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# Surviving Medical Device Preemption under 21 U.S.C. 360k: Clarifying Pleading Standards for Parallel Claims Following Twombly and Iqbal.

Ashley Abraham\*

## I. Introduction

Medical devices run the gamut on riskiness. Devices such as elastic bandages pose almost no risk, while replacement heart valves, when malfunctioning, can be life-threatening. Because they pose a greater threat, the riskier devices are subject to greater regulation by the Food and Drug Administration (FDA) than those devices that are relatively safe.<sup>1</sup> Some of the most benign devices are exempt from review before being marketed, while most other devices require only a premarket notification to the FDA through a relatively simple process called 510(k) clearance.<sup>2</sup> However, some devices are subject to a rigorous process of premarket approval (PMA) under Section 515 of the Food Drug and Cosmetic Act (FD&CA).<sup>3</sup> Specifically, these devices are used to support or sustain human life or to prevent impairment of human health, or include those that present a potentially great risk of illness or injury.<sup>4</sup>

Almost paradoxically, manufacturers of the riskiest devices face a lesser chance of state tort liability for defective manufacturing due to a preemption provision of the Medical Device Amendments of 1976 (MDA) to the FD&CA. According to *21 U.S.C. § 360k(a)*, states cannot establish any requirement for medical devices that is different from or in addition to requirements promulgated by the federal government relating to the safety and effectiveness of

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\* J.D. Candidate, Seton Hall University School of Law, 2013; Pharm.D., Rutgers, The State University of New Jersey, Ernest Mario School of Pharmacy, 2010. First and foremost, this comment is dedicated to Christ, for whom I labor. I am extremely grateful to Professors Jordan Paradise and Adam Steinman for their invaluable insight and guidance throughout the writing process. I would also like to thank Jennifer Fasolino for her encouragement and mentorship. A special thanks to my family and friends for their continued patience, love and support.

<sup>1</sup> Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, *Food and Drug Law* 981(3d ed. 2007).

<sup>2</sup> Hutt, *supra* note 1, at 993; BD. ON POPULATION HEALTH AND PUB. HEALTH PRACTICE, INST. OF MED., *MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS* 3 (2011).

<sup>3</sup> 21 U.S.C. § 360e (2006).

<sup>4</sup> *Id.*

the device.<sup>5</sup> As interpreted by the Supreme Court in *Medtronic, Inc. v. Lohr*,<sup>6</sup> state tort claims against manufacturers of 510(k) cleared devices are not preempted because the 510(k) process, without more, does not constitute a requirement that “relates to the safety or effectiveness of the device”<sup>7</sup> since “the 510(k) process is focused on *equivalence*, not safety.”<sup>8</sup> In *Riegel v. Medtronic, Inc.*,<sup>9</sup> however, the Supreme Court determined that the preemption clause does apply to PMA devices to the extent that the state regulations or tort claims hold manufacturers to a standard that is higher than or different from that required by the federal government.<sup>10</sup> Therefore, as long as the state requirements parallel federal requirements, the state tort claims would not be preempted.<sup>11</sup>

Circuits have been split as to how to plead parallel claims with the added confusion of the sufficiency of pleading standards set forth by *Bell Atlantic Corp. v. Twombly*<sup>12</sup> and *Ashcroft v. Iqbal*.<sup>13</sup> These recent Supreme Court decisions urge plaintiffs to avoid conclusory allegations while still alleging a plausible claim for relief.<sup>14</sup> In the context of PMA medical device manufacturing defect claims, courts are divided regarding exactly which facts are sufficient to properly plead a parallel claim and have established a spectrum of standards. These standards range from extremely generalized pleadings to pleadings with great specificity regarding the specific problem with the medical device that can be linked to the plaintiff's injury. Additionally, since the state requirements must parallel federal requirements, plaintiffs must allege that some federal requirement has been violated. The medical devices at issue are subject

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<sup>5</sup> 21 U.S.C. § 360k(a) (2006).

<sup>6</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

<sup>7</sup> 21 U.S.C. § 360k(a)(2) (2006).

<sup>8</sup> *Lohr*, 518 U.S. at 493 (citations omitted).

<sup>9</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

<sup>10</sup> *Id.* at 330 (citing 21 U.S.C. § 360k(a)(1)).

<sup>11</sup> *Id.*

<sup>12</sup> *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

<sup>13</sup> *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009).

<sup>14</sup> *Id.* at 1949 (quoting *Twombly*, 550 U.S. at 570).

to both general controls, such as Current Good Manufacturing Practices (CGMPs), as well as device-specific PMA requirements.<sup>15</sup> While CGMPs are extensively described and readily available to the public in 21 C.F.R. § 820,<sup>16</sup> many of the PMA documents are confidential.<sup>17</sup> Consequently, although plaintiffs may be able to allege that a specific CGMP has been violated, specificity with regard to PMA requirements is less feasible. Despite this inequality in availability of documents, some courts are requiring plaintiffs to plead violations of CGMPs and PMA requirements with great specificity, while other courts are more lenient.

The disparity in pleading standards will almost certainly lead to forum shopping between the federal courts of appeals. Consequently, some plaintiffs may have no remedy at all if their claims cannot pass muster under too stringent a standard. Conversely, too lenient of a test would deprive manufacturers of the protection Congress intended to provide to them to encourage medical device development under strict federal oversight. Since this issue relates to the riskiest of devices, substantial injury with minimal to no recovery is not only possible, it is probable. With stakes as high as these, clarification of the issue is not only necessary, it is urgent.

This Comment proceeds as follows: Part II will address the background and history of medical device regulation and preemption of state law claims. Part III will discuss the differing standards applied by the circuit courts. Part IV will analyze the issue of pleading standards and propose a workable standard under which plaintiffs can plead parallel claims with the specificity required by *Twombly* and *Iqbal*. The proposed two-step solution to the problem of varying pleading standards would require plaintiffs first to ensure that their claims are not preempted by

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<sup>15</sup> 21 U.S.C. § 360j(e)(1) (2006).

<sup>16</sup> 21 C.F.R. § 820 (2012); Food and Drug Administration, *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, FDA.GOV, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm> (Apr. 28, 2011).

<sup>17</sup> *Bausch v. Stryker*, 630 F.3d 546, 560–61 (7th Cir. 2010).

premising the claims on a violation of an FDA-mandated general or device-specific requirement, and then to plead with as much specificity as is possible at the stage of judicial proceeding. If the plaintiff's claim is premised on a violation of general control, such as a CGMP, the plaintiff should plead a specific violation. However, if the claim is premised on a violation of a PMA requirement, great specificity may not be possible because all the PMA documents are not available to the plaintiff. Thus, in assessing the sufficiency of the pleadings, courts should take into account the availability of federal requirements upon which the claims are premised. Finally, Part V will summarize the proposed solution and conclude.

