No. 10-1524

In the

Supreme Court of the United States

Dan Cooks, *et al.*,

Petitioner,

v.

Carolina Laboratories, Inc.

Respondent.

On Writ of Certiorari To The
United States Court of Appeals
For the Thirteenth Circuit

PETITIONER'S BRIEF ON THE MERITS

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Questions Presented

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

II. 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)?

Table of Contents

Table of Authorities

Statutes

Cases

Secondary Materials

STATEMENT OF THE CASE

This is a personal injury case arising from Estella Marie Cook's life-altering injury caused by vaccines manufactured by Carolina Laboratories ("Respondent") (R. at 1). Dan and LoEtta Cooks ("Petitioners"), individually and on behalf of their minor daughter, Estella Marie Cooks filed suit against Respondent because Estella Marie suffered severe injuries after receiving Respondent's vaccines which contained toxic levels of the substance mercury (R. at 9). Between March 1996 and October of 1998, Estella received three doses of Respondent's thimerosal-containing Diphteria and Tetanus Toxoids and Pertussis ("DTP") – Haemophilus influenza type b ("Hib") combination vaccine (R. at 1). As a result, thirteen year-old Estella Marie suffers from neurological developmental delays, learning disabilities, social delays and deficits, impaired motor skills, gastrointestinal illness, and immune system dysfunction (R. at 1). Petitioners' claims under Grace law include strict liability and negligence. Specifically, Petitioner asserts that Respondent could and should have manufactured children's vaccines without thimerosal (R. at 9).

Dan and LoEtta Cooks filed a petition on Estella Marie's behalf with the National Vaccine Injury Compensation Program ("NVICP") on September 3, 2001, pursuant to 42 U.S.C. § 300aa-1 *et seq.* (R. at 1–2). On November 5, 2003, the Cooks filed a notice of withdrawal in the NVICP, and the Clerk of the U.S. Court of Federal Claims entered a judgment of withdrawal on January 14, 2004 (R. at 2). On March 14, 2007, the Cooks filed their complaint with the Grace District Court asserting two claims against Respondent. First, Respondent was negligent in failing to conduct adequate safety tests to determine whether thimerosal was safe and nontoxic to humans (R. at 2). Secondly, the Cooks assert strict products liability for design defect because Respondent's vaccine was defectively designed and a safer alternative existed (R. at 2). The

district court held that the Cooks' pleading adequately stated a claim but found that the National Vaccine Injury Act of 1986 ("Vaccine Act") preempts any state tort claims for design defects (R. at 7). The court of appeals rejected the district court's finding that the Vaccine Act preempts all design defect claims (R. at 10). Instead, the court of appeals held the Vaccine Act allows Petitioners' design defect claim and ruled against preemption (R. at 10). However, the court dismissed Petitioners' claim pursuant to Rule 12(b)(6) for failure to adequately state a claim, stating Petitioners' claim did nothing more than provide a formulaic recitation of the elements of a design defect claim (R. at 12).

SUMMARY OF THE ARGUMENT

Estella Marie will suffer from vaccine-related injuries for the rest of her life. These injuries could have been avoided if Respondent had only conducted adequate tests to determine whether thimerosal was safe or acknowledged that a safer alternative existed. At no time has Respondent defended the vaccine as safe or defended the steps taken to design the vaccine. Instead, Respondent attempts to hide behind language in the Vaccine Act to claim that vaccine manufacturers have blanket immunity from design defect claims. Respondent continually emphasizes that Estella Marie's claims must be preempted to ensure the continuing vitality of the vaccine market. However, Respondent fails to explain how blanket tort immunity will promote a stable vaccine market. More importantly, Respondent fails to explain how providing blanket immunity will protect children like Estella Marie from suffering the same life-long injuries.

The court of appeals correctly held that Petitioners' claims are not preempted. The court of appeals followed the preemption analysis established by this Court and reviewed the relevant statutes with a presumption against preemption. The plain language of the Vaccine Act allows Petitioners' design defect claim. Conversely, Respondent's interpretation of the Vaccine Act

renders important language as a nullity. Although it is not necessary to explore legislative history, it also refutes preemption because the purpose of the Vaccine Act is to supplement state tort law, not provide blanket immunity for vaccine manufacturers. Because Petitioners' claims are not preempted, Grace state law applies. Grace state law utilizes the risk-utility analysis to determine if there is a design defect. In order to assert a claim for a design defect, a plaintiff must show that the risks inherent in the product outweigh the benefits of the product. Further, a plaintiff must show that an alternative feasible design exists to have a valid design defect claim.

Traditionally, plaintiffs were only required to a put the defendant on notice of the claim against them by offering a short and plain statement of the facts. However, this Court has introduced a new standard that now must be met at the pleading stage of litigation. This plausibility standard, often referred to as the *Twombly* pleading rules, requires that the factual allegations contained within the complaint give rise to a plausible claim for relief. The appellate court was erroneous in their application of the *Twombly* pleading rules because they summarily dismissed Petitioners' complaint stating the complaint does nothing more than provide a formulaic recitation of the elements of a design defect claim. This reasoning was erroneous because the appellate court failed to recognize the factual allegations in the complaint as giving rise to a plausible claim for relief. As a result the appellate court was in error by granting Respondent's 12(b)(6) motion to dismiss.

STANDARD OF REVIEW

The standard of review is *de novo* when reviewing a 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 (6th Cir. 2006).

ARGUMENT

I. The Court of Appeals Correctly Held that the National Childhood Vaccine Injury Act of 1986 Does not Preempt Petitioners' Design Defect Claim

The National Childhood Vaccine Injury Act of 1986 ("Vaccine Act") provides a system for a person injured by a vaccine to obtain compensation from a fund financed by a tax on vaccines. 42 U.S.C. §§ 300aa-11, 300aa-12 (2006). The Vaccine Act requires that a person injured by a vaccine initiate a proceeding in the Court of Federal Claims before he or she may bring a state court tort action against the manufacturer. *Id.*§ 300aa(a)(2)(A). For the most part, the injured person may only initiate a state court tort proceeding if he or she rejects the judgment of the Court of Federal Claims. *Id.* §§ 300 aa-11(a)(2)(A)(I), (ii), 300aa-21(a), (b). Although a person must first move through the Court of Federal Claims, the Vaccine Act expressly preserves state tort claims for those who reject the Court of Federal Claims' ruling. *Id.* §§ 300aa-22(a), (e).

Despite the Vaccine Act expressly allowing state tort claims, Respondent claims federal law preempts any state tort law claims for a design defect and relies on subsection (b)(1) of the Vaccine Act which states:

> "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 warning."

42 U.S.C. § 300aa-22(b)(1) (2006) (emphasis added). Respondent essentially equates Food and Drug Administration approval with a determination that side effects are "unavoidable." *Am. Home Products Corp. v. Ferrari*, 668 S.E.2d 236, 237 (Ga. 2008), *petition for cert. filed*, 77 U.S.L.W. 3531 (U.S. Mar. 1, 2008) (No. 08-1120). In other words, Respondent claims that as a matter of law, injuries from vaccines are unavoidable.

