No. 10-1524

IN THE

SUPREME COURT OF THE UNITED STATES

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

BRIEF FOR RESPONDENT

Team No. 10

ATTORNEYS FOR RESPONDENT

QUESTIONS PRESENTED

I. Whether Congress intended to preempt state product liability suits against vaccine manufacturers for design defects, when it established the National Childhood Vaccine Injury Act of 1986 for the purposes of quickly compensating victims of vaccine-related injuries while keeping vaccine prices low and vaccine manufacturers in the market.

II. Whether the heightened pleading standards set forth by this Court in *Twombly* allow a design defect claim to survive a Fed. R. Civ. P. 12(b)(6) motion to dismiss, where the complaint alleges general factual allegations and the complainant relies on the discovery process in order to plead more specifically.

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The opinion of the United States District Court for the District of Grace is unreported but appears in the record at pages 1–8. The decision of the United States Court of Appeals for the Thirteenth Circuit is also unreported and appears in the record at pages 9–13.

CONSTITUTIONAL AND STATUTORY PROVISIONS

The following constitutional provisions and federal rules are relevant to the determination of this case and may be found in the Appendices: U.S. Const. art. VI, cl. 2, Fed. R. Civ. P. 8(a)(2), and Fed. R. Civ. P. 12(b)(6). This case also involves the interpretation of 42 U.S.C. § 300aa-22, which provides, in pertinent part:

> 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.

National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22(b)(1) (1986).

STATEMENT OF THE CASE

This suit was brought in the United States District Court for the State of Grace by the Petitioners, parents of 12-year-old Estella Marie Cooks who claim she was injured after receiving three doses of a combination vaccine manufactured by Respondent, Carolina Laboratories, Inc. (R. 1–2.) According to Petitioners' complaint, their daughter suffered several neurological injuries as a result of a preservative in the vaccine.[1] (R. 1.) Among the neurological injuries alleged are social and developmental delays, social deficits, and immune system dysfunction. (R. 1.)

[1] "The parties do not dispute that the product administered . . . is a vaccine under the Vaccine Act." (R. 1.)

The Vaccine. Petitioners' daughter received the combination vaccine, Diphteria and Tetanus Toxoids and Pertussis (DTP)—Haemophilus influenza type b (Hib), in three dosages over a two-year period, from March 1996 to October 1998. (R. 1.) The vaccine contained a thimerosal preservative, which is an organic compound approximately fifty percent mercury by weight. (R. 1.) The vaccine was "produced in accordance with FDA-approved specification" and Petitioners do not claim that the vaccine was defectively prepared or manufactured. (R. 1.) Petitioners also do not contend that the warnings supplied by Respondent were inadequate. (R. 1.) Rather, Petitioners' defective design claims rest solely on the presence of thimerosal in the vaccine, which they conclude resulted in their daughter's injuries. (R. 1.)

The National Childhood Vaccine Injury Act of 1986. Petitioners' daughter was first administered the vaccine in 1996, ten years after Congress had enacted the National Childhood Vaccine Injury Act of 1986 (Act), 42 U.S.C. §§ 300aa-1–34 (1986). (R. 1.) The Act was established primarily in response to two concerns which were raised by vaccine-related injuries. First, the inconsistency, expense, delay, and unpredictability of the tort system in compensating claims of vaccine-injured children, and second, the negative impact on the childhood vaccine market as a result of tort litigation. (R. 5.)

For injuries and deaths traceable to vaccinations, the Act establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system. A petitioner to the Vaccine Court need only show that he received a vaccine and then "suffered certain symptoms within a defined period." (R. 5.) (citing 42 U.S.C. §§ 300aa-13, 300aa-14 (1986)). "Petitioners are compensated because they suffered harm from the vaccine—even a 'safe' one—not because they demonstrated wrongdoing on the part of the manufacturer." H.R. Rep. No. 99-908 at 24.

The Vaccine Act allows a petitioner to pursue claims under the vaccine compensation program as well as in civil actions governed by state law. 42 U.S.C. § 300aa-22(a); (R. 5.) However, Congress excluded certain claims from being brought under state law, namely those which are a result of "unavoidable side effects." 42 U.S.C. § 300aa-22(b). Congress modeled § 22 of the Vaccine Act after comment k of the Restatement (Second) of Torts § 402A (1965). H.R. Rep. No. 99-908 at 24. "The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding 'unavoidably unsafe' products . . . apply to the vaccines covered in the bill and that such products not be subject of liability in the tort system." *Id.*

Procedural History. Petitioners initially filed a petition for compensation with the National Vaccine Injury Compensation Program (Vaccine Program) in 2001, five years after their daughter was first administered the vaccine. (R. 1.) They subsequently withdrew their petition two years later to pursue a civil action for "damages, costs, punitive damages, and other legal or equitable relief" against Respondent under Grace state law. (R. 2.) Petitioners' two-count complaint was based on negligence and strict liability. First, Petitioners asserted that Carolina Labs "negligently failed to conduct adequate safety tests" to determine whether the thimerosal preservative in the combination vaccine was safe and nontoxic to humans in the doses administered, and Petitioners further asserted that the vaccine was defectively designed and a safer alternative existed. (R. 2.) Petitioners additionally contend in their complaint that Carolina Labs "should have manufactured children's vaccines without thimerosal prior to their daughter's vaccination." (R. 3.) Petitioners claim they are unable to plead more specific allegations prior to discovery. (R. 3.)

Two issues are relevant to the determination of this case. (R. 2–3.) First is whether § 22 of the Vaccine Act preempts Petitioners' design defect claims under Grace state law. Respondent contends that § 22(b) of the Vaccine Act sweeps broadly as "a total bar on design defect claims arising from vaccine-related injuries so long as the vaccine was produced in accordance with FDA-approved specifications." (R. 2.) Petitioner argues that the Vaccine Act bars only those design defect claims which arise from side effects determined to be "unavoidable" on a case-by-case basis. (R. 3.)

The second issue before this Court is whether Petitioners have adequately pled their claim in order to survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6). (R. 3.) Respondent argues that Petitioners' factual allegations are insufficient to survive such a motion, while Petitioners claim they have "sufficiently pled all of the elements of a cause of action for design defect." (R. 2–3.)

