

defendants than the risks of an adverse judgment. With this swing in the pendulum, the Supreme Court recently acted once again to prevent abuses of the judicial process. In *Twombly* and *Iqbal*, the Court held that the sue-first-discovery-later paradigm that had emerged following *Conley* was unacceptable, and it tightened the pleading standards to put an end to this practice.

The Supreme Court took its first big step away from *Conley* in *Bell Atlantic Corporation v. Twombly*.⁸ In *Twombly*, the Supreme Court focused squarely on the abuses that had arisen in the wake of the *Conley* “no set of facts” pleading standard. The Court explained that “when the allegations in a complaint, however true, could not raise a claim of entitlement to relief, ‘this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.’”⁹

It is no answer to say that a claim just shy of a plausible entitlement to relief can, if groundless, be weeded out early in the discovery process through “careful case management” given the common lament that the success of judicial supervision in checking discovery abuse has been on the modest side. And it is self-evident that the problem of discovery abuse cannot be solved by “careful scrutiny of evidence at the summary judgment stage,” much less “lucid instructions to juries”; the threat of discovery expense will push cost-conscious defendants to settle even anemic cases before reaching those proceedings.¹⁰

Thus, the Court held that “something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with a ‘largely groundless claim’ be allowed to ‘take up the time of a number of other people with the right to do so representing an *in terrorem* increment of the settlement value.’”¹¹

After placing *Conley* in its original factual context, the Court squarely rejected the “no set of facts” pleading standard:

We could go on, but there is no need to pile up further citations to show that *Conley*’s “no set of facts” language has been questioned, criticized, and explained away long enough. To be fair to the *Conley* Court, the passage should be understood in light of the opinion’s preceding summary of the complaint’s concrete allegations [of discrimination], which the Court quite reasonably understood as amply stating a claim of relief. But the passage so often quoted fails to mention this understanding on the part of the Court, and after puzzling the profession for 50 years, this famous observation has earned its retirement.¹²

The Court then announced a new pleading standard: to survive a motion to dismiss for failure to state a claim, a complaint must have enough “factual enhancement [to bring it across] . . . the line between possibility and plausibility of entitlement to relief.”¹³ With that, the new “plausibility” pleading standard was born.

Although courts and commentators initially debated the reach and import of the *Twombly* plausibility standard because of the antitrust context in which it arose, the Court resolved the debate in 2009 with its decision in *Ashcroft v. Iqbal*,¹⁴ in which

it stated that its “decision in *Twombly* expounded the pleading standard for *all civil actions*.”¹⁵ The Court also elucidated its new plausibility pleading standard, making it clear that Rule 8 “demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.”¹⁶ The Court stated:

To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to “state a claim to relief that is plausible on its face.” A claim has facial plausibility [only] when the plaintiff *pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged*. The plausibility standard is not akin to a “probability requirement,” but *it asks for more than a sheer possibility that a defendant has acted unlawfully*. Where a complaint pleads facts that are “merely consistent with” a defendant’s liability, it “stops short of the line between possibility and plausibility of ‘entitlement to relief.’”¹⁷

Applying this plausibility standard in *Iqbal*—where the plaintiff alleged that following the September 11th attacks the Attorney General and others designated him a suspected terrorist and then detained him in violation of his Constitutional rights—the Court focused on the essential elements of the plaintiff’s claim and concluded that the plaintiff “must plead sufficient factual matter to show that [the Attorney General and others named in the complaint] adopted and implemented the detention policies at issue not for a neutral, investigative reason but for the purpose of discriminating on account of race, religion, or national origin.”¹⁸ Looking for factual matter, the Court disregarded the plaintiff’s “bare” and “conclusory” allegations, which it determined were “not entitled to the assumption of truth.”¹⁹ Looking to the factual matter set out in the plaintiff’s complaint, the Court noted that the plaintiff had alleged “that ‘the [FBI], under the direction of [the defendants], . . . arrested and detained thousands of Arab Muslim men . . . as part of its investigation of the events of September 11.’”²⁰ The plaintiff had further alleged “that ‘[t]he policy of holding post-September-11th detainees in highly restrictive conditions of confinement until they were “cleared” by the FBI was approved by Defendants . . . in discussions in the weeks after September 11, 2001.’”²¹ Assuming these allegations were true, the Court nonetheless determined that the plaintiff had “not ‘nudged [his] claims’ of invidious discrimination ‘across the line from conceivable to plausible.’”²² Although the plaintiff’s factual allegations arguably were consistent with a discriminatory purpose, the Court relied upon “its judicial experience and common sense”²³ to conclude that the pleaded facts likely demonstrated a non-discriminatory purpose behind the defendants’ conduct. “[G]iven [the] more likely explanations, [the plaintiff’s allegations] d[id] not plausibly establish” a cause of action against the defendants.²⁴