If accepted, Respondent's argument would bar any state design defect claims against manufacturers, even if there is a safer and feasible alternative design. The court of appeals correctly rejected this argument and found that subsection (b)(1) only preempts those design defect claims against the manufacturers of vaccines found to be unavoidably unsafe on a case-by-case basis (R. at 11).

Although there are three different types of preemption and each warrants a different analysis, Respondent fails to differentiate which type of preemption supposedly applies to the Vaccine Act.[1] Federal law can supersede or preempt state law through express preemption, field preemption, or implied preemption. Express preemption forecloses state action by express language in a congressional enactment that mandates state law be displaced. S*ee, e.g.*, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992). Field preemption occurs by implication from the depth and breadth of a congressional scheme that occupies the legislative field. *See, e.g.*, *Fidelity Fed. Sav. & Loan Assn. v. De la Cuesta*, 458 U.S. 141, 153 (1982). Implied preemption is when federal law supersedes state law by implication because of a conflict with a congressional enactment. S*ee, e.g., Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869–74 (2000). Because Respondent points to the express language of the Vaccine Act to claim preemption, one can only assume Respondent asserts express preemption.

Instead of following preemption precedent established by this Court, Respondent relies directly on legislative history to support an interpretation of the Vaccine Act that preempts design defect claims. The court of appeals refuted this by correctly following this Court's preemption analysis (R. at 10–11). First, the Appellate Court looked at the plain language of subsection (b)(1) and acknowledged that the term "unavoidably dangerous" mirrored the

[1] Federal preemption is an affirmative defense on which the defendant bears the burden of proof." *Cambridge Literary Props., Ltd., v. W. Goebel Porzellanfabrik G.m.b.H. & Co. KG*, 510 F.3d 77, 102 (1st Cir. 2007), cert. denied, 129 S. Ct. 58 (2008).

language in Comment *k* of § 402A of the Restatement (Second) of Torts (R. 10). The court then explored the majority interpretation of Comment *k*, which decides if a product is "unavoidably dangerous" on a case-by-case basis (R. at 10). The majority interpretation is important because it aligns with this Court's required presumption against preemption. *See, e.g., Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005). The court then found that the conditional language in subsection (b)(1) would be read as a nullity if design defect claims were preempted (R. at 11).

One should only resort to legislative history "when necessary to interpret ambiguous statutory text." *Bedroc Ltd., LLC v. United States*, 541 U.S. 176, 187 n. 8 (2004). Despite this, all of the jurisdictions ruling for preemption of the Vaccine Act rely heavily on the legislative history. *See, e.g., Bruesewitz v. Wyeth,* 561 F.3d 233 (3d Cir. 2009), *cert. granted*, 78 U.S.L.W. 3082 (U.S. Mar. 8, 2010) (No. 09-152); *Blackmon v. Am. Home Products Corp.*, 328 F.Supp. 2d 659 (S.D. Tex. 2004). The court of appeals found Congressional intent clearly rejects preemption (R. at 11). Only then did it turn to legislative history to even further refute Respondent's preemption argument (R. at 11). Other than the Thirteenth Circuit, only one jurisdiction has correctly followed this Court's preemption analysis and that court found Vaccines are not "unavoidably dangerous" as a matter of law but must be explored on a case-by-case basis. *See Am. Home Products Corp. v. Ferrari*, 668 S.E.2d 236, 237 (Ga. 2008), *petition for cert. filed*, 77 U.S.L.W. 3531 (U.S. Mar. 1, 2008) (No. 08-1120). Absent preemption, Grace state law applies to Petitioners' claims (R. at 2 n.4). Grace state law allows Petitioners' design defect claim because Grace applies a risk-utility analysis in design defect claims that requires a case-by-case analysis of the existence of a feasible alternative design (R. at 3).

A. Respondent Disregarded the Preemption Analysis Required by this Court

This Court has developed a process to determine if a federal act expressly preempts state law. *See Medtronic v. Lohr,* 518 U.S. 470, 485–86 (1996). Before beginning the preemption analysis, one starts by "identify[ing] the domain expressly pre-empted." *Id.* at 484 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992)). In this case, Respondent claims the domain the Vaccine Act expressly bars is design defect claims (R. at 2). Once the domain has been identified, the preemption analysis begins with the text of the preemption statute to analyze its scope. *Medtronic*, 518 U.S. at 484. Thus, any preemption analysis begins by reading the "plain wording of the clause," as this "necessarily contains the best evidence of Congress' pre-emptive intent." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62–63 (2002).

Congress actually crafted an express preemption clause in the Vaccine Act stating, "Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death."[2] 42 U.S.C. § 300aa-22(a) (2006). Subsection (b)(1) frees vaccine manufacturers from civil actions for damages from vaccine-related injuries or deaths "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." *Id.* § 300aa-22(b)(1) (emphasis added). "Thus, in construing subsection (b)(1), 'we are presented with the task of interpreting a statutory provision that expressly pre-empts state law.'" *Am. Home Products Corp. v. Ferrari,* 668 S.E.2d 236, 237 (Ga. 2008), *petition for cert. filed*, 77 U.S.L.W. 3531 (U.S. Mar. 1, 2008) (No. 08-1120) (quoting *Medtronoic v. Lohr,* 518 U.S. 470, 484 (1996)). "Interpretation of that language does not occur in a contextual vacuum." *Medtronic,* 518

[2] Although this subsection does "preempt state law to the extent stated[,] . . . by expressly reserving state courts a role with respect to claims made under the Act, [it] does not preclude state courts from adjudicating issues raised regarding it." *Am. Home Products Corp. v. Ferrari,* 668 S.E. 2d 236, 238 (Ga. 2008), citing *Militrano v. Lederle Laboratories,* 769 N.Y.S. 2d 839, 843 (N.Y. App. Div. 2003), aff'd 810 N.Y.S.2d 506 (N.Y. 2006).

U.S. at 485. Instead, a preemption analysis must be informed by two presumptions. *Id.* First, we "start with the assumption the historic police powers of the States [a]re not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress." *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997). This is because "the States are independent sovereigns in our federal system, [and] we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic*, 518 U.S. at 485. Second, the "purpose of Congress is the ultimate touchstone." *Id.* "Congress' intent, of course, primarily is discerned from the language of the preemption statute and the 'statutory framework surrounding it.'" *Id.* at 486 (quoting *Gade v. Nat'l Solid Wastes Mgmt. Assn.*, 505 U.S. 88, 111 (1992)).

This Court further clarified how to discern Congressional intent in *Bates v. Dow Agrosciences.* 544 U.S. 431 (2005). *Bates* rejected heavy reliance on legislative history by clarifying that when there is a plausible[3] reading that refutes preemption, courts "cannot resort to an examination of legislative history to discern Congressional intent." *Id.* at 449. Instead, any federal statutory ambiguities are to be resolved against preemption. *Id.* Thus, we must begin our preemption analysis with the plain language of subsection (b)(1) and the Vaccine Act as a whole with a presumption against preemption.

