No. 10-1524

IN THE SUPREME COURT OF THE UNITED STATES

April Term, 2010

Dan Cooks, *et. al.*,

Petitioners,

v.

Carolina Laboratories, Inc.,

Respondent.

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

BRIEF FOR THE PETITIONER

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QUESTIONS PRESENTED

I. Does Congress's inclusion of conditional language in subsection (b)(1) of the National Childhood Vaccine Injury Act of 1986 limit the pre-emptive scope of the statute to design defect suits against vaccine manufacturers brought by plaintiffs whose injuries were caused by unavoidable vaccine side-effects?

II. Under the Conley and Twombly pleading standards does the plaintiff state a claim for which they are entitled to relief when they allege a specific test a vaccine manufacturer failed to implement that lead to the improper use of the vaccine?

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IN THE SUPREME COURT OF THE UNITED STATES

No. 05-1701

ALISON HUXLEY,

Petitioner,

v.

STATE OF WYTHE,

Respondent.

ON WRIT OF CERTIOARARI
TO THE SUPREME COURT OF THE UNITED STATES

BRIEF FOR THE RESPONDENT

STATEMENT OF THE CASE

Estella Marie Cooks, the twelve-year old daughter of plaintiffs Dan and LoEtta Cooks, suffers severe injuries caused by the vaccine manufactured by the defendant, Carolina Laboratories. As a baby, Estella received three doses of the defendant's thimerosal vaccine between March 1996 and October 1998. These injections contained approximately 50% mercury by weight.

It is the toxic mercury in the vaccine that caused Estella's injuries. Estella suffers neurological injuries including developmental delays, social delays and deficits, and impaired motor skills. Also attributed to the mercury in the injections are Estella's gastrointestinal illnesses and dysfunction of her immune system.

For the injuries Estella sustained, the Cooks filed a timely petition with the National Vaccine Injury Compensation Program (NVICP) in September 2001. Two years later the Cooks exercised their option to reject the NVICP judgment and pursue legal action in civil court. In March 2007, the Cooks filed a complaint with two claims with the Wicked County Court of Common Pleas. Defendant removed to the United States District Court for the District of Grace. Both parties agree that Grace law applies in this situation if the action is not preempted by federal statute.

Count I in the Cooks' complaint alleges that Carolina Laboratories negligently failed to conduct adequate safety tests to determine if the thimerosal vaccine was safe and nontoxic to humans in the doses administered. Count II asserts strict products liability because the vaccine was defectively designed and a safer alternative existed. The Cooks do not assert any defects with the preparation, manufacturing, and warnings supplied with the vaccine.

The United States District Court for the District of Grace found that the Cooks' complaint was adequately pleaded, but the action against the vaccine manufacturer was preempted by federal statute and dismissed the complaint with prejudice. The Cooks' appealed to gain relief for their daughter.

The United States Court of Appeals for the Thirteenth Circuit disagreed with the lower court's ruling that the federal statute preempted the state civil action. However, the Thirteenth Circuit found that the Cooks did not adequately state their claim and granted the Defendant's

12(b)(6) motion to dismiss. For opposite reasons from the district court, the court of appeals affirmed the lower court's decision.

SUMMARY OF THE ARGUMENT

There exists a presumption against the claim that a federal statute pre-empts state law claims unless, and until, the party arguing in favor of pre-emption can rebut this presumption by demonstrating that it was Congress's clear and manifest purpose for the statute to have such pre-emptive effect. This presumption is even stronger when the focus of the legislation is an area generally subject to state control. Courts will not find for a party arguing in favor of pre-emption unless that party has demonstrated that Congress indeed *intended* to displace or modify state law in an area where the states' police powers have generally regulated.

As the text and linguistic structure of a statue serves as the strongest piece of evidence regarding Congress's pre-emptive intent, the Supreme Court of Georgia correctly held that the Vaccine Act only pre-empts those suits where the court has decided—after engaging in a case-by-case analysis—that the plaintiff suffered injuries as a result of unavoidable vaccine side-effects. American Home Products Corp. v. Ferrari, 668 S.E.2d 236, 237 (Ga. 2008). Even if there are two ways to interpret the statutory text, this Court must abide by its duty to accept the reading that disfavors preemption.

Not only does the plain wording of the Vaccine Act fail to demonstrate that Congress intended to preempt all design defect suits against vaccine manufacturers, the Act's legislative history weighs in favor of limiting its pre-emptive scope to claims where the plaintiff cannot make an argument for a safer alternative vaccine design. The 1986 Commerce Report makes no attempt to distinguish between the remedies that different classes of "vaccine-injured" people

can seek. The Report also makes numerous references to the various frustrations that those plaintiffs claiming that they were injured by a defectively designed vaccine faced in their often-futile civil suits, before recommending that they seek redress in the better alternative to the tort system: the new compensation system. Furthermore, the 1987 Budget Report describes how Congress considered and rejected an amendment that would have accomplished such broad pre-emption, leaving no doubt that Congress did not purport to bar all design defect claims.

Finally, not only is construing the Vaccine Act as having very narrow pre-emptive scope consistent with Congress's reasons for enacting the statute, but holding that the statute has broad pre-emptive effect would actually frustrate congressional intent by encouraging vaccine manufacturer apathy and preventing innocent vaccine-injured plaintiffs from recovering quickly and easily. Therefore, this Court must affirm the holding of the Thirteenth Circuit Court of Appeals that the Vaccine Act does not pre-empt all design defect product liability suits against vaccine manufacturers.

Regarding the Defendant's 12(b)(6) motion to dismiss, the United States Court of Appeals for the Thirteenth Circuit improperly granted the motion by misapplying the pleading standards found in Ashcroft v. Iqbal. 129 S. Ct. 1937 (2009). The Cooks' adequately stated a claim for which relief could be granted by notifying the Defendant of exactly which type of tests it failed to run to determine the safety of their product for young children.