The depth of the Supreme Court’s analysis in *Iqbal*—indeed, the very notion that factual context and common sense play a role in the evaluation of every plaintiff’s complaint—stands in stark contrast to the deference previously paid to plaintiff’s allegations under the *Conley* “no set of facts” standard. The *Twombly* and *Iqbal* decisions make clear that it is no longer sufficient for plaintiffs to allege facts that are consistent with

their theory of liability. Rather, plaintiffs must now set forth facts that provide a plausible basis to believe they can establish each element of their legal claims.

II. The Impact Of The Plausibility Standard on Pharmaceutical Product Liability Litigation

In one sense, the impact of the *Twombly* and *Iqbal* decisions may be measured by the response to them. In just over two and a half years, *Twombly* has been cited in over 22,700 opinions. And as of January 10, 2010, less than eight months after the opinion was issued, *Iqbal* had been cited in over 4,500 judicial opinions. On the flip side, *Twombly* and *Iqbal* have been roundly criticized for placing too onerous a pleading burden upon plaintiffs. United States Senator Arlen Specter of Pennsylvania recently called for legislation to reinstate the *Conley* “no set of facts” standard. The Senator introduced Senate Bill 1504, called the “Notice Pleading Restoration Act of 2009,”²⁵ which provides:

Except as otherwise expressly provided by an Act of Congress or by an amendment to the Federal Rules of Civil Procedure which takes effect after the date of enactment of this Act, a Federal court shall not dismiss a complaint under rule 12(b)(6) or (e) of the Federal Rules of Civil Procedure, except under the standards set forth by the Supreme Court of the United States in *Conley v. Gibson*²⁶

The bill was co-sponsored by Senator Feingold. After it was introduced, it was immediately referred to the Senate Judiciary Committee, which held a hearing on December 2, 2009. At that hearing, John Payton, the President and Director of the NAACP’s Legal Defense and Educational Fund, called the plausibility pleading standard “nothing short of an assault on our democratic principles.”²⁷ Likewise, on October 27, 2009, the U.S. House of Representatives Judiciary Committee’s Subcommittee on the Constitution, Civil Rights and Civil Liberties held a hearing entitled “Access to Justice Denied—*Ashcroft v. Iqbal*.” At that hearing, Arthur R. Miller, co-author of the treatise *Federal Practice and Procedure*, testified that the heightened pleading standard has “come at the expense of the values of access to the federal courts and the ability of citizens to secure an adjudication of the merits of their claims.”²⁸

While it is clear that there has been a paradigmatic shift in the legal landscape, the specific parameters of the new environment are still taking shape. In pharmaceutical product liability litigation, only a handful of cases to date provide any detailed analysis of the plaintiffs’ burden under the new pleading standard. While these cases demonstrate the possibilities inherent in a disciplined application of the plausibility pleading standard, the full impact of *Twombly* and *Iqbal* with regard to the fundamental premises of pharmaceutical product liability litigation arguably has not yet been felt.

The initial promise of *Twombly* and *Iqbal* is demonstrated in a recent opinion from the Southern District of Ohio in which a defendant succeeded in securing dismissal of a panoply of different legal causes of action allegedly arising from the plaintiff’s ingestion of a prescription medication.²⁹ As is typical in prescription drug product liability litigation, the plaintiff in *Frey* alleged a variety of different legal causes of action for

which she claimed the right of monetary relief, including failure to warn, manufacturing defect, and design defect, relying particularly in her non-warnings claims on formulaic recitations of the elements of each legal theory. Prior to *Twombly*, plaintiffs routinely were allowed to pursue discovery on these claims despite the lack of any specific factual support in their complaint because defendants could not establish “beyond doubt that the plaintiff[] [could] prove no set of facts in support of his claim which would entitle him to relief.”³⁰ As the *Frey* Court recognized at the very first pre-trial conference shortly after *Twombly* was issued, however, and once again in its ruling on defendant’s motion to dismiss, *Twombly* has shifted the burden to plaintiffs to set forth a plausible factual basis for his claimed entitlement of relief. In *Frey*, the defendant argued that the plaintiff had not made such a showing with respect to their manufacturing defect and design defect claims.³¹ The court agreed.