Both the district court and appellate court dismissed Petitioners' claim, but on differing grounds. (R. 8, 13.) The district court held that while Petitioners' design defect claims were sufficiently pled "to present claims for design defect under Grace state law," their claims were barred by the Vaccine Act and therefore had to be dismissed. (R. 3, 7.) The court of appeals disagreed that all defective design claims against a vaccine manufacturer were preempted by the Vaccine Act. (R. 10.) However, it affirmed the district court's dismissal, holding that Petitioners failed to plead sufficient factual allegations to satisfy the pleading standard under *Bell Atl. Corp. v. Twombly,* 550 U.S. 544 (2007). (R. 12.) Petitioner subsequently filed a petition for a writ of certiorari, which this Court granted. (R. 14.)

SUMMARY OF THE ARGUMENT

I.

First, Petitioners' design defect claims in both strict liability and negligence are preempted by the National Childhood Vaccine Injury Act of 1986. This conclusion is consistent with Congress's intent for enacting the vaccine legislation. While congressional purpose is the ultimate touchstone to any preemption case, courts must start with the "assumption that the historic police powers of the States [are] not to be superseded by . . . [a] Federal Act unless that [is] the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1974). This presumption against preemption can be overcome, as in this case, where legislative history reveals clear congressional intent to preempt state law. The congressional discussion behind the enactment of the Vaccine Act reveals that Congress enacted the Vaccine Act to respond to "an upsurge of vaccine-related litigation that threatened to drive manufacturers away from vaccine production or to cause remaining manufacturers to increase their prices significantly." *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 663 (S.D. Tex. 2004). Thus, since curbing litigation in order to protect the childhood vaccination market is clearly the reason for enacting the legislation, it unquestionably follows that any interpretations of the Act's provisions must be consistent with that purpose.

The plain language of § 22 of the Act, taken as a whole, reveals Congress's intent to preempt all design defect claims brought against vaccine manufacturers, including Petitioners. The provision states plainly that Congress's intent was to preclude tort claims for "unavoidably unsafe" vaccine side effects, except in those limited circumstances where there is an inadequate warning or a manufacturing defect claim being alleged. Petitioners claim that the determination of whether a vaccine's side effects are "unavoidably unsafe" should be decided on a case-by-case basis. However, this interpretation of the provision is inconsistent with congressional intent to

curb litigation against vaccine manufacturers. Petitioners' interpretation would open the door for any person injured by a vaccine to bring a claim and require a court to determine, on a case-by-case basis, that the side effect was unavoidably unsafe. Thus, vaccine manufacturers would still be forced into litigation and Congress's purpose for the Vaccine Act would be defeated.

Section 22 is unquestionably an express preemption provision where Congress clearly manifests its intent to preempt *all* design defect claims except in limited circumstances. A case-by-case determination of "unavoidably unsafe" would defeat Congress's purpose and intent for the Act. For these reasons, this Court should affirm the judgment of the Court of Appeals for the Thirteenth Circuit and dismiss Petitioners' design defect claims under Grace state law because they have been preempted by the Vaccine Act.

II.

Second, even if this Court does not find that the Vaccine Act preempts Petitioners' design defect claims, this Court should dismiss Petitioners' suit pursuant to the federal rules for failing to allege sufficient factual allegations in a pleading in accordance with the heightened pleading standards found in *Twombly*. The federal rules require a short and plain statement of the claim showing that the pleader is entitled to relief. In *Twombly,* and later in *Iqbal* this Court clarified that in order to survive a 12(b)(6) motion to dismiss, a pleading must establish sufficient factual allegations to raise a right to relief above the speculative level.

Legal conclusions are not factual allegations. While a court determining a motion to dismiss must accept as true all factual allegations in a complaint, this standard is inapplicable to legal conclusions. This Court's recent development of jurisprudence interpreting the federal rules requires more than broad allegations or legal conclusions. A claimant must do more than merely state that the possibility of allegations is possible or conceivable.

In the instant case, Petitioners' complaint is couched with legal conclusions and is ripe with assertions devoid of factual enhancements. A formal recitation of the elements of a cause of action is insufficient to carry a claim past a motion to dismiss. Petitioners do not state evidence or provide sufficient factual allegations to support their causes of action; instead, Petitioners offer a threadbare recital of the formal elements of a products liability claim supported by conclusory statements. Such pleadings are insufficient and must be dismissed pursuant to this Court's decisions in both *Twombly* and *Iqbal*.

Petitioners claim they are unable to plead more specifically without first conducting discovery. However, a party armed with nothing more than a deficient complaint is not entitled access to discovery. The initial threshold requirements for substantial pleadings is needed to put defendants on notice of claims that are being brought against them. However, Petitioners failed to state sufficient factual allegations in support of their design defect claim and consequently would not be entitled to relief. Such a minimal showing is insufficient to put a party on notice of what claims are being brought, and is prohibited by Rule 8.

Although the complaint alleges *some* facts, it is not enough to nudge the claims across the line from conceivable to plausible. Instead, Petitioners would waste the time and money of both the parties and the courts in the hope that discovery will yield details upon which they can substantiate their claims. Because Petitioners' pleadings fail to meet the threshold required by the federal rules, they are not entitled to discovery, and their complaint must therefore be dismissed.

Moreover, a holding to the contrary would only expose defendants to unnecessary financial burdens. Should this Court allow for plaintiffs to bring insufficiently pleaded claims ripe with conclusory allegations, defendants would be faced with a no-win situation: settle claims

that lack merit, or face harm to reputation, increased discovery costs, and ultimately an increase in prices to the consumer. Such a holding would render a detrimental impact to manufacturers, consumers, and the federal court system, while only providing a benefit to few claimants.

ARGUMENT & AUTHORITIES

A court's order granting a motion to dismiss for failure to state a claim under Rule 12(b)(6) is reviewed de novo. *Morrison v. Marsh & McLennan Cos.*, 439 F.3d 295 (6th Cir. 2006). If any basis for the dismissal is supported by Rule 12(b)(6), a reviewing court should affirm. *Torch Liquidating Trust v. Stockstill*, 561 F.3d 377, 384 (5th Cir. 2009). A court will assume the truth of all well-pleaded facts in the complaint and draw reasonable inferences in the light most favorable to the plaintiff. *Dias v. City and County of Denver*, 567 F.3d 1169, 1178 (10th Cir. 2009). However, this assumption is inapplicable when the complaint relies on a recital of the cause of action supported by mere conclusory statements. *See Iqbal*, 129 S.Ct. at 1949.

I. THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986 PREEMPTS PETITIONERS' DESIGN DEFECT CLAIMS UNDER GRACE STATE LAW.

