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

No. 10-1524

IN THE

Supreme Court of the United States

Spring term 2010

Dan Cooks, et al.,
Petitioner,

-V-

Carolina Laboratories, Inc.
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES SUPREME COURT

RESPONDENTS' BRIEF ON THE MERITS

Team 12R

QUESTIONS PRESENTED

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

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

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STATEMENT OF THE CASE

I. CONGRESS PROVIDES A SYSTEM FOR THOSE INJURED BY VACCINATIONS TO BE COMPENSATED WHILE PRESERVING IMPORTANT PUBLIC HEALTH GOALS

In recognition that the availability and use of childhood vaccines "is among the Nation's top public health priorities" and that a small but significant number of those vaccinated have been injured as a result, Congress passed the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"). H.R. No. 99-908, (1986), as reprinted in 1986 U.S.C.C.A.N. 6344. In so doing, Congress hoped to ensure the realization of two goals; first, to "achieve optimal prevention of human infectious diseases through immunization", and second, that all individuals who are injured by the administration of those vaccines have access to compensation. *Id* at 3. These objectives recognize a national interest in protecting the vaccine supply as well as the principle in tort law of compensation for injury. Blackmon v. American Home Products, 328 F. Supp.2d 659, 663-66 (S.D. Texas 2004). In pursuit of those goals, Congress established a no-fault compensation program to assure the adequacy of the vaccine supply and compensate that portion of the population who are injured as a result of the administration of such vaccines.

Under the provisions of the Vaccine Act, the injured individual must first file a petition for compensation with the National Vaccine Injury Compensation Program ("NVICP"). 42 U.S.C. § 300aa-1 et seq. The NVICP gives the plaintiff the opportunity to obtain a judgment under the program; if the plaintiff is not satisfied with the judgment or desires to pursue alternative compensation, they may elect to withdraw from the remedy provided by the NVICP. After accepting a judgment under the NVICP, a plaintiff is foreclosed from pursuing additional compensation against a vaccine manufacturer in a civil tort action. 42 U.S.C.A § 300aa-21(a).

II. THE USE OF THE TRADITIONAL FORMULATION OF THE DTP-HIB VACCINE AND RESULTANT INJURY TO ESTELLA MARIE COOK

Millions of dollars are poured into disease prevention and the development of vaccines each year in the United States. Staff of H. Comm. On Energy & Commerce, 99th Cong., *Childhood Immunizations*, at III. As a result of this and other factors, Congress has assigned the responsibility for overseeing the manufacturing, regulation, and public health recommendations to the Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control. *Id.* The vaccination approval process includes specific criteria that a vaccine must meet before it can be released into a highly regulated market. These agencies are charged with promulgating standards and recommendations in connection with each specific vaccine. *Id.*

Specifically, the DTP vaccine is widely administered to infants at two, four, six, and eighteen months of age. Ackley v. Wyeth Laboratories, Inc., 919 F.2d 397 (1990). Widespread use of the vaccine in accordance with these standards has resulted in a marked decline in the number of reported cases of pertussis,[1] tetanus[2], and diphtheria[3]. The Federal government has an interest in the continuation of this positive trend. *Id.*

Because of the inherent dangers that come from a lack of preservative in multi-dose vaccine vials, the United States Code of Federal Regulations require that a preservative component be incorporated into the design of the vaccine. 21 C.F.R. 610.15(a). Thimerosal, the preservative highlighted in the present case, has been widely used since the 1930's to prevent

[1] From a reported high of 265,269 cases in 1934; the number of pertussis cases decreased to 2,276 in 1984. Staff of H. Comm. On Energy & Commerce, 99th Cong., *Childhood Immunizations*, at 10 (1986).
[2] In 1948, 601 cases of tetanus were reported; in recent years, the number of reported cases has remained around 90. About two-thirds of those cases are in patients over 50, suggesting that the adult population may be inadequately protected against tetanus. *Id.* at 8.
[3] Over 200,000 cases of diphtheria were reported as early as 1921. In 1984, the average incidence was a mere 3 cases per year. *Id.* at 6-7.

vaccine contamination with harmful microbes. *Childhood Immunizations* at I. It is also a component of the DTP-Hib vaccine marketed by Carolina Laboratories.

Congruent to the existing recommended vaccination schedule, like many young children her age, the Petitioner received three doses of the DTP-Hib vaccine manufactured by Carolina Laboratories. Rec. at 1. As a result of the thimerosal formulation in the vaccine, the Petitioner alleges she suffers from specific injuries which were of they type anticipated in the Vaccine Act as those that would flow to a "small but significant" segment of those vaccinated. H.R. No. 99-908, (1986), as reprinted in 1986 U.S.C.C.A.N. 6344. Estella's injuries include the impairment of motor skills, gastrointestinal illness, immune system dysfunction, and various neurological injuries. Rec. at 1; *see also* the Vaccine Injury Table, 42 C.F.R. § 100.3.

III – PROCEDURAL HISTORY

On September 3, 2001, pursuant to 42 U.S.C.§ 300aa-1, Dan and LoEtta Cooks filed a petition for compensation under the NVICP on behalf of their daughter. Rec. at 1-2. Though the record in the present case contains little information as to the reasons for doing so, the Cooks subsequently withdrew that petition two years later on November 5, 2003. Seven days after the withdrawal was granted by the Clerk of the U.S. Court of Federal Claims, the Cooks filed an election to file a civil action that has ultimately resulted in the present litigation. Rec. at 2. The complaint was initially filed in the Wicked County Court of Common Pleas, but was removed to the federal court system based on diversity jurisdiction. Rec. at 2. The Petitioner's claims include design defect allegations under theories of both strict liability and negligence. Rec. at 2. The adequacy of warnings and claims of manufacturing defect are not asserted by this Petitioner; in fact, Petitioner asserts the warnings provided were adequate. *Id.*

Carolina Laboratories moved for dismissal in district court on two grounds; one, the Petitioner's design defect claims were barred by the Vaccine Act; and two, the Petitioner's complaint was insufficient under the Federal Rules of Civil Procedure. While the district court held that the claims relating to design defect were sufficient to present a cause of action, they also held that the Vaccine Act preempted state law and that the plaintiff's design defect claims were consequently barred by the Vaccine Act. Accordingly, the court then granted the defendant's motion to dismiss.

On appeal, the Petitioner maintained the same claims previously asserted in the district court. The U.S. Court of Appeals for the Thirteenth Circuit ultimately affirmed the district court's decision, but on different grounds. Regarding the preemption claim, the court held that the Vaccine Act limited the immunity of vaccine manufacturers, and that all design defect claims were not preempted by the Vaccine Act. With respect to the sufficiency of the complaint, the court held that the Petitioner had "not alleged any facts that would permit the Court to conclude that there was a defect in the design of the vaccine." Rec. at 13. After upholding the district court's dismissal of the complaint, certiorari was granted by the United States Supreme Court.

SUMMARY OF THE ARGUMENT

I. Recent jurisprudence of this country has given no validity to threadbare complaints, comprised only of vague, unsubstantiated allegations. The 13th Circuit correctly applied the *Twombly* pleading rules when it granted Respondent's 12(b)(6) motion to dismiss for failure to state a claim for which relief could be granted. 550 U.S. 544 (2007). The Petitioner's complaint does not contain enough factual matter to constitute a plausible claim that is harmonious with the underlying policies of the applicable pleading rules.