## **II. Background**

### **A. Evolution of Medical Device Regulation**

The regulation of medical devices by the FDA was not always as stringent or extensive as it today. In fact, although the FDA was created in the latter part of the nineteenth century,<sup>18</sup> the agency only gained jurisdiction over medical devices through the FD&CA of 1938.<sup>19</sup> But this Act merely prohibited adulteration and misbranding of food, drugs, devices, and cosmetics already on the market.<sup>20</sup> The 1938 Act also required a showing of safety for drugs through premarket notification.<sup>21</sup> In 1962, the FDA was given authority to review new drugs for safety *and efficacy* through a premarket approval process.<sup>22</sup> However, unlike with new drugs, the 1962 Act did not require new medical devices to obtain premarket approval from the FDA.<sup>23</sup> Recognizing that some high risk devices, such as surgical sutures, contact lenses and injectable

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<sup>18</sup> Food and Drug Administration, *About FDA: History*, FDA.GOV, <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm>.

<sup>19</sup> Hutt, *supra* note 1, at 13.

<sup>20</sup> Hutt, *supra* note 1, at 13.

<sup>21</sup> Hutt, *supra* note 1, at 13.

<sup>22</sup> Hutt, *supra* note 1, at 14.

<sup>23</sup> Hutt, *supra* note 1, at 976.

silicone, required a higher level of regulatory control, the FDA attempted to classify them as drugs rather than devices.<sup>24</sup>

Throughout this time, the states, rather than the Federal government, regulated the introduction of most new medical devices.<sup>25</sup> However, the regulatory landscape began to change in the 1960s and 1970s, as complex medical devices, such as the heart pacemaker, the kidney dialysis machine and defibrillators, proliferated and some failed.<sup>26</sup> Congress passed the MDA, which initiated a regime of detailed federal oversight.<sup>27</sup> The MDA added several provisions to the 1962 Act, thus creating “a complex and novel system for regulating the development, introduction, and marketing of medical devices.”<sup>28</sup>

## **B. Classification and Approval of Medical Devices**

One of the major features of the MDA is its system of medical device classification. Assignment to one of three classes is “based on the level of control necessary to assure the safety and effectiveness of the medical device.”<sup>29</sup> Devices in all three classes are subject to general controls, which include “the basic adulteration and misbranding provisions as well as applicable good manufacturing practice regulations, banned device regulations, and notification and repair, replacement, or refund requirements.”<sup>30</sup>

Class I devices, such as elastic bandages and examination gloves, require the lowest level of oversight because the general regulatory controls of the FD&CA are sufficient to assure safety

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<sup>24</sup> Hutt, *supra* note 1, at 976–77.

<sup>25</sup> Riegel v. Medtronic, Inc., 552 U.S. 312, 315 (2008).

<sup>26</sup> Hutt, *supra* note 1, at 978; Riegel, 552 U.S. at 315.

<sup>27</sup> Riegel, 552 U.S. at 316.

<sup>28</sup> Hutt, *supra* note 1, at 980.

<sup>29</sup> Food and Drug Administration, *Device Classification*, FDA.GOV, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (last updated Apr. 27, 2009).

<sup>30</sup> Hutt, *supra* note 1, at 981.

and effectiveness.<sup>31</sup> Class II devices include powered wheelchairs and surgical drapes, and are devices for which general controls are not sufficient but enough information is available to develop special controls.<sup>32</sup> The FDA establishes these special controls, which include performance standards and post-market surveillance measures.<sup>33</sup> Class III devices receive the most federal oversight because general controls are insufficient to assure safety and effectiveness and there is not enough information available to establish special controls.<sup>34</sup> In general, Class III devices, which include replacement heart valves, implanted cerebella stimulators and pacemaker pulse generators, are used to support or sustain human life or to prevent impairment of human health, or they present a potentially great risk of illness or injury.<sup>35</sup>

The MDA also describes a system for introduction of medical devices to the market that operates wholly independently of the classification system.<sup>36</sup> There are three ways a medical device can lawfully be marketed: (1) through premarket notification (PMN) to FDA under Section 510(k) of the FD&CA;<sup>37</sup> (2) through a premarket approval (PMA) application under Section 515 of the FD&CA;<sup>38</sup> or (3) as an exempt device not subject to either the PMN or PMA processes because it poses only non-significant risks.<sup>39</sup>

In order to receive 510(k) clearance of a device, manufacturers must simply demonstrate that the device to be marketed is at least as safe and effective as, or “substantially equivalent” to,

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<sup>31</sup> Hutt, *supra* note 1, at 980; Riegel, 552 U.S. at 316 (citing 21 U.S.C. § 360c(a)(1)(A)).

<sup>32</sup> Hutt, *supra* note 1, at 980; Riegel, 552 U.S. at 316 (citing 21 U.S.C. § 360c(a)(1)(B)).

<sup>33</sup> Hutt, *supra* note 1, at 980–81; Riegel, 552 U.S. at 316 (citing 21 U.S.C. § 360c(a)(1)(B)).

<sup>34</sup> Hutt, *supra* note 1, at 980.

<sup>35</sup> Riegel, 552 U.S. at 317 (citing 21 U.S.C. § 360c(a)(1)(B)(ii)).

<sup>36</sup> Hutt, *supra* note 1, at 980.

<sup>37</sup> Food Drug and Cosmetic Act § 510(k), 21 U.S.C. § 360(k) (2006).

<sup>38</sup> Food Drug and Cosmetic Act § 515, 21 U.S.C. § 360e (2006).

<sup>39</sup> Hutt, *supra* note 1, at 981, 991–92; Food and Drug Administration, *How to Market Your Device*, FDA.GOV, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm> (last updated Mar. 18, 2010).

a legally marketed device.<sup>40</sup> Substantial equivalence is found if the new device has the same intended use as the predicate device and has the same technological characteristics as the predicate device.<sup>41</sup> If the technological characteristics are different from the predicate device, the manufacturer must show that the new device does not raise new questions of safety and effectiveness and that the device is at least as safe and effective as the legally marketed device.<sup>42</sup> However, unlike the PMA process, 510(k) PMN does not require a safety and efficacy assessment for the device to be marketed.<sup>43</sup> Because it is the simplest, cheapest, and fastest way to bring to market a new medical device that is not exempt from premarket review, the 510(k) clearance process has become a key part of medical device regulation.<sup>44</sup> According to the Institute of Medicine, about a third of all medical devices are cleared through the 510(k) pathway, while the majority of the remaining devices are exempt from premarket review (67%).<sup>45</sup>

In contrast, only about 1% of devices enter the market through the PMA process.<sup>46</sup> The PMA process is very rigorous and requires manufacturers to submit what is usually a multivolume application.<sup>47</sup> The application includes, among other things:

full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to

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<sup>40</sup> Food Drug and Cosmetic Act § 510(k); 21 U.S.C. § 360(k) (2006); Food and Drug Administration, *Premarket Notification(510k)*, FDA.GOV, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (last updated Sep. 3, 2010).

