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Surviving Medical Device Preemption under 21 U.S.C. 360k: Clarifying Pleading Standards for Parallel Claims in the Wake of *Twombly* and *Iqbal*

Ashley Abraham Williams*

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. Not surprisingly, riskier devices are subject to greater regulation by the Food and Drug Administration (FDA) because they pose a greater threat.¹ Some of the most benign devices are exempt from review altogether before being marketed, and most others require only a premarket notification to the FDA through the relatively simple 510(k) clearance process.² Devices that present a potentially great risk of illness or injury, however, such as those used to support or sustain human life or prevent impairment of human health,³ are subject to a rigorous process of premarket approval (PMA) under Section 515 of the Food Drug and Cosmetic Act (FD&CA).⁴

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 (MDA) of 1976 to the FD&CA. Pursuant to 21 U.S.C. § 360k(a), states cannot establish requirements for medical devices that are different from or additional to the requirements promulgated by the federal government relating to the safety and effectiveness of

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¹ PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW 981 (Robert C. Clark et al. eds., 3d ed. 2007).

² 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) [hereinafter INST. OF MED.].

³ Hutt, *supra* note 1, at 993.

⁴ 21 U.S.C. § 360e (2006).

the device.⁵ As interpreted by the Supreme Court in *Medtronic, Inc. v. Lohr*,⁶ 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”⁷ since “the 510(k) process is focused on *equivalence*, not safety.”⁸ In *Riegel v. Medtronic, Inc.*,⁹ 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 standard demanded by the federal government.¹⁰ Therefore, as long the state requirements parallel federal requirements, the state tort claims are not preempted.¹¹

Circuits are split as to how one must plead parallel claims, particularly in light of the added confusion regarding pleading standards that *Bell Atl. Corp. v. Twombly*¹² and *Ashcroft v. Iqbal*¹³ set forth. These Supreme Court decisions urge plaintiffs to avoid conclusory allegations, while still alleging a plausible claim for relief.¹⁴ 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 thus, the federal appellate courts have established a spectrum of standards. These standards range from extremely generalized pleadings to pleadings with great specificity as to the particular problem with the medical device and its link 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

⁵ 21 U.S.C. § 360k(a) (2006).

⁶ 518 U.S. 470 (1996).

⁷ 21 U.S.C. § 360k(a)(2) (2006).

⁸ *Lohr*, 518 U.S. at 493 (citations omitted).

⁹ 552 U.S. 312 (2008).

¹⁰ *Id.* at 330 (citing 21 U.S.C. § 360k(a)(1) (2006)).

¹¹ *Id.*

¹² 550 U.S. 544 (2007).

¹³ 556 U.S. 662 (2009).

¹⁴ *Id.* at 1949 (quoting *Twombly*, 550 U.S. at 570).

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

This disparity of pleading standards will almost certainly lead to plaintiff forum shopping between the federal courts of appeals. As a result, some plaintiffs may have no remedy at all if their claims cannot pass muster under too stringent a standard. Conversely, too lenient a test will deprive manufacturers of the protections Congress intended to provide them: encouraging medical device development under strict federal oversight. Since this issue directly correlates to the riskiest of devices, substantial injury with minimal to no recovery is not only possible, it is probable. With the stakes so high, immediate clarification of the issue is necessary.

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*.

¹⁵ 21 U.S.C. § 360j(e)(1) (2006).

¹⁶ 21 C.F.R. § 820 (2012); *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, FOOD AND DRUG ADMINISTRATION (Apr. 28, 2011), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm>.

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

The proposed two-step solution to the problem stresses that varying pleading standards will require plaintiffs first to ensure that their claims are not preempted by premising the claims on a violation of an FDA-mandated general or device-specific requirement. Plaintiffs must then plead with as much specificity as is possible at the pleadings stage of the 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. If the claim is premised on a violation of a PMA requirement, however, great specificity may not be possible because not all the PMA documents are 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.

