No. 10-1524

IN THE SUPREME COURT OF THE UNITED STATES

DAN COOKS, *et al*.,

Petitioners

-V-

CAROLINA LABORATORIES, INC.

Respondent

ON APPEAL FROM THE UNITED STATES
COURT OF APPEALS THIRTEENTH CIRCUIT

BRIEF FOR THE RESPONDENT

Team #13

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JURISDICTION AND STANDARD OF REVIEW

The Plaintiffs filed their complaint against Carolina Laboratories in the Wicked County Court of Common Pleas. Carolina Laboratories removed the case to the District Court for the District of Grace pursuant 28 U.S.C. §1332 (2006). The United States District Court for the District of Grace entered final judgment dismissing the Plaintiff's claim against Carolina Laboratories with prejudice on March 25, 2008. *Cooks v. Carolina Laboratories, Inc*., No. 08-cv-04132 (D. Grace March 25, 2008). Plaintiffs filed a timely notice of appeal, and the United States Court of Appeals for the Thirteenth Circuit affirmed the district court's dismissal. *Cooks v. Carolina Laboratories, Inc*., No. 09-1032 (13th Cir. Aug. 6, 2009). The jurisdiction of the appellate court rests on 28 U.S.C. §1291 (2006). The Plaintiff filed a timely petition for writ of certiorari. The Supreme Court granted certiorari to examine the preemption issue of state products liability issues and also to examine pleading rules pursuant to Civil Rule of Procedure 12(b)(6).

Federal Rule 12(b)(6) is a question of law, and therefore is subject to de novo review. *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 569 (6th Cir. 2003); *Inge v. Rock Fin. Corp.*, 281 F.3d 613, 625 (6th Cir. 2002). Fed. R. Civ. P. 12(b)(6) permits a court to dismiss a case for "failure to state a claim for which relief can be sought." A judge, when ruling on a 12(b)(6) motion to dismiss, "must accept as true all factual allegations contained in the complaint. "The purpose of Rule 12(b)(6) is to allow a defendant to test whether, as a matter of law, the plaintiff is entitled to relief even if everything alleged in the complaint in true." *Mayer v. Mylod*, 988 F.2d 635, 638 (6th Cir. 1993). The function of a motion to dismiss is to test the adequacy of a

complaint, not to resolve disputed facts or to decide the merits of the case. *Kost v. Kozakiewicz*, 1 F.3d 176, 183 (3d Cir. 1993).

STATEMENT OF ISSUES

1. Under the Supremacy Clause of the United States Constitution may individuals bring state law design defect claims when Congress has passed extensive legislation as an alternative to such claims?

2. Does legislative history give interpreters of a law a chance to understand the intent of the legislature?

3. When there is a complaint void of factual allegations, is that complaint well pled?

4. When there are few facts in a claim, does that mean the claim is plausible?

STATEMENT OF THE CASE

This court is being asked to affirm the United States Court of Appeals for the Thirteenth Circuit's decision granting Carolina Laboratories' motion to dismiss. This motion should be affirmed because the Petitioners failed to state a claim for design defects for which relief can be sought.

This motion arises out of the Cooks alleging that Carolina Laboratories failed to do adequately do tests to determine whether there was a safer alternative to their Diphteria and Tetanus Toxoids and Pertussis ("DTP") – Haemophilus influenza type b ("Hib") combination vaccine. Carolina Laboratories filed a motion to dismiss for two grounds. First, Carolina Laboratories filed a motion to dismiss under Fed. R. 12(b)(6), stating that the Petitioners complaint that Carolina Laboratories failed to conduct safety tests failed to state a claim for relief. Second, Carolina Laboratories are barred by section 22(b) of the Vaccine Act, which bars

design defects claims raised under vaccine related injuries, as long as the vaccine was made in accordance of FDA guidelines. The district court found that the Petitioner's strict liability products liability claim was preempted by the Vaccine Act, and dismissed the Petitioner's claim with prejudice. The Plaintiff appealed the ruling of the district court. The court of appeals affirmed the ruling of the district court, holding that the Petitioner's failed to adequately state a claim for which relief can be sought. The Petitioners filed a petition for writ of certiorari, and the United States Supreme Court granted certiorari.

STATEMENT OF FACTS

Carolina Laboratories is a company that makes vaccines for children. Appellants Dan and LoEtta Cooks, individually and on behalf of their daughter, sued Carolina Laboratories. *Cooks v. Carolina Laboratories, Inc.*, No. 08-cv-04132 (D. Grace March 25, 2008). Appellants claim that the "DTP" and "Hib" combination vaccine that Carolina Laboratories created gave their daughter neurological damage. *Id.* The vaccine, which was used by the Cooks' daughter three times within a two and a half year span, contained thimerosal, which is an organic compound which contains mercury. *Id.* They allege that Carolina Laboratories failed to test the vaccine and determine whether the vaccine was safe and if a safer alternative was present. *Id.*

SUMMARY OF THE ARGUMENT

A vaccine manufacturer's main goal is to create a product that keeps people from contracting harmful diseases. If there were no vaccines, many people would be overcome by

deadly and debilitating ailments. The goal of vaccine manufacturers, such as Carolina Laboratories, is to keep the populace healthy. Unfortunately, vaccines, like all medicine, are not one hundred percent perfect, and can contain some side effects. These small side effects are minor compared to the greater good that the vaccines provide. If vaccine manufacturers had to worry about the possible side effects, society would be harmed, because vaccine manufacturers would be apprehensive about a few people being harmed instead of their goal to help the greater good.

