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 FROM THE
UNITED STATES COURT OF APPEALS
FOR THE THIRTEENTH CIRCUIT

BRIEF OF PETITIONERS

Submitted by Team #5

QUESTIONS PRESENTED

I. Under the National Childhood Vaccine Act of 1986, does a child suffering from injuries alleged to be the result of an avoidable design defect have a state law cause of action against a vaccine manufacturer when the Act bars only claims arising from unavoidable side effects?

II. Under Grace state law, did the petitioner satisfy the *Twombly* pleading standard for a design defect claim by alleging that respondent knew its vaccine contained a dangerous substance yet failed to conduct adequate testing, that a safer alternative existed, and that petitioner suffered injuries consistent with those associated with the dangerous substance?

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STATEMENT OF THE CASE

Twelve-year old Estella Marie Cook suffers from numerous neurological disabilities, including, developmental delays, learning disabilities, and impaired motor skills. *Cooks v. Carolina Labs.*, No. 08-cv-04132, slip op. at 1 (D.C. Grace Mar. 25, 2008). Her parents believe that these injuries were caused by three vaccinations that Estella received between March 1996 and October 1998. *Id.* The vaccines were produced by Carolina Laboratories and contained thimerosal, which is 50% mercury by weight. *Id.* Estella's parents believe the thimerosal caused her disabilities. *Id.*

On September 3, 2001, the Cooks filed a timely petition with the National Vaccine Injury Compensation Program ("NVICP") pursuant to federal law. *Id.* at 1-2. On November 5, 2003, the Cooks filed a notice of withdrawal with the NVICP. *Id.* at 2. The Cooks filed an election to file a civil action on January 21, 2004. *Id.*

On March 14, 2007, the Cooks filed a Complaint in the District Court of Grace against Carolina Laboratories, alleging negligence for failing to conduct adequate safety tests on the vaccines and strict liability for design defect. *Id.* Defendant moved to dismiss, arguing that the Cooks' claims were preempted by the National Childhood Vaccine Act of 1986 ("Vaccine Act") and that the Cooks failed to allege sufficient facts to state a claim for relief under Grace law. *Id.* at 2-3.

The District Court of Grace found that the Cooks had adequately pled a cause of action for design defect under Grace law. *Id.* at 3-4. However, the court concluded that the Vaccine Act preempted state law claims for defective design against vaccine manufacturers, and granted Defendant's motion to dismiss. *Id.* at 7. The Court of Appeals for the Thirteenth Circuit affirmed, albeit for different reasons. *Cooks v. Carolina Labs.*, No. 09-1032, slip op. at 13 (13th Cir. August 6, 2009). The appellate court concluded that while the Cooks' claim was not barred

by the Vaccine Act, they failed to plead sufficient facts to satisfy the standard set out in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). *Id.* at 11-13. Subsequently, the Cooks filed and were granted a writ of certiorari to the Supreme Court of the United States. *Cooks v. Carolina Labs.*, No. 09-1032 (13th Cir. 2009), *cert. granted*, (U.S. Apr. 9, 2010) (No. 10-1524).

SUMMARY OF THE ARGUMENT

In resolving the first issue, this Court should adhere to its well-settled presumption against preemption and affirm the judgment of the Court of Appeals. Lacking a clear and manifest intent to preempt all design defect claims, the Vaccine Act only bars claims against manufacturers where the vaccine was properly prepared and still carried unavoidable side effects. Moreover, the statute's plain language demonstrates the necessity of a case-by-case determination of design defect claims. To hold otherwise would require a reader to cast aside whole phrases and ignore sentence construction.

While the text of the Vaccine Act itself is not ambiguous, the legislative history nonetheless affirms Congress' intent to allow some plaintiffs asserting defective design claims to seek recourse in the tort system. Like the plain language, the precursor to the Act contains purposefully limited language which leaves open the possibility of case-by-case determinations. Additionally, a report from the committee responsible for passing the Act and a subsequent report effectuating the compensation system both support the conclusion that Congress intended for civil courts to retain some role in deciding whether particular vaccines were "unavoidably unsafe."

Evident in the text and legislative history, the policy underlying the Vaccine Act indicates that Congress never intended to provide manufacturers with blanket immunity from design

defect claims. Instead, Congress realized that potential litigation can serve to encourage manufacturers to design the safest possible vaccines.

