Drugs, Devices & Discovery:
Using Fee-Shifting to Resolve the Twombly/Iqbal Problem for Parallel Claims Under the FDCA

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I. INTRODUCTION

What else can be said about Twombly and Iqbal? Among lower federal courts, Twombly is now one of the top three most cited Supreme Court decisions of all time (and Iqbal is not far behind). Among scholars, Twombly and Iqbal are a popular target of study, criticism, and even ridicule. Commentators disagree, for example, whether plausibility pleading will shut the courtroom doors to aggrieved plaintiffs, spare defendants from costly discovery, or have any effect at all.

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2 In March 2010, Professor Adam Steinman noted that Twombly and Iqbal were being cited more frequently than any other Supreme Court case, ranking #7 and #76, respectively, on the list of the most cited Supreme Court decisions of all time. Adam N. Steinman, The Pleading Problem, 62 STAN. L. REV. 1293, 1295 n.9, 1357 tbl.1 (2010). As of March 2014, according to a search I conducted on WestlawNext, Twombly has surpassed the Supreme Court cases that were ranked #3–#6 on Professor Steinman’s list, see id. at 1357 tbl.1, amassing more than 93,000 total citations in the lower federal courts. Similarly, the citations to Iqbal have grown tenfold (to approximately 71,000) since Professor Steinman published his article.

3 It is hard to understand the ire that these cases have provoked from some scholars. See, e.g., Dawinder S. Sidhu, First Korematsu and Now Ashcroft v. Iqbal: The Latest Chapter in the Wartime Supreme Court’s Disregard for Claims of Discrimination, 58 BUFF. L. REV. 419, 426 (2010) (ranking Iqbal side-by-side with Korematsu in terms of the “worst decisions in Supreme Court history”); Steve Subrin, Ashcroft v. Iqbal: Contempt for Rules, Statutes, the Constitution, and Elemental Fairness, 12 NEV. L.J. 571 passim (2012) (choosing Iqbal as his candidate for “The Worst Supreme Court Case Ever”).


These scholarly debates, though lively, remain theoretical and abstract. Civil-procedure scholars have not yet found a class of cases where Twombly and Iqbal make it impossible for plaintiffs to proceed to discovery.7 This Article contends, however, that such a class of cases exists: state-law tort claims against medical-device manufacturers.

After the Supreme Court’s decision in Riegel v. Medtronic, Inc.,8 most private suits against manufacturers of medical devices are preempted by the Food, Drug, and Cosmetic Act (FDCA).9 The only exceptions are so-called “parallel claims”—state-law causes of action based solely on violations of federal law. However, the federal requirements that apply to medical-device manufacturers are contained in premarket approval agreements that are confidential. Therein lies the rub for an injured plaintiff: to access discovery after Twombly and Iqbal, the complaint must contain enough factual material to state a plausible claim, yet all of the relevant factual material is confidential and out of reach.

The Twombly/Iqbal problem for parallel claims is significant: it leaves injured consumers uncompensated and device manufacturers underdeterred. Unsurprisingly, the lower federal courts have struggled to apply plausibility pleading to parallel claims. Most appellate courts have faithfully adhered to Twombly and Iqbal, even though it leaves injured plaintiffs with no remedy at all. The Seventh Circuit has adopted a more plaintiff-friendly approach, but it stretched the reasoning of Twombly and Iqbal to get there.

Both of these approaches are flawed. This Article contends that, instead of adjusting pleading standards, fee-shifting provides a more promising solution. Other civil-procedure scholars have mentioned fee-shifting as a potential avenue for regulating the discovery process.10 This Article takes their suggestions a step further by crafting a specific fee-shifting mechanism and applying it to a particular class of claims.

This Article proceeds in four parts. Part II gives some background information about medical devices, preemption, and pleading standards. Part III discusses the circuit split over the application of Twombly and Iqbal to parallel claims. Part III also explains how the Seventh Circuit employed faulty legal analysis but identified an important policy problem that needs to be addressed. To remedy the Twombly/Iqbal problem for parallel claims, Part IV advocates that Congress enact a one-way fee-shifting mechanism, whereby plaintiffs could access premarket approval agreements if they will pay the defendant’s discovery costs should their claims prove unsuccessful. Part V briefly concludes.

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7 Some commentators posit that Twombly and Iqbal have made it more difficult for particular types of claims to survive a motion to dismiss. See, e.g., Victor D. Quintanilla, Beyond Common Sense: A Social Psychological Study of Iqbal’s Effect on Claims of Race Discrimination, 17 MICH. J. RACE & L. 1, 5 (2011) (employment discrimination cases); Patricia Hatamyar Moore, An Updated Quantitative Study of Iqbal’s Impact on 12(b)(6) Motions, 46 U. RICH. L. REV. 603, 605 (2012) (civil rights cases); Raymond H. Brescia, The Iqbal Effect: The Impact of New Pleading Standards in Employment and Housing Discrimination Litigation, 100 Ky. L.J. 235, 239–40 (2012) (employment and housing discrimination cases). However, the impact of Twombly and Iqbal in these areas has been marginal, at best. See Engstrom, supra note 6.
8 552 U.S. 312 (2008).
II. BACKGROUND

Before discussing the circuit split over Twombly/Iqbal and parallel claims, this Part provides some essential background information. Section A explores key provisions of the FDCA—specifically, the premarket approval process for Class III medical devices. Section B discusses the Supreme Court’s decision in Riegel v. Medtronic, Inc., which held that state-law claims regarding medical devices are preempted unless they parallel federal law. Section C summarizes Twombly and Iqbal and the extent to which these decisions changed the pleading standards in federal court.

A. Regulating Medical Devices Under the FDCA: The Premarket Approval Process

The FDCA authorizes the United States Food and Drug Administration (FDA) to regulate both drugs and medical devices. “Drugs” include pills, liquids, and anything else that is “metabolized” in order to treat a disease.11 A “medical device” is essentially everything that is not a drug—i.e., an “instrument,” “machine,” “implant,” or “component.”12 Medical devices range from relatively innocuous items like Band-Aids and tongue depressors to life-saving technologies like pacemakers and surgical lasers.13

Congress began regulating medical devices in 1976 with the enactment of the Medical Device Amendments (MDA).14 The MDA groups medical devices into three classes.15 Class III devices are subjected to the most stringent federal oversight. These devices are considered much riskier because they either (1) are used in life-or-death situations or (2) lack scientific studies about their safety and effectiveness.16 FDA must grant premarket approval (PMA) to Class III devices before they can be sold to the public.17

PMA is a rigorous, time-consuming, and expensive process. Manufacturers of Class III devices must submit a multivolume application to FDA that includes all studies and investigations of the device, every component of the device, how the device is manufactured, samples of the device, and the proposed labeling for the device.18 FDA spends an average of 1,200 hours reviewing each application for PMA.19 Then, the agency weighs the costs and benefits of introducing the device into the market.20 If FDA approves the device, the agency imposes specific regulations regarding its design, manufacture, and labeling, which are codified in a PMA agreement.21 The manufacturer must follow the requirements laid out in the PMA agreement and may not make any modifications to the device without approval from FDA.22 Because PMA agreements contain trade secrets and other sensitive information, they are mostly confidential.23

11 21 U.S.C. § 321(g)-(h).
12 Id. § 321(h).
16 Id. § 360c(a)(1)(C).
17 Id. § 360e.
18 See Riegel, 552 U.S. at 317–18.
19 Id. at 318.
20 Id. at 318–19.
21 Id. at 319.
22 Id.
B. Preemption and Parallel Claims After Riegel

Beyond its obvious costs, the PMA process also provides regulatory benefits. Most importantly, the MDA contains a preemption provision for medical devices. Under section 360k:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.24

The Supreme Court considered how this preemption provision applied to Class III medical devices in *Riegel v. Medtronic, Inc.* 25 The plaintiffs in *Riegel* brought a diversity suit against Medtronic for injuries that Mr. Riegel sustained from an allegedly defective catheter (a Class III medical device). 26 The Riegels brought several state-law claims against Medtronic related to the design, manufacture, and labeling of the catheter.27 Medtronic contended that the Riegels’ claims were preempted by section 360k of the FDCA. Thus, the Supreme Court had to decide whether the Riegels’ common-law claims were “different from, or in addition to” the relevant federal requirements and whether the claims “relate[d] to the safety or effectiveness of the device.”28 According to Justice Scalia’s majority opinion, this latter determination was straightforward: safety and effectiveness are the “very subjects” of products liability and negligence.29 Moreover, the state-law claims were clearly “different from” the federal requirements; the Riegels were alleging that Medtronic violated state tort law even though the company complied with federal law.30 Thus, the Riegels’ state-law claims were preempted.