The proper test for the Cooks' action is the well-established standard found in Conley v. Gibson. 355 U.S. 41 (1957). Conley requires that a claim be dismissed only if there are no set of facts upon which relief could be granted. Id. at 45-46. Because the Cooks' identified that the Defendant failed to perform certain tests prior to releasing their product, they correctly stated their claim for relief.

The pleading standard established by the Supreme Court in Iqbal, 129 S. Ct. at 1937, relies on the heightened standard established in Bell Atl. Corp. v. Twombly. 550 U.S. 544 (2007). These cases should not apply to the Cooks' claim because the defendant is not multiple large corporations or a government official, but merely a drug manufacturer. In the alternative, if the Iqbal standard is applied in this case, the Cooks' meet the pleading standard because of the specificity with which they allege the Defendant's tortuous behavior. 129 S. Ct. at 1937. Therefore, the court must reverse the judgment of the lower court and overturn the granting of the motion to dismiss for failure to state a claim.

ARGUMENT

I. Because it was not Congress's "clear and manifest" intent to supersede the power of the states to regulate the vaccine industry, the Vaccine Act does not bar all state product liability suits for design defect.

In this case, a young girl who suffers from neurological injures as a result of receiving a mercury-containing DTP vaccine was wrongly denied her right to seek redress in state court against the manufacturer of the vaccine that caused her injuries. Because the language and context of the Vaccine Act do not show that it was Congress's clear and manifest intent to pre-empt the law in an area traditionally occupied by the states, Respondent has not met his burden of rebutting the heightened presumption against pre-emption. Accordingly, this Court should affirm the holding of the United States Court of Appeal's for the Thirteen Circuit (Thirteenth Circuit) that the Vaccine Act does not pre-empt all civil suits for defective design.

The Supreme Court has identified three types of pre-emption cases: express pre-emption, implied conflict pre-emption, and field pre-emption. Bruesewitz v. Wyeth Labs., 561 F.3d 233, 239-240 (3d. Cir. 2009). Today, this Court faces the task of construing the scope of an express pre-emption clause found in the Vaccine Act. American Home Products Corp. v. Ferrari, 668 S.E.2d 236, 237 (Ga. 2008). When read together, 42 U.S.C. § 300aa-22(a) (subsection (a)) and 42 U.S.C. § 300aa-22(b)(1) (subsection (b)(1)) demonstrate that Congress intended the Vaccine Act to pre-empt state law to some degree. The real question, then, is the scope of that pre-emptive effect.

The Court always begins this analysis by examining the actual text of the preemption clause. Meditronic, Inc. v. Lohr, 518 U.S 470, 485 (1996). Additionally, judicial interpretation of the pre-emptive scope of the language "does not occur in a contextual vacuum. Rather, that interpretation . . . must rest primarily on 'a fair understanding of *congressional purpose*.'" Meditronic, 518 U.S. at 485-86 (quoting Cipollone v. Ligget Group, Inc., 505 U.S. 504, 530 n.27 (1992)). Congressional purpose is gleaned not only from the text of the pre-emption clause, but also from the framework surrounding the statute, including its legislative history, and its "object and policy." United States v. Heirs of Boisdore, 49 U.S. 113, 122 (1849).

Read most naturally, the text of subsections a and b1 demonstrate that Congress intended the scope of pre-emption to extend only to those design defect claims brought by plaintiffs who have suffered injury or death due to *unavoidable* vaccine side effects. The language of subsection (b)(1), including both the actual words used and the overall tone that the arrangement of those words creates, and the surrounding statutory framework show that Congress never intended to infringe upon the ability of the states to regulate vaccines to such a degree that state product liability suits for defective design would be entirely barred. Thus, it was correct for the

Thirteenth Circuit to hold that subsection (b)(1) of the Vaccine Act pre-empts all design defect claims against vaccine manufacturers.

A. Respondent failed to carry its burden of rebutting the "presumption against pre-emption," because the language of the Vaccine Act's pre-emption clauses and the Act's surrounding statutory framework show Congress intended that only those design defect claims based on unavoidable injuries be barred.

The mere existence of an express pre-emption clause in the Vaccine Act does not demonstrate that it was Congress's intent to pre-empt all design defect suits against vaccine manufacturers. Rather, it simply "tells [this Court] that Congress intended to supersede or modify state law to some extent." Riegel v. Medtronic, Inc., 552 U.S. 312, 334 (2008) (Ginsberg, J., dissenting). In determining whether the Vaccine Act pre-empts all civil suits against vaccine manufacturers, this Court has always been guided by the conviction "that Congress does not cavalierly pre-empt state-law causes of action," Meditronic, 518 U.S. at 485. This, in turn, has created a high presumptive hurdle against pre-emption, one that must be cleared by the party arguing for pre-emption. Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 255 (1984).

When a statute legislates in an area of traditional state regulation, the "presumption against pre-emption is *heightened*." Riegel v. Medtronic, Inc., 552 U.S. 312, 334 (2008) (Ginsberg, J., dissenting) (emphasis added). Because a heightened presumption against pre-emption is required, any ambiguities in the congressional intent must be viewed in favor of the party arguing against pre-emption. As Bruesewitz noted, states' police powers encompass immunization of its inhabitants because "[t]hat issues of health and safety have traditionally fallen within the province of state regulation is beyond refute" and "[t]hat safety of vaccines is an

issue of health and safety," Bruesewitz v. Wyeth Labs., 561 F.3d 233, 235, 240 (3d. Cir. 2009). Despite acknowledging that the Vaccine Act encroaches on an area where states traditionally operate, however, the Bruesewitz court failed to apply this heightened presumption against presumption. As such, Bruesewitz does not represent persuasive precedent for this Court.