The *Frey* plaintiff’s allegations in support of her manufacturing defect and design defect claims were typical of those commonly seen in pharmaceutical product liability litigation. *Frey*’s manufacturing defect claims were fully stated as follows:

[1.] The product which was consumed by Plaintiff was defective in design or construction at the time it left the Defendants’ control.

[2.] Defendants failed to design, manufacture, test, and control the quality of [the product] such that when it left the control of the Defendant, it deviated in a material way from the design specifications, formula or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula or performance standards.

[3.] As a direct and proximate result of the defect in manufacture or construction by Defendants, Plaintiff, suffered the injuries and damages set forth herein.³²

While somewhat more fulsome, *Frey*’s design-defect claim consisted mainly of the following allegations:

[1.] When [the product]... left the control of the Defendants, the foreseeable risks associated with its design or formulation exceeded the benefits associated with that design or formulation.

....

[2.] At the time the product left the control of the Defendants, a practical and technically feasible alternative design or formulation was available that would have prevented the harm for which the claimant seeks to recover compensatory damages without substantially impairing the usefulness or intended purpose of the product.

....

[3.] As a direct and proximate result of defect in design or formulation by Defendants, Plaintiff suffered, and will continue to suffer, the injuries and damages set forth herein.³³

In granting defendant's motion to dismiss, the court made clear that the familiar recitation of these legal claims is no longer sufficient in the post-*Twombly* world to state a cause of action. The court held that Frey's manufacturing defect claim did "nothing more than provide a formulaic recitation of the elements of a claim under the [product liability] statute," and therefore the complaint "failed to allege any facts that would permit the Court to conclude that a manufacturing defect occurred and that the defect was the proximate cause of Amanda Frey's alleged injuries."³⁴ Thus, the court found that Frey's "allegations in this regard fall far short of the sufficiency standard set forth in *Twombly*."³⁵ Likewise, the court held that Frey's design defect claim "once again simply provided a formulaic recitation of the elements of a claim under the [product liability] statute," and therefore the complaint failed to "allege[] any facts that would permit the Court to conclude that there was a defect in the design or formulation of [the product] and that the defect was the proximate cause of Amanda Frey's alleged injuries."³⁶ Notably, the Court also rejected the plaintiffs' request for leave to amend and dismissed the claims with prejudice because the plaintiffs "failed to demonstrate that an amendment to the complaint would not be futile."³⁷

III. The Promise Of The Plausibility Pleading Standard in Pharmaceutical Product Liability Litigation

Frey is a leading indicator of the changes that are to come in pharmaceutical product liability litigation under the new plausibility pleading standard. By weeding out the plaintiffs' formulaic legal claims, the *Frey* court's ruling will limit the burdens that would otherwise be imposed on the defendant in responding (through discovery and otherwise) to legal theories devoid of any factual support and will focus the litigation on the plaintiff's burden under her narrower failure to warn theory. With the subsequent expansion of the *Twombly* holding in *Iqbal* (which was issued after the *Frey* briefing), however, and as the courts become more familiar with the requirements imposed by this new pleading standard, a larger question arises: what facts must a pharmaceutical product liability plaintiff allege before being allowed to proceed to discovery on a failure to warn claim?

To date, few published decisions discuss the impact of the *Twombly/Iqbal* plausibility standard in the context of failure-to-warn claims. In *Bailey v. Janssen Pharmaceutica, Inc.*, the Eleventh Circuit affirmed dismissal of failure-to-warn claims after finding the plaintiff's allegations insufficient to show either that the warning was inadequate or that the failure to warn proximately caused the plaintiff's injury.³⁸ In *Lewis v. Abbott Laboratories*, the district court dismissed a *pro se* plaintiff's failure-to-warn claims because the plaintiff did not plead facts to show that the defendant failed to provide adequate warnings to her doctors.³⁹ However, these two cases cite the *Twombly* and *Iqbal* cases only in passing and offer little substantive discussion of the heightened pleading standard and its true impact on failure-to-warn allegations.