This court should also find that Plaintiffs have sufficiently pled their cause of action to survive Defendant's motion to dismiss. Plaintiffs' Complaint is clearly satisfactory under the current pleading standard to state a products liability claim. Plaintiffs have made specific factual allegations corresponding to each factor considered under Grace's risk-utility analysis, which is used to determine if a product suffered from a design defect. Recent case law also supports the conclusion that Plaintiffs have met their burden.

Requiring more from Plaintiffs at this stage in the proceedings would impose an improper pleading standard by compeling Plaintiffs to produce evidence prior to discovery. In addition, dismissing the Complaint would not only discourage vaccine manufacturers from conducting adequate product testing, but would also bar from recovery similarly situated plaintiffs who have been injured by a defective vaccine.

ARGUMENT

I. THE NATIONAL CHILDHOOD VACCINE ACT OF 1986 PREEMPTS ONLY THOSE STATE LAW DESIGN DEFECT CLAIMS THAT ARE DETERMINED ON A CASE-BY-CASE BASIS TO BE UNAVOIDABLE.

The question of whether a particular federal statute preempts matters of state law raises issues of federalism that are as old as our Constitution. "It is a familiar and well-established principle that the Supremacy Clause (citation omitted) invalidates state laws that 'interfere with, or are contrary to,' federal law." *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (quoting *Gibbons v. Ogden*, 9 Wheat. 1, 211 (1824)). However, "it is equally clear that the Supremacy Clause does not give unelected federal judges *carte blanche* to

use federal law as a means of imposing their own ideas of tort reform on the States." *Geier v. Am. Honda Motor Corp.*, 529 U.S. 861, 894 (2000). Out of respect for state sovereignty, courts are therefore instructed to presume "that state laws—particularly those, such as the provision of tort remedies to compensate for personal injuries, that are within the scope of the States' historic police powers—are not to be pre-empted . . . unless it is the clear and manifest purpose of Congress to do so." *Id*; *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996) (noting that "Congress does not cavalierly pre-empt state-law causes of action").

This Court has also provided specific guidance for addressing preemption issues. As a starting point, "'[t]he purpose of Congress is the ultimate touchstone' in every preemption case." *Lohr*, 518 U.S. at 485 (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). This purpose is best determined by looking to the text of the preemption statute and then to the "'statutory framework' surrounding it." *Lohr*, 518 U.S. at 486 (quoting *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in judgment). However, if the statutory text is ambiguous with regard to Congressional intent, it is then appropriate to look to legislative history. *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 187 n.8 (2004).

The statute currently in question, the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 *et seq.* ("Vaccine Act" or "Act"), contains a preemption clause, the scope of which is sharply disputed. The relevant portion of this Act begins with the general rule that, unless otherwise provided, "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-22(a) (2006). The next section provides most of the circumstances under which a State law claim *will* be preempted. Under this section, vaccine manufacturers cannot be held liable in tort for injuries that "resulted from side effects that were unavoidable even though the vaccine

was properly prepared and was accompanied by proper directions and warnings." § 300aa-22(b)(1). Additionally, a manufacturer can create a presumption that it has included "proper directions and warnings" by complying with various federal labeling regulations. § 300aa-22(b)(2).

While vaccines are beneficial for society as a whole, the Vaccine Act was passed in response to injuries to children like Estella Marie Cooks, who suffer catastrophic harm after receiving their childhood immunizations. *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 559, 663 (S.D. Tex. 2004). Under the Act's compensation system, a victim suffering from vaccine-related injuries is not required to prove fault or causation. *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 2 (1st Cir. 1994). In exchange for these relaxed standards of traditional liability, a victim who accepts compensation under the Act surrenders her right to sue in tort and agrees to a predetermined cap on damages. *Id.* at 3. However, if the victim so chooses, she may "opt out" of the system and retain her right to sue under state law. *Id.* Rather than serving as a complete substitute for state law, the Act represents "an appealing alternative to the tort system" for those victims who are either unwilling or unable to pursue their claims in court. H.R. REP. NO. 99-908, at 26 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6367.