To determine the sufficiency of a complaint under the framework of the Federal Rules of Civil Procedure, this Court must first identify any conclusory allegations in the complaint. *Id.* After such an identification is made, the court shifts to an analysis of the plausibility of the complaint. For purposes of a motion to dismiss, only claims that are facially plausible have the necessary heft to show that the pleader is entitled to relief. *Id.* at 545.

Count I of the Petitioner's complaint contains conclusory allegations that do not state a cause of action for negligence in accordance with the governing pleading principles. In order to establish negligence under the substantive law, the Petitioner must clearly demonstrate the element of breach. The State of Grace has adopted a risk-utility analysis to determine design defect; an indispensible element of the substantive law to establish breach. This analysis requires a balancing of the utility of an alternative design against the resultant risks of implementing such a design. Consequent to the lack of a suggested reasonable alternative design in the complaint, the Petitioner has failed to plead the fundamental information required by the substantive law that governs negligence claims in the State of Grace. As a result, the complaint was properly dismissed.

Additionally, Count II fails to adequately address the same required elements under substantive law. As with Count I, the lack of a suggested feasible design alternative is fatal to the sufficiency of the complaint. The Petitioner's complaint, while providing an elemental and partial recitation of the legal elements for a claim of action under the substantive law, does not provide the factual allegations to survive a motion to dismiss. Coupled with the societal value and success of the DTP-Hib vaccine, the general allegation that the Respondent should have manufactured a vaccine without thimerosal is not sufficient to state a claim for design defect. Accordingly, the complaint was properly dismissed as to Count II.

The third and final aspect of the Petitioner's complaint that proves fatal in terms of sufficiency is that it fails to contain adequate information to allow the reasonable defendant the opportunity to file a proper response. The complaint, not containing an allegation of a more specific alternative design, forecloses the defendant from using both specific denials and affirmative defenses; both of which are tools and privileges given to the defendant under the Federal Rules of Civil Procedure. Additionally, without an alleged design alternative, the defendant is left to the whim of the plaintiff during the discovery process in potentially being required to submit to endless discovery requests designed to help the plaintiff "discover" if a claim for which they are entitled to relief ultimately exists. This result runs counter to the goals and principles of the judicial system. For this reason, the complaint was properly dismissed.

II. Petitioner's design defect claim is expressly preempted by the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"). Section 22(b) expressly immunizes vaccine manufacturers from liability for all claims except manufacturing defects and improper directions or inadequate warnings.

Congressional intent to preempt state law must be unmistakably clear. Express preemption arises when there is explicit language commanding state law to be displaced. Through the statutory text of the Vaccine Act, Congress intended to expressly preempt specific and enumerated instances. After it has been determined that there is an express preemption, the scope and extent of the preemption must be defined. Looking to the purpose of the statute as a whole, the plain language of the statute explicitly conveys Congress's intent that design defect claims should only be brought through the compensation program provided by the Vaccine Act.

Although it is clear through the plain language, the authoritative legislative history that surrounds the enactment of the Vaccine Act fully supports Congress' intent to bar all design

defect claims. The House Committee report directly states that only when there is a manufacturing defect or labeling defect can a claim be brought forth in state tort system.

Finally, the overall structure of the Vaccine Act reflects the fact that Congress delegated vaccine regulation and responsibility to expert governmental agencies. Congress has set forth, through multiple sections of the Vaccine Act, that the Secretary of Health and Human Services was given authority to create a National Vaccine Program. The Program was to consist of a variety of committees to regulate and be responsible for vaccine research, development, safety, and licensing. It is this group of committees, not a jury, that is charged with making decisions concerning vaccine regulation. Therefore, Congress conveyed their intent to bar design defect claims through the state tort system, and the Petitioner's tort claim should be dismissed.

ARGUMENT

I – THE COURT OF APPEALS CORRECTLY APPLIED THE TWOMBLY PLEADING RULES WHEN IT GRANTED THE RESPONDENT'S MOTION TO DISMISS

In granting the Respondent's motion to dismiss, the Court of Appeals properly followed this Court's established interpretations of legislatively adopted Rules of Civil Procedure. In *Bell Atlantic v. Twombly*, this Court delineated a two-step analysis in determining the sufficiency of the complaint under the Federal Rules of Civil Procedure. 550 U.S. 544 (2007). First, the court must take all factual allegations in the complaint as true. *Id.* at 556. Subsequently, the court then determines whether the complaint asserts a facially "plausible" claim for which relief can be granted. *Id.* The Petitioner's complaint in the case before this Court was properly dismissed by the court of appeals because it ultimately does not contain enough factual matter to allow this Court to infer a plausible claim. Further, this claim as it is currently constituted has serious implications relating to the Respondent's ability to file a proper and adequate response.

a. Petitioner's Complaint Fails To Assert The Required Amount Of Factual Allegations Which, When Entitled To The Assumption Of Truth, State A Claim For Which Relief Can Be Granted

In considering a motion to dismiss pursuant to Federal Rule of Civil Procedure 12 (b)(6), all factual allegations set forth in the complaint have to be accepted as true. US v. Gaubert, 499 U.S. 315, 327 (1991). Additionally, those factual allegations have to be construed in the light most favorable to the plaintiff. Scheuer v. Rhodes, 416 U.S. 233, 236 (1974). Thus, a determination of the factuality of the plaintiff's statements is a crucial first step in the sufficiency analysis. *Twombly,* 550 U.S. at 570. In the case at bar, the Petitioner's complaint constitutes in greater part only legal conclusions and, as such, those statements are not entitled to a presumption of truth. *Id. See, e.g.*, Ashcroft v. Iqbal, 129 S.Ct. 1937 (2009) (holding that the Federal Rules do not require the court to accept a complaint's conclusory statements as true). Moreover, the complaint not only lacks formal sufficiency under Rule 8 (a)(2), but also lacks substantive sufficiency in that the complaint does not contain the necessary statements of fact that would constitute a legal claim under the relevant substantive law.

As this Court held in *Twombly,* the "tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." 550 U.S. at 555. This Court further construed this standard by holding that "we are not bound to accept as true a legal conclusion couched as a factual allegation." *Iqbal,* 129 S.Ct at 1950. Moreover, in regards to the relationship of pleadings and discovery, Rule 8 may provide for "a short and plain statement of the claim," but it does not unlock the doors of discovery for a plaintiff who has plead "nothing more than conclusions." FED. R. CIV. P. 8 (A)(2); *Iqbal,* 129 S.Ct at 1950.

Frey v. Novartis Pharmaceuticals illustrates the practical application of this decision. 642 F. Supp. 2d 787 (S.D. Ohio 2009). The plaintiff in this case asserted claims of

manufacturing defect, design defect, and negligence in warning of the risks associated with an anticonvulsant medication she had been prescribed by her physician. *Id.* at 790. In applying this Court's holdings in both *Twombly* and *Iqbal*, the *Frey* court focused on the substantive law that would ultimately detail the elements the plaintiff would be required to prove at trial. *Id.* at 792-93. Under Ohio law, the plaintiff is required to allege facts that would permit the court to conclude that there was a defect in the design of the medication, and that the defect was a proximate cause of the plaintiff's injuries. *Id*. Citing *Twombly*, the court held that the "plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 791 (quoting *Twombly*, 550 U.S. at 555).

