra* note 25, at 864 (“But even with this beefed up FDA, there remains a critical enforcement role for private litigants and state tort claims. For years, scholars and judges have argued in favor of tort suits as catalysts for regulatory action.”).

<sup>170</sup> See, e.g., MCGARITY, *supra* note 160, at 202 (“The notorious litigation over breast implant medical devices provides a good case in point. . . . [D]iscovery . . . was prying information from company files indicating that the companies knew that implants were leaking[ and] that they had withheld the results of short-term animal studies from [the] FDA.”); Kessler & Vladeck, *supra* note 155, at 494–95 (“[T]here is no doubt that . . . [litigation against manufacturers] ‘was uniquely successful in divulging important, asymmetric information about the risks of implants held by implant manufacturers.’” (quoting Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 715 (2007))).

<sup>171</sup> See Brief for Respondent at 31–35, *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768), 2000 WL 1591271 (arguing against implied preemption of fraud-on-the-agency claims).

<sup>172</sup> *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001).

<sup>173</sup> See *id.* at 351.

<sup>174</sup> *Id.*

Such a risk is less present in the context of parallel claims. The incentive for manufacturers to submit documents to avoid fraud-on-the-FDA liability triggers during the premarket approval process—when manufacturers may submit additional studies and reports to set up the argument in postmarket litigation that they did not defraud the FDA. But there are no extraneous documents that a manufacturer can submit to the FDA during premarket approval to avoid liability for violating industry-wide CGMPs when it actually manufactures devices for the market. Likewise, even though allowing parallel claims based on violations of the FDA’s reporting requirements could create an incentive for manufacturers to submit more postmarket information, the FDA already requires manufacturers to submit such information in the form of reports about adverse incidents and injuries.<sup>175</sup> Furthermore, such reports are not the type of unnecessary documents that waste the FDA’s time and resources.

The second reason that the Court found fraud-on-the-agency claims too disruptive is that such claims subject federal agencies to the discovery process. *Buckman* did not directly address this possibility, but several Justices expressed this concern during the oral argument for *Warner-Lambert Co. v. Kent*, a case that dealt with the scope of *Buckman*.<sup>176</sup> Plaintiffs bringing fraud-on-the-agency claims need information “concerning whether a manufacturer misrepresented or withheld information that it was required to submit . . . [and] concerning the agency’s internal deliberations.”<sup>177</sup> Such discovery could disrupt FDA decision making and delay the introduction of products into the market.

This concern also is less compelling in the context of parallel claims. To support parallel claims, plaintiffs seek discovery from manufacturers, not the FDA itself.<sup>178</sup> Plaintiffs may seek access to premarket approval specifications for particular products, and admit-

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<sup>175</sup> See Medical Device Reporting, 21 C.F.R. § 803 (2010) (explaining reporting requirements). For a discussion of the FDA’s industry-wide reporting regulation and what it requires, see *supra* note 22.

<sup>176</sup> Justice Kennedy explained that “discovery” could be “exhaustive and quite burdensome.” Transcript of Oral Argument at 29, *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008) (No. 06-1498). Similarly, Justice Alito asked whether, if they upheld the statute, “[t]here wouldn’t be discovery of internal processes within the FDA?” *Id.* at 37. And Justice Ginsburg asked if it would be “disrupting the FDA by taking depositions of examiners to find out what went on at the FDA?” *Id.* at 39.

<sup>177</sup> Brief for the United States as Amicus Curiae Supporting Petitioners at 22, *Warner-Lambert Co.*, 552 U.S. 440 (No. 06-1498), 2007 WL 421889.

<sup>178</sup> I have been unable to find any case in which a plaintiff has sought information from the FDA for a parallel claim.

tedly, these materials are not public.<sup>179</sup> But even though premarket specifications are private, plaintiffs still can seek them directly from the manufacturers. Nor is there reason to think that because the documents are nonpublic, FDA decision making would somehow be influenced or disrupted if plaintiffs were to obtain premarket approval specifications from manufacturers through discovery.

Finally, fraud-on-the-FDA claims allow plaintiffs to hijack the FDA's enforcement decisions. According to the Supreme Court in *Buckman*, the FDA has statutory flexibility to pursue any number of possible enforcement actions in response to potential violations.<sup>180</sup> This flexibility reflects the fact that the agency must accomplish what are, at times, conflicting goals: expedient introduction of products onto the market and protection of consumers from defective or dangerous products.<sup>181</sup> Indeed, the Court has described the FDA's enforcement prerogatives as similar to those of a prosecutor.<sup>182</sup> Thus, the comparison goes, if plaintiffs are able to bring parallel claims based on violations of industry-wide regulations, a nonexpert jury could determine that a violation authorizes a damage award when the FDA might have determined that the same violation should not be punished.

There are two reasons why parallel claims based on violations of FDA regulations should not be impliedly preempted for disrupting the FDA's enforcement decisions. First, the disruption argument proves too much. Every court, with one exception,<sup>183</sup> that has impliedly preempted claims based on violations of industry-wide FDA regulations has also suggested that plaintiffs could bring claims based on violations of device-specific requirements. Dictum to this effect is not surprising; the *Riegel* Court explicitly said that plaintiffs can bring

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<sup>179</sup> See *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir. 2010) (“[T]he FDA’s specific federal manufacturing requirements are set forth in the agency’s PMA approval files that are accessible, without discovery, only to Medtronic and to the FDA.”).

<sup>180</sup> See *Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349 (2001) (“The FDA . . . has at its disposal a variety of enforcement options that allow it to make a measured response to suspected [violations]. This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives.” (internal citations omitted)).