Despite this Court's strong presumption against preemption and the Vaccine Act's role as a mere alternative to the tort system, the Defendant insists that this Act preempts all design defect claims. Under a plain reading of the statute, only "unavoidable" injuries are preempted, making the Defendant's position unacceptable. Furthermore, the legislative history surrounding this Act demonstrates that its drafters never intended for the statute to provide broad immunity from all design defect claims. Finally, the policy behind the Act is promoted by allowing some design defect claims, because the Act was never intended to protect manufacturers from claims

caused by their own wrongdoing.

A. The plain text of the Vaccine Act demonstrates that the Act only preempts defective design claims against manufacturers where a vaccine was properly prepared and still carried unavoidable side effects.

Based purely on the language of the Vaccine Act, this Court should conclude that the Act preempts only some design defect claims. As with any interpretation question, "[s]tatutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the Legislative purpose." *Park 'N Fly, Inc. v. Dollar Park 'N Fly, Inc.*, 469 U.S. 189, 194 (1985). Furthermore, in looking to the language of the Vaccine Act, this Court is bound by the "cardinal principle of statutory construction that courts must give effect, if possible, to every clause and word of a statute." *Williams v. Taylor*, 529 U.S. 362, 364 (2000). Considered along with the strong presumption against preemption in traditional state law fields, these principles demand an especially narrow reading of the Vaccine Act's preemption provisions. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992) (adopting a narrow reading of preemption provisions "in light of the presumption against the pre-emption of state police power regulations").

With the aid of these interpretative guideposts, the text of the Vaccine Act alone reveals several reasons why the Act does not preempt all defective design suits. First, interpreting the statute to bar all defective design claims would render a significant clause in the statute meaningless. Second, the conditional structure of the Act's preemption provision shows that Congress intended for claims to be evaluated on a case-by-case basis. And third, the Defendant's contention that compliance with FDA specifications is sufficient to avoid design defect claims is not supported by the text of the Act, or by the narrow reading that courts give to these clauses.

1. Barring all design defect claims would remove any meaning from the "unavoidable adverse side effects" requirement of the preemption provision.

The Vaccine Act, by its express terms, only preempts those design defect claims that arise from *unavoidable* side effects caused by otherwise properly-designed vaccines. 42 U.S.C. § 300aa-22(b)(1). In construing statutes, this Court has repeatedly emphasized that judges must not violate the "elementary canon of construction that a statute should be interpreted so as not to render one part inoperative." *Colautti v. Franklin*, 439 U.S. 379, 392 (1979); *Mountain States Tel. & Tel. Co. v. Pueblo*, 472 U.S. 237, 249 (1985); *Dep't of Revenue of Or. v. ACF Indus., Inc.*, 510 U.S. 332, 341 (1994). However, to read the Vaccine Act's preemption clause as a complete shield for manufacturers, regardless of the level of care that was taken in producing a vaccine, would be to eliminate the "unavoidability" requirement from the statute. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 240 (Ga. 2008).

In *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005), this Court powerfully reaffirmed its commitment to interpreting statutes so as to preserve every clause. There, a pesticide manufacturer argued that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) preempted all state law claims for inadequate labeling. *Id.* at 436. The statute barred any State from imposing labeling requirements that were "in addition to or different from" FIFRA requirements. *Id.* The Court rejected the manufacturer's argument. It held that by preempting only those requirements that deviated from FIFRA, Congress must have intended to preserve any claims that were consistent with the federal scheme. *Id.* at 447. Importantly, the Court also criticized the defendant for attempting to purge language from the statute: "Conspicuously absent from the submissions by [defendant and amicus] is any plausible alternative interpretation of 'in addition to or different from' that would give that phrase

meaning. Instead, they appear to favor reading those words out of the statute." *Id.* at 448. While the defendant's "amputated version" of the statute would have barred all state law claims, the full text created a separate class of claims that were not preempted. *Id.* at 449.

Unsatisfied with merely rejecting the defendant's attempt to rewrite the work of Congress, the *Bates* Court went further. Even if the defendant's interpretation of FIFRA had been plausible, the Court stated that it was obligated to adopt the interpretation that permitted state law claims. *Id.* In so doing, it noted that "[i]n areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'" *Id.* (quoting *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)).

Given this precedent, the Vaccine Act cannot be read to preempt all design defect claims without regard for individual determinations of avoidability. Just as the statute in *Bates* did, the preemption provision here creates two separate classes of claims. Claims for injuries that were unavoidable despite the manufacturer's best efforts to prevent them are preempted; claims for injuries that could have been avoided but for the manufacturer's shortcomings are not.