B. The Court of Appeals Applied the Proper Preemption Analysis and Correctly Rejected Respondent's Preemption Argument

The court of appeals followed the structure outlined above and correctly ruled that the Vaccine Act does not preempt state tort design defect claims. First, the court identified the statute at issue, 42 U.S.C. § 300aa-22(b)(1) (R. at 11). Next, it identified the allegedly preempted

[3] The court uses the term, "plausible" in this context to determine if there is a reasonable reading of the statute. However, this is different from the "plausibility" standard discussed later to determine the sufficiency of factual allegations found in a pleading to survive a 12(b)(6) motion to dismiss.

domain, which is a design defect claim against vaccine manufacturers (R. at 10). Then, the court turned to the plain language of the statute (R. at 10). In doing so, the court acknowledged that that language is modeled directly from Comment *k* of § 402A of the Restatement (Second) of Torts (R. at 10). The court then applied the majority interpretation of Comment *k* which determines if something is "unavoidably dangerous" on a case-by-case basis (R. at 10–11). The court supported this by looking at the conditional, plain language of subsection (b)(1) (R. at 11). Only after establishing a presumption against preemption did the court turn to legislative history, which it found further refuted Respondent's preemption argument (R. at 11). In concluding, the court rejected Respondent's interpretation of subsection (b)(1) because it would have the "perverse effect of granting complete tort immunity from design defect liability to an entire industry" (R. at 11). Finally, the court stated that "[i]n the absence of any clear and manifest congressional purpose to achieve that result [preemption], we must reject such a far-reaching interpretation of the Vaccine Act" (R. at 11).

1. The Definition of "Unavoidable" Is Found in Comment *k* of § 402A of Restatement (Second) of Torts

It is clear that federal law preempts state law claims against those injuries that were "unavoidable." *See* 42 U.S.C. § 300aa-22 (b)(1) (2006). However, the term "unavoidable" is not defined in the Vaccine Act. Congress modeled subsection (b)(1) after Comment *k* of § 402A of the Restatement (Second) of Torts which is titled "Unavoidably Unsafe Products." H.R. Rep. No. 99-908, at 25-26 (1986). Comment *k* defines when a manufacturer is immune from design defect claims. A product that is unavoidably unsafe alleviates a seller of strict liability because:

> "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . . . Such 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 . . . drugs, vaccines, and the like . . . ."

Restatement (Second) of Torts § 402A. Thus, if a product meets the definition in Comment *k*, it is an unavoidably unsafe product and the seller is relieved of strict liability.

2. The Majority of Jurisdictions Interpret the Definition of "Unavoidably Unsafe Products" in Comment *k* on a Case-by-Case Basis

Even if Respondent's argument for blanket immunity was just as plausible as a case-by-case analysis, "we would nevertheless have a duty to accept the reading that disfavors pre-emption." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005). The term "unavoidably unsafe" as defined in Comment *k* has been interpreted in two ways. The majority of jurisdictions apply the definition of "unavoidably unsafe products" on a case-by-case basis. *See, e.g.*, *Hill v. Searle Labs.*, 884 F.2d 1064, 1068–70 (Ark. 1989); *Toner v. Lederle Labs.*, 732 P.2d 297, 308–11 (Idaho 1987); *Freeman v. Hoffman-La Roche*, 618 N.W.2d 827, 836–40 (Neb. 2000); *Castrignano v. E.R. Squibb & Sons*, 546 A.2d 775, 781 (R.I. 1988). These jurisdictions apply a risk-utility balancing test and consider the availability of other drugs addressing the same problem to determine if the drug or vaccine is unavoidably unsafe. *Id.* Conversely, a minority of jurisdictions apply Comment *k* to mean that all prescription drugs or vaccines are unavoidably unsafe as a matter of law. *See, e.g.*, *Brown v. Superior Court*, 44 Cal.3d 1049, 1060–65 (Cal. 1988); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 92 (Utah 1991); *Young v. Key Pharm.*, 922 P.2d 59, 62–65 (Wash. 1996). This interpretation bars any state tort design defect claims against vaccine manufacturers based upon the reasoning that vaccines are unavoidably unsafe as a matter of law. *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 846 (N.Y. 2005). Thus, the core question in our preemption analysis hinges on whether it is plausible to apply "unavoidable" in subsection

(b)(1) to vaccines in the same way the majority of jurisdictions apply Comment *k*, on a case-by-case basis.

The court of appeals followed the majority approach and found that subsection (b)(1) does not preempt state design defect claims (R. at 10). The court rejected Respondent's minority argument after thoroughly examining the text of subsection (b)(1) and acknowledging that there are two plausible readings (R. at 11). All vaccines are not unavoidably dangerous as a matter of law (R. at 11). Instead, whether a vaccine is "unavoidably dangerous" must be considered on a case-by-case basis (R. at 11). The court stressed that because a case-by-case exploration of "unavoidably unsafe products" is both plausible and well-accepted by a majority of jurisdictions, the statute must be read to refute preemption (R. at 11).

3. The Conditional Language of Subsection (b)(1) Refutes Preemption

The court of appeals further supported its Comment *k* analysis by looking to the plain language of subsection (b)(1) (R. at 11). Subsection (b)(1) frees vaccine manufacturers from civil actions for damages from vaccine-related injuries or deaths "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." 42 U.S.C. § 300aa-22(b)(1) (2006) (emphasis added). If this Court accepts Respondent's argument that all vaccines are unavoidably unsafe, then the conditional language in subsection (b)(1) will be a nullity (R. at 11). Instead, "[t]he conditional nature of this clause contemplates the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable." *Am. Home Products Corp. v. Ferrari*, 668 S.E.2d 236, 240 (Ga. 2008), *petition for cert. filed*, 77 U.S.L.W. 3531 (U.S. Mar. 1, 2008) (No. 08-1120). Congress could have easily omitted this clause and made the bar to civil liability conditional on proper preparation and warnings but chose not to. *Id.* at 240. For

example, if Congress had omitted the clause in dispute, subsection (b)(1) would alleviate liability "if the vaccine was properly prepared and was accompanied by proper directions and warnings." *Id.* This "amputated version . . . would no doubt have clearly and succinctly commanded the preemption of *all* state tort claims." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 448–49 (2005). However, the statute is best understood as barring liability only for those side effects which were unavoidable by means other than proper manufacturing and packaging. *Am. Home Products*, 668 S.E.2d at 240. If such effects were avoidable by an alternative feasible design, liability is not completely barred. *Id.*

4. Legislative History of the Vaccine Act Expressly Negates Preemption

The court of appeals correctly began its preemption analysis with the plain language of the Vaccine Act and garnered congressional intent from the plain language and overall structure of the statute (R. at 11). Rather than discussing the structure of the Vaccine Act, Respondent continually points to a committee report which states, claimants "should pursue recompense in the compensation system, not the tort system." H.R. Rep. No. 99-908, at 24 (1986). Respondent uses isolated legislative history to have the Court believe that Part B of the Vaccine Act bars state tort claims. The actual language of the Vaccine Act quickly refutes this. Part B of the Vaccine Act does not bar state tort claims. Instead, it provides additional remedies for persons injured by vaccines if they elect to reject a judgment made under the compensation program in Part A and to take action directly against the vaccine manufacturer. *Id.* at 3.

