

THE MEDICAL DEVICE FEDERAL PREEMPTION TRILOGY: SALVAGING DUE PROCESS FOR INJURED PATIENTS

Demetria D. Frank-Jackson*

I. INTRODUCTION

For nearly forty years, federal preemption in medical device cases has been an unpredictable and controversial area of jurisprudence. As a result of the most recent Supreme Court decision in *Riegel v. Medtronic*, manufacturers of the most dangerous medical devices are practically immune from lawsuits initiated by victims injured by defective devices due to federal preemption.¹ Unbeknownst to most medical device consumers, who rely on physicians to select medical devices and rarely even know the manufacturer of such products, the *Riegel* opinion restricts the opportunity for would-be plaintiffs all over the country who have experienced negative side effects and in the most egregious cases even death, due to medical device malfunction or misuse. In addition, new pleading rules in federal court have presented further obstacles for patients injured by these highly dangerous products.

Following the enactment of the 1976 Medical Device Amendments (“MDA”), which included a federal preemption clause pertaining to causes of action against manufacturers of certain medical devices, the lower courts had great difficulty ascertaining to what extent state common law claims were preempted by federal law.² This article focuses on the continued difficulty the courts have had interpreting and applying the preemption provision of the MDA even following three subsequent medical device rulings by the Supreme Court in *Medtronic v. Lohr*, *Buckman v. Plaintiffs’*

* Professor Demetria D. Frank-Jackson is currently an Assistant Professor at the University of Wyoming School of Law where she instructs courses in Evidence, Civil Pretrial, Trial Practice and Appellate Practice. Demetria attended the University of Texas School of Law and prior to law teaching, was a toxic tort attorney where she represented injured plaintiffs in products liability lawsuits. Demetria has also served as an Associate Judge for the City of Dallas and the City of Houston.

1. *Riegel v. Medtronic*, 552 U.S. 312, 312 (2008) (holding that the federal preemption provision in § 360k potentially bars any common-law state causes of action relating to a premarket approved device’s safety or effectiveness).

2. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended at 21 U.S.C. §§ 360–360n (2006)).

Legal Committee and *Riegel v. Medtronic*.³ This article also examines the pleading standard articulated by the Supreme Court in *Bell Atlantic Corp. v. Twombly* and the grave effect that ruling has had on medical device litigants.⁴

The lower courts' misinterpretation and misapplication of *Buckman*, *Riegel* and *Twombly*, collectively referred to in this Article as "the trilogy cases," has virtually resulted in jurisprudential tort reform, leaving thousands of patients seriously injured by certain types of medical devices without remedy and denied due process.⁵ Since the rulings in the trilogy cases, even the most seriously injured patients being represented by the most diligent attorneys risk summary judgment or 12(b)(6) motion dismissal in federal court based on federal preemption.

Because the Supreme Court has contributed little to the federal preemption debate except confusion with its rulings in the trilogy cases, it is necessary for Congress to revisit the MDA to better-articulate Congressional intent of achieving a balance between consumer protection and state regulatory chaos.⁶ Hence, Part IV of this Article examines the many mistakes made by federal courts in applying the trilogy cases so that the same ambiguities currently present in the MDA can be avoided in any future versions of this legislation.

Moreover, until the courts receive guidance from Congress through much-needed legislation, there are three steps lower courts should follow to avoid improperly denying access to the judicial system in medical device

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

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

5. Though *Medtronic v. Lohr* was the first medical device case addressed by the Supreme Court, it is not one of the cases referred to in "the trilogy" since it did not have as substantial of an effect on medical device litigation as the *Buckman* and *Riegel* cases because this case addressed a device that was not premarket approved by the FDA and therefore not subject to the preemption provision of the MDA. *Lohr*, 518 U.S. at 478–81. However, this is not to understate the importance of *Lohr* as it is heavily cited by courts evaluating the federal preemption issue in medical device cases. See discussion *infra* Part II.B.

6. Congress has attempted on several occasions, to no avail, to amend the Medical Device Amendments to clarify the fact that the federal preemption provision of the MDA does not exempt medical device manufacturers from state tort liability actions. Sponsored by the late Senator Edward Kennedy, the most recent bill proposal introduced in the 111th Congressional session in 2009 in both the House and Senate, stated simply, "Nothing in this section shall be construed to modify or otherwise affect any action for damages of the liability of any person under the law of any State." S. 540 [111th]; H.R. 1346 [111th]. If passed, the amendment would have applied to pending and subsequent medical device actions. *Id.* However, neither bill received a House or Senate vote and died. See also, H.R. 6381[110th] and S. 3398[110th], a previously-proposed replica of this bill introduced during the 110th Congressional session.

cases: (1) severely limit application of the *Buckman* ruling, since in most cases, a *Buckman* analysis is unwarranted; (2) show reluctance in preempting state law claims under *Riegel* given the lack of guidance afforded by that ruling; and (3) avoid dismissal of medical device complaints based on a perceived “heightened” pleading standard as articulated in *Twombly*. Part V of this Article examines not only why these steps are necessary for the preservation of medical device patient due process, but also posits why following these steps is suitable in light of the historical context of the MDA and federal pleading rules.

To provide context, Part II of this Article provides a brief overview of the MDA and *Medtronic v. Lohr*, the first Supreme Court case addressing the MDA’s preemption provision and Part III of this Article examines the Supreme Court rulings in the trilogy cases which have severely limited consumer rights concerning recovery for personal injuries sustained by defective medical devices.

II. BACKGROUND

A. The Medical Device Amendments of 1976

Prior to the Medical Device Amendments of 1976, the regulation of medical devices was primarily a responsibility of the states and devices did not require safety or effectiveness clearance prior to entering the stream of commerce.⁷ Medical devices were typically only removed from the market if adulterated or misbranded.⁸ The MDA developed a scheme of federal regulation for medical devices while sweeping back authority from the state regulatory schemes through its preemption provision embedded in § 360k(a) disallowing some state claims against medical device manufacturers of certain medical devices.⁹

Enacted to “provide for the safety and effectiveness of medical devices intended for human use,” the MDA classifies medical devices into three categories based on the risk these devices pose to the general public.¹⁰ Class I devices are those that “present no unreasonable risk of illness or injury” and are subject to minimal regulation by “general controls.”¹¹ Although they may be marketed without advance FDA approval, manufacturers of Class II devices must comply with federal performance

7. *Id.* at 475–76.

8. 21 U.S.C. § 351 (2006).

9. *Lohr*, 518 U.S. at 475; *Riegel*, 552 U.S. at 316.

10. *Lohr*, 518 U.S. at 476.

11. 21 U.S.C. § 360c(a)(1)(A). *See also Lohr*, 518 U.S. at 476–77.

regulations called “special controls.”¹² Finally, Class III devices are those that “support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury.”¹³ Some examples of Class III devices are: pacemakers, catheters, and knee, hip or pelvic prosthetics.

The cause for controversy is devices that fit into the third category subject to premarket approval (hereinafter “PMA”) by the FDA before it may be introduced to the market.¹⁴ The purpose of the PMA process is to “provide the FDA with a ‘reasonable assurance,’ that the device is both safe and effective.”¹⁵ Class III medical device manufacturers must submit a lengthy application evaluating the device’s manufacturing process, design, safety, and effectiveness.¹⁶

The FDA purportedly spends approximately 1,200 hours of review of each device subject to premarket approval.¹⁷ During the review process, the agency “must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness for such use.”¹⁸ Further, the FDA may approve devices that “present great risks if they nonetheless offer great benefits in light of available alternatives.”¹⁹

Though purported to establish heightened regulation of Class III devices through its premarket approval requirement, the MDA also included a preemption provision, which states in part:

§ 360k. State and local requirements respecting devices:

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

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

12. 21 U.S.C. § 360c(a)(1)(B). *See also Lohr*, 518 U.S. at 477

13. 21 U.S.C. § 360c(a)(1)(C). *See also Lohr*, 518 U.S. at 477.

14. Certain Class III devices are not required to undergo the premarket approval process. Class III devices that were marketed prior to enactment of the MDA are allowed to remain on the market until the FDA initiates the PMA process. 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1) (2010). Additionally, for devices that are “substantially equivalent” to a predicate device, the manufacturer may opt to endure the less extensive § 510(k) process. 21 U.S.C. § 360e(b)(1)(B). Section 510(k) submissions must include “[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement.” 21 C.F.R. 807.87(f) (2010). *See also Buckman v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 345 (2001).

15. 21 U.S.C. § 360e(d)(2)(A)-(B). *See also Buckman*, 531 U.S. at 344.

16. *Riegel v. Medtronic*, 552 U.S. 312, 317–18 (2008).

17. *Lohr*, 518 U.S. at 477.

18. 21 U.S.C. § 360c(a)(2)(C); *Riegel*, 552 U.S. at 318.

19. *Riegel*, 552 U.S. at 318.

(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 Act²⁰

The problem for medical device recipients arises when premarket approved devices subject to the preemption provision fail. Arguably, the Medical Device Amendments were enacted to afford consumers greater protection from dangerous medical devices.²¹ However, the inherent ambiguity of the preemption provision, resulting in the prevailing medical device case law, has significantly limited consumer ability to recover through the tort system once they have been injured by defective devices.

B. *Medtronic v. Lohr*

Following the enactment of the MDA, the district courts were in sharp disagreement on the correct reading of the federal preemption statute necessitating interpretation of this provision by the Supreme Court.²² The

20. 21 U.S.C. § 360k(a).

21. The MDA was enacted largely in response to thousands of injuries suffered by medical devices in the 1960s and early 1970s, most notably, by women using the Dalkon Shield intrauterine device. See *In re N. Dist. of Cal., Dalkon Shield IUD Prods. Liab. Litig.*, 693 F.2d 847 (9th Cir. 1982). Complaints against the Dalkon Shield manufacturer included uterine perforations, infections, ectopic and uterine pregnancies, spontaneous abortions, fetal injuries and birth defects, sterility hysterectomies and several deaths. *Id.* at 848–49.

22. Following the MDA, some courts interpreted the preemption provision to bar all state law claims against medical device manufacturers. See *King v. Collagen*, 983 F.2d 1130, 1137 (1st Cir. 1993) (holding the MDA expressly preempts all strict liability, negligence and fraud state law claims); *Martin v. Telectronics Pacing Sys.*, 70 F.3d 39, 42 (6th Cir. 1995) (concluding the MDA’s preemption provision preempts state product liability claims and there is nothing in the U.S. Constitution that protects the existence of common-law causes of action); *Stamps v. Collagen*, 984 F.2d 1416, 1421 (5th Cir. 1993) (holding that state tort liability would impose “a requirement either different from, or in addition to,” federal requirements in favor of preempting the plaintiff’s claims); *Talbott v. C.R. Bard*, 63 F.3d 25, 27 (1st Cir. 1995) (holding that the MDA preempts all state tort law claims).

Some courts read the preemption provision to bar only certain types of state causes of action. See *Duvall v. Bristol-Myers-Squibb*, 65 F.3d 392, 400 (4th Cir. 1995) (holding that express warranty claims “based on FDA-mandated labeling, packaging, or advertising” are preempted, but an express warranty claim is not preempted if it “is based on a manufacturer’s voluntarily-made representations regarding its product”); *Feldt v. Mentor*, 61 F.3d 431, 438 (3rd Cir. 1995) (concluding that the MDA does not preempt express warranty and fraud advertising claims but does preempt negligence, strict liability, breach of implied warranty and fraud claims); *Lohr v. Medtronic*, 56 F.3d 1335, 1352 (11th Cir. 1995) (holding that plaintiff’s negligent design and strict liability claims did not establish any specific design requirement conflicting with state law and were therefore not barred by the preemption provision; but plaintiff’s negligent manufacture and failure to warn claims would be different from or in addition to FDA requirements and were therefore preempted); *Mitchell v. Collagen*, 67 F.3d 1268, 1275–86 (7th Cir. 1995) (holding that the MDA preempts express warranty claims but does not preempt implied warranty, mislabeling and fraud claims).

highly anticipated *Medtronic v. Lohr* came two decades after the Medical Device Amendments of 1976 and was expected to put an end to some of the controversy surrounding the included preemption provision.²³

Defendant Medtronic's pacemaker at issue in the case, however, entered the market as a 510(k) exempt device and surpassed the more stringent PMA process.²⁴ Essentially, Medtronic argued, the plain language of the MDA should preempt "any and all common law claims brought by an injured plaintiff against a manufacturer of medical devices" and that any common law cause of action is a "requirement . . . different from, or in addition to" the FDA approved federal standards mandated by the MDA.²⁵

Rejecting this argument, the *Lohr* court determined that PMA-exempt devices do not receive federal preemption protection.²⁶ Consistent with the intent of the MDA in establishing greater regulation of dangerous medical devices, the *Lohr* court noted, "it is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."²⁷ Ultimately, the *Lohr* court ruled, though the FDA may not require pre-market approval for medical devices "substantially equivalent" to devices on the market through the 510(k) process, the preemption doctrine does not "shield a manufacturer from liability" if it decides to forgo the PMA process.²⁸

Though the *Lohr* court did not preempt the plaintiff's claims, it was clear in its analysis that at least to some extent, premarket approved device manufacturers enjoyed *some* type of immunity to *some* types of state law claims.²⁹ As if making an admonition that the federal preemption issue

Other courts' analysis of the preemption provision turned on whether the FDA set requirements specific to the medical device in question. See *Anguiano v. E.I. Du Pont De Nemours & Co.*, 44 F.3d 806, 809 (9th Cir. 1995) (noting, "the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device."); *Kennedy v. Collagen*, 67 F.3d 1453, 1459-60 (9th Cir. 1995) (stating, "[t]he federal law requiring the premarket approval of Class III devices was not enacted in order to free manufacturers from the everyday burdens of the marketplace after they are permitted to enter it."); *Lamontagne v. E.I. Du Pont de Nemours & Co.*, 41 F.3d 846, 853 (2nd Cir. 1994) (concluding, "[s]tate or local requirements are preempted only when the Food and Drug Administration has established *specific counterpart regulations or there are other specific requirements applicable to a particular device* under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.").

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

24. *Id.* at 475-76.

25. *Id.* at 486.

26. *Id.* at 487. Section 510(k) submissions must include "[a] statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement." 21 C.F.R. 807.87(f); see also *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 345 (2001).

27. *Lohr*, 518 U.S. at 487.

28. *Id.*

29. *Id.* at 482-83.

would resurface in a less neatly packaged scenario than the one addressed by the *Lohr* court, Justice Breyer acknowledged in a concurring opinion the ambiguity of the MDA's preemption provision noting that the provision "makes clear that federal requirements may preempt state requirements, but . . . says next to nothing about just when, where, or how they may do so[.]"³⁰

Unfortunately, the majority's very narrow ruling in the *Lohr* case did little to clarify how far the medical device federal preemption provision reached. Hence, the question of what state law claims were preempted by the MDA still remained, even following *Lohr*, and the lower courts were again left to run amuck with conflicting interpretations of the preemption provision.

III. THE TRILOGY CASES

Following the Medical Device Amendments and *Medtronic v. Lohr*, there have been three Supreme Court cases that have provided the current judicial landscape of medical device litigation, which I refer to as "the trilogy."