The Petitioners have failed to state a claim for which relief can be sought. Carolina Laboratories filed a 12(b)(6) motion to dismiss, stating that relief cannot be sought since the Petitioners failed to adequately state a claim for which relief can be sought. The purpose of a 12(b)(6) motion to dismiss is to keep plaintiffs from filling the courts with frivolous and unwarranted claims, merely trying to win a settlement.

To withstand a Federal Rule 12(b)(6) motion to dismiss, the Petitioners must provide enough facts, and not just a recitation of the elements showing a cause of action. Also, the Petitioners must plead sufficient facts so the court can draw reasonable inferences, creating a plausible argument. Otherwise, courts would be packed with plaintiffs making allegations without any grounds on which to file suit. If any plaintiff gave ungrounded, bald assertions, void of facts, the justice system would be bogged down with plaintiffs trying to make money, and those who had valid or plausible complaints would not be heard as quickly.

When the Petitioners filed their complaint against Carolina Laboratories, they only gave a bare recital of the elements for a violation of a design defect. The complaint put forth by the Petitioners gave very little insight to why they are entitled to relief from Carolina Laboratories.

Also, the Petitioners never amended their complaint, which could have given the Petitioners a chance to enhance their complaint. Either the Petitioners did not have any other facts to develop their argument, or they did not think it was important to amend the complaint.

Furthermore, the court is unable to draw a reasonable inference from the Petitioners' complaint. The purpose of a well pleaded complaint is to give the court an opportunity to make reasonable deductions based on the facts put forward. The Petitioners have offered very few, if any, facts to show that Miss Cooks was injured by the vaccine created by Carolina Laboratories. Furthermore, to prevail on a design defect claim, the Petitioners had to put forward facts showing that there was a safer alternative for the vaccine and Carolina Laboratories failed to do adequate tests to determine if there was a safer alternative. Although it is possible that Carolina Laboratories failed to adequately conduct tests, which resulted in Miss Cooks harm, the lack of factual allegations do not advance the complaint to plausible. The Petitioners have given no details to support their accusations against Carolina Laboratories, and therefore the complaint should be dismissed pursuant to Federal Rule 12(b)(6).

When there is a federal law and a state law discussing the same issue, the Supremacy Clause allows the Federal Law to preempt the state law claims. The Childhood Vaccine Act was passed by Congress to offer a no-fault compensation system as an alternative to the tort system. In drafting the Childhood Vaccine Act Congress expressly preempted all alternative state law defect claims. The plain language of the statute expressly preempts claims such as the Petitioners' in the present case. The adoption of the principles in the Restatement of Torts only furthers the intent of Congress to preempt all state law defect claims. The language of the

Childhood Vaccine Act provides that there shall be no liability for vaccine manufactures for unavoidable injuries thus expressly preempting *any* state law claim.

Courts routinely examine the legislative history of Congress surrounding the passage of a bill to uncover the intent of Congress. The intent of Congress is clearly expressed in the legislative history in the present case. Congress found childhood vaccines to be of the utmost importance to national health. Congress also found that vaccines were in relative low supply and the loss of a single manufacturer could have significant repercussions for children across the country. With the passage of the Childhood Vaccine Act Congress intended to protect vaccine manufactures from liability so as to ensure an adequate supply of vaccines. Congress clearly intended to avoid a case by case review of vaccine defect claims due to the potential of nearly unlimited liability for manufactures. The legislative history surrounding the Childhood Vaccine Act proves that the only plausible reading of the act is that it preempts all state law claims.

ARGUMENT

I. The Petitioners' complaint should be dismissed because he failed to state a claim upon which relief may be sought.

The Petitioners failed to adequately state a claim for relief, and according the Federal Rules of Civil Procedure, the Petitioner's claim should be dismissed. Pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court may dismiss a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) contests the legal sufficiency of a complaint. *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002). The Supreme Court, in *Conley v. Gibson*, allowed a dismissal of a claim only if "no set of facts" could support the claim. *Conley v. Gibson*, 355 U.S. 41, 45-46, (1957).

However, the pleading rules set forth in *Bell Atlantic v. Twombly*, overruled the holding in *Conley*, and compelled the plaintiff to add more to the complaint. The standards in *Twombly* require a claim for relief under 12(b)(6) to contain "more than labels and conclusions" and do not allow "a formulaic recitation of the elements of a cause of action." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Under *Twombly*, the Supreme Court clarified the standard when addressing a 12(b)(6) motion. *Id.* at 553-62. A plaintiff must state sufficient and specific factual allegations in order "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555; *Gurfein v. Ameritrade, Inc.*, No. 07-3591-cv, 2009 U.S. App. LEXIS 4007, at *1 (2d Cir. Feb. 27, 2009). A 12(b)(6) motion must be looked at in combination with Rule 8(a)(2) of the Federal Rule of Civil Procedure, and that a dismissal should be granted if a plaintiff has failed to plead "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570; *Reliable Consultants, Inc. v. Earle*, 517 F.3d 738, 742 (5th Cir. 2008).

In *Ashcroft v. Iqbal,* the Supreme Court further elaborated the two principles essential in its decision in *Twombly*. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). First, under Rule 8(a)(2), plaintiffs do not need to include "detailed factual allegations" but there needs to be more than "an unadorned, the-defendant-unlawfully-harmed-me accusation is needed." *Id.* at 1949 (quoting *Twombly*, 550 U.S. at 555). Second, the Court stated that " (a) claim has factual plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 1950 (citing *Twombly*, 550 U.S. at 556). Based on those two rules, the Supreme Court established a framework for

considering a motion to dismiss under Rule 12(b)(6). Since the Petitioners' complaint does not provide any facts to support the claim for relief, the complaint should be dismissed.