The Supreme Court's analyses in *Twombly* and *Iqbal*—and particularly the Court's rejection of detailed factual allegations because of their failure to address each of the necessary elements of the plaintiffs' claims—suggests that pharmaceutical product

liability plaintiffs will in the future be required to conduct a far more thorough pre-filing investigation and identify a far more complete factual basis for a failure to warn claim than has heretofore been the case. In both *Twombly* and *Iqbal*, the plaintiffs alleged specific facts in support of their complaints. In *Twombly*, the plaintiffs' antitrust complaint included detailed factual recitations of specific actions taken by or among local telephone operating carriers (the "Baby Bells" or "ILECs"), which the plaintiffs alleged impeded the entry into the marketplace of competing local carriers ("CLECs").⁴⁰ In *Iqbal*, the plaintiffs' constitutional claims were premised upon an even more-detailed factual discussion of the detention and treatment both of the named plaintiff and Arab Muslims generally following the September 11 attacks.⁴¹

In each case, however, the Court explained that the recitation of facts in a complaint that is merely consistent with a plaintiff's theory of liability—even a detailed recitation of such facts—is not enough. As the Court explained in *Iqbal*, "Where a complaint pleads facts that are merely consistent with the defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief."⁴² The Court instructed that "[d]etermining whether a complaint states a plausible claim for relief will... be a context-specific task that requires the reviewing court to draw upon its judicial experience and common sense."⁴³ This analysis requires a court to test a plaintiff's factual allegations against each of the elements needed to support the legal claim. Thus, for example, in *Iqbal*, the Court held that the plaintiffs' specific factual allegations of mistreatment—even if indicative of unconstitutional discrimination in some respects—did not state a cause of action because the plaintiffs had not set forth facts plausibly showing that the defendants "purposefully adopted a policy of classifying post-September 11 detainees as 'of high interest' because of their race, religion, or national origin," as necessary under the specific legal theory of recovery proffered in the case.⁴⁴

If the Supreme Court's plausibility standard is faithfully applied to pharmaceutical product liability complaints, many failure-to-warn claims will never advance beyond the pleadings stage. With minor variations among jurisdictions, a cause of action in strict liability for failure to warn is comprised of five essential elements:

- (1) a risk of harm that is inherent in the product or that may arise from the intended or reasonably anticipated use of the product;
- (2) a reasonably foreseeable or actually foreseen risk of harm at the time the product is marketed;
- (3) a failure to provide any warning of the danger or a failure to provide an adequate warning (or instructions) of the danger;
- (4) the absence of the warning (or instruction) must render the product unreasonably dangerous; and
- (5) the failure to warn (or instruct) must constitute a causative nexus in the product user's injury.⁴⁵

Using these basic elements as the framework for their complaints, many pharmaceutical plaintiffs allege little more than that a

drug was prescribed, its labeling contained inadequate warnings, and the failure to warn proximately caused the plaintiff's injuries. This is particularly the case in pharmaceutical mass tort litigation, where plaintiffs' attorneys often generate cut-and-paste pleadings for hundreds or thousands of plaintiffs, revealing little about the facts—let alone the *essential* facts behind any particular plaintiffs' claims. But *Twombly* and *Iqbal* make it clear that such unsubstantiated, conclusory allegations cannot sustain a claim. Rather, every plaintiff asserting failure-to-warn allegations must plead *sufficient factual matter* demonstrating a *plausible* cause of action that is not subject to an "obvious alternative explanation."⁴⁶

What then should be required of a plaintiff alleging a cause of action for failure to warn? Under the Court's decisions in *Twombly* and *Iqbal*, it does not appear to be enough to merely allege that a drug manufacturer should have known about the alleged risks of their product absent some plausible factual showing that this risk was apparent to the defendant at the time the drug was prescribed. Nor, as is often the case, does it seem that a subsequent FDA-mandated labeling change alone would set forth a plausible basis for a claim that the manufacturer reasonably or actually new of the alleged risk at the time of prescription, given the "obvious alternative explanation" that the labeling change was required due to new, previously unrecognized risks. Likewise, plaintiffs cannot rest on simple formulaic allegations that the prescribing physician was unaware of the alleged risk or that a different warning label would have changed the physician's prescribing decision. The plausible bases for such factual allegations are a necessary predicate under *Twombly* and *Iqbal* for plaintiffs to state a cause of action.

Plaintiffs in pharmaceutical product liability litigation can be expected to argue that they should not be held to strict application of the *Twombly/Iqbal* standard because of an alleged inequity of information between plaintiffs and corporate defendants. However, defendants would counter that this objection overlooks the plaintiffs' pre-existing, pre-suit duty to investigate the validity of their claims⁴⁷ and the fact that this modern age provides plaintiffs with myriad fact-generating and fact-gathering tools. For example, plaintiffs often can gather significant information about a drug's known or anticipated risk event profile from information that is publicly available on the FDA website or obtainable through FOIA requests, from clinical trial information available on the drug manufacturer's website, or through published literature, most of which is also available online. Furthermore, product liability plaintiffs, unlike defendants, have the ability to speak with their prescribing physicians and thereby obtain facts necessary to support allegations that a warning was inadequate and that the inadequacy proximately caused the plaintiff's injuries.