In this case, the plaintiff's complaint alleged that the defendant had marketed a drug "whose risks were not known to the general public, and that they cannot particularly allege that the scientific makeup of the drug is defective for a specific reason without conducting discovery." *Id.* at 792. The plaintiff had, the court said, alleged an element of the legal claim, but failed to plead enough under Ohio law to sufficiently state all the factual elements of a legal, cognizable claim. *Id.* at 795. Assuming adequate warnings, under Ohio law, the plaintiff was required to plead that the foreseeable risks associated with the contested design exceeded the benefits associated with that design. *Id*. at 792. The complaint did not contain allegations relating to those elements for a design defect claim, and consequently the court held the complaint must be dismissed for lack of substantive sufficiency. *Id.* at 795.

The *Frey* court further applied the *Twombly* standard in holding that, while the complaint at least facially asserted factual allegations, the supposed factual allegations were a partial recitation of the legal elements of the claim. Consequently, they were not entitled to the

assumption of truth. *Id.* at 793. *See* Ashcroft v. Iqbal, 129 S.Ct. 1937 (2009) (holding plaintiff's claims of discrimination were deemed too conclusory to be entitled to the assumption of truth); *See also* Lewis v. Abbot Laboratories, No. 08 Civ. 74802009, WL 2231701 (S.D. New York. 2009) (dismissing plaintiff's allegations because of their legal conclusory nature). Accordingly, the utility of the first prong of the *Twombly* analysis is that it provides for an assessment of both the category of the complaint's allegations - factual or conclusory - and a review of whether those claims adequately address the required elements under substantive law. *Id*. *See generally* Bell Atlantic v. Twombly, 550 U.S. 544, 570 (2007).

1. The Petitioner's Complaint Does Not Contain The Requisite Factual Allegations Related To The Elements Of The Applicable Substantive Law

The substantive law concerning the issues presented with the case at bar is found in the Restatement (Third) of Torts: Products Liability §6. The Restatement, as well as the State of Grace, has adopted a risk-utility analysis in determining the defectiveness of design of a drug, product, or vaccine.[4] R. at 3-4. Because the proponent of the strict liability design defect claim must ultimately prove that the risks of danger inherent in the challenged design outweigh the benefits of the drug as designed, the proponent's pleadings must also contain factual allegations of a specific and feasible design alternative. Barton v. Adams Rental, 938 P.2d 532 (Colorado 1997). *See also* Blue v. Environmental Engineering, Inc., 828 N.E.2d 1128 (Illinois 2005). The complaint in the case at bar fails to plead this important and required element.

The substantive law, as contained in the Restatement and adopted in the State of Grace, reflects the belief that some products are incapable of being made safe, but their intended and

[4] The Restatement provides: "A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risk and therapeutic benefits, would not proscribe the drug or medical device for any class of patients." RESTATEMENT (THIRD) OF TORTS §6C (1998).

ordinary purpose justify their use. RESTATEMENT (SECOND) OF TORTS §402A CMT. K (1965). As a result of the value placed on certain classes of drugs and vaccines, the plaintiff must conclusively prove at trial that a feasible design alternative existed. *Id*. Without affirmative proof of an alternative feasible design, it is generally impossible for the plaintiff to establish that the product's ultimate design was defective. *See* McCarthy v. Olin, 119 F.3d 148, 155 (N.Y. 1997). As a result, it is necessary for the plaintiff to include their proposed design alternative in the complaint.

Much like the plaintiff in the *Frey* case, the Petitioners in the case at bar have plead in a formulaic manner partial elements of a cause of action under the applicable substantive law. *Twombly,* 550 U.S. at 555. The complaint alleges that Petitioner did indeed receive three doses of the DTP-Hib vaccine, that she has injuries, and that those injuries resulted from her use of the vaccine. R. at 1. Under the *Twombly* approach to pleading, these statements would be entitled to the presumption of truth for the purposes of a 12 (b)(6) motion to dismiss. However, the principles underlying the risk-utility approach for design defect claims that the State of Grace has adopted would not permit a general allegation that the Respondent "should have manufactured children's vaccines without thimerosal prior to their daughter's vaccination" to suffice. R. at 3. That allegation, along with other "general factual allegations," is not specific enough to provide anything more than a partial recitation of the elements of a design defect claim under Grace law. R. at 4. Resultantly, the complaint fails to state a claim for which relief can be granted in relation to the Petitioner's design defect claim under a theory of strict liability.

2. The Complaint Fails To Assert The Necessary Factual Allegations To Establish A Negligence Claim Under Grace State Law

To state a cause of action for negligence in accordance with the governing pleading principles in *Twombly,* a plaintiff must allege that the defendant owed a duty, that the defendant

breached that duty, and that this breach caused the plaintiff damages. *See, e.g.*, Fla. Dep't of Corrections v. Abril, 969 So.2d 201, 204-05 (Fla. 2007). In the case at hand, the factual specificity the complaint lacks with regard to the breach element demands the complaint be dismissed for failure to state a claim for which relief can be granted.

To make a determination regarding design defect, the State of Grace has adopted a risk-utility analysis. R. at 3-4. Various factors are considered when determining the outcome of this balance, including the cost and feasibility of an alternative design. Not only is proof of a reasonable alternative design a factor to be considered in a risk-utility balance, most courts hold that proof is almost always a necessary element of a design defect claim. General Motors Corp. v. Edwards, 482 So.2d 1176, 1192 (Ala. 1985).

The purpose of risk-utility analysis, particularly in relation to negligence claims, is to determine "whether the risk of injury might have been reduced or avoided." *McCarthy*, 119 F.3d at 156. Without affirmative proof of a feasible alternative design, a plaintiff cannot usually establish that a manufacturer has been negligent; especially in regards to the particular components used in the chosen design. By failing to identify at the pleading stage a reasonable design alternative, the Petitioner failed to properly assert a breach of the Respondent's duty to exercise reasonable care. Without containing the necessary statements of fact that would comprise a cognizable legal claim, the Petitioner's claims fail under the standard delineated by this Court in both *Twombly* and *Iqbal*.

This principle has been applied most recently in *Gomez v. Pfizer,* No. 09-22700-CIV, 2009 WL 4908937 (S.D. Fla. December 21, 2009). In that case, the plaintiff asserted a claim of negligence and strict liability after being diagnosed with medication-induced Steven-Johnson syndrome. *Id.* at 1. In applying both the principles outlined in *Twombly* and *Iqbal*, along with

the principles of relevant substantive law, the court focused on the amount of factual allegation in the complaint. The court held, in congruence with the defendant's assertion, that "[the negligence counts] offer nothing more than a recitation of the elements of duty and breach, generally, and a general recitation of alleged breaches, untethered to any actual facts...." *Id.* at 2.

Specifically, the plaintiff's complaint in *Gomez* alleged failure to design two pain medications, Motrin and Tylenol, in a reasonably safe condition so as not to cause injury. Complaint, *Gomez v. Pfizer*, No. 1:09-cv-22700-UU (S.D. Fla., October 9, 2009). The plaintiff's complaint further alleged that the use of these products "solely … or in combination with one another" caused Mrs. Gomez's damages. *Id.* 13-16.

