2010 AUGUST A. RENDIGS, JR.
NATIONAL PRODUCTS LIABILITY MOOT COURT COMPETITION

No. 10-1524

IN THE SUPREME COURT OF THE UNITED STATES

April Term 2010

Dan Cooks, *et al.*,

Petitioners

-V-

Carolina Laboratories, Inc.

Respondent

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE THIRTEENTH CIRCUIT

University of Cincinnati College of Law
And
Rendigs, Fry, Kiely & Dennis, LLP
Attorneys at Law
Cincinnati, OH

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF GRACE

Dan Cooks, *et al.*,

Plaintiffs

-V-

Carolina Laboratories, Inc.,

Defendant

No. 08-cv-04132

March 25, 2008, Decided

OPINION

SCARLET, *District Judge*

Presently before the Court is Defendant's Motion to Dismiss pursuant to Civil Rule of Procedure 12(b)(6). For the reasons that follow, the Court finds Plaintiffs' claims are barred by the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"), 42 U.S.C. § 300aa-1 *et seq.* Accordingly, Defendant's Motion will be **GRANTED**.

I. Background

A. Factual Background

Twelve-year old Estella Marie Cooks suffers from neurological injuries which her parents believe were caused by a product made by the Defendant.[1] Between March 1996 and October 1998 Estella Marie received three doses of Carolina Laboratories' thimerosal-containing Diphteria and Tetanus Toxoids and Pertussis ("DTP") – Haemophilus influenzae type b ("Hib") combination vaccine.[2] Thimerosal is an organic compound which is approximately 50% mercury by weight. According to the Complaint, the mercury contained in the thimerosal preservative was toxic and led to Estella Marie's injuries.

B. Procedural Background

Dan and LoEtta Cooks filed a timely petition for compensation on Estella Marie's behalf with the National Vaccine Injury Compensation Program ("NVICP") on September 3, 2001,

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[1] The Complaint alleges Estella Marie's neurological injuries include developmental delays, learning disabilities, social delays and deficits, the impairment of motor skills, gastrointestinal illness, and immune system dysfunction.

[2] The parties do not dispute that the product administered to Estella Marie is a vaccine under the Vaccine Act. *See* 42 C.F.R. § 100.3 (Vaccine Injury Table).

pursuant to 42 U.S.C. § 300aa-1 *et seq.*[3] On November 5, 2003, the Cooks filed a notice of withdrawal in the NVICP, and judgment was entered on the withdrawal by the Clerk of the U.S. Court of Federal Claims on January 14, 2004, pursuant to 42 U.S.C. § 300aa-21(b). The Cooks filed an election to file a civil action on January 21, 2004, pursuant to 42 U.S.C. § 300aa-21(a).

On March 14, 2007, Plaintiffs filed their Complaint with this Court, individually and as parents of Estella Marie Cooks. The Complaint proceeds with two counts under Grace law against the vaccine manufacturer Carolina Laboratories.[4] Count I alleges Carolina Laboratories negligently failed to conduct adequate safety tests to determine whether thimerosal was safe and nontoxic to humans in the doses administered. Count II asserts strict products liability for design defect, in that the vaccine was defectively designed and a safer alternative existed.[5] Plaintiffs are suing for damages to Estella Marie, costs, punitive damages, and other legal or equitable relief the Court deems just and proper.

Plaintiffs initially filed their Complaint in the Wicked County Court of Common Pleas. Defendant removed the case to this Court based on diversity of citizenship, pursuant to 28 U.S.C. § 1332. [6]

II. Parties' Contentions

A. Defendant

Defendant moves to dismiss Plaintiffs' causes of action, first, on the grounds that Plaintiffs' design defect claims against it are barred by § 22(b) of the Vaccine Act. Defendant construes this section of the Vaccine Act to impose a total bar on design defect claims arising from vaccine-related injuries so long as the vaccine was produced in accordance with FDA-approved specification. According to Defendant, the plain language of the Vaccine Act reflects the intent of Congress to preempt state law claims for design defects. Defendant argues that this is a broad immunity, not subject to case-by-case review in the courts.