Given these readily available sources of pre-filing information, defendants argue, plaintiffs who rely upon only formulaic recitations of fact in their complaints either have not satisfied their Rule 11 inquiry obligations or do not have the required factual basis to demonstrate the required plausible basis for recovery. As the Supreme Court noted, although "Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, ... it does not unlock the doors of discovery for a plaintiff armed with nothing

more than conclusions."⁴⁸ Courts should not "forget that proceeding to . . . discovery can be expensive,"⁴⁹ and therefore "a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed."⁵⁰ With its rulings in *Twombly* and *Iqbal*, the Supreme Court thus has provided pharmaceutical defendants with a powerful weapon against unsubstantiated, formulaic claims of wrongdoing and has imposed discipline upon plaintiffs in the filing of pharmaceutical product liability complaints.

Endnotes

1 Lisa Girion, *State Vioxx Trial Is Set as Drug Suits Boom; An Explosion in Litigation Spurs Calls for Legal Reform and Regulatory Changes*, L.A. TIMES, June 27, 2006.

2 *Id.*

3 Information concerning the number and nature of product liability MDL proceedings was distilled from reports made available via the official website of the Judicial Panel on Multidistrict Litigation. See http://www.jpml.uscourts.gov/General_Info/statistics/statistics (2009).

4 355 U.S. 41 (1957).

5 See *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009); *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544 (2007).

6 *Conley*, 355 U.S. at 45-46.

7 *Id.* at 47-48.

8 550 U.S. 544 (2007).

9 *Id.* at 558 (quoting 5 Wright & Miller § 1216, at 233-34).

10 *Id.* at 559 (citations omitted).

11 *Id.* at 557-58 (quotation marks and citation omitted).

12 *Id.* at 562-63.

13 *Id.* at 557 (quotation marks and citation omitted).

14 129 S. Ct. 1937 (2009).

15 *Id.* at 1953 (quotation marks and citation omitted) (emphasis added).

16 *Id.* at 1949. Quoting *Twombly*, the Court also reiterated that a "pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id.* (quoting *Twombly*, 550 U.S. at 555).

17 *Id.* at 1949 (quoting *Twombly*, 550 U.S. at 556, 557, 570) (citations omitted) (emphasis added).

18 *Id.* at 1948-49.

19 *Id.* at 1951 ("We begin our analysis by identifying the allegations in the complaint that are not entitled to the assumption of truth. Respondent pleads that petitioners 'knew of, condoned, and willfully and maliciously agreed to subject [him]' to harsh conditions of confinement 'as a matter of policy, solely on account of [his] religion, race, and/or national origin and for no legitimate penological interest.' The complaint alleges that Ashcroft was the 'principal architect' of this invidious policy, and that Mueller was 'instrumental' in adopting and executing it. These bare assertions, much like the pleading of conspiracy in *Twombly*, amount to nothing more than a 'formulaic recitation of the elements' of a constitutional discrimination claim, namely, that petitioners adopted a policy because of, not merely in spite of, its adverse effects upon an identifiable group. As such, the allegations are conclusory and not entitled to be assumed true . . . It is the conclusory nature of [the plaintiffs'] allegations, rather than their extravagantly fanciful nature, that disentitles them to the presumption of truth." (citations and quotation marks omitted)).

20 *Id.*

21 *Id.*

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

23 *Id.* at 1950.

24 *Id.* at 1951.

25 See, e.g., David Ingram, *Specter Proposes Return to Prior Pleading Standard*, NAT'L L.J. July 24, 2009, available at www.law.com/jsp/article.jsp?id=1202432493166.

26 S. 1504, 111th Cong. § 2 (2009).

27 *Has the Supreme Court Limited Americans' Access to Courts?: Hearing Before the S. Comm. on the Judiciary*, 111th Cong. (2009) (statement of John Payton, President and Director-Counsel, NAACP Legal Defense and Educational Fund, Inc.), available at <http://judiciary.senate.gov/pdf/12-02-09%20Payton%20Testimony.pdf>. In opposition, the U.S. Chamber of Commerce and forty business associations and individual companies sent a letter to the Senate committee arguing that the “drastic change in standards” proposed in the legislation “would impose enormous costs on already struggling businesses and further impede economic recovery” and “would overwhelm[] the federal judicial system with frivolous lawsuits.” See Letter from U.S. Chamber of Commerce et al. to Senators Patrick J. Leahy and Jeff Sessions, at 1 (Dec. 1, 2009), available at <http://www.uschamber.com/issues/letters/2009/091201s1504.htm>.