A. The Petitioners provides no factual allegations in their complaint, and under *Twombly*, the complaint should be dismissed under Rule 12(b)(6).

Since the Petitioners failed to give facts in regards to their complaint, it should be dismissed according to Rule 12(b)(6). The Supreme Court, in *Twombly*, stated that the fact that a court takes all allegations in a complaint as true is irrelevant when determining legal conclusion. *Twombly*, 550 U.S. 555. According to the standards set forth in *Twombly*, a detailed set of facts alleging a harm are not necessary, but "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 129 S. Ct. at 1950 (citing *Twombly*, 550 U.S. 555). "Nor does a complaint suffice if it tenders (a) 'naked assertion' devoid of further factual enhancement." *Id*. at 1949 (quoting *Twombly*, 550 U.S. 557).

In general, courts "may not look beyond the four corners of the plaintiff's pleadings." *Whiddon v. Chase Home Finance*, No. 1:09-CV-460, U.S. Dist. WL3297294, at *2 (E.D. Tex. Oct. 14, 2009) (citing *Indest v. Freeman Decorating, Inc.*, 164 F.3d 258, 261 (5th Cir. 1999)). A court will accept all the factual allegations and assertions in a light most favorable to the non-moving party. *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006). However, courts do not presume the truth of legal conclusions simply because they are cast as factual allegations in the plaintiff's complaint. *Clegg v. Cult Awareness Network,* 18 F.3d 752, 754-55. (9th Cir. 1994). A court "will not accept bald assertions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations." *McCullough v. Zimmer, Inc.*, No. 08cv1123, 2009 U.S. Dist. LEXIS 21815, at *11 (W.D. Penn. March 18, 2009 (citing *In re*

Rockefeller Ctr. Props. Secs. Litig., 311 F.3d 198, 215 (3d Cir. 2002)). "Bare allegations of legal conclusions" are not adequate because they "are not the core facts." *In re Delorian Motor Co.*, 991 F.2d 1236, 1240 (6th Cir. 1993).

The complaint, according to Federal Rule of Civil Procedure 8(a)(2), should include facts and be more than plain conclusions and speeches. The Federal Rules of Civil Procedure require that the plaintiff's complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "The threshold requirement of Rule 8(a)(2) (is) that the 'plain statement' possess enough heft to 'sho(w) that the pleader is entitled to relief." *Twombly*, 550 U.S. at 555. The practical importance of Rule 8 is that "something beyond the mere possibility of loss causation" must be stated so a plaintiff with "a largely groundless claim" does not take up the court's time. *Id.* at 557-58 (citing *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 347 (2005); (quoting *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 741 (1975)).

The Petitioners' complaint only contains a recitation of the elements. The complaint does not contain any facts to develop the assertions made. Therefore, the complaint should be dismissed under Rule 12(b)(6).

In order to withstand a 12(b)(6) motion to dismiss, there needs to be factual allegations. In *McCullough v. Zimmer Inc.*, the plaintiff was an orthopedic manufacturer of various surgical instruments and medical supplies. *McCullough*, at *3. The plaintiff sued the defendant, another manufacturer, for federal anti-kickback statute and the federal False Claims Act. *Id.* at *4. The plaintiff contended that the defendant kept others in the medical instrument industry to compete with the defendant. *Id.* at *5. After the plaintiff filed its complaint, the defendant filed a motion

to dismiss, stating that the plaintiff failed to state a claim for relief. *Id.* at *8-9. The court stated that the plaintiffs had no facts, and the allegations were only "mere conclusions." *Id.* at *29.

The court went on to say that the plaintiffs failed to acknowledge the standards set forth in *Twombly*. *Id.* Since the plaintiffs failed to produce factual allegations in regards to an antitrust claim against the defendants, the court granted the defendant's motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6).

Factual allegations are required to withstand a 12(b)(6) motion to dismiss according to *Twombly*. In *Lutz v. United States*, the plaintiff brought suit against the IRS for violations of Title 26 and Title 44 of the U.S. Code. *Lutz v. U.S.*, No. 06-1177, 2007 WL 1954438, at *1 (D.D.C. July 5, 2007). The government filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). *Id*. The court, applying the standards from *Twombly*, granted the government's motion to dismiss. *Id.* at *4. The court determined that the plaintiff simply recited the elements of the cause of action, and has not asserted any factual allegations in his complaint. *Id.*

The court made a point to show the connection between Federal Rule of Civil Procedure 12(b)(6) and Rule 8(a)(2). *Id.* The court said that there has to be a "showing" of facts, and not a "blanket assertion." *Id.* The court went on to say that since there were no factual allegations in the complaint, "it (was) hard to see how (the) claimant could satisfy the requirement of not only 'fair notice' of the nature of the claim, but also 'grounds' on which the claim rests." *Id.* Since the plaintiff provided no factual allegations in his complaint, the court granted the government's motion to dismiss. *Id.*

Amended complaints have a better chance of withstanding a motion to dismiss for failure to state a claim, if the plaintiff adds facts to the original complaint. In *Van Billiard v. Farrell Distributing Corporation*, an employee sued his employer for violating fiduciary duties required by the Employee Retirement Income Security Act. *Van Billiard v. Farrell Distributing Corp.*, No. 2:09-CV-78, 2009 U.S. Dist. LEXIS 112381, at *1-2; (Dist. Vermont; Dec. 3, 2009). The employee amended his complaint by adding facts to the complaint, and the court denied the defendant's motion to dismiss under Rule 12(b)(6). *Id.* at *2-3. The court declared that the employee's amended complaint "allege(d) sufficient facts," which withstood the motion. *Id.* at *14 Since the plaintiff was able to add sufficient facts in their amended complaint, the court denied the defendant's motion to dismiss on two of the three counts brought up. *Id.* at *19.