By arguing that the Act bars all design defect claims, the Defendant is attempting to read a crucial clause out of the statute. "[T]he rule against superfluities instructs courts to interpret a statute to effectuate all its provisions, so that no part is rendered superfluous." *Hibbs v. Winn*, 542 U.S. 88, 89 (2004). Accepting the Defendant's "amputated version" of the Vaccine Act would violate this basic rule and would be a stark departure from this Court's established precedent regarding statutory interpretation.

Finally, even if this Court decides that the Vaccine Act is ambiguous regarding design defect claims, blanket preemption would still not be appropriate. The Defendant contends that

the text of the Act reveals the intent of Congress to bar all design defect claims. *Cooks*, No. 08-cv-4132, slip op. at 2. Even if this reading is plausible, it is not obvious enough to defeat the heavy presumption against preemption. Any intention to bar common law claims in traditional areas of state sovereignty must be expressed in a "clear and manifest" fashion. *Bates*, 544 U.S. at 449. The Vaccine Act only preempts claims stemming from unavoidable side effects, and it does not specifically address claims for defective design. 42 U.S.C. § 300aa-22(b)(1). Based on the limited nature of this preemption clause, it can hardly be said that Congress has expressed a "clear and manifest" intention to bar all state law design defect claims. Where a court encounters two equally plausible interpretations of a statute, only one of which suggests that preemption is appropriate, it has a "duty to accept the reading that disfavors pre-emption." *Bates*, 544 U.S. at 449.

2. The limited structure of the Vaccine Act's preemption clause demonstrates that state law claims must be evaluated on a case-by-case basis.

If Congress had wished to preempt all design defect claims, it would have written the Vaccine Act to reflect this intention. Instead, the Act creates specific categories of claims for which injuries may not be compensated under state tort law, while remaining silent regarding other categories. As this Court has stated, "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." *Cipollone*, 505 U.S. at 517. Under this canon of interpretation, the broad exclusion of all design defect claims is objectionable.

The Supreme Court of Georgia recently stressed the limited nature of the preemption clause in holding that the Vaccine Act does not bar all design defect claims. In *American Home Products Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008), the court focused on the "conditional nature" of this preemption clause, under which claims are preempted only *if* an injury is caused

by unavoidable side effects. *Id.* at 390. Since this shield on liability is dependent upon an injury being "unavoidable," then there must also be *avoidable* side effects for which victims are allowed to sue under state law. *Id.* Under this construction, the preemptive reach of the statute "barr[ed] liability only for those side effects which were unavoidable by means other than proper manufacturing and packaging." *Id.* The Thirteenth Circuit employed the same reasoning in deciding this issue in the current case. *Cooks*, No. 09-1032, slip op. at 11.

Congress has specifically defined the preemptive reach of the Vaccine Act to include only unavoidable side effects. Where the reach of a statute does not extend to claims for avoidable defects, the Court must imply that they are not preempted. *See Cipollone*, 505 U.S. at 517. In their Complaint, Plaintiffs allege simply that the Defendant's vaccine was defectively designed because a safer alternative existed. *Cooks*, No. 08-cv-4132, slip op. at 2. Presumably, this safer alternative would not have caused any injuries to Estella Marie Cooks. If discovery proves this assertion to be true, then the side effects of Defendant's vaccine would be avoidable.

3. Defendant's contention that the Vaccine Act requires only compliance with FDA regulations to exclude design defect claims is unsupported by the text.

In moving to dismiss the Complaint, the Defendant argues that where a vaccine was manufactured in compliance with FDA regulations, all design defect claims should be preempted. *Cooks*, No. 08-cv-4132, slip op. at 2. Stated bluntly, this argument has no support in the text of the Vaccine Act. In fact, the only way to tie this interpretation to the actual text of the Act is through a wild extrapolation of subsection (b)(2), which covers claims for inadequate warnings. This provision states that, "a vaccine shall be presumed to be *accompanied by proper directions and warnings* if the vaccine manufacturer shows that it complied in all material respects with all requirements" of various federal regulatory statutes. 42 U.S.C. § 300aa-

22(b)(2) (emphasis added).