II. Background

A. Evolution of Medical Device Regulation

FDA regulation of medical devices was not always as stringent or extensive as it is today. In fact, although the FDA was created in the latter part of the nineteenth century,¹⁸ the agency only gained jurisdiction over medical devices through the FD&CA of 1938.¹⁹ Yet, this Act merely prohibited adulteration and misbranding of food, drugs, devices, and cosmetics already on the market.²⁰ The 1938 Act also required a showing of safety for drugs through premarket notification.²¹ In 1962, the FDA gained authority to review new drugs for safety *and efficacy* through a premarket approval process.²² Unlike with new drugs, however, the FD&CA of 1962 did not require new medical devices to obtain premarket approval from the FDA.²³ Recognizing that some high risk devices, such as surgical sutures, contact lenses, and injectable silicone,

¹⁸ *About FDA: History*, FOOD AND DRUG ADMINISTRATION (Mar. 1, 2013), <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm>.

¹⁹ Hutt, *supra* note 1, at 13.

²⁰ *Id.*

²¹ *Id.*

²² *Id.* at 14 (emphasis added).

²³ *Id.* at 976.

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

Throughout this time the states, rather than the federal government, regulated the introduction of most new medical devices.²⁵ In the 1960s and 1970s, however, amid the proliferation and occasional failure of complex medical devices – such as the heart pacemaker, the kidney dialysis machine, and defibrillators – the regulatory landscape began to change.²⁶ As a result, Congress passed the MDA of 1976, which initiated a regime of detailed federal oversight.²⁷ The MDA added several provisions to the 1962 Act, creating “a complex and novel system for regulating the development, introduction, and marketing of medical devices.”²⁸

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.”²⁹ Devices in all three classes are subject to general controls, which include “basic adulteration and misbranding provisions as well as applicable good manufacturing practice regulations, banned device regulations, and notification and repair, replacement, or refund requirements.”³⁰

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 their safety and effectiveness.³¹ Class II devices include powered wheelchairs and surgical drapes,

²⁴ *Id.* at 976–77.

²⁵ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008).

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

²⁷ *Riegel*, 552 U.S. at 316.

²⁸ Hutt, *supra* note 1, at 980.

²⁹ *Device Classification*, FOOD AND DRUG ADMINISTRATION (Apr. 27, 2009), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm>.

³⁰ Hutt, *supra* note 1, at 981.

³¹ Hutt, *supra* note 1, at 980; *Riegel*, 552 U.S. at 316 (citing 21 U.S.C. § 360c(a)(1)(A) (2006)).

devices for which general controls are not sufficient but enough information is available to develop special controls.³² The FDA establishes these special controls, which include performance standards and post-market surveillance measures.³³ Class III devices, such as replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators, receive the most federal oversight because general controls are insufficient to assure their safety and effectiveness, and there is not enough information available to establish special controls without further scientific studies.³⁴ In general, devices are assigned to Class III if (1) they are used to support or sustain human life or to prevent impairment of human health, or (2) they present a potentially great risk of illness or injury.³⁵

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

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, a legally marketed device.⁴⁰ Substantial equivalence is found if the new device has the same

³² Hutt, *supra* note 1, at 980; *Riegel*, 552 U.S. at 316 (citing 21 U.S.C. § 360c(a)(1)(B) (2006)).

³³ Hutt, *supra* note 1, at 980–81; *Riegel*, 552 U.S. at 316–17 (citing 21 U.S.C. § 360c(a)(1)(B) (2006)).

³⁴ Hutt, *supra* note 1, at 980.

³⁵ *Riegel*, 552 U.S. at 317 (citing 21 U.S.C. § 360c(a)(1)(B)(ii) (2006)).

³⁶ Hutt, *supra* note 1, at 980.

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

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

³⁹ Hutt, *supra* note 1, at 981, 991–92; *How to Market Your Device*, FOOD AND DRUG ADMINISTRATION (Mar. 18, 2010), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm>.

⁴⁰ Food Drug and Cosmetic Act § 510(k); 21 U.S.C. § 360(k) (2006); *Premarket Notification (510k)*, FOOD AND DRUG ADMINISTRATION (Sep. 3, 2010),

intended use as the predicate device and has the same technological characteristics as the predicate device.⁴¹ 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.⁴² Unlike the PMA process, however, 510(k) PMN does *not* require a safety and efficacy assessment for the device to be marketed.⁴³ Since 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.⁴⁴ 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 (67%) are exempt from premarket review.⁴⁵

In contrast, only about 1% of devices enter the market through the PMA process.⁴⁶ The PMA process is very rigorous and requires manufacturers to submit, what is usually, a multivolume application.⁴⁷ 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 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

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>.