*Riegel* did not hold, however, that all state-law claims against device manufacturers are preempted by the MDA. Rather, the Court carved out an exception for so-called “parallel claims.”31 According to the Court, section 360k “does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”32 The Supreme Court did not specify which types of claims could be parallel or what exactly a plaintiff would need to allege to avoid preemption in the future.

Given the Supreme Court’s lack of clarity in *Riegel*, the law on parallel claims remains murky.33 Nevertheless, some general principles have emerged. First, a parallel

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26 *Id.* at 320.
27 *Id.*
28 *See* 21 U.S.C. § 360k(a).
29 *Riegel*, 552 U.S. at 323.
30 *Id.* at 330.
31 *Id.*
32 *Id.*
33 *See* J. David Prince, *The Puzzle of Parallel Claims, Preemption, and Pleading the Particulars*, 39 WM. MITCHELL L. REV. 1034, 1051 (2013) (“While many cases have raised the issue of whether a state-law claim merely parallels federal requirements applicable to a medical device, they are inconsistent in their outcomes and are not entirely clear. . . .”); *see also* Demetria D. Frank-Jackson, *The Medical Device Federal Preemption Trilogy: Salvaging Due Process for Injured Patients*, 35 S. ILL. U. L.J. 453, 470 (2011) (“*Riegel* [did not] give much direction as to what constitutes a parallel claim, and the district courts have largely had to figure this out for themselves.”).
claim must be grounded in state law. Congress did not provide plaintiffs with a federal cause of action under the FDCA, either expressly or impliedly. Second, a parallel claim must actually be parallel—the state-law duty must exactly mirror a federal-law requirement. The most straightforward example of a parallel claim is negligence per se, where a violation of federal law also constitutes a breach of the defendant’s state-law duty of care. Plaintiffs have also alleged other types of parallel claims—design defects, manufacturing defects, failures-to-warn, etc.—with varying degrees of success. Importantly, the relevant federal requirements that govern a particular Class III device are primarily located in the manufacturer’s PMA agreement with FDA: the document that contains the labeling, design, and manufacturing requirements for each medical device. As a result, the PMA agreement is often an essential source of information for plaintiffs pleading parallel claims.

As mentioned above, the FDCA itself does not create a private right of action. Therefore, U.S. district courts lack federal question jurisdiction over parallel claims. Nevertheless, these cases are commonly litigated in federal court because the parties are diverse and the defendant-manufacturer files a notice of removal. But once the case arrives in federal court, the federal pleading standards apply—namely, Twombly and Iqbal.

34 See Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 349 n.4 (2001) (“The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: ‘[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.’ 21 U.S.C. § 337(a).”); see also, e.g., In re Orthopedic Bone Screw Prods. Liab. Litig., 193 F.3d 781, 788 (3d Cir. 1999) (“It is well settled . . . that the FDCA creates no private right of action.”); PDK Labs, Inc. v. Friedlander, 103 F.3d 1105, 1113 (2d Cir. 1997) (same); Bailey v. Johnson, 48 F.3d 965, 968 (6th Cir. 1995) (same).

35 See Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996) (holding that parallel state-law claims are not preempted when they “merely provide[] another reason for manufacturers to comply with identical existing ‘requirements’ under federal law.”).

36 See, e.g., Martin v. Medtronic, Inc., 254 F.3d 573, 583 (5th Cir. 2001) (“In the context of the PMA process, we agree that state tort suits that allege, as the basis of their claim, that the approved FDA requirements have not been met are not preempted.”). However, many states preclude negligence per se when the underlying statute does not create a private right of action. See Mark Herrmann et al., The Meaning of the Parallel Requirements Exception Under Lohr and Riegel, 65 N.Y.U. ANN. SURV. AM. L. 545, 573 & n.169 (2010) (collecting cases). This presents an obvious obstacle when plaintiffs rely on the FDCA. See supra note 34.

37 See Herrmann et al., supra note 36, at 575–79.

38 See Jean Macchiaroli Eggen, Navigating Between Scylla and Charybdis: Preemption of Medical Device “Parallel Claims,” 9 J. HEALTH & BIOMEDICAL L. 159, 175–83, 189–93 (2013); see also In re Medtronic Inc., 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (“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 Corp., 584 F. Supp. 2d 1298, 1301 (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.”’).


40 See supra note 34.

41 See, e.g., Bailey v. Johnson, 48 F.3d 965, 968 (6th Cir. 1995) (dismissing a parallel claim for lack of jurisdiction where the plaintiff only alleged federal question jurisdiction).


43 Many states have adopted the pleading requirement of Twombly and Iqbal as well. Jill Curry & Matthew Ward, Are Twombly & Iqbal Affecting Where Plaintiffs File? A Study Comparing Removal Rates by State, 45 TEX. TECH L. REV. 827, 856 (2013) (listing twelve states with fact-pleading, as opposed to notice-pleading, standards). Thus, even if a case asserting parallel claims is not removed, plaintiffs may face
C. Twombly and Iqbal: A (One-Off?) Revolution in Pleading Standards

Most readers are already familiar with Twombly and Iqbal—two landmark cases that are now required reading for all first-year law students. Nevertheless, it is helpful to briefly recount the two key holdings from those decisions, especially given their outsized importance in cases involving parallel claims.

First, Twombly and Iqbal replaced the lax notice-pleading requirements from Conley v. Gibson with a more stringent plausibility standard. According to the Supreme Court, a complaint must state a claim to relief that is “plausible on its face,”44 as determined by a judge’s “judicial experience and common sense.”45 Plausibility requires “more than a shear possibility that the defendant has acted unlawfully.”46 Furthermore, the plausibility of a claim depends on the amount of factual material that the plaintiff includes in the complaint; district courts “are not bound to accept as true a legal conclusion couched as a factual allegation.”47 Plaintiffs cannot merely offer “a formulaic recitation of the elements” or an “unadorned, the-defendant-unlawfully-harmed-me accusation.”48

The second major holding from Twombly and Iqbal has not drawn as much scholarly attention, but it is equally important. Combined, the two cases stand for the proposition that the Federal Rules of Civil Procedure are trans-substantive: they apply the same way in every case. After Twombly, courts and commentators thought that plausibility pleading might be limited to antitrust cases.49 However, the Court explicitly rejected this argument in Iqbal: “Our decision in Twombly expounded the pleading standard for all civil actions, and it applies to antitrust and discrimination cases alike.”50 Indeed, the text of Rule 8(a)(2) is clearly and broadly written; it does not make an exception for antitrust or any other type of case.51 Thus, the plausibility standard from Twombly and Iqbal applies in equal measure to every type of civil litigation in the federal courts (with the exception of fraud52).