Absent clear congressional intent to the contrary, the preemption analysis should end with the acceptance of the clause refuting preemption. *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005). Legislative history should only be used when there is an ambiguity in statutory

language. *Bedroc Ltd., LLC v. United States*, 541 U.S. 176, 187 n. 8 (2004). There are two possible readings of the Vaccine Act, and the majority's interpretation refutes preemption. Thus, the preemption analysis should end before legislative history is ever discussed. Recognizing this, the court of appeals only briefly discussed legislative history to refute the district court's incorrect reliance on isolated portions of House Committee reports (R. at 11).

This Court discourages relying on legislative history absent an ambiguity in the plain statutory language. *Bedroc Ltd., LLC*, 541 U.S. at 187 n. 8. Despite this, Respondent continues to isolate portions of the Vaccine Act's legislative history to refute the strong presumption against preemption. Respondent manipulates legislative history to claim that the Vaccine Act's compensation system is meant to be one's only means of relief from a vaccine-related injury. Respondent cites to a portion of the Commerce Committee's report stating, "[i]f they [injured claimants] 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." H.R. Rep. No. 99-908, at 24 (1986). However, isolating this portion of the committee report divorces it from important context. In fact, just one paragraph before this statement, the committee explains that a compensation system should be developed so that even if there was no fault on the part of the manufacturer, children can recover for a vaccine-related injury. *Id.*

Even if this Court relies on legislative history, that history refutes preemption. States interpret Comment *k* in accordance with their own state tort law, and Congress crafted subsection (b)(1) knowing about the ongoing ambiguity amongst the states in interpreting Comment *k*. *Id.* at 26. Despite this, Congress chose to adopt the same language as Comment *k*. *Id.* Therefore, the

committee reports actually support a case-by-case analysis of "unavoidably unsafe" for those jurisdictions that follow the majority interpretation of Comment *k*.

Although Respondent relies heavily on isolated portions of the Vaccine Act's legislative history, they fail to acknowledge a subsequent Budget Committee report which expressly rejects preemption. When Congress passed the Vaccine Act in 1986 it did not include a source of payment for compensation. H.R. Rep. No. 100-391(1), at 690 (1987). Instead, it made "the compensation program and accompanying tort reforms contingent on the enactment of a tax to provide funding for the compensation." *Id.* One year later, when Congress passed legislation to fund the program, the House Committee on the Budget addressed and refuted Respondent's preemption argument. The report states:

> "It is not the Committee's intention to preclude court actions under applicable law. The Committee's intent at the time of considering the Act and in these amendments was and is to leave otherwise applicable law unaffected, except as expressly altered by the Act and the amendments. An amendment to establish as part of this compensation system that a manufacturer's failure to develop safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act. *Further, the codification of Comment (k) of the Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe.* The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. *This question is left to the courts to determine in accordance with applicable law*."

Id. at 691 (emphasis added). This report is by the same committee which originally considered the Vaccine Act just a year before and is relevant to "shed [] light on allegedly ambiguous language" and "certainly constitutes a prophylactic against adopting a tortured reading of an otherwise plain statute." *Grapevine Imports v. United States*, 71 Fed. Cl. 324, 335 (2006).

5. The Purpose of the Vaccine Act Is to Supplement State Tort Law, Not Provide Blanket Immunity for Vaccine Manufacturers

The Committee report for the Vaccine Act set forth goals to ensure that "all children in need of immunization have access to them [vaccines] and to ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries." H.R. Rep. No. 99-908, at 3 (1986). Additionally, it stressed the importance of stabilizing the vaccine market and preventing a threat of shortages. *Id.* Respondent emphasizes the goal of "stabilizing the market" and coincidentally, securing the vaccine manufacturer's profit line. However, this Court has found that "blanket immunity from tort liability would remove an incentive for developing safer alternative designs." *Bates v. Dow Agrosciences*, 544 U.S. 431, 450 (2005). Respondent fails to explain how preempting Petitioners' design defect claims will promote discovery of safer alternative designs. *Am. Home Products Corp. v. Ferrari*, 668 S.E.2d 236, 393 (Ga. 2008), *petition for cert. filed*, 77 U.S.L.W. 3531 (U.S. Mar. 1, 2008) (No. 08-1120).

Congress created the Vaccine Act so that "Vaccine-injured persons will now have an appealing alternative to the tort system." H.R. Rep. No. 99-908, at 26 (1986). Subsection (b)(1) was not passed merely to protect vaccine manufacturers from design defects suits. As the court of appeals reiterated, accepting Respondent's interpretation of subsection (b)(1) "would 'have the perverse effect of granting complete immunity from design defect liability to an entire industry…'" *Am. Home Products Corp.*, 668 S.E.2d at 394 (quoting *Medtronic v. Lohr*, 518 U.S. 470, 487 (1996)); (R. at 11). The Vaccine Act was not meant to provide blanket immunity to vaccine manufacturers. Instead, the Vaccine Act protects manufacturers from liability from unavoidable side effects. *Am.*

Home Products, 668 S.E.2d at 393. Other language in the 1986 committee report carries a similar implication by recognizing a "no-fault compensation system," which awards vaccine injured persons "even if the manufacturer has made as safe a vaccine as possible." H.R. Rep. No. 99-908, at 26 (1986).

C. Only One Other Court Addressing Vaccine Design Defect Claims Properly Follows this Court's Preemption Analysis

When there are two plausible readings of a statute there is a "duty to accept the reading that disfavors pre-emption." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005). Those courts which have found that the Vaccine Act preempts state design defect claims disregarded the majority interpretation of Comment *k* and instead determined the congressional purpose of the Vaccine Act by relying heavily on isolated legislative history. *See Bruesewitz v. Wyeth*, 561 F.3d 233, 244 (3d Cir. 2009), *cert. granted*, 78 U.S.L.W. 3082 (U.S. Mar. 8, 2010); *Sykes v. Glaxo-SmithKline*, 484 F.Supp. 2d 289, 302 (E.D.Pa.2007) (same district court as *Bruesewitz)*; *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 844–45 (N.Y. 2005); *Blackmon v. Am. Home Products Corp.*, 328 F.Supp. 2d 659, 663–64 (S.D.Tex. 2004); *Wright v. Aventis Pasteur, Inc.*, Trial Order, 2008 WL 4144386 (Pa. Commw. Ct. Aug. 27, 2008). Only one court properly adhered to this Court's precedent and ruled against preemption. In *American Home Products v. Ferrari*, the Georgia Supreme Court discussed two plausible readings of subsection (b)(1) of the Vaccine Act. 668 S.E.2d 236, 237 & 239 (Ga. 2008), *petition for cert. filed*, 77 U.S.L.W. 3531 (U.S. Mar. 1, 2008) (No. 08-1120). *Ferrari* adhered to the principle that absent strong evidence of contrary Congressional purpose, the reading disfavoring preemption should be accepted. *Id.* at 388. After being unable to find any strong evidence to support preemption, *Ferrari* found the Vaccine Act allows design defect claims. *Id.* at 243.