⁴¹ 21 U.S.C. § 360c(i) (2006); *Premarket Notification (510k)*, FOOD AND DRUG ADMINISTRATION (Sep. 3, 2010), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>.

⁴² *Premarket Notification (510k)*, FOOD AND DRUG ADMINISTRATION (Sep. 3, 2010), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>.

⁴³ Hutt, *supra* note 1, at 993 (emphasis added).

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

⁴⁵ INST. OF MED., *supra* note 2, at 4.

⁴⁶ INST. OF MED., *supra* note 2, at 4.

⁴⁷ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18 (2008) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996)); *see also* 21 C.F.R. § 814.9 (2012); Food Drug and Cosmetic Act § 515, 21 U.S.C. § 360e (2006).

of, such device’; samples or device components required by the FDA; and a specimen of the proposed labeling.⁴⁸

After reviewing the application, the FDA may: (1) grant or deny approval of the proposed medical device; or (2) condition approval upon further research,⁴⁹ adherence to performance standards,⁵⁰ restrictions upon sale or distribution, or compliance with other requirements as described by the agency.⁵¹ The FDA may also impose device-specific restrictions.⁵² 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.”⁵³ Changes must be approved through a supplemental application for PMA, which the FDA will evaluate under essentially the same criteria as the initial application.⁵⁴

C. MDA Express Preemption Clause, 21 U.S.C. § 360k(a)⁵⁵

The MDA contains an express preemption clause (Section 360k), 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.⁵⁶

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

⁴⁹ 21 U.S.C. § 360e(d) (2006).

⁵⁰ 21 C.F.R. § 861.1(b)(3) (2012).

⁵¹ *Id.* § 814.82.

⁵² 21 U.S.C. § 360j(e)(1) (2006).

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

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

⁵⁵ 21 U.S.C. § 360k(a)[hereinafter Section 360k].

⁵⁶ 21 U.S.C. § 360k(a).

Thus, the clause prohibits 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 additional to any federal requirements for the device.

In 1996, the Supreme Court examined the preemptive scope of Section 360k in considering whether it reaches 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.⁵⁷ The FDA found that the device was substantially equivalent to a preexisting device and cleared the marketing of the device.⁵⁸ Consequently, the device was subject only to general controls found in the Code of Federal Regulations.⁵⁹ The FDA emphasized, however, that the clearance “should not be construed as an endorsement of the pacemaker lead's safety.”⁶⁰

Plaintiff Lohr, after having been 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[.]’”⁶¹ Medtronic argued that Lohr’s claims were preempted by Section 360k.⁶² The Court found this argument unpersuasive, and held that the express preemption clause does not apply to 510(k) cleared medical devices.⁶³ 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”⁶⁴ because “the 510(k) process is focused on *equivalence*, not safety.”⁶⁵ The Court noted

⁵⁷ 518 U.S. 470, 480 (1996).

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.* at 481.

⁶² *Id.*

⁶³ 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).

⁶⁴ 21 U.S.C. § 360k(a)(2) (2006).

⁶⁵ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (citing *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1348 (11th Cir. 1995)).

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[.]”⁶⁶ 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 therefore, state law tort claims against manufacturers of 510(k) cleared devices are allowed to proceed.

Although courts had held tort claims against manufacturers of devices cleared by 510(k) as 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.⁶⁷ The district court dismissed Riegel’s tort claims on MDA preemption grounds.⁶⁸ The Second Circuit and the Supreme Court affirmed the dismissal.⁶⁹ 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.”⁷⁰ 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.⁷¹

After finding that premarket approval imposes “requirements” that are subject to preemption, the Court addressed whether the plaintiff’s tort claims “rel[ied] upon ‘any requirement’ of [state] law applicable to the [device] that is ‘different from, or in addition to’

⁶⁶ *Id.*

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

⁶⁸ *Id.* at 320–21.

⁶⁹ *Id.* at 321.