Although the Court in Twombly and Iqbal claimed to be merely “interpreting” Rule 8,53 the decisions marked a dramatic departure from the liberal regime of notice pleading.54

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45 Iqbal, 556 U.S. at 679.
46 Id. at 678.
47 Twombly, 550 U.S. at 555 (emphasis added) (citation omitted).
48 Iqbal, 556 U.S. at 678; Twombly, 550 U.S. at 555.
50 Iqbal, 556 U.S. at 684 (2009) (emphasis added) (citation and internal quotation marks omitted).
51 See FED. R. CIV. P. 8(a)(2) (requiring complaints to contain a “short and plain statement of the claim showing that the pleader is entitled to relief”); see also FED. R. CIV. P. 1 (explaining that the Rules apply “in all civil actions and proceedings in the United States district courts”).
52 See FED. R. CIV. P. 9(b) (requiring a heightened pleading standard for fraud claims).
53 Iqbal, 556 U.S. at 684.
54 See Fitzpatrick, supra note 6, at 1622, 1628, 1635 (characterizing Twombly and Iqbal as a “jarring shift,” a “fundamental[] transform[ation],” and a marked departure from the Court’s prior precedents).
What prompted this change? As Professor Brian Fitzpatrick has explained, the costs of discovery have skyrocketed in recent years due to the emergence of multinational corporations and advanced file-storage technologies. Document review in a single case can cost millions of dollars. As Professor Brian Fitzpatrick has explained, the costs of discovery have skyrocketed in recent years due to the emergence of multinational corporations and advanced file-storage technologies. Document review in a single case can cost millions of dollars. In Twombly and Iqbal, the Supreme Court finally seemed attuned to these costs and the attendant risk of nuisance settlements—perhaps due to the appointment of Chief Justice Roberts, the only Justice with recent experience in private litigation. The Twombly Court voiced concerns that “the threat of discovery expense will push cost-conscious defendants to settle even anemic cases.” The Court repeated this refrain in Iqbal, worrying that a plaintiff armed with “a largely groundless claim” could use discovery to “take up the time of a number of other people” in order to extract “an in terrorem increment of the settlement value.” Front-end constraints at the pleading stage are needed, according to the Court, because judges are unwilling and unable to exercise supervision over the discovery process.

Given the Court’s seeming departure from prior precedent and its newfound concern with discovery costs, many commentators thought that Twombly and Iqbal would dramatically increase the number of complaints that were dismissed in the lower federal courts. However, this prediction did not come to fruition: the consensus of empirical studies suggests that Twombly and Iqbal have had little, if any, effect. Professor Fitzpatrick explains these counterintuitive results by drawing on an earlier article by Christopher Fairman about the pre-Twombly pleading practices in the lower federal courts. In essence, the lower federal courts had tightened up pleading standards years ago; the Supreme Court was simply catching up in Twombly and Iqbal. Since the Court merely ratified what the lower federal courts were doing anyway, it is unsurprising that Twombly and Iqbal have not fundamentally changed the situation on the ground for litigants.

This Article does not challenge the empiricists on this point. For the vast majority of cases, Twombly and Iqbal will have little effect on day-to-day litigation in federal courts. However, there is one notable, yet overlooked exception: parallel claims against medical

55 Id. at 1638–42.
56 Id. at 1640.
57 See id. at 1633 n.75 (noting that, other than Chief Justice Roberts, no other Justice on the Supreme Court has been in private practice since the 1970s).
60 Twombly, 550 U.S. at 559 (“Judges can do little about impositional discovery when parties control the legal claims to be presented and conduct the discovery themselves.” (quoting Easterbrook, supra note 10, at 638)).
61 See, e.g., Stephen B. Burbank, Pleading and the Dilemmas of Modern American Procedure, 93 Judicature 109, 110 (2009) (“As a result of Twombly and Iqbal, lower federal courts so inclined are essentially free to use that standard to rid their dockets of cases deemed to place unwarranted demands on the judiciary or that are for some other reason disfavored.”); Kevin M. Clermont & Stephen C. Yeazell, Inventing Tests, Destabilizing Systems, 95 Iowa L. Rev. 821, 823 (2010) (“The headline need no longer equivocate after [Twombly and Iqbal]: Pleading Left Bleeding. The Court has revolutionized the law on pleading.”); Thomas P. Gressette, Jr., The Heightened Pleading Standard of Bell Atlantic Corp. v. Twombly and Ashcroft v. Iqbal: A New Phase in American Legal History Begins, 58 Drake L. Rev. 401, 455 (2010) (“There can be no doubt that [Twombly and Iqbal] mark[] the beginning of a new phase in the history of American pleading requirements.”).
62 See Engstrom, supra note 6.
63 See Fitzpatrick, supra note 6, at 1631–34 (citing, inter alia, Christopher M. Fairman, The Myth of Notice Pleading, 45 Ariz. L. Rev. 987 (2003)).
64 Id.
device manufacturers. In these cases, *Twombly* and *Iqbal* present not just a challenge, but an *insurmountable barrier* for plaintiffs who have been injured by medical devices.  

### III. Analysis

The lower federal courts have begun to acknowledge the difficulties that plaintiffs face when the pleading standard from *Twombly* and *Iqbal* meets the preemption doctrine from *Riegel*. Section A of this Part explains the precise nature of this problem. Section B then explores the various approaches that the circuit courts have taken to address this issue. Sections C and D look specifically at the Seventh Circuit—the outlier among the federal courts of appeals—and contend that it misapplied *Twombly/Iqbal* but tapped into an important policy concern that needs to be resolved.

#### A. The *Twombly/Iqbal* Problem for Parallel Claims

Commentators have described the pleading standard from *Twombly* and *Iqbal* as a “grave,”66 “astronomical,”67 and “virtually impossible”68 burden for plaintiffs who try to plead parallel claims against device manufacturers. The *Twombly/Iqbal* problem for parallel claims stems from the confidential nature of PMA agreements. As explained above, PMA agreements contain the design, manufacturing, and labeling requirements that FDA imposes on a Class III medical device—i.e., the federal-law requirements that a plaintiff would rely on when asserting a parallel claim.69 However, because PMA agreements contain trade secrets and other sensitive business information, they are confidential and cannot be obtained by the public (absent formal discovery).70 *Twombly* and *Iqbal* require plaintiffs to include enough factual material to “nudge[] their claims across the line from conceivable to plausible.”71 Yet, plaintiffs possess virtually no relevant factual information until they obtain a copy of the PMA agreement. For instance, without the PMA agreement, the plaintiff does not know what federal requirements the defendant was supposed to follow, whether the defendant violated any of those requirements, or whether that violation caused the plaintiff’s injury. Put simply, plaintiffs need the facts to get discovery, but they need discovery to get the facts.

Consider, for example, the complaint filed in *Funk v. Stryker Corp.*72 There, Ronald Funk brought a suit for damages based on injuries he sustained from a prosthetic hip that Stryker Corp. manufactured.73 Funk’s initial complaint included a negligence claim that stated the following:

3. Defendant breached the duties it owed to Plaintiff, failed to exercise ordinary care, and was negligent in the following particulars, among others:

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65 See infra notes 66–68.
66 Frank-Jackson, supra note 33, at 454.
68 Williams, supra note 39, at 130.
69 See supra notes 38–39 and accompanying text.
70 See 21 C.F.R. § 814.9 (2014); Frank-Jackson, supra note 33, at 494.
72 631 F.3d 777 (5th Cir. 2011).
73 Id. at 779.
(a) designing, manufacturing and marketing a hip prosthesis that is defective in that it has a high propensity of poor bone fixation to occur;

(b) designing, manufacturing and marketing a hip prosthesis that is defective in that it has a high propensity for dislocation, wear and fracture of the prosthesis to occur;

. . . .

(g) failing to warn consumers in general, and Plaintiff or her physicians specifically, of the risk that the hip prostheses could become loose; . . . .

The prosthetic hip in question was a Class III medical device that had obtained PMA, so Stryker Corp. quickly moved to dismiss the complaint as preempted under Riegel. Realizing the error of his ways, Funk attempted to file an amended complaint that would assert non-preempted parallel claims. He added the following provisos to his negligence claim (which are underlined here):

3. Defendant breached the duties it owed to Plaintiff, failed to exercise ordinary care, and was negligent in the following particulars, among others:

(a) designing, manufacturing and marketing a hip prosthesis that contained impurities, residues and bacteria in violation of the FDA requirements and standards;

(b) designing, manufacturing and marketing a hip prosthesis that contained impurities, residues and bacteria in violation of the manufacturing processes approved by the FDA;

. . . .

(g) failing to adequately warn consumers in general, and Plaintiff or her physicians specifically, of the increased risk of infection with use of the prosthesis due to it containing impurities, residues and bacteria in violation of the FDA requirements and standards;

. . . .