The court acknowledged both the considerable length of the complaint[5] and the numerous allegations outlined therein; nevertheless the court held that the complaint failed to "adequate[ly and upon a] factual basis" state all the elements of the claim. *Gomez*, 2009 WL 4908937 at *2. The court further held that the complaint lacked specificity because it made "no individualized allegations against either [Defendant]" and, in consequence of the lack of specificity, failed to establish the duty element. *Id.* The court was compelled to grant the motion to dismiss. *Id.*

Much like the plaintiff in the *Gomez* case, the Petitioner in the instant case has failed to assert the required factual allegations that would allow a court to recognize a claim for relief under the applicable substantive law. *Twombly,* 550 U.S. at 555. A partial pleading does not satisfy the risk-utility analysis adopted by the State of Grace, in that a partial pleading fails to contain sufficient factual detail to establish breach of duty. Similarly, the Petitioner's complaint

[5] The plaintiff's complaint was comprised of a total of "***nineteen*** pages containing over ***eighty-seven*** allegations." Complaint, *Gomez v. Pfizer*, No. 1:09-cv-22700-UU (S.D. Fla., October 9, 2009);

suffers the same setback as the plaintiff's complaint in *Gomez*; the lack of specificity necessary to make a negligence claim legally recognizable under substantive law is absent.

The pleading in the present case contains a general claim that the Respondent failed to conduct adequate safety tests to determine whether thimerosal was safe and non-toxic to humans in the dose administered. R. at 2. The complaint also alleges "as a result of the mercury exposure, [Petitioner] suffered neurological injuries" and lists several of the specific injuries; for example, "developmental delays, learning disabilities, social delays and deficits…." R. at 1. Under *Twombly* principles, these statements would be entitled to the presumption of truth for the purposes of a 12 (b)(6) motion to dismiss. *Twombly*, 550 U.S. at 556.

However, under the substantive law of the State of Grace, claims for design defect under strict liability and negligence theories are to be evaluated under a risk-utility analysis. In relation to both theories of liability, a factual assertion of an alternative design must be contained in the pleadings in order to satisfy substantive sufficiency requirements. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §6 (1998). The Petitioner's complaint in the case at bar has not satisfied the demands of either formal or substantive sufficiency and consequently should be dismissed pursuant to Federal Rule of Civil Procedure 12 (b)(6).

b. The Factual Content Of The Petitioner's Complaint Is Not Supported By The Necessary Framework To Create A Plausible Claim For Which Relief Can Be Granted

Though detailed factual allegations are not required at the pleading stage, the factual allegations contained within a plaintiff's complaint require enough factual specificity "to raise a right to relief above the speculative level." *Twombly,* 550 U.S. at 545. Further, even a complaint comprised entirely of non-conclusory, factual allegations that are entitled to the presumption of truth must still meet a threshold standard of plausibility. *Iqbal*, 129 S.Ct. at 1949. In the case at

bar, there is not enough factual specificity to allow this Court to draw a plausible inference that Carolina Laboratories is liable to the Petitioner for design defect in either strict liability or negligence theories. R. at 2.

This Court has held that the plausibility pleading standard has two basic underpinning principles: First, courts are not required to accept as true legal conclusions or "legal conclusions couched as factual allegation(s)." *Twombly* 550 U.S. at 555 (quoting *Papasan v. Allain,* 478 U.S. 265, 286 (1986)). Thus, "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, will not suffice" to state a claim that is plausible on its face. *Id*., *See also* Iqbal, 129 S.Ct. at 1949 (holding that a complaint does not suffice if it tenders "naked assertions devoid of further factual enhancement"). Second, only claims that contain a "plausible claim for relief" can survive a motion to dismiss. *Iqbal* 129 S.Ct. at 1950.

The relevant legal standard is initially explained by this Court's interpretation of Rule 8 (a) in *Bell Atlantic v. Twombly*. 550 U.S. 544 (2007). Specifically, this Court explained that a plaintiff's obligation under Rule 8 (a)(2) to provide the grounds for his or her entitlement to relief "requires more than labels or conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 555. This Court further clarified that the factual allegations in a plaintiff's complaint "must be enough to raise a right to relief above the speculative level." *Id.* at 556. The complaint must contain enough factual matter to raise a *reasonable expectation* that discovery will reveal evidence to prove the elements of the claim under the applicable substantive law. *Id.* (emphasis added).

More recently, this Court has upheld and firmly entrenched the *Twombly* plausibility requirement in holding that allegations in a complaint must move the claims "across the line from conceivable to plausible." *Iqbal,* 129 S.Ct. at 1951. The *Twombly* interpretation of this

Rule 8 requirement necessitated that the complaint must contain more than a "sheer possibility" that the defendant has acted unlawfully. *Twombly*, 550 U.S. at 556. It is not enough that the plaintiff simply plead facts that are *consistent* with the defendant's liability; such a complaint "stops short of the line between possibility and plausibility of entitlement to relief." *Iqbal*, 129 S.Ct. at 1949. Succinctly put, the plausibility standard requires more than "the defendant-unlawfully-harmed me" accusations. *Id.* Importantly, both the *Twombly* and the *Iqbal* courts framed their analysis in terms of the applicable substantive law.

In considering both the facts at issue in *Iqbal* and the need for plausibility, this Court considered the likelihood of other possible explanations for the alleged conduct. *Id*. at 1950. *See also* Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308 (2007) (holding that the court must consider plausible, non-culpable explanations for the defendant's conduct). This Court found that the factual allegations in the plaintiff's complaint would support two sets of inferences and that because an "alternative explanation existed," the plaintiff's assertions were not "plausible conclusions." *Id.* at 1951-52. This holding solidifies the concept that the complaint is not sufficient for purposes of a Rule 12 (b)(6) motion to dismiss if it contains a set of facts from which a court could infer two or more possible conclusions, or where the conclusion asserted by the plaintiff is merely *consistent* with the defendant's alleged liability. *See generally* Bell Atlantic v. Twombly, 550 U.S. 544 (2007); *see also* Ashcroft v. Iqbal, 129 S.Ct. 1937 (2009).

The difficulty that comes with this standard is apparent, but Supreme Court precedence is not without guidance. For instance, shortly after the *Twombly* decision, the Court applied this standard in holding that "plausible, non-culpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff" must be considered. *Tellabs*, 551 U.S. at 324. This Court considered the legislative history and provisions of the applicable substantive law – the

Private Securities Litigation Reform Act ("PSLRA"). *Id.* at 318. The PSLRA was used to determine the level of specificity required in the pleading to meet the plausibility standard. Congress, with the PSLRA, intended to "curb perceived abuses of the § 10 (b) private action nuisance filings, targeting of deep-pocket defendants, and vexatious discovery requests." *Id.* at 320, (quoting H. R. Conf. Rep. No. 104-369 at 31 (1995)). This Court relied heavily on Congress's intent with the statute in holding the plaintiff's complaint deficient. *Id.* at 329.

In determining the plausibility of the complaint at issue, a comparative inquiry concerning alternate explanations in light of the relevant substantive law and legislative pronouncement on the issue must be made. *See* Tellabs, 551 U.S. 308. When this inquiry is conducted in the present case, the conclusion to be made is that the complaint lacks congruence with legislative pronouncement in relation to design defect, and additionally, the complaint fails to allege all of the elements necessary under substantive law.

In recognition of the fact that society enjoys great benefits from childhood immunization programs and the concern that a small but significant number of children are injured by these vaccinations, Congress passed the National Vaccine Injury Compensation Act of 1986 ("Vaccine Act"). 42 U.S.C. § 300aa-1 (1986). *See also*, H.R. No. 99-908, (1986), as reprinted in 1986 U.S.C.C.A.N. 6344. The Vaccine Act was passed in large part because of an increase in vaccine-related litigation and the dual concerns that manufacturers would either cease vaccine production or significantly increase vaccine prices. *Blackmon*, 328 F. Supp.2d at 663. The Vaccine Act provides a way for those who have recognized injuries to be compensated while preserving the benefits of having a vaccination program available that is beneficial to a large part of the population and that is not cost-prohibitive. H.R.Rep. No. 99-908, at 4 (1986), as reprinted in 1986 U.S.C.C.A.N. 6345-46.