⁷⁰ 21 U.S.C. § 360k(a) (2006).

⁷¹ *Riegel*, 552 U.S. at 322–23.

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.’”⁷² In other words, the Court had to decide whether state tort duties constitute “requirements” under the MDA.⁷³ 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.⁷⁴

The Court reasoned that “[a]bsent any other indication, reference to a State’s ‘requirements’ includes its common-law duties.”⁷⁵ 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.”⁷⁶ 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.’”⁷⁷ While legislatures can at least be expected to apply a cost-benefit analysis, juries see “only the cost of a more dangerous design.”⁷⁸ Thus, of course common law duties would be included in the scope of preemption as would any state regulation or statute.⁷⁹

The major issue is whether these state common law duties require anything different from or additional to federal requirements. *Riegel* left open the 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 in addition to’ the

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

⁷³ *Id.* at 323.

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

⁷⁵ *Id.* at 324.

⁷⁶ *Id.* at 325.

⁷⁷ *Riegel*, 552 U.S. at 325 (quoting *Lohr*, 518 U.S. at 504).

⁷⁸ *Id.*

⁷⁹ *Id.*

requirements imposed by federal law.”⁸⁰ 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.”⁸¹

Since common law tort claims against manufacturers of PMA medical devices that require anything different from or additional to federal requirements are preempted by Section 360k, the question remains: what types of claims are *not* preempted? Most circuits agree that claims premised on violations of FDA requirements would not be preempted. Yet, many circuits have dismissed claims at the pleadings phase because they have not properly pled parallel claims. With little instruction from the *Riegel* decision, the federal circuits have produced a myriad of standards under which to plead parallel claims. While some circuits require only generalized allegations of violations of FDA standards, others demand great specificity regarding the particular violation of distinct and identifiable FDA standards.

D. *Twombly* and *Iqbal*'s Pleading Standards

Since most manufacturers try to dismiss claims at an early stage, plaintiffs need to know how to properly plead their parallel claims in accordance with *Riegel*'s requirements. Adding to plaintiff confusion, however, are the ill-defined standards set forth in the two-pronged approach of *Bell Atl. Corp. v. Twombly*⁸² and *Ashcroft v. Iqbal*,⁸³ which determine the sufficiency of pleadings to survive a motion to dismiss in all civil actions, regardless of subject matter.⁸⁴ *Twombly* and *Iqbal* urge plaintiffs to avoid conclusory allegations or “a formulaic recitation of

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

⁸¹ *Id.* (citing *Lohr*, 518 U.S. at 495).

⁸² *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).

⁸³ *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

⁸⁴ *Id.* at 1953 (quoting Fed. R. Civ. P. 1).

the elements of a cause of action.”⁸⁵ Such legal conclusions are to be disregarded, and the remaining non-conclusory allegations are assumed to be true.⁸⁶

The remaining non-conclusory allegations must then 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.”⁸⁷ Plaintiffs must plead parallel claims with sufficient facts to survive a motion to dismiss in accordance with *Twombly* and *Iqbal* and their imprecise standard of the sufficiency of factual content. Conflicting opinions about which facts are sufficient to properly plead a parallel claim have caused disparity between federal circuit courts. 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.⁸⁸ More demanding courts, such as the Eleventh Circuit, however, have held that plaintiffs must allege both the federal requirement allegedly violated and the specific defect in the medical device.⁸⁹

III. Circuit Splits: What Constitutes Enough Specificity?

A. A Spectrum of Standards

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

⁸⁵ *Twombly*, 550 U.S. at 555.

⁸⁶ *Iqbal*, 556 U.S. at 679.

⁸⁷ *Id.* at 678 (quoting *Twombly*, 550 U.S. at 570).

⁸⁸ *See, e.g.*, *Bausch v. Stryker Corp.*, 630 F.3d 546, 555–56 (7th Cir. 2010).