Nevertheless, the district court and the court of appeals still dismissed Funk’s amended complaint under Rule 12(b)(6) for failure to state a claim.

It is easy to see why complaints like Funk’s do not satisfy the plausibility standard from Twombly and Iqbal. When Funk amended his complaint to avoid Riegel preemption, he simply restated his allegations and tacked on the phrase “in violation of FDA requirements.” However, this addendum is the quintessential example of what the

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75 Defendants Stryker Corporation, Stryker Sales Corporation and Howmedica Osteonics Corp.’s Rule 12(b)(6) Motion to Dismiss, Funk, 673 F.Supp.2d 522 (No. 09CV00733), 2009 WL 2352516.
76 See Defendants’ Motion to Strike and Motion for Leave to File Further Briefing in Response to Plaintiff’s Amended Complaint, Funk, 673 F.Supp.2d 522 (No. 09CV00733), 2009 WL 4737759.
77 First Amended Complaint, Funk, 673 F.Supp.2d 522 (No. 09CV00733), 2009 WL 4737758 (emphasis added).
78 Funk v. Stryker Corp., 631 F.3d 777, 779 (5th Cir. 2011).
79 See First Amended Complaint, supra note 77.
Twombly} Court characterized as “a legal conclusion couched as a factual allegation.” Funk clearly had no idea whether Stryker Corp. violated FDA requirements because the PMA agreement that contained those requirements was confidential. Thus, his addenda, though necessary to avoid preemption, were speculative and wholly conclusory.

Indeed, a plaintiff suing a Class III device manufacturer generally only knows two facts prior to discovery: (1) she was injured and (2) the defendant’s device caused her injury. However, the mere fact that the plaintiff was injured does not prove that the defendant violated a PMA requirement: medical devices are inherently dangerous, and FDA grants PMA with full knowledge that some adverse side effects are inevitable. According to Twombly, factual claims that are equally consistent with both legal and illegal behavior do not satisfy the plausibility requirement. Nor do these two facts plausibly suggest that the defendant’s alleged violation of its PMA agreement caused the plaintiff’s injuries—a prima facie element of all tort claims. The plaintiff’s injuries may have resulted from something the manufacturer did that actually complied with its PMA agreement. Accordingly, the proper application of Twombly and Iqbal should normally result in the dismissal of parallel claims.

B. The Resulting Circuit Split

This result seems hard to swallow. On the one hand, the Supreme Court held in Riegel that Congress chose not to preempt all state-law claims against device manufacturers. Yet, on the other hand, parallel claims—the only remaining non-preempted claims—are impossible to plead under Twombly and Iqbal. The federal courts have struggled to reconcile these seemingly diametric mandates. A circuit split has emerged over how Twombly and Iqbal ought to apply to parallel claims—a split that some scholars believe will eventually be resolved by the Supreme Court.

The Fifth, Eighth, and Eleventh Circuits take what this Article refers to as a “too bad, so sad” approach. These courts recognize the difficulties that parallel claims face.

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81 See Riegel v. Medtronic, Inc., 552 U.S. 312, 318 (2008); Heisner ex rel. Heisner v. Genzyme Corp., No. 08-C-593, 2008 WL 2940811, at *9 (N.D. Ill. July 25, 2008) (“Within the context of § 360k . . . the word ‘defect’ carries much less meaning, as any such ‘defect’ falling within the scope of the PMA essentially carries no weight for purposes of showing liability under state law.”)
82 See Twombly, 550 U.S. at 556–57 (dismissing an antitrust complaint that alleged parallel conduct because such conduct was consistent with both competitive and anti-competitive behavior); see also Funk v. Stryker Corp., 673 F. Supp. 2d 522, 531–32 (S.D. Tex. 2009) (rejecting plaintiff’s “circular” argument “that because he was injured . . . [the defendant] therefore violated FDA regulations”), aff’d, 631 F.3d 777 (5th Cir. 2011).
84 See Gross v. Stryker Corp., 858 F. Supp. 2d 466, 503 (W.D. Pa. 2012) (“[N]umerous district courts across the country have dismissed [PMA device] actions in their entirety at the motion to dismiss stage.”); Frank-Jackson, supra note 33, at 463 (“[S]cores of district courts have dismissed patients’ claims at the initial pleading stage . . . .”); see also William M. Janssen, Iqbal “Plausibility” in Pharmaceutical and Medical Device Litigation, 71 La. L. Rev. 541, 598 (2010) (finding that Iqbal was responsible for the dismissal of 21% of all pharmaceutical and medical device cases, which includes (but is not limited to) parallel claims against device manufacturers).
85 Compare Wolicki-Gables v. Arrow Int’l, Inc., 634 F.3d 1296 (11th Cir. 2011), and In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200 (8th Cir. 2010) [hereinafter Medtronic Leads], and Funk v. Stryker Corp., 631 F.3d 777 (5th Cir. 2011), with Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010).
86 Mitchell M. Breit et al., Charting the Course in Medical Device Preemption, 49-SEP TRIAL 28, 28 (2013).
87 See Wolicki-Gables, 634 F.3d 1296 (11th Cir. 2011); Medtronic Leads, 623 F.3d 1200 (8th Cir. 2010); Funk, 631 F.3d 777 (5th Cir. 2011).
under *Twombly* and *Iqbal*, but they conclude that plaintiffs are simply out of luck. In the words of the Eleventh Circuit, “Plaintiffs cannot simply incant the magic words ‘[Defendant] violated FDA regulations’ in order to avoid preemption.”\(^{88}\) Instead, these circuits require a well-pleaded parallel claim to (1) identify the specific PMA requirement that the defendant allegedly violated and (2) explain how that particular violation caused the plaintiff’s injury.\(^{89}\) Plaintiffs can rarely (if ever) meet these requirements.\(^{90}\)

Although a majority of courts follow the too-bad-so-sad approach, the Seventh Circuit has adopted a different standard. In *Bausch v. Stryker Corp.*, the Seventh Circuit was asked to apply the plausibility pleading standard to several parallel claims.\(^{91}\) Ms. Bausch, to her credit, stated quite a bit more factual detail in her parallel claims than the average plaintiff; her complaint noted that FDA had investigated one of Stryker Corp.’s facilities and found manufacturing deficiencies regarding the device in question (a device that was later recalled by Stryker Corp.).\(^{92}\) Thus, *Bausch* may have come out the same way even in one of the too-bad-so-sad circuits.\(^{93}\)

Nevertheless, the Seventh Circuit did not rule on narrow factual grounds, but rather spoke more broadly about how lower courts should apply *Twombly* and *Iqbal* to parallel claims in the future:

> [D]istrict courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.\(^{94}\)

In this portion of the opinion, the Seventh Circuit seemed to advocate a relaxed version of the plausibility standard in cases involving parallel claims against Class III device manufacturers. The Seventh Circuit explicitly endorsed the view of a dissenting judge in the Eighth Circuit that “a plaintiff’s pleading burden should be commensurate with the amount of information available to them [sic].”\(^{95}\) Otherwise, plaintiffs with parallel claims face an “impossible pleading standard” because “much of the critical information is kept confidential as a matter of federal law.”\(^{96}\)

C. *The Seventh Circuit Misapplied Twombly and Iqbal*

The Seventh Circuit’s decision to relax the normal pleading requirements for parallel claims is perhaps appealing from a policy perspective, yet its legal moorings are somewhat shaky. The too-bad-so-sad approach appears to be a more faithful application of Supreme Court precedent.

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\(^{88}\) *Wolicki-Gables*, 634 F.3d at 1301 (quoting *In re Medtronic Inc.*, 592 F.Supp.2d 1147, 1158 (D. Minn. 2009)).

\(^{89}\) See id. at 1301; *Medtronic Leads*, 623 F.3d at 1208; *Funk*, 631 F.3d at 782.

\(^{90}\) See supra Part III.A.

\(^{91}\) 630 F.3d 546 (7th Cir. 2010).