Of course, there is support for the proposition that compliance with FDA regulations can sometimes serve to preempt state tort law claims. However, that precedent is clearly distinguishable from the present case. In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), this Court held that the Medical Device Amendments of 1976 (MDA) preempted tort claims for injuries caused by any device that had received FDA premarket approval. Under this statute, states could not alter the requirements of the MDA relating to the "safety and effectiveness of [a] device." *Id.* at 316 (quoting Medical Device Amendments of 1976, 21 U.S.C.A. § 360k(a) (2006)). FDA premarket approval was pivotal in establishing federal safety standards. As the Court observed, FDA approval "is in no sense an exemption from federal safety review—it *is* federal safety review." *Id.* at 323 (emphasis in original). With this framework in place, the Court simply had to determine what requirements were imposed by the approval process and then compare them to the requirements imposed by Plaintiff's state law claims. *Id.* at 321-22. Because it found these sets of requirements to be inconsistent, the Court held that the Plaintiff's claims were expressly preempted by the plain text of the MDA. *Id.* at 325.

In contrast to the statutory scheme examined in *Riegel*, the Vaccine Act does not incorporate any broad federal safety requirements that are designed to address every personal injury claim. 21 U.S.C. § 360k(a). Rather, the Vaccine Act begins with a general rule, which allows state law claims for vaccine-related injuries. 42 U.S.C. § 300aa-22(a). The relevant preemption clause creates a narrow exception, simply barring claims for unavoidable injuries. § 300aa-22(b)(1). It does not impose a sweeping restriction on all state law requirements like the MDA provision did in *Riegel*; nor does it establish any independent federal standard of safety review. Instead, under the Vaccine Act, compliance with FDA regulations simply creates a

presumption of "proper directions and warnings." § 300aa-22(b)(2). This presumption can even be rebutted "by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance [with the regulations]." § 300aa-22(b)(2)(B).

When dealing with areas that have been traditionally reserved for state law, such as citizen health and safety, this Court has held that preemption statutes should be given a very narrow interpretation. *See Cipollone*, 505 U.S. at 518. Despite this principle, the Defendant argues that compliance with FDA specifications should somehow create an irrebutable presumption that a vaccine was not defectively designed. Not only does this interpretation lack support from the text of the Vaccine Act, it is also not required by this Court's precedent in addressing FDA regulations and preemption.

B. The legislative history of the Vaccine Act demonstrates that its drafters did not intend to provide manufacturers with broad immunity from all claims.

The legislative history of the Vaccine Act supports a Congressional intention to allow claims for avoidable design defect claims. In this case, the Thirteenth Circuit held that subsection (b)(1) of the Act "clearly does not preempt all design defect claims against vaccine manufacturers." *Cooks*. No. 09-1032, slip op. at 11. Nevertheless, the court looked to the Act's legislative history to extinguish any doubt. *Id.* Other courts, while not admitting that the language of (b)(1) is ambiguous per se, have also supplemented their interpretations with legislative history. *See, e.g.*, *Ferrari*, 668 S.E.2d 236; *Militrano v. Lederle Labs.*(*Militrano II*), 810 N.Y.S.2d 506 (N.Y. App. Div. 2006). Three sources, each building upon the last, all support the Plaintiffs' position in this case—comment k to section 402A of the Restatement (Second) of Torts, a 1986 House Report, and a 1987 bill amending the Vaccine Act.

1. Comment k supports the conclusion that the Vaccine Act only preempts design defect claims where a vaccine-related injury was unavoidable.

Congress based subsection (b)(1) of the Vaccine Act on comment k to section 402A of the Restatement (Second) of Torts. H.R. REP. NO. 99-908, 1986 U.S.C.C.A.N. 6344, 6366-67. This comment addresses "unavoidably unsafe products." RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). It provides that some products simply cannot be "made safe for their intended and ordinary use" due to the limits of human knowledge and experience. §402A cmt. k. For purposes of manufacturer liability, such products are neither "defective" nor "unreasonably dangerous" where they are "properly prepared, and accompanied by proper directions and warnings." §402A cmt. k. This provision was intended to protect manufacturers whose products, although "unavoidably unsafe" at the time of production, have benefits that justify their risks. *Tansy v. Dacomed Corp.*, 890 P.2d 881, 885 (Okla. 1994).