⁸⁹ *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 Corp.*,⁹⁰ established the lowest standard of 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.⁹¹ The district court granted defendant’s motion to dismiss, holding that the common law claims were preempted.⁹² On appeal, however, the Seventh Circuit held that state law claims based on violations of federal law are not expressly preempted by Section 360k.⁹³

The Seventh Circuit 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.⁹⁴

The court found that, because some of the PMA documents are confidential with “no public access to complete versions of these documents,” it would be simply impossible for plaintiffs to allege specific violations.⁹⁵ The court also noted that allegations of general controls violations, such as CGMPs violations, were sufficient because many FDA regulations that are not product-

⁹⁰ 630 F.3d 546 (7th Cir. 2010).

⁹¹ *Id.* at 549.

⁹² *Id.*

⁹³ *Id.* at 552.

⁹⁴ *Id.* at 561.

⁹⁵ *Id.* at 560–61.

specific are still vital to producing safe and effective medical devices.⁹⁶ 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 considered whether a plaintiff must point to a specific defect in the device.⁹⁷ The court 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.”⁹⁸ Thus, plaintiffs are required to plead neither a specific federal regulation violation nor a specific defect in the medical device.⁹⁹

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

The Fifth Circuit, in *Funk v. Stryker*,¹⁰⁰ took a slightly more restrictive approach than the Seventh Circuit. This case, like *Bausch v. Stryker*,¹⁰¹ involved the Trident hip replacement system. The court affirmed the dismissal of plaintiff Funk’s complaint because his claims did not satisfy the “required pleading standards to set forth a cognizable claim[.]”¹⁰² 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.”¹⁰³ The plaintiff also relied on the doctrine of *res*

⁹⁶ *Bausch*, 630 F.3d at 555; *but see* *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 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).

⁹⁷ *Bausch*, 630 F.3d at 561.

⁹⁸ *Id.*

⁹⁹ *Id.* at 560.

¹⁰⁰ *Funk v. Stryker*, 631 F.3d 777 (5th Cir. 2011).

¹⁰¹ *Bausch*, 630 F.3d 546.

¹⁰² *Funk*, 631 F.3d at 780.

¹⁰³ *Id.* at 782.

ipsa loquitur to allege a manufacturing defect.¹⁰⁴ 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.¹⁰⁵

Since the court found that the complaint lacked specificity with regard to both the defect and the federal requirement allegedly violated, it is unclear whether the court requires both specifications.¹⁰⁶ It can be inferred, however, that the Fifth Circuit requires at least one or more of these elements.¹⁰⁷

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 (Sprint Fidelis Leads)*,¹⁰⁸ the Eighth Circuit examined manufacturing defect claims against the manufacturer of the Sprint Fidelis Lead, a wire that helps an implanted defibrillator detect arrhythmias and delivers a shock to restore normal rhythm.¹⁰⁹ Although the FDA granted premarket approval to Medtronic in 2004, the company issued a recall of the product in 2007.¹¹⁰ Thereafter, the FDA announced a recall of the device.¹¹¹ Several patients implanted with the device filed a consolidated complaint against Medtronic alleging failure-to-warn, design defect, and manufacturing defect claims.¹¹² The Eighth Circuit found that the failure-to-warn claim was precisely what Section 360k preempted because it required the manufacturer to provide warnings

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *See generally Funk*, 631 F.3d at 780.

¹⁰⁷ *See generally Funk*, 631 F.3d at 780.

¹⁰⁸ 623 F.3d 1200 (8th Cir. 2010) [hereinafter *Sprint Fidelis Leads*].

¹⁰⁹ *Id.* at 1203.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

in addition to the ones required by the FDA's PMA application approval.¹¹³ 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.¹¹⁴

The district court dismissed the manufacturing defect claim, holding that a claim premised on a violation of CGMPs was insufficient to overcome preemption under Section 360k.¹¹⁵ 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.¹¹⁶ On appeal, 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.¹¹⁷ The Eighth Circuit conceded that this argument may be compelling, but found it did not apply in the case at bar because the plaintiffs disclaimed the need for discovery in order to be better able to identify a specific federal requirement that Medtronic allegedly violated when manufacturing the leads.¹¹⁸ In affirming the dismissal, however, 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 alleged that *all* Sprint Fidelis Leads have an unreasonably high failure risk because they utilize unreliable spot welding.¹¹⁹ The FDA, however, actually approved the

¹¹³ *Id.* at 1205.