<sup>41</sup> 21 U.S.C. § 360c(i) (2006); Food and Drug Administration, *Premarket Notification(510k)*, FDA.GOV, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (last updated Sep. 3, 2010).

<sup>42</sup> Food and Drug Administration, *Premarket Notification (510k)*, FDA.GOV, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (last updated Sep. 3, 2010).

<sup>43</sup> Hutt, *supra* note 1, at 993.

<sup>44</sup> Hutt, *supra* note 1, at 993; INST. OF MED., *supra* note 2, at 4.

<sup>45</sup> INST. OF MED., *supra* note 2, at 4.

<sup>46</sup> INST. OF MED., *supra* note 2, at 4.

<sup>47</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18 (2008) (citing 21 U.S.C. § 360e(c)(1)) (internal citations omitted); *see also* 21 C.F.R. § 814.9 (2012); *see also* Food Drug and Cosmetic Act § 515.

the applicant; a ‘full statement’ of the device’s ‘components, ingredients, and properties and of the principle or principles of operation’; ‘a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device’; samples or device components required by the FDA; and a specimen of the proposed labeling.<sup>48</sup>

After reviewing the application, the FDA may grant or deny approval of the proposed medical device, or condition approval on further research,<sup>49</sup> adherence to performance standards,<sup>50</sup> restrictions upon sale or distribution or compliance with other requirements as described by the agency.<sup>51</sup> The FDA may also impose device-specific restrictions.<sup>52</sup> Once PMA is granted, the manufacturer cannot, without permission from the FDA, make any changes to the “design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.”<sup>53</sup> Changes must be approved through a supplemental application for PMA, which will be evaluated under essentially the same criteria as the initial application.<sup>54</sup>

### **C. MDA Express Preemption Clause, 21 U.S.C. § 360k(a)<sup>55</sup>**

The MDA contains an express preemption clause, which provides the basis for preemption of medical device state tort law claims. The clause states:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--  
(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and  
(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.<sup>56</sup>

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<sup>48</sup> 21 U.S.C. § 360e(c)(1) (2006); *see also* 21 C.F.R. § 814.9 (2012).

<sup>49</sup> 21 U.S.C. § 360e(d) (2006).

<sup>50</sup> 21 C.F.R. § 861.1(b)(3) (2012).

<sup>51</sup> *Id.* § 814.82.

<sup>52</sup> 21 U.S.C. § 360j(e)(1) (2006).

<sup>53</sup> 21 U.S.C. § 360e(d)(6)(A)(i) (2006).

<sup>54</sup> *Id.* § 360e(d)(6); 21 C.F.R. § 814.39(c) (2012).

<sup>55</sup> 21 U.S.C. § 360k(a) will hereinafter be referred to as “Section 360k.”

<sup>56</sup> 21 U.S.C. § 360k(a).

Thus, the clause would prohibit state regulations and state tort claims against manufacturers of medical devices if those claims are based on requirements relating to the safety or effectiveness of the device that are different from or in addition to any federal requirements for the device.

In 1996, the Supreme Court examined the preemptive scope of Section 360k in considering whether it applies to 510(k) cleared medical devices. In *Medtronic, Inc. v. Lohr*, defendant Medtronic notified the FDA of its intent to market a pacemaker lead through the 510(k) process.<sup>57</sup> The FDA found that device was substantially equivalent to a preexisting device and cleared the marketing of the device.<sup>58</sup> Consequently, the device was subject only to general controls found in the Code of Federal Regulations.<sup>59</sup> The FDA emphasized, however, that the clearance “should not be construed as an endorsement of the pacemaker lead's safety.”<sup>60</sup>

Plaintiff Lohr, after being seriously injured by an allegedly defective lead, filed a complaint against Medtronic alleging a negligent “breach of Medtronic’s ‘duty to use reasonable care in the design, manufacture, assembly, and sale of the subject pacemaker’ . . . .”<sup>61</sup> Defendant Medtronic argued that Lohr’s claims were preempted by Section 360k.<sup>62</sup> The Court found this argument unpersuasive and held that the express preemption clause does not apply to 510(k) cleared medical devices.<sup>63</sup> In analyzing the preemption clause, the Court found that the 510(k) process, without more, does not constitute a requirement that “relates to the safety or effectiveness of the device”<sup>64</sup> because “the 510(k) process is focused on *equivalence*, not

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<sup>57</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 480 (1996).

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.* at 481.

<sup>62</sup> *Id.*

<sup>63</sup> Gregory J. Wartman, *Life After Riegel: A Fresh Look at Medical Device Preemption One Year After Riegel v. Medtronic, Inc.*, 64 Food Drug L.J. 291, 294 (2009).

<sup>64</sup> 21 U.S.C. § 360k(a)(2) (2006).

safety.”<sup>65</sup> The Court noted that although the FDA may examine 510(k) applications with a concern for the safety and effectiveness of the device, the agency does not “require” such devices to “take any particular form for any particular reason[.]”<sup>66</sup> Thus, unlike the more rigorous PMA process, the 510(k) process does not provide any requirements relating to safety or efficacy upon which to affix a basis for preemption under Section 360k, and state law tort claims against manufacturers of 510(k) cleared devices are allowed.

Although tort claims against manufacturers of devices cleared by 510(k) were held to be not preempted by Section 360k in 1996, the issue of preemption of claims relating to PMA devices was left unanswered until 2008 when the Supreme Court decided *Riegel v. Medtronic, Inc.* There, plaintiff Riegel was allegedly seriously injured by defendant Medtronic’s Evergreen Balloon Catheter, a Class III device that received premarket approval from the FDA.<sup>67</sup> The district court dismissed Riegel’s tort claims on MDA preemption grounds.<sup>68</sup> The Second Circuit and the Supreme Court affirmed the dismissal.<sup>69</sup> In following its analysis in *Lohr*, the Supreme Court decided the threshold issue of whether the PMA imposes a “requirement” that “relates to the safety or effectiveness of the device.”<sup>70</sup> The Court held that “premarket approval, in contrast [to 510(k) clearance], imposes ‘requirements’ under the MDA as [it] interpreted in *Lohr*. Unlike general labeling duties, premarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review--it *is* federal safety review.”<sup>71</sup>

After finding that premarket approval imposes “requirements” that are subject to preemption, the Court addressed whether the plaintiff’s tort claims “relied upon ‘any

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<sup>65</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (citations omitted).

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

<sup>67</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008).

<sup>68</sup> *Id.* at 320–21.

<sup>69</sup> *Id.* at 321.

<sup>70</sup> 21 U.S.C. § 360k(a) (2006).