In this case Respondent has not succeeded in carrying its heightened burden of rebutting the presumption that Congress did not act to preempt all design defect suits in state courts. Not only does the language of subsection (b)(1) show that Congress intended to bar only some—not all—design defect claims, the surrounding statutory framework and the policy behind creating the federal compensation system adds contextual support to the conclusion that the Vaccine Act was never meant to serve as a blanket ban on manufacturer liability for defectively designed vaccines.

1. The language of the statute alone demonstrates that Congress did not intend for the Vaccine Act to bar all design defect claims.

In determining the scope of an express pre-emption clause, "[e]vidence of pre-emptive purpose is sought in the *text and structure* of the statute at issue." CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664, (1993) (emphasis added). Both the actual wording of the Act and the way in which Congress chose to arrange that language demonstrate that Congress's pre-emptive intent was limited in scope to those design defect suits in which the plaintiff's injury or death was an unavoidable side effect of the vaccine.

a. The conditional clause illustrates Congress's intent to preserve some design defect claims by allowing courts to engage in case-by-case analysis of whether side effects were unavoidable.

When determining the pre-emptive effect of a statute, courts "must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993). The plain wording of the Vaccine Act demonstrates a congressional intent to preserve those design defect claims where a plaintiff is arguing that there was a safer alternative vaccine design that would not have caused her injuries. Respondent would have the Court ignore the conditional clause that Congress intentionally included in the statue and instead interpret an "amputated version" of subsection (b)(1) to conclude that Congress intended to bar all design defect suits.

This Court has previously stated that it will not read words out of a statute in order to find for the party arguing for pre-emption. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 448-49 (2005). Indeed, the possibility of an amputated version of the statute actually undermines a finding of clear and manifest pre-emptive intent. The fact "[t]hat Congress added the remainder of the provision is evidence of its intent to draw a distinction between" side effects that are avoidable, for which a plaintiff may bring a civil suit, and those that are not. Id. at 449. As such, not only does the statutory language not support Respondent's contention that it was Congress's clear and manifest intent to bar vaccine manufacturers from liability for all design defect claims, it actually demonstrates that it was Congress's objective *not* to place a blanket ban on such suits.

Furthermore, this construction of the statute does not, as Bruesewitz suggested, conflict with the fact the fact that subsections a and b, when read together, constitute an express pre-emption clause. The Bruesewitz court cited its own circuit when it mistakenly concluded that an express pre-emption provision carries with it "an explicit statutory command that state law be displaced," Bruesewitz v. Wyeth Labs., 561 F.3d 233, 242-43 (3d. Cir. 2009) (quoting St. Thomas-St. John Hotel & Tourism Ass'n, Inc. v. Virgin Islands, 218 F.3d 232, 238 (3d Cir.

2000)). Bruesewitz argued that "the *Ferrari* Court's construction is contrary to the structure of the Act because it does not bar any design defect claims . . . ." Id. at 246.

Bruesewitz is unpersuasive in light of the court's misinterpretation of the actual significance of an express pre-emption clause. In fact, "[a] pre-emption clause tells [the Court] that Congress intended to supersede *or modify* state law *to some extent*." Riegel v. Medtronic, Inc., 552 U.S. 312, 334 (2008) (Ginsberg, J., dissenting) (both emphases added). The emphasized words are significant because they demonstrate that an express pre-emption provision does not need to have the sole effect of displacing state law.

Contrary to what Bruesewitz argued, the Vaccine Act does comport with this pre-emption standard. First, the pre-emption provisions modify state tort law procedurally by requiring every plaintiff to seek redress in the Vaccine Court before availing themselves of state law remedies. Additionally, Bruesewitz's conclusion that a case-by-case analysis of design defect suits does not bar any design defect is incorrect because it relies on the erroneous perception that all jurisdictions apply the same test when addressing design defect claims. Though many jurisdictions, including Grace, have adopted the Restatement (Third) of Torts: Products Liability § 2 "risk-utility" test as the standard for design defect, there still are states that have retained the Restatement (Second) of Torts: Products liability § 402A (§ 402A) "consumer expectations" test as the sole or primary test for design defect. See Green v. Smith & Co., 629 N.W.2d 727, 741 (Wis. 2001) ("Wisconsin strict products liability law applies the consumer-contemplation test and only the consumer contemplation test in all strict products liability cases.").

Under the § 402A consumer expectations test, the issue is whether the product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. § 402A cmt. I (1965). Courts following the consumer expectations test decide whether the

product at issue was defectively designed without considering whether there was a reasonable alternative design. See Sumnicht v. Toyota Motor Sales, U.S.A., Inc., 360 N.W.2d 2 (Wis. 1984) (rejecting the claim that Wisconsin strict products liability law requires proof of a reasonable alternative design). Thus, in a defective vaccine design case, absent pre-emption, states adhering to the consumer expectations test would inquire as to whether the particular side effects suffered by the plaintiff would have been contemplated by the ordinary consumer. Yet subsection (b)(1) requires courts to engage in a case-by-case analysis to determine whether the side effects were unavoidable, meaning that a plaintiff must show that there was a reasonable, safer alternative to the vaccine with which she was administered.

Clearly, then, in those states where product liability law would normally not require a plaintiff to make such a showing, the plaintiff must now do so because of the pre-emptive effect of the Vaccine Act. As such, the assertion that allowing case-by-case assessment of vaccine injury cases will not actually bar any design defect claims upon which the Bruesewitz so strongly based its holding—is flawed; design defect suits based solely on a claim that the vaccine failed to conform to consumer expectations *are barred* by the Vaccine Act.

b. The "positive structure" of subsection (a) shows that Congress intended for the pre-emption provision to have a narrow scope.