\(^{92}\) Id. at 559.

\(^{93}\) Several courts have distinguished *Bausch* on these grounds, i.e. that the complaint in that case included much more factual detail than usual. See, e.g., White v. Stryker Corp., 818 F. Supp. 2d 1032, 1040 (W.D. Ky. 2011); Desabio v. Howmedica Osteonics Corp., 817 F. Supp. 2d 197, 205 (W.D.N.Y. 2011); Rhynes v. Stryker Corp., No. 10–5619 SC, 2011 WL 5117168, at *5 (N.D. Cal. Oct. 27, 2011). However, the portions of *Bausch* where the Seventh Circuit clarified how *Twombly* and *Iqbal* should apply to parallel claims were not dicta and are an equally important part of the opinion.

\(^{94}\) *Bausch*, 630 F.3d at 558.

\(^{95}\) Id. at 561 (quoting *Medtronic Leads*, 623 F.3d at 1212 (Melloy, J., dissenting)).

\(^{96}\) Id. at 560.
Bausch misapplied the Supreme Court’s holdings in Twombly and Iqbal in two primary ways. First, the Seventh Circuit got the rationale behind Twombly and Iqbal exactly backward. According to the Seventh Circuit, plaintiffs need access to discovery before they can be expected to make out a parallel claim.97 Yet, Twombly and Iqbal both emphasize the opposite: plaintiffs should not be able to access discovery until they can state a plausible claim to relief with factual detail. The Twombly Court held that “some threshold of plausibility must be crossed at the outset before a . . . case should be permitted to go into its inevitably costly and protracted discovery phase.”98 Likewise, the Court in Iqbal reiterated that “Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.”99 Twombly and Iqbal equipped Rule 8(a)(2) with some real teeth and instructed the federal courts to be gatekeepers of the discovery process. The Seventh Circuit’s approach in Bausch seems like a statement from the bygone era of Conley v. Gibson, where pleadings were not much more than a formality.

The Seventh Circuit also departed from the other major holding from Twombly/Iqbal, i.e. that the Federal Rules of Civil Procedure are trans-substantive. Bausch endorsed a sliding-scale approach to pleadings, where the plaintiff’s burden is “commensurate with the amount of information available.”100 However, the Iqbal decision directly undermines this argument. The plaintiff in Iqbal accused several government officials of discrimination when the FBI arrested and imprisoned him in the wake of the 9/11 attacks.101 Much of the information that Iqbal needed to state his claims was likely classified, including the role that defendants Mueller and Ashcroft played in the alleged events.102 Yet the Iqbal Court refused to modify the pleading standards to account for Iqbal’s lack of access to information.103 It is hard to see why the confidentiality of PMA agreements is meaningfully different from the confidentiality of national security information—if anything, the latter seems less accessible to plaintiffs. Instead, the better reading of Iqbal is that the Federal Rules of Civil Procedure are trans-substantive; they do not change even when a plaintiff lacks access to information.

D. The Seventh Circuit Identified an Important Policy Problem

Despite its legal missteps, the Seventh Circuit did highlight an important policy problem. Under a proper application of Twombly and Iqbal, plaintiffs bringing parallel claims against Class III device manufacturers do indeed face an “impossible pleading standard” because PMA agreements are confidential.104 True, plaintiffs can obtain some information by submitting requests under the Freedom of Information Act (FOIA).105 But FOIA requests are notoriously slow, and the key portions of the PMA agreement—the design, engineering, and manufacturing specifications—are redacted in whatever copies

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97 Id. at 558 (“Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.” (emphasis added)).
100 Bausch v. Stryker Corp., 630 F.3d 546, 561 (7th Cir. 2010).
101 Iqbal, 556 U.S. at 667–69.
102 Cf. El-Masri v. United States, 479 F.3d 296, 309 (4th Cir. 2007) (finding that questions such as the nature of intelligence operations and what the head of the CIA knew about them are confidential state secrets).
103 See Iqbal, 556 U.S. at 684 ("Our decision in Twombly expounded the pleading standard for all civil actions, and it applies to antitrust and discrimination cases alike.").
104 Bausch, 630 F.3d at 560.
105 See Breit et al., supra note 87, at 30.
the plaintiff receives. In order to successfully assert a parallel claim, plaintiffs need access to the complete PMA agreement.

It may not be immediately obvious why the Twombly/Iqbal problem is even a “problem” at all. If plaintiffs can no longer sue after the fact, then the regulatory onus simply shifts to FDA to prevent injuries before the fact. Indeed, ex ante regulation is the dominant form of governance in Europe. The Supreme Court hinted at the desirability of such a regime in Riegel when it expressed skepticism about the ability of state courts to efficiently regulate medical devices. Unlike the “experts at the FDA” who use “cost-benefit analysis” to weigh the risks of a particular device, “[a] jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.” Arguably then, Class III medical devices should only be subjected to regulation by FDA.

Yet, this argument underestimates the important benefits that supplementary state-law claims could provide. First and foremost, tort remedies are essential to compensate plaintiffs for their injuries. An FDA-only regime may deter device manufacturers by threatening them with investigations and sanctions. However, without compensatory damages, individuals who suffer injuries from a medical device must foot their own hospital bills and doctors’ fees—a daunting task for many Americans. Compensation is especially important in this context because Class III devices pose an especially high risk of catastrophic injury.

Furthermore, FDA may not even do an adequate job deterring dangerous behavior by device manufacturers. FDA, like all agencies, is subject to capture by the industries that it regulates. In fact, the medical device arena is particularly prone to capture due to the small number of players involved, their strong incentives to organize, and the inability of the general public to understand complex scientific information. Capture, in turn, leads to lax regulations and weak enforcement by an agency. Furthermore, FDA recently reported that it lacks sufficient resources to conduct complete oversight over medical products—a concern that has been independently validated by the nonpartisan Governmental Accountability Office. Thus, FDA may be neither willing nor able to achieve its desired deterrence objectives.

These inadequacies are important because the American legal system should strive for full deterrence and full compensation. Such a regime minimizes the overall cost of accidents to society in the most efficient manner. A vibrant regime of parallel claims would facilitate both goals. It would increase compensation by awarding damages to

106 Id. at 30–31.
109 See Frank-Jackson, supra note 33, at 491 (“The bottom line is federal regulatory agencies very rarely compensate plaintiffs for tort damages.”).
110 See id.
111 See Williams, supra note 39, at 125.
112 See Raymond, supra note 42, at 776–77.
113 See id. at 776 n.148 (applying the “client politics” model created by James Q. Wilson to the medical device industry).
114 See id. at 776–77.
115 See U.S. Gov’t Accountability Office, GAO-09-581, Food & Drug Administration: FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs (2009) (citing a need for more information but concluding that “FDA reports that it cannot do all that is asked of it and our analysis of the agency’s activities confirms this.”).
injured plaintiffs, and it would increase deterrence by empowering private attorneys
general to go after noncompliant device manufacturers when FDA fails to do so.117

Moreover, parallel claims do not pose a serious threat to regulatory uniformity.
By definition, state-law claims must exactly parallel federal law, or else they will be
preempted under Riegel.118 Uniformity concerns should not arise unless state courts
are systematically less likely to enforce federal law. However, a recent empirical study
discredits this assumption, finding broad parity between state and federal courts in
the specific context of parallel claims.119 Thus, the desire to create uniform standards
for device manufacturers does not present an especially powerful justification for an
FDA-only regime.

Perhaps the simplest (and most powerful) argument against an ex ante, FDA-only
approach is that Congress never intended to create such a regulatory scheme. Professor
Demetria Frank-Jackson has identified evidence in the legislative history of the MDA
suggesting that Congress did not intend to completely preempt state-law claims and
only wanted to increase protection for consumers.120 But legislative history aside, there
is a much simpler and more reliable indicium of congressional intent: the text of the
MDA. The preemption provision in section 560k only covers state-law claims that are
“different from, or in addition to” federal requirements.121 All nine Justices in Riegel read
this to mean that, instead of complete preemption, Congress intended to carve out an
exception for parallel claims.122 However, as explained above, Twombly and Iqbal make
parallel claims a pipedream for most plaintiffs, leaving Congress’s intentions unfulfilled.