Comment k has been variously interpreted and applied in the context of vaccine-related injuries. *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 835 (Neb. 2000). In some cases, it has been used to support a holding that the Vaccine Act preempts all design defect claims. *See, e.g., Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 248 (3rd Cir. 2009). In others, it has been applied to support the holding that a defective design must be adjudicated on a case-by-case basis. *See*, *e.g.*, *Ferrari*, 668 S.E.2d at 239.

As explained above, the defendant in *Ferrari* essentially argued that any injury from an FDA-approved vaccine should be deemed "unavoidable" as a matter of law. *Ferrari*, 668 S.E.2d at 237. The court, however, held that determining whether a vaccine-related injury is "unavoidable" requires a case-specific analysis. *Id.* at 242. In so doing, the Court alluded to three ways in which Comment k supports the plain language of the Vaccine Act.

First, Comment k only refers to "*some* products" that cannot reasonably be made safe. § 402A cmt. k (1965) (emphasis added). The Restatement drafters therefore must have recognized that there are many other products in use that *are* capable of being made safe. This supports the conclusion that subsection (b)(1) must contemplate avoidable vaccine injuries. *See Toner v. Lederle Labs.*, 732 P.2d 297, 308 (Idaho 1987) ("Obviously, the comment does not apply to *all* drugs.") (emphasis in original). Second, the conditional construction of subsection (b)(1) furthers the policy underlying Comment k. Decisions adopting the majority view of comment k "emphasize that blanket immunity from tort liability would remove an incentive for developing safer designs." *See Militrano v. Lederle Labs.* (*Militrano I*), 769 N.Y.S.2d 839, 846 (N.Y. App. Div. 2003) (citing *Hill v. Searle Labs.*, 884 F.2d. 1064, 1069 (8th Cir. 1989)); *Freeman v. Hoffman La-Roche, Inc.*, 618 N.W.2d 827, 839 (Neb. 2000). Finally, "the present state of human knowledge" referred to in Comment k is a relative term that invites a case-by-case determination of the bounds of medical knowledge both at the time a vaccine was manufactured and when it was administered. In other words, there is no reason to refer to the "present state" of knowledge and experience if courts are supposed to ignore that knowledge and experience and instead create broad immunity for manufacturers. Certainly, no one would argue that a toy manufacturer who uses lead-based paint in the year 2010 deserves immunity because of the limited scientific knowledge that existed fifty years ago.

Like the Georgia Supreme Court in *Ferrari*, other courts have relied on Comment k as a guide for addressing design defect claims. *See, e.g.*, *Tansy*, 890 P.2d at 886; *Toner v. Lederle Labs.*, 732 P.2d 297, 306 (Idaho 1987). In determining whether a particular product is "unavoidably unsafe," these courts have examined, on a case-by-case basis, the decisions behind a product's design and the availability of safer alternatives. In *Tansy v. Dacomed Corp.*, 890

P.2d 881 (Okla. 1994), the court concluded that Comment k demands a risk-benefit analysis. *Id.* at 886. The court classified Comment k as an affirmative defense that requires the defendant to satisfy certain conditions. *Id.* For one, at the time of manufacture, the product could not have been made any safer. *Id.* Satisfaction of this condition and others was to be determined by a jury on a case-by-case basis. *Id.*; *see also Toner*, 732 P.2d at 306 (*quoting* Britt Wesley Hanson, *Can a Prescription Drug be Defectively Designed?*—Brochu v. Ortho Pharmaceutical Corp., 31 DEPAUL L.REV. 247, 254(1981)) (noting that the applicability of Comment k must be decided on a case-by-case basis and stating that "[t]he statement that drugs are unavoidably [dangerous], and therefore within the protection of Comment k, has become almost tautological").

Like the plain language of the Vaccine Act, Comment k supports the conclusion that the Act preempts only design defect claims where a vaccine-related injury has been determined on a case-by-case basis to be unavoidable. This Court should adopt the majority view of Comment k that Congress did not intend to preempt all design defect claims.

2. A report issued by the committee primarily responsible for passing the Vaccine Act shows that Congress wanted the tort system to remain available for some design defect claims.

