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

What else can be said about Twombly\(^1\) and Iqbal\(^2\)? Among lower federal courts, Twombly will soon be the most cited Supreme Court decisions of all time.\(^3\) Among scholars, Twombly and Iqbal are a popular target of study, criticism, and even ridicule.\(^4\) Commentators debate, for example, whether plausibility pleading will shut the courtroom doors to aggrieved plaintiffs,\(^5\) spare defendants from costly discovery,\(^6\) or have any effect at all.\(^7\)

This paper will not revisit these meta-level debates. Rather, it focuses on a specific policy problem that civil-procedure scholars have mostly overlooked: the intersection of Twombly/Iqbal and the preemption provision of the Food, Drug, and Cosmetic Act (“FDCA”).\(^8\) After the Supreme Court’s decision in Riegel v. Medtronic, Inc.,\(^9\) most private suits against manufacturers of medical devices are preempted. 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 obtain

---

3 See Adam N. Steinman, The Pleading Problem, 62 STAN. L. REV. 1293, 1360 & n.9 (2010).
access to 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 mightily over how to properly 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 had to stretch the reasoning of *Twombly* and *Iqbal* to get there. This paper argues that both approaches are flawed. Instead of tinkering with pleading standards, fee-shifting provides a more promising solution to this impasse.

This paper proceeds in four parts. Part II gives some background information about medical devices, preemption, and pleading standards. Part III outlines 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 simultaneously identified an important policy problem that needs to be addressed. To remedy the *Twombly*/*Iqbal* problem for parallel claims, Part IV advocates that Congress should enact a one-way fee-shifting mechanism, whereby plaintiffs could access premarket approval agreements but would be required to pay the defendant’s discovery costs if their claim was unsuccessful. Part V briefly concludes.

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 U.S. 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. A “medical device” is essentially everything that is not a drug—i.e., an “instrument,” “machine,” “implant,” or “component.” Medical devices range from relatively innocuous items like Band-Aids and tongue depressors to life-saving technologies like pacemakers and surgical lasers.

Congress began regulating medical devices in 1976 with the enactment of the Medical Device Amendments (“MDA”). The MDA groups medical devices into three classes. 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. The FDA must grant premarket approval (“PMA”) to Class III devices before they can be sold to the public.

PMA is a rigorous, time-consuming, and expensive process. Manufacturers of Class III devices must submit a multivolume application to the 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. The FDA spends an average of

---

12 *See Riegel*, 552 U.S. at 315–16.
1,200 hours reviewing each application for PMA. Then, the agency weighs the costs and benefits of introducing the device into the market. If the FDA approves the device, the agency imposes specific regulations regarding the design, manufacture, and labeling of the device, which are codified in a PMA agreement. The manufacturer must follow the requirements laid out in the PMA agreement and may not make any modifications to the device without approval from the FDA.\textsuperscript{15} Because PMA agreements contain trade secrets and other sensitive information, they are mostly confidential.\textsuperscript{16}

\textit{B. Preemption and Parallel Claims After Riegel}

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

\begin{quote}
[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.\textsuperscript{17}
\end{quote}

The Supreme Court considered how this preemption provision applied to Class III medical devices in \textit{Riegel v. Medtronic, Inc.}

The plaintiffs in \textit{Riegel} brought a diversity suit against Medtronic for injuries that Mr. Riegel sustained from an allegedly defective catheter (a Class III medical device). The Riegels brought several state-law claims against Medtronic related to the design, manufacture, and labeling of the catheter.\textsuperscript{18} 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

\textsuperscript{15} \textit{Riegel v. Medtronic, Inc.}, 552 U.S. 312, 317–19 (2008)
\textsuperscript{16} \textit{See} 21 C.F.R. § 814.9 (2014).
\textsuperscript{17} 21 U.S.C. § 360k(a).
\textsuperscript{18} \textit{Riegel}, 552 U.S. at 320.
and whether the claims “relate[d] to the safety or effectiveness of the device.”

According to Justice Scalia’s majority opinion, this latter determination was straightforward: safety and effectiveness are the “very subjects” of products liability and negligence. 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. 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.” 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.” 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. Nevertheless, some general principles have emerged. First, a parallel 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—

---

19 See 21 U.S.C. § 360k(a).
20 *Riegel*, 552 U.S. at 323.
21 *Id.* at 330.
22 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 Plaintiffs*, 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.”).
23 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
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 the 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.