¹¹⁴ *Sprint Fidelis Leads*, 623 F.3d at 1206.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 1207.

¹¹⁹ *Id.* at 1206.

use of spot welding in a PMA Supplement.¹²⁰ Thus, the court held that, *as pleaded and argued*, the manufacturing defect claims were not parallel to federal requirements, but rather were a direct attack on the FDA’s decision to approve the PMA Supplement.¹²¹ Therefore, the Eighth Circuit held that the 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.¹²²

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.”¹²³ Accordingly, at a minimum, the Eighth Circuit requires plaintiffs to point to a specific federal requirement. 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[.]”¹²⁴ Therefore, it is unclear whether the Eighth Circuit requires plaintiffs to allege a specific defect in addition to a FDA requirement violation.

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

In *Wolicki-Gables v. Arrow International*,¹²⁵ the Eleventh Circuit established the strictest pleading standard of the four of cases, requiring plaintiffs to allege both the federal requirement allegedly violated and the specific defect in the medical device.¹²⁶ Plaintiff Wolicki-Gables alleged state law claims against Arrow, the manufacturer of a PMA-approved implanted pain management pump system, for product liability, negligence, vicarious liability, and loss of

¹²⁰ *Sprint Fidelis Leads*, 623 F.3d at 1207.

¹²¹ *Id.* at 1206.

¹²² *Id.* at 1207.

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ 634 F.3d 1296 (11th Cir. 2011).

¹²⁶ *Id.* at 1301–02.

consortium.¹²⁷ The complaint alleged a failure to reasonably design the device, failure to reasonably manufacture the device, and failure to reasonably provide adequate warnings.¹²⁸ The Eleventh Circuit concluded that the complaint inadequately pleaded 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.”¹²⁹

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 opposite ends of the pleading standards spectrum, and the Fifth and Eighth Circuits fall somewhere in between: on one end, plaintiffs need not allege either a specific defect or a specific federal requirement that has been violated; on the other, 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 uncertain about how much they need to allege based on the jurisdiction in which they file their claims. This disparity also leaves defendant manufacturers with uncertainty about where and for what actions they may be sued.

The Supreme Court must intervene and unify the circuits’ standards for several reasons. First, PMA medical device parallel claims usually involve substantial injury due to the nature of the medical devices and the high risks they potentially pose. Substantial injury could mean substantial liability for medical device manufacturers. Early dismissal of cases under a nearly impossible pleading standard may leave injured plaintiffs without a remedy – a remedy that Congress did not intend to bar. Conversely, allowing claims to go forward under too lenient a

¹²⁷ *Id.* at 1298–99.

¹²⁸ *Id.* at 1301.

¹²⁹ *Id.* at 1301–02; Note that the procedural posture of this case is an affirmation of a grant of summary judgment. The precise language of the holding specifies that the complaint must allege the defect and the federal requirement violated.

standard can deprive manufacturers of the protections Congress intended to afford. The FDA employs a very rigorous premarket approval process, and the threat of liability for unsubstantiated claims may discourage manufacturers from pursuing research and development of potentially life-saving devices.

Second, the Supreme Court must 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.”¹³⁰ On the one hand, to a defendant manufacturer, this goal may signify an 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 themselves¹³¹ are 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, the possibility of forum shopping is heightened since there is such disparity of pleading standards between the circuits. Given the choice, plaintiffs will choose the circuit whose rules are most amenable to them. Forum shopping gives plaintiffs an “opportunity to gain an unjust victory in litigation or to achieve an unjust settlement.”¹³² 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.’”¹³³ 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

¹³⁰ FED. R. CIV. P. 1.

¹³¹ *See, e.g.*, FED. R. CIV. P. app. 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.”).

¹³² Kevin M. Clermont & Theodore Eisenberg, *Exorcising the Evil of Forum-Shopping*, 80 CORNELL L. REV. 1507, 1515 (1995).

¹³³ *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)).

against them when their affiliations with the State are so continuous and systematic as to render them essentially at home in the forum State.”¹³⁴ General jurisdiction forums can 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 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.¹³⁵ 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.