The Third Circuit is the only other federal court of appeals besides the Thirteenth Circuit to address whether the Vaccine Act preempts design defect claims. In *Bruesewitz v. Wyeth*, the Third Circuit decided that vaccines are "unavoidably dangerous," and provided blanket immunity for vaccine manufacturers. 561 F.3d 233, 243 (3d Cir. 2009), *cert. granted*, 78 U.S.L.W. 3082 (U.S. Mar. 8, 2010). However, even a cursory view of *Bruesewitz* clearly illuminates the Third Circuit's failure to adhere to this Court's preemption precedent. First, in *Bruesewitz*, the court concedes begrudgingly, that there are two plausible interpretations of subsection (b)(1). *Id.* at 245. However, rather than honor the presumption against preemption clearly required by this court in *Bates v. Dow Agrosciences*, the court chose to apply the interpretation of subsection (b)(1) which bars state tort design defect claims. *Id.* at 246. Rather than discuss the plain language of the act, the court then affirmed its finding by exploring congressional intent via legislative history.[4] *Id.* at 247. *Bruesewitz* focused on isolated portions of committee reports to affirm its minority interpretation of Comment *k*. *Id.* at 247–52. Because it disregarded a presumption against preemption and relied heavily on legislative history, *Bruesewitz* directly conflicts with the preemption analysis required by this Court.

D. Respondent Failed to Prove that Their Vaccine Was Unavoidably Unsafe as Required by Grace State Law

Once a party decides to reject the decision of the Court of Federal Claims, the Vaccine Act requires that "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) (2006). Both parties have agreed that absent preemption, Grace state law applies to the Petitioner's design defect claim (R. at 2). "Existing

[4] Ironically, the Third Circuit extensively discussed legislative history's shortcomings before relying on it throughout the opinion. *See Bruesewitz*, 561 F.3d at 244 (quoting "As a point of fact, there can be multiple legislative intents because hundreds of men and women must vote in favor of a bill in order for it to become a law." *Morgan v. Gay*, 466 F.3d 276, 278 (3d Cir. 2006); "[l]egislative is itself often murky, ambiguous, and contradictory," and "may give unrepresentative committee members-or, worse yet, unelected staffers and lobbyists-both the power and the incentive to . . . secure results they were unable to achieve through the statutory text." *Exxon Mobil Corp. v. Allapatrah Servs., Inc.*, 545 U.S. 546, 568 (2005)).

Grace product liability law does not encompass the minority rule insulating vaccine manufacturers from strict liability" (R. at 3). Instead, Grace state law follows the majority's interpretation of Comment *k* and allows design defect claims based on a risk utility analysis, which is considered on a case-by-case basis (R. at 4). Because Grace state law and the Vaccine Act allow Petitioner's claims, the Court must next turn to the sufficiency of Petitioners' pleading.

II. The Court of Appeals Improperly Interpreted this Court's Holding in *Twombly* and Therefore Erroneously Granted Respondent's 12(b)(6) Motion to Dismiss

The plausibility standard announced in *Bell Atlantic Corp., v. Twombly* departs from traditional notice pleading standards set forth by *Conley v. Gibson*. Scholars and practitioners have been at a loss to explain just how far a departure the *Twombly* plausibility standard has taken from *Conley's* notice pleading. In understanding the breadth of this departure, this Court notes the *Twombly* standard varies depending on the circumstances of each case. This Court's limited holdings applying the standard as well as the lower courts' application provide tremendous guidance for determining what "plausibility" in pleading requires. This Court has expressed that when examining a pleading under the plausibility standard, one must keep several contextual understandings in mind. The most important understanding is that the *Twombly* plausibility standard is not a heightened pleading standard. *Twombly's* plausibility standard is still a form of notice pleading that must comport with the Federal Rules of Civil Procedure and accompanying forms. This Court was very specific in *Twombly* when stating, "we do not require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp., v. Twombly*, 550 U.S. 544, 570 (2007).

In applying the *Twombly* plausibility standard, this Court has implied the importance that each claim is unique. This Court implied this by taking great pains, and pages, to examine the pleadings only after a thorough discussion of the factual and legal backgrounds of each case. *See,*

e.g., *Id.* Legal backgrounds are important because they provide a backdrop of significant legal consequences and policy considerations. The pleadings offered are then more adequately examined in light of those considerations. This provides the court with greater guidance for their determination of whether or not the pleading rises to the level of plausible. The factual backgrounds of the case are crucial because they establish a baseline of normal conduct within the particular field from which the claim derives. This baseline conduct is crucial because the factual allegations of a claim can only be conclusively labeled plausible or implausible when a claim is juxtaposed against this particular baseline of activity.

The court of appeals summarily dismissed Petitioners' claim in hardly more than 25 lines without any discussion of the above considerations. In the court of appeals' failure to correctly apply the plausibility standard, they erroneously granted Respondent's motion to dismiss Petitioners' otherwise plausible claim for relief.

A. Examination of The Underlying Law is a Vital Threshold Inquiry in Answering Whether a Complaint is Sufficient Under the *Twombly* Pleading Standard

In order to understand what constitutes a plausible claim under *Twombly*, it is important to understand what must be pled within the context of the underlying law. In the present case, it has been stipulated by both parties that absent preemption, Grace law will apply (R. at 2 n. 3). Grace state law recognizes three types of product liability claims: (1) defective design, (2) defective manufacture, and (3) inadequate warning or failure to warn (R. at 3). Furthermore, Grace state law does not encompass the minority rule insulating vaccine manufacturers from strict liability (R. at 3). Petitioners assert strict products liability for design defect (R. at 2). Petitioners support this claim by stating the vaccine was defectively designed and a safer alternative existed (R. at 2). Therefore, we must first examine what must be pled under the risk-utility analysis of design defect according to Grace state law.

The Supreme Court of Grace has determined that claims for design defect are to be evaluated under a risk-utility analysis, balancing the risk inherent in the product design against the utility of the product designed (R. at 4.) Under Grace law the fact finder 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 (R. at 4). Further, the weighing of these factors is generally a question for the jury (R. at 4).

When moving under a design defect cause of action in a jurisdiction that employs the risk-utility analysis, plaintiffs must establish that the risk inherent in the product as designed outweighs the utility of the product. *Carter v. Johns-Manvill Sales Corp.*, 557 F.Supp 1317, 1320 (E.D. Tex. 1983). In theory, no product can be completely accident proof. *See, e.g., De Rosa v. Remington Arms Co.* 509 F.Supp. 762, 766 (E.D. N.Y. 1981). Thus, determining if a product is defectively designed ultimately involves a balancing of the likelihood of harm against the burden of taking precautions against the harm. *Id.* This balancing analysis determines whether the benefits of the challenged design outweigh the risk of danger inherent in the design. *Id.* Therefore, the risk-utility analysis is a broad examination of the product in question. This broad examination allows the plaintiff to allege, and the fact finder to consider, a myriad of factors which may ultimately lead to the conclusion that the product is defectively designed. This is important because the risk-utility analysis will be used to determine what the *Twombly* standard requires to adequately plead a design defect case under Grace state law.

B. Federal Rule of Civil Procedure 8(a) Requires Only a Short, Plain Statement of the Claim Showing that the Pleader is Entitled to Relief

In order to understand what is required of pleadings under *Twombly*, a brief historical background of pleading in the federal system is necessary. Federal Rule of Civil Procedure 8(a)

dictates a pleading that states a claim for relief must contain a short and plain statement of the claim showing that the pleader is entitled to relief. Fed. R. Civ. P. 8(a)(1). This rule "marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era" *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1950 (2009).