In § 300aa-22 of the Vaccine Act, Congress has set forth a standard, applicable to claims brought under the Act, that releases manufacturers of vaccines from liability if the plaintiff's injuries were the result of "side effects that were unavoidable." 42 U.S.C.A. § 300aa-22 (1986). The corollary to this - when a vaccine or drug is "reasonably safe" - was carried over from the substantive law at issue in the present case. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §6 (1998). This idea of a "reasonably safe" design is suggestive of a comparison between two competing designs, especially when the jurisdiction has elected a risk-utility analysis as a test of negligent and strict liability design defect claims. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §6 CMT. F (1998). The State of Grace has elected such an analysis for use with claims like the ones at issue in the present case.

The significance of the Vaccine Act legislation and history in regards to the pleading plausibility standard in a civil claim is Congress's recognition of alternative responses to the plaintiff's claims of strict liability; all of which hearken back to a risk-utility analysis. *See* H.R.Rep. No. 99-908 (1986), as reprinted in 1986 U.S.C.C.A.N. 6345-46. From this idea of comparing two alternative designs, along with the value society places on a vaccination program, follows the logical presumption that the initial design of the vaccine is within acceptable limits proposed by the federal government and its regulatory agencies. Consequently, the specification of an alternative design would be necessary for two reasons: 1) to overcome the initial presumption that the vaccine as designed is safe because it has met applicable governmental standards, and 2) to avoid prejudicing the defendant such that he is unable to form an appropriate response to the complaint. *Id; see also* Zielinski v. Philadelphia Piers, 139 F. Supp. 408 (E.D. Penn. 1956) (court holding that compliance with Federal Rule 8(b) requires some specificity in order to allow a party to frame a proper response).

The factual content of the Petitioner's complaint, analyzed under the *Twombly* standard, requires this Court to uphold the lower court's decision. The complaint's factual allegations, even when given the assumption of truth, do not overcome the *Twombly* plausibility requirement. In asserting a claim of design defect as the ultimate cause of the Petitioner's injuries, the complaint fails to contain allegations that move those particular claims into the realm of plausibility. *Iqbal*, 129 S.Ct. at 1949. The Petitioner alleges design defect in relation to the safety of the vaccine; specifically, that the Respondent should not have used the thimerosal preservative component in the design of the vaccine. It is not in controversy that the Petitioner was administered the recommended dosages of the DPT-Hib vaccine, and, separately, that Petitioner suffered neurological injuries consistent with mercury poisoning.

However, while the Petitioners generally allege that these adverse side effects were the result of an "unlawful" act, the Petitioners do not contend that the DTP-Hib vaccine contained inadequate warnings of the possibility of side effects. In fact, all parties agree that Carolina Laboratories provided adequate and proper warnings with their product. R. at 2. In effect, even if this Court takes the Petitioner's factual allegation that thimerosal caused their daughter's injuries as true, their admitted awareness of the possibility of side effects and their choice to assume that risk anyway offers an alternative theory. Taken in light of this possible alternative explanation, the complaint's allegations are not propelled past the line of mere conceivability. Therefore, even if the allegation of causation is assumed, the complaint does not allege adequate facts in order to contain more than a sheer possibility that the Respondents acted in such a way that gives the Petitioners a plausible claim to relief.

Additional alternative explanations exist, and all are options that would need not be considered at this stage in the litigation if the Petitioner had undertaken to allege a modicum of

facts that would allow a court to recognize a plausible claim for relief. Facts that may help a court recognize the plausibility of a claim would include factual allegations in relation to the elements of the substantive law. Because the State of Grace has adopted a risk-utility analysis, the Petitioner is required to prove during the trial stage of the litigation a reasonable alternative to the Respondent's use of thimerosal. At that stage, the Respondent would then be required to show that the design, as utilized, was preferable. The Respondent is not required to blindly rebut every conceivable alternative; such an arrangement would cause an unfair and unreasonable shift of burden and run contra to the goal of fundamental fairness in the judicial system.

However, had the Petitioner alleged a reasonable design alternative at the pleading stage, that allegation would be entitled to the assumption of truth for purposes of the motion to dismiss. Resultantly, the court may find it somewhat easier to recognize a plausible claim. However, there is no such allegation in the complaint, and the proper conclusion is that the Petitioners have failed to plead a plausible claim for which they are entitled to relief.

C. The Petitioner's Complaint Is Insufficient Because It Lacks The Requisite Factual Content And Subsequently Denies The Respondent The Ability To File A Proper Response

Federal Rule of Civil Procedure 8 (a)(2) requires "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8 (A)(2). The goal of this rule relates to the requirement that the defendant receive "fair notice of the claim and the grounds on which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957). Therefore, an appropriate object of the Rules' pleading requirements is that the defendant have an opportunity to know what claims are being brought against it and to be able to formulate a proper response. In the case at bar, the allegations in the pleading lack sufficient clarity to permit the defendant to formulate a response that preserves their rights and obligations under the pleading rules.

1. The Complaint In The Present Case Prejudices The Respondent Such That He Is Excluded From Using Issue-Narrowing Specific Denials And Precludes His Use Of Affirmative Defenses In His Responsive Pleading

Rules 8 (b) and 8 (c) govern the defendant's response. FED. R. CIV. P. 8 (B) AND (C). Specifically, these two rules direct the defendant to either admit or deny the allegations contained in the complaint, allege defenses to the claims in the complaint, or to assert any counterclaims. *Id.* Rule 8 (b)(3) conveys the option a defendant has to either *generally* deny the plaintiff's allegations or to *specifically* deny designated allegations. *Id.* (emphasis added). General denials, while permissible under the rule, are customarily disfavored given that one of the purposes of the pleadings is to narrow the issues for debate at trial. Zielinski v. Philadelphia Piers, 139 F. Supp. 408 (1956). If a party doesn't use a general denial, they must "either specifically deny designated allegations or generally deny all except those specifically admitted." FED. R. CIV. P. 8 (B)(3). Further, if a defendant does not deny allegations in the complaint, they are deemed as admissions. FED. R. CIV. P. 8 (B)(6).

Rule 8 (c) works in tandem with Rule 8 (b). It is important to note that, while 8 (c) contains a list of permissive affirmative defenses, it is not an all-inclusive list. In *Ingraham v. United States*, the court reiterated the principle and underlying policy of Rule 8 (c) in holding that affirmative defenses must be contained in the defendant's response to the complaint in order to refrain from prejudicing the plaintiff. 808 F.2d 1075, 1078 (1987). In applying that principle to the facts before them, the *Ingraham* court held that because the affirmative defense in question was not included in the defendant's responsive pleading, the defendant had effectively waived the right to raise it. *Id.* Thus, it becomes important that the defendant raise all possible affirmative defenses in the responsive pleading.

Also important to the analysis of the case at bar is the idea that a defense is an affirmative one if "it raises a new matter that shows, if the asserted facts were true, they wouldn't have their usual legal effect." *Id.* at 1079. As applied to the present case, this objective has serious implications. First, underlying the substantive law regarding a vaccine manufacturer's liability is the concept of an "unavoidably unsafe" design. A vaccine is "unavoidably unsafe" if the foreseeable therapeutic benefits are sufficiently great in relation to the risks of harm posed by the vaccine. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6C (1998). Consequent to the designation of a vaccine as "unavoidably unsafe" is that the manufacturer is insulated from liability. *Id*. Thus, if the vaccine can be declared as such, the dual allegations in the Petitioner's complaint relating to safety and defective design do not have the usual legal effect.