IV. Disparate Pleading Standards and a Workable Unifying Framework

This Comment details a workable framework under which a plaintiff may successfully shape his or her complaint against a manufacturer of a PMA medical device:¹³⁶

First, a plaintiff must decide whether his or her claims parallel federal requirements and are consequently not preempted. The best way to ensure that the claims parallel federal

¹³⁴ *Brown*, 131 S. Ct. at 2851 (internal quotation marks omitted).

¹³⁵ Medtronic, Inc., *Locations*, MEDTRONIC.COM, <http://www.medtronic.com/about-medtronic/locations/index.htm> (Sept. 27, 2010).

¹³⁶ The Supreme Court is yet to offer a uniform standard.

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 “basic adulteration and misbranding provisions as well as applicable good manufacturing practice regulations, banned device regulations, and notification and repair, replacement, or refund requirements.”¹³⁷ Thus, plaintiffs are best advised 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 the pleadings stage of the judicial proceedings. The adequacy of factual content should be determined by the two-pronged approach of *Twombly* and *Iqbal*, under which courts should disregard mere legal conclusions that are not supported by factual allegations. Then, looking at the remaining non-conclusory allegations, courts should “assume their veracity” and ask “whether they plausibly give rise to an entitlement to relief.”¹³⁸ 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.”¹³⁹ Plausibility is not probability, but it is more than mere conceivability.¹⁴⁰

Additionally, determining plausibility is a “context-specific task that requires the reviewing court to draw on its judicial experience and common sense.”¹⁴¹ The two-pronged test of *Twombly* and *Iqbal* does not articulate any special accommodations for situations where

¹³⁷ Hutt, *supra* note 1, at 981.

¹³⁸ *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

¹³⁹ *Id.* at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

¹⁴⁰ *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.”).

¹⁴¹ *Iqbal*, 556 U.S. at 679.

essential information to state a claim is simply unavailable at the pleadings stage, such as access to complete versions of PMA documents. In these instances, courts should use “common sense”¹⁴² 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.

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 in *Sprint Fidelis Leads*.¹⁴³ The court’s reasoning in that case was 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 simply because CGMPs are not device-specific, that a manufacturer cannot be held liable for violating them. This rule does not serve either the purpose of tort law or of Section 360k preemption. The Seventh Circuit raised a compelling argument in *Bausch v. Stryker Corp.*: FDA regulations that are not device-specific are still vital to producing safe and effective medical devices.¹⁴⁴ For example, 21 C.F.R. § 820.70(e) requires manufactures to have procedures in place to prevent contamination of equipment that could adversely affect product quality.¹⁴⁵ 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 even

¹⁴² *Id.*

¹⁴³ *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab.Litig.* 623 F.3d 1200, 1206 (8th Cir. 2010).

¹⁴⁴ *Bausch v. Stryker Corp.*, 630 F.3d 546, 555 (7th Cir. 2010).

¹⁴⁵ 21 C.F.R. § 820.70(e) (2012).

death. Surely, protecting manufacturers 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.¹⁴⁶ The distinction between general and specific requirements produced the exact opposite conclusion in *Lohr* that it did in *Sprint Fidelis Leads*. *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 general requirements and does not require manufacturers to go through the rigorous PMA process.¹⁴⁷ Thus, as with non-PMA devices, claims based on violations of CGMPs should not be preempted by Section 360k.

The second inquiry then is with how much specificity a plaintiff must plead general control violations. A mere statement that CGMPs were violated should be insufficient. Instead, plaintiffs should allege that a *specific* CGMP has been violated that has led to the manufacturing defect. CGMPs, unlike device-specific PMA regulations, are available to the public in 21 C.F.R. § 820.¹⁴⁸ The FDA has extensively described CGMPs in Subparts A through O of 21 C.F.R. § 820.¹⁴⁹ 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 procedures.¹⁵⁰ Plaintiffs can readily access these regulations, which apply to all medical device manufacturers, through a simple internet search.

¹⁴⁶ *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996).

¹⁴⁷ *Lohr*, 518 U.S. at 493; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008).

¹⁴⁸ 21 C.F.R. § 820 (2012); *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, FOOD AND DRUG ADMINISTRATION (Apr. 28, 2011), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm>.