<sup>71</sup> *Riegel*, 552 U.S. at 322–23.

requirement’ of [State] law applicable to the [device] that is ‘different from, or in addition to’ federal requirements and that ‘relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.’”<sup>72</sup> In other words, the Court had to decide whether state tort duties constitute “requirements” under the MDA.<sup>73</sup> Using its interpretation in *Lohr*, the Court posited that negligence and strict liability common-law actions do impose “requirements” under the MDA and would be preempted by Section 360k.<sup>74</sup> The Court reasoned that “[a]bsent any other indication, reference to a State’s ‘requirements’ includes its common-law duties.”<sup>75</sup> Furthermore, “[s]tate tort law that requires a manufacturer’s catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.”<sup>76</sup> Drawing on its reasoning in *Lohr*, the Court explained that “it is implausible that the MDA was meant to ‘grant greater power (to set state standards different from, or in addition to, federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes.’”<sup>77</sup> While legislatures can at least be expected to apply a cost-benefit analysis, juries see only the costs of a more dangerous design.<sup>78</sup> Thus, of course common-law duties would be included in the scope of preemption as would any state regulation or statute.<sup>79</sup>

The crux of the matter lies within whether these state common-law duties require anything different from or in addition to federal requirements. *Riegel* left open a window for some state-law based claims against manufacturers when it stated in dicta that “[s]tate requirements are pre-empted under the MDA only to the extent that they are ‘different from, or

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<sup>72</sup> *Id.* at 323 (quoting 21 U.S.C. § 360k(a)).

<sup>73</sup> *Id.* at 323.

<sup>74</sup> *Id.* at 323–24 (alteration in original) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 512 (1996)).

<sup>75</sup> *Id.* at 324.

<sup>76</sup> *Id.* at 325.

<sup>77</sup> *Riegel*, 552 U.S. at 325 (quoting *Lohr*, 518 U.S. at 504) (internal quotation marks omitted).

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

in addition to' the requirements imposed by federal law.”<sup>80</sup> Therefore, the MDA “does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”<sup>81</sup>

Since common-law tort claims against manufacturers of PMA medical devices that require anything different from or in addition to federal requirements are preempted by Section 360k, the question becomes, what types of claims are *not* preempted? Most circuits have agreed that claims premised on violations of FDA requirements would not be preempted. However, many circuits have dismissed claims at the pleadings phase because they have not properly pleaded parallel claim. With little instruction from the Supreme Court in *Riegel*, circuits have produced a myriad of standards under which to plead parallel claims.

#### **D. Pleading Standards of *Twombly* and *Iqbal***

Because most manufacturers will try to dismiss claims at an early stage, plaintiffs will need to know how to properly plead their parallel claims in accordance with *Riegel*'s requirements. Adding to the confusion about how to properly plead parallel claims are the ill-defined standards set forth in the two-pronged approach of *Bell Atlantic Corp. v. Twombly*<sup>82</sup> and *Ashcroft v. Iqbal*,<sup>83</sup> which determines the sufficiency of pleadings to survive a motion to dismiss in all civil actions, regardless of subject matter.<sup>84</sup> *Twombly* and *Iqbal* urge plaintiffs to avoid conclusory allegations or “a formulaic recitation of the elements of a cause of action.”<sup>85</sup> Such legal conclusions are to be disregarded, and the remaining non-conclusory allegations are assumed to be true.<sup>86</sup> The Court then requires that the remaining non-conclusory allegations

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<sup>80</sup> *Id.* at 330 (quoting 21 U.S.C. § 360k(a)(1)).

<sup>81</sup> *Id.* (citing *Lohr*, 518 U.S. at 495).

<sup>82</sup> *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

<sup>83</sup> *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009).

<sup>84</sup> *Id.* at 1953 (quoting Fed. R. Civ. P. 1).

<sup>85</sup> *Twombly*, 550 U.S. at 555.

<sup>86</sup> *Iqbal*, 129 S. Ct. at 1950.

must have “facial plausibility [such that] the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”<sup>87</sup> Plaintiffs must plead parallel claims with sufficient facts to survive a motion to dismiss in accordance with these Supreme Court decisions and their imprecise standard of sufficiency of factual content. The disparity between circuit courts lies within deciding exactly which facts are sufficient to properly plead a parallel claim. Lenient courts, such as the Seventh Circuit, have held that a plaintiff must allege neither a specific federal regulation violation nor a specific defect in the medical device.<sup>88</sup> However, some courts, such as the Eleventh Circuit, have held that plaintiffs must allege both the federal requirement allegedly violated and the specific defect in the medical device.<sup>89</sup> This Comment will further examine the debate about whether either or both of these holdings meet the pleading standards set forth in *Twombly* and *Iqbal*.

### **III. Circuit Splits: How Much Specificity is Enough?**

#### **A. A Spectrum of Standards**

Circuits are split as to how to properly plead parallel claims against manufacturers of PMA medical devices. While some courts allow for generalized allegations of violations of FDA standards, other courts require plaintiffs to point to specific defects in the devices and specific FDA requirements that have been violated. The following discussion of four representative circuit court cases demonstrates the wide spectrum of pleading standards for parallel claims to survive preemption under Section 360k.

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<sup>87</sup> *Id.* at 1949 (quoting *Twombly*, 550 U.S. at 570).

<sup>88</sup> *See e.g.*, *Bausch v. Stryker*, 630 F.3d 546 (7th Cir. 2010).

<sup>89</sup> *See e.g.*, *Wolicki-Gables v. Arrow International*, 634 F.3d 1296, 1301–02 (11th Cir. 2011).

**i. Lowest Standard: Plaintiffs Must Specify Neither the Federal Requirement Allegedly Violated Nor the Defect**

The Seventh Circuit, in *Bausch v. Stryker*,<sup>90</sup> has established the lowest standard among the circuits in parallel claim pleading requirements. In that case, plaintiff Bausch simply alleged that manufacturers of the PMA approved Trident-brand ceramic-on-ceramic hip replacement system (“the Trident”) “violated federal law” in manufacturing the Trident and brought this suit under Illinois common law negligence and strict liability for a defective product.<sup>91</sup> The district court granted defendants’ motion to dismiss, holding that the common law claims were preempted.<sup>92</sup> However, on appeal, the Seventh Circuit held that state law claims based on violations of federal law are not expressly preempted by Section 360k.<sup>93</sup>

The court focused on the difficulties associated with requiring plaintiffs to plead with too much specificity. With regard to alleging a violation of a specific federal requirement, the court opined that “[f]or [Bausch] to plead with any more detail that her claims were ‘based entirely on a specific defect in the Trident that existed outside the knowledge and regulations of the FDA,’ she would need access to the confidential materials in the [PMA] application setting forth the medical device’s specifications.”<sup>94</sup> The court found that because some of the PMA documents are confidential, with “no public access to complete versions of these documents,” for plaintiffs to allege specific violations would be simply impossible.<sup>95</sup> The court also noted that allegations of violations of general controls such as CGMPs were sufficient because many FDA regulations

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<sup>90</sup> *Bausch*, 630 F.3d 546 (7th Cir. 2010).