The congressional power to preempt state law is derived from the Supremacy Clause of the United States Constitution. *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 208 (1985) (citing *Hines v. Davidowitz*, 312 U.S. 52 (1941)). Article VI declares the laws of the United States to be "'the supreme Law of the Land . . . and any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. This Court has recognized three ways in which federal law may supersede state law: through express preemption, implied conflict

preemption, and field preemption.[2] *See Hillsborough County, Fla. v. Automated Med. Labs., Inc.,* 471 U.S. 707, 713 (1985). Once express preemption has been determined based on the language of a provision, a court's next step is to determine the scope of that preemptive provision, based on congressional purpose, and intent. *See Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 243 (2009).

In any preemption case, "[t]he purpose of Congress is the ultimate touchstone." *Retail Clerks v. Schermerhorn,* 375 U.S. 96, 103 (1963). Thus, congressional intent is the focus of courts in reviewing federal law; when Congress has evidenced the intent to occupy a field of law, state law must yield. *Crosby v. Nat'l Foreign Trade Council,* 530 U.S. 363, 372 (2000) (citing *California v. ARC America Corp.,* 490 U.S. 93, 100 (1989)).

When preemption is sought in a field that has traditionally been left to the states, the assumption is that the police powers of the states will not be displaced by federal law unless that is the "clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947). However, the police powers of a state must still yield to federal law absent any congressional intent for preemption where the state law actually interferes with, or is contrary to federal law. *Gade v. Nat'l Sold Wastes Mgmt. Ass'n,* 505 U.S. 88, 108 (1992).

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[2] *See* Susan Raeker-Jordan, *The Pre-Emption Presumption that Never Was: Pre-Emption Doctrine Swallows the Rule*, 40 ARIZ. L. REV. 1379, 1383 (1998).

> Under the Supremacy Clause, federal law may supersede state law in several different ways. First, when acting within constitutional limits, Congress is empowered to pre-empt state law by so stating in express terms. In the absence of express pre-emptive language, Congress' intent to pre-empt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress left no room for supplementary state regulation. Pre-emption of a whole field also will be inferred where the field is one in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.

Id.

The three types of preemption have all been articulated by this Court. *See Hillsborough County,* 471 U.S. at 713. Federal law expressly preempts state law where the federal law contains express language requiring preemption.[3] *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001). Implied conflict preemption can occur when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[4] *Hines*, 312 U.S. at 67. Finally, field preemption occurs when Congress reserves a field, leaving no room for state regulation in that particular field of law.[5] *United States v. Locke*, 529 U.S. 89, 111 (2000).

A. Section 300aa-22 Is An Express Preemption Provision.

Section 22 of the Vaccine Act is an express preemption provision because it contains language expressly requiring preemption. In construing an express preemption clause, a court must begin with the examination of the "plain wording of the clause," as this "necessarily contains the best evidence of Congress's pre-emptive intent." *Sprietsma v. Mercury Marine,* 537 U.S. 51, 62–63 (2002).

The Third Circuit has dealt with a similar congressional provision. In *Bruesewitz,* the Court of Appeals for the Third Circuit analogized the provisions of the Vaccine Act to the Federal Cigarette Labeling and Advertising Act. *Bruesewitz,* 561 F.3d at 242. The Federal

[3] *See Lorillard Tobacco Co. v. Reilly,* 533 U.S. 525 (2001). The *Lorillard* Court reviewed the Federal Cigarette Labeling and Advertising Act's language. *Id.* The Court held the language of the Act stating "[n]o requirement or prohibition based on smoking and health shall be imposed under State law . . ." expressly preempted state law. *Id.* (citing 15 U.S.C. § 1334).

[4] The *Hines* Court dealt with the Alien Registration Act of 1940. 312 U.S. at 53. In finding that Congress had intended the Alien Registration Act to preempt state law, the Court reviewed the legislative history of the Act, comments made during the Senate hearings prior to the Act's passage, and even portions of the bill that were ultimately omitted from the finalized Act. *Id*. at 70-74.

[5] *Locke* dealt with federal regulation of the general seaworthiness of tankers and their crews. 529 U.S. at 110. This Court found that the federal government's regulation of the "design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning" of tanker vessels left no room for state regulation in the same field. *Id*. at 111, 117.

Cigarette Labeling and Advertising Act was deemed by this Court to be an express preemption provision, based on its language that "'no statement relating to smoking and health other than the statement required by section 1333 of this title, shall be required on any cigarette package.'" *Id.* (quoting *Lorillard Tobacco Co.,* 533 U.S. at 541). The *Bruesewitz* court held the language of that provision was "analogous to subsection 22(b)(1) of the Vaccine Act, which states that 'no vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were unavoidable.'" *Id.* The court explained that while a provision stating that "no state shall pass laws with the following exceptions" is broader than a provision stating that "state law applies with the following exceptions," the breadth of the provision would not alter or interrupt clear congressional intent to override state law civil action claims in specifically defined circumstances. *Id*. at 243. Relying on this Court's reading of the Federal Cigarette Labeling and Advertising Act, the *Bruesewitz* court concluded that § 22 is also an express preemption provision. *Id.*

State courts have also recognized that causes of action under the Vaccine Act are expressly preempted unless all the remedies for vaccine related injuries under federal law are exhausted. *Cook. v. Children's Med. Group, P.A.,* 756 So.2d 734, 743 (Miss. 1999). In *Cook,* the plaintiff had received vaccinations from the defendant hospital. *Id.* at 736. After some time had passed, the plaintiff began exhibiting signs of autism, including an expressive language disorder, which his parents later learned could be caused by the vaccinations plaintiff had been given. *Id.* at 737. The plaintiff filed suit against the hospital for fraud, which the court dismissed based on reasons other than preemption. *Id.* at 741. However, in issuing its decision, the court explained that while the fraud claim was dismissed for other reasons, the plaintiffs had not

properly filed for damages relating to the vaccine. *Id*. at 742. Observing that the Vaccine Act was the correct vehicle for damages relating to a vaccine, any action brought should have gone through the Vaccine Act first. *Id.* The plaintiff was required to first exhaust his remedies under the Vaccine Act before it is proper for him to file in state court. *Id.* at 743.

A similar outcome was reached in an action for design defect and failure to warn claims in an appellate court in the state of New York. *Militrano v. Lederle Lab.,* 26 A.D.3d 475, 478 (N.Y. App. Div. 2006). In *Militrano*, an infant suffered a seizure moments after being administered a vaccination of Tetramune by the defendant hospital and doctors. *Id.* at 475. After the plaintiffs filed suit for design defect in the New York Supreme Court, defendants filed, and were granted a motion for summary judgment stating that the claim was preempted by the Vaccine Act. *Id.* at 476. After a short and direct analysis of the House Committee Report, the New York Court of Appeals affirmed the dismissal recognizing that the "the intent of Congress to preclude all design defect claims with respect to vaccines covered by the Vaccine Act is clear." *Id.* at 477.