Accordingly, if a defendant knows that the proposed alternative design compels the current design into the category of "unavoidably unsafe," the defendant is required to, in his responsive pleading, assert that as an affirmative defense. FED. R. CIV. P. 8 (C). As discussed in Section I (a)(1) of this brief, the proponent of a design defect claim has the burden of raising and proving that an alternative design existed. *See* RESTATEMENT (SECOND) OF TORTS §402A CMT. K (1965). This risk-utility analysis, coupled with the defendant's right to assert an affirmative defense, does not require exacting details, but it does require some specificity in the plaintiff's complaint. Only if a specific alternative is alleged can the defendant make the assertion that the vaccine is "unavoidably unsafe" in correlation with that alternative. *See generally* Tansy v. Dacomed, 890 P.2d 881, 886 (1994) (holding the "unavoidably unsafe" designation is an affirmative defense where the product is properly manufactured and contains adequate warnings). Moreover, this necessary specificity would allow the defendant to particularly deny one of many possible alternatives the plaintiff is alleging would be safer. This, in turn, would

allow the court to dismiss a potentially meritless case, remove the unjustified consequence of placing on the defendant the undoubtedly heavy burden of compliance with endless demands for pretrial discovery, and preserve the defendant's right to assert an affirmative defense.

As a rule, after the proponent of a design defect claim raises the allegation of a specific design alternative, the burden then shifts to the defendant to prove that the proposed alternative's safety gains do not outweigh the product's usefulness as designed by reducing efficacy. Because the Petitioner's complaint lacks the necessary specificity, the burden is put on the Respondent in the first instance; a result not comprehended by the Federal Rules of Civil Procedure or modern jurisprudence in relation to design defect claims.

A congruous problem created by this lack of specificity in the Petitioner's complaint is related to the demands the substantive law places on the defendant in asserting an affirmative defense under comment k. Comment k provides an affirmative defense for manufacturers of vaccines; not a blanket exception from immunity. RESTATEMENT (SECOND) OF TORTS §402A CMT. K (1965). This provision is very specific in the elements a defendant would need to prove if asserting comment k as an affirmative defense. First, the defense is only available for those drugs or vaccines that are "unavoidably unsafe." Because the value placed on the drug or vaccine is so great, and there are certain side effects that cannot be designed away without losing those benefits, the Restatement gives defendants the opportunity to show that an alleged design alternative is not appropriate. Additionally, this defense applies only where the product is properly manufactured and contains adequate warnings. *Tansy,* 890 P.2d at 886 (1994). Because the Petitioner in the case at bar is not contending that the vaccine administered to their daughter was either deficient in the warnings given nor contained a defect from the manufacturing process, this affirmative defense would, as a rule, be available to the defendant.

2. The Complaint's Lack Of Specificity And Pertinent Information Prejudices The Respondent Such That He Is Unable To Form An Adequate Response

The requirement of some specificity is essential in light of the explanation of Rule 8 (a)(2)'s threshold requirement by this Court in *Twombly* that the "plain statement possess enough heft to show that the pleader is entitled to relief." *Twombly,* 550 U.S. at 545. This forces a complaint to contain more than a "blanket assertion of entitlement to relief." *Id.* at 556.

There are dual goals of this requirement. The first and most obvious is to allow only "plausible" claims to advance past a 12 (b)(6) challenge. *Id.* The second includes notifying the defendant of the grounds on which the claim rests such that defendant has enough information with which to form a response. *Id.* This also accomplishes a primary goal of the judicial system; that of preventing trial by surprise, undue delay, and unnecessary expense in the discovery stage of claims that lack merit. *See Twombly*, 550 U.S. at 546. Additionally, because "the threat of discovery expense will push cost-conscious defendants to settle even the most anemic cases," the fair notice provision of Rule 8 (a)(2) is not met when a plaintiff's complaint lacks the details needed for the defendant to prepare both a response and, quite possibly, the strategy with which they will argue the case moving forward. *Id.*

The Petitioner's complaint in the case before this Court does two things. First, the complaint as written poses serious concerns for the integrity of the pleading process in foreclosing the Respondent's ability to assert an affirmative defense when one is contained and available within the substantive law. Second, it forces the burden to unfairly shift entirely to the Respondent in effectively requiring him to both raise all possible alternative designs, and then to prove that the design they ultimately utilized was the most efficacious and safe.

The Petitioner in this case did not plead, as they are required to do by the substantive law governing this issue, a specific and feasible design alternative. For these reasons, the complaint in this case is altogether insufficient.

II. THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986 PREEMPTS STATE PRODUCT LIABILITY SUITS FOR DESIGN DEFECTS

With the passage of the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), Congress had a twofold purpose: to prevent manufacturers from ceasing vaccine production or significantly increasing prices, while at the same time hoping to compensate victims of vaccine-related injuries quickly. R. at 5. Through the plain language of the Vaccine Act, Congress intended to expressly preempt state tort liability law in specific and enumerated instances. Specifically, one of the instances where state law is preempted by federal law is in design defect claims. When an examination of the plain language of the Vaccine Act is made, the conclusion to be drawn is that § 300aa-22 (b) bars all claims based on the defective design of vaccines. In addition to the expression of Congressional intent through the plain language of the Vaccine Act, the legislative history also conveys Congress's intent to preempt all design defect claims. Additionally, the overall structure of the Vaccine Act indicates that Congress entrusted vaccine regulation and responsibility to qualified federal agencies and not to the juries of the fifty states.

a. Section 300aa-22(b) Of The National Childhood Vaccine Injury Act Of 1986 Is A Federal Express Preemption Of State Tort Liability Law

Through the plain language of the Vaccine Act, Congress stated that state tort liability law was expressly preempted in certain enumerated instances. It must first be determined whether Congress intended, through the statute, to preempt State law.

The Supremacy Clause of the United States Constitution provides many different ways in which a federal enactment may supersede state law. Bruesewitz v. Wyeth Inc., 561 F.3d 233, 238

(3d Cir. 2009). Accordingly, this Court has recognized three categories of preemptions: express preemption, implied conflict preemption, and field preemption. *Id*. at 239.

A federal law expressly preempts state law if its language requires it to do so. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 541 (2001). The first determination a court must make in relation to express preemption is whether Congress's "clear and manifest purpose" is for the Federal Act in question to supplant State law. *Bruesewitz*, 561 F.3d at 239. Express preemption arises when there is an explicit statutory command that state law be displaced. *Id*. at 243. Courts, however, must begin their analysis by applying a presumption against express preemption. *Id.* at 240. When faced with two plausible readings of statutory text, the courts must accept the reading that disfavors preemption. *Id*. The presumption against preemption is overcome when the plain language or legislative history provides clear evidence supporting the express preemption. *Id*.

In *Lorillard Tobacco Co.*, this Court held that the Federal Cigarette Labeling and Advertising Act was an express preemption. 533 U.S. at 542. The statute declared, "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.* at 541. This Court noted through the language, it was clear that Congress explicitly precluded the requirement for any additional information or statements on cigarette packages beyond what was already stated. *Id*. at 542.