<sup>181</sup> See *id.*

<sup>182</sup> See *Heckler v. Chaney*, 470 U.S. 821, 835 (1985) (“The [FDCA’s] enforcement provisions thus commit complete discretion to the Secretary to decide how and when they should be exercised.”).

<sup>183</sup> *Bass v. Stryker Corp.*, No. 4:09-CV-632-Y, 2010 WL 3431637 (N.D. Tex. Aug. 31, 2010), seemed to hold that even a violation of a premarket approval specification would be impliedly preempted. *Id.* at \*15–16.

genuinely parallel claims.<sup>184</sup> But there is no principled argument that claims based on violations of device-specific requirements are less disruptive to FDA enforcement priorities than claims based on industry-wide requirements. The argument that the latter must be preempted to protect the FDA's flexibility, taken to its logical conclusion, negates the possibility of any parallel claims—a doctrinal impossibility after *Riegel*.

Second, the need to preserve the FDA's enforcement monopoly is less compelling in the context of parallel claims than it is in the context of fraud-on-the-FDA claims. The FDA has a better institutional capacity than private parties to respond to manufacturer fraud,<sup>185</sup> since fraud claims are based on manufacturer conduct during the premarket approval process.<sup>186</sup> Throughout this process, manufacturers must furnish the FDA with all of the data, reports, studies, and samples that the agency needs to develop requirements. Agency discretion over fraud claims related to these materials is therefore both logical and efficient.<sup>187</sup>

But the FDA's comparative advantages vis-à-vis private litigants does not hold when it comes to manufacturers' postmarket violations. The FDA's monitoring and enforcement actions often fail because of the huge size of the regulated industry and the small size of the agency's budget.<sup>188</sup> Parallel claims based on violations of the FDA's industry-wide regulations provide the FDA with information about how manufacturers are operating at a time when they are no longer under direct supervision—i.e., after a device is on the market. Furthermore, such claims allow litigants to fund monitoring activities and force information disclosures through the discovery process.<sup>189</sup> To be

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<sup>184</sup> See *supra* Part I.A.2 (discussing the parallel claims exception to express preemption in *Riegel*).

<sup>185</sup> There is some reason to believe that the actual premarket approval process rarely results in better response to manufacturer fraud. For a discussion of whether the premarket approval process actually affords consumers sufficient protection, see *Blunt v. Medtronic, Inc.*, 760 N.W.2d 396, 412 (Wis. 2009) (Bradley, J., concurring). Justice Bradley remarked that based on recent whistleblower reports, “[i]t is not at all apparent that the FDA approval process actually guarantees a minimum level of safety for medical devices. . . . [T]he scientific review process for medical devices at FDA has been corrupted and distorted by current FDA managers, thereby placing the American people at risk.” *Id.* (quoting Letter from Nine FDA Scientists to John D. Podesta, Presidential Transition Team 1 (Jan. 7, 2009)).

<sup>186</sup> See *Buckman*, 531 U.S. at 343 (discussing plaintiffs' fraud theory).

<sup>187</sup> See *supra* note 14–15 and accompanying text (discussing the premarket approval process).

<sup>188</sup> See *supra* notes 157–66 and accompanying text (discussing FDA shortcomings in postmarket activities).

<sup>189</sup> See *supra* notes 167–70 and accompanying text (discussing private litigation as a catalyst to enforcement).

sure, there is some tension between my argument here—that parallel claims complement the FDA’s regulatory role—and my argument in Part III.B.2—that parallel claims are arguably categorically compensatory and thus do not intrude into the regulatory relationship between the FDA and the medical device industry. However, the Court faced this same tension in *Silkwood* and found that the fact that damage remedies can alter behavior does not change their fundamentally compensatory nature.<sup>190</sup>

#### CONCLUSION

Critics and defenders alike heralded *Riegel* as creating legal immunity for the manufacturers of medical devices. Although the Supreme Court clearly indicated that plaintiffs could bring claims premised on violations of federal regulations, many courts, including the Eighth Circuit in the consolidated *Sprint Fidelis* litigation, have found that claims based on violations of industry-wide regulations, such as the CGMPs and reporting regulations, are expressly and/or impliedly preempted. This unyielding approach to preemption is undesirable. First, injured plaintiffs may be denied compensation because their tort suits are blocked and because the FDA is not empowered to ensure that injured victims of improperly manufactured devices receive damages. Second, defendant-manufacturers avoid sanction for violating federal regulations because the costs associated with monitoring and enforcement actions are often prohibitive for the FDA.

But this broad approach to preemption is not doctrinally compelled, nor is it sound policy. Several trial courts and the Seventh and Fifth Circuits have found that plaintiffs’ claims based on violations of non-device specific regulations should survive preemption because they do not impose different or additional requirements on manufacturers and do not interfere with the FDA’s enforcement monopoly. These lawsuits fall within the traditional domains of state authority to provide compensation for injured consumers and to promote public health and safety. As more lawsuits against medical-device manufacturers arise, reviewing courts should not distort the Supreme Court’s preemption decisions by providing absolute immunity to manufacturers.

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<sup>190</sup> 464 U.S. 238, 263–64 (1984) (Blackmun, J., dissenting) (noting that compensatory damages “have an indirect impact on [a manufacturer’s] daily operations,” but arguing they are different from punitive damages because the two types of damages have different purposes and therefore compensatory damages should not be preempted). Blackmun’s proposition did not divide the majority from the dissent. I cite it here because it is the clearest articulation of how damage awards can have indirect regulatory effects but retain a compensatory purpose.