B. Legislative History Reveals Congress' Intent to Preempt Certain Tort Claims.

Once it has been established that an express preemption provision exists, the next step in a preemption case is to determine the scope and reach of the provision. *Id.* The primary task of this Court, in determining whether Petitioners' design defect claims are preempted, is to ascertain the intent of Congress. *Cal. Fed. Sav. & Loan Ass'n v. Guerra,* 479 U.S. 272, 280 (1987). "Preemption is a question of congressional intent . . . the best source for divining that intent is the committee reports on the bill." *Lederle Labs.,* 810 N.Y.S.2d at 508. However, in determining the scope of a preemption provision, courts must operate under a presumption against preemption. *Bruesewitz,* 561 F.3d at 239. This presumption can be overcome by a clear showing of Congress's intent to preempt. *Id.*

Congress's intentions with regard to the Vaccine Act can be found in the Act's legislative history, as well as inferred from Congress's purposes for establishing the Vaccine Act:

> This statute, designed to become effective upon the passage of subsequent legislation to provide a fund for compensation payments thereunder, offered a simple, expeditious, and informal method of establishing eligibility for compensation for injuries or death resulting from the administration of any of certain vaccines, deemed by Congress to be particularly prone to cause adverse reactions.

Russell G. Donaldson, *Construction and Application of National Childhood Vaccine Injury Act*, 129 A.L.R. Fed. 1, 2a (1996). Furthermore, the First Circuit has recognized Congress's intent to use this simple and expeditious method to keep the vaccination manufacturers from "large, uncertain tort liability." *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994). In *Schafer*, the First Circuit expounded the great importance of keeping manufacturers' costs low and vaccines affordable by having this Act remove the strain of this type of liability.[6] *Id.* *See, also,*

[6] The Third Circuit expounded on this issue, stating:

> Vaccines benefit those who are vaccinated, and they have public benefits as well – when parents vaccinate their own children, they also help stop the spread of a disease that can injure others. And, even though vaccines themselves cause a small number of serious injuries or deaths, their widespread use dramatically reduces fatalities. For example, the DPT vaccine itself may cause 150 or so incidents of serious neurological damage and the polio vaccine may itself cause about five annual incidents of paralysis. But before widespread vaccination, whooping cough, for example, killed about 7,500 (mostly) children in a single year, diphtheria killed about 15,000, and polio injured, paralyzed, or killed about 57,000. Thus, despite the price to be paid in vaccine-caused injuries, widespread vaccination . . . has virtually wiped out these devastating diseases . . . [B]ecause vaccines benefit so many (and harm so few), even small vaccine price increases, if followed by even a small decline in vaccinations, can cause more public harm through added disease than the sum-total of all the harm vaccines themselves cause through side-effects . . . [T]he availability of a state tort remedy . . . interferes with the Act's efforts to lower manufacturers' costs. The Act seeks to achieve its cost-reducing purpose, not by denying compensation to victims . . . but by reducing the litigation and insurance costs related to lengthy, complex tort procedures, and random large tort awards. And, more importantly, it discourages victims from brining those traditional tort cases by providing fairly generous, more easily obtainable, Vaccine Court awards.

H.R. Rep. No. 99-908, at 2 (1986) (background and need for legislation), *as reprinted in* 1986 U.S.C.C.A.N. 6355, 6345.

Congress instituted the Vaccine Act and corresponding Vaccine Program in order to streamline the method with which those injured by vaccines could receive compensation for their injuries. *See* H. R. Rep. No. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6355; *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995). "[T]he Committee believes that once this system is in place and manufacturers have a better sense of their potential litigation obligations, a more stable childhood vaccine market will evolve." *Id.* at 7. The Committee referred to the House Committee on Energy and Commerce, which had jurisdiction over the Vaccine Act and guided it through legislation. *Bruesewitz,* 561 F.3d at 247. The Committee and Congress were concerned that the "withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, the resurgence of preventable diseases." H. R. Rep. No. 99-908, at 7.

Section 22(a) of the Vaccine Act states, "[e]xcept 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." 42 U.S.C. § 300aa-22(a). When this provision is read in conjunction with the backdrop of congressional intent, there is no denying that Congress intended to at least preempt *some* tort claims, specifically those in subsections (b), (c), and (e). Both *Shalala* and the congressional record provide clear evidence that one of Congress's main objectives for enacting the Vaccine Act was to ensure the continued availability of childhood vaccination programs. Clearly, Congress determined that limiting a vaccine manufacturer's tort liability would help to accomplish this purpose.

Shafer, 20 F.3d at 4 (internal citations omitted).

C. Congress Intended to Preempt *All* Design Defect Claims.

The correct interpretation of a preemption provision requires that Congress's intent be discerned through an examining of "explicit statutory language and the structure and purpose of the statute." *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 138 (1990). A court's "ultimate task in any pre-emption case is to determine whether state regulation is consistent with the structure and purpose of the statute as a whole." *Gade,* 505 U.S. at 98. Implied preemption may exist even in the presence of express preemption, if a state regulation has the effect of "frustrating the accomplishment and execution of the full purposes and objectives of Congress." *Hines,* 312 U.S. at 67.

1. The legislative history of the statute reveals Congress's intent to preempt all design defect claims.

In *Blackmon,* the district court held that the plaintiffs could not pursue their claims outside of the Vaccine Act because § 22(b) barred "all defective design claims under the conditions outlined in the statute." 328 F. Supp. 2d at 663–64. The court reached its conclusion by looking to "the origins" of § 22(b), which it found in the Report of the Committee on Energy and Commerce, H.R. Rep. No. 99-908. *Id.* at 664. Congress revealed in the report that it modeled § 22(b) after Comment k of the Restatement (Second) of Torts § 402A. *Id.* at 664. Comment k, dealing with unavoidably unsafe products, provides that, "a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like . . . ." Restatement (Second) of Torts § 402A cmt. k (1966).

The *Blackmon* court further found Congress's clear intent to "relegate design defect claims to the compensation system" in the following passage of the Act's legislative history: "accordingly, if [vaccine-injured persons] 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." *Blackmon,* 328 F. Supp.2d at 664–65 (quoting H.R. Rep. No. 99-908, at 26). The *Blackmon* court interpreted this passage to mean that a person harmed by a vaccine was barred from bringing a design defect claim, either in strict liability or negligence, since only inadequate warnings or manufacturing defects were available to plaintiffs outside of the Act. *Id.* at 666. Other courts have reached this same conclusion based on the Vaccine Act's legislative history. *See Bruesewitz,* 561 F.3d at 243; *Sykes v. Glaxo-SmithKline,* 484 F. Supp.2d 289, 297 (E.D. Pa. 2007).