A. *Buckman v. Plaintiffs' Legal Committee*

The first trilogy case, *Buckman v. Plaintiff's Legal Committee* was hoped to bring clarity to the federal preemption debate since *Lohr* did not specifically address the effect of the preemption provision on common law causes of action.³¹ However, the *Buckman* decision was another huge upset to the medical device world, injured patients—practitioners and medical device manufacturers alike—since it specifically declined to address the scope of the federal preemption provision.³²

The first issue relevant to a discussion of the *Buckman* ruling is the allegations made by the plaintiffs in that case. The *Buckman* plaintiffs did not plead traditional common law causes of action such as negligence or strict liability, and instead, asserted that the device's premarket application contained fraudulent misrepresentations to the FDA.³³ Furthermore, the plaintiffs alleged, had such representations not been made, the FDA would

30. *Id.* at 505.

31. *Buckman*, 531 U.S. at 341.

32. *Id.* at 348.

33. *Id.* at 343.

not have given the device market clearance and plaintiffs would not have been injured.³⁴

Drawing from conflict preemption principals previously addressed by the Supreme Court, the *Buckman* Court also determined that even if a plaintiff's claims are not expressly preempted by § 360k(a), they may be nevertheless impliedly barred under 21 U.S.C. § 337(a), which states in part, "[a]ll such proceedings for the enforcement, or to restrain violations . . ." on the medical device provisions "shall be by and in the name of the United States."³⁵ The *Buckman* Court reasoned that because policing fraud against federal agencies is not a traditional function of the states, and the FDA has wide latitude in punishing those that defraud the FDA, a state law fraud-on-the-FDA claim conflicts with the FDA's regulatory scheme and is therefore impliedly preempted.³⁶ Hence, the Court reasoned, "the FDCA leaves no doubt that it is the federal government's burden to prosecute suits for noncompliance with the medical device provisions rather than "private litigants" and the *Buckman* plaintiffs' claims conflicted with, and therefore were impliedly preempted by, federal law.³⁷

However, *Buckman* should not be read in an over-simplistic way. The *Buckman* plaintiffs attempted to "assert a freestanding federal cause of action based on violation of FDA regulations; the plaintiffs did not assert violation of a state tort duty."³⁸ Hence, not only did the *Buckman* Court warn to stay clear of fraud-on-the-FDA allegations, but to survive implied preemption, the conduct on which the claim is based must be the type of conduct that would traditionally give rise to liability under state law even if the FDCA had never been enacted.³⁹ Although much of the *Buckman* Court's opinion focuses on the problem of the plaintiff's FDA-fraud allegations, in the very last few sentences of the Court's ruling, this broader preemption principal is mentioned.⁴⁰

In introducing this additional bar to common-law causes of action against medical device manufacturers, the Court reasoned that in order to avoid implied preemption, the plaintiff's claim must be premised on the type of conduct that would traditionally give rise to liability under state law even if the FDCA had never been enacted.⁴¹ Accordingly, the *Buckman* Court noted, though the ruling in *Lohr* allows certain state-law causes of

34. *Id.* See also *Silkwood v. Kerr-McGee*, 464 U.S. 238 (1984); *Geier v. Am. Honda Motor*, 529 U.S. 861 (2000).

35. *Buckman*, 531 U.S. at 347–49.

36. *Id.*

37. *Id.*

38. *Hughes v. Boston Scientific*, 631 F.3d 762, 775 (5th Cir. 2011).

39. *Buckman*, 531 U.S. at 352–53 (2001); *Riley v. Cordis*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009).

40. *Buckman*, 531 U.S. at 353.

41. *Id.* at 353.

action that “parallel federal safety requirements,” a proper *Lohr* analysis does not mean that “any violation of the FDCA will support a state-law claim.”⁴²

Much like the opinion in *Lohr*, the *Buckman* Court’s restricted analysis again left the most pertinent medical device litigation question unanswered—what state law claims, if any, survive federal preemption under the MDA?

B. *Riegel v. Medtronic*

The most ambiguous and contentious chapter in the medical device trilogy came in an 8-1 decision holding that the federal preemption provision in § 360k potentially bars any common-law state causes of action relating to a premarket approved device’s safety or effectiveness.⁴³ Since the medical device at issue in *Riegel* involved a premarket approved device (unlike *Lohr*), and the plaintiff’s allegations were based on traditional common law causes of action (unlike *Buckman*), the *Riegel* opinion was expected to become the prime medical device jurisprudence addressing federal preemption.⁴⁴ Nevertheless, *Riegel* contributed very little to the federal preemption debate except more confusion, and the “tenets” established in *Riegel* were in large part restatements of *Lohr*, *Buckman* and the MDA.

First, reiterating the “safety or effectiveness” language of the MDA, the *Riegel* Court made clear that any common law claim pertaining to “safety or effectiveness” of a premarket approved device is potentially subject to federal preemption since “the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application.”⁴⁵

After concluding that the *Riegel* plaintiffs’ claims did indeed relate to safety and effectiveness, the *Riegel* Court then took on the task of addressing the ambiguity of the term “requirement” in the preemption provision.⁴⁶ In doing so, the Court rejected plaintiffs’ argument that her

42. *Id.*

43. *Riegel v. Medtronic*, 552 U.S. 312, 321–30 (2008).

44. *Id.* at 322–23. The *Riegel* Court distinguished *Lohr* due to the fact that the device in question in *Lohr* was not premarket approved and only subjected to “substantial-equivalence review” under the § 510(k) process. *Id.* at 322. The PMA device in the *Riegel* case, the Court noted, was subject to a much higher level of scrutiny particular to the device and therefore, “the attributes that *Lohr* found lacking in § 510(k) review[,]” were present in the *Riegel* case. *Id.* at 323. In its distinction, Justice Scalia writing for the majority insisted that the PMA process is “in no sense an exemption from federal safety review—it *is* federal safety review.” *Id.*

45. *Id.* at 323.

46. *Id.* at 327. Though the *Riegel* Court acknowledges that one of its primary responsibilities in evaluating whether the plaintiffs’ claims are preempted is to determine “whether the Riegels’

state common law claims of negligence, strict-liability, and implied warranty were not preempted even if they imposed “requirements” since the general duties imposed by those claims are not specific to medical devices.⁴⁷ Declining to follow the suggestion of its predecessor *Lohr*, the majority posited, “[n]othing in the statutory text suggests that the preempted state requirement must apply only to the relevant device, or only to medical devices and not to all products and all actions in general.”⁴⁸

Next, the majority declares that § 360k does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations just as long as the “state duties imposed ‘parallel’ rather than add to, federal requirements.” However, the Court did not examine whether the Riegels’ claims were “parallel” reasoning that the assertion was not raised by the Riegels before the lower district court nor in plaintiffs’ petition for certiorari.⁴⁹

Albeit with no helpful elaboration, ultimately, the *Riegel* Court seemed to develop the following tenets: (1) since the FDA requires premarket approved devices to be marketed with very little deviation from the specifications in the device’s approval application, premarket approved devices are subject to federal preemption protection; (2) common law claims that relate to safety and effectiveness “different from, or in addition to” the federally mandated requirements are preempted under the MDA; and (3) common law claims that “parallel” the FDA requirements are not expressly preempted by the preemption provision.⁵⁰

In examining these tenets, and the district courts’ difficulty in applying them, it can easily be assessed that a number of questions were left unaddressed by *Riegel*. First, though the Court posited that the FDA requires manufacturers to adhere closely to the specifications set forth in their PMA approval application, it did not take the further step of ruling that when a manufacturer deviated from those specifications, it lost its right of preemption. Second, it did not examine what common law state causes of action set forth “requirements” that are “different from or in addition to” the

common-law claims are based upon . . . requirements with respect to the device that are ‘different from, or in addition to’ the federal ones,” Justice Scalia’s opinion never specifically addresses this question. *Id.* at 321–22.

47. *Id.* at 322.

48. *Id.* at 327–28. The *Lohr* Court announced previously on the same issue, “§ 360k refers to ‘requirements’ many times throughout its text. . . . In each instance, the word is linked with language suggesting that its focus is device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries.” *Medtronic v. Lohr*, 518 U.S. 470, 489 (1996).

49. *Riegel*, 552 U.S. at 330.

50. *Id.* at 323, 328–30.

federal regulatory scheme that would exclude claims from being considered “parallel” and therefore preempted § 360k.⁵¹

C. *Bell Atlantic Corporation v. Twombly*

As if *Riegel* did not leave the medical device preemption pool muddled enough, several months prior to *Riegel* the Supreme Court decided *Bell Atlantic Corp. v. Twombly*.⁵² Though it was probably not the Supreme Court’s intent for *Twombly* to add additional precedent to the prevailing medical device jurisprudence specifically, since *Twombly* was not a case addressing medical device preemption, scores of district courts have dismissed patients’ claims at the initial pleading stage (sometimes even without the use of federal preemption) based on the heightened pleading requirements articulated in *Twombly*.⁵³

Twombly involved a Sherman Anti-trust Act case examining what is required of a plaintiff’s complaint to survive a federal 12(b)(6) motion to dismiss.⁵⁴ To avoid dismissal, the *Twombly* Court noted, a plaintiff must plead “enough facts to state a claim to relief that is *plausible on its face*.”⁵⁵

Obviously, *Twombly* was not the first Supreme Court case addressing 8(a)(2) pleading requirements—it had been a half a century since the federal pleading standard had been visited by the High Court when it then announced, “Federal Rule of Civil Procedure 8(a)(2) requires only ‘a short and plain statement of the claim showing that the pleader is entitled to relief,’ in order to” defeat a 12(b)(6) motion for dismissal.⁵⁶ The *Twombly* Court, however, effectively rejected its own precedent that “once a claim has been stated adequately, it may be supported by showing *any set of facts* consistent with the allegations in the complaint . . .” and stated that the former guide did not set forth “the minimum standard of adequate pleading to govern a complaint’s survival.”⁵⁷

Further, the Court noted, despite the liberal pleading standard allowed by *Conley*, Rule 8(a)(2) “requires a ‘showing’ rather than a blanket

51. *Id.* at 330.

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

53. *See* *Anthony v. Stryker*, No. 1:09-cv-2343, 2010 U.S. Dist. LEXIS 31031 (N.D. Ohio Mar. 18, 2010); *Gelber v. Stryker*, 752 F. Supp. 2d 328 (S.D.N.Y. 2010); *Heisner v. Genzyme*, No. 08-C-593, 2010 U.S. Dist. LEXIS 21339 (N.D. Ill. Mar. 8, 2010); *Horowitz v. Stryker*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009); *Ilarraza v. Medtronic*, 677 F. Supp. 2d 582 (E.D.N.Y. 2009); *Redinger v. Stryker*, No. 5:10 CV 104, 2010 WL 1995829 (N.D. Ohio May 19, 2010); *Steen v. Medtronic*, No. 3:10-CV-936-L, 2010 U.S. Dist LEXIS 65579 (N.D. Tex. June 25, 2010).

54. *Twombly*, 550 U.S. at 544.

55. *Id.* at 570 (emphasis added).

56. *Conley v. Gibson*, 355 U.S. 41, 45–46 (1957).

57. *Twombly*, 550 U.S. at 563 (emphasis added).

assertion, of entitlement to relief.”⁵⁸ That is, the complaint must not only give the defendant “fair notice” but must also state the “‘grounds’ on which the claim rests.”⁵⁹

Unfortunately, much like the requisite medical device cases addressed by the Supreme Court, much was left to be desired with *Twombly* as well. Not only were the federal courts unclear on how to evaluate *Twombly*’s new “facial plausibility” pleading standard, but both practitioners and courts were unsure of whether it was even relevant to cases outside the Sherman Anti-trust Act context.⁶⁰

The Supreme Court attempted to answer both questions almost exactly two years later in *Ashcroft v. Iqbal*, another case addressing adequacy of pleading for survival of a 12(b)(6) motion to dismiss.⁶¹ First, the *Iqbal* Court attempted to clarify the “plausible on its face” language used by the *Twombly* court explaining, “[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”⁶² Second, the *Iqbal* Court made clear that the pleading standard adapted in *Twombly*, was indeed intended to be applicable to civil pleadings across the board and not solely those involving Anti-trust Act claims.⁶³

In explaining this procedural departure from *Conley*, the *Iqbal* Court reiterates two additional pleading evaluation principles.⁶⁴ First, in evaluating this plausibility standard, courts must accept as true all of the allegations contained in a complaint with the exception of legal conclusions noting, “while legal conclusions can provide the framework of a complaint,

58. *Id.* at 555 n.3.

59. *Id.*

60. In two separate places in *Twombly* the Court suggests that its ruling is only applicable in the Sherman Act context, noting, “[w]e granted certiorari to address the proper standard for pleading an *antitrust conspiracy* . . .” and “[t]his case presents the antecedent question of what a plaintiff must plead in order to state a claim under § 1 of the Sherman Act.” *Id.* at 553, 555 (emphasis added).

61. *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009).

62. *Id.* at 1949. Echoing the *Twombly* Court’s admonition of the prior pleading standard set in *Conley*, the *Iqbal* Court noted, “the pleading standard Rule 8 announces does not require ‘detailed factual allegations’ but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation” and “[w]here a complaint pleads facts that are ‘merely consistent with’ a defendant’s liability, it ‘stops short of the line between possibility and plausibility of ‘entitlement to relief.’”” *Id.* at 1949. In explaining this procedural departure from *Conley*, the *Iqbal* Court reiterates two additional pleading evaluation principles. *Id.* at 1949–50. First, in evaluating this plausibility standard, the court must accept as true all of the allegations contained in a complaint with the exception of legal conclusions noting, “[w]hile legal conclusions can provide the framework of a complaint, they must be supported by factual allegations.” *Id.* Second, “only a complaint that states a plausible claim for relief survives a motion to dismiss” and that determining whether claims are plausible is a “context-specific task.” *Id.*

63. *Id.* at 1953.

64. *Id.* at 1949–50.

they must be supported by factual allegations.”⁶⁵ Second, “only a complaint that states a plausible claim for relief survives a motion to dismiss” and that determining whether claims are plausible is a “context-specific task.”⁶⁶

In its ruling the *Iqbal* Court also made clear that the pleading standard adapted in *Twombly*, was indeed intended to be applicable to civil pleadings across the board and not solely those involving Anti-trust Act claims.⁶⁷

IV. THE TRILOGY IN ACTION

The district courts’ misapplication and misconstruction of the trilogy cases have essentially resulted in thousands of persons seriously injured by Class III medical devices without remedy or compensation for those injuries—to the point where the trilogy cases now raise an issue of due process for patients receiving medical devices in treatment. Making three critical mistakes in application of the trilogy cases, *Bass v. Stryker* is a perfect example of the fatal interplay between the Supreme Court’s federal preemption rulings in *Buckman* and *Riegel* and the pleading requirements set forth in *Twombly*.⁶⁸

Bass involved allegations against the manufacturer of a hip prosthetic, Stryker, in which the plaintiff alleged several traditional state causes of action including: strict liability, negligence, breach of express warranty, breach of implied warranty of merchantability and fitness for a particular purpose and violation of the Texas Deceptive Trade Practices Act.⁶⁹ Bass alleged that following a hip replacement surgery in which a Stryker-manufactured prosthetic was implanted, he began experiencing pain in his hip that increased incrementally over the years following.⁷⁰ As a result, Bass underwent a hip revision surgery where it was discovered that the portion of the prosthetic that replaces and functions as the socket portion of the hip joint had failed to fuse with Bass’ hip bone.⁷¹ Stryker, of course, maintained that each of Bass’ claims was preempted by the MDA.⁷²

The clearest error of the *Bass* court is its application of the *Buckman* ruling and § 337(a). Specifically, the *Bass* court noted, “[e]ven assuming that Plaintiff’s claims are parallel claims, and therefore not preempted by § 360k(a), they are nevertheless preempted by § 337(a) because there is no

65. *Id.*

66. *Id.*

67. *Id.* at 1953.