In 1957, the seminal case of *Conley v. Gibson* gave practitioners guidance as to what adequate pleadings entail. 355 U.S. 41, 45–46 (1957). *Conley* created the "no set of facts" standard. *Id.* This standard requires 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. *Id.* Further, this Court reasoned that the Federal Rules of Civil Procedure do not require a claimant to set out in detail the facts upon which he bases his claim. *Id.* at 47. Rather, the Rules require a short and plain statement of the claim that give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. *Id.* Finally, *Conley* noted that the pleading stage of litigation is not the most appropriate or effective stage to weed out meritless claims. *Id.* at 47–48. Instead "such simplified notice pleading is made possible by the liberal opportunity for discovery and the other pretrial procedures established by the Rules to disclose more precisely the basis of both claim and defense and to define more narrowly the disputed facts and issues." *Id.* at 48.

1. *Twombly* "Retired" the "No Set of Facts" Language of *Conley v. Gibson,* and Adopted a "Plausibility" Standard to be Applied in Determining Whether a 12(b)(6) Motion to Dismiss Shall be Granted

For decades, the *Conley v. Gibson* "no set of facts" language was the staple for pleading standards. *See Bell Atlantic Corp., v. Twombly*, 550 U.S. 544 (2007). *Twombly* overruled *Conley*'s "no set of facts" standard, and introduced the current plausibility standard concluding,

"we do not require heightened fact pleading specifics, but only enough facts to state a claim to relief that is plausible on its face." *Id.* at 570.

The plausibility standard as set forth in *Twombly* was further explained in *Ashcroft v. Iqbal*. 129 S.Ct. 1937 (2009). In *Iqbal*, this Court held that a pretrial detainee's complaint failed to plead sufficient facts to state a claim for purposeful and unlawful discrimination. *Id. Iqbal* started with the plausibility standard laid down in *Twombly* and reiterated that labels and conclusions or formulaic recitations of the elements of a cause of action will not do. *Id.* at 1949. *Iqbal* further articulated that the plausibility standard is not akin to a probability requirement. *Id.* Instead, the plausibility standard requires more than a sheer possibility that a defendant has acted unlawfully. *Id.* Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief. *Id*.

Iqbal clarifies the *Twombly* standard by setting forth two working principles. The first principle is that the court must accept as true all of the allegations contained in a complaint, but this principle does not apply to legal conclusions. *Id.* at 1949. Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. *Id.* at 1950. Determining whether a complaint states a plausible claim for relief is a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. *Id.* Also, while legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. *Id*. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement of relief. *Id.*

2. The *Twombly* Pleading Standard Is Not a Heightened Pleading Standard

When analyzing any pleading under the *Twombly* standard, it is of paramount importance to note that this standard is not a form of heightened pleading akin to pleading special matters

under Rule 9. *Bell Atlantic Corp., v. Twombly*, 550 U.S. 544, 569 n. 14 (2007). The *Twombly* holding was quite clear when it stated that this Court was not imposing a strict probability standard at the pleading stage. *Id.* at 556. Rather, *Twombly* imposed a standard that equates to slightly greater than possible. *Id.*

Shortly after *Twombly*, this Court provided insight, or for some, confusion, about this standard stating, "[s]pecific facts are not necessary; the statement need only give the defendant fair notice of what the claim is and the grounds upon which it rests." *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (quoting *Twombly*, 550 U.S. at 555). Of importance in *Erickson* is that while it relies on *Twombly*, it never once mentions the word plausibility or the standard of plausibility regarding a 12(b)(6) motion to dismiss. *Id*. Furthermore, this Court noted, through citation, that the *Twombly* pleading rules are merely an enhanced form of the familiar notice pleading standards set forth by *Conley v. Gibson. Id.* Even more, this Court has held steadfast to the assertion that Form 11 in the Federal Rules of Civil Procedure would satisfy the current *Twombly* standard by stating, "[a] defendant wishing to prepare an answer in the simple fact pattern laid out in Form 9 [now Form 11] would know what to answer." *Twombly*, 550 U.S. at 565 n. 10. All of this leads one to the logical conclusion: the *Twombly* plausibility standard is neither a rigid nor high standard to meet.

As one might guess, the enigmatic plausibility standard has sparked significant academic and practical debate. However, scholars are in much agreement that absent legislative amendment to the Federal Rules, the *Twombly* standard is not a significant departure from notice pleading under *Conley v. Gibson*. *See, e.g.*, Kevin Clermont & Stephen Yeazell, *Inventing Tests, Destabilizing Systems*, 95 Iowa L. Rev. (forthcoming Mar. 2010); Robert G. Bone, *Twombly, Pleading Rules, and the Regulations of Court Access*, 94 IOWA L. REV. 873 (2009).

3. Pleading Under *Twombly* is a Context Specific Task

In order to conclude that a particular pleading has stated a plausible claim under the *Twombly* standard, one must analyze the pleading in question with a firm grasp of the context from which the complaint arose. This Court explained this idea stating,

> "[a] statement of parallel conduct, even conduct consciously undertaken, *needs some setting* suggesting the agreement necessary to make out a § 1 [Sherman Anti-Trust] claim; without that further circumstance pointing toward a meeting of the minds, an account of a defendant's commercial efforts stays in neutral territory. An allegation of parallel conduct is thus much like a naked assertion of conspiracy in a § 1 complaint: it gets the complaint close to stating a claim, but without some further factual enhancement it stops short of the line between possibility and plausibility of 'entitlement to relief.'"

Twombly, 550 U.S. at 1966 (emphasis added). Many scholars interpret this as meaning that when looking at a particular complaint, it is crucial to interpret that complaint with a sufficient understanding of normal practices within the particular field from which the complaint arises. *See, e.g.*, Bone, 94 IOWA L. REV. at 873. Once the complaint establishes this "baseline" for normal conduct within a particular context, it must then state activities, actions or omissions supported by factual allegations beyond that baseline, thus leading to a plausible inference of a claim *Id.* at 884–85. The respondent's claim in *Twombly* failed because they asked this Court to draw an inference from perfectly legal conduct, within the context of the telecommunications industry, to that of illegal conduct under § 1 of the Sherman Act. *See Twombly*, 550 U.S. at 544. This Court was unwilling to make such an unreasonable inference and therefore dismissed the complaint as resting on implausible grounds. *Id.* at 570.