The legislative history of the Vaccine Act supports the conclusion that the Act preempts all design defect claims, including those based in negligence. To say otherwise would be to completely ignore the legislative history of the Act, which Petitioners and the Court of Appeals for the Thirteenth Circuit assert. The *Bruesewitz* court correctly stated in its conclusion that the legislative history of the Act supports a claim for the preemption of all design defect claims:

> First, the Committee report repeatedly stressed the importance of vaccine development and availability. Second, it expressed serious concern over the withdrawal of even a single vaccine manufacturer from the marketplace. Third . . . [it] emphasized that the new system would reduce and stabilize litigation costs while also enabling manufacturers to estimate the costs associated with compensation. Finally, it explicitly stated that injured individuals could only seek redress in the state tort system for certain manufacturing defect and warning claims.

Bruesewitz, 561 F.3d at 248–49.

***2.* A case-by-case reading of "unavoidably unsafe" interferes with the Act's manifest purpose.**

Petitioners attempt to twist Congress's plain language by contending that the "unavoidably unsafe" language of § 22(b)(1) must be construed on a case-by-case basis. Petitioners claim that the Vaccine Act only preempts claims once a fact-finder has made a

determination that the vaccine's side effects are unavoidably unsafe. However, such an interpretation is erroneous. Petitioners' interpretation would have the effect of interfering and directly contradicting Congress's manifest purpose in enacting the Vaccine Act.

Courts have recognized that legislative intent also shows that a determination of "unavoidably safe" side effects on a case-by-case basis goes against Congress's purpose for the Act. *Sykes v. Glaxo-SmithKline,* 484 F. Supp.2d at 301. In *Sykes*, a young mother went into receive a vaccination containing thimerosal, containing Diptheria, Tetanus Toxoids, and Pertussis. *Id.* at 292. While receiving these vaccinations, she was pregnant with her unborn child, Wesley, who has since developed neurological and neuro-developmental injuries from the reception of these vaccines. *Id.* Wesley's mother and father brought a timely petition on his behalf for the injuries incurred for strict products liability and negligence. *Id.* at 294.

The Eastern District of Pennsylvania has looked at the cause of action before this Court and also determined that such an action is preempted by the Vaccine Act. *Id.* at 323. The court specifically looked at the language contained in H.R. Rep. No., 99-908 and determined that Congressional intent was clear in having the Vaccine Act's compensation system govern complaints about injuries from a properly manufactured vaccine. *Id.* at 300. Furthermore, the court opined that to let a jury decide on a case by case basis whether a side effects of a vaccine were unavoidably unsafe would be "inconsistent with the policy behind the Vaccine Act," and "strips the passage of all meaning." *Id.* at 301.

The Supreme Court of Georgia, in *America Home Products Corp. v. Ferrari,* held an interpretation of § 22(b) identical to Petitioners' and that of the Court of Appeals for the Thirteenth Circuit. 668 S.E.3d 236, 240 (Ga. 2008). It focused on the seemingly conditional nature of the clause "if the injury or death resulted from side effects that were unavoidable." 668

S.E.2d at 240. The *Ferrari* court declared the conditional nature of the "if" clause implied that some vaccine-related injuries might be avoided. *Id.* Thus, it concluded that Congress, by including a conditional "if" phrase, intended for the Act to preempt state law only where it can be determined, on a case-by-case basis, that the particular side effects of the vaccine were unavoidable. *Id.*

This Court has stated that "in expounding a statute, we must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *Pilot Life Ins. Co. v. Dedeaux,* 481 U.S. 41, 51 (1987). By placing so much emphasis on the "if," the *Ferrari* Court unjustifiably looked to one phrase rather than the Act in its entirety. The *Bruesewitz* court rejected the *Ferrari* court's case-by-case reading of the statute. *Bruesewitz,* 561 F.3d at 246. "If we interpret the Vaccine Act to allow case-by-case analysis of whether particular side effects are avoidable, *every* design defect claim is subject to evaluation by a court." *Id.* (emphasis added).

Petitioners' interpretation of § 22(b) of the Vaccine Act would require a case-by-case determination of what types of vaccines are "unavoidably unsafe," and would "protect manufacturers from liability *only* on meritless claims." *Blackmon,* 328 F. Supp.2d at 665 (emphasis added). This interpretation is contrary to Congress's manifested purpose for creating the Act. The *Blackmon* court explained that, "Congress passed [the Act] to preserve the supply of vaccines and thereby prevent 'deadly, disabling, but preventable infectious disease.'" *Id.* at 663 (quoting H.R. Rep. No. 99-908, at 4). The court explained that the Vaccine Act reflected 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."[7] *Id.* Thus, one of Congress's chief concerns for enacting the Vaccine Act was to curb direct litigation of vaccine manufacturers to ensure the continued availability and low cost of childhood vaccinations. *Id.*; *see also Shafer*, 20 F.3d at 4 (explaining Congress's intent in passing the Vaccine Act was to ensure that the social benefit of vaccines would remain and that consumers would continue to enjoy low-priced vaccines).

The Thirteenth Circuit overlooked Congress's manifest purpose of the Act when it agreed with Petitioners that § 22(b) called for a case-by-case determination of "unavoidably unsafe." The court focused on the "conditional nature of this clause," carving out an additional provision where none existed. (R. 11.) Every design defect claim should not be subject to evaluation by a court. *See Bruesewitz*, 561 F.3d at 246. This result is clearly contrary to congressional intent.

The court of appeals reasoned that § 22(b)(1) "protects vaccine manufacturers from all suits." (R. 11.) However, this conclusion has the "perverse effect of granting complete tort immunity from design defect liability to an entire industry." (R. 11.) The court then held this result was contrary to Congress's manifest purpose and is a "far-reaching interpretation of the Vaccine Act." (R. 11.) The court of appeals failed to evaluate its conclusion in light of Congress's manifested purpose, as expressed in its congressional report. As the *Bruesewitz* court stated, such an interpretation would subject vaccine manufacturers to design defect claims every time an injury occurs. Such a holding is directly contrary to Congress's primary purpose: curbing the vast amount of litigation that vaccine manufacturers may be subjected to. Therefore, this Court should find that because the Vaccine Act does not call for a case-by-case

[7] *See* Daniel A. Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U.L. REV. 1853, 1856 (1995) (discussing legislative attempt to reform vaccine product liability litigation) Congressional proposal "demonstrate the continuing difficulties our nation faces in its attempt to establish a workable balance between product availability and product safety." *Id.*

determination of "unavoidably unsafe" side effects for design defect claims, and because Congress manifestly intended for all design defect claims to be preempted, all of Petitioners' design defect claims are preempted and should be dismissed.