The Petitioners offer very little facts to support their products liability claim. Just as in the case of *McCullough*, the Cooks simply stated the elements of a cause of action, and offered no facts to support their accusations. The complaint set forth gives no insight to back up the Petitioners' claims. Even though this Court is supposed to take the facts in the complaint as true, and in a light most favorable to the plaintiffs, there are no facts put forth in the complaint for this Court to take as true. The Petitioners only have conclusions that are not backed up by any evidence. The Petitioners did not support the allegation that the vaccine created by Carolina Laboratories harmed Miss Cooks.

The Petitioners failed to give a "showing of facts" in their complaint, pursuant to Rule 8(a)(2). As was in the case with *Lutz*, the Petitioners simply put forth a "blanket assertion" for a design defect claim. Since Rule 8(a)(2) is looked at when determining a Rule 12(b)(6) motion to dismiss, it should not be taken lightly that complaints must set forth facts in order to withstand a

motion to dismiss. The court in *Lutz*, using the analysis of *Twombly*, found that complaint needed to be more fact inclusive. Since the Petitioner's complaint is as barren of facts as the complaint in *Lutz*, the *Twombly* analysis would deem that the claim of the Petitioners should be dismissed.

Also, the Petitioners did not to provide any data to support their claim of a design defect on Carolina Laboratories' vaccine. The Petitioners did not put forth any facts to show that Carolina Laboratories failed to make sure its vaccine was safe, and that there were no better alternatives available. All the Petitioners did was recite the elements of a vaccine design defect and asked the court for relief based on those bald assertions.

The Petitioners never attempted to amend their complaint, even though they had plenty of occasions to add facts to the complaint. In many cases where a complaint can be dismissed for failure to state a claim, the plaintiff is given "at least on chance to amend the complaint under rule 15(a)" if the plaintiff requests one. *Cruse v. Clear Creek Ind. School Dist.*, No. G-08-095, 2008 U.S. Dist. LEXIS 50114, at *5; (S.D. Tex. July 1, 2008); (citing *Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.,* 313 F.3d 305, 329 (5th Cir. 2002). The Petitioners would have known that Carolina Laboratories filed a motion to dismiss for failure to state a claim for which relief cannot be sought. They would have known that the lack of facts in their complaint would have been an issue. If the Petitioners would have requested a chance to amend their complaint to provide sufficient facts, the court would more than likely of granted the Petitioners at least one opportunity to make amendments, and provide more facts.

Instead of requesting a chance to amend the complaint to support it with more facts, the Petitioners were content to only recite the threadbare elements, void of any facts to support what

they claim. The Petitioners could have taken the time to make changes to their complaint as they obtained information, which was the case in *Van Billiard v. Farrell Distributing Corporation*. Instead, the Petitioners assumed that a recitation of elements would suffice, or they did not have any facts to improve the allegations against Carolina Laboratories.

If bald assertions are the only requirement to withstand a Rule 12(b)(6) motion to dismiss, the courts would be clogged with plaintiffs who wanted to sue others without any facts to back up the allegations. The purpose of requiring a well-pleaded complaint with factual allegations keeps plaintiffs from filing frivolous lawsuits. The reasoning of the Supreme Court's decision in *Twombly* to require factual enhancement in a claim is to disallow people such as the Petitioners from keeping the courts filled with shallow claims which provide no facts that show relief can be sought. Furthermore, the Petitioners made no effort to amend their complaint, even though there was time to do so, which shows that the Petitioners did not have any facts, or did not care enough about their complaint to attempt to improve their claim. Therefore, this Court should uphold the decision to grant Carolina Laboratories' motion to dismiss.

B. The Petitioners' complaint is not facially plausible, because the claim does not plead factual content, and the court is unable to draw an inference that Carolina Laboratories is liable for a design defect claim.

The Petitioners failed to state a claim that is factually plausible, and according to the standards set forth in *Twombly*, the complaint should be dismissed. The Supreme Court stated in *Twombly*, and further affirmed in *Ashcroft v. Iqbal*, that a "claim has factual plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 1937 S.Ct. at 1949 (citing *Twombly*, 550 U.S. at 555). The plausibility standard "asks for more than a sheer possibility that a defendant

has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556). "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility.'" *Id.* at 1949 (quoting *Twombly*,550 U.S. at 557). The complaint set forth by the Petitioners only shows a possibility of harm caused by Carolina Laboratories, and does not cross the threshold into plausibility. Therefore, this Court should dismiss the Petitioners' complaint.