---

26 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, 575–79 (2010).
29 See supra note 23.
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,” as determined by a judge’s “judicial experience and common sense.” Plausibility requires “more than a sheer possibility that the defendant has acted unlawfully.” 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.” Plaintiffs cannot merely offer “a formulaic recitation of the elements” or an “unadorned, the-defendant-unlawfully-harmed-me accusation.”

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. 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

34 Iqbal, 556 U.S. at 679.
35 Id. at 678.
36 Twombly, 550 U.S. at 555 (citation omitted) (emphasis added).
37 Iqbal; 556 U.S. at 678; Twombly, 550 U.S. at 555.
38 See, e.g., Airborne Beepers & Video, Inc. v. AT&T Mobility LLC, 499 F.3d 663, 667 (7th Cir. 2007); Keith Bradley, Pleading Standards Should Not Change After Bell Atlantic v. Twombly, 102 NW. U.L. REV. COLLOQUIY 117 (2007).
discrimination cases alike.” 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. 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 fraud).

Although the Court in Twombly and Iqbal claimed to be merely “interpreting” Rule 8, the decisions marked a dramatic departure from the liberal regime of notice pleading. 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. In Twombly and Iqbal, the Supreme Court finally seemed attuned to these costs and the attendant risk of nuisance settlements—perhaps due to 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

---

40 See Fed. R. Civ. P. 8(a)(2); see also Fed. R. Civ. P. 1 (explaining that the Rules apply “in all civil actions and proceedings in the United States district courts” (emphasis added)).
41 See Fed. R. Civ. P. 9(b).
42 Iqbal, 556 U.S. at 684.
43 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).
44 Id. at 1638–42.
45 Id. at 1640.
46 See id. at 1633 n.75 (noting that, other than Chief Justice Roberts, no other member of the Supreme Court has been in private practice since the 1970s).
pleading stage are needed, according to the Court, because judges are unwilling and unable to exercise supervision over the discovery process.\(^{49}\)

Given the Court’s seeming departure from prior precedent and its newfound concern with discovery costs, many commentators thought that \textit{Twombly} and \textit{Iqbal} would dramatically increase the number of complaints that were dismissed in the lower federal courts.\(^{50}\) However, this prediction did not come to fruition: the consensus of empirical studies suggests that \textit{Twombly} and \textit{Iqbal} have had little, if any, effect.\(^{51}\) Professor Fitzpatrick explains these counterintuitive results by drawing on an earlier article by Christopher Fairman about the pre-\textit{Twombly} pleading practices in the lower federal courts.\(^{52}\) In essence, the lower federal courts had tightened up pleading standards years ago; the Supreme Court was simply catching up in \textit{Twombly} and \textit{Iqbal}.\(^{53}\) Since the Court merely ratified what the lower federal courts were doing anyway, it is unsurprising that \textit{Twombly} and \textit{Iqbal} have not fundamentally changed the situation on the ground for litigants.

This paper does not challenge the empiricists on this point. For the vast majority of cases, \textit{Twombly} and \textit{Iqbal} will indeed have little effect on day-to-day litigation in federal courts. However, there is one notable, yet overlooked exception: parallel claims against medical device manufacturers. In these cases, \textit{Twombly} and \textit{Iqbal} present not just a challenge, but an \textit{insurmountable barrier} for plaintiffs who have been injured by medical devices.

\(^{49}\) \textit{Twombly}, 550 U.S. at 559.


\(^{51}\) \textit{See} Engstrom, \textit{supra} note 6.

\(^{52}\) \textit{See} Fitzpatrick, \textit{supra} note 6, at 1631–34 (citing, \textit{inter alia}, Christopher M. Fairman, \textit{The Myth of Notice Pleading}, 45 ARIZ. L. REV. 987 (2003)).

\(^{53}\) \textit{Id.}
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,”“astronomical,” and “virtually impossible” 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 the 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. 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). *Twombly* and *Iqbal* require plaintiffs to include enough factual material to “nudge[] their claims across the line from conceivable to plausible.” Yet, plaintiffs possess virtually no relevant factual information until they obtain a copy of the PMA agreement. For

---

54 Frank-Jackson, *supra* note 22.
56 Williams, *supra* note 28.
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.

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 the 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

59 See Riegel, 552 U.S. at 318.
60 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).
61 See Frank-Jackson, supra note 22, at 463 (“[S]cores of district courts have dismissed patients’ claims at the initial
pleading stage . . . .”).
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 heard by the Supreme Court.