II. PETITIONERS FAIL TO ALLEGE SUFFICIENT FACTUAL ALLEGATIONS IN SUPPORT OF ANY DESIGN DEFECT CLAIMS THEY MAY HAVE.

Rule 8(a)(2) requires that a pleading contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This Court, in *Twombly*, shed light on the "short and plain statement" requirement to mean more than just "labels and conclusions and formulaic recitation of the elements of a cause of action." 550 U.S. at 555. Specific facts in pleadings are not necessary. *Erickson v. Pardus,* 551 U.S. 89, 93 (2007). Furthermore, the well-pleaded complaint standard does not require that recovery be likely. *Scheuer v. Rhodes,* 416 U.S. 232, 236 (1974) ("A well-pleaded complaint may proceed even if it appears that a recovery is very remote and unlikely"). *Id.* However, the complaint must state a *plausible* claim for relief, *Iqbal,* 129 S.Ct. at 1950, and something "beyond the mere possibility of loss causation must be alleged." *Dura Pharms., Inc. v. Broudo,* 544 U.S. 336, 347 (2005).

A. Petitioners' Complaint Consists of Legal Conclusions, Not Factual Allegations.

A court is not "bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain,* 478 U.S. 265, 286 (1986). Where a complaint consists of mere legal conclusions and lacks sufficient factual allegations to render a claim plausible, the complaint will be dismissed. *See Iqbal,* 129 S.Ct. at 1942–43. While the pleading standards of the Federal Rules of Civil Procedure are intended to be liberal, they are also intended to serve as a gate keeper, separating legitimate claims from those that have no prospect of success. *See Leeds v. Meltz*, 75 F.3d 51, 53 (2d Cir. 1996) ("While the pleading standard is a liberal one, bald assertions and conclusions of law will not suffice."). This Court's decisions in both *Twombly*

and *Iqbal* confirm that a complaint must contain more than a "formulaic recitation of the elements of a cause of action . . . ." *Iqbal*, 129 S.Ct. at 1949 (quoting *Twombly*, 550 U.S. at 555). Instead, a plaintiff must include sufficient "factual matter" to provide "plausible grounds" to infer that the allegations of the complaint are true. *Id*. Requiring plausibility is not so strict as to require "probability," but nevertheless requires that allegations are more than merely possible or conceivable. *Id*. Consequently, simply alleging a scant possibility that allegations of a complaint may have a grain of truth is insufficient to satisfy Rule 8(a).

1. *Twombly* requires more than assertions devoid of factual enhancement.

This Court first interpreted the heightened factual sufficiency standards required by Rule 8 for a plaintiff's pleadings in *Twombly*. In *Twombly*, the defendants were several telecommunication conglomerates who were facing a putative class action law suit by their consumers. 550 U.S. at 550. The plaintiff's brought a cause of action under the Sherman Act, alleging that the defendants had attempted to restrict trade by engaging in conduct in each of their respective areas to restrict the growth of new telecommunication companies. *Id.* The complaint alleged that due to the absence of meaningful competition between the companies and other markets, the plaintiffs believed the defendants had entered into a "contract, combination or conspiracy to prevent competitive entry in their respective local telephone and/or high speed internet services markets." *Id.* at 551.

In reviewing the sufficiency of the pleadings this Court noted that Federal Rule of Civil Procedure 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). This Court had previously held that the requirements of Rule 8 are satisfied whenever the pleading gives the defendant fair notice of the claim and on what grounds the plaintiffs are resting their claim. *Conley v. Gibson*, 355 U.S. 41, 47 (1957). *Conley*'s liberal standard provided that a cause of action "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." *Id.* at 45–46. Some courts have read this sentence in isolation, allowing claims to survive unless they are factually impossible based upon the reading of the pleadings. *See Nagler v. Admiral Corp.,* 248 F.2d 319, 326 (2d Cir. 1957). The liberal construction of such a passage is what pushed this Court to ultimately overturn *Conley* when deciding *Twombly*. 550 U.S. at 562.

The complaint filed by the plaintiffs in *Twombly* did not allege any facts sufficient to support their antitrust claim. 550 U.S. at 552. While the complaint did outline the allegation of conspiracy and parallel conduct of the organizations to stunt business growth in their market, there were no factual statements to support these conclusions. *Id.* at 566. This Court has consistently held that grounds for relief sought must contain more than mere labels or conclusions accompanied with a recitation of the elements of a cause of action. *Papasan v. Allain*, 478 U.S. 265, 286 (1986). The plaintiffs in *Twombly* made their pleadings ripe with conclusions about the defendants entering into a conspiracy, but alleged nothing factual to support it, such as the existence of a meeting, an agreement, or plan. *Id.* at 550–51. Consequently, because no factual allegations existed in the pleadings to support their conclusions, the Court determined that they failed to state a valid antitrust claim.

2. The *Iqbal* Court expanded the *Twombly* decision to all motions to dismiss.

In *Iqbal*, this Court clarified the heightened pleading standards it established in *Twombly*. Among other things, the *Iqbal* Court affirmed that the *Twombly* standards applied to all motions to dismiss. *Iqbal*, 129 S.Ct. at 1942–43. The Court articulated two principles behind the *Twombly* decision: (1) a court does not have to accept as a true legal conclusions in a complaint; and (2) only a complaint stating plausible claim for relief survives a motion to dismiss. *Id.*

While the facts of *Twombly* dealt narrowly with the pleading requirements for plaintiffs bringing antitrust claims under the Sherman Act, this Court expanded its decision, holding that the pleading requirements established by *Twombly* applied much more broadly than just in antitrust matters. *Id*. at 1949. In *Iqbal*, the respondent was a prisoner who filed suit against a number of federal officials, alleging they adopted an unconstitutional policy that subjected him to harsh conditions of confinement because of his race, religion, or national origin. *Id*. at 1951. Furthermore, the prisoner alleged that former Attorney General Ashcroft was the "principal architect" of this invidious policy, and that Robert Mueller, Director of the Federal Bureau of Investigation was "instrumental" in adopting and executing the policy. *Id*. The complaint further alleged that "each [government official] knew of, condoned, and willfully and maliciously agreed to subject" him to these harsh conditions. *Id*. These statements, similarly to the allegations in *Twombly*, offered no factual allegation to support a constitutional claim.