In 1986, the House Committee on Energy and Commerce, which was in charge of the Vaccine Act, issued a report ("House Report" or "1986 Report") that sheds light on the intent behind the Act. H.R. REP. NO. 99-908, *reprinted in* 1986 U.S.C.C.A.N. 6344. This report supports the plain reading interpretation that Congress never intended the Vaccine Act to preempt *all* design defect claims.

There are two passages in the House Report at the center of the debate over the Vaccine Act's preemptive scope. The first passage, which describes the committee's adoption of Comment k, is cited in favor of plaintiffs who wish to bring state law tort claims. *See e.g.,*

Ferrari, 668 S.E.2d at 240. The second passage, which suggests the proper forum for vaccine-related claims, is cited in favor of defendants and preemption. *See, e.g.*, *Militrano II*, 810 N.Y.S.2d at 508. Read together, however, these passages show that Congress planned for the tort system to remain available for some design defect plaintiffs.

In adopting Comment k, the drafters of the Vaccine Act intended that the Comment's principle "regarding 'unavoidably unsafe' products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system" H.R. REP. NO. 99-908. In this case, the phrase "those products which *in the present state of human skill and knowledge cannot be made safe*," is at issue. However, even a court that ultimately held that the Vaccine Act preempts all design defect claims, recognized that this phrase "appears to leave open the possibility of a design defect claim with respect [to] vaccines covered by the . . . Act." *Militrano II*, 810 N.Y.S.2d at 508.

The second debated passage from the 1986 House Report refers to the compensation system envisioned in the Vaccine Act. In this passage, the drafters noted that "[v]accine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law . . . that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system." H.R. REP. NO. 99-908. The issue disputed in this case whether this passage *requires* plaintiffs asserting claiming design defect to remain in the compensation system. Courts holding that the Vaccine Act preempts all design defect claims assert that this passage "clearly" indicates a Congressional intention to "relegate design defect claims to the compensation system." *Blackmon*, 328 F. Supp. 2d at 664-65; *see also Militrano*

II, 810 N.Y.S.2d at 508. Viewing this passage as "clearly" excluding design defect claims from the tort system, however, requires a blurring of certain words. The term "appealing alternative" does not suggest a mandate, but rather indicates only that the compensation system is intended to attract plaintiffs who wish to avoid the pitfalls of protracted civil trials. *See Ferrari*, 668 S.E.2d at 241 (noting that some plaintiffs "should find the compensation system appealing even though [they are] authorized to attempt to prove the existence of a safer design in the tort system").

In addition to the specific language used in the House Report, the statements on the floor of Congress before the passage of the Act also indicate the drafters' intent to preserve some state design defect claims. During those debates, the Bill's main sponsor stated that "[i]f an injury is the result of a bad vaccine or one inadequately researched or warned of, then the courts could still make awards." 132 CONG. REC. H9943-02 (1986). He added that those children who are "the innocent statistics of the necessary war on such diseases as polio or whooping cough would not *have* to go to court to get their medical bills paid." *Id.* (emphasis added). Like the words used in the 1986 House Report, these statements do not indicate that the tort system is off-limits for all design defect claims.

Read together, and in consideration of the Vaccine Act's plain language and foundational principles, these two debated passages demonstrate that Congress intended the tort system to be available to some design defect claims.

3. A 1987 amendment to the Vaccine Act indicates the drafters wanted the courts to determine whether a particular vaccine is "unavoidably unsafe."

In addition to Comment k and the 1986 House Report, a 1987 amendment to the Vaccine Act further supports the plain language of the text. A report by the House Committee on the Budget ("Budget Report") indicates that that the Vaccine Act was not intended to provide vaccine manufacturers with blanket immunity. Moreover, the Budget Report indicates that

whether a vaccine was "unavoidably unsafe" was meant to be determined on a case-by-case basis.

As it was originally passed, the Vaccine Act did not provide a source of funding for the compensation system. H.R. REP. NO. 100-391(I), at 690, *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365. After the enactment of a tax to provide funding, the Budget Committee issued a report explaining the purpose of the amendment and further clarifying the intent of the Vaccine Act. H.R. REP. NO. 100-391(I), at 691. The Budget Report stated:

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

H.R. REP. NO. 100-391(I), at 691.

Because the Budget Committee "did not play a role in the drafting or passage of the Vaccine Act," it has been presumed that the Committee that is referred to in this passage is the Energy and Commerce Committee. *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 250 (3rd Cir. 2009). Accordingly, this passage supports the availability of design defect tort actions in two ways.