Of course, if the Twombly/Iqbal problem continues unabated, it could be argued that
Congress has acquiesced to the current state of affairs, where Rule 12(b)(6) keeps the
vast majority of parallel claims out of federal court.123 However, this proposition seems
dubious. Congressional inaction is notoriously weak evidence of legislative intent.124
Instead of acquiescence, inaction may simply reflect Congress’s ignorance of Supreme
Court decisions, the difficulties inherent in the legislative process, or both.125 Moreover,
inaction is more relevant because what matters is the intent of the enacting

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benefits of allowing private parties to assist in regulation via litigation, emphasizing their advantages in
detection and information-gathering).

118 See supra note 35 and accompanying text.

119 See Raymond, supra note 42, at 764 (“[T]here is broad parity between state and federal courts on
preemption and parallel claims, with in fact more state judges finding preemption than federal judges.”).

120 See Frank-Jackson, supra note 33, at 485–88.


122 Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008). The Riegel decision was 8–1, with a concurrence
by Justice Stevens and a dissent from Justice Ginsburg. These two Justices, however, essentially agreed with
the Court’s discussion of parallel claims; indeed, they would have given the MDA even less preemptive effect.
See generally id. at 330–32 (Stevens, J., concurring in part and concurring in the judgment); id. at 333–45
(Ginsburg, J., dissenting).

123 In the wake of Riegel, several bills were introduced in Congress that would have overturned the
Court’s decision. None were ever enacted. See Gregory J. Wartman, Life After Riegel: A Fresh Look at Medical

124 Bob Jones Univ. v. United States, 461 U.S. 574, 600 (1983) (“Ordinarily, and quite appropriately,
courts are slow to attribute significance to the failure of Congress to act on particular legislation.”); Wyeth v.
Levine, 555 U.S. 555, 603 (2009) (Thomas, J., concurring in the judgment) (“[O]nce the Court shows a
willingness to guess at the intent underlying congressional inaction, the Court could just as easily rely on its
own perceptions regarding congressional inaction to give unduly broad pre-emptive effect to federal law.”);
Schweiker v. Chilicky, 487 U.S. 412, 440 (1988) (Brennan, J., dissenting) (“Inaction, we have repeatedly
stated, is a notoriously poor indication of congressional intent . . . .”).

125 See Lawrence C. Marshall, “Let Congress Do It”: The Case for an Absolute Rule of Statutory Stare
(not its current members), and those intentions cannot be changed without going through the formal legislative process.\textsuperscript{126}

Furthermore, with \textit{Twombly/Iqbal} and parallel claims, congressional inaction is an even less persuasive argument, since this issue stems from the interaction of a statute and a \textit{procedural rule}. While Congress presumably legislates with its other statutes in mind,\textsuperscript{127} the Federal Rules are considered the domain of the Supreme Court, not Congress.\textsuperscript{128} It is unrealistic to assume that Congress has carefully considered the various interactions between the MDA (enacted in 1976) and the courts’ pleading standards (which changed dramatically in 2009 with the \textit{Iqbal} decision). Thus, the better argument seems to be that Congress intended to allow parallel claims against device manufacturers, but \textit{Twombly} and \textit{Iqbal} are now frustrating that goal.

However, the Seventh Circuit’s solution to this problem—tinkering with the pleading standards—is also lacking. PMA agreements are always confidential, so every plaintiff with a parallel claim could cite \textit{Bausch} to justify getting around the plausibility standard of \textit{Twombly/Iqbal}. Overturning \textit{Twombly} and \textit{Iqbal}, like many civil-procedure scholars advocate,\textsuperscript{129} is also not a satisfying alternative. As explained above, discovery has become quite expensive, which gives plaintiffs who get past Rule 12(b)(6) the leverage they need to extract a nuisance settlement from the defendant.\textsuperscript{130} These nuisance settlements, in turn, overdeter defendants and discourage them from performing socially beneficial behavior.\textsuperscript{131} These risks are only amplified in the context of medical devices. The PMA process is already expensive and time-consuming,\textsuperscript{132} so an abundance of nuisance settlements could dissuade device manufacturers from researching and developing potentially life-saving technologies. Instead, a middle ground is needed.

\textbf{IV. Solution}

The intersection of \textit{Twombly/Iqbal} with parallel claims presents a serious, unresolved policy problem. The federal courts of appeals have advanced two approaches, but neither is satisfactory. On the one hand, the too-bad-so-sad approach correctly interprets \textit{Twombly} and \textit{Iqbal}, but it leaves injured plaintiffs uncompensated and device manufacturers underdeterred. On the other hand, the Seventh Circuit’s permissive interpretation of \textit{Twombly} and \textit{Iqbal} is more plaintiff-friendly, but it is legally unsound and threatens device manufacturers with costly nuisance claims. This Article advocates a third way: Congress should create a one-way fee-shifting mechanism for parallel claims. This mechanism would allow plaintiffs to access discovery if they agree to pay the defendant’s discovery costs in the event that the case is dismissed at summary judgment. Section A of this Part provides a brief synopsis of the mechanics of fee-

\textsuperscript{126} \textit{Id.} at 193–96.

\textsuperscript{127} This presumption is sometimes known as the “whole code” canon. \textit{See Lisa Schultz Bressman et al., The Regulatory State} 232–35 (2010). However, given the massive breadth of the U.S. Code, this interpretative rule is less about congressional intent and more about the need to give coherence to the entire corpus juris. \textit{See Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts} 252–53 (2012).

\textsuperscript{128} \textit{See Fitzpatrick, supra} note 6, at 1635–36.

\textsuperscript{129} \textit{See supra} note 4.

\textsuperscript{130} \textit{See supra} notes 58–60 and accompanying text.

\textsuperscript{131} A. Mitchell Polinsky & Steven Shavell, \textit{Punitive Damages: An Economic Analysis}, 111 \textit{Harv. L. Rev.} 869, 878 (1998) (describing the overdeterrence problem and the desirability of a products-liability regime where the “magnitude of damages is equal to the harm the defendant has caused”).

\textsuperscript{132} \textit{See supra} notes 19–20 and accompanying text.
shifting. Section B then fleshes out how a one-way fee-shifting mechanism could work in the medical device context.

A. Fee-Shifting in Litigation: A Primer

The American Rule—whereby each side pays for their own litigation expenses—is firmly entrenched in the United States. Congress has occasionally created exceptions via fee-shifting statutes. However, absent explicit statutory authorization, courts refuse to require the losing party to pay the other side’s fees. Thus, even a prevailing party in the United States can be saddled with significant litigation expenses.

The American Rule stands in contrast to the English Rule—the “loser pays” mechanism used in other countries. Under the English Rule, losing parties must pay their own litigation expenses and the expenses of the other side. Stated differently, the English Rule forces litigants to internalize some of the other side’s litigation costs. Proponents of the English Rule believe that it deters frivolous litigation: plaintiffs must hesitate before pursuing weak cases because the costs associated with losing are much higher. Unsurprisingly then, tort reformers in the United States often propose replacing the American Rule with the English Rule in order to combat the perceived ills of excess litigation and its impact on the American economy.

However, the traditional English Rule also has some serious downsides, both empirically and theoretically. On the empirical side, the Rule tends to raise the frequency and cost of litigation wherever it is introduced. In 1980, doctors’ groups in Florida successfully lobbied the state legislature to adopt the English Rule in medical malpractice cases. Five years later, those same doctors’ groups were clamoring for the Rule to be repealed. Medical malpractice cases under Florida’s English Rule were


135 See Alyeska Pipeline Serv. Co. v. Wilderness Soc’y, 421 U.S. 240, 237 (1975) (“In the United States, the prevailing litigant is ordinarily not entitled to collect a reasonable attorneys’ fee from the loser. . . . [W] e are convinced that it would be inappropriate for the Judiciary, without legislative guidance, to reallocate the burdens of litigation . . . .”).