If a complaint does not state a plausible claim for relief, the complaint must be dismissed according to Rule 12(b)(6). In *Bell Atlantic Corporation v. Twombly*, consumers of a telephone and internet provider brought a suit against incumbent local exchange carriers (ILECs). *Twombly*, 550 U.S. at 550. The consumers' complaint stated that the ILECs violated section 1 of the Sherman Antitrust Act by conspiring to restrain trade . *Id*. The ILECs filed a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), stating that the consumers who filed the complaint failed to state a claim to which relief should be granted. *Id.* The Supreme Court granted certiorari and examined the requirements of Rule 12(b)(6). *Id.* at 553. The Court overruled the established precedent set forth in *Conley v. Gibson*, and required more facts to withstand a Rule 12(b)(6) motion to dismiss. *Id.* at 570.

The Court took the time to discuss the need of plausibility in a plaintiff's complaint. The Court said the consumers' complaint of conspiracy "(came) up short." *Id.* at 564. The Court said that "nothing contained in the complaint invests either the action or inaction alleged with a plausible suggestion of conspiracy." *Id.* at 566. Although it was a possibility that the ILECs could have committed a conspiracy, it is just as likely that the ILECs were acting in a perfectly lawful manner. *Id.* at 566-67. The Court thought that the plaintiffs "have not nudged their

claims across the line from conceivable to plausible, (and) their claim must be dismissed." *Id.* at 570.

The plausibility standard is further expanded in *Ashcroft v. Iqbal*. In this case, Iqbal filed a complaint against a number of defendants, including the United States government, the Attorney General, and the director of the Federal Bureau of Investigation. *Ashcroft v. Iqbal*, 129 S.Ct. 1944. The plaintiff's complaint alleged that the defendants willfully and maliciously allowed him to be confined on the basis of his religion and ethnicity. *Id.* at 1944. The defendants mentioned filed a motion to dismiss the complaint, stating the plaintiff failed to show their involvement in Iqbal's treatment. *Id.* The Court applied the standards set forth in *Twombly* and decided that Iqbal's complaint "fail(ed) to state a claim for purposeful and unlawful discrimination against petitioners." *Id.* at 1954. The Court went on to say that even if Iqbal was able to prove that he was arrested because of discrimination, Iqbal had to prove that the government purposely adopted a policy of detaining people of high interest based on race, religion, or national origin.

The Supreme Court, as in *Twombly*, examined the plausibility of Iqbal's complaint. *Id.* at 1951. Iqbal claimed that Ashcroft and the government officials designated Iqbal a person "of high interest" because of race, religion, and national origin. *Id.* The court said that Iqbal's complaint had to "contain facts that plausibly (show) that petitioners purposefully adopted a policy" of discrimination. *Id.* at 1952. Since Iqbal failed to present facts that plausibly showed discrimination, the Court reversed the decision of the court of appeals remanded the complaint to be examined similarly to *Twombly*. *Id.* at 1954.

The Petitioners have failed to state a plausible claim according to *Twombly*. The Petitioners claim that Miss Cooks was injured because she ingested a vaccine that contained ethyl mercury, which was known to have neurotoxic properties. However, the Appellants have failed to offer any evidence to support their theory that Carolina Laboratories did not conduct sufficient tests to determine whether there was a safer substitute to thimerosal. The Petitioners merely offered the elements of a design defect claim, and the lack of facts to support the claim does not make the argument plausible.

The Petitioners offer no plausible evidence to support their claim that Miss Cooks was injured by the vaccine created by Carolina Laboratories. While it is possible that the vaccine created could have caused neurological injuries, the Petitioners failed to "nudge their claims across the line from conceivable to plausible." Just like both *Twombly* and *Iqbal*, the Cooks have not pled enough facts to support what they allege. Although the Cooks would not have all the information needed to support their claim, they need more than allegations and conclusions in order to make their claim plausible.

The Petitioners' complaint has the same problems found in *Iqbal*. The Petitioners, like in Iqbal, do not have to merely show causation, the complaint must allege a pattern of wrongdoing, and both cases failed to do so. The Petitioners claim that there were not adequate tests done to determine there was a substitute. Even if the Petitioners can show that Miss Cooks' injury was caused by thimerosal in the vaccine, which by itself would be not enough to be entitled to relief. The Petitioners must offer at least some evidence to show that Carolina Laboratories did not adequately test its vaccine.

If the Petitioners would have put forth some sort of dependable evidence to support the design defect claim, then their complaint would have some merit. Merely stating that Carolina Laboratories failed to test whether thimerosal was non-hazardous and harmless for humans is not enough to make the complaint plausible. The Petitioner's complaint, just like the complaints in *Twombly* and *Iqbal*, hopes to show a cause of action without any evidence to support the allegations put forth. While all three complaints show a possibility of wrongdoing, the standards in *Twombly* require a higher standard of fact pleading in order for courts to make reasonable inferences.

The Supreme Court's decision in *Twombly* overruled the old standard of pleading in *Conley*. The decisions of *Twombly* and *Iqbal* are proof that the Supreme Court is tired of complaints with no substance, and now wishes that allegations have a foundation. The Petitioner's complaint contains the same type of vacant accusations that the *Twombly* and *Iqbal* decisions wanted to eliminate. Since the Petitioners have failed to state deatails for their design defect claim, they have failed to plausibly state a claim for which relief can be sought, Carolina Laboratories motion to dismiss should be granted.

The Petitioners fail to write a complaint that is enhanced with facts, and has only offered "bald assertions" to support its complaint. Furthermore, the Appellants have failed to "nudge" the complaint from conceivable to plausible. Therefore, the Appellants have failed to state a claim upon which relief can be sought, and as a matter of law, this Court should grant Carolina Laboratories' Rule 12(b)(6) motion to dismiss.