In addition, even if Congress did not intend to preclude design defect claims, Defendant maintains that Plaintiffs fail to allege facts sufficient to

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[3] The filing of a petition under the NVICP stays the running of state statutes of limitations. *See* 42 U.S.C. § 300aa-16(c). The NVICP then gives a petitioner the choice to accept the judgment obtained under the program and surrender his tort rights or to reject that judgment and pursue a civil action for damages. *See* 42 U.S.C. § 300aa-21(a).

[4] The parties do not dispute that, absent preemption, Grace law will apply in this case.

[5] Plaintiffs do not assert that there was any defect with the preparation or manufacture of the vaccine and the warnings supplied were adequate.

[6] Carolina Laboratories is incorporated in Delaware, but has always had its principal place of business in New Jersey. Plaintiffs are domiciled in the State of Grace.

state a claim for design defect under Grace state law.

B. Plaintiffs

Plaintiffs disagree with Defendant's construction of the Vaccine Act and argue that the Vaccine Act only bars design defect claims if the side effects are determined, on a case-by-case basis, to be "unavoidable." Plaintiffs claim their defective design claims are permitted because the injuries suffered by Estella Marie were avoidable.

Plaintiffs further contend that they have sufficiently pled all of the elements of a cause of action for design defect. In support of their design defect claims, Plaintiffs allege that Defendant marketed a drug whose risks were not known to the general public and should have manufactured children's vaccines without thimerosal prior to their daughter's vaccination. Plaintiffs assert that they cannot plead their specific allegations more particularly without conducting discovery.

III. Standard for Rule 12(b)(6) Motion to Dismiss

A motion to dismiss for failure to state a claim upon which relief can be granted challenges the legal sufficiency of a claim, not the facts supporting it. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). In ruling on a Rule 12(b)(6) motion, a court must regard as true all of the factual allegations in the complain, *Erickson v. Pardus*, 551 U.S. 89, 94 (2007), as well as any facts that could be proved that are consistent with those allegations, *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984), and view those facts in the light most favorable to the plaintiff, *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). The court may grant a Rule 12(b)(6) motion only if it "appears beyond doubt" that the party bringing the claim cannot prove any facts that would entitle it to relief. *Conley*, 355 U.S. at 46. But, the court does not have to accept legal conclusions that are couched as factual allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Under established precedent, a district court is not obligated *sua sponte* to provide a plaintiff with an opportunity to amend her complaint prior to dismissing it with prejudice. *See Wagner v. Daewoo Heavy Inds. Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002) (en banc) ("A district court is not required to grant a plaintiff leave to amend his complaint *sua sponte* when the plaintiff, who is represented by counsel, never filed a motion to amend nor requested leave to amend before the district court.").

IV. Discussion

A. Adequacy of the Pleadings

Plaintiffs' design defect claims are sufficient to present claims for design defect under Grace state law. Grace law recognizes three types of product liability claims: (1) defective design, (2) defective manufacture, and (3) inadequate warning or failure to warn.

Existing Grace product liability law does not encompass the minority rule insulating vaccine manufacturers from strict liability. Rather, the risk-benefit analysis comports with the Supreme Court of Grace's determination

that claims for design defect are to be evaluated under a risk-utility analysis balancing the risks inherent in product design against the utility of the product designed. The factfinder may consider a number of factors, including the gravity and severity of the danger caused by the design, the avoidability of the danger, and the ability to eliminate the danger without impairing the product's usefulness. Further, the weighing of these factors is generally a question for the jury.

The standard on a motion to dismiss is normally generous. *See Iqbal v. Hasty*, 490 F.3d 143, 157-58 (2d Cir. 2007) (noting that specific factual allegations are generally only necessary to make a claim plausible). Plaintiffs' Complaint plainly alleges that Defendant:

> Failed to conduct adequate safety tests to determine whether the thimerosal was safe and nontoxic to humans in the dose administered to infants or small children with each individual injection of a thimerosal-containing shot, with each single-day administration of multiple thimerosal-containing shots, or with the cumulative administration of multiple shots during the first 24 months of a child's life, pursuant to the recommended pediatric immunization schedule.