136 See Fitzpatrick, supra note 6, at 1644.


138 Katz & Sanchirico, supra note 133, at 1–2.

139 See Fitzpatrick, supra note 6, at 1645.


142 Katz & Sanchirico, supra note 133, at 30.

143 Id.
lasting much longer, and defendants were paying substantially more in both settled and litigated cases. The United Kingdom has reported similar results from its experience with the English Rule.

This outcome is unsurprising from a theoretical standpoint. Basic principles of law-and-economics explain why the English Rule tends to discourage settlement, prolong cases, and raise the overall cost of litigation. According to the traditional model of litigation, the plaintiff calculates the expected value of her case by multiplying her odds of winning by the amount of damages she could recover. The defendant makes the same calculation, multiplying his odds of losing at trial by the amount of damages he expects to pay. Assume there is a hypothetical plaintiff who thinks she has an 80% chance of recovering $100,000. Her expected value is $80,000. Assume also that the hypothetical defendant believes he has a 50% chance of losing $100,000. His expected value is $50,000. In a world of zero litigation costs, the plaintiff in this hypothetical would accept nothing less than $80,000 and the defendant would pay nothing more than $50,000. In other words, these parties would not settle.

However, real-world litigation is expensive, and settlement allows the parties to avoid the costs of litigation. Thus, the parties must factor these costs into their expected-value calculations (since, under the American Rule, the parties will pay their own legal fees regardless of the outcome). Assume that, in the hypothetical above, the costs of proceeding to trial will be $20,000 for each party. Accordingly, if the case goes to trial, the plaintiff now expects to recover $60,000, and the defendant expects to lose $70,000. There is now a settlement range of $60,000–$70,000 where both parties would be better off by avoiding trial. These parties would likely settle.

Of course, litigation costs and expected trial outcomes are not independent variables; spending more money on a case often increases a litigant’s probability of success. Assume, for example, that our hypothetical plaintiff can spend an additional $10,000 in litigation expenses and increase her odds of winning by 10%. If she made this investment, her expected value would still be $60,000. Thus, she would have no incentive to spend the extra $10,000 because it would not increase her expected recovery. A similar calculus applies on the defense side.

The English Rule upsets this traditional model in two ways. First, it decreases the likelihood of settlement. If the loser is required to pay the winner’s litigation expenses, then both parties will discount their expenses accordingly. In the example above, assume again that the litigation will cost each side $20,000. Under the English Rule,
the plaintiff’s expected litigation costs are now $8,000,$^{152}$ and the defendant’s costs are $20,000.$^{153}$ Under this scenario, the plaintiff will settle for no less than $72,000,$^{154}$ but the defendant will pay no more than $70,000. Therefore, these parties would not settle under the English Rule, even though they would have under the American Rule.

Second, the English Rule gives both parties an incentive to spend more on the litigation. Assume again that the plaintiff could spend an additional $10,000 to increase her odds of winning by 10%. Under the English Rule, this $10,000 is discounted by $8,000 (since she might win and have her litigation costs shifted to the defendant), so the plaintiff’s extra investment increases her expected value from $60,000 to $88,000.$^{155}$ Thus, the plaintiff now has an incentive to spend more on her case, although her additional expenditure would have been irrational under the American Rule. The defendant has the same incentives.

In sum, the traditional English Rule is not an ideal solution, given its tendency to increase the overall costs of litigation. However, the traditional English Rule has two important features: (1) it applies to all aspects of the case, and (2) it applies to both plaintiffs and defendants. A more limited version of the English Rule—like the one proposed in the next Section—could minimize these problems and structure the parties’ incentives in a more productive manner.

**B. A One-Way Fee-Shifting Solution for Parallel Claims**

This Article contends that Congress should amend the MDA to create a one-way fee-shifting mechanism that allows plaintiffs to access a defendant’s PMA agreement if the plaintiff agrees to pay the defendant’s discovery costs should the complaint be dismissed at the summary judgment stage (or earlier). Congress, rather than the courts, will need to implement this reform, given the Supreme Court’s refusal to deviate from the American Rule absent statutory authorization.$^{156}$ Likewise, private parties are unlikely to make such an agreement on their own; medical device manufacturers have no incentive to reveal any information to plaintiffs because *Twombly* and *Iqbal* already keep these cases out of court.$^{157}$ Thus, congressional action is required.

The fee-shifting mechanism envisioned here would be employed in the following manner. First, a plaintiff bringing a parallel claim would file an ordinary complaint, which would invoke the fee-shifting mechanism and request to see the defendant’s PMA agreement. If the complaint adequately set out the legal elements for one or more parallel claims,$^{158}$ then the court would allow the plaintiff to proceed to discovery, even though the complaint lacked factual material about how the defendant violated its PMA agreement or how that violation caused the plaintiff’s injury. Then, one of two scenarios would unfold. First, if the plaintiff discovers that the defendant did not violate its PMA agreement, she will dismiss the case and pay the defendant’s discovery expenses. On

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152 \[20\% \times (\$20,000 + \$20,000) = 20\% \times \$40,000 = \$8,000\]

153 \[50\% \times (\$20,000 + \$20,000) = 50\% \times \$40,000 = \$20,000\]

154 \[80\% \times \$100,000 - \$8,000 = \$80,000 - \$8,000 = \$72,000\]

155 \[90\% \times \$100,000 - \$2,000 = \$90,000 - \$2,000 = \$88,000\]


157 See Richard A. Nagareda, *1938 All Over Again? Pretrial as Trial in Complex Litigation*, 60 DePaul L. Rev. 647, 685 (2011) (“*Twombly* and *Iqbal* give the defendant no strategic reason to support—whether by rule change or by private contract in a given case—an alternative whereby it would trade away its chance at hitting the dismissal lottery.”).
the other hand, if the plaintiff discovers a potential violation of the PMA agreement, she will proceed to summary judgment. If the defendant prevails at summary judgment and the case is dismissed, then the plaintiff must pay the defendant’s discovery costs (and her own). If the plaintiff prevails at summary judgment on at least one parallel claim,159 then the American Rule applies, and the litigation proceeds like any other case.

Discovery costs are uniquely well-suited for a fee-shifting rule.160 Under the current system, a plaintiff who gets past the pleading stage gets unfettered access to discovery.161 Moreover, defendants pay their own discovery costs, so plaintiffs have an incentive to ask for as much information as possible, driving up the defendant’s legal fees to coerce a quick settlement.162 However, under a fee-shifting regime, plaintiffs would have to internalize some of the defendant’s discovery costs—i.e., the defendant’s fees multiplied by the probability that the plaintiff will lose at summary judgment.163 This, in turn, encourages plaintiffs to avoid discovery requests that are not cost-beneficial, and it discourages plaintiffs from bringing suits at all if their likelihood of success is below 50%.164

Why adopt a one-way fee-shifting mechanism rather than a reciprocal rule? As explained above, two-way fee-shifting gives litigants an incentive to spend more money to increase their odds of winning.165 When both parties can potentially shift their litigation expenses to the other side, they can become embroiled in a tit-for-tat arms race, where each dollar spent by the other side must be reciprocated in kind. One-way fee-shifting, on the other hand, does not create this incentive, at least not to the same degree. The party who has no chance of recovering her fees—here, the plaintiff—cannot discount her litigation expenses by the odds that she prevails. In fact, she must factor in the odds that she will lose and be forced to pay the defendant’s fees. Thus, the plaintiff lacks an incentive to participate in the arms race, which should substantially curtail the increased litigation costs that are associated with the traditional English Rule. Theoretical models bear this out.166

Of course, one-way fee-shifting creates perverse incentives of its own. Under a one-way rule like the one proposed here, the defendant would have an incentive to drive up its own discovery costs in order to make litigation less palatable for the plaintiff.167 However, this concern is less worrisome in the context of parallel claims against Class III device manufacturers. As explained before, the information that the plaintiff

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159 This rule could be modified to require the plaintiff to completely prevail at summary judgment. However, if a plaintiff files a lawsuit and demonstrates that the defendant violated federal law in at least one way, this seems like something that the legal system should reward.