68. *Bass v. Stryker*, No. 4:09-CV-632-Y, 2010 U.S. Dist. LEXIS 90226 (N.D. Tex. Aug. 31, 2010).

69. *Id.* at *2.

70. *Id.* at *1–2.

71. *Id.*

72. *Id.* at *2–3.

private right of action under the FDCA.”⁷³ Essentially, the *Bass* court reasoned, if a state common-law claim is not preempted by § 360k(a) because it is deemed “parallel” based on violation of federal regulations, § 337(a) functions to preempt any common law claims based on violations of the FDCA since the United States has “exclusive rights to enforce the FDCA.”⁷⁴ As interpreted by the *Bass* court, § 337(a) places plaintiffs in the precarious position of avoiding allegations of defendant’s noncompliance with FDCA regulations notwithstanding the requirement to state a “parallel” claim premised on violations of the FDCA under *Riegel*. As discussed in more detail below, this is a grave misinterpretation of § 337(a) as cited by the *Buckman* court.⁷⁵

Next, while the *Bass* court acknowledges that parallel claims survive preemption under *Riegel*, it makes a finding of preemption while never actually contrasting *Bass*’ common law claims with the applicable federal law.⁷⁶ Although the *Bass* court attempted to offer a lackluster basis for concluding that the plaintiff’s common law claims were not parallel by stating that *Bass* made “no attempt to relate the alleged deficiencies and deviations to the premarket-approval process,” deviation from the PMA process specifically is not what *Riegel* requires.⁷⁷ Additionally, such reasoning clearly presents a problem for medical device recipients since compliance with the FDA premarket approval process does not necessarily render a device free from defect.

The *Bass* case illustrates another common problem with the district courts’ application of the trilogy cases. Although the *Bass* complaint is riddled with factual detail of the allegations against the medical device manufacturer and its violations of federal law that would seemingly withstand *Twombly* scrutiny, the court concluded that the “unelaborated allegations” in *Bass*’ complaint did not provide enough facts to support a

73. *Id.* at *17.

74. *Id.* at *15–16.

75. *See infra* Part V.A.

76. Instead, the *Bass* court makes the conclusory finding that the plaintiff, “failed to plead parallel claims within the meaning of *Riegel*.” *Bass*, 2010 U.S. Dist. LEXIS 90226, at *14.

77. Instead, *Riegel* notes, “[s]tate requirements are pre-empted under the MDA only to the extent that they are ‘different from, or in addition to’ the requirements imposed by federal law.” *Riegel v. Medtronic*, 552 U.S. 312, 330 (2008). *Riegel* never states that a deviation from the PMA process is specifically required and none of the circuit courts that have examined the issue come to this conclusion. *Id.* *See also* *Bausch v. Stryker*, 630 F.3d 546 (7th Cir. 2010); *Howard v. Sulzer Orthopedics*, 382 Fed. App’x 437 (6th Cir. 2010); *Hughes v. Boston Scientific*, 631 F.3d 762 (5th Cir. 2011); *Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic (In re Medtronic)*, 623 F.3d 1200 (8th Cir. 2010); *Wolicki-Gables v. Arrow Int’l*, 634 F.3d 1296 (11th Cir. 2011).

cause of action and warranted 12(b)(6) dismissal based on Bass' failure to properly allege "parallel" claims.⁷⁸

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78. To the contrary, Bass' complaint was riddled with detail of the allegations against manufacturer Stryker. As discussed in further detail in Part V, Subsection C, *Twombly's* "heightened pleading" merely requires that Bass nudge his claims "across the line from conceivable to plausible." *Bell Atl. v. Twombly*, 550 U.S. 544, 570 (2007); *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950–51 (2009). Specifically, Bass alleges in his First Amended Complaint, *inter alia*: Stryker was required to comply with FDA regulations: at ¶ 21 Bass alleges "Pursuant to [Stryker's] PMA approval, Stryker was required to comply with the FDA's standards and requirements established and approved through the PMA process." Complaint at *8-9, *Bass*, 2010 U.S. Dist. LEXIS 90226, 2009 U.S. Dist. Ct. Pleadings LEXIS 52357 at *8–9. Stryker's failure to comply with FDA regulations (and deviation from federal "requirements," which arguably, also establishes a "parallel" claim under *Riegel*): at ¶ 23 Bass cites to an FDA warning letter issued to Stryker defendant following an inspection, which explicitly states that the defendant's devices at its manufacturing facility in Cork, Ireland "were adulterated within the meaning of section 21 U.S.C. § 351(h) in that 'the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found in Title 21, Code of Federal Relations [sic] (C.F.R.), Part 820.'" *Id.* at *9–10. FDA's recognition of Stryker's violation of federal regulations: at ¶ 24 Bass cites to an FDA-issued inspection and resulting List of Inspectional Observations issued to Stryker noting multiple violations in the manufacturing process including:
- (a) [f]ailure to establish and maintain adequate procedures for implementing a corrective and preventative action, as required by 21 CFR 820.100(a) . . . ;
 - (b) [f]ailure to establish and maintain adequate procedures to control product that fails to conform with specified requirements, including the evaluation of non-conforming products, as required by 21 C.F.R. 820.90(a);
 - (c) [f]ailure to timely make changes to procedures to lessen confusion and better assure that root causes of non-conforming product are identified;
 - (d) [f]ailure to manufacture blister sealing used for sterilized products according to the federal requirements in that the blister sealing temperature, time and pressure settings were outside of the specified and validated operating parameters;
 - (e) [f]ailure to establish and maintain adequate procedures to implement and record changes in methods and procedures needed to correct and prevent identified quality problems, as required by 21 CFR 820.100(a)(5) including failing to verify and implement changes to reduce the Final Rinse Tank bioburden;
 - (f) [f]ailure to establish and maintain adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the products meet current approved specifications, as required by 21 CFR 820.90(b)(2)."
- Id.* at *10–11. Stryker's federal violations affected Bass' specific device: at ¶ 25 Bass cites to a recall initiated by the defendant for devices manufactured at defendant's Cork, Ireland facilities, which included Bass's specific hip device, following investigations "into deviations between specifications and processes for manufacturing required by the FDA whereby, among other failures, excessive bioburden, viable microorganisms, were found in the final rinse tank thereby contaminating the devices. . . ." *Id.* at *11–12. The complaint also alleges that the recall was initiated because excessive manufacturing residuals "in excess of those permitted by the FDA were found on the Trident devices," including Bass' specific recalled hip device. *Id.* at *12. Stryker's federal violations, which affected Bass' specific device, caused injuries to Bass: at ¶ 28 the Bass complaint alleges facts that "orthopedic surgeons have expressed the opinion that residues coat the back of the acetabular cup and prevent boney ingrowth . . . prevent[ing] the cup from being securely held into the sock which results in a loose cup." *Id.* at *13. Further, the plaintiff alleged, that such residues present in Bass' acetabular cup caused its loosening and necessitated revision. *Id.* If the Bass complaint cannot survive a *Twombly* analysis with the above level of detail, it is extremely difficult to see what medical device pleadings would.

Though most courts do not dismiss plaintiffs' claims based on all three of the reasons provided by the *Bass* court, *Bass* is representative of some of the common problems injured patients face in the federal courts' application of the trilogy cases.

A. *Buckman* in Action

A number of federal courts have taken an approach similar to *Bass* to the detriment of the nation's medical consumers in application of the ruling in *Buckman*, finding that § 337(a) disallows private actions for violations of the FDCA.⁷⁹ Hence, a claim could conceivably survive preemption under *Riegel* comporting with § 360k(a), and nevertheless fail a preemption analysis under § 337(a), even if the claims do not resemble the fraud-on-the-FDA claims stated by the *Buckman* plaintiffs. As noted in *Timberlake v. Synthes Spine, Inc.*, "when Sections 337(a) and 360k(a)—as construed in *Buckman* and *Riegel*, respectively—are read together, nearly all types of claims concerning FDA-approved medical devices are preempted."⁸⁰

In an attempt to identify what types of claims alleging defects in an FDA-approved medical device are not preempted under these two provisions read together, some district courts note that only a claim specifically alleging that a device was not manufactured in accordance with its PMA specifications can survive preemption.⁸¹ However, many plaintiffs attempting to advance such claims allege that a manufacturer's misstatements or misinformation during the PMA process resulted in

79. See *Clark v. Medtronic*, 572 F. Supp. 2d 1090 (D. Minn. 2008); *Cornwell v. Stryker*, No. 1:10-cv-00066-EJL, 2010 WL 4641112 (D. Idaho Nov. 1, 2010); *Hughes v. Boston Scientific*, 669 F. Supp. 2d 701 (S.D. Miss. 2009); *In re Medtronic, Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. 2009); *Lewkut v. Stryker*, 724 F. Supp. 2d 648 (S.D. Tex. 2010); *McCutcheon v. Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917 (N.D. Ill. 2008); *Riley v. Cordis*, 625 F. Supp. 2d 769 (D. Minn. 2009); *Stengel v. Medtronic*, No. CV 10-318-TUC-RCC, 2010 WL 4483970 (D. Ariz. Nov. 9, 2010); *Timberlake v. Synthes Spine*, No. V-08-4, 2011 U.S. Dist. LEXIS 17034 (S.D. Tex. Feb. 18, 2011).

80. *Timberlake*, 2011 U.S. Dist. LEXIS 17034 at *30 (citing *In re Medtronic*, 592 F. Supp. 2d at 1161).

81. *In re Medtronic*, 592 F. Supp. 2d at 1161 (stating, "*Riegel* left open a back door for plaintiffs: claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA are not preempted."); *Parker v. Stryker*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) ("[t]o properly allege parallel claims, the complaint must set forth facts showing 'action or inaction in [] efforts to take part in the PMA process or implement its results.'"); *Stevens v. Pacesetter*, No. 3:07-cv-3812, 2008 U.S. Dist. LEXIS 26880 at *3, (D.S.C. Apr. 1, 2008) (noting, "the decision in *Riegel* disposes of [a plaintiffs] claims except to the extent any claim might be construed as alleging a failure to comply with the federal standards which were established through the PMA process."); *Timberlake*, 2011 U.S. Dist. LEXIS 17034 at *19 (noting a "narrow category" of claims may survive federal preemption analysis based on manufacturer failure to comply with the PMA process).

market clearance of a defective device.⁸² District courts typically conclude that these causes of action are essentially identical to fraud-on-the-FDA claims and consequently run afoul to the basic premise stated in *Buckman*.⁸³

For example, in *Stengel v. Medtronic, Inc.*, where the plaintiff sought to amend his complaint to state “parallel” causes of action by premising the claims on federal violations, the court denied the plaintiff’s motion to amend concluding that adding the necessary language to establish a parallel claim would render the claim impliedly preempted under *Buckman*.⁸⁴ Specifically, plaintiff sought to amend his traditional negligence claim to assert that the defendant “failed to warn/inform the FDA and medical physicians that their medical devices could cause granulomas, in violation of their duties under the FDCA.”⁸⁵ However, the *Stengel* court denied plaintiff’s motion to amend finding:

[T]he new allegations in the proposed amended complaint suggest Plaintiff is now raising a fraud/failure to warn claim against Defendant. Under *Buckman*, Plaintiff’s new claim is impliedly preempted. . . . Plaintiff’s new allegations rest on violations of the FDCA. As such, his new claim of fraud/failure to warn would not exist had the FDCA not been enacted.⁸⁶

Furthermore, even if a cause of action based on PMA non-compliance were adequately stated, some district courts have concluded that § 337(a) preempts *all* claims against premarket approved medical device manufacturers.⁸⁷ In finding that “private actions to enforce the MDA are expressly prohibited” under § 337(a), the *Clark v. Medtronic, Inc.* court equated the plaintiff’s argument that the device manufacturer failed to disclose all available information in its premarket approval application with the fraud-on-the-FDA allegations posed by the plaintiffs in *Buckman*.⁸⁸ The court concluded that claims against a manufacturer of a premarket approved device are preempted under § 337(a) even if the plaintiff could illustrate that a defendant failed to comply with the PMA process since “Congress has granted the FDA exclusive power to enforce MDA premarket approvals.”⁸⁹ Unfortunately, this inappropriate application of *Buckman* is

82. *Clark*, 572 F. Supp. 2d at 1094; *Hughes*, 669 F. Supp. 2d at 711; *McCutcheon*, 586 F. Supp. 2d at 922; *Riley*, 625 F. Supp. 2d at 786; *Timberlake*, 2011 U.S. Dist. LEXIS 17034 at *28–29.

83. *Id.*

84. *Stengel*, 2010 WL 4483970 at *3.

85. *Id.*

86. *Id.*

87. *Clark*, 572 F. Supp. 2d at 1095; *see also* *Cornett v. Johnson & Johnson*, 998 A.2d 543, 556 (N.J. Super. Ct. App. Div. 2010).

88. *Clark*, 572 F. Supp. 2d at 1095.

89. *Id.*

only one way in which courts consistently dismiss patient claims against medical device manufacturers.

B. *Riegel* in Action

Though each of the Supreme Court medical device federal preemption cases state that pleading a ‘parallel’ cause of action prevents federal preemption dismissal under 360k(a), neither *Lohr*, *Buckman*, nor *Riegel* give much direction as to what constitutes a parallel claim, and the district courts have largely had to figure this out for themselves.⁹⁰ Though many federal courts have made gallant attempts to assess the viability of common law claims under the “parallel claim” language used thrice by the Supreme Court, the ambiguity in the preemption provision and the broad ruling of the Supreme Court in *Riegel* give the courts wide latitude for interpretation of which state common law requirements deserve preemption.

For example, in *Prudhel v. Endologix, Inc.*, the court reasoned, “[f]or state law to be preempted, federal law must impose requirements on a device, and state law must impose *additional requirements*.”⁹¹ Additionally, the court noted, some state law claims that require “more than mere noncompliance with federal requirements,” do not necessarily call for preemption if the “state law claim does not impose conflicting requirements on the manufacturer[] thereby disrupt[ing] the federal regulatory scheme.”⁹² Other courts like *Heisner v. Genzyme Corp.*, have held that state requirements are preempted unless they are “genuinely equivalent” and “state and federal requirements are not equivalent if a manufacturer could

90. *Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic (In re Medtronic)*, 623 F.3d 1200, 1204 (8th Cir. 2009) (noting, “[t]he contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined.”); *Prudhel v. Endologix*, No. S-09-0661 LKK/KJM, 2009 U.S. Dist. LEXIS 64402, at *18, *25 (E.D. Cal. July 8, 2009) (noting, “Districts courts have divided on what constitutes a ‘parallel claim’ under *Riegel*” and “courts are further divided as to what Twombly requires of a plaintiff seeking to plead a parallel claim.”); *White v. Stryker*, No. 3:10-CV-544-H, 2011 U.S. Dist. LEXIS 32568, at *12 (W.D. Ky. Mar. 25, 2011) (stating, “while establishing a framework for this broad preemption, *Riegel* also raised many new questions.”).