In *Bruesewitz*, the court concluded that the Vaccine Act contained express preemption clauses. 561 F.3d at 242. The court noted that the strongest language indicating an express preemption would include phrases akin to, "no state shall" or "state law is preempted." *Id*. The court held that Congress clearly intended through the plain language of §300-22(a) of the Vaccine Act to displace state law in several specific and enumerated instances. *Id*. Moreover, the court said that although the language may not have been used in the traditional sense, the

provision stating, "except as provided by subsections (b), (c), and (e) of this section State law shall apply..." had the same decisive effect as the traditional express preemption phrases. *Id*. at 243.

The same interpretation of the plain language of the Statute applies to the case before this Court today. It is clear from the language that Congress was decisively creating an express preemption to state tort liability law in subsections (b), (c), and (e). Consequently, when enacting the Vaccine Act, Congress provided explicit language conveying an express preemption on state tort liability claims.

b. The Language Of Section 300aa-22(b) Preempts Design Defect Claims

After an examination of the plain language of the relevant provision, the only plausible reading of § 22(b) of the Vaccine Act is that it preempts all claims arising from allegations of design defect. This conclusion is the only interpretation that gives significance and authority to every word Congress used in the whole of § 300aa-22.

The best evidence of Congress's preemptive intent, when viewing an express preemption section, is examining the "plain wording of the clause." Id. at 239 (quoting Sprietsma v. Mercury Marine, 537 U.S. 51, 62-63 (2002)). Courts must "identify the domain expressly preempted by that language," when the text is ambiguous. *Id*. (quoting Medtronic Inc. v Lohr, 518 U.S. 470, 416 (1996)). This Court has said that Congressional purpose is the "ultimate touchstone" when determining the scope of an express preemption clause. *Id*. (citing Lorillard Tobacco Co., 533 U.S. at 541). Additionally, courts may be guided by the overall structure and purpose of a statute and its surrounding regulatory scheme to affect business, consumers, and the law. *Id*. at 243. This Court has affirmed 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."

Id. (quoting Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 51 (1987)). Allowing the court to consider a statute's purpose, structure, and regulatory scheme applies even in the light of the presumption against preemption. *Id*.

As a result of this form of analysis, the court in *Bruesewitz* held that design defect claims were expressly preempted under the Vaccine Act. *Id*. at 251. The court examined each subsection of §300aa-22[6] separately, and then looked at them together as a whole to ascertain the meaning behind § 22(b). *Id*. at 245. The court held that subsection (a) expressly preempts state law to the extent indicated in subsections (b), (c), and (e). Subsections (b) and (c) utilize identical introductory language, stating that "no vaccine manufacturer will be liable in a civil action for damages arising from a vaccine related injury or death associated with the administration of a vaccine...." *Id*. (quoting National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22 (1986)). Further, subsection (e) prohibits states from excluding civil actions that are otherwise "not barred by this part," asserting that other parts of § 300aa-22 are designed to bar some claims entirely. *Id*. The court held that when the three subsections are read together, it is clear that Congress intended subsections (b) and (c) as an outright bar to some design defect claims. *Id*.

Additionally, the court in *Bruesewitz* specifically stated that the term "unavoidable" in § 22(b) could conceivably be read as requiring courts to determine on a case-by-case basis of whether a vaccine design defect was unavoidably unsafe. *Id*. However, the court quickly dismissed this alternative reading after determining that §22(b) was, in the very least, a bar to some design defects. *Id*. at 246. If read in this alternative manner, every design defect claim would be subject to evaluation by a court; thus never barring any design defects. *Id*. This led the court to affirmatively determine that § 22(b) bars all design defects. *Id*.

[6] See Appendix A for § 300aa-22 in its entirety.

The facts of *Bruesewitz* mirror those in the case at bar. Petitioner has brought forth a design defect claim for which Congress expressed an intent that it be processed through the compensation program established by the Vaccine Act. R. at 1. The language of § 22 of the Vaccine Act, when taken as a whole, manifestly conveys that subsection 22(b) prevents design defect claims. Although Petitioner can read a single part of 22(b) in a contrary manner, this Court has held that the statute as a whole must be considered in making the determination in relation to statutory meaning. *Bruesewitz*, 561 F.3d at 243. In other words, courts should not be guided by a singular element when determining the meaning of a statute. *Id*.

Similarly, in *Blackmon*, the court held that the language in § 22 of the Vaccine Act barred all design defect claims. 328 F. Supp. 2d 659, 664 (S.D. Texas 2004). The court concluded that when read against the background of products liability law, the language of § 22(b) shows Congress's intent to foreclose all design defect claims against vaccine manufacturers. *Id*. In reaching their conclusion, the court believed that the drafters were obviously aware of the three different heads of products liability (design defect, manufacturing defect, and inadequate warnings), yet § 22(b) only identifies two: manufacturing defect and inadequate warnings. *Id*. The statute singles out these two claims as variables that determine whether a claimant may sue the manufacturer for a vaccine related injury. *Id*. Ultimately, the court held that if the alleged defect doesn't fall within one of these two enumerated categories, the defect is considered "unavoidable" and the claimant's design defect claim is barred. *Id*.

The facts of *Blackmon* are analogous to those in the current case. When looking at the text of subsection 22(b), it states "no vaccine manufacturer shall be liable ... if the injury or death resulted from side effects that were unavoidable *even though the vaccine was accompanied by proper directions and warnings*." 42 U.S.C. § 300aa-22(b) (emphasis added). This plain

language of the statute makes clear that vaccine manufacturers are immune from any civil liability unless the injuries at issue could have been avoided either by proper preparation of the vaccine or by proper directions and warnings. Petitioner could argue that subsection 22(b) should have included language making clear that vaccine design defect claims were preempted. However, Congress purposefully chose language to bar all claims, not just those labeled "design defect," with the exception of manufacturing and failure to warn claims.

Therefore, after an analysis of the plain language of § 300aa-22, it is clear that Congress intended to bar design defect claims under state tort liability law.

c. The Relevant Legislative History Reflects Congress's Intention To Bar Design Defect Claims From State Tort Liability

The intent of Congress to preempt all design defect claims is found not only in the text of the statute, but also in the rich legislative history that is contemporaneous with the enactment of the Vaccine Act.

When interpreting ambiguous statutory construction, a court must look to the legislative history surrounding the relevant provision. *Bruesewitz,* 561 F.3d at 244. Where the statutory language does not express Congress's intent explicitly, a court habitually refers to the legislative history. *Id*. This Court has said it is appropriate to turn to the legislative history as an additional tool of analysis even if the text of the statute is unambiguous. *Garcia v. U.S.*, 469 U.S. 70, 75 (1984). However, only the most extraordinary showing of contrary intentions from that data would justify a limitation on the "plain meaning" of the statutory language. *Id*. When a court looks to legislative history, the authoritative record of congressional intent is the Committee Report on the provision that subsequently became law. *Id*. at 76.