<sup>91</sup> *Id.* at 549.

<sup>92</sup> *Id.*

<sup>93</sup> *Id.* at 552.

<sup>94</sup> *Id.* at 561.

<sup>95</sup> *Id.* at 560–61.

that are not product-specific are still vital to producing safe and effective medical devices.<sup>96</sup> Thus, even though a plaintiff may not be able to allege a specific violation of the PMA requirements because of the inability to access confidential documents, he or she can allege a violation of the CGMP and successfully avert preemption.

The Seventh Circuit also posited that requiring plaintiffs to allege a specific defect in the medical device would be unreasonable and too onerous because inspecting the device “outside of a discovery process” to locate its defect “would risk charges of spoliation of evidence.”<sup>97</sup> Thus, plaintiffs are required to plead neither a specific federal regulation violation nor a specific defect in the medical device.<sup>98</sup>

**ii. A Little Higher: Plaintiffs Must Specify at Least the Federal Requirement Allegedly Violated or the Defect**

The Fifth Circuit, in *Funk v. Stryker*,<sup>99</sup> has taken a slightly more restrictive approach than the Seventh Circuit. This case, like *Bausch v. Stryker*,<sup>100</sup> involved the Trident hip replacement system. The court affirmed the dismissal of plaintiff Funk’s claims because his claims did not satisfy the “required pleading standards to set forth a cognizable claim[.]”<sup>101</sup> The plaintiff’s complaint simply stated that the device contained a manufacturing defect because it was manufactured in a way that violated “FDA standards and requirements” and “manufacturing processes and design approved by the FDA.”<sup>102</sup> The plaintiff also relied on the doctrine of *res*

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<sup>96</sup> *Bausch*, 630 F.3d at 555; *but see* *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1206 (8th Cir. 2010) (affirming the district court’s finding that violations of CGMPs are not specific requirements under the MDA and thus would be preempted).

<sup>97</sup> *Bausch*, 630 F.3d at 561.

<sup>98</sup> *Id.* at 560.

<sup>99</sup> *Funk v. Stryker*, 631 F.3d 777 (5th Cir. 2011).

<sup>100</sup> *Bausch*, 630 F.3d 546.

<sup>101</sup> *Funk*, 631 F.3d at 780.

<sup>102</sup> *Id.* at 782.

*ipsa loquitur* to allege a manufacturing defect.<sup>103</sup> The court found the complaint “impermissibly conclusory and vague” because it did

not specify the manufacturing defect; nor [did] it specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury. Nor [did] the complaint tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process.<sup>104</sup>

Because the court found the complaint lacking in specificity with regards to both the defect and the federal requirement allegedly violated, it is unclear whether both specifications are required. However, it can be inferred that the Fifth Circuit requires at least one or more of these elements.

**iii. Even Higher: Plaintiffs Must Specify the Federal Requirement  
Allegedly Violated and Perhaps Also the Defect**

In *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*,<sup>105</sup> the Eighth Circuit examined manufacturing defect claims against the manufacturer of the Sprint Fidelis Lead, a wire that helps an implanted defibrillator detect an arrhythmia and deliver a shock to restore normal rhythm.<sup>106</sup> Although the FDA granted premarket approval to Medtronic in 2004, the company issued a recall of the product in 2007.<sup>107</sup> Thereafter, the FDA announced a Class I recall of the device.<sup>108</sup> Several patients implanted with the device filed a consolidated complaint against Medtronic alleging failure to warn, design defect and manufacturing defect claims.<sup>109</sup> The court found that the failure to warn claim was exactly what was preempted by Section 360k because it required the manufacturer to provide warnings in addition to the ones required by the

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<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 (8th Cir. 2010).

<sup>106</sup> *Id.* at 1203.

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

FDA's PMA application approval.<sup>110</sup> The court also found that the design defect claim was preempted by Section 360k because it was a direct attack on the FDA's approval of the design, and thus, would hold the manufacturer to a higher standard than that required by the FDA.<sup>111</sup>

With regard to the manufacturing defect claim, the district court dismissed the claim, holding that a claim premised on a violation of CGMPs was insufficient to overcome preemption under Section 360k.<sup>112</sup> According to the district court, CGMPs are too general to qualify as a specific federal requirement under the MDA unlike specific requirements in the PMA for the Sprint Fidelis Leads.<sup>113</sup> On appeal to the Eighth Circuit, the plaintiffs asserted that requiring them to allege a specific violation of the PMA was an impossible standard because of their limited access to the confidential PMA documents before discovery.<sup>114</sup> The Eighth Circuit conceded that this argument may be compelling, but found it did not apply in this case because plaintiffs disclaimed the need for discovery to be better able to identify a specific federal requirement that Medtronic allegedly violated when manufacturing the leads.<sup>115</sup> However, in affirming the dismissal, the Eighth Circuit did not explicitly affirm the district court's reasoning regarding the insufficiency of claims based on violations of CGMPs to overcome preemption under Section 360k.

The plaintiffs also based their claim on the allegation that *all* Sprint Fidelis Leads have an unreasonably high risk of failure because of their use of unreliable spot welding.<sup>116</sup> However, the FDA actually approved the use of spot welding in a PMA Supplement.<sup>117</sup> Thus, the court held that *as pleaded and argued* the manufacturing defect claims were not parallel to federal

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<sup>110</sup> *Id.* at 1205.

<sup>111</sup> *In re Medtronic, Inc.*, 623 F.3d at 1206.

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Id.* at 1207.

<sup>116</sup> *Id.* at 1206.

<sup>117</sup> *In re Medtronic, Inc.*, 623 F.3d at 1207.

requirements, but rather a direct attack on the FDA’s decision to approve the PMA Supplement.<sup>118</sup> Therefore, as with the design defect claims, the Eighth Circuit held that manufacturing defect claims were preempted because direct attacks on the FDA’s approval of the device would hold the manufacturer to a higher standard than that required by the FDA.<sup>119</sup>

Essentially, the Eighth Circuit held that the “[p]laintiffs simply failed to adequately plead that Medtronic violated a federal requirement specific to the FDA’s PMA approval of this Class III device.”<sup>120</sup> Thus, it seems that, at a minimum, the Eighth Circuit would require plaintiffs to point to a specific federal requirement. And when faced with a hypothetical in which the plaintiff, without discovery, could not know the exact defect in the device, the court merely opined that courts must “exercise care in applying *Riegel*’s parallel claim principle at the pleading stage[.]”<sup>121</sup> Therefore, it is unclear whether the Eighth Circuit would require plaintiffs to allege a specific defect.