91. *Prudhel*, 2009 U.S. Dist. LEXIS 64402, at *9 (emphasis added). *Prudhel* represents one of the most liberal interpretations of the “parallel claim” language used in *Riegel*. *Prudhel* involved various state law claims against the manufacturer of a stent that purportedly became disengaged during insertion into Edwin Prudhel during an aortic stent graft repair operation, causing his death. *Id.* at *4–6. *Inter alia*, plaintiffs alleged that prior manufacturing lots of the stents had been recalled because the tip of the stent was known to separate from the catheter sheath inner core during insertion of the graft, causing injuries such as the ones sustained by Edwin Prudhel. *Id.* Although the plaintiff’s state law strict liability manufacturing defect claim required a standard that was literally “different from” the federal requirements in its “reckless and unreasonable” elements, the court concluded that the plaintiff’s claims paralleled the FDCA requirements because the claim required “no additional behaviors on part of the manufacturer other than adherence to the specifications and requirements set forth the by the FDA.” *Id.* at *22.

92. *Id.*

be held liable under state law while complying with federal requirements.”⁹³

Most courts, while recognizing the need to determine whether the plaintiffs’ claims are “different from, or in addition to” federal requirements or “parallel,” never actually compare the common law claims with applicable federal law.⁹⁴ For example, in *Williams v. Cyberonics*, the court never considered whether the plaintiffs’ common law claims were consistent with federal regulations, and the ruling instead turned on the Williams plaintiffs’ failure to make a showing “that the medical device was not manufactured in accordance with FDA standards.”⁹⁵ Similar to *Bass*, the *Williams* court overlooked the necessary comparison between the plaintiff’s common law claims and federal regulations and disregarded the possibility of device flaws despite fulfillment of the premarket approval process, presumptively stating:

Riegel is loud and clear: if a manufacturer complies with the premarket approval, it gets a free pass No state common-law claim can survive if it allows a claimant to proceed without showing a departure from federal standards. There simply is no wiggle room to find otherwise To avoid federal preemption, a plaintiff must make some showing that the medical device was not manufactured in accordance with FDA standards.⁹⁶

A number of district courts have held similar to the *Williams* court and required plaintiffs to demonstrate a manufacturer deviation from federal FDA standards in order to assert a parallel cause of action.⁹⁷ In an attempt

93. *Heisner v. Genzyme*, No. 08-C-593, 2010 U.S. Dist. LEXIS 21339, at *6 (N.D. Ill. Mar. 8, 2010) (citing *McMullen v. Medtronic*, 421 F.3d 482, 489 (7th Cir. 2005)).

94. *Bass v. Stryker*, No. 4:09-CV-632-Y, 2010 U.S. Dist. LEXIS 90226 (N.D. Tex. Aug. 31, 2010); *Gelber v. Stryker*, 752 F. Supp. 2d 328 (S.D.N.Y. 2010); *Steen v. Medtronic*, 2010 U.S. Dist. LEXIS 65579 (N.D. Tex. June 25, 2010); *Williams v. Cyberonics*, 388 Fed. App’x 169 (3rd Cir. 2010).

95. *See, e.g., Williams v. Cyberonics*, 654 F. Supp. 2d 301 (E.D. Pa. 2009), *aff’d by Williams v. Cyberonics*, 388 Fed. App’x 169 (3d Cir. 2010).

96. *Id.* at *9–10.

97. *Bass*, 2010 U.S. Dist. LEXIS 90226, at *13 (where the court dismissed plaintiff’s claims partially because plaintiff did not “allege a failure to comply with any particular regulation nor how that failure caused [the] injuries”); *Heisner*, 2010 U.S. Dist. LEXIS 21339, at *6 (“plaintiff’s failure to plead a relevant statute alone gives this Court sufficient grounds to dismiss all related claims.”); *Gelber*, 752 F. Supp. 2d 328 (S.D.N.Y. 2010); *Ibarra v. Medtronic*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009) (stating for a pleading to state a parallel claim, it would need to allege that the manufacturer “violated a particular federal specification referring to the device at issue”); *Lemelle v. Stryker Orthopaedics*, 698 F. Supp. 2d 668, 678–79 (W.D. La. 2010) (where the court noted, “the plaintiff has not sufficiently pled his state law [] claim with sufficient factual information or clarity for this Court to determine whether the requirements [] seek to impose additional or different requirements than those imposed by the FDA . . . nowhere in the plaintiff’s complaint

to identify what state causes of action fail preemption analysis, one district court noted:

To escape preemption by § 360k(a) . . . a state-law claim must be premised on the breach of a state-law duty that is the same as a duty imposed under the FDCA (or one of its implementing regulations) . . . [t]he conduct that is alleged to give the plaintiff a right to recover under state law must [also] be conduct that is forbidden by the FDCA.⁹⁸

Five of the eleven circuit courts have examined medical device preemption under *Riegel*, and each confirm that in order for a parallel cause of action to be properly alleged, the claims must be premised on a violation of federal law or deviation from federal standard.⁹⁹ Essentially, the circuit courts conclude the common law claims must go beyond alleging violation of federal statute, and the pleadings should contain sufficient detail of *how* the federal regulations were violated.¹⁰⁰ Recall, however, that asserting a

does the plaintiff mention the FDA”); *Parker v. Stryker*, 584 F. Supp. 2d 1298, 1300–01 (D. Colo. 2008) (to properly allege parallel claims, the complaint must set forth facts showing “action or inaction in . . . efforts to take part in the PMA process or implement its results”); *Poole v. Hologic*, No. 10-314, 2010 U.S. Dist. LEXIS 76653, at *20 (W.D. La. July 29, 2010) (court further noted, “absent any allegation that the [device] used in Mrs. Poole’s surgery failed to conform to the FDA-approved standards . . . plaintiffs’ manufacturing defect claims fall within the scope of *Riegel* and are preempted by the MDA”); *Williams*, 654 F. Supp. 2d at 306 (“[t]o avoid federal preemption, a plaintiff must make some showing that the medical device was not manufactured in accordance with FDA standards”); *Yost v. Stryker*, No. 2:09-cv-28-FtM-29DNF, 2010 U.S. Dist. LEXIS 27079, at *13 (M.D. Fla. 2010) (stating, “[s]ince plaintiff’s First Amended Complaint only asserts a state law, without reference to a federal violation, his claim is preempted”).

98. *Riley v. Cordis*, 625 F. Supp. 2d 769, 776 (D. Minn. 2009).

99. *Bausch v. Stryker*, 630 F.3d 546 (7th Cir. 2010); *Howard v. Sulzer Orthopedics*, 382 Fed. App’x 437 (6th Cir. 2010); *Hughes v. Boston Scientific*, 631 F.3d 762 (5th Cir. 2011); *Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic (In re Medtronic)*, 623 F.3d 1200 (8th Cir. 2010); *Wolicki-Gables v. Arrow Int’l*, 634 F.3d 1296 (11th Cir. 2011); *See also Funk v. Stryker Corp.*, 631 F.3d 777 (5th Cir. 2011) (not analytically considering the “parallel claim” issue and primarily addressing procedural issues involved in the case).

100. This is consistent with many district court rulings on the subject as well. In most cases where plaintiffs have been successful, the plaintiff was able to allege violations of federal statute coupled with references to specific facts illustrating the defendant’s deviating behavior. For instance, in *Phillips v. Stryker*, the Plaintiff plead that the manufacturer was in violation of federal statute 21 U.S.C. § 351 because the hip prosthetic manufactured by the defendant failed to conform to several provisions of the CGMP. *Phillips v. Stryker*, No. 3:09-CV-488, 2010 WL 2270683, at *2–8 (E.D. Tenn. June 3, 2010). In pleading this allegation, the plaintiff cited an FDA warning letter in his complaint as well as factual allegations related to the recall of the device in question. *Id.* The court noted in its conclusion that the plaintiff had adequately stated “parallel” causes of action that the plaintiff “successfully alleged that the defendants failed to comply with FDA regulations in manufacturing the device . . . [and] advanced several theories of state common law liability to link those compliance failures to the ultimate failure of the device.” *Id.* at *21.

violation of federal regulation invites an improper *Buckman* analysis, as demonstrated above.

In the most recent of the five circuit court decisions, *Wolicki-Gables v. Arrow International, Inc.*, the Eleventh Circuit specifically noted that to properly state parallel claims, the plaintiff must allege that “the defendant violated a particular federal specification referring to the device at issue.”¹⁰¹ Similar to the district court’s decision in *Bass*, the Eleventh Circuit concluded that the plaintiffs’ failed to demonstrate that their common law negligence and strict liability claims were parallel, but never advises how these claims were “different from or in addition to” the FDCA’s federal regulations other than noting that the allegations did not “set forth any specific problem, or [fail] to comply with any FDA regulations that can be linked to the injury alleged.”¹⁰²

In *Hughes v. Boston Scientific Corporation*, the Fifth Circuit came to a different result.¹⁰³ The court noted that in accordance with *Riegel* and *Lohr*, “a medical device manufacturer is protected from liability under state-law tort claims related to a defective or dangerous device to the extent that the manufacturer has complied with federal statutes and regulations.”¹⁰⁴ However, the court stated, “a manufacturer is not protected from state tort liability when the claim is based on the manufacturer’s violation of applicable federal requirements.”¹⁰⁵

To support her proposed “parallel” failure to warn claim and Boston Scientific’s federal violations, the plaintiff presented evidence that Boston violated FDA Medical Device Reporting regulations. Specifically, Hughes alleged that some of the first and second degree burns caused by the device that Boston Scientific failed to report to the FDA was in violation of Boston’s duty to “report any device that ‘may have caused or contributed to death or serious injury’” under 21 C.F.R. §803.3.¹⁰⁶ In further support, Hughes offered expert testimony that some of the burns Boston failed to report “necessitated medical or surgical intervention to preclude permanent injuries.”¹⁰⁷ The court found that this testimony, along with allegations that the FDA directed Boston Scientific to begin reporting more burns, was sufficient to show federal violations necessary to assert a parallel claim.¹⁰⁸

The Seventh Circuit has evaluated the issue as well in *Bausch v. Stryker* and understood the MDA’s “different from or in addition to”

101. *Wolicki-Gables*, 634 F.3d at 1301.

102. *Id.* at 1302–03 (citing *Ilaraza v. Medtronic*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009)).

103. *Hughes*, 631 F.3d at 762.

104. *Id.* at 767.

105. *Id.*

106. *Id.* at 769.

107. *Id.* at 766–67.

108. *Id.* at 773–74.

language to require preemption dismissal unless “the plaintiff can show that the [state] requirements are “genuinely equivalent.”¹⁰⁹ Further, “where there are ‘both state and federal requirements to the same effect, then the state requirements will not be different from, or in addition to, the federal requirements.’”¹¹⁰

In support of her strict liability and negligence claims, Bausch alleged that the device was implanted in her body six days after the FDA informed Stryker that a component of one of its hip implants was “adulterated” and that the companies’ manufacturing process failed to comply with federal standards.¹¹¹ The complaint further alleged that the hip implanted into Bausch failed, requiring surgical removal and replacement. Stryker later recalled a component of the hip implant with the same catalogue number as the one she had received on her initial surgery.¹¹² The court determined that plaintiff’s assertion based on defendant’s violations of the Quality Systems Regulations and Good Manufacturing Practices, codified in 21 C.F.R. § 820.1(a)(1) of the FDCA, were sufficient to state a parallel claim under *Riegel*.¹¹³

The Sixth Circuit held a similar view in *Howard v. Sulzer Orthopedics, Inc.*, stating that plaintiff’s negligence *per se* claim alleging that defendant had violated § 820.70(h) of the Good Manufacturing Practices of the FDCA was sufficient to state a parallel claim.¹¹⁴ Specifically, the plaintiff alleged that oily residue left on his knee implant during the manufacturing process was in violation of federal regulations requiring removal of manufacturing materials such as lubricating oil.¹¹⁵ Contrasting the *Howard* plaintiff’s claims from others that make broad-based allegations citing provisions of the FDCA, the court noted that the particular Good Manufacturing Practices provision that Howard cited was “not so vague as to be incapable of enforcement” and suggested that the court may not have come to the same conclusion had Howard not specified a specific Good Manufacturing Practices provision that had been violated.¹¹⁶

The Eight Circuit, however, did not share the more liberal approach to analyzing a parallel claim as articulated in the *Hughes*, *Bausch* and *Howard* courts. First acknowledging that “[t]he contours of the parallel claim exception [to the MDA preemption provision] were not addressed in *Riegel*

109. *Bausch v. Stryker*, 630 F.3d 546, 552 (7th Cir. 2010).

110. *Id.*

111. *Id.* at 559.

112. *Id.*

113. *Id.* at 555–56.

114. *Howard v. Sulzer Orthopedics*, 382 Fed. App’x 436 (6th Cir. 2010).

115. *Id.* at 439.

116. *Id.*

and are as-yet ill-defined,” the *Medtronic Leads* court went on to address whether each of plaintiffs’ multiple theories of recovery under state law were “different from or in addition to” the federal requirements.¹¹⁷ With regards to plaintiffs’ failure to warn claims, plaintiffs asserted that Medtronic was negligent in continuing to market the original version of its leads after the FDA had given approval to sell a modified version.¹¹⁸ The court concluded, however, that this claim was not parallel to the federal requirements since the FDA never prohibited the defendant from continuing to sell the modified version, and therefore there was no federal violation.¹¹⁹

The court further held that plaintiffs’ design defect claims were likewise preempted since the plaintiffs’ complaint did not contain allegations that the device sold by the defendant manufacturer was not the product design approved in defendant’s PMA supplement.¹²⁰ Similarly, the court noted that plaintiffs failed to adequately plead that defendant violated a federal requirement with respect to its manufacturing claims since the plaintiffs only generally alleged noncompliance with the FDA Current Good Manufacturing Practices.¹²¹ Finally, the *Medtronic Leads* court preempted plaintiffs’ breach of express warranty claims that defendant’s leads “were safe, effective and fit for their intended use” since to succeed on such a claim, plaintiffs would need to show that defendant’s leads were not “safe and effective,” a finding that would be in opposition to the FDA’s approval of Medtronic’s PMA supplement.¹²²

The five circuit court rulings clearly demonstrate the diversity of views amongst the federal courts regarding parallel claim interpretation. Even under the most lenient *Bausch* standard, the Seventh Circuit found a parallel claim existed in part because the plaintiff could point to an FDA

117. *Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic (In re Medtronic)*, 623 F.3d 1200, 1204 (8th Cir. 2010).

118. *Id.* at 1205. The court further noted that plaintiff’s argument that the application of *Twombly* created an impossible pleading standard because the FDA’s specific federal manufacturing requirements are set forth in the agency’s PMA approval files that are accessible, without discovery, only to Medtronic and to the FDA. This agreement would have carried more weight “in a case where a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit.” *Id.* The court went on to distinguish such cases from the multiple-plaintiffs’ claims the court was addressing, noting: “[p]laintiffs alleged that state law entitles every person who has an implanted Sprint Fidelis Lead to damages . . . and to equitable relief . . . because all Sprint Fidelis Leads have an unreasonably high risk of fracture failure.” *Id.* Additionally the court mentioned that “[i]n the district court, Plaintiffs conceded that the PMA Supplement doubtless authorized the use of spot welding, and they specifically disclaimed the need for discovery in opposing Medtronic’s motion to dismiss.” *Id.*

119. *Id.*

120. *Id.* at 1206.

121. *Id.* at 1207.