II. The Childhood Vaccine Act Expressly Preempts State Law Products Liability Actions

The Plaintiffs' claims against Carolina Laboratories are preempted by Congress and the enactment of The Childhood Vaccine Act (herein "Vaccine Act"). This court has identified two major instances where preemption occurs. First, where federal law expressly preempts state or local law and second where preemption is implied. *Gade v. National Solid Waste Management,* 505 U.S. 96 Congress can achieve implied preemption one of two ways. First, field preemption and second, conflict preemption. *Id*. In the present case Congress has expressly preempted the Plaintiffs' state law claims. Several courts have found that the Vaccine act modifies state tort law. *See Brice v. Secretary of HHS,* 240 F.3d 1367, 1368-69 (Fed.Cir.2001). The First Circuit specifically noted that Vaccine Act "provide[s] certain federal modifications of state tort law." *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994). The language of the Vaccine Act, specifically Section 22 expressly preempts state law products liability claims as pled by the Plaintiffs.

First, to determine the plain meaning of a law and in turn if there is express preemption, "we begin with the language of the statute. If the language of the statute expresses Congress's intent with sufficient precision, the inquiry ends there." *United States v. Gregg,* 226 F.3d 253, 257 (3d Cir.2000). Then, "Where the statutory language does not express Congress's intent unequivocally, a court traditionally refers to the legislative history." *Id.*

A. The Language of The Childhood Vaccine Act, Specifically Section 22, constitutes express Preemption and therefore bars the Plaintiff's Design Defect Claims

The language of Section 22 of the Vaccine Act expressly preempts Plaintiffs' state law claims. The Appellate Court erred in its holding that State law was not preempted by the Vaccine

Act. This court should find, as did the District Court, that the Vaccine act preempts all state law defect claims.

This court has declared that "[u]nder the supremacy clause … any state law, however clearly within a state's acknowledged power, which interferes with or is contrary to federal law, must yield." *Gade v. National Solid Waste Management Association,* 505 U.S. 88, 108 (1992). This court has held that "[u]nder the Supremacy Clause, federal law may supersede state law in several different ways." *Hillsborough County, Fla., v. Automated Med. Labs., Inc.,* 471 U.S. 707, 713, (1985). It is a well established legal principle that "[o]ver the years, the Supreme Court has recognized three types of preemption: express preemption, implied conflict preemption, and field preemption. *Id.* At issue in this case is the doctrine of express preemption. The doctrine of express preemption is also well established, "[a] federal enactment expressly preempts state law if it contains language so requiring." *Lorillard Tobacco Co. v. Reilly,* 533 U.S. 525, 541, (2001).

Section 22 of the Vaccine Act alters civil actions for vaccine-related injury by stating that "[e]xcept as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a). Section 22(b) states, "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death ... if the injury or death resulted from side effects that were unavoidable." 42 U.S.C. § 300aa-22(b).

In *Bruesewitz v. Wyeth Inc.* the Third Circuit found that the language of Section 22 expressly preempted state law. In *Bruesewitz,* as a child, Hannah Bruesewitz was administered several DPT vaccines to prevent tetanus. *Bruesewitz v. Wyeth Inc,* 561 F.3d 233, 236. (3d Cir. 2009). After her third shot she suffered several seizures. *Id.* As a result of which she would likely

require at least some lifelong medical care. *Id.* The court held that Subsection (b) "declares that manufacturers are immune from liability for claims arising from "unavoidable" injuries and deaths related to vaccine administration, thereby prohibiting states from regulating in this area." *Id.* at 243. The court also found that when reading subsections (b), (c), and (e) together "it becomes clear that Congress intended that subsections (b) and (c) should be an outright bar to some claims." *Id.* at 245.

In *American Home Prods. Corp. v. Ferrari* the Georgia Supreme court reaches the opposite conclusion as the *Bruesewitz* court. *See Am. Home Prods. Corp. v. Ferrari,* 668 S.E.2d 236 (Ga.2008). In *Ferrari,* the plaintiffs brought suit "alleging that their son suffered neurological damage caused by vaccines" that he was given as a child. *Id.* at 237. The court found that if Congress had intended to preempt state law claims it would have omitted the unavoidable clause of Section 22(b). *See Ferrari,* 668 S.E.2d 236, 42 U.S.C. § 300aa-22(b). The *Bruesewitz* court disagrees with *Ferrari, "t*he *Ferrari* Court's construction of § 300aa-22 could create an awkward dichotomy in the case law of these states-their courts would be required to engage in case-by-case analysis" of claims brought under the act. *Bruesewitz,* 561 F.3d 246. Finally, of the *Ferrari* decision, *Bruesewitz* states, "Congress could not have intended such a result, as § 300aa-22 makes clear that Congress intended to preempt and bar certain claims." *Id.*

In the present case, the Petitioner's claim a variety of design defect claims against the Defendant, Carolina Labs Inc. *Cooks v. Carolina Laboratories, Inc*., No. 08-cv-04132 (D. Grace March 25, 2008). This court should find that the language of the Vaccine act expressly preempts state law defect claims. The plain language of Section 22(b)(1) states that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or

death ... if the injury or death resulted from side effects that were unavoidable." 42 U.S.C. § 300aa-22(b)(1). The 'unavoidable' language clearly shows intent of Congress to preempt state all state law claims, including the Petitioner's defect claims in the present case. Assuming that a vaccine is properly prepared and labeled there can be no liability to the manufacturer. Such labeling and any relevant required warnings are strictly regulated by statute. *See* 21 U.S.C.A. § 301 *et seq.* (Federal Food, Drug, and Cosmetic Act).