The Fifth, Eighth, and Eleventh Circuits take what this paper refers to as a “too bad, so sad” approach. These courts recognize the difficulties that parallel claims face 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.” Instead, a well-pleaded parallel claim in these circuits must (1) identify the specific PMA requirement that the defendant allegedly violated and (2) explain how that particular violation caused the plaintiff’s injury. Plaintiffs can rarely (if ever) meet these requirements.

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. Ms. Bausch, to her credit, stated quite a bit more factual detail in her parallel claims than the average plaintiff; her complaint noted that the 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

---


63 Mitchell M. Breit et al., *Charting the Course in Medical Device Preemption*, 49-SEP TRIAL 28, 28 (2013).

64 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).

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

66 See id. at 1301; *Medtronic Leads*, 623 F.3d at 1608; Funk, 631 F.3d at 782.

67 See supra Part III.A.

68 630 F.3d 546 (7th Cir. 2010).
Stryker Corp.). Thus, *Bausch* may have come out the same way even in one of the too-bad-so-sad circuits.

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.

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].” 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.”

**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, but its legal moorings are somewhat shaky. The too-bad-so-sad approach appears to be a more faithful application of Supreme Court precedent.

---

69 *Id.* at 559.

70 Several courts have distinguished *Bausch* on these grounds, i.e. that the complaint in that case included much more factual detail. *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). 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.

71 *Bausch*, 630 F.3d at 558.

72 *Id.* at 561 (quoting *Medtronic Leads*, 623 F.3d at 1212 (Melloy, J., dissenting)).

73 *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.\(^{74}\) 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.”\(^{75}\) 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.”\(^{76}\) *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.”\(^{77}\) 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.\(^{78}\) Much of the information that Iqbal needed to state his claims was likely classified, including the role that defendants Mueller and Ashcroft

---

74 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)).
77 Bausch v. Stryker Corp., 630 F.3d 546, 561 (7th Cir. 2010).
78 *Iqbal*, 556 U.S. at 667–69.
played in the alleged events. Yet the *Iqbal* Court refused to modify the pleading standards to account for Iqbal’s lack of access to information. 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. True, plaintiffs can obtain some information by submitting requests under the Freedom of Information Act (“FOIA”). 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 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 the 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

---

79 *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).
80 *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.”).
81 *Bausch*, 630 F.3d at 560.
82 *See* Breit et al., *supra* note 64, at 30.
83 *Id.* at 30–31.
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.”85 Arguably then, Class III medical devices should only be subjected to regulation by the 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.86 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.87 Compensation is especially important in this context because Class III devices pose an especially high risk of catastrophic injury.88

Furthermore, the FDA may not even do an adequate job deterring dangerous behavior by device manufacturers. The FDA, like all agencies, is subject to capture by the industries that it regulates.89 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.90 Capture, in turn, leads to lax regulations and weak enforcement by an agency.91 Furthermore, the FDA recently reported that it lacks sufficient resources to conduct complete oversight over medical products—a concern that has

86 See Frank-Jackson, supra note 22, at 491 (“The bottom line is federal regulatory agencies very rarely compensate plaintiffs for tort damages.”).
87 See id.
88 See Williams, supra note 28, at 125.
89 See Raymond, supra note 31, at 776–77.
90 See id. at 776 n.148.
91 See id. at 776–77.
been independently validated by the nonpartisan Governmental Accountability Office. Thus, the 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 injured plaintiffs, and it would increase deterrence by empowering private attorney generals to go after noncompliant device manufacturers when the FDA fails to do so.

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. There is a simple and reliable indicium of congressional intent in this context: 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. All nine Justices in Riegel read this to mean that, instead of complete preemption, Congress intended to carve out an exception for parallel claims. However, as explained above, Twombly and Iqbal make parallel claims a pipedream for most plaintiffs, leaving Congress’s intentions unfulfilled.