122. *Id.* at 1207–08.

investigation and warning related to the device at issue, as well as Stryker's subsequent recall of the device used in the patient's surgery. Many plaintiffs do not have such incriminating evidence at their disposal, but obviously this does not mean the devices that they have been injured by are more effective than those that do. Thus, the lack of parallel claim analysis by each of the three Supreme Court medical device cases examining federal preemption invite dismissal of perfectly permissible claims by courts like *Bass* and the potential for pleading a state common law claim that is not "different from or in addition to" federal requirements, and therefore not federally preempted, largely depends on which court the plaintiff chooses.

C. *Twombly* in Action

Although Federal Rule of Civil Procedure 8(a)(2) merely requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief," an overwhelming number of courts applying *Twombly* find in favor of the defendants' dismissal motions interpreting *Twombly* to establish an impractical heightened pleading requirement.¹²³ In the medical device context, federal courts have determined that *Twombly* requires that plaintiffs "demonstrate a cognizable link between the defendant's federal violations and plaintiff's injury."¹²⁴ Hence, not only must the allegations against the manufacturer meet *Twombly*-level specificity in stating a "facially plausible" claim for relief, but the "parallel claim" requirement is examined on the initial pleadings through the lenses of this plausibility standard as well.

Consequently, patients injured by medical devices seemingly face an *even higher* pleading standard than the "plausibility" requirement articulated by *Twombly* through the necessity to state "parallel claims" at the initial pleading stage of the lawsuit under *Riegel*, notwithstanding the difficulty the district courts have experienced in ascertaining what constitutes a parallel claim. As one district court noted in finding that the plaintiff had failed to adequately plead "parallel" claims under the standard set forth in *Twombly*:

123. *Anthony v. Stryker*, No. 1:09-cv-2343, 2010 U.S. Dist. LEXIS 31031 (N.D. Ohio Mar. 18, 2010); *Covert v. Stryker*, No. 1:08CV447, 2009 U.S. Dist. LEXIS 68962 (M.D.N.C. Aug. 5, 2009); *Franklin v. Medtronic*, No. 09-CV-02301-REB-KMT, 2010 U.S. Dist. LEXIS 71069 (D. Colo. May 12, 2010); *Funk v. Stryker*, 673 F. Supp. 2d 522, 531 (S.D. Tex. 2009); *Gelber v. Stryker*, 752 F. Supp. 2d 328 (S.D.N.Y. 2010); *Heisner v. Genzyme*, No. 08-C-593, 2010 U.S. Dist. LEXIS 21339 (N.D. Ill. Mar. 8, 2010); *Horowitz v. Stryker*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009); *Ilarraza v. Medtronic*, 677 F. Supp. 2d 582 (E.D.N.Y. 2009); *Steen v. Medtronic*, No. 3:10-CV-936-L, 2010 U.S. Dist. LEXIS 65579 (N.D. Tex. June 25, 2010).

124. *Gelber*, 752 F. Supp. 2d at 334.

[i]n order to “survive” MDA pre-emption under *Twombly*, a plaintiff must point to a specific federal requirement, show how it was violated, and in this case, show how said violation resulted in the injury complained of.¹²⁵

Oftentimes, claims are dismissed because the pleaders lack details in their allegations about what specific federal law the medical device manufacturer violated.¹²⁶ For instance, in *Ilarraza v. Medtronic, Inc.*,

125. *Covert*, 2009 U.S. Dist. LEXIS 68962 at *46.

126. *See Anthony*, 2010 U.S. Dist. LEXIS 31031; *Bass v. Stryker*, 4:09-CV-632-Y, 2010 U.S. Dist. LEXIS 90226 (N.D. Tex. Aug. 31, 2010); *Covert*, 2009 U.S. Dist. LEXIS 68962; *Franklin*, 2010 U.S. Dist. LEXIS 71069; *Prudhel v. Endologix*, No. S-09-0661 LKK/KJM, 2009 U.S. Dist. LEXIS 64402 (E.D. Cal. July 8, 2009); *In re Medtronic, Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. 2009). Some examples of specific facts alleged by plaintiffs that aided courts in deciding in the plaintiffs’ favor that a “facially plausible claim” had been alleged in the complaint are:

1. Plaintiff’s defective manufacture claims were not dismissed on pleadings where plaintiff alleged that following a hip replacement surgery where defendant’s hip replacement device was implanted, plaintiff began to experience problems with the hip, ultimately leading to a second surgery to remove the prosthetic. *Bausch v. Stryker*, 630 F.3d 546, 558–60 (7th Cir. 2010). Plaintiff’s complaint alleged facts showing that defendant knew, prior to plaintiff’s first surgery, that the hip implant device was defective. *Id.* Plaintiff’s complaint also referenced an FDA-issued warning letter addressed to the defendant that stated the device in question was “adulterated due to manufacturing methods . . . not in conformity with industry and regulatory standard.” *Id.* The complaint also alleged facts that the specific device implanted into the plaintiff was subject to a recall issued on the device. *Id.*

2. Plaintiff was allowed to precede on several theories of liability by alleging that the manufacturer’s hip devices had dimensional anomalies which were the subject of three recalls on three separate batches of the device in question (two by the FDA and one by the defendant). *Warren v. Howmedica*, No. 4:10-CV-1346-DDN, 2010 U.S. Dist. LEXIS 129662, at *1–8 (E.D. Mo. Dec. 8, 2010). Plaintiff also referenced a warning letter issued by the FDA referring to the defendant’s device as “adulterated,” as defined in 21 U.S.C. § 351(h). *Id.* In citing this warning letter, the plaintiff also alleged that the methods used in the device’s manufacturing process were not in conformity with the Current Good Manufacturing Practice requirements of the FDCA. *Id.* The plaintiff also referenced an additional warning letter issued to the defendant following two FDA inspections discovering the defendant’s devices were “adulterated.” *Id.*

3. A district court denied defendant’s motion to dismiss plaintiff’s claims where the plaintiff alleged that defendant failed to comply with FDA regulations in manufacturing its hip prosthetic and referenced an FDA warning letter issued to the defendant following an inspection of one of the defendant’s manufacturing facilities that cited to several violations of federal regulations. *Phillips v. Stryker*, No. 3:09-CV-488, 2010 WL 2270683, at *1–8 (E.D. Tenn. June 3, 2010). Plaintiff also alleged facts in reference to defendant’s recall of the device that applied to the plaintiff’s implanted hip prosthetic. *Id.*

4. On a breach of express warranty claim against a manufacturer of a hip prosthetic labeled to have only a .5% defect rate, multiple plaintiffs alleged that the rate of defect was much higher than .5%. *Huber v. Howmedica*, No. 07-2400 (JLL), 2008 U.S. Dist. LEXIS 106479 (D.N.J. Mar. 10, 2009). The plaintiff further alleged the failure of the device to adhere to the .5% defect rate gave rise to a claim for breach of express warranty since the claimed .5% failure rate was the basis of a bargain for the device. *Id.*

5. On a strict liability manufacturing defect claim against the manufacturer of a stent graft device, plaintiffs asserted in pleadings that defendant’s stent malfunctioned during a surgical procedure causing plaintiffs’ decedent’s death. *Prudhel*, 2009 U.S. Dist. LEXIS 64402, at *22–23. Specifically, plaintiff alleged that the tip cap of the stent’s delivery device became disengaged

where the plaintiff sustained an injury from a medical pump implant and alleged that the defendant manufacturer violated several federal regulations, specifically the MDA's Current Good Manufacturing Practices.¹²⁷ Citing *Twombly* for the proposition that federal pleading requirements "require dismissal of complaints that do nothing more than engage in a 'formulaic recitation of the elements of a cause of action,'" the court concluded that the plaintiff's allegations did "nothing more than recite unsupported violations of general regulations, and fail[ed] to tie such allegations to the injuries alleged," and dismissed the common law claims.¹²⁸

Additionally, the courts readily dismiss claims where the plaintiff's complaint fails to link the federal violation to the injury sustained by the device recipient.¹²⁹ For instance, in *Franklin v. Medtronic, Inc.*, where the

during insertion into the decedent. *Id.* Plaintiffs also referenced that prior manufacturing lots of the stents had been recalled because "the tip may separate from the catheter . . . during insertion of the graft." However, the court dismissed plaintiff's other claims of strict liability design defect, negligence and breach of express and warranty without prejudice. *Id.* at *25.

6. Plaintiff sufficiently plead under 12(b)(6) where he was able to point to the alleged violation of premarketing packing requirements applicable to the particular medical device at issue. *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 801–802 (W.D. La. 2008). Specifically, plaintiff's complaint alleged it was necessary that the medical device be packaged in a particular way in accordance with FDA specifications which protected the device from damage during shipping and surgery and that the manufacturer failed to package the device in the required manner. *Id.* The complaint further asserted that the faulty packaging caused the device to malfunction, and the plaintiff suffered injuries as a result of the malfunction. *Id.* Finally, the pleading alleged the device had been subject to two recalls as a result of incorrect packaging and plaintiff's doctor had problems with the device in three patients within 30 days. *Id.* The court did not find dispositive the fact that the plaintiff could not at the pleading stage identify the particular size, model or lot number of the device used in the plaintiff's procedure or identify the device as one of the devices affected by the recall. *Id.*

Though these cases illustrate courts that have allowed survival of plaintiffs' claims, with the pleading of very specific facts, this level of specificity with regards to defendant manufacturer conduct is rarely available at the complaint stage of the lawsuit. Oftentimes, the plaintiff is not privy to the manufacturer's specific conduct during the design and manufacturing process unless and until she has had the opportunity to conduct discovery. *Bausch*, 630 F.3d at 558.

127. *Ilarraza*, 677 F. Supp. 2d at 582.

128. *Id.* at 588 (citing *Bell Atl. v. Twombly*, 550 U.S. 544, 555 (2007)).

129. See, e.g., *Anthony*, 2010 U.S. Dist. LEXIS 31031, at *10 (N.D. Ohio Mar. 18, 2010) (noting that the plaintiff "did not specifically mention either the FDA or its regulations" nor "plead any facts that would lead this court to plausibly infer that Stryker's noncompliance with FDA regulations led to his injury"); *Bass*, 2010 U.S. Dist. LEXIS 90226, at *16 (stating, "[p]laintiff has not specifically alleged how Defendants have failed to meet [federal] specifications or that such a failure has even occurred."); *Covert*, 2009 U.S. Dist. LEXIS 68962, at *44 ("[plaintiff] has not alleged any particular non-conclusory link between th[e] alleged wrongdoing and his particular injuries."); *Franklin v. Medtronic*, No. 09-cv-02301-REB-KMT, 2010 U.S. Dist. LEXIS 71069, at *23 ("[m]erely alleging that Defendant generally failed to comply with federal requirements is insufficient to overcome the preemptive reach of [federal law] without some factual detail as to why Defendant violated federal regulations." (citation omitted)); *Funk v. Stryker*, 673 F. Supp. 2d 522, 531 (S.D. Tex. 2009) (observing that plaintiff "provides no facts in support of his conclusory allegations"); *Horowitz v. Stryker*, 613 F. Supp. 2d 271, 283 (E.D.N.Y. 2009) (explaining that "[t]he generalized allegations made in plaintiff's complaint call for . . . amplification here as the

plaintiff alleged that had her “health care providers and/or the FDA known the risks and dangers associated with Defendant’s Defibrillators,” she would not have had the device implanted in her body, the court determined that the plaintiff’s complaint was devoid of specific allegations of the defendant’s conduct or how that conduct caused the plaintiff’s injuries.¹³⁰ The court concluded that the plaintiff failed to state a parallel claim because she “failed to allege any facts establishing a causal connection between Defendant’s alleged failure to comply with FDA regulations and her alleged injuries.”¹³¹

Though few in number, some courts have maintained a more liberal pleading standard in the medical device context even post-*Twombly/Iqbal*.¹³² For example, in *Hofts v. Howmedica* the plaintiff satisfied *Twombly*’s pleading requirement by alleging that Howmedica was negligent in the manufacturing process of the device and certain parts of the device’s components did not satisfy the FDA’s PMA standards, resulting in “unreasonably dangerous manufacturing defects.”¹³³ Although Howmedica made the usual arguments that Hofts’ claims “failed to allege that Howmedica deviated from the manufacturing process approved by the FDA during the PMA process” under *Riegel*, the *Hofts* court maintained that to

relationship between defendants’ federal violations and plaintiff’s injury seems implausible.”); *White v. Stryker*, No. 3:10-CV-544-H, 2011 U.S. Dist. LEXIS 32568, at *21–22 (W.D. Ky. Mar. 25, 2011) (“[p]laintiff’s allegations here are so general and so absent any reference to federal standards, that the Court has no basis for determining whether they plausibly assert ‘parallel’ claims.”).

130. *Franklin*, 2010 U.S. Dist. LEXIS 71069, at *29–30.

131. *Id.* at *28.

132. *Hofts v. Howmedica*, 597 F. Supp. 2d 830 (S.D. Ind. 2009); *Huber v. Howmedica*, No. 07-2400 (JLL), 2009 U.S. Dist. LEXIS 91526 (D.N.J. Mar. 10, 2009); *Lemelle v. Stryker Orthopaedics*, 698 F. Supp. 2d 668 (W.D. La. 2010); *Warren v. Howmedica Osteonics*, No. 4:10 CV 1346 DDN, 2010 U.S. Dist. LEXIS 129662 (E.D. Mo. Dec. 8, 2010); *Prudhel v. Endologix*, No. S-09-0661 LKK/KJM, 2009 U.S. Dist. LEXIS 64402 (E.D. Cal. July 8, 2009); *see also Cornett v. Johnson & Johnson*, 998 A.2d 543 (N.J. Super. Ct. App. Div. 2010). *But see, Covert*, 2009 U.S. Dist. LEXIS 68962 at * 39 (stating *Twombly* requires more from a plaintiff pleading a case such as that attempted by Plaintiff Covert than the *Hofts* court would demand and finding more persuasive cases that reject *Hofts* with regard to the pleading standard under *Twombly*); *Gelber v. Stryker*, 752 F. Supp. 2d 328, at *13 (S.D.N.Y. 2010) (“courts have specifically pointed out that *Hofts* is unique in applying such a lax pleading standard.”); *Horowitz*, 613 F. Supp. 2d at 283, n.5 (“[r]equiring the plaintiff to plead his claims with more specificity, according to the *Hofts* court, would amount to an unusually stringent application of *Twombly* . . . [o]n the contrary, requiring amplification as to how the defendants’ alleged federal violations relate to the plaintiff’s claims is exactly what *Twombly* contemplates, especially where such a connection is implausible.” (citations omitted)); *Ilarraza*, 677 F. Supp. 2d at 589 (“[t]he court declines to follow [*Hofts*] court’s analysis, and instead follows the larger number of courts that have rejected the sufficiency of pleading nothing more than the violation [of a federal regulation] in support of a parallel claim.”).