#### **iv. Highest Standard: Plaintiffs Must Specify Both the Federal Requirement Allegedly Violated and the Defect**

In *Wolicki-Gables v. Arrow International*,<sup>122</sup> the Eleventh Circuit established the strictest pleading standard on the spectrum by requiring plaintiffs to allege both the federal requirement allegedly violated and the specific defect in the medical device.<sup>123</sup> Plaintiff Wolicki-Gables alleged state law claims for product liability, negligence, vicarious liability, and loss of consortium against Arrow, the manufacturer of a PMA approved implanted pain management pump system.<sup>124</sup> The complaint alleged a failure to reasonably design the device, failure to

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<sup>118</sup> *Id.* at 1206 .

<sup>119</sup> *Id.* at 1207.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *Wolicki-Gables v. Arrow International*, 634 F.3d 1296 (11th Cir. 2011).

<sup>123</sup> *Id.* at 1301–02.

<sup>124</sup> *Id.* at 1298–99.

reasonably manufacture the device, and failure to reasonably provide adequate warnings.<sup>125</sup> The court concluded that the complaint was inadequate to properly plead a parallel claim because the allegations did not “set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged.”<sup>126</sup>

### **B. Irreconcilable Differences: Why These Standards Are Too Different to Coexist and a Call to Unify the Circuits**

The Seventh and Eleventh Circuits stand on extreme opposite sides of the spectrum of pleading standards, and the Fifth and Eighth Circuits stand somewhere in between. On one end, plaintiffs do not have to allege either a specific defect or a specific federal requirement that has been violated. On the other end, plaintiffs must allege both a specific defect and a specific federal requirement. These differing standards are completely incongruous. Consequently, this disparity between circuits leaves plaintiffs with uncertainty about how much they need to allege depending on in which circuit they file their claims. The disparity also leaves defendant manufacturers with uncertainty about where and for what actions they can be sued. For the reasons stated below, these incongruent standards should no longer coexist.

The Supreme Court should step in and unify the circuits for several reasons. First, PMA medical device parallel claims usually involve substantial injury because of the nature of the medical devices and the potentially high risks they pose. Substantial injury could mean substantial liability for medical device manufacturers. Early dismissal of cases under a pleading standard too difficult to meet can leave injured plaintiffs without a remedy that Congress did not intend to bar. However, allowing claims to go forward under too lenient a standard can deprive manufacturers of the protection Congress intended to afford them to encourage medical device

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<sup>125</sup> *Id.* at 1301.

<sup>126</sup> *Id.* at 1301–02; Note that the procedural posture of this case is an affirmation of a grant of summary judgment. However, the language of the holding specifies that the complaint must allege the defect and the federal requirement violated.

development under a system of federal oversight. Premarket approval is already a very rigorous process and opening up liability for unsubstantiated claims may discourage manufacturers from pursuing research and development of potentially life saving devices.

Second, the Supreme Court should seek to uphold the stated goal of the Federal Rules of Civil Procedure to promote the “just, speedy, and inexpensive determination of every action and proceeding.”<sup>127</sup> To a defendant manufacturer, this goal may signify early dismissal of a frivolous claim. On the other hand, an injured plaintiff may find that pleading standards that require intense investigation and alleging of facts that are far more specific than those required by the forms provided in the Federal Rules themselves<sup>128</sup> is unjust and contrary to the stated goal. This is especially true where the facts needed to allege such specific violations are inaccessible to plaintiffs before the discovery process.

Third, since there is such disparity in pleading standards between the circuits, there is susceptibility for forum shopping. Given the choice, plaintiffs will choose the circuit whose rules will be most amenable to them. Forum shopping can give plaintiffs an “opportunity to gain an unjust victory in litigation or to achieve an unjust settlement.”<sup>129</sup> Under the principle of specific jurisdiction, corporations are open to suit in a certain state “when the suit ‘aris[es] out of or relate[s] to the defendant’s contacts with the forum.’”<sup>130</sup> Thus, manufacturers can be sued in the forum where the plaintiff experiences injury after use of the medical device. Additionally, “[a] court may assert general jurisdiction over foreign . . . corporations to hear any and all claims against them when their affiliations with the State are so continuous and systematic as to render

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<sup>127</sup> Fed. R. Civ. P. 1.

<sup>128</sup> *See, e.g.*, Fed. R. Civ. P. Form 11 (Complaint for Negligence); *see also* Fed. R. Civ. P. 84 (“The forms in the Appendix suffice under these rules and illustrate the simplicity and brevity that these rules contemplate.”).

<sup>129</sup> Kevin M. Clermont & Theodore Eisenberg, *Exorcising the Evil of Forum-Shopping*, 80 CORNELL L. REV. 1507, 1515 (1995).

<sup>130</sup> *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 131 S. Ct. 2846, 2853 (2011) (alteration in original) (quoting *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 n.8 (1984)).

them essentially at home in the forum State.”<sup>131</sup> Forums that would come under this type of general jurisdiction would include states of incorporation, principle places of business, headquarters locations, and perhaps even sites with major factories. Consider all the different forums in which Medtronic, Inc. could be sued: (1) any state where the plaintiff experiences an injury; (2) Minnesota—Medtronic’s state of incorporation and location of its World Headquarters; (3) California, Tennessee, Florida, and Washington—locations of Medtronic’s main business units; (4) Texas, Massachusetts, Michigan, Colorado, Connecticut, Arizona, and Indiana—locations of Medtronic’s research and development facilities, manufacturing facilities, and distribution centers; and (5) Georgia and New Jersey—educational centers where medical professionals learn how to use Medtronic’s products.<sup>132</sup> At a minimum, Medtronic could be sued in the First, Second, Third, Fifth, Sixth, Seventh, Eighth, Ninth, Tenth, and Eleventh Circuits. At least four of these circuits have different pleading standards, and plaintiffs could certainly choose the circuit that would be most favorable to their interests. Medtronic is only one of the many medical device manufacturers that could be negatively affected by this strong susceptibility for forum shopping.

To rectify the aforementioned evils, this Comment urges the Supreme Court to step in and unify the disparate pleading standards.

#### **IV. Analysis: Disparate Pleading Standards and a Workable Unifying Framework**

Although the Supreme Court has yet to offer a uniform standard, this Comment provides a workable framework under which a plaintiff can shape his or her complaint against a manufacturer of a PMA medical device.

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<sup>131</sup> Brown, 131 S. Ct. at 2851 (internal quotation marks omitted).

<sup>132</sup> Medtronic, Inc., *Locations*, MEDTRONIC.COM, <http://www.medtronic.com/about-medtronic/locations/index.htm> (Sept. 27, 2010).