Moreover, the section of Plaintiffs' Complaint discussing Plaintiffs' general factual allegations sheds light on the nature of the risks allegedly posed by dangerous levels of ethyl mercury, a substance known by Defendant to have neurotoxic properties.[7]

The very nature of a products liability action—where the cause or source of the defect is not obvious to the consumer—makes it difficult for a plaintiff to pinpoint a specific source of defect against one entity along the chain of distribution prior to discovery. *Bailey v. Janssen Pharmaceutica, Inc.*, 288 Fed. App'x 597, 605 (11th Cir. 2008). It is difficult for a plaintiff at such an early stage in the litigation to know the source of the defect that was responsible for the harm caused. *Id*. Thus, it would be difficult at this stage of the litigation for the Cooks to particularly allege the exact deficiencies in Carolina Laboratories' testing procedures, despite Defendant's insistence that Plaintiffs specifically plead the source of the defect.

Because Plaintiffs' Complaint gives adequate notice of the Plaintiffs' accusations, Plaintiffs' design defect claims have been sufficiently pled.

B. National Childhood Vaccine Injury Act of 1986

1. Vaccine Act in General

[7] "As a result of the mercury exposure, Estella Marie suffered neurological injuries, including developmental delays, learning disabilities, social delays and deficits, the impairment of fine motor skills, gastrointestinal illness, immune system dysfunction, and other symptoms of mercury poisoning. Some of his injuries are likely to be permanent."

While most children derive a great benefit from childhood vaccination, "a small but significant number have been gravely injured." *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 663-66 (S.D. Tex. 2004). Vaccine-related injuries raise two concerns: (1) the inconsistency, expense, delay, and unpredictability of the tort system in compensating claims of vaccine-injured children; and (2) the instability and uncertainty of the childhood vaccine market inevitably caused by the risks of tort litigation. *Id*. With the passage of the Vaccine Act, Congress hoped to prevent manufacturers from ceasing vaccine production or significantly increasing their prices, while at the same time hoping to compensate victims of vaccine-related injuries quickly. *See Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994).

"The Vaccine Act reflects a congressional determination that the disappearance or unavailability of childhood vaccines would cause far greater harm than the inevitable but limited injuries caused by the vaccines themselves." *Blackmon*, 328 F. Supp. 2d at 663-66 (citing *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995)). In effect, the Act "ensures that all children who are injured by vaccines have access to sufficient compensation for their injuries." H.R. Rep. No. 99-908 at 4 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6345. A person alleging a vaccine-related injury can obtain compensation by filing a petition with the Vaccine Court. The petitioner need not prove fault nor causation; he only needs to show that he received the vaccine and then suffered certain symptoms within a defined period. *See* 42 U.S.C. §§ 300aa-13, 300aa-14.

In the event a plaintiff seeking compensation for vaccine-related injuries does not accept the judgment of the Vaccine Court and elects to pursue claims in state or federal court, the Vaccine Act includes certain limitations on state tort claims designed to "free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufacturers in the market." *Schafer*, 20 F.3d at 4. The limitations are stated in 42 U.S.C. § 300aa-21, and convey Congress's intent to supersede, or preempt, state tort law standards and create legal protections that apply in any civil action brought against a vaccine manufacturer.

The pertinent part of the Vaccine Act that modifies state tort law, and is at issue in this case, provides:

> (a) General Rule
>
> Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
>
> (b) Unavoidable adverse side effects; warnings
>
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the

> administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.
>
> (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 *et seq.*] and *section 262* of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiffs shows--
>
> (A) that the manufacturer engaged in the conduct set forth in *subparagraph (A)* or *(B)* of *section 300aa-23(d)(2)* of this title, or
>
> (B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).
>
> (c) Direct warnings
>
> The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.
>
> …
>
> (e) Preemption
>
> No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

42 U.S.C. § 300aa-22.

As the words of the statute indicate, the Vaccine Act provides that

"[s]tate law shall apply to a civil action" for "vaccine-related injury," except in certain situations including if a plaintiff's vaccine-related injury resulted from side effects that were unavoidable even though the vaccine was properly prepared.