133. *Hofts*, 597 F. Supp. 2d at 836.

require more specific allegations would impose a heightened pleading requirement and exceed the requirements of *Twombly*.¹³⁴

If taken by itself, *Twombly* would probably have very little bearing on medical device case outcome in most instances compared to other areas of civil litigation.¹³⁵ However, *Twombly* has been cited in medical device cases as authority for dismissing complaints that fail to plead sufficient detail of a “parallel” claim that might otherwise escape dismissal under the MDA’s federal preemption provision.¹³⁶ The requirement to provide such detail at the pleading stage not only with regards to the manufacturer’s federal violations, but specifically how such violations caused the plaintiff’s injuries, obviously requires more evidence than many plaintiffs possess at the initial phases of the lawsuit prior to conducting discovery.¹³⁷ Notwithstanding carefully detailed pleading that might easily meet the “facial plausibility” standard articulated by *Twombly*, the allegations in medical device cases are commonly dismissed not for lack of notice to the defendant or the “plausibility” of the plaintiff’s claims, but because of the perceived failure “to plead parallel claims within the meaning of *Riegel*.”¹³⁸

V. A BETTER APPLICATION OF THE TRILOGY CASES

While the MDA clearly contemplates that there are common law causes of action that survive federal preemption, none of the requisite Supreme Court cases have identified what manufacturer conduct, or lack thereof, gives rise to a prosecutable state common law claim.¹³⁹ If nothing

134. *Id.* at 840–41.

135. *But see*, William M. Janssen, *Iqbal "Plausibility" in Pharmaceutical and Medical Device Litigation*, 71 LA. L. REV. 541 (2011) (discussing the rate in which motions to dismiss are granted in pharmaceutical and medical device cases completely turning on a *Twombly/Iqbal* analysis, noting, “[a]most 79% of the time, [*Twombly/Iqbal*] simply did not affect dispositive pleading motions in this cohort of cases . . . [i]n about 21% of the cases studied, [*Twombly*] was—based on language used in the opinions by the deciding courts—possibly impactful to all or part of the court’s disposition of a pending motion to dismiss. . . . It hardly seems credible to discount as inconsequential anything that happens about 21% of the time.”) *Id.* at 598.

136. *See* *Anthony v. Stryker*, No. 1:09-cv-2343, 2010 U.S. Dist. LEXIS 31031 (N.D. Ohio Mar. 18, 2010); *Bass v. Stryker*, 4:09-CV-632-Y, 2010 U.S. Dist. LEXIS 90226 (N.D. Tex. Aug. 31, 2010); *Covert*, 2009 U.S. Dist. LEXIS 68962; *Franklin*, 2010 U.S. Dist. LEXIS 71069; *Prudhel*, 2009 U.S. Dist. LEXIS 64402; *In re Medtronic, Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. 2009).

137. *Bausch v. Stryker*, 630 F.3d 546, 558 (7th Cir. 2010).

138. *Bass*, 2010 U.S. Dist LEXIS 90226 at *13.

139. *Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic (In re Medtronic)*, 623 F.3d 1200, 1205 (8th Cir. 2010) (noting, “the contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined”); *Prudhel*, 2009 U.S. Dist. LEXIS 64402, at *18, 25 (noting that “[d]istricts Courts are divided on what constitutes a ‘parallel claim’ under *Riegel*” and that courts are “further divided as to what *Twombly* requires of a plaintiff seeking to plead a parallel claim.”); *White v. Stryker*, No. 3:10-CV-544-H, 2011 U.S. Dist LEXIS 32568, at *12 (W.D. Ky. Mar. 25, 2011)

else, *Bass* instructs, despite detailed pleading and ample pre-litigation case analysis and investigation, the courts' wide latitude of interpretation of the MDA and trilogy cases is the most formidable barrier to prosecuting medical device claims. The obscurity of the trilogy cases has become a triple threat to persons injured by Class III medical devices resulting in repeated denial of due process and seeming jurisprudential tort reform. It is with this judicial backdrop that this article suggests the following methods for courts' application of the trilogy cases.

A. *Buckman's* Application Should be Very Limited

The basic ruling in *Buckman* is simple—an individual plaintiff cannot assert claims, such as fraud-on-the-FDA, against a manufacturer for noncompliance with the medical device provisions that would not otherwise give rise to common law liability.¹⁴⁰ Despite this relatively straightforward ruling and principal, courts have applied *Buckman* inappropriately in favor of preemption resulting in the dismissal of claims that should otherwise survive preemption analysis.¹⁴¹

One fatal misconstruction of *Buckman* has been the finding that even if common law claims are not barred by the federal preemption provision § 360k, they are nevertheless impliedly barred under § 337(a), which states, “all such proceedings for the enforcement, or to restrain violations” on the medical device provisions “shall be by and in the name of the United States.”¹⁴² Courts that subscribe to this *Buckman* interpretation reason that state common law claims that parallel federal law by alleging violations of

(stating, “while establishing a framework for this broad preemption, Riegel also raised many new questions”).

140. *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352–53 (2001). Though noncompliance with federal law may be cited by the plaintiff as evidence of the behavior that ultimately led to the plaintiff's injury, the claim must involve the type of conduct that would give rise to liability under state law even if the FDCA had never been enacted. *Id.*; see also *Riley v. Cordis*, 625 F. Supp. 2d 769, 776 (D. Minn. 2009).

141. *Bass*, 2010 U.S. Dist. LEXIS 90226; *Clark v. Medtronic*, 572 F. Supp. 2d 1090 (D. Minn. 2008); *Cornwell v. Stryker*, No. 1-10-00066-EJL, 2010 WL 4641112 (D. Idaho Nov. 1, 2010); *Hughes v. Boston Scientific*, 669 F. Supp. 2d 701 (S.D. Miss. 2009); *In re Medtronic, Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. 2009); *Lewkut v. Stryker*, 724 F. Supp. 2d 648 (S.D. Tex. 2010); *McCutcheon v. Zimmer Holdings*, 586 F. Supp. 2d 917, 922 (N.D. Ill. 2008); *Riley v. Cordis*, 625 F. Supp. 2d 769 (D. Minn. 2009); *Stengel v. Medtronic*, No. 10-318-TUC-RCC, 2010 WL 4483970 (D. Ariz. Nov. 9, 2010); *Timberlake v. Synthes Spine*, No. V-08-4, 2011 U.S. Dist. LEXIS 17034 (S.D. Tex. Feb. 18, 2011).

142. *Buckman*, 531 U.S. at 350, 352.

the FDCA are essentially “equivalent” to fraud on the FDA claims, and thus, *Buckman* preemption applies.¹⁴³

Nevertheless, *Buckman*’s application should be limited to those circumstances where the plaintiff’s claims are premised on violations *against the FDA* and/or fails to state a traditional common law cause of action. Conversely, consistent with *Riegel*, *Buckman* should not be applied in instances where the plaintiff asserts manufacturer violations *of the FDCA* in conjunction with a common law claim. In support, there is ample evidence that the *Buckman* Court’s quoting of § 337(a) was not intended to have the effect of barring all claims against manufacturers of medical devices.

First, the plurality in *Buckman* never states that § 337(a) serves to preempt *all* individual state tort claims alleging FDA violations. To the contrary, the *Buckman* Court acknowledges that claims that “parallel” FDA regulations would be allowable and suggests that had plaintiffs relied on traditional tort law that predated the FDCA, the claims may not have been preempted.¹⁴⁴ Further, if the *Buckman* Court’s intent in citing to § 337(a) was to bar all (or even most) common law claims, then it would not have gone through such great lengths in explaining the historical context of conflict preemption in finding that the *Buckman* plaintiffs’ claims were impliedly preempted, and instead, would have simply dismissed plaintiffs’ claims based solely on application of § 337(a).¹⁴⁵

Second, if it were the Supreme Court’s intent in *Buckman* to interpret § 337(a) to abolish all state law claims premised on violations of the FDCA, not only would the Court have stated so with no uncertain terms, but there would have been no need for the Supreme Court to examine the subsequent *Riegel*. Further, although *Riegel* clearly contemplates “parallel” claims alleging FDCA violations that survive federal preemption, there is absolutely no mention of *Buckman* nor § 337(a) in the *Riegel* opinion. It seems apparent that § 337(a) would have received at least a little attention from the *Riegel* Court if it were intended to bar all common law claims

143. See *Cornett v. Johnson & Johnson*, 998 A.2d 543, 556 (N.J. Super. Ct. App. Div. 2010) (stating, “[r]egardless of how the plaintiff styles a state claim, if it is a claim that could not be articulated but for the existence of a federal requirement that was allegedly violated, it is functionally equivalent to a claim that is grounded solely on the federal violation, and is therefore impliedly preempted.”); see also *Clark*, 572 F. Supp. 2d at 1095.

144. *Buckman*, 531 U.S. at 352–53.

145. However, it does make sense to bar claims premised on violations *against* the FDA under conflict preemption principals as raised by the *Buckman* Court. However, plaintiffs are advised to steer clear of any allegations that pertain to violations of the FDCA’s regulatory provisions absent a showing that the plaintiff could make the same allegation under a common law cause of action. The question practitioners should ask is how does the potential claim entitle the particular plaintiff to relief? If the answer is not promulgated by some underlying traditional common-law tort principal, such as a duty to the consumer, the answer is probably nothing.

alleging FDCA violations in the face of the *Riegel* Court's parallel claim exception to preemption. Hence, the district courts that preempt by equating the FDA's enforcement powers granted under § 337(a) with state common law claims that allege a device manufacturer's federal violations, do so inappropriately under *Riegel*.¹⁴⁶

Moreover, the language of § 337(a) is quite clear on what types of claims it prohibits—those that seek to “enforce” or “restrain” violations of the FDCA—and says nothing about excluding common law claims based on manufacturer duties owed to consumers. Though defendant manufacturers have continuously (and successfully) posited that common law tort actions have a regulatory effect, this is not the traditional function of the common law tort system. Unlike federal regulatory agencies, the tort system cannot impose restrictions on a manufacturer's advertising or labeling, give clearance to market dangerous products, or even take harmful products off the market.

Finally, when an injured party files a lawsuit against a defendant manufacturer of a device that has allegedly injured them, enforcement of the relevant law is rarely, if ever, the relief requested and is usually monetary compensation for the injuries sustained. Just because a jury may award damages to a harmed plaintiff based on a manufacturer's tortious conduct, tort actions should not be deemed “enforcement” or “restraint” as contemplated by § 337(a) because common law actions do not have the direct ability to do either. Indeed, the relationship between common law tort actions and the regulation of medical device manufacturers is a very obscure one, and there is no data supporting that a product liability lawsuit against any manufacturer has ever derived an *intended* regulatory result.

Moreover, the pleading of FDCA violations by the injured patient rarely warrants *Buckman* preemption so long as the allegations are grounded in traditional tort law.¹⁴⁷ Still, far too many lower courts have

146. *Riegel* clearly states that “360k does not prevent a State from providing a damages remedy for claims premised on “violations of the FDA regulations.” *Riegel v. Medtronic*, 552 U.S. 312, 330 (2008).

147. *Bausch v. Stryker*, 630 F.3d 546, 557 (7th Cir. 2010). For instance, a defendant-manufacturer in one district court argued that the plaintiff's claim that the defendant's device was “adulterated” under 21 U.S.C. § 351(h) must be preempted under *Buckman* because the plaintiff could not point to a state tort duty requiring that the defendant avoid manufacturing a product that was not adulterated. *Id.* The court disagreed with defendant's implied preemption argument, noting “[w]hile there may not be a ‘traditional state tort law’ claim for an ‘adulterated’ product . . . the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law.” *Id.* The court further reasoned, “[t]he evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient.” *Id.*

misapplied the *Buckman* ruling to the point where its ruling now seems hardly cognizable.

B. Courts Should be More Reluctant to Preempt Common Law Claims under *Riegel*

Although *Riegel* specifically states at the very end of its ruling that, “360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations,” the rest of the opinion is so contrary to this proclamation that it is hard to see what state common law claims the *Riegel* Court contemplated would survive 360k.¹⁴⁸ Additionally, since the *Riegel* Court specifically declined to address what state causes of action “parallel” rather than add to federal requirements, lower courts that cite *Riegel* in favor of preemption risk dismissing state claims that are perfectly permissible under § 360k(a).¹⁴⁹ Some lower courts have even acknowledged that *Riegel* does not provide adequate guidance on what constitutes a “parallel” claim or survive MDA preemption.¹⁵⁰

Hence, without specific instruction from *Riegel* on medical device parallel-claim-evaluation, lower courts must look at the legislative context from which the MDA’s preemption provision was born and the established principals behind federal preemption. When examining the MDA’s preemption provision within this relevant framework, there is a strong case that the preemption provision should not apply to common law tort causes

148. For instance, the *Riegel* Court notes, “while the common-law remedy is limited to damages, a liability award can be, indeed is designed to be, a potent method of governing conduct and controlling policy.” *Riegel*, 552 U.S. at 324. The opinion further notes in response to the dissent’s suggestion that Congress would not “remove all means for judicial recourse” for consumers injured by FDA-approved devices, that “this is exactly what a pre-emption provision clause for medical devices does by its terms.” *Id.* at 326. Further, *Riegel* suggests that common law tort remedies are even *more threatening* to the federal regulatory scheme than state positive laws stating in reference to the MDA “excluding common-law duties from the scope of pre-emption would make little sense . . . one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation . . . it is implausible that the MDA was meant to ‘grant greater power to a single state jury than to state officials acting through state administrative or legislative processes.’” *Id.* at 325. (emphasis added)

149. Since the MDA is unclear on what causes of action are preempted, the only causes of action that are safely preempted by the MDA are those that present “requirements” that are more stringent than traditional state causes of action. Arguably, these are the types of regulations the drafters of the MDA were most concerned with in the first place. See *Massachusetts v. Hayes*, 691 F.2d 57 (1st Cir. 1982).

150. See *Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic (In re Medtronic)*, 623 F.3d 1200, 1204 (8th Cir. 2010) (noting, “the contours of the parallel claim exception were not addressed in *Riegel* and are as-yet ill-defined”); *White v. Stryker*, No. 3:10-CV-544-H, 2011 U.S. Dist LEXIS 32568, at *12 (W.D. Ky. Mar. 25, 2011) (stating, “while establishing a framework for this broad preemption, *Riegel* also raised many new questions.”).

of action at all, and should instead, only apply to specific state statutes and regulations that potentially conflict with federal regulations.

1. Congress Did Not Intend to Ban All Common Law Causes of Action Against Medical Device Manufacturers

At the time the MDA was enacted, the primary concern was protection of consumers, so it is quite ironic that the legislation has become the epitome of manufacturer protection. There is an abundance of evidence suggesting that the preemption provision of the MDA was not intended to broadly exclude all state causes of action against medical device manufacturers (or even most) as so many district courts have interpreted. Hence, courts should be less hasty to preempt and must “start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”¹⁵¹

First, the legislative history of the MDA suggests that Congress had no intention to abandon all state common law tort remedies with respect to medical devices, and in fact consistent with public demand at the time, the MDA was initiated to provide *additional* protection to consumers. The MDA was spawned following public outcry for greater regulation of medical devices after a series of medical device failures in the early 1970s.¹⁵²

Among these device failures was the Dalkon shield, an intrauterine device used by “two million American women, and hundreds of thousands of women overseas, before the very significant health hazards of the device became known.”¹⁵³ As noted in the introduction of the Senate Report on the bill, “many of the deaths and much of the illness attributed to this device could have been prevented if the medical device legislation . . . had

151. *Medtronic v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Rice v. Santa Fe Elevator*, 331 U.S. 218, 230 (1947)). Moreover, “any time a federal court holds that a state law remedy is preempted it creates tension within our federalist system.” 16-107 JAMES WM. MOORE ET AL., *MOORE'S FEDERAL PRACTICE - CIVIL* § 107.14 (3d ed. 2004). Therefore, the Supreme Court has counseled that if a decision “will upset the usual constitutional balance of federal and state powers . . . ‘it is incumbent upon the federal courts to be certain of Congress’s intent before finding that federal law overrides’ this balance.” *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (quoting *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 243 (1985)); *see also Lohr*, 518 U.S. at 486–491.