92 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.”).
95 21 U.S.C. § 360k(a).
96 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 less preemptive effect. See generally Riegel v. Medtronic, Inc., 552 U.S. 312, 330–32 (2008) (Stevens, J., concurring); id. at 332–45 (Ginsburg, J., dissenting).
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.\textsuperscript{97} However, this proposition seems dubious. Congressional inaction is notoriously weak evidence of legislative intent.\textsuperscript{98} Instead of acquiescence, inaction may simply reflect Congress’s ignorance of Supreme Court decisions, the difficulties inherent in the legislative process, or both.\textsuperscript{99} Moreover, inaction is mostly irrelevant because what matters is the intent of the enacting Congress (not its current members), and those intentions cannot be changed without going through the formal legislative process.\textsuperscript{100}

Furthermore, with 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 procedural rule. While Congress presumably legislates with its other statutes in mind,\textsuperscript{101} the Federal Rules are considered the domain of the Supreme Court, not Congress.\textsuperscript{102} 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 Iqbal decision). Thus, the better argument seems to be that Congress intended to allow parallel claims against device manufacturers, but Twombly and Iqbal are now frustrating that goal.

\textsuperscript{97} In the wake of Riegel, several bills were introduced in Congress that would have overturned the Court’s decision. None were ever enacted. \textit{See} Gregory J. Wartman, \textit{Life After Riegel: A Fresh Look at Medical Device Preemption One Year After} Riegel v. Medtronic, Inc., 64 \textit{FOOD \\& DRUG L.J.} 291, 310–11 (2009).

\textsuperscript{98} 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) ("[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.").


\textsuperscript{100} \textit{Id.} at 193–96.

\textsuperscript{101} This presumption is sometimes known as the “whole code” canon. \textit{See} LISA SCHULTZ BRESSMAN ET AL., \textit{THE REGULATORY STATE} 232–35 (2010). However, given the massive breadth of the U.S. Code, this presumption 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, \textit{READING LAW: THE INTERPRETATION OF LEGAL TEXTS} 252–53 (2012).

\textsuperscript{102} \textit{See} Fitzpatrick, \textit{supra} note 6, at 1635–36.
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 *Bausch* to justify getting around the plausibility standard of *Twombly/Iqbal*. 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. These nuisance settlements, in turn, overdeter defendants and discourage them from performing socially beneficial behavior.\(^{103}\) These risks are only amplified in the context of medical devices. The PMA process is already expensive and time-consuming;\(^{104}\) an abundance of nuisance settlements could dissuade device manufacturers from researching and developing potentially life-saving technologies. Instead, a middle ground is needed.

### IV. Solution

The intersection of *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 *Twombly* and *Iqbal*, but it leaves injured plaintiffs uncompensated and device manufacturers underdeterred. On the other hand, the Seventh Circuit’s permissive interpretation of *Twombly* and *Iqbal* is more plaintiff-friendly, but it is legally unsound and threatens device manufacturers with costly nuisance claims. This paper 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

---


104 See supra notes 19–20 and accompanying text.
mechanics of fee-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.\textsuperscript{105} Congress has occasionally created exceptions via fee-shifting statutes.\textsuperscript{106} However, absent explicit statutory authorization, courts refuse to require the losing party to pay the other side’s fees.\textsuperscript{107} Thus, even a prevailing party in the United States can be saddled with significant litigation expenses.\textsuperscript{108}

The American Rule stands in contrast to the English Rule—the “loser pays” mechanism used in other countries.\textsuperscript{109} Under the English Rule, losing parties must pay their own litigation expenses and the expenses of the other side.\textsuperscript{110} Stated differently, the English Rule forces litigants to internalize some of the other side’s litigation costs.\textsuperscript{111} 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.\textsuperscript{112} Unsurprisingly then, tort reformers

---


\textsuperscript{106} MANUAL FOR COMPLEX LITIGATION (4TH) § 14.11 (2004) (identifying over 150 fee-shifting statutes covering a range of subject matters).

\textsuperscript{107} See Alyeska Pipeline Serv. Co. v. Wilderness Soc’y, 421 U.S. 240, 247 (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 . . . .”).

\textsuperscript{108} See Fitzpatrick, supra note 6, at 1644.


\textsuperscript{110} Katz & Sanchirico, supra note 105, at 1–2.

\textsuperscript{111} See Fitzpatrick, supra note 6, at 1645.