In addition to the fact that the conditional statutory language demonstrates congressional intent not to pre-empt all design defect claims, the way in which Congress chose to structure two Vaccine Act subsections further supports the conclusion that Congress intended for the Act to have a narrow pre-emptive effect.

As the Bruesewitz court acknowledged, "[t]he scope of a pre-emption provision

stating that 'no state shall pass laws with the following exceptions' may well be broader than a provision stating 'state law applies with the following exceptions,'" with the latter representing the structure of the Vaccine Act. Bruesewitz v. Wyeth Labs., 561 F.3d 233, 243 (3d. Cir. 2009). The court then went on to state that despite this truth, "the breadth of a provision does not alter the import of the underlying language . . . ." Id. Yet, in finding pre-emption of all design defect claims, the court actually ignores its own observations about statutory language. The court instead deceptively analogizes the language from subsection (b)(1) of the Vaccine Act ("[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death") to language from the statute at issue in Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) ("no [s]tatement relating to smoking and health other than the statement required by *section 1333* of this title, shall be required on any cigarette package"). In so doing, the court attempts—but fails—to divert attention away from what actually shows congressional intent: the fact that subsection (b)(1) contains additional conditional language that that the statute in *Lorillard* did not, which severely limits its pre-emptive scope, and the fact that subsection (a) uses language to explicitly preserve state actions, rather than expressly limit them.

The overall arrangement of the language in the Vaccine Act and creates a positive tone, which bolsters the already-heightened presumption against pre-emption in this case. Such linguistic structure demonstrates that Congress only intended for the Vaccine Act to have a very narrow pre-emptive effect: namely that design defect claims are barred only when the plaintiff suffered side-effects that were unavoidable.

c. Even if there are two plausible alternative readings of subsection (b)(1), the Court has the duty to accept the reading that disfavors pre-emption.

Petitioner does not dispute there are two possible readings of the statutory text at issue. Petitioner does not, however, believe that there are two *plausible* readings of subsection (b)(1). The only plausible reading is that the inclusion of a conditional clause was intentional: Congress meant for courts to undertake a case-by-case inquiry to determine the avoidability of the vaccine's side effects. Even if the Court determines that there a is second plausible reading of subsection (b)(1) that would bar all design defect claims, however, and even if the Court determines that the alternative reading of the statutory text is "just as plausible" as the reading Petitioner advances, the Court "would nevertheless have a *duty* to accept the reading that disfavors pre-emption." Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005) (emphasis added). This duty exists "even in the event of an express pre-emption clause," like the one present in this case. Bruesewitz, 561 F.3d at 240.

The Bruesewitz court based its holding that the Vaccine Act pre-empts all design defect claims against a vaccine manufacturer the fact that "in the face of clear evidence, the presumption against pre-emption can be overcome." Id. Indeed, such a presumption can be overcome through a showing of clear and manifest expression of congressional intent to pre-empt. What cannot be overcome, however, is the Court's obligation to reject the statutory interpretation that favors pre-emption when the *text itself* clearly supports more than one plausible understanding. Even Bruesewitz acknowledged its duty, "[w]hen faced with two equally plausible readings of statutory text . . . 'to accept the reading that disfavors pre-emption.'" Id. Yet, despite stating that "there are two possible interpretations of *subsection (b),*" the court "concluded that a 'clear and manifest expression of congressional intent supports the" reading favoring pre-emption. Bruesewitz, 561 F.3d at 245.

The Bruesewitz court thus mistakenly conflated two divergent principles in reaching the conclusion that the Vaccine Act bars design defect claims. Pre-emption cases necessarily involve parties who are advocating conflicting conclusions regarding the *pre-emptive effect* of a statute. But the issue of beginning a pre-emption analysis with a presumption against pre-emption and looking for evidence of congressional intent to rebut that presumption is distinct from the Court's duty to accept a reading that disfavors pre-emption when there are two different, plausible readings of the *language of a statute*. Thus, while the presumption against pre-emption is a rebuttable one, the supposition that an express pre-emption provision that has two plausible readings does not pre-empt state-law causes of action is irrefutable.

The Court recognized this in Bates, when it overturned the Fifth Circuit, which had found in favor of the party arguing pre-emption, because such a holding was not in line with the Court's duty to accept the meaning of the statutory language "in addition to or different from" in the way that disfavored pre-emption. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005). Because this case also involves two opposing, yet equally plausible readings of subsection (b)(1) of the Vaccine Act, Bates controls. As such, the Bruuesewitz court acted in dereliction of its duty to read the statute in the way that disfavors pre-emption, and this Court must find that the Vaccine Act does not preempt all state claims for design defect.

2. The Vaccine Act's legislative history confirms that Congress did not enact subsection (b)(1) with the purpose of pre-empting all civil suits for design defect.

A deep-rooted principle of pre-emption law is that "[t]he 'purpose of Congress is the ultimate touchstone of pre-emption analysis.'" Wyeth v. Levine, 129 S. Ct. 1187, 1194 (2009)

(quoting Meditronic v. Lohr, 518 U.S. 470, 485 (1996) (internal quotation marks omitted)). Often, congressional purpose is ascertained through statutory text; resort to legislative history to determine the pre-emptive scope of a statute is appropriate "only when necessary to interpret ambiguous statutory text." BedRoc Ltd., v. United States, 541 U.S. 176, 187 n.8 (2004). Where the plain meaning of the statutory text will not support the reading offered by one party, this Court has not allowed that reading to instead come "in through the back door" by invoking legislative history. Id. at 186; doing so presumes "that 'the legislature was ignorant of the meaning of the language it employed." Id. at 186-87 (quoting Montclair v. Ramsdell, 107 U.S. 147, 152 (1883)).