2. Plaintiffs' Defective Design Claims against Defendant Are Barred

Plaintiffs' defective design claim against Carolina Laboratories, based on a strict liability theory is barred. The purpose of the Vaccine Act would not be served if defective design claims could be tried before juries. A case-by-case determination of whether a vaccine was unavoidably unsafe would defeat the protection the Act was intended to provide vaccine manufacturers.

The legislative history of § 22(b) clearly supports the conclusion that Congress intended to protect vaccine manufacturers from liability for defective design claims. If a vaccine-injured person "cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system." 1986 U.S.C.C.A.N. at 6367.

In addition, product liability law and comment k to the Restatement (Second) of Torts § 402A aid this holding. The Vaccine Act mirrors this established area of tort law for unavoidably unsafe products and limits the strict liability of vaccine manufacturers for vaccine-related injuries to claims that the vaccine deviated from its FDA-approved design or it was not accompanied by proper warnings (and thereby eliminates strict liability defective design claims). Here, Plaintiffs do not claim that Defendant deviated from the FDA-approved design for the vaccines and the warnings supplied were adequate. Accordingly, Plaintiffs' strict liability design defect claim is preempted by the Vaccine Act.

Significantly, the Vaccine Act limits a manufacturer's liability for design defects regardless of the cause of action. Therefore, Plaintiffs' defective design claim based on negligence is preempted for the same reasons as the strict liability claim. The text of the Vaccine Act that limits a manufacturer's liability is not directed toward any particular cause of action. Section 22(b)(1) states broadly that no manufacturer "shall be liable in a civil action for damages arising from a vaccine-related injury or death." "A civil action for damages" includes a product liability claim based on strict liability as well as negligence. *See Blackmon*, 328 F. Supp. 2d at 666 ("While comment k is restricted to strict liability claims, § 22(b) is not."). Thus, Plaintiffs' negligent design defect claim is also barred by the Act.

V. Conclusion

For the reasons discussed above, all claims against vaccine defendant Carolina Laboratories are dismissed with prejudice. An appropriate Order follows.

ORDER

AND NOW, this 25th day of March, 2008, upon consideration of all outstanding motions filed, and all

responses thereto, it is hereby **ORDERED**:

1.) Defendant Carolina Laboratories' Motion to Dismiss is **GRANTED**. All defective design claims against Carolina Laboratories are preempted and dismissed for the reasons set forth in the preceding opinion.

UNITED STATES COURT OF APPEALS
FOR THE THIRTEENTH CIRCUIT

Dan Cooks, *et al.*,

Appellants

-V-

Carolina Laboratories, Inc.,

Appellee

No. 09-1032

August 6, 2009, Decided

Before MUSTARD, PEACOCK, and PLUM, Circuit Judges

PLUM, *Circuit Judge*

Plaintiffs-Appellants appeal from the district court's decision dismissing their claims for design defect against the Defendant-Appellee.

For the following reasons, we **AFFIRM**.

I. Introduction

Appellants Dan and LoEtta Cooks, individually and on behalf of their minor daughter, brought suit against Appellee Carolina Laboratories, a vaccine manufacturer, alleging that their daughter suffered neurological damage caused by a vaccine made with the preservative thimerosal, which contained the toxic substance mercury. Appellants' claims under Grace law included strict liability and negligence. They alleged Defendant failed to conduct adequate tests to determine whether thimerosal was safe and that a safer alternative existed.

The district court granted Defendant's motion to dismiss, ruling that Appellants' design defect claims were preempted by the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"), 42 U.S.C. § 300aa-1 *et seq*. Appellants filed a timely notice of appeal.

II. Jurisdiction

This Court has jurisdiction of Appellants' appeal pursuant to 28 U.S.C. § 1291, as the district court's order granting the Defendant's motion to dismiss is an appealable final decision.