First, a plaintiff should decide whether the claims parallel federal requirements and are consequently not preempted. The best way to ensure that the claims parallel federal requirements is to premise the claim on a violation of an FDA mandated requirement for the device. In the context of devices that have received premarket approval, the FDA requires manufacturers to follow both general controls and special device-specific controls. Recall that general controls include “the basic adulteration and misbranding provisions as well as applicable good manufacturing practice regulations, banned device regulations, and notification and repair, replacement, or refund requirements.”<sup>133</sup> Thus, it makes sense to base claims of manufacturing defects upon violations of these general controls as well as special device-specific controls that are described in a device’s premarket approval.

Second, violations should be pled with as much factual specificity as possible at this stage of the judicial proceedings. The adequacy of factual content should be determined by the two-pronged approach of *Twombly* and *Iqbal*. In these two cases, the Supreme Court opined that courts should disregard mere legal conclusions that are not supported by factual allegations. Then, looking at the remaining non-conclusory allegations, “assume their veracity” and ask “whether they plausibly give rise to an entitlement to relief.”<sup>134</sup> Facial plausibility is found “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”<sup>135</sup> Plausibility is not probability, but it is more than mere conceivability.<sup>136</sup> Additionally, determining plausibility is a “context-specific

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<sup>133</sup> Hutt, *supra* note 2, 981.

<sup>134</sup> *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009).

<sup>135</sup> *Iqbal*, 129 S. Ct. at 1950 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

<sup>136</sup> *Twombly*, 550 U.S. at 556, 570 (“Asking for plausible grounds to infer an agreement does not impose a probability requirement at the pleading stage” and “Because the plaintiffs here have not nudged their claims across the line from conceivable to plausible, their complaint must be dismissed.”).

task that requires the reviewing court to draw on its judicial experience and common sense.”<sup>137</sup> The two-pronged test of *Twombly* and *Iqbal* does not articulate any special accommodations for situations where essential information to state a claim is simply unavailable at the pleadings stage, such as access to complete versions of PMA documents. However, this Comment proposes that courts should use “common sense”<sup>138</sup> and allow for a generalized statement that the PMA requirements have been violated. Therefore, the specificity with which to plead violations may differ between general and special PMA controls depending on how much information is actually available to the plaintiff.

In light of the disparity of availability of information regarding general and device specific PMA requirements, the following discussion will separately analyze the pleading standards for claims based on violations of general controls and claims based on violations of special controls as specified in the PMA files.

#### **A. Claims Based on Violations of General Controls Such As Current Good Manufacturing Practices**

Manufacturing defect claims premised on violations of CGMPs should not be preempted solely because CGMPs are general requirements and not device-specific, as was erroneously held by the district court of *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*.<sup>139</sup> The court’s reasoning in that case was seriously flawed for several reasons. The goal of tort product liability law is to protect the interests of injured consumers, and the goal of Section 360k preemption is to not hold manufacturers to a higher or different standard than to which the federal government holds them. CGMPs are part of the federal standards. It makes little sense that just because CGMPs are not device-specific that a manufacturer cannot be held

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<sup>137</sup> *Iqbal*, 129 S. Ct. at 1950.

<sup>138</sup> *Id.*

<sup>139</sup> *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1206 (8th Cir. 2010).

liable for violating them. This rule does not serve either the purpose of tort law or of Section 360k preemption. Rather, in *Bausch v. Stryker*, the Seventh Circuit raised a compelling argument: FDA regulations that are not device-specific are still vital to producing safe and effective medical devices.<sup>140</sup> For example, 21 C.F.R. § 820.70(e) requires manufactures to have in place procedures to prevent contamination of equipment that could adversely affect product quality.<sup>141</sup> Although this is only a general requirement that applies to all devices, regardless of how it came to market, a violation of this requirement could have devastating effects, such as bacterial infection leading to sepsis and eventual death. Surely, protecting manufactures from liability for these types of violations is not what Congress envisioned when drafting the Section 360k preemption provision.

Furthermore, as established in *Lohr*, manufacturers of 510(k) cleared devices are liable for violations of general controls such as CGMPs.<sup>142</sup> The distinction between general and specific requirements produced the exact opposite conclusion in *Lohr* that it did in *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*. *Lohr* established that claims premised on violations of general requirements are *not* preempted because general requirements are not worthy of the protection that the PMA devices receive; unlike for PMA devices, the FDA does not make a safety or efficacy assessment in demanding compliance with those general requirements and does not require manufacturers to go through the rigorous PMA process.<sup>143</sup> Thus, as with non-PMA devices, claims based on violations of CGMPs should not be preempted by Section 360k.

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<sup>140</sup> *Bausch v. Stryker*, 630 F.3d 546, 555 (7th Cir. 2010).

<sup>141</sup> 21 C.F.R. § 820.70(e) (2012).

<sup>142</sup> *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996).

<sup>143</sup> *Lohr*, 518 U.S. at 493; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008).

The second inquiry then is with how much specificity a plaintiff has to plead a violation of a general control. A mere statement that CGMPs were violated should be insufficient. Plaintiffs should allege that a specific CGMP has been violated that has led to the manufacturing defect. Furthermore, CGMPs, unlike device-specific PMA regulations, are available to the public in *21 C.F.R. § 820*.<sup>144</sup> The FDA has extensively described CGMPs in Subparts A through O of *21 C.F.R. § 820*.<sup>145</sup> The content of these regulations include, but are not limited to, auditing procedures, design controls, production and process controls, labeling and packaging controls, and handling, storage, distribution and installation.<sup>146</sup> Plaintiffs can readily access these regulations, which apply to all medical device manufacturers, through a simple search on the internet. Thus, discovery, cabined or otherwise, is not necessary to allege which regulation the manufacturer has violated.

### **B. Claims Based on Violations of Special Controls Specified in Premarket Approval Files**

Claims premised on violations of device-specific requirements contained in a PMA certainly parallel federal requirements, and according to *Riegel* would be the subject of preemption to the extent that the state tort duties are ‘different from, or in addition to’ the requirements imposed by federal law.’<sup>147</sup> However, if the duties parallel rather than add to the requirements imposed by federal law, the claims would not be preempted.

The major issue with regard to PMA violations is with how much specificity a plaintiff must shape his or her claim. *Twombly* and *Iqbal* urge plaintiffs to avoid conclusory allegations. According to the Supreme Court, “[t]hreadbare recitals of the elements of a cause of action,

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<sup>144</sup> 21 C.F.R. § 820 (2012); Food and Drug Administration, *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, FDA.GOV, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm> (Apr. 28, 2011).

<sup>145</sup> 21 C.F.R. §§ 820.1–820.250 (2012).

<sup>146</sup> 21 C.F.R. §§ 820.22, 820.30, 820.70–820.75, 820.120–820.130, 820.140–820.170 (2012).