¹⁴⁹ 21 C.F.R. §§ 820.1–820.250 (2012).

¹⁵⁰ 21 C.F.R. §§ 820.22, 820.30, 820.70–820.75, 820.120–820.130, 820.140–820.170 (2012).

Thus, a plaintiff does not need to reach the discovery phase of trial before he can allege which general 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.¹⁵¹ If, however, the duties parallel rather than add to the requirements imposed by federal law, the claims would not be preempted. Hence, plaintiffs should premise their claims on the device-specific requirements set forth in a PMA, provided they have access to the PMA documents.

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, supported by mere conclusory statements, do not suffice.”¹⁵² Therefore, a statement alleging that the PMA has been violated, and has consequently 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.¹⁵³ Courts following the Seventh Circuit’s framework, however, would point out that pleading with specificity would be virtually impossible if plaintiffs do not have access to complete versions of the PMA.¹⁵⁴ The Seventh Circuit’s concern is valid because, as the Code of Federal Regulations explains, unless previously disclosed to the public, much of

¹⁵¹ *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)).

¹⁵² *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

¹⁵³ *Wolicki-Gables v. Arrow International*, 634 F.3d 1296, 1301 (11th Cir. 2011).

¹⁵⁴ *Bausch v. Stryker Corp.*, 630 F.3d 546, 560–61 (7th Cir. 2010).

the information and data in a PMA are not available for public viewing.¹⁵⁵ This undisclosed information consists of, *inter alia*, manufacturing methods and processes, including quality control procedures.¹⁵⁶ 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.”¹⁵⁷ 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 courts,”¹⁵⁸ and as such, Form 11 must be accepted as sufficient.¹⁵⁹

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.”¹⁶⁰ 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. The Federal Circuit has affirmed that Form 18, however, is in line with the *Twombly* standard for pleadings because it “give(s) the defendant fair notice of what the . . .

¹⁵⁵ 21 C.F.R. § 814.9(h) (2012); *see also id.* § 814.9(d)(2) (a request made under the Freedom of Information Act (FOIA) will not overcome the confidentiality rules for PMA files); *see also id.* § 814.9(d)(2) (a FOIA request can only be made “for investigations involving an exception from informed consent.”).

¹⁵⁶ *Id.* § 814.9(h)(1);

¹⁵⁷ FED. R. CIV. P. app. Form 11.

¹⁵⁸ FED. R. CIV. P. 1.

¹⁵⁹ FED. R. CIV. P. 84.

¹⁶⁰ FED. R. CIV. P. app. Form 18.

claim is and the grounds upon which it rests.”¹⁶¹ 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,”¹⁶² courts should be lenient with regard to how much specificity they require from a plaintiff alleging a violation of a PMA device-specific requirement. Common sense dictates that a plaintiff cannot allege that which he does not yet know. Consequently, since he does not know 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 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, via the preemption clause, this logic is severely flawed. Leniency in the pleading standard would simply mean that the preemption question might instead be decided at the summary judgment phase of the litigation rather than at the pleadings phase. The mere fact that Congress necessitated state law non-parallel claims to be preempted does not mean they have to be done at the pleading stage. A more lenient pleading standard does not undermine preemption; it merely pushes the question to

¹⁶¹ *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1356 (Fed. Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

¹⁶² *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

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 requirements. Anything greater is just not possible and would leave injured plaintiffs with no recourse, which is simply intolerable.

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, a unified standard instead should be applied to all parallel claims. As the Supreme Court iterated in *Riegel*, state law claims premised upon violations of FDA regulations would hold manufacturers to duties that “‘parallel’, rather than add to, federal requirements.”¹⁶³ Claims premised on violations of both general and device-specific 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,¹⁶⁴ 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 of allegations of device-specific PMA-requirement violations.

Finally, although not the focus of this Comment, there may be roles for the FDA and the medical device industry in resolving the issue of specificity for claims premised on violations of

¹⁶³ *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

¹⁶⁴ *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570).

device-specific PMA requirements. Since the major problem seems to be that many of the PMA documents are inaccessible at the pleading 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. In a society as litigious as ours, however, 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. Thus, the roles of the FDA and the medical device industry will likely continue to remain limited.