160 Indeed, many scholars have proposed such a rule for all civil cases as an alternative to the plausibility standard that the Court imposed in Twombly and Iqbal. See supra note 10.

161 See Fitzpatrick, supra note 6, at 1644 (“Because pleading standards are all-or-nothing, once they are surpassed, plaintiffs are entitled to the ‘all.’”).

162 See Easterbrook, supra note 10, at 647 (“The paradigm impositional discovery request comes from a party thinking it has a relatively small chance of prevailing . . . but wanting to convey the message: ‘This suit will cost you $1 million whether I win or not; we can split that in settlement.’”); Fitzpatrick, supra note 6, at 1644.

163 See Fitzpatrick, supra note 6, at 1645.

164 See Easterbrook, supra note 10, at 647; Fitzpatrick, supra note 6, at 1645.

165 See supra Part IV.A.

166 See Mark Liang & Brian Berliner, Fee Shifting in Patent Litigation, 18 VA. J.L. & TECH. 59, 95–100 (2013) (demonstrating, with a theoretical model, that a pro-defendant one-way fee-shifting mechanism would decrease the frequency and cost of litigation).

167 See Fitzpatrick, supra note 6, at 1645; Liang & Berliner, supra note 166, at 107.
wants is mostly located in the manufacturers’ PMA agreement. Thus, the plaintiff should be able to make an initial discovery request that asks for no more than the PMA agreement—an important document that the defendant should be able to retrieve quickly and cheaply. Given the control that plaintiffs have over the discovery process (as the requesting party), combined with their access to risk-transferring mechanisms (like contingency fees), a one-way fee-shifting mechanism should not overly burden injured plaintiffs.

It still may seem unfair to place more risk on a one-shot plaintiff, rather than a repeat-player defendant. However, at the discovery stage, corporate defendants are actually disadvantaged vis-à-vis individual plaintiffs. Large corporate defendants bear the brunt of the costs of discovery; they possess the lion’s share of the relevant documents, and they must hire attorneys to sift through their massive file-storage databases. Thus, a one-way shifting rule actually distributes the costs of discovery more equitably between the parties. And regardless, the rule proposed in this Article would be optional for plaintiffs; if a plaintiff had enough information to survive Twombly and Iqbal, she could file an ordinary complaint without invoking the fee-shifting device. Plaintiffs would be free to avoid whatever unfairness is created by one-way fee-shifting.

Moreover, courts already use one-way fee-shifting in many cases, so any alleged unfairness is already present in the status quo. The Federal Rules empower courts to shift the costs of discovery on a case-by-case basis (though, fee-shifting needs to be automatic, rather than discretionary, to really achieve its benefits). Furthermore, Congress has enacted over two hundred statutes with one-way fee-shifting provisions (typically they are pro-plaintiff mechanisms). Indeed, one-way fee-shifting is just another regulatory mechanism in Congress’s arsenal that it can choose based on the particular regulatory context. It is hard to see why a general concern with treating plaintiffs and defendants differently should matter when there are good policy-based reasons for doing so. With parallel claims, a one-way fee-shifting rule simply recognizes that plaintiffs should bear more litigation risk than usual, since device manufacturers

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168 See supra notes 38–39 and accompanying text.
169 Congress may also want to amend Fed. R. Civ. P. 26(a) to allow plaintiffs in these cases to waive initial disclosures so that defendants cannot run up discovery expenses that way.
170 See Easterbrook, supra note 10, at 646 (responding to the argument that fee-shifting will discourage plaintiffs from bringing meritorious cases by stating that “the bar—which through the contingent fee device offers representation to many who could not pay hourly rates—readily could . . . spread the risk of unsuccessful ventures and cover the costs from successful ones.”).
171 The terms “one-shot” and “repeat player” refer to the disadvantages and advantages that certain parties have in litigation due to their size, wealth, experience, and risk preferences. These concepts were made famous by Marc Galanter in Why the “Haves” Come Out Ahead: Speculations on the Limits of Legal Change, 9 LAW & SOC’y REV. 95 (1974).
172 See Fitzpatrick, supra note 6, at 1637–43; Jonathan T. Molot, Fee Shifting and the Free Market, 66 VAND. L. REV. 1807, 1808 (2013) (“Corporate America is perhaps the most vocal critic of litigation expense—understandably so, given that large, deep-pocketed businesses so often are targeted as defendants and bear a disproportionate share of litigation’s burdens.”).
173 See Fed. R. Civ. P. 26(e) (“[T]he court . . . may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . . ”); e.g., Fed. R. Civ. P. 26(b)(2)(B) (allowing fee-shifting in the context of electronically stored information).
174 See William H. Wagener, Note, Modeling the Effect of One-Way Fee Shifting on Discovery Abuse in Private Antitrust Litigation, 78 N.Y.U. L. REV. 1887, 1896–98 (2003) (contending that judges are generally unwilling to shift discovery costs and that it is too hard for parties to predict ex ante when such shifting will occur); Redish & McNamara, supra note 10, at 821 (same).
176 See generally Margaret H. Lemos, Special Incentives to Sue, 95 MINN. L. REV. 782 (2011).
already go through an expensive PMA process and typically bear more of the costs of discovery.

Of course, medical device manufacturers would certainly lobby against this proposed reform.\textsuperscript{177} After all, \textit{Twombly} and \textit{Iqbal} currently give them de facto immunity from parallel claims. Nevertheless, the one-way fee-shifting mechanism proposed here could actually benefit device manufacturers. No matter the pleading standard, injured plaintiffs are going to keep filing parallel claims, and device manufacturers are going to keep paying their attorneys to draft answers and motions to dismiss. A fee-shifting mechanism, however, could stem some of this litigation by creating a kind of signaling mechanism. If several plaintiffs sue a particular manufacturer, access its PMA agreement, and lose their cases, it would become clear to the outside world that the manufacturer has not violated any PMA requirements. This, in turn, could deter other potential plaintiffs from suing the manufacturer in the first place.

Manufacturers will undoubtedly want assurances that the sensitive information in their PMA agreement will stay confidential. But such procedures are already available. Courts routinely employ mechanisms like protective orders and in-camera review to safeguard litigants' trade secrets, and these techniques could be used in medical device litigation as well.\textsuperscript{178} Finally, regardless of manufacturers' concerns, the burdens imposed by a fee-shifting mechanism are likely justified by the deterrence benefits to society and the compensation benefits to injured plaintiffs.\textsuperscript{179}

\section*{V. Conclusion}

The promise of \textit{Riegel} has not been fulfilled. While the \textit{Riegel} Court interpreted the preemption provision of the MDA broadly, it also acknowledged a continued role for parallel claims against device manufacturers. Yet, due to the pleading requirements of \textit{Twombly} and \textit{Iqbal}, parallel claims exist only on the pages of the U.S. Reports. In practice, PMA agreements are confidential, so plaintiffs can rarely, if ever, obtain enough factual information to survive a 12(b)(6) motion. Neither Congress nor the Court likely predicted how \textit{Twombly/Iqbal}, \textit{Riegel}, and the confidentiality of PMA agreements would interact. Nevertheless, this oversight, if left unaddressed, will have serious consequences for the health and safety of millions of Americans.

The lower federal courts have understandably struggled to reconcile these various legal rules. But rather than the too-bad-so-sad approach or a relaxation of the pleading standards, a different solution is in order. Congress should enact a one-way fee-shifting mechanism that allows plaintiffs to access PMA agreements, but only if they agree to pay the defendant’s discovery costs (should their claim prove unmeritorious). While no reform is perfect, this mechanism would strike a much better balance between compensating injured plaintiffs, deterring dangerous manufacturers, and preventing abusive litigation tactics.

\textsuperscript{177} See Nagareda, supra note 157, at 685.
\textsuperscript{178} See generally 26 \textsc{Wright & Miller} § 5652 (2013); \textsc{Melvin F. Jager}, 1 \textsc{Trade Secrets L.} § 5:33 (2013).
\textsuperscript{179} See supra Part III.D.