C. Petitioners Pled Sufficient Factual Allegations to Give Rise to a Plausible Claim under the *Twombly* Standard

Petitioners' complaint sufficiently alleges a strict products liability cause of action for design defect against Respondent's DTP-Hib vaccine (R. at 2). Petitioners' complaint states that between the dates of March 1996 and October 1998, twelve-year old Estella Marie Cooks suffered neurological injuries as a result of being injected with Respondent's thimerosal-containing vaccine (R. at 1). The neurological injuries complained of include developmental delays, learning disabilities, social delays and deficits, the impairment of motor skills, gastrointestinal illness, and immune system dysfunction (R. at 1 n. 1). Furthermore, Petitioners' complaint stated that Respondents, "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" (R. at 4). Furthermore, the factual allegations proffered by Petitioners highlight the risks associated with thimerosal, claiming, "[a]s a result of the mercury exposure, Estella Marie suffered neurological injuries […] some of her injuries are likely to be permanent (R. at 4 n. 7). Petitioners also claim that the benefits are minimal associated with thimerosal because it is only a preservative (R. at 1). Further, the complaint notes, "[t]he vaccine product injected into Estella Marie was unreasonably dangerously defective because it contained dangerous levels of ethyl mercury, a substance known to the defendants to have neurotoxic properties. The unreasonably dangerous and defective products described were a substantial contributing cause of plaintiff's neurodevelopmental injuries" (R. at 12–13, n. 12). Finally, Petitioners identify an alternative design when they claim the Respondent should have

manufactured children's vaccines without thimerosal prior to their daughter's vaccination (R. at 3).

The court of appeals erred in granting Respondent's 12(b)(6) motion because the court incorrectly applied Petitioners' plea to the two working principles required by *Twombly*'s plausibility standard. The court of appeals dismissed Petitioners' claim after only looking at the first tenet of *Twombly*. This tenet states that the court must accept as true all of the allegations contained in the complaint. However, that acceptance is inapplicable to legal conclusions. *Iqbal*, 129 S.Ct at 1949. The court of appeals erroneously dismissed Petitioners' complaint stating, "[a]ppellant's [c]omplaint [*sic*] does nothing more than provide a formulaic recitation of the elements of a design defect claim" (R. at 12).

This holding was erroneous for two reasons. First, the appellate court failed to note that while legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. *Iqbal*, 129 S.Ct. at 1950. Petitioners' complaint uses legal conclusions as a framework by asserting that "the vaccine product injected into Estella Marie was unreasonably and dangerously defective" (R. at 12 n. 8). However, this legal conclusion is supported by factual allegations when the complaint states the product was unreasonably and dangerously defective "because [the vaccine] contained dangerous levels of ethyl mercury, a substance known to the defendants to have neurotoxic properties" (R. at 12 n. 8). Secondly, the court of appeals was in error because they failed to recognize that when there are well-pled factual allegations, a court must assume their veracity and determine whether they plausibly give rise to an entitlement of relief. *Iqbal*, 129 S.Ct. at 1950. Here, the factual allegations of the significant risks, the minimal benefits, and the alternative feasible design, were never given the assumption of truth because

the court of appeals failed to correctly apply the *Twombly* analysis. Instead the court quickly dismissed the complaint because a conclusory statement was found in the complaint.

Once the first principle of *Twombly* has been passed, the second tenet must be analyzed. This principle states, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* Petitioners' complaint contains sufficient factual matter to state a claim to relief that is plausible on its face. *Twombly*, 550 U.S. at 570. Thus, approaching this complaint within the context of strict products liability, under the second *Twombly* principle, the court of appeals erroneously granted Respondent's 12(b)(6) motion to dismiss. Looking first to the context from which the claim derives, a baseline must be established for acceptable commercial activity. For vaccinations, this baseline activity shall be that of producing vaccinations that do not contain certain subparts widely known to cause significant health hazards to the patients who are required to receive the vaccine. There is an element of Respondent's vaccine, thimerosal or ethyl mercury, that is widely known within the medical community to cause significant health risks. With this fact stated in the complaint and being duly given the assumption of truth under the first *Twombly* principle, Petitioners have established activity that departs from the industry baseline activity. Therefore, Petitioners' claim supports a plausible inference of a defective design.

The court of appeals erroneously applied the *Twombly* pleading standard for two reasons. First, the court of appeals disregarded this Court's guidance in *Iqbal* and summarily dismissed Petitioners' factual allegations as legal conclusions. Second, if the factual allegations in the complaint had been given the assumption of truth required by *Twombly*, the court would have found a plausible claim for relief. Because it failed to adhere to these basic tenets, the court of appeals erred in granting Respondent's 12(b)(6) motion to dismiss.

D. Lower Courts' Application of the Plausibility Standard Bolsters the Assertion that Petitioners' Complaint Satisfies the *Twombly* Standard

The *Twombly* standard is relatively new among federal jurisprudence. Thus, looking to the lower courts for practical application is instructive. The lower courts support the conclusion that Petitioners' claim states a plausible claim for relief. Several lower courts have dismissed complaints for the defective design of medical devices and drugs, but several cases have also survived post-*Twombly* motions to dismiss. Upon closer examination of some of the more oft cited cases, one finds that Petitioners' pleadings are distinguishable from those dismissed and more closely analogous to those surviving dismissal.

1. Pleadings Dismissed for Failure to State a Claim are Distinguishable from Petitioners' Pleadings

In *Heck v. American Med. Sys., Inc.*, plaintiff's complaint alleging strict products liability was dismissed on a 12(b)(6) motion after he had an opportunity to amend his pleading. No. CCB-07-2101, 2008 WL 1990710 (D. Md. Apr. 30, 2008). Applying the *Twombly* standard, the court dismissed the petitioner's amended complaint stating, "Despite the court's clear notice that the original complaint failed to specify which theories Dr. Heck [petitioner] was pursuing, the amended complaint does little to resolve this defect." *Id.* at *2. Furthermore, the court noted, "the amended complaint baldly concludes that the AMS 800 was 'defective'; the defendant was 'negligent' in the manufacture of the device; the device was 'warranted as good and in functional condition' …. The amended complaint thus includes language that could sound in tort, contract or product liability law." *Id.* The complaint was dismissed because there was never a specific theory of recovery asserted and because the claim did not sufficiently put the defendant on notice of the claims plaintiff sought to bring before the court. *Id.*

Heck is highly distinguishable from the case at bar because Petitioners here have specifically pled the cause of action they are pursuing - design defect. Furthermore, Petitioners have pled sufficient factual allegations in support of their claim. These factual allegations make the claim plausible on its face and put the Respondent on notice of the claims brought before the Court.

In *Lewis v. Abbott Labs.*, yet another amended complaint was dismissed for failure to state a claim. No. 08 Civ. 7480(SCR)(GAY), 2009 WL 2231701 (S.D. N.Y. July 24, 2009). In *Lewis* the court dismissed plaintiff's allegations because they were wholly conclusory, and lacked any factual allegations. *Id.* at *4. The court was correct in granting defendant's motion to dismiss because the complaint literally was a "threadbare recital" stating, "(1) Depakote is inherently dangerous and (2) its side effects outweigh its benefits." *Id.* These two claims were not supported by any factual allegations. As a result, the Court concluded that there was no plausible claim for relief and therefore the claim must be dismissed. *Id.* at *7. Unlike the plaintiffs in *Lewis*, the Petitioners' pleadings in this case recite the elements of a cause of action, and then use those elements as a framework for their complaint. Once this framework has been laid, Petitioners support that framework with factual allegations that rise to the level of a plausible claim for relief (R. at 3).