III. Standard of Review

We review *de novo* the district court's order granting a motion to

dismiss for failure to state a claim under Rule 12(b)(6). *E.g.*, *Morrison v. Marsh & McLennan Cos.*, 439 F.3d 295 (6th Cir. 2006). We may affirm dismissal on any basis supported by the Rule 12(b)(6) record. *E.g.*, *Torch Liquidating Trust v. Stockstill*, 561 F.3d 377, 384 (5th Cir. 2009).

A motion to dismiss pursuant to Rule 12(b)(6) operates to test the sufficiency of the complaint. The first step in testing the sufficiency of the complaint is to identify any conclusory allegations. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. at 1949 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "[A] plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citations and quotation marks omitted). Although the court must accept well-pleaded factual allegations of the complaint as true for purposes of a motion to dismiss, the court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Id*.

After assuming the veracity of all well-pleaded factual allegations, the second step is for the court to determine whether the complaint pleads "a claim to relief that is plausible on its face." *Iqbal*, 129 S. Ct. at 1949, 1950 (citing *Twombly*, 550 U.S. at 556, 570 (rejecting the traditional 12(b)(6) standard set forth in *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957))). A claim is facially plausible when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S. Ct. at 1949 (citing *Twombly*, 550 U.S. at 556). The standard for plausibility is not akin to a "probability requirement," but it requires "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 129 S. Ct. at 1949 (citing *Twombly*, 550 U.S. at 556).

IV. Discussion

Appellee contends that the allegations against it are insufficiently pled. Therefore, it is necessary to determine (1) whether it is legally possible to assert design defect claims under the Vaccine Act and (2) given the relevant legal standards, whether Appellants' show a possible cause of action.

A. National Childhood Vaccine Injury Act of 1986

The district court erred in holding that 42 U.S.C. § 300aa-22(b)(1) preempts all claims that a vaccine was defectively designed.

Congress modeled subsection (b)(1) after comment k to § 402A of the Restatement (Second) of Torts. Comment k has been interpreted in a variety of ways and there is a wide range of disagreement regarding its application. *Freeman v. Hoffman-La Roche, Inc*., 618 N.W.2d 827, 835 (Neb. 2000). Most of the states that have adopted comment k have applied it in a more limited fashion and on a case-by-case basis. *See, e.g.*, *Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 726 (Ga. Ct. App. 2003); *Tansy v. Dacomed*

Corp., 890 P.2d 881, 886, n.2 (Okla. 1994).

The text of subsection (b)(1) is most consistent with the majority understanding of comment k. Under that subsection, a vaccine manufacturer is not civilly liable "if the [vaccine-related] injury or death resulted from side effects that were unavoidable…." The conditional nature of this clause contemplates the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable.

This construction of 42 U.S.C. § 300aa-22(b)(1) is bolstered by the 1986 committee report that states:

> The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding "unavoidably unsafe" products, i.e., those products which in the present sense of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.

H.R. Rep. 99-908, at 26, as reprinted in 1986 U.S.C.C.A.N. 6344, 6367. As acknowledged in *Militrano v. Lederle Laboratories*, this wording "appears to leave open the possibility of a design defect claim with respect [to] vaccines covered by the Vaccine Act…." 810 N.Y.S.2d 506, 508 (N.Y. App. Div. 2006). Further, the committee report does not use language which indicates that use of the compensatory system is mandatory. The report provides that "[v]accine-injured persons will now have an appealing alternative to the tort system." H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367. Accordingly, Congress defended the new compensation system by assuming that it would attract even vaccine-injured persons who may be able to prove that the vaccine was not made as safe as reasonably possible.

This analysis is consistent with the structure and purpose of the Vaccine Act as a whole. Having thoroughly examined both the text of 42 U.S.C. § 300aa-22(b)(1) and the congressional intent behind that subsection and the entire Act, we hold that subsection (b)(1) clearly does not preempt all design defect claims against vaccine manufacturers, but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe.