152. *See* S. Rep. No. 94-33, at 6 (1975) (“Some 10,000 injuries were recorded, of which 731 resulted in death. For example, 512 deaths and 300 injuries were attributed to heart valves; 89 deaths and 186 injuries to heart pacemakers; 10 deaths and 8,000 injuries to intrauterine devices.”); 122 Cong. Rec. 5859 (1976) (as noted by Representative Waxman, “[a] 10-year FDA death-certificate search found over 850 deaths tied directly to medical devices.”).

153. S. Rep. No. 94-33, at 1–2.

been in effect when the Dalkon shield was developed.”¹⁵⁴ As one witness at the 1973 committee hearings on the bill noted:

[u]nder current standards of nonregulation in the United States, I could take a paperclip and fashion it into an IUD. I could begin inserting it into women without even informing them that it is an experimental and never-tested IUD, and I would not even have to inform the FDA of my newly invented IUD.¹⁵⁵

It was this level on *non-regulation* with which Congress was concerned, and resulted in enactment of the MDA. As Senator Edward Kennedy explained introducing the bill in the Senate in 1976, “[t]he legislation is written so that the benefit of the doubt is always given to the consumer . . . after all it is the consumer who pays with his health and his life for medical device malfunctions.”¹⁵⁶

Further, as the *Lohr* Court noted, at no point in the introduction of the MDA to Congress, in the hearings, Committee Reports, or debates was there a suggestion that the legislation’s proponents desired a “sweeping preemption of traditional common-law remedies against manufacturers and distributors of defective devices . . . [i]f Congress intended such a result, its failure to even hint at it is spectacularly odd, particularly since Members of both Houses were acutely aware of ongoing product liability litigation.”¹⁵⁷

The importance of legislative intent to preemption analysis is also underscored by Justices Stevens’ and Justice Ginsburg’s respective concurring and dissenting opinions in *Riegel*. Understanding the grave effect of the majority’s interpretation of § 360k(a), Justice Stevens noted, “the significance of the pre-emption provision in the Medical Device Amendments of 1976 . . . was not fully appreciated until many years after it was enacted.”¹⁵⁸

Justice Ginsburg’s dissent, detailed with a recital of preemption jurisprudence and Congressional motives relating to the MDA, was in stark contrast to the majority’s opinion which was devoid of any attention to the preemption doctrine or Congressional intent.¹⁵⁹ Citing several notable previous Supreme Court cases addressing preemption, Justice Ginsburg

154. *Id.*

155. *Id.* at 8.

156. 121 CONG. REC. 10688 (1975).

157. *Medtronic v. Lohr*, 518 U.S. 470, 491 n.13 (1996).

158. *Riegel v. Medtronic*, 552 U.S. 312, 330–31 (2008) (Justice Stevens, concurring).

159. *Id.* at 335 (Justice Ginsburg, dissenting) (citing *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005)).

noted that “[t]he purpose of Congress is the ultimate touchstone of pre-emption analysis.”¹⁶⁰

Reiterating the sentiments of the *Lohr* court, Justice Ginsburg also pointed out, “Congress did not regard FDA regulation and state tort law claims as mutually exclusive.”¹⁶¹ The sole dissenter, she remarked that the MDA as interpreted by the majority, “cut deeply into a domain historically occupied by state law . . .” and cites to authority suggesting that where there is more than one possible interpretation of a preemption clause, the court should accept the reading that disfavors preemption.¹⁶² Further, Justice Ginsburg noted, “[t]he Court’s broad reading of § 360k(a) . . . was not mandated by Congress and is at odds with the MDA’s central purpose: to protect consumer safety.”¹⁶³

Similarly, Justice Stevens also made the point that there was “nothing in the pre-enactment history of the MDA that suggested that Congress thought state tort remedies impeded the development of medical devices” and agreed with the dissent that the passage of the MDA was Congressional intent to provide more protection against medical device manufacturers, not less.¹⁶⁴ Justice Stevens further argued that the *Riegel* majority’s opinion regarding Congressional motives with regards to the MDA was misstated when it determined that “excluding common-law duties from the scope of the pre-emption provision would make little sense.”¹⁶⁵

Given that neither the MDA nor any other federal law speaks to redress for plaintiffs when they have been harmed by a defective medical device, Congress did not clearly signal “its intent to deprive States of any role in protecting consumers from the dangers inherent in many medical devices.”¹⁶⁶ Moreover, the fact that the MDA is itself silent with respect to what common law claims are preempted by clearance of the PMA process is significant.¹⁶⁷

160. *Id.* at 334 (Justice Ginsburg, dissenting) (citing *Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992)).

161. *Id.* at 343–44.

162. *Id.* at 333, 335.

163. *Id.* at 345 (Justice Ginsburg, dissenting).

164. *Id.* at 331 (Justice Stevens, concurring).

165. *Id.* at 325, 331–32 (majority at 325; Justice Stevens, concurring at 331–32).

166. *Medtronic v. Lohr*, 518 U.S. 470, 489 (1996); *see also* *Silkwood v. Kerr-McGee*, 464 U.S. 238, 251 (1984) (as the Supreme Court acknowledged in *Silkwood*, if Congress intended to give a defendant immunity from individual tort actions, Congress would have expressly stated that intent in less ambiguous terms or this intent would, at a minimum, be reflected in the legislative history).

167. Additionally, the legislative facts in the medical device context are consistent with those evaluated by the Supreme Court in *Silkwood* in which the court was called upon to evaluate preclusion of state tort remedies under the Atomic Energy Act of 1954. *Silkwood*, 464 U.S. at 251. As the *Silkwood* Court reasoned, “[t]here is no indication that Congress even seriously considered precluding use of such remedies when it enacted the Atomic Energy Act of 1954 or when it amended it in 1959 . . . [t]his silence takes on added significance in light of Congress’ failure to

As noted by *Lohr*, when Congress enacted § 360k, it was more concerned with “the problem of specific, conflicting state statutes and regulations rather than general duties enforced by common-law actions.”¹⁶⁸ The purpose of the MDA was to develop a better regulatory system for medical devices that would provide consumers more protection.¹⁶⁹ If the goal was for manufacturers to strictly adhere to this new federal system, it makes sense to allow manufacturers an exemption from specific state statutes that differ from the federal regulations. However, it does not make sense to allow manufacturers escape liabilities that arise solely due to the inherent danger or condition of its devices.

The *Lohr* Court was also correct when it stated that the term “requirements” as used in the MDA, pertained to “specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries.”¹⁷⁰ The “different from or in addition to” language set forth in the preemption provision supports this proposition and suggests that Congress was looking toward preempting State “requirements” that would impede the FDA’s role of regulating effectively, and was much less concerned with common law actions that have no proven intentional regulatory effect.

2. *The Conclusions Reached in Riegel Defy Sound Preemption and Tort Principals*

The primary argument offered by proponents of *Riegel* in favor of preemption—that state common-law tort remedies necessarily interfere with federal regulatory objectives—is not an established principal in federal preemption doctrine.¹⁷¹ Traditionally, federal law only trumped state law when either: (1) the two are in direct conflict and it is impossible to comply with both; or (2) where a federal law is so comprehensive that there would be no role for state law to fill.¹⁷² As illustrated in the remainder of this section, neither of these situations applies to common law tort actions against device manufacturers seeking monetary damages. This is

provide any federal remedy for persons injured by such conduct . . . [i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.” *Id.*

168. *Lohr*, 518 U.S. at 489–90. *Lohr* also notes, in 360k subsection (b) the FDA is given “authority to exclude certain ‘requirements’ from the scope of the pre-emption statute.” *Id.* However, *Lohr* further notes, of the 22 exemptions from pre-emption that the FDA has granted, “none even remotely resemble common-law claims.” *Id.*

169. *Id.* at 475–76.

170. *Id.* at 488.

171. See *Riegel v. Medtronic*, 552 U.S. 312, 322–26 (2008).

172. *Silkwood*, 464 U.S. at 248 (citing *Pacific Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm’n*, 461 U.S. 190 (1983)).

significant because although the *Riegel* Court purports to leave the door open to a set of undefined so-called “parallel claims,” it gave medical device manufacturer defendants plenty of ammunition to advance seemingly traditional conflict preemption arguments by equating state regulatory statutes with common law actions, thereby excluding almost all common law claims whether plausibly “parallel” or not.

Though defendants have craftily advanced preemption arguments by equating positive state laws with common law actions that provide a monetary remedy to plaintiffs harmed by defective medical devices, this is a wholly inappropriate inference. Of course, a state statute, for example, that requires a hearing test evaluation by a physician or audiologist prior to purchase of a hearing aid despite federal law waiving this requirement, should be preempted on the grounds that it would conflict with federal law.¹⁷³ Such a statute would have a regulatory intent and effect, in a field occupied by the FDA. It does not necessarily follow, however, that tort actions stemming from a defect in such a device also have the same regulatory effect.

The Supreme Court has examined this proposition in other contexts. In *Silkwood v. Kerr McGee*, for example, the Court evaluated the States’ traditional authority to provide tort remedies to its citizens and the Federal Government’s desire to maintain exclusive regulatory authority over the safety aspects of nuclear power through the Atomic Energy Act.¹⁷⁴ Although the legislation was enacted because of the States’ “inability to formulate effective standards” for the “operation of nuclear power plants,” the Supreme Court found no indication that Congress ever intended to eliminate state tort remedies when the statute was enacted.¹⁷⁵

Rejecting the defendants’ conflict preemption argument, the Court concluded that allowing state tort actions and the award of punitive damages did not conflict with the federal regulatory scheme since paying both federal fines and state-imposed punitive damages would not be physically impossible nor did exposure to punitive damages frustrate any purpose of the federal remedial scheme.¹⁷⁶ The *Silkwood* Court also disagreed with the defendant’s frustration of purpose argument noting that the award of punitive damages did not hinder the accomplishment of the purposes stated in the Act.¹⁷⁷ As the *Silkwood* Court noted, “Congress did not believe that it was inconsistent to vest the [federal government] with exclusive regulatory authority over the safety aspects of nuclear

173. *Massachusetts v. Hayes*, 691 F.2d 57 (1st Cir. 1982).

174. *Silkwood*, 464 U.S. at 248.

175. *Id.* at 250–51.

176. *Id.* at 253–54.

177. *Id.* at 255.

development while at the same time allowing plaintiffs . . . to recover for injuries caused by nuclear hazards.”¹⁷⁸

Consider also *Sprietsma v. Mercury Marine*, where the Supreme Court considered whether a state common law tort action seeking damages from an outboard boat motor manufacturer was preempted by the Federal Boat Safety Act of 1971.¹⁷⁹ The Federal Boat Safety Act examined by the Court included an express preemption provision very similar to the MDA preemption provision which states in part, “a State or political subdivision of a State may not establish, continue in effect or enforce a law or regulation . . . that is not identical to a regulation prescribed under . . . this title.”¹⁸⁰

Despite the defendant’s argument that the express preemption provision preempted all state positive law and common law claims, the court reiterated the sentiments of the *Silkwood* Court noting that “[i]t would have been perfectly rational for Congress not to preempt common law claims, which unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims.”¹⁸¹

The Supreme Court also examined the common-law-tort-as-regulation subject in *Bates v. Dow Agrosciences*, where the facts are even more on point to the medical device preemption issue.¹⁸² In that case, the court decided whether the Federal Insecticide, Fungicide, and Rodenticide Act (FIFR Act) preempts state common-law claims seeking damages.¹⁸³ Containing a near-identical provision like the one found in the MDA, the FIFR Act preemption provision directs, “a State shall not impose or

178. *Id.* at 258. *See also* *Goodyear Atomic v. Miller*, 486 U.S. 174 (1988). The Supreme Court examined whether the Supremacy Clause, or federal preemption principals, bars a state administrative agency from awarding an increased workers’ compensation benefit based on violations of state safety standards at a federally owned nuclear plant operated by a private contractor. The Court found that the additional award was acceptable and clearly viewed monetary damages as substantially different from positive state law: and noted, “Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not” under the Supremacy Clause. *Id.* at 186.

179. *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002).

180. 46 U.S.C. § 4306 (2006); *see also* *Sprietsma*, 537 U.S. at 58–59. Note that The Act also includes a savings clause stating “compliance with this chapter . . . does not relieve a person from liability at common law or state law.” 46 U.S.C. § 4311 (2006). Note however, the Court suggests that it would have come to the same conclusion even absent this savings clause noting that the language in the preemption provision “is most naturally read as not encompassing common law claims . . .” *Id.* at 63.

181. *Sprietsma*, 537 U.S. at 64.

182. *Bates v. Dow Agrosciences*, 544 U.S. 431 (2005).

183. *Id.*

continue in effect any requirements for labeling or packaging in addition to or different from” federal regulatory requirements.¹⁸⁴

Notwithstanding this preemption provision, the Court specifically addressed the term “requirement” as used in the provision and in doing so made the distinction between a state’s regulatory statutes (positive law) and individual common law claims.¹⁸⁵ Coming to a very different conclusion than the *Riegel* Court on the meaning of the term “requirement,” the *Bates* Court decided that the preemption provision did not preclude the plaintiff’s common-law tort claims and explained, “[a] requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.”¹⁸⁶

From the above-noted cases the inference can be made that preemption provisions, unless expressly noted otherwise, do not serve to preempt general common law tort claims seeking damages, and instead, target positive state law and/or direct regulatory state measures.

Further, these cases consistently note the compensatory role the tort system serves to consumers. The bottom line is federal regulatory agencies very rarely compensate plaintiffs for tort damages. The fundamental essence of the American products liability tort system is the recognition that even medically or socially beneficial products cannot be created without flaw and can cause injury to the consumer. The development of these products is encouraged through allowing them to enter the stream of commerce, despite the potential inherent danger of those products, for the benefit of the consumer and the profit of the company. However, medical device advances should never be inspired by the lack of recourse for plaintiffs when those products injure or kill.

When considering the above, it makes the suggestion that the MDA preemption provision somehow gives medical device manufacturers a “free pass” from tort liability seem misguided at the very least.¹⁸⁷ Instead of reading the *Riegel* ruling as a blanket scapegoat toward federal preemption where people have been injured by defective devices, the courts should look at the legislative intent of the MDA and apply its preemption provision sparingly to instances where a State’s positive regulatory measures are at issue.

184. *Id.* at 442.

185. *Id.* at 445.

186. *Id.*

187. See *Williams v. Cyberonics*, No. 09-3800, 2010 U.S. App. LEXIS 16060, at *9–10 (3rd Cir. July 30, 2010) (stating, “*Riegel* is loud and clear: if a manufacturer complies with the premarket approval, it gets a free pass.” (emphasis added)).