As the previous discussion illustrates, the plain wording of the Vaccine Act's express pre-emption clauses unambiguously shows that Congress never intended for the Act to have the broad pre-emptive effect Respondent advocates. The inclusion of the conditional clause in subsection (b)(1) and the overall narrow pre-emptive effect that subsection (a) creates demonstrate that Congress did not purport to entirely bar design defect claims against vaccine manufacturers.

Even if the word "unavoidable" and the rest of the statutory language does not alone resolve the issue of the Vaccine Act's pre-emptive effect, however, the statutory context surrounding the enactment of the Vaccine Act—namely the 1986 Report from the House Committee on Energy and Commerce (Commerce Report) and the 1987 Report from the House Committee on the Budget (Budget Report)—affirms the lack of congressional intent to pre-empt all products liability suits against vaccine manufacturers for design defect.

a. Comments from the Commerce Report affirm that Congress never purported to bar state design defect claims.

Because the House Committee on Energy and Commerce "had jurisdiction over the Vaccine Act and guided the legislation through passage," Bruesewitz v. Wyeth Labs., 561 F.3d 233, 247 (3d. Cir. 2009), it is an appropriate document to consider to try to understand Congress's clear and manifest purpose in enacting the Vaccine Act. Analyzing—not just reading—the language in the Commerce Report, confirms that the Thirteenth Circuit was correct in holding that subsection (b)(1) pre-empts all state tort claims for defectively designed vaccines.

Most importantly, the Commerce Report does not use language which would demonstrate Congress's intent to treat differently distinct classes of vaccine-injured parties. Rather, the Report makes it clear that "the bill does not prohibit *a vaccine-injured person* who has completed compensation proceedings from going on to court . . . ." H.R. Rep. 99-908, at 12 (1986) (emphasis added). Furthermore, f the compensation program proves unsatisfactory, and "a vaccine-injured person elects to reject the system's findings and award and go on to court, he or she is free to do so." Id. This "perverse distinction" which Respondent seeks to create between different classes of injured plaintiffs "is not required or even suggested by the broad language Congress chose in the [Vaccine Act]" or in the Commerce Report, and this Court should "not turn somersaults to create it." Riegel v. Medtronic, Inc., 552 U.S. 312, 325 (2008).

Additionally, the Commerce Report does not, as Bruesewitz concluded, "state in precise and certain terms that [there should be] immunity in liability for all design defects . . . ." Bruesewitz, 561 F.3d at 248 (3d. Cir. 2009). As the Georgia Supreme Court noted when it held that the Vaccine Act does not bar all design defect claims against vaccine manufacturers, "the committee report does not use language which indicates that use of the compensation system is mandatory." American Home Products Corp. v. Ferrari, 668 S.E.2d 236, 241 (Ga. 2008). The Report easily could have used an obligatory modal verb ("must," "shall," "may not")—as

Congress did several times in the actual text of the Vaccine Act—rather than the permissive modal verb "should." In fact, the Commerce Report twice makes clear that the compensation system in place under the Vaccine Act is meant to provide an *additional* route of recovery for a vaccine-injured plaintiff. The Report first calls the no-fault compensation system a "better[] alternative," H.R. Rep. 99-908, at 24 (1986) and again refers to the system as "an appealing alternative to the tort system." Id. As such, Bruesewitz misinterpreted what the House Committee on Energy and Commerce actually meant when it wrote that injured parties whose claim against a manufacturer is not based on a manufacturing defect or a failure to warn adequately "should pursue recompense in the compensation system, not the tort system."

Rather than serving to demonstrate Congress's intent that design defect claims not be heard in state courts, the use of the word "should" is a reflection of the fact that the Vaccine Act was created specifically because there are instances where "no recovery may be available" for a plaintiff suing based on the theory that a vaccine has been defectively designed. H.R. Rep. 99-908, at 6 (1986). "Yet futures have been destroyed and mounting expenses must be met." Id. The correct interpretation of "should pursue recompense in the compensation system" language, then, is the one the Ferrari court offers: "if a vaccine-injured person does not have a claim for a manufacturing or warning defect, he should find the compensation system appealing even though he is authorized to attempt to prove the existence of a safer design in the tort system." Ferrari, 668 S.E.2d at 241.

Moreover, Congress's adoption of Comment *k* from § 402A in enacting the Vaccine Act does not undermine the assertion that Congress did not intend to bar all design defect claims against vaccine manufacturers. When Congress set forth the principle from Comment *k* "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," H.R. Rep. 99-908, at 26 (1986), it understood this principle in the same way as the majority of state courts. Rather than serve as an automatic bar to design defect claims against drug manufacturers, courts use "a case-by-case approach in which they consider Comment *k* an affirmative defense and apply a risk/utility balancing test in which the availability of other drugs addressing the same problem is considered in determining whether the particular drug at issues is unavoidably unsafe." Militrano v. Lederle Labs., 769 N.Y.S.2d 839, 846 (2003). The language of subsection (b)(1) is consistent with this interpretation because it charges courts to use a case-by-case approach to determine whether a plaintiff may be able to prove that the injuries she suffered were a result side effects that could have been avoided through the use of a safer vaccine.

Furthermore, though the question the Court certified is whether the Vaccine Act pre-empts state product liability suits for design defect, not whether a plaintiff could ultimately succeed on such a claim by demonstrating the existence of a safer alternative vaccine design, this case presents a perfect example of the type of design defect claim Congress did not intend for the Vaccine Act to pre-empt.