28 Prepared Statement of Prof. Arthur R. Miller, N.Y.U. School of Law, submitted to the United States House of Representatives, Subcommittee on the Constitution, Civil Rights and Civil Liberties of the Committee on the Judiciary, Oct. 27, 2009 at 6, available at <http://judiciary.house.gov/hearings/pdf/Miller091027.pdf>.

29 See *Frey v. Novartis Pharmaceuticals Corporation*, 642 F. Supp. 2d 787 (S.D. Ohio 2009). In the interest of full disclosure, the authors represent the defendant in this litigation.

30 *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957).

31 The defendant initially sought dismissal of plaintiff's failure-to-warn claim on the ground of preemption, but this part of the defendant's motion was withdrawn following the United States Supreme Court's ruling in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

32 Plaintiff's Amended Complaint at 5-6, *Frey v. Novartis Pharms. Corp.*, (No. 1:07-cv-00317-HJW (S.D. Ohio) (filed Sept. 5, 2008) (Doc. 18).

33 *Id.* at 6-7.

34 *Frey*, 642 F. Supp. 2d at 795.

35 *Id.*

36 *Id.*

37 *Id.* at 796.

38 288 F. App'x. 597, 608-09 (11th Cir. 2008).

39 2009 WL 2231701, at *5 (S.D.N.Y. July 24, 2009).

40 *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544 (2007). For example, the plaintiffs alleged that the anticompetitive conduct included “making unfair agreements with the CLECs for access to ILEC networks, providing inferior connections to the networks, overcharging, and billing in ways designed to sabotage the CLECs' relations with their own customers.” *Id.* at 550-551.

41 *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009). The complaint alleged, for example, that the named plaintiff's jailors

kicked him in the stomach, punched him in the face, and dragged him across his cell without justification, subjected him to serial strip and body-cavity searches when he posed no risk to himself or others and refused to let him and other Muslims pray because there would be “[n]o prayer for terrorists.”

Id. at 1944 (internal record citations omitted). More broadly, the complaint alleged that the defendants had “arrested and detained thousands of Muslim men . . . as part of its investigation of the events of September 11 . . . and that the policy of holding post-September 11th detainees in highly restrictive

conditions of confinement until they were ‘cleared’ by the FBI was approved by” the specifically-identified, government-official defendants. *Id.*

42 *Id.* at 1949 (quoting *Twombly*, 550 U.S. at 557) (quotation marks omitted).

43 *Id.* at 1950.

44 *Id.* at 1952.

45 See, e.g., *Reese v. Mercury Marine Div. of Brunswick Corp.*, 793 F.2d 1416, 1420 n.1 (5th Cir. 1986) (applying Texas law); *Strong v. U-Haul Co. of Mass., Inc.*, 2007 WL 433268, at *3 (S.D. Ohio Feb. 2, 2008) (“[T]he basic common elements of all of plaintiffs' failure to warn claims are: (1) defendants knew or should have known of the risks associated with the product; (2) defendants failed to warn plaintiffs about those risks; and (3) the failure to warn was the proximate cause of plaintiffs' injuries.”) (applying Ohio law).

46 *Twombly*, 550 U.S. at 568.

47 Rule 11 of the Federal Rules of Civil Procedure “stresses the need for some prefiling inquiry into both the facts and the law to satisfy [counsel's] affirmative duty [to investigate].” *Albright v. Upjohn Co.*, 788 F.2d 1217, 1221-1222 (6th Cir. 1986); see also *Pretrial Order #39, In Re Digitek Prod. Liab. Litig.*, MDL No. 1968 (S.D. W. Va. Aug. 26, 2009) (reciting pre-suit obligations imposed by Rule 11 and permitting limited discovery to determine whether plaintiffs' counsel had reasonable basis for a claim prior to filing the suit alleging adverse reaction caused by a defective drug product).

48 *Iqbal*, 129 S. Ct. at 1950.

49 *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544, 558 (2007).

50 *Id.* (quoting *Associated Gen. Contractors of Cal., Inc. v. Carpenters*, 459 U.S. 519, 528 n.17 (1983)) (quotation marks omitted).