Finally, in *Burks v. Abbott Labs.*, the court dismissed a claim pursuant to a 12(b)(6) motion based on the reasoning that although there were factual allegations in the complaint, those factual allegations did not rise to the level of plausible. 639 F.Supp. 2d 1006, 1016 (D. Minn. 2009). *Burks'* reasoning follows closely to the "baseline" activity analysis detailed above. In *Burks*, an infant fell severely ill from ingesting baby formula due to a bacteria in the formula called *E. Sakazakii*. *Id.* at 1006. It is of crucial importance in *Burks* that the bacteria in the

formula was harmless to infants with healthy immune systems. *Id.* at 1010. However, the plaintiff in *Burks* had a particularly susceptible immune system. *Id.* Thus, when trying to characterize the product as unreasonably dangerous in the complaint, the plaintiffs failed because the product was only unreasonably dangerous to infants with particularly weak immune systems. *Id.* at 1016. In other words, plaintiffs failed to define activities that departed from the baseline of acceptable activity within the baby formula industry. The court applied this baseline analysis when granting defendant's motion to dismiss and stated, "It appears that powdered infant formula, even when it contains *E. Sakazakii* bacteria, is not harmful to healthy infants over the age of 30 days old. That is, it appears that only neonates or infants with specific health issue are susceptible to *E. Sakazakii* infection." *Id.*

Petitioners' case is also distinguishable from *Burks*. Petitioners have noted that thimersol is dangerous not only to the plaintiff harmed, Estella Marie, but is also dangerous to all consumers (R. at 3). Therefore, the factual allegations set forth in Petitioners' complaint identify an unreasonably dangerous characteristic of the product that departs from acceptable baseline activity within the vaccine industry. Thus, the claim is plausible on its face.

2. Cases Allowing Plaintiffs' Claims to Survive a Motion to Dismiss Are Analogous to the Present Case

Focusing on cases that have survived motions to dismiss in the post-*Twombly* era leads to the conclusion that the pleadings in the present case should not be dismissed. In *Ivory v. Pfizer*, the plaintiff asserted a strict products liability claim for the prescription drug Chantix. No. 09-0072, 2009 WL 3230611 (W.D. La. Sept. 30, 2009). The court initially found that the complaint was merely a formulaic recitation of the elements of the Louisiana Products Liability Act. *Id.* at *1–2. However, the court appropriately applied the *Twombly* standard and stated the counts in the complaint, "must be read in context with the entire petition, including the one hundred and

four factual averments immediately preceding [the complaint]. *Id.* at *2. The court then concluded that the factual averments are more than sufficient to raise a right to relief above the speculative level." *Id.* at *3 (citing *Bell Atlantic Corp., v. Twombly*, 550 U.S. 544 (2007)).

Here, Petitioners have asserted their claim by utilizing a recitation of the elements of a cause of action (R at 3). This recitation is immediately followed by factual allegations that the court must accept as true. *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1950 (2009). Granted, Petitioners' complaint does not list over one hundred factual allegations. However, Petitioners provide clear and succinct factual allegations from which an inference may fairly be drawn that evidence on these material points will be introduced at trial. *Ivory*, 2009 WL 3230611 at *3.

In *Braden v. Tornier Inc.*, very persuasive reasoning is found to support the position that Petitioners' claim should not be dismissed. In *Braden*, the plaintiff claimed that after having a prosthetic toe, manufactured by the defendant, implanted, the implant failed and they were forced to have it removed. *Braden v. Tornier, Inc.*, No. C09-5529RJB, 2009 WL 3188075, *2 (W.D. Wash. Sept. 30, 2009). The complaint was rather minimal, but it did contain factual allegations in support of the claim. *Id.* The court reasoned that the plaintiff's non-conclusory allegations and reasonable inferences from that content, are sufficient under *Iqbal* to show that they have stated a "claim to relief that is plausible on its face." *Id.* at *3. Defendant asserted that the plaintiff should be forced to provide more factual allegations about their claim and more specifically identify their unsafe design theory. *Id.* The court rejected this because the "plaintiffs properly point out that whether a product's defect was due to its design or manufacture is the sort of information that is gained in discovery." *Id.* Additionally, the court commented "to force plaintiffs to plead facts in support of the theory would shut the courthouse doors before the

plaintiffs had an opportunity to meaningfully engage in the process. This reaches well beyond the Supreme Court's holding in *Twombly* and *Iqbal*." *Id.*

Braden is analogous to the case at bar because both of the pleadings contain limited factual allegations. However, these factual allegations rise to the level of plausibility, and therefore, should survive a motion to dismiss under the *Twombly* standard. Furthermore, the court in *Braden* touches on the very important consideration that in products liability cases, it would be inappropriate to "shut the courthouse doors before plaintiffs [have] an opportunity to meaningfully engage in the process." *Id.* For the preceding reasons, Petitioners' claim should not be dismissed pursuant to Respondent's 12(b)(6) motion for failure to state a claim.

E. If the Court Is Not Convinced the Claim Offered by Petitioners Asserts a Plausible Claim for Relief, the Court Should Allow Petitioners Leave to Amend Their Complaint

If the Court finds that the factual allegations in Petitioners' claim do not state a claim for relief that is plausible on its face, Petitioners argue in the alternative that it would be proper for this Court to allow leave to amend the complaint pursuant to Federal Rule of Civil Procedure 15(a). The unique characteristic of this case that is determinative of whether or not a leave to amend should be permitted is that the pleadings entered in the district court were governed by the standard set forth in *Conley v. Gibson*. These claims were not governed by the *Twombly* plausibility standard because *Iqbal* had not yet expanded the scope of *Twombly* as applicable to all civil actions. When petitioners filed their complaint, *Twombly* was narrowly construed and only applied to Sherman Antitrust Cases. *See Twombly*, 550 U.S. at 544. Furthermore, a case dealing with a similar timing issue stated, "[c]ourts are free to grant a party leave to amend whenever 'justice so requires,' and requests for leave should be granted with 'extreme liberality.'" *Moss v. U.S. Secret Service*, 572 F.3d 962, 972 (9th Cir. 2009) (allowing leave to

amend when plaintiffs filed their amended complaint on September 26, 2006, and the Supreme Court issued its opinion in *Twombly* on May 21, 2007). The *Moss* court further stated, "[p]laintiffs deserve a chance to supplement their complaint with factual content in the manner that *Twombly* and *Iqbal* require." *Id.*

Respondents will most likely counter this alternative argument with the assertion that a district court is not required to grant a plaintiff leave to amend a 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. *See Wagner v. Daewoo Heavy Inds. Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002). However, this argument is quickly disposed of by the "extreme liberality" and when "justice so requires" language found in *Moss*. Furthermore, when dismissing for failure to state a claim, a district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts. *Doe v. United States*, 58 F.3d 494, 497 (9th Cir. 1995); *Cook, Perkiss & Liehe v. N. Cal. Collection Service*, 911 F.2d 242, 247 (9th Cir. 1990).

Therefore, if the Court is not satisfied with the factual allegations contained in Petitioners' complaint, the Court should allow leave to amend because of the unique timing characteristics of this case.

CONCLUSION

The Vaccine Act does not preempt Grace State law, and Petitioners have asserted a plausible claim for relief. For these reasons, Petitioners respectfully request that this Court find the appellate court erred in granting Respondent's 12(b)(6) motion to dismiss.