One of Petitioner's allegations is that the vaccine with which she was injected was defectively designed and that there existed a safer alternative. From the limited case facts provided in the record it appears that the mercury-containing DTP vaccine Petitioner received was the one commonly referred to as the "whole cell" DTP vaccine. Petitioner was never given the chance to demonstrate the existence of an alternative vaccine that would not have caused her injuries. Still, it is reasonable to assume, based on the dates of her shots (1996-1998), that she planned to argue that the whole cell DTP vaccine with which she was injected was defective because of the existence of a reasonable, safer design: the acellular DTaP vaccine. While in 1986, the year in which when the Commerce Report was written, manufacturers may have been able to assert a Comment *k* state-of-the-art affirmative defense against such a design defect

claim, there is, at the very least, an arguable question of fact regarding the presence of a viable alternative to the whole cell DTP vaccine in the years in which Petitioner was vaccinated. Therefore, under the interpretation the Petitioner advances, Petitioner's claim should ultimately be allowed to proceed in the District of Grace.

b. The Budget Report further supports the assertion that Congress did not intend for the Vaccine Act to bar all design defect claims.

If any doubt remains regarding the congressional purpose behind enacting the Vaccine Act, the Budget Report, which was issued soon after Congress passed legislation to fund the compensation program, makes clear that Congress never purported to insulate vaccine manufacturers from liability for design defect; indeed, the Budget Report actually attempts to clear up any confusion over the effect Congress intended for Vaccine Act to have. The Budget Report says that "[i]t [was] not the Committee's intention to preclude court actions under applicable law," H.R. Rep. 100-391(I), at 691 (1987), and "stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left open to the courts to determine in accordance with applicable law." Id.

Furthermore, the Report stated that the Committee considered—and ultimately rejected—an amendment to the Vaccine Act that would have prevented plaintiffs from using a manufacturer's failure to use a safer vaccine as grounds for liability. Even the Bruesewitz court acknowledges "that '[f]ew principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language.'" Bruesewitz v. Wyeth Labs., 561 F.3d 233, 249-

250 (3d. Cir. 2009) (quoting INS v. Cardoza-Fonseca, 480 U.S. 421, 442-443 (1987) (internal quotation marks and citation omitted)). Yet the Bruesewitz court believed it had "no basis to conclude that the Budget Report [was] an accurate reflection of what transpired before the Energy and Commerce committee, or . . . the motivations underlying Congress's enactment of the Vaccine Act." Bruesewitz, 561 F.3d at 250. This conclusion is weak for two reasons.

First, there is some disagreement on whether the same Committee actually produced both the 1986 and 1987 Reports. Compare American Home Products, Corp. v Ferrari, 668 S.E.2d 236, 241 (Ga. 2008) (stating that the 1987 committee report was issued "by the same committee which originally considered the Vaccine Act and which produced the 1986 report") with Bruesewitz, 561 F.2d at 251 ("[T]he subsequent report was not issued by the committee with jurisdiction over the legislation, but by a committee which played no role in passage of the Vaccine Act."). As such, the worry that "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one," Bruesewitz, 561 F. 2d at 250 (quoting United States v. Price, 361 U.S. 304, 313 (1960)), may be moot in this case. Second, as previously stated, it is the act of rejecting an amendment that alone imports the *objective conclusion* that Congress did not want such language in the statute. With regards to the Vaccine Act amendment, then, the important takeaway is that Congress considered and rejected the amendment, not whether the Budget Committee, and not the Commerce Committee, actually reported that fact.

Most importantly, regardless of whether the 1987 committee report serves to clarify the conditional language in the Vaccine Act that Respondent claims is ambiguous, it "certainly constitutes a prophylactic against adopting a tortured reading of an otherwise plain statute." Grapevine Imports v. United States, 71 Fed. Cl. 324, 355 (2006). Hence, the 1987 Budget Report lends credence the conclusion that this Court should construing the Vaccine Act as only pre-empting some design defect claims.

B. Finding that the Vaccine Act does not pre-empt state product liability suits for design defect is consistent with the various policy rationales underlying Congress's decision to create the Vaccine Act.

In addition to examining the structure and plain wording of the statutory text and the purpose as shown through the legislative history, courts also look to the policy behind the creation of the statute. Kelly v. Robinson, 479 U.S. 36, 43 (1986). By holding that the Vaccine Act bars only those design defect claims in which the plaintiff suffered side-effects that were unavoidable, this Court does not frustrate Congress's purpose in enacting the Vaccine Act. Rather, such a finding is consistent with the policy "factors that served as 'the catalyst for the passage' of the statute." Bruesewitz v. Wyeth Labs., 561 F.3d 233, 244 (3d. Cir. 2009) (quoting Cipollone v. Ligget Group, Inc., 505 U.S. 504, 519 (1992)).

1. Congress's two overriding purposes behind establishing the "no fault" compensation system under the Vaccine Act continue to be served by allowing courts to engage in a case-by-case analysis for design defect claims.

The Commerce Report shows that, in enacting the Vaccine Act, Congress was motivated principally by a desire to provide a better remedial system for both vaccine injured plaintiffs and for vaccine manufacturers, not by an intent to deprive injured parties of their ability to seek redress in the tort system. Congress acknowledged that the dichotomy of seeking redress either in the civil tort system or through a settlement arrangement with the vaccine manufacturer had proven unsatisfactory for both the injured plaintiffs and the vaccine manufacturers. Through the

Vaccine Act, Congress sought to "establish a Federal 'no-fault' compensation program under which awards [could] be made to vaccine-injured persons quickly, easily, and with certainty and generosity," and which would give "manufacturers . . . a better sense of their potential litigation obligations, [creating] a more stable childhood vaccine market . . . ." H.R. Rep. No. 99-908, at 3 (1986).