The remaining text of Section 22(b)(1) goes one to say " [n]o vaccine manufacturer shall be liable in a civil action…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). In the present case the Petitioner's claims are unmistakably preempted by the plain language of Section 22(b). Congress was clear when it stated that there shall be no liability in *any* civil action, including the plaintiff's.

This court should find, as did the *Bruesewitz* court, that the language of the Vaccine Act expressly preempts any state law claims. The *Ferrari* court presents a flawed solution to the issue. As the *Bruesewitz* court noted, if the *Ferrari* holding is followed, "every design defect claim is subject to evaluation by a court." *Bruesewitz,* 561 F.3d 246. This would render the Special Claims Court established by Congress to handle vaccine cases essentially useless. Due to the caps in damages and attorney fees imposed by the Vaccine Act, plaintiffs would have more incentive to bring their claims in Federal or State courts. *See* 42 U.S.C.A. § 300. As the *Bruesewitz* court stated, "Congress could not have intended such a result, as § 300aa-22 makes clear that Congress intended to preempt and bar certain claims." *Bruesewitz,* 561 F.3d 246.

This court should find that Congress expressly preempted state law defect claims as a result of the plain language of the Vaccine Act. Not only does the language and existing case law support this finding, legislative history proves that the only plausible reading of the Vaccine act is that of preemption.

B. The Legislative History Surrounding the Formulation of the Vaccine Act Supports a Finding of Preemption

The legislative history surrounding the enactment of the Vaccine Act clearly shows that Congress intended to preempt state law. Therefore, the Appellate court erred in holding that State law was not preempted by the Vaccine Act. This court should find, as did the District Court, that Congress intended to preempt state law claims with the enactment of the Vaccine Act.

Courts must operate under the assumption that the historic police powers of the States are not to be superseded by a federal Act unless that is the clear and manifest purpose of Congress. U.S Const. art. VI, cl. 2. To determine the existence of preemption, this court has determined that "[t]he question of whether a certain state action of preempted by federal law is one of congressional intent." *Gade*, 505 U.S. at 96. This court has also remarked that, "[c]ongressional purpose if the 'ultimate touchstone' of our inquiry." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 540-541 (2001). This Court has acknowledged that when examining Congressional intent the authoritative record is the Committee Report on the bill that became law. *See Garcia v. United States*, 469 U.S. 70, 76 (1984).

Congress determined that "that the disappearance or unavailability of childhood vaccines would cause far greater harm than the inevitable but limited injuries caused by the vaccines themselves." *Blackmon* 328 F.Supp.2d at 663-666. Specifically congress noted that "The loss of

any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard in this country." H.R. REP. NO. 99-908 at 6348 (1986). In passing the Act into law Congress stated that it "believes that this bill offers another, better, alternative" to the tort system. *Id.* at 6367. The Vaccine Act was passed when, to prevent interference with the supply of vaccines, Congress found it necessary to protect manufacturers from a plethora of current and future lawsuits. *Id*. at 6345-48. Significantly, the reported noted that the Vaccine Act would "change most state laws" pertaining to vaccine injuries but that these changes were appropriate "in light of the availability of a comprehensive and fair compensation system." *Id.* at 6369.

The Committee Report states "This provision sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second)." H.R. REP. NO. 99-908 at 6367 (1986). Specifically that "a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects even through the vaccine was properly prepared and accompanied by proper directions and warnings." *Id.* The Committee concluded that if injured individuals "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." *Id.* at 6370.

The first case to address the issue of preemption and the Vaccine Act was *Militrano v. Lederle Laboratories.* In *Militrano,* similar to this present case, the plaintiffs alleged that the pharmaceutical company could have manufactured a safer drug that would not have harmed their minor child. *Militrano v. Lederle Laboratories, 769* N.Y.S.2d 839, 841 (Sup. Ct. 2003). The trial court found that section 22 preempted all of the plaintiffs' claims and stated that, "Congress

did not intend that national vaccine policy be determined by the vagaries of a jury's determination on a case-by-case basis." *Id.* at 845. The *Militrano* court specifically relied on Comment k of Section 402A in its conclusion that the Vaccine act preempted state law claims, stating that "[c]omment *k* has remained the centerpiece of virtually all prescription drug litigation." *See Militrano v. Lederle Laboratories, 769* N.Y.S.2d 532. The court went on to hold that the "[c]ommittee's discussion of the issue clearly establishes Congress' determination that the Comment k defense bars all [vaccine design defect] claims" *Id.* at 508.

In *Blackmon v. American Home Products* the court also examined the legislative history of the Vaccine Act. The Court found that the majority of children derive a great benefit from the multitude of vaccines available on the market. However, "a small but significant number have been gravely injured." *Blackmon v. Am. Home Prods. Corp.,* 328 F.Supp.2d 659, 663-66 (S.D.Tex.2004). As the number of children injured as a result of vaccines two primary concerns arose: "(1) the inconsistency, expense, delay, and unpredictability of the tort system in compensating claims of vaccine-injured children; and (2) the instability and uncertainty of the childhood vaccine market inevitably caused by the risks of tort litigation." *Id.* The *Blackmon* court concluded that the legislative history "indicates rather clearly the Committee's intent to relegate design defect claims to the [Vaccine Court] compensation system." *Id.* at 665.