<sup>147</sup> *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)).

supported by mere conclusory statements, do not suffice.”<sup>148</sup> Therefore it would seem that a statement that the PMA has been violated and has thus led to the plaintiff’s injury is insufficient. Courts like the Eleventh Circuit would require plaintiffs to point to a specific PMA requirement that has allegedly been violated.<sup>149</sup> However, courts following the Seventh Circuit would posit that pleading with specificity would be virtually impossible if plaintiffs do not have access to complete versions of the PMA.<sup>150</sup> There is definite validity to the Seventh Circuit point of view because as the Code of Federal Regulations explains, unless previously disclosed to the public, much of the information and data in a PMA are not available for public viewing.<sup>151</sup> This undisclosed information consists of, *inter alia*, manufacturing methods and processes, including quality control procedures.<sup>152,153</sup> If the very information upon which plaintiffs must premise their manufacturing defect claims is undisclosed, how then can plaintiffs plead with specificity that a certain PMA requirement has been violated?

Furthermore, a study of the Federal Rules of Civil Procedure Appendix of Forms reveals that some seemingly bare complaints pass muster under the *Twombly* and *Iqbal* standard, namely Forms 11 and 18. Form 11, a Complaint for Negligence, states in pertinent part, “[o]n --date--, at --place--, the defendant negligently drove a motor vehicle against the plaintiff.”<sup>154</sup> There is no factual allegation as to how the defendant drove negligently, whether he violated a certain driving regulation, or what is considered negligent. Nevertheless, the Federal Rules of Civil Procedure “govern the procedure in all civil actions and proceedings in the United States district

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<sup>148</sup> *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

<sup>149</sup> *Wolicki-Gables v. Arrow International*, 634 F.3d 1296, 1301 (11th Cir. 2011).

<sup>150</sup> *Bausch v. Stryker*, 630 F.3d 546, 560–61 (7th Cir. 2010).

<sup>151</sup> 21 C.F.R. § 814.9(h) (2012).

<sup>152</sup> *Id.* § 814.9(h)(1).

<sup>153</sup> A request made under the Freedom of Information Act (FOIA) will not overcome the confidentiality rules for PMA files. A FOIA request can only be made “for investigations involving an exception from informed consent,” under 21 C.F.R. § 814.9(d)(2).

<sup>154</sup> Fed. R. Civ. P. Appx. Form 11.

courts,”<sup>155</sup> and as such, Form 11 must be accepted as sufficient.<sup>156</sup> Similarly, Form 18, a Complaint for Patent Infringement, states simply that “defendant has infringed and is still infringing the Letters Patent by making, selling, and using --*electric motors*-- that embody the patented invention, and the defendant will continue to do so unless enjoined by this court.”<sup>157</sup> This complaint does not allege how defendant has infringed the patent with any detail as to the technology involved or whether the infringement is literal or by the doctrine of equivalents. However, the Federal Circuit has affirmed that Form 18 is in line with the *Twombly* standard for pleadings because it “give(s) the defendant fair notice of what the . . . claim is and the grounds upon which it rests.”<sup>158</sup> It follows that a complaint for defective manufacturing of a PMA medical device need not allege with great specificity the exact PMA requirement that has been violated. A contrary rule requiring greater specificity for PMA device manufacturing defect claims would be inconsistent with the examples given in the Federal Rules of Civil Procedure.

Since the plausibility of a claim is governed by principles of “common sense,”<sup>159</sup> courts should be lenient with regard to how much specificity they require for alleging a violation of a PMA device-specific requirement. Common sense would advise that a plaintiff cannot allege that which he does not yet know. Consequently, since he does not the contours of the device-specific requirements in a PMA, he cannot allege that a specific requirement has been violated. As long as a plaintiff can allege specific facts such as when he used the device, what was the nature of the injury, and how the injury was related to the device, a statement like “a manufacturing requirement in the PMA file of the device has been violated,” should suffice. An

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<sup>155</sup> Fed. R. Civ. P. 1.

<sup>156</sup> Fed. R. Civ. P. 84.

<sup>157</sup> Fed. R. Civ. P. Appx. Form 18.

<sup>158</sup> *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1356 (Fed. Cir. 2007) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

<sup>159</sup> *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009).

allegation of this type would be akin to a Form 11 or Form 18 statement regarding a defendant's conduct.

Moreover, although manufacturers may claim that a lenient pleading standard would deprive them of the statutory protection Congress sought to afford them with the preemption clause, this logic is severely flawed. Leniency in the pleading standard would simply mean that the preemption question might have to get decided at the summary judgment phase of trial after discovery rather than at the pleadings phase. The mere fact that Congress wanted state law claims that are not parallel to be preempted does not mean it has to be done at the pleadings phase. A more lenient pleading standard does not undermine preemption; it merely pushes the question to after we have a chance to see what the evidence truly shows.

Thus, while greater specificity is required for alleging violations of general controls such as CGMPs, less specificity should be allowed for alleging violations of device-specific PMA violations. Anything greater is just not possible and would leave injured plaintiffs with no recourse; this is simply not tolerable.

## **V. Conclusion**

Several circuit courts have applied different standards in determining whether a plaintiff has sufficiently stated a parallel claim that will escape Section 360k preemption in light of *Twombly* and *Iqbal*. Since variant standards can lead to forum shopping, unequal administration of the law, and early dismissal of claims brought by seriously injured plaintiffs, this Comment proposes a unified standard that should be applied to all parallel claims. As the Supreme Court iterated in *Riegel*, state law claims that are premised that violations of FDA regulations would hold manufacturers to duties that “‘parallel’, rather than add to, federal requirements.”<sup>160</sup> This Comment proposes that claims premised on violations of both general and device-specific

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<sup>160</sup> *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

controls should pass muster as parallel claims. Furthermore, while *Twombly* and *Iqbal* require plaintiffs to allege enough facts to state a plausible claim for relief,<sup>161</sup> these cases do not stand for the proposition that plaintiffs must be required to plead more facts than they can possibly know. While plaintiffs would have complete access to general controls such as CGMPs because of their public availability, many PMA documents are confidential and inaccessible to plaintiffs. Therefore, courts should require plaintiffs to specify which general control has been violated but show leniency with regard to specificity in allegations of device-specific PMA requirements.

Lastly, although not the focus of this Comment, there may be a role for the FDA and the medical device industry in resolving the issue of specificity for claims premised on device-specific PMA requirements. Since the major problem seems to be that many of the PMA documents are inaccessible at the pleadings stage, in the interest of protecting consumers, the FDA may promulgate regulations to mandate that these essential documents be made public in order to preserve non-frivolous claims. However, in a society as litigious as ours, manufacturers may not be so willing to comply. Consequently, an increase in potential lawsuits could stifle the incentive for continued development of valuable medical devices.

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<sup>161</sup> *Iqbal*, 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 570).