Contrary to what Bruesewitz concluded, both of these goals are accomplished by the sole fact that a party seeking redress based on a vaccine-related injury or death is first required to go through the compensation program. Construing the statue in the way that allows state courts to consider on a case-by-case basis claims of defective vaccine design will not, as the Bruesewitz court argues, "undoubtedly increase the costs and risks associated with litigation" or "undermine a manufacturer's efforts to estimate and control costs." Bruesewitz v. Wyeth Labs., 561 F.3d 233, 249 (3d. Cir. 2009). The Bruesewitz court failed to keep in mind that one of the principal motivating factors behind the creation of the Vaccine Act was the fact that "opportunities for redress and restitution [for vaccine-injured plaintiffs were] limited, time-consuming, expensive, and often unanswered." H.R. Rep. No. 99-908, at 6 (1986). For these reasons, even though they have the right to do so, the large majority of vaccine-injured plaintiffs will not even contemplate rejecting a Vaccine Court award in order to pursue difficult and uncertain recovery in the tort system. Indeed, even the Committee who wrote the Commerce Report "anticipated that the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards will *divert a significant number of potential plaintiffs from litigation*." Id. at 13 (emphasis added).

As such, Bruesewitz's belief that "each of the objectives extolled by the Commerce Report would be undermined if design defect claims were permitted under the statute" is without support. Therefore, the court's reliance on that belief to reach the conclusion that Congress could

not have intended for subsection (b)(1) to preserve some design defect claims is misguided, and this Court should not find Bruesewitz persuasive.

2. Granting complete tort immunity from design defects to the entire vaccine industry may have the perverse effect of preventing the creation of safer vaccines and of frustrating Congress's goal to ensure that vaccine-injured plaintiffs are compensated quickly and generously.

The Bruesewitz court stated that Congress intended for the Vaccine Act to "provide an umbrella under which manufacturers *would* improve the safety of their products while remaining immune from design defect claim." Bruesewitz v. Wyeth, Inc., 508 F. Supp. 2d 430, 445 (E.D. Pa. 2007) (emphasis added). This assertion cannot be true. What Congress did want, was for "more emphasis [to] be placed on the research and production of other vaccines." H.R. Rep. 99-908, 7 (1986). Yet providing manufacturers with the complete protection that the Bruesewitz court advocated will instead lead to vaccine manufacturer apathy: because manufacturers are aware that they will never be subject to liability for design defect, and thus, never have to defend against a claim that there is a reasonable alternative vaccine design, they have no incentive to conduct research and create a safer product.

Additionally, if design defect claims can never proceed in court, plaintiffs will not have the opportunity to flesh out and present their claims of reasonable alternative vaccine designs. As such, allowing vaccine manufacturers to enjoy complete immunity for defectively designed products will create a self-perpetuating cycle of lethargy on the part of vaccine manufacturers, ultimately draining valuable resources from the compensation system as the same vaccines continue to injure—even kill—innocent victims.

Furthermore, a finding that the Vaccine Act bars all design defect claims has the potential to substantially undercut Congress's goal to ensure that vaccine-injured people recover "quickly, easily, and with certainty and generosity," H.R. Rep. 99-908, at 3. The structure of the compensation program means certain plaintiffs—subject to the vagaries of the Vaccine Court—will be denied recovery. If a plaintiff has suffered injuries not listed in the Vaccine Injury Table, and has failed to establish the vaccine was the "cause in fact" of her injury, she is unable to recover. See Andreu v. Sec'y of Health and Human Services, 568 F.3d 1367, 1374 (Fed. Cir. 2009) ("The Vaccine Act provides two separate mechanisms to obtain benefits: table claims and causation in fact claims."). The plaintiff may indeed have been injured by the vaccine, yet, under Respondent's reading of the Vaccine Act, the plaintiff will have been entirely foreclosed from recovering for the injuries she has suffered.

This contradicts the principle that "[t]he presumption against preemption is even stronger against preemption of state remedies, like tort recoveries, when no federal remedy exists." Abbot v. American Cyanamid Co., 844 F.2d 1108, 1112 (4th. Cir. 1988) Even though the plaintiff may appeal the decision to the United States Court of Appeals for the Federal Circuit, some claims that truly merit recovery under the Vaccine Act will nonetheless be denied. The tort system, then, must serve as a safety net to catch those innocent, vaccine-injured plaintiffs the Vaccine Court lets slip through the cracks of the compensation system. Therefore, this Court should affirm the holding of the Thirteenth Circuit Court of Appeals that the National Childhood Vaccine Injury Act does not pre-empt state product liability suits for design defect.

II. The Cooks adequately stated a claim for which relief could be granted by informing the Defendant exactly what type of test it failed to use to ensure the safety of their vaccine.

The Cooks stated a claim that could entitle them to relief against the Defendant vaccine manufacturer. Under FRCP 8(a), the Cooks need a short and plain statement that shows their entitlement to relief. Fed. R. Civ. P. 8(a). The purpose of such a rule is to put the defendant on notice for what unlawful actions the plaintiff refers to and the damages expected. The Cooks stated that the Defendant failed to conduct adequate safety tests on humans to determine if their vaccine, that included known neurotoxins, was safe for pregnant women, infants, and small children. The Cooks' high level of specificity in their claim against the Defendant clearly meets the standard required of Rule 8(a) by alerting Defendant of exactly what unlawful action occurred.

A. The long-used Conley "no set of facts" standard should apply to the Cooks' claim because the policy concerns found in Twombly and Iqbal do not apply to the Defendant.

The Cooks claim meets the standard for pleadings under Conley v. Gibson. 355 U.S. at 41. The Supreme Court has long adhered to the "no set of facts" standard for pleading found in Conley that allows dismissal of claims only if there exists no set of facts to support the plaintiff's claim. Id. at 45. This standard is met by the Cooks because they allege the Defendant failed to test their product on young children to determine if it was the safest alternative for preventative treatment. The lack of a certain test that would have illuminated problems with the Defendant's product before entering the market is clearly a set of facts that can give rise to a claim against the Defendant.