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.113

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.114 Five years later, those same doctors’ groups were clamoring for the Rule to be repealed.115 Medical malpractice cases under Florida’s English Rule were lasting much longer, and defendants were paying substantially more in both settled and litigated cases.116 The United Kingdom has reported similar results from its experience with the English Rule.117

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.118 According to the traditional model of litigation,119 the plaintiff calculates the expected value of her case by multiplying her odds of winning by the amount of

---

114 Katz & Sanchirico, supra note 105, at 30.
115 Id.
116 Id.
119 See, e.g., SHAVELL, supra note 118, at 401–03. The traditional model assumes rational, risk-neutral actors whose only goal is to maximize their recovery or minimize their losses. This assumption, of course, does not always hold up in real-world litigation. Nevertheless, this model is useful because it helps isolate the effects of particular litigation dynamics.
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.

\[
\begin{align*}
120 & \quad 80\% \times \$100,000 - \$20,000 = \$80,000 - \$20,000 = \$60,000 \\
121 & \quad 50\% \times \$100,000 + \$20,000 = \$50,000 + \$20,000 = \$70,000 \\
122 & \quad 90\% \times \$100,000 - \$30,000 = \$90,000 - \$30,000 = \$60,000 \\
123 & \quad 40\% \times \$100,000 + \$30,000 = \$40,000 + \$30,000 = \$70,000 = \$50,000 + \$20,000 = (50\% \times \$100,000) + \$20,000
\end{align*}
\]
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 $8,000,124 and the defendant’s costs are $20,000.125 Under this scenario, the plaintiff will settle for no less than $72,000,126 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 $88,000.127 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.

124 20% x ($20,000 + $20,000) = 20% x $40,000 = $8,000
125 50% x ($20,000 + $20,000) = 50% x $40,000 = $20,000
126 80% x $100,000 – $8,000 = $80,000 – $8,000 = $72,000
127 90% x $100,000 – $2,000 = $90,000 – $2,000 = $88,000
B. A One-Way Fee-Shifting Solution for Parallel Claims

This paper 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. 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. 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, 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 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

---

129 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.”).
discovery costs (and her own). If the plaintiff prevails at summary judgment on at least one parallel claim, then the American Rule applies, and the litigation proceeds like any other case.

Discovery costs are uniquely well-suited for a fee-shifting rule. Under the current system, a plaintiff who gets past the pleading stage gets *unfettered* access to discovery. 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. 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. 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%.

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. 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,

---

130 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, e.g., Fitzpatrick, supra note 6, at 1645–46; Martin H. Redish & Colleen McNamara, *Back to the Future: Discovery Cost Allocation and Modern Procedural Theory*, 79 GEO. WASH. L. REV. 773, 821–22 (2011).
131 See Fitzpatrick, supra note 6, at 1644 (“Because pleading standards are all-or-nothing, once they are surpassed, plaintiffs are entitled to the ‘all.’”).
132 See Frank H. Easterbrook, *Discovery as Abuse*, 69 B.U. L. REV. 635, 647 (1989); Fitzpatrick, supra note 6, at 1644.
133 See Fitzpatrick, supra note 6, at 1645.
134 See Easterbrook, supra note 132, at 647; Fitzpatrick, supra note 6, at 1645.
135 See supra Part IV.A.
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.\footnote{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).}

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.\footnote{See Fitzpatrick, supra note 6, at 1645; Liang & Berliner, supra note 136, at 107.} 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 wants is mostly located in the manufacturers’ PMA agreement. Thus, the plaintiff should be able to make an initial discovery request\footnote{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.} 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.\footnote{See Easterbrook, supra note 132, 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 . . . ”).}

It still may seem unfair to place more risk on a one-shot plaintiff, rather than a repeat-player defendant.\footnote{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. See Marc Galanter in Why the “Haves” Come Out Ahead: Speculations on the Limits of Legal Change, 9 LAW & SOC’Y REV. 95 (1974).} However, at the discovery stage, corporate defendants are actually disadvantaged vis-à-vis individual plaintiffs. Large corporate defendants like medical device manufacturers are the parties who 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 paper 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.

Of course, medical device manufacturers would certainly lobby against this proposed
reform. After all, Twombly and Iqbal currently give manufacturers 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. Finally,
regardless of manufacturers’ concerns, the burdens imposed by a fee-shifting mechanism are

---

141 See Fitzpatrick, supra note 6, at 1637–43; Jonathan T. Molot, Fee Shifting and the Free Market, 66 VAND. L.
REV. 1807, 1808 (2013).
142 See Nagareda, supra note 129, at 685.
likely justified by the deterrence benefits to society and the compensation benefits to injured plaintiffs.

V. Conclusion

The promise of *Riegel* has not been fulfilled. While the *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 *Twombly* and *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 *Twombly/Iqbal*, *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 over how 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.