In *Bruesewitz,* the court held that the legislative history behind the Vaccine Act further strengthened their initial determination that it was Congress's intent to preempt all design defect

claims. 561 F.3d at 251. The court examined the House Committee Report ("the Report") for a more complete assessment of Congress's intent. *Id*. at 248. The Report declared that childhood vaccinations were one of the most important and effective programs in American public health history. H.R. No. 99-908 at 4 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344. The Report also stated that these programs were being threatened by tort claims resulting from individuals injured by vaccines approved by the Food and Drug Administration ("FDA"). *Id*. This was, essentially, leading to increases in the cost of vaccines, the withdrawal of some manufacturers from the market, and a decreased rate of immunization. *Id*. The Report further suggests that there is no perfect vaccine on the market and that a small but significant number of children had serious adverse reactions. *Id*. at 6. It then stated that "despite these possibilities ... it is safer to take the required shots than to risk the health consequences of contracting the diseases...." *Id*. The Committee expressed concern that the "withdrawal of even a single manufacturer" would present a major dilemma for childhood vaccinations. *Id*. at 7. The court noted the Report demonstrates that the Vaccine Act was motivated by Congress's belief that an alternate compensation system would reduce exorbitant awards, create a stable, predictable basis for estimating liability, as well as compensating those injured by the administration of vaccines. *Bruesewitz,* 561 F.3d at 247.

The court then noted that the Report specifically addressed § 300aa-22, the section at issue in the case before this Court today. *Id*. The Report declared that some provisions would "change most State laws" related to vaccine injuries and deaths. *Id*., (quoting H.R. No. 99-908 at 25). Yet, it deemed this an appropriate change in light of the compensation system provided by the Vaccine Act. *Id*.

The court then remarked that the Report stated, in § 22, the Vaccine Act reflected the principle of Restatement (Second) of Torts § 402A comment k. *Id.* at 247. This provision

maintains sellers of certain products, including vaccines, should not be strictly liable for harm caused by their products when it is not possible to make these products entirely safe. *Id.* at 247-48 (citing RESTATEMENT (SECOND) OF TORTS §402A CMT. K. (1965)). Finally, the court determined that the Report stated in precise and certain terms by its reference to "comment k" and the language used in 22(b), the result was immunity for liability in relation to all design defect claims in civil actions, whether liability rests on theories of strict liability or negligence:

> "I[f] [injured individuals] cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper warnings [they] should pursue recompense in the compensation system, not the tort system." Id., (quoting H.R.Rep. No. 99-108 at 26).

See Blackmon, 328 F. Supp. 2d at 665 ("The last passage indicates rather clearly the Committee's intent to relegate design defect claims to the compensation system….")

Again, the facts of *Bruesewitz* are analogous to those in the case at hand. It is obvious that Congress viewed the compensation program as the only tool to address any design defect claims, and this was in recognition of their expressed desire to maintain public health goals. H.R. No. 99-908 at 26. The Report expressed the imperative nature of encouraging vaccine manufacturers to remain in the market and produce vaccines that are cost effective in correlation to important public health goals. *Id*. at 5. This outcome would not be conceivable if vaccine manufacturers are forced to constantly battle design defect claims based on the unavoidably unsafe nature of the vaccines they produce. In fact, the increase in civil litigation relating to design defect claims was the impetus that led to Congress's concern with the status of the immunization system in the first instance. *Id*. Congress expressed concern in the Report that these situations often involve young children whom are badly injured or killed, and who are free from wrongdoing. *Id*. at 26. Consequently, even if the defendant manufacturer may have made as safe a vaccine as possible, a court or jury undoubtedly would find it difficult to rule in favor of

the "innocent" manufacturer if the equally "innocent" child has to bear the risk of the loss. *Id*. A case-by-case analysis of the "unavoidable" issue would have this same effect. Thus, it seems apparent that Congress was concerned that juries would find that the side effects were always avoidable in light of the situation and choices placed before them.

Furthermore, as referenced above, the Report states directly that only when the vaccine is improperly prepared or has improper warnings would the tort system be an appropriate manner in which to seek compensation. *Id*. This statement alone clearly shows that all claims, whether under negligence or strict liability, are barred unless they deal with those two situations. *Id*.

In *Sykes v. Glaxo-Smithkline*, the court held that the legislative history supported a construction of 22(b) that would bar all defective design claims. 484 F. Supp.2d 289, 300 (E.D. Penn. 2007). The court looked at the same language in the Report referenced above in the *Bruesewitz* case. *Id*. Again, the court ruled that the correct application of this language was that unless the vaccine was improperly prepared or contained improper warnings or directions, all other claims should only be brought through the compensation program as provided in the Vaccine Act. *Id*. The court believed that this statement was conclusive in that design defect claims were required to be addressed through the compensation program. *Id*., *See* Militrano v. Lederle Laboratories, 810 N.Y.S. 2d 506, 508 (New York 2006) ("based upon the language in the House Committee Report, the intent of Congress to preclude all design defect claims with respect to vaccines covered by the Vaccine Act is clear")

Because the facts in *Sykes* are analogous to those in the case at bar, the same conclusion is warranted. It is evident that the language in the Report, mentioning only manufacturing and failure to warn defects, expresses that these are the only factors to be addressed in the tort

system. The legislative history further indicates the intent of Congress, that design defect claims are preempted from state tort liability law.

d. The Overall Structure Of The Vaccine Act Reflects That Congress Delegated Vaccine Design Regulation And Responsibility To Expert Governmental Agencies

The structure of the Vaccine Act supports the conclusion that Congress intended § 22 to preempt all design defect claims and contradicts any suggestion that allowing such claims to be evaluated by juries is an appropriate means to promote vaccine safety.

In *Sykes*, the court held that many factors, addressed throughout the whole of the Vaccine Act, preempted all design defect claims. *Id*. at 301. The court noted that Congress had established a comprehensive regulatory scheme, administered by the FDA, to control the design and distribution of prescription drugs, including vaccines. *Id*. The court felt that to permit juries in each state to pass judgment on the design of childhood vaccines could interfere with the federal government's efforts to establish a uniform national standard for childhood vaccines. *Id*. The court noted that the Vaccine Act, in § 27, delegates questions of vaccine safety to the Secretary of Health and Human Services. *Id*.

The Vaccine Act established a National Vaccine Program and set up agencies to maintain and regulate vaccine safety. H.R. No. 99-908 at 6. Section 27 mandates that the Department of Health and Human Services "promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 27, 1987, and promote the refinement of such vaccines." 42 U.S.C. § 300aa-27(a)(1). It further directs the Secretary to:

> "make or assure improvements in ... the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines. *Id*.

The Vaccine Act builds upon existing law under which the FDA strictly regulates the formulation, production, and labeling of childhood vaccines. H.R. No. 99-908 at 8.

Congress intended that the government agencies entrusted with overseeing national health policy should oversee the development of safer vaccines and decide which vaccines should be marketed nationally.

The language of the Vaccine Act can only be read as preempting design defect claims in state tort liability law. When an examination of the plain language of the Vaccine Act is made, the conclusion to be drawn is that § 300aa-22(b) bars all tort claims, unless they involve manufacturing or labeling inadequacies. In addition to the expression of Congressional intent through the plain language of the Vaccine Act, the legislative history explicitly conveys Congress's intent to preempt all design defect claims. Further, the overall structure of the Act indicates that Congress entrusted vaccine regulation and responsibility strictly to the Secretary of Health and Human Services and to the Committees in which the Secretary works in tandem. Finally, Congressional intent to preempt design defect claims has been recognized in all previous § 22 decisions, with one limited exception. Consequently, this Court should find that Petitioner's design defect claims are preempted by the Vaccine Act.

CONCLUSION

For the foregoing reasons, this Court should uphold the decision of the Thirteenth Circuit Court of Appeals when it granted Respondent's motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) and should reverse the appellate court's decision on the question of design defect claim preemption in state product liability suits.

Respectfully submitted,

Team 12R

APPENDIX A

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

(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; warning

(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).

(c) Direct warnings

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, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.