Finally, In *Sykes v. Glaxo-SmithKline,* eleven year old Wesley Sykes suffers from neurological injuries that he and his parents claim are caused by several vaccines. *Sykes v. Glaxo-SmithKline* 484 F. Supp. 2d 289, 292 (E.D. Pa. 2007). Wesley and his parents claimed that his injuries were cause from a series of pediatric vaccines he received. *Id.* The court noted that these vaccines had two things in common, "they were manufactured by a defendant in this action

and they contained the preservative thimerosal." *Id.* The court in *Sykes* found that Section 22 bars all design defect claims. *Id.* at 299. Despite the injuries to the plaintiff, the court held that an opposite conclusion would "undermine the congressional mandate by replacing the federal agencies' role with state juries and it would destroy the uniformity Congress intended to establish with the Vaccine Act." *Id.* at 299-303.

In the present case, applying the unambiguous legislative history, it is apparent that Congress intended to preempt state law products liability claims with the passage of the Vaccine Act. This court should find that the legislative history clearly indicates Congress' intent to preempt all state law defect claims. If this court allows Plaintiffs to bring claims in state court it would undermined the purpose of the Vaccine Act and the clear intent of Congress.

Essentially, if this court finds that the Petitioner's claims are not preempted, it would allow a case by case analysis of all vaccine related injuries. Such an analysis would do little to protect the few manufacturers of childhood vaccines. As stated above Congress determines that, "[t]he loss of any of the existing manufacturers of childhood vaccines at this time could create a genuine public health hazard in this country." H.R. REP. NO. 99-908 at 6348 (1986) The *Bruesewitz* court addressed the hazards of a case by case analysis finding that such an analysis would "undoubtedly increase the costs and risks associated with litigation." *Bruesewitz,* 561 F.3d 249. The unpredictability of the tort system, as discussed in *Blackmon* above, would also impose a higher risk and therefore cost on vaccines manufacturers. Increased cost and risk stand plainly in contrast to Congress' clear intent behind the Vaccine Act, to offer a better alternative to the tort system. H.R. REP. NO. 99-908 at 6367.

Comment K of the Restatement of Torts is also significant in this case. As discussed above, by adopting the principles set forth in the restatement, Congress intended that all state law claims be preempted. When addressing the issue the *Bruesewitz* court noted that any other conclusion would "effectively impose an affirmative obligation on vaccine manufacturers to pursue, regardless of cost, the countless avenues through which they could develop a safer vaccine." *Bruesewitz,* 561 F.3d 249. Congress adopted the principles of Comment K to further its incentive to vaccine manufactures to continue manufacturing lifesaving vaccines. This finding is supported by the conclusion of the *Militrano* court when it determined that Comment K barred all state law claims.

The *Bruesewitz* court found additional potential dangers in a case by case analysis. In its discussion of Comment K, the court stated that Comment K required that "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." *Bruesewitz,* 561 F.3d 247-248. This provision of Comment K is important to this courts analysis. The legislative history behind the Vaccine Act presents a hypothetical a case where a child is badly injured or even killed by a vaccine. H.R. REP. NO. 99-908 at 6347. In that case, the manufacturer would be strictly liable despite producing a vaccine that was as safe as possible. *Id.* Comment K remedies this situation and for that reason the principles were adopted by congress in the Vaccine Act. Congress found that in that hypothetical it is unlikely a "court or jury undoubtedly will find it difficult to rule in favor of the 'innocent' manufacturer if the equally 'innocent' child has to bear the risk of loss with no other possibility of recompense." *Id.* at 6347. If this court does not find preemption, Congress' fears will come true and despite manufacture's efforts to produce a safe product, they will be held strictly liable in courts across the country.

In short, essentially all of the purposes behind the passage of the Vaccine Act would be undermined unless this court finds that the Vaccine Act preempts state law claims. Congress created the alternative compensation method to strike a balance between the interests of injured children, vaccine manufacturers and the public as whole. *See* H.R. REP. NO. 99-908 at 6351 (1986). In *Blackmon* the court noted that a small number of people are injured by vaccines but still found that Congress had preempted state law defect claim. *See Blackmon v. Am. Home Prods. Corp.*, 328 F.Supp.2d 659. As the court did in *Blackmon, Bruesewitz* and *Sykes,* this court should find through legislative history that Congress intended to preempt state law claims by enacting the Vaccine Act.

Congress acknowledged that childhood vaccines are "one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. REP. NO. 99-908 at 6345 (1986). But at the same time, the loss of even one vaccine manufacturer would "genuine public health hazard in this country." H.R. REP. NO. 99-908 at 6348 (1986). If this court finds that the Vaccine Act does not preempt state law claims it will open the gates to litigation. A finding of preemption will be consistent with both the express language of the Vaccine Act and the Congressional intent expressed in the passing of the act.

CONCLUSION

The complaints set forth by Petitioners should be dismissed. First, the Petitioners failed to state a claim for which relief can be sought. In their complaint, the Petitioners failed to use facts to enhance their complaint, and only recited the elements for relief. Since there is no well-pleaded complaint, the allegations do not cross the line from possible to plausible, and the Court is unable to make inferences about the complaint.

Second, the Vaccine Act preempts the state law strict liability claim. The literal interpretation of the Vaccine Act expressly preempts the state law claim. Also, the legislative intent of the Vaccine Act shows that the Vaccine Act's purpose is to preempt state law claims, so vaccine manufacturers, such as Carolina Laboratories, can make vaccines to help people without fear of strict liability products liability claims.

For the above reasons, this Court should affirm the ruling of the court of appeals and dismiss the Petitioner's Complaint.