The respondent in *Iqbal* argued that the *Twombly* Court's decision was narrow, only applying to antitrust matters. *Id*. at 1953. This Court rejected the respondent's contentions, explaining that *Twombly* was based upon the application and interpretation of Rule 8 of the Federal Rules of Civil Procedure. *Id*. at 1950–51. Such allegations were conclusory and not entitled to be assumed true. *Id*. at 1951. The Court explained that it was not rejecting the respondent's bald allegations because they were unrealistic or nonsensical but instead because conclusory allegations are not entitled to a presumption of truth. *Id*.

The Court also analyzed the prisoner's allegations to determine if they plausibly suggested an entitlement to relief. The complaint in *Iqbal* alleged that defendant Mueller detained thousands of Arab Muslim men in the wake of September 11, 2001 and held the detainees until they were cleared by the FBI and approved by both Ashcroft and Mueller. *Id*.

While such allegations were consistent with the defendants' purposeful designation of detainees because of their race, religion, or national origin, they did not plausibly establish a purpose. *Id*. The Court explained that the September 11th attacks were perpetrated by Arab-Muslim hijackers, and that a policy directing law enforcement officials to arrest and detain individuals because of their suspected link to the attacks would result in disparate, incidental impact on Arab Muslims; although, the purpose of the policy was not to target Arabs or Muslims. *Id*. When faced with the obvious alternative explanation for the arrests versus a finding of purposeful, invidious discrimination, the Court could not find that discrimination was a plausible conclusion. *Id*. at 1951–52.

Moreover, even if the facts gave rise to a plausible inference that respondent's arrest was the result of unconstitutional discrimination, that inference was insufficient to entitle the respondent to relief. *Id*. at 1952. The prisoner was required to allege more thorough factual content to nudge his claim of purposeful discrimination "across the line from conceivable to plausible." *Id*. (quoting *Twombly*, 550 U.S. at 570). Furthermore, the Court explained that the federal rules are not solely applicable to antitrust matters, but instead apply to "all civil actions and proceedings in the United States district courts." *See* Fed. R. Civ. P. 1. Rule 8 "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation," requiring that a plaintiff plead a claim which is "plausible on its face."[8] *Iqbal*, 129 S.Ct. at 1949 (citations

[8] *See* Andree Sophia Blumstein, *A Higher Standard*, 43 TENN. B.J. 12, 12 (2007).

> [P]laintiffs . . . should no longer count on bare-bones, conclusory pleadings to get them past a motion to dismiss and into the discovery process with the hope of developing facts to support their claims. *Twombly* signifies a migration from what has been a fairly liberal standard governing pleadings in civil litigation for the past 50 years.

Id.

omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Plausibility requires more than "a sheer possibility that a defendant has acted unlawfully." *Id.* Since the prisoner in *Iqbal* failed to meet these heightened pleading standards under *Twombly,* this Court held that his claim must be dismissed. *Id.* at 1942.

Furthermore, this Court stated, "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 1949. Petitioners' complaint in this case does just that and, like the complaint in *Iqbal,* must also be dismissed pursuant to the *Twombly* standards.

3. The Thirteenth Circuit correctly overruled the district court and held that Petitioners's claims were insufficient.

The court of appeals correctly found that Petitioners' complaint did "nothing more than provide a formulaic recitation of the elements of a design defect claim." (R. 12.) Here, Petitioners' allegations do nothing more than parrot the language of a products liability claim in an attempt to substantiate their claim. Rather than alleging sufficient facts, Petitioners state that Carolina:

> 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 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.

(R. 12–13, n.8.) The Court of Appeals for the Thirteenth Circuit correctly noted that Petitioners failed to "state any scientifically reliable evidence to support their allegations that [Carolina

Laboratories] failed to conduct adequate tests to determine whether thimerosal was safe and that a safer alternative existed." (R. 12–13.) Instead, Petitioners merely mimicked the language of a products liability claim, alleging nothing more than conclusions of law. These conclusory allegations are analogous to the claims in *Iqbal* that federal officials acted unconstitutionally by willfully and maliciously agreeing to subject the prisoner to harsh conditions. As the court of appeals correctly found, Petitioners do not bother to support their claims of inadequate testing with any scientifically reliable evidence. (R. 12–13.) Rule 8 does not permit Petitioners to plead the minimal elements of their cause of action, contend that these statements are general allegations, and have the claim survive a motion to dismiss. *See Iqbal*, 129 S.Ct. at 1954.

4. The district court erroneously relied on *Conley*, which is directly contrary to the decision in *Twombly*.

The district court erred in relying on *Conley*'s less stringent pleading standards in finding that Petitioners' complaint was sufficient. Under *Conley,* a complaint could be dismissed only if it "appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson,* 355 U.S. 41, 45–46 (1957). However, *Twombly* sufficiently abrogated *Conley* when this Court stated that "after puzzling the profession for 50 years, this famous observation . . . has earned its retirement . . . and is best forgotten." *Twombly*, 550 U.S. at 563. Rather than acknowledging the progression of this Court's jurisprudence, the district court instead applied *Conley*'s dated interpretation of the federal rules. The erroneous application of overturned law incorrectly determined that Petitioner's legal conclusions survived Carolina Laboratories' motion to dismiss.

B. Petitioners' Complain Is So Deficient That They Are Not Entitled to Discovery.

Petitioners contend that they have alleged enough factual allegations in order to conduct discovery, wherein they would be able to plead the facts more specifically. This contention fails

under both *Twombly* and *Iqbal.* In both cases, this Court has held that a plaintiff armed with a deficient complaint is not entitled to "unlock the doors of discovery." *Iqbal,* 129 S.Ct. at 1950.

1. Pleadings containing only broad legal conclusions rather than factual allegations are insufficient to reach the discovery phase.

The *Twombly* Court further explained that one of the main designs of the federal rules was to ensure that defendants were put on notice of what claims were being brought against them. *See Twombly*, 550 U.S. at 555. In *Twombly,* this Court plainly stated that when the allegations in a complaint are unable to 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." *Twombly,* 550 U.S. at 558 (quoting *Daves v. Hawaiian Dredging Co.,* 114 F. Supp. 643, 645 (Haw. 1953)). Simply restating the legal test for a products liability claim is insufficient to provide Carolina Laboratories with fair notice. *Id.* Forcing Carolina Laboratories to guess about the bases of Petitioners' claims is prohibited by Rule 8. The issue is not whether a plaintiff will prevail, but whether the claimant is entitled to offer evidence to support the claim. *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974).