While the Conley standard no longer applies in all civil actions, the core purpose of the test makes it a viable standard. Id. The intent behind a claim is to give the defendant notice

about the alleged violation. The Conley standard provides the defendant notice and keeps out frivolous law suits by making sure that there is a set of facts to support an cause of action again the defendant. Id. The Cooks' assertion that the Defendant failed to test their product adequately on their intended audience gives the Defendant notice and alleges a clear set of facts under which the Defendant could be found liable.

1. The heightened pleading standard in Twombly is applicable only to anti-trust suits that would involve multiple defendants, not the Cook's case against a single defendant.

The heightened pleading standard that Twombly established should not apply to the single defendant against whom the Cooks bring suit. 550 U.S. at 544. Twombly sued Bell Atlantic Corporation alleging that the parallel conduct it had shown with the other phone companies established facts to support an anti-trust violation. Id. at 551. The mere allegation that parallel conduct existed is not enough to prove an anti-trust violation. These facts might be obtained in discovery, but the court did not allow such a process to begin without a more plausible claim stated by the plaintiff. By the mere allegation of anti-trust, discovery in this case would have included most all of the phone companies in the country. This heightened pleading standard was limited to anti-trust cases, in the majority opinion written by Souter, because of the high cost impact a lower standard would have on so many large defendants for a single suit. Id. at 558. In the instant case, there is only one defendant and specific allegations of a failure by the Defendant to conduct specific tests. Therefore, the heightened pleading standard should not apply.

The Cooks' claim is also distinguishable from the rejected Twombly claim because the specific actor and action is alleged. Twombly did not assert who the tortuous actor was or when the action occurred. 550 U.S. at 564 n.10. This lack of information in the plaintiff's complaint contributed to the court's finding that they failed to state a claim. In the Cooks' case they specifically identify the Defendant as the tortuous actor and identify the time as being before the product was put to market and when it was in the testing phase. This increased specificity in the Cooks' claim distinguishes it from the Twombly case and supports a different outcome – the denial of the Defendant's motion to dismiss.

2. The extension of the Twombly pleading standard in Iqbal should be limited to government officials, not private corporations.

While Iqbal extended the heightened pleading standard beyond anti-trust actions, the special circumstances in Iqbal involving national security distinguish it from the Cooks' claim against the Defendant. 129 S. Ct. at 1950-51. Iqbal involved a suit against several high ranking national security officials within the United States government who could claim immunity from the suit at any time during the proceedings. Id. at 1942-44. Against such high ranking officials as these, the court saw fit to require that the claim be plausible. Id. at 1949. The instant case brought by the Cooks is not against high ranking government officials, nor over a matter of national security. Instead, the Cooks are seeking relief from a private corporation that does business in our country. Therefore, the extension of the heightened pleading standards should not apply.

B. The Cooks stated a plausible claim to relief that also meets the pleading standard of Iqbal.

While Iqbal's standard for pleadings is high, the Cooks complaint meets the specificity requirements within it. Iqbal stands for the dismissal of claims that only state that the "defendant-unlawfully-harmed-me" and lack any substantive facts. Id. at 1949. It does not, however, stand for the fact that all pleadings have to have factual allegations described in detail. Id. A plaintiff must plead more than simply conclusions of law under the Iqbal standard. Id. at 1950. While the Cooks do not have the exact details on the tests the Defendant failed to perform, they do have factual information that the Defendant did fail to perform adequate tests on the product before introducing it to the market. This raises such claims above the purely speculative level and creates a plausible cause that the Defendant acted negligently an violated Grace state law.

CONCLUSION

By requesting that this Court find that the Vaccine Act bars all design defect claims against vaccine manufacturers, Respondent asks this Court to expand the pre-emptive scope of the Act far beyond what Congress intended. The plain wording and structure of the Vaccine Act, the Act's statutory framework as evidenced by legislative history, and the object and policy of the Act, evince that Congress purported for courts to engage in case-by-case analysis to determine which design defect claims are pre-empted. As such, not only is Respondent unable to carry its burden of showing clear and manifest congressional intent to pre-empt all state product

liability suits for design defect, the evidence actually demonstrates that Congress intended *not* to bar plaintiffs alleging defective vaccine design from seeking redress in the tort system.

Petitioner has also given notice to the Respondent about the specific tests it failed to run on the vaccine. The specificity of the claim made by Petitioner rises above the purely speculative and is not a legal conclusion couched in an accusation. Because of the substantial differences in the instant case and those within Iqbal, the Iqbal heightened standard should not apply. Therefore, the Petitioner asks that this Court limit the scope of the Iqbal case to high ranking United States Government officials. In the alternative, the Petitioner requests that this Court find the Petitioners claims adequately stated with specificity under the Iqbal standard.

For the foregoing reasons, Petitioner respectfully requests that the Court affirm the Thirteenth Circuit's holding "that subsection (b)(1) clearly does not pre-empt all design defect claims against vaccine manufacturers, but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the particular vaccine was unavoidable safe." Dan Cooks v. Carolina Laboratories, Inc., No. 09-1032 (13th Cir. Aug. 9, 2009). Petitioner further requests that this Court overturn the Thirteenth Circuit's judgment dismissing Petitioner's claim.

Respectfully submitted,

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Brian Cannon
Counsel for the Respondent

March 12, 2010

CERTIFICATE OF SERVICE

This document certifies that six copies of the foregoing brief were mailed, and one copy emailed, to the Rendigs National Products Liability Moot Court Tournament on this twelfth day of March 2010.

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