C. Courts Must Avoid a Heightened Pleading Standard in the Name of *Twombly*

Federal preemption arguments are commonly raised by defendant manufacturers on a Federal Rule of Civil Procedure 12(b)6 motion to dismiss.¹⁸⁸ However, few medical device complaints should be dismissed on a motion to dismiss for failure to meet the pleading requirements of *Twombly/Iqbal* due to federal preemption. Not only are such challenges to medical device plaintiffs' allegations better suited for summary judgment after the parties have had the opportunity to conduct discovery, but more importantly, courts should show reluctance in dismissal because of the lack of clarity on what *Twombly* requires in the medical device litigation context.¹⁸⁹

First, the plain language of *Twombly* rejects the idea that its holding represents a heightened or altering of the traditional pleading requirements.¹⁹⁰ *Twombly* merely established two "easy to clear hurdles" in pleading an 8(a)(2)-compliant complaint: (1) fair notice to the defendant; and (2) a plausible right to relief.¹⁹¹ As *Twombly* and subsequent medical device and non-medical device cases alike have acknowledged, pleading specific facts are not necessary, and the complainant "need only 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'"¹⁹² Though the "facial plausibility" pleading requirement articulated by *Twombly* has been more controversial than the notice issue, *Iqbal*

188. Hence, even if plaintiff brings claims in state court, complaints should address *Twombly* pleading challenges and preemption issues at the outset since federal removal and/or a motion to dismiss will surely follow. Many courts routinely (and inappropriately) dismiss plaintiffs' claims that do not address federal preemption challenges *with prejudice* disallowing the plaintiff the opportunity to amend the complaint to address the purported pleading deficiencies. *See, e.g.*, Anthony v. Stryker, No. 1:09-cv-2343, 2010 U.S. Dist. LEXIS 31031 (N.D. Ohio Mar. 18, 2010); Bass v. Stryker, No. 4:09-CV-632-Y, 2010 U.S. Dist. LEXIS 90226 (N.D. Tex. Aug. 31, 2010); Bausch v. Stryker, No. 08 C 4248, 2008 U.S. Dist. LEXIS 99118 (N.D. Ill. Dec. 9, 2008); Forslund v. Stryker, No. 09-2134 (JRT/JJK), 2010 U.S. Dist. LEXIS 104227 (D. Minn. Sept. 30, 2010); Heisner v. Genzyme, No. 08-C-593, 2010 U.S. Dist. LEXIS 21339 (N.D. Ill. Mar. 8, 2010); Horowitz v. Stryker, 613 F. Supp. 2d 271 (E.D.N.Y. 2009); Parker v. Stryker, 584 F. Supp. 2d 1298 (D. Colo. 2008); Poole v. Hologic, No. 10-314, 2010 U.S. Dist. LEXIS 76653 (W.D. La. July 29, 2010); Steen v. Medtronic, No. 3:10-CV-936-L, 2010 U.S. Dist. LEXIS 65579 (N.D. Tex. June 25, 2010).

189. Bausch v. Stryker, 630 F.3d 546, 561–62 (7th Cir. 2010) (stating that the district committed an error when it granted defendant's 12(b)(6) motion to dismiss rather than requiring the defendant plead preemption as an affirmative defense and later moving for judgment on the pleadings under Rule 12(c)).

190. Boykin v. Keycorp, 521 F.3d 202, 213–14 (2d Cir. 2008); C. Sensations v. City of Grand Rapids, 526 F.3d 291, 296 (6th Cir. 2008); CBT Flint Partners v. Goodmall Sys., 529 F. Supp. 2d 1376 (N.D. Ga. 2007); EEOC v. Concentra Health Servs., 496 F.3d 773, 776 (7th Cir. 2007).

191. *Concentra Health Servs.*, 496 F.3d at 776.

192. *Id.* *See also* Hofts v. Howmedica, 597 F. Supp. 2d 830 (S.D. Ind. 2009); Bausch v. Stryker, 630 F.3d 546 (7th Cir. 2010).

instructs that a claim has facial plausibility when the plaintiff “pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”¹⁹³

Not only have many courts dismissed 8(a)(2)-compliant pleadings based on a *Twombly* analysis in medical device cases, but the *Twombly* pleading issue is further complicated by the necessity that a plaintiff state a “parallel claim” under *Riegel*. In effect, this has required plaintiffs state “parallel claims” not only to rebut the presumption of preemption, but also to survive dismissal motions. As outlined above, stating a parallel claim is a highly difficult task, given the lack of direction in the *Riegel* ruling. Hence, courts should look at the pleading requirements of *Twombly* and the parallel claim requirement of *Riegel* as two distinct issues, and again, show restraint in dismissing claims based on *Riegel* at the initial pleading stage.¹⁹⁴

Imposing that plaintiffs properly state a parallel claim to survive pleading dismissal, when there is no clear precedence on what parallel causes of action exist, is a near-impossible burden and invites arbitrary dismissal of claims against medical device manufacturers.¹⁹⁵ Accordingly, if the complaint contains factually-sufficient allegations that give the defendant fair notice of the claims against it that would otherwise survive a *Twombly/Iqbal* analysis, the causes of action should not be dismissed solely based on the perceived failure to state a “parallel” claim.¹⁹⁶ If, however, a

193. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1944 (2009).

194. Despite this Article’s position that the *Twombly* heightened pleading issue and the *Riegel* parallel claim requirement should be treated as two distinct issues, the reality for practitioners is most courts evaluate these matters as one and the same. Consequently, if the plaintiff fails to state a “parallel claim” in a medical device complaint, the pleading inevitably risks failing a *Twombly* analysis. Though many plaintiff practitioners are typically reluctant to file claims in federal court, every medical device complaint should be drafted to meet a *Twombly* analysis whether the plaintiff’s case is originally filed in federal or state court. The reason for this is medical device defendants routinely file removal motions after being served with a medical device state court complaints arguing that the cause of action involves a federal question since the regulation of medical devices is governed by the FDCA and because the issue is federally preempted. Once the case is removed to federal court, the federal rules apply, including the heightened pleading standard in *Twombly*. See FED. R. CIV. P. 81(c) stating “[t]hese rules apply to civil actions removed . . . from state courts and govern procedure after removal.” See also *Willy v. Coastal*, 503 U.S. 131, 135–36 (1992).

195. Additionally, the perception that a parallel claim has not been alleged, since there has been no determination on what constitutes a parallel claim, does not necessitate a finding that an entitlement to relief is not “plausible on its face” under *Twombly* and *Iqbal*.

196. See *White v. Stryker*, No. 3:10-CV-544-H, 2011 U.S. Dist. LEXIS 32568, at *13 (W.D. Ky. Mar. 25, 2011) (“In the context of MDA preemption, *Twombly* and *Iqbal* make a plaintiff’s job more difficult than it would be in a typical product liability case . . . [w]hen facing MDA preemption, a plausible cause of action requires, among other things, a showing that the alleged violation of state law parallels a violation of federal law . . . [t]his additional step requires some greater specificity in the pleadings . . . our appellate courts have been unable to agree upon the precise level of that specificity.”).

plaintiff fails to plead an essential element of its common law claim, (e.g., that the alleged defect in the product was a proximate cause of the plaintiff's injuries) then obviously the pleading fails a *Twombly/Iqbal* analysis and should be dismissed.¹⁹⁷

Furthermore, the rationale behind the traditional relaxed pleading standards of the Federal Rules was not to keep litigants out of court, but rather to keep them in and subsequently allow the merits of the claim to survive or fail through the pretrial process.¹⁹⁸ Given this historical backdrop, and the fact that even under *Twombly/Iqbal* “the court must consider all well-pled allegations in a complaint as true,” and “must construe all factual allegations in the light most favorable to the plaintiff,” a complaint that pleads sufficient facts to appropriately state a cause of action and give the defendant notice should not be dismissed for failure to state a “parallel” claim.¹⁹⁹

Additionally, although *Twombly* contemplates that a proper pleading contain specific statements of “circumstances, occurrences and events in support of the claim[s] presented,” *Iqbal* heeds that “[d]etermining whether a complaint states a plausible claim for relief . . . [should] be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.”²⁰⁰

In applying a common-sense approach to medical device complaints, courts must consider that much of the product-specific information about manufacturing needed to state the specifics of such a claim is proprietary information kept confidential by federal law and would not be available to the plaintiff until formal discovery is conducted.²⁰¹ The Seventh Circuit has acknowledged in the medical device context that, “the victim of a genuinely

197. For example, though the plaintiff in *Ilaraza v. Medtronic* asserted numerous violations of the FDCA, he failed to tie the allegations to the injuries alleged. *Ilaraza v. Medtronic*, 677 F. Supp. 2d 582 (E.D.N.Y. 2009). The court noted that the plaintiff in that case “failed to set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged,” and hence, the plaintiff did nothing more than “recite unsupported violations of general regulations.” *Id.* The court also noted that the device in question, an implanted pain medication pump, functioned for five years without incident before a CT scan revealed a break in the catheter portion of the implanted pump. *Id.* Therefore, the court held, absent specific facts connecting the federal violations with the injury, “the allegation that general manufacturing violation caused the particular problem [that plaintiff experienced] seems all the more remote.” *Id.*

198. *Bell Atl. v. Twombly*, 550 U.S. 544, 575 (2007) (Justice Stevens citing *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506 (2002) in dissenting opinion); *Leatherman v. Tarrant Cnty.*, 507 U.S. 163, 168–69 (1993); *Conley v. Gibson*, 355 U.S. 41, 47–48 (1957).

199. *Twombly*, 550 U.S. at 589; *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009).

200. *Iqbal*, 129 S. Ct. at 1937.

201. *Bausch v. Stryker*, 630 F.3d 546, 558 (7th Cir. 2010). *See also* *Sprint Fidelis Prods. Liab. Litig. v. Medtronic (In re Medtronic)*, 623 F.3d 1200, 1209 (8th Cir. 2010) (where the dissent notes, “to apply *Twombly* rigidly without permitting discovery . . . effectively creates an impossible-to-achieve specificity requirement”).

defective product . . . may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem.”²⁰² As a result, it is quite typical in product liability actions to allow the injured plaintiff to plead multiple theories of liability, then pursue discovery on each theory.²⁰³

Finally, without Congressional advisement on what is required to state a plausible claim for relief with regards to medical device complaints specifically, the district courts should err on the side of caution in dismissing claims since doing so leaves injured patients with no future remedy. Obviously, pleading requirements vary depending on the nature of the case, and fair notice under Rule 8(a)(2) absolutely depends on the type of case—some complaints will require a greater level of detail to make a showing that the pleader is entitled to relief.²⁰⁴ Since pleading requirements have become so significant to the preemption discussion in medical device cases, federal court cohesion on *Twombly*'s effect on plaintiffs' claims is necessary and should be addressed by amendment to the MDA and/or Federal Rules of Civil Procedure.²⁰⁵

This proposition is not meant to suggest that every area of civil litigation should be visited by Congress post-*Twombly* in order to articulate what is required for proper pleading. However, the medical device preemption issue has been the source of massive controversy for nearly four decades even before the *Twombly* pleading issue was introduced. The injection of *Twombly* into medical device litigation, as interpreted in conjunction with *Riegel*, could very well represent the complete demise of deserving claims against medical device manufacturers. Accordingly, as a matter of public policy and judicial efficiency, identification by higher authority of the proper content of a medical device complaint is necessary.

VI. CONCLUSION

202. *Bausch*, 630 F.3d at 560.

203. *Id.* See also *Braden v. Tornier*, No. C09-5529RJB, 2009 WL 3188075, at *3 (W.D. Wash. Sept. 30, 2009) (stating, “[p]laintiffs properly point out that whether a product’s defect was due to its design or manufacture is the sort of information that is gained in discovery . . . [t]o force plaintiffs to plead facts in support of the theory would shut the courthouse doors before Plaintiffs had an opportunity to meaningfully engage in the process.”).

204. *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 230 (3d Cir. 2008).

205. The Federal Rules have spoken specifically to other complex areas of litigation, such as patent litigation. See FED. R. CIV. P. 84; see also *CBT Flint Partners v. Goodmall Sys.*, 529 F. Supp. 2d 1376, 1380 (N.D. Ga. 2007) (where the court was able to look at Fed. R. Civ. P. 84. Form 16, which provides a model for stating a claim in a patent infringement case, and contains “extremely barebones factual allegations identifying the patent and the infringing product.” The court was able to look at the model complaint and determine “[t]he form is not appreciably different from the allegations contained in the [plaintiff’s] Complaint . . . ” and prevented dismissal of the plaintiffs’ claims based on application of *Twombly*).

Because of the loud cry from large business for massive tort reform, which has been repeatedly rejected over the past two decades, court officials have been woefully persuaded to blatantly ignore over a century of well-settled tort and procedural law precedence in favor of denying due process to those injured by hazardous devices. This tort referendum in disguise warrants not only careful consideration by judges all over the country, but by lawmakers as well as the American public considering the enormous investment this country has made in medical devices implanted in patients all over the nation.²⁰⁶ With regards to consumer safety, the goal for the courts, legislature and public should, and always must be, to find a delicate balance between compensation for the injured and promotion of medical innovation. The current tort regime with respect to medical devices and the injured strikes nowhere near that necessary balance.

Healthcare is one of the most important and highly contested issues in modern politics, and medical device manufacturers have purchased front row seats to observe the political crossfire as they sit back and joyfully watch while shielded from liability due to federal preemption. They well-know that the recent governmental push for stricter device manufacturer scrutiny through certain provisions of the Patient Protection and Affordable Care Act is a promising starting point for safer device products and consumer recourse; however, as the MDA and the FDA premarket approval process has taught over the last four decades, there is simply no replacement for the necessary and vital role of the American tort system to consumer safety.²⁰⁷

206. A Senate Finance Committee report issued in late 2010 showed that Medicare paid more than \$108.9 billion from 2003 to 2009 for 6.9 million procedures in which medical devices were used. *See* Staff of Comm. on Finance, 111th Cong., Report on Cardiac Stent Usage at St. Joseph Medical Center 57 (Comm. Print 2010).

207. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). The Act included a number of provisions that would affect medical device manufacturers and healthcare providers. First, the Act seeks to increase scrutiny of the financial relationship between device manufacturers and physicians by requiring manufacturers to begin recording any physician payments worth more than \$10 (including any payments in the form of stock options, research grants, consulting fees, and medical conference travel). *See* H.R. 3200 [111th] at <http://www.gpo.gov/fdsys/pkg/BILLS-111hr3200ih/pdf/BILLS-111hr3200ih.pdf>. The legislation also included expansion of the definitions of “abuse” and “fraud” with respect to the Anti-Kickback Statute and False Claims Act promoting increased government oversight of the healthcare industry and medical device companies. *Id.* The bill also proposes better dissemination of comparative effectiveness research to the public and limitations on special interest organization influence on the Centers for Medicare and Medicaid Services. *Id.* A 2.6 percent excise tax on medical device sales expected to generate more than \$20 billion in ten years to offset the costs of increased coverage for Americans. *See* Patient Protection and Affordable Care Act Pub. L. No. 111-148, 124 Stat. 119 (2010); *see also* Pub. L. No. 111-148, 124 Stat. 1029, Sec. 1405 (2010). Note that the initial healthcare bill also proposed a national medical device registry requiring device makers to register distributed devices by type, model and serial number and was intended to

Unfortunately for those injured and/or killed by the most dangerous medical devices, the courts' improper application of the trilogy cases stiffens Class III medical device manufacturers' incentives to remain cautious and thoughtful toward the safety of the products they place on the market. Until the Medical Device Amendments are reformed by the legislature and courts begin to take heed of the grave injustices they are doing thousands across the country, manufacturers are practically given a golden ticket to promote and push premature and dangerous devices through the premarket approval process and into the stream of commerce.

assist the Department of Health and Human Services in evaluating the safety and effectiveness of medical devices through tracking means. *See* H.R. 3200 [111th] at <http://www.gpo.gov/fdsys/pkg/BILLS-111hr3200ih/pdf/BILLS-111hr3200ih.pdf>. However, the registry was not included in the final version of the legislation.