This Court directly addressed Petitioners' contentions when it held that discovery could not be relied on for details because the parties "in theory *cannot* know the details" that will come from the process. *Twombly,* 550 U.S. at 560 n.6. Petitioners hope that discovery will yield details upon which it can strengthen its allegations. This is simply an all-too optimistic approach which must be rejected by this Court. Petitioners, like all other plaintiffs bringing forth a claim, must allege sufficient facts to make their claim plausible *prior* to proceeding to discovery. *Iqbal*, 129 S.Ct. at 1949. This Court correctly stated in *Broudo:* "Something beyond 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 people, with the right to do so representing an *in terrorem* increment of the settlement value." *Broudo,* 544 U.S. at 347.

The *Twombly* Court was unwilling to allow plaintiffs access to the judicial tool of discovery to try and prove a claim that may not even exist due to the lack of factual allegations and only broad legal conclusions stated in their complaint. *Twombly*, 550 U.S. at 560. Failing to allege factual complaints and relying only on broad legal conclusions have historically been an indicator of a plaintiff who is looking for a claim rather than sitting on one. The First Circuit, even before *Tombley*, has held that "conclusory allegations in a complaint, if they stand alone, are a danger sign that the plaintiff is engaged in a fishing expedition." *DM Research, Inc. v. Coll. of Am. Pathologists,* 170 F.3d 53, 55 (1st Cir. 1999). This type of conduct does not serve the purpose of Federal Rule of Civil Procedure 8(a), because in order to receive access to discovery, a plaintiff must first make sufficient *factual* allegations in order to drag the defendant past the pleading threshold. *Id.*

2. Allowing discovery for cases involving deficient pleadings places an unreasonable burden upon defendants.

Burdens on the defendants dragged past this threshold are not limited to just the use of their time and exposure to liability; often there can be a substantial financial burden as well. This Court noted that "discovery accounts for as much as 90 percent of litigations costs when discovery is actively employed." *Twombly,* 550 U.S. at 559 (citations omitted). In a time when the economy is stifling and companies all across the United States are making cuts to budgets, pay rolls, and employee benefits, businesses may simply be unwilling to endure the steep legal fees and clerical costs that come along with the discovery process.[9] Thus, the mere threat of

[9] Obama: Recession's Not Over Yet, CNNMoney.com, Aug. 1, 2009, http://money.cnn.com/2009/08/01/news/economy/obama.economy.reut/index.htm (last visited Mar. 2, 2010) (discussing the recession and economic decline in the United States).

discovery would be enough to cause "cost-conscious defendants" to want to settle even "anemic cases." *Id.* (quoting *Car Carriers, Inc. v. Ford Motor Co.,* 745 F.2d 1101, 1106 (7th Cir. 1984)). This Court explained that the costs of modern litigation and the increasing caseload on federal courts "counsels against sending the parties into discovery where there is no reasonable likelihood that the plaintiffs can construct a claim from the events related in the complaint." *Id.* at 558.

Petitioners cannot wait on discovery in order to bolster their allegations. To allow Petitioners to do so would open up a floodgate of litigation from other vaccine-injured persons who may or may not have a plausible claim for relief. In *Iqbal*, the petitioner argued that relaxed pleading requirements should apply when the court allowed limited discovery for the petitioners to maintain their qualified-immunity defense in conjunction with the motion to dismiss the pleadings. *Iqbal,* 129 S. Ct. at 1953. However, this Court recognized that to do so would be contrary to the purpose of the qualified-immunity rule, as its main purpose is to free officials from the concerns of litigation such as disruptive discovery. *Id.* It is important to remember that while litigation is necessary, it "exacts heavy costs in terms of efficiency and expenditure of valuable time and resources that might otherwise be directed to the proper execution of . . . work." *Id.* Similarly, in a products liability case, the purpose of dismissing pleadings which have failed to factually assert a valid cause of action is appropriate to enable parties to be free from the unreasonable costs and burdens of unnecessary discovery. By allowing these cases to continue past the pleadings phase without factual allegations will only further waste the time and resources of not only these defendants, but the judicial system as well.

More specifically, allowing factually deficient pleadings in cases involving injuries caused by a vaccination would be expressly against the will of Congress. Allowing lawsuits that

have not been sufficiently pled go into the discovery stage would only increase the litigation costs for vaccine manufactures and thus, increase the costs of vaccines to consumers. The result of these consequences would be in direct contrast to Congress's purpose for enacting the National Childhood Vaccine Injury Act of 1986. Congress explicitly stated that as part of "a result of this increase in litigation, the prices of vaccines have jumped enormously. The number of childhood vaccine manufacturers has declined significantly." H.R. Rep. No. 99-908, at 4–5 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345. Allowing cases which have not been sufficiently pled to survive the dismissal phase would pass these overly burdensome costs on to the consumer and manufacturers and prevent the National Childhood Vaccine Injury Act from effectively completing its purpose.

Petitioners' complaint fails to contain sufficient factual allegations to make their claims plausible under the standards created by this Court in *Twombly* and *Iqbal. Iqbal,* 129 S.Ct. at 1953; *Twombly,* 550 U.S. at 569. Consequently, this Court should dismiss Petitioners' complaint under Rule 12(b)(6).

CONCLUSION

The Court of Appeals for the Thirteenth Circuit erred in finding that Petitioners' design defect claims were not preempted by the National Childhood Vaccine Injury Act of 1986. However, the court of appeals correctly applied *Twombly* pleading rules and dismissed Petitioners' claims for design defect after finding that Petitioners' complaint lacked sufficient factual allegations to survive a motion to dismiss. This Court should therefore AFFIRM the judgment of the United States Court of Appeals for the Thirteenth Circuit.

Respectfully submitted,

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COUNSEL FOR RESPONDENT

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APPENDIX A

UNITED STATES CONSTITUTIONAL PROVISIONS

U.S. Const. art. VI, cl. 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

APPENDIX B

FEDERAL RULES OF CIVIL PROCEDURE

Fed. R. Civ. P. 8

General Rules of Pleading

(a) Claim for Relief.

A pleading that states a claim for relief must contain:

*****

(2) a short and plain statement of the claim showing that the pleader is entitled to relief;

*****

Fed. R. Civ. P. 12

Defenses and Objections: When and How Presented; Motion for Judgment on the Pleadings; Consolidating Motions; Waiving Defenses; Pretrial Hearing

*****

(b) How to Present Defenses.

Every defense to a claim for relief in any pleading must be asserted in the responsive pleading if one is required. But a party may assert the following defenses by motion:

*****

(6) failure to state a claim upon which relief can be granted;

**

APPENDIX C

NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986

42 U.S.C. § 300aa-22

Standards of Responsibility

(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 plaintiff 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).

*****

(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.