The district court erred when it concluded that § 22(b)(1) protects vaccine manufacturers from all suits. Although the Act provides for limited no-fault compensation, the district court's construction of subsection (b)(1) would have the perverse effect of granting complete tort immunity from design defect liability to an entire industry. In the absence of any clear and manifest congressional purpose to achieve that result, we must reject such a far-reaching interpretation of the Vaccine Act.

B. Adequacy of the Pleadings

Having determined that the Vaccine Act does not preempt all design defect claims against vaccine manufacturers, it remains to determine whether Appellants' allegations are sufficient to satisfy the necessary pleading standard.

The district court erred in holding that Appellants' design defect claims have been sufficiently pled. Initially, it should be noted that the district court's reliance on *Iqbal v. Hasty*, 490 F.3d 143, 155-58 (2d Cir. 2007), *rev'd*, *Iqbal*, 129 S. Ct. at 1954, was misguided. Although some predicted earlier than others that the enhanced pleading requirements established in *Twombly* would apply to pleading in all actions, with its recent decision in *Iqbal*, the Supreme Court has removed all doubt.

In *Bell Atlantic Corporation v. Twombly*, the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in *Conley v. Gibson* that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Twombly*, 550 U.S. at 561 (quoting *Conley*, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. This "does not impose a probability requirement at the pleading stage," but instead "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of" the necessary element. *Id*. at 556.

In *Ashcroft v. Iqbal*, the Supreme Court affirmed that *Twombly* standards apply to all motions to dismiss. 129 S. Ct. at 1949. Two working principles underlie the Court's decision in *Twombly*. *Id*. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. *Twombly*, 550 U.S. at 555. Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. *Id*. at 556. Determining whether a complaint states a plausible claim for relief requires the reviewing court to draw on its judicial experience and common sense. *Iqbal*, 129 S. Ct. at 1950.

Applying the sufficiency standard set forth in *Twombly* and affirmed in *Iqbal*, Appellants' claims for design defect against Appellee must be dismissed pursuant to Rule 12(b)(6). Appellants' Complaint does nothing more than provide a formulaic recitation of the elements of a design defect claim. Significantly, Appellants' Complaint alleges nothing more than conclusions of law[8] and fails to state any scientifically

[8] For example:

> The vaccine product injected into [Minor Name] was unreasonably and dangerously defective because it contained dangerous levels of ethyl mercury, a substance known to the defendants to have neurotoxic properties.
>
> Defendants failed to conduct adequate safety

reliable evidence to support their allegations that Appellee failed to conduct adequate tests to determine whether thimerosal was safe and that a safer alternative existed.

Civil Rule of Procedure 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions. *Iqbal*, 129 S. Ct. at 1950. After *Iqbal*, we expect that tort complaints would become more fact-inclusive and less rhetoric.

Because they have not alleged any facts that would permit the Court to conclude that there was a defect in the design of the vaccine in question and that the defect was the proximate cause of Estella Marie's alleged injuries, Appellants' claims for design defect must be dismissed.

V. Conclusion

For the foregoing reasons, we **AFFIRM** the district court's dismissal of the case.

> tests to determine whether thimerosal was safe and nontoxic to humans in the doses administered to pregnant women, infants or small children with each individual injection of a thimerosal-containing shot, with each single-day administration of multiple thimerosal-containing shots, or with the cumulative administration of multiple shots during the first 24 months of a child's life, pursuant to the recommended pediatric immunization schedule.
>
> The unreasonably dangerous and defective products described were a substantial contributing cause of plaintiff's neurodevelopmental injuries.

THE SUPREME COURT OF
THE UNITED STATES

Dan Cooks, *et al.*,

Petitioners,

-V-

Carolina Laboratories, Inc.,

Respondent

No. 10-1524

This petition for writ of certiorari to the United States Court of Appeals for the Thirteenth Circuit is hereby granted that this Court may hear and consider the following issues:

1. Does the National Childhood Vaccine Injury Act of 1986 preempt state product liability suits for design defects?

2. Did the appellate court properly apply the *Twombly* pleading rules when it granted Respondent's motion to dismiss pursuant to Civil Rule of Procedure 12(b)(6)?