First, the Report demonstrates that a proposal to give vaccine manufacturers blanket immunity from design defect claims was rejected by the Energy and Commerce Committee when the bill was being considered. The significance of this rejection is premised on the canon

of statutory construction that "Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." *Bruesewitz*, 561 F.3d at 249 (*quoting Immigration & Naturalization Serv. v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987)).

In addition to referencing the rejected amendment, this passage from the Budget Report indicates that the determination of whether a vaccine was "unavoidably unsafe" is a question for the courts, to be decided on a case-by-case basis. As the above-quoted passage concludes, "This question is left to the courts to determine in accordance with applicable law." H.R. REP. NO. 100-391(I), at 691.

Although cognizant of the implications of the Budget Report, the *Bruesewitz* court contended that "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *Bruesewitz*, 561 F.3d at 250 (*quoting U.S. v. Prince*, 361 U.S. 304, 313 (1960)). The court added that the dangers spawning from a subsequent inference of intent are "amply present" with the 1987 Budget Report. As applied to this situation, the court's statement is an exaggeration. Here, the Budget Report was issued just one year after the passage of the Vaccine Act. It was also published by a committee, which, while not directly involved in the Act's passage, was essential in ensuring its utility. Moreover, the Supreme Court has never flatly prohibited the use of subsequent legislation to infer prior intent. *Foyle v. Lederle Labs.*, 674 F.Supp. 530, 533 (E.D.N.C. 1987); *see also Rainwater v. United States*, 356 U.S. 590 (1958) (addressing the regulations of an administrative agency and stating that subsequent statements of congressional intent "might be controlling").

C. Defendant's argument that the Vaccine Act provides manufacturers with blanket immunity is not supported by the policies underlying the Act.

An individual determination of whether a vaccine is unavoidably unsafe advances the twin aims of the Vaccine Act—to compensate vaccine-injured victims and to promote the

widespread production of vaccines. Defendant's contentions that the Vaccine Act immunizes them from design defect liability as long as their vaccines are FDA-approved cannot be reconciled with these aims.

Congress passed the Vaccine Act to compensate vaccine-injured persons "quickly, easily, and with certainty and generosity." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir. 1999) (quoting H.R. REP. NO. 99-908 at 3). Concerning children, the Act implicitly recognizes that the absence of particular vaccines would cause more harm than the injuries caused by the vaccines themselves. *Blackmon*, 328 F. Supp. 2d at 663-66. To prevent the manufacturers from either leaving the vaccine market or increasing prices exponentially, Congress created the Vaccine Act. *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994).

Although the Act protects manufacturers, it does so only for the good of the public. Defendant's argument that the Act gives manufacturers blanket immunity from tort liability mistakenly assumes that Congress was singularly concerned about the financial prosperity of vaccine producers. Moreover, such a construction would "have the perverse effect of" insulating from design defect claims an industry that Congress believed needed the threat of litigation as an incentive for producing safer vaccines. *Lohr*, 518 U.S. at 487.

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), this Court rejected a nearly identical argument for blanket preemption in the related field of medical devices. In so doing, the court noted that "it would take language much plainer than the [relevant statutory text] to convince us that Congress intended" to bar all design defect claims. *Id.* at 487. This precise sentiment was echoed a decade later, when the Court stated that if Congress had "intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly. *Bates*, 544 U.S. at 449.

As stated earlier, Congress' intent not to give manufacturers blanket immunity is supported by the Vaccine Act's legislative history. Introducing the Act, the Bill's primary sponsor stated that "the tort system serves as a constant incentive to regulators and manufacturers alike to keep the vaccine supply as safe as it can be." 132 CONG. REC. E2461-01 (1986). He added, "There is a real value to preserving that incentive, and I will oppose any effort to eliminate liability for negligence under state and federal law." 132 CONG. REC. E2461-01 (1986).

Proposals to give manufacturers blanket immunity have also been rejected at least twice. The first rejection came when the American Law Institute was considering the adoption of Comment k. 38 ALI Proc. 19, 90-98 (1961). The second, according to the House Budget Committee, occurred when the Energy and Commerce Committee originally debated the Vaccine Bill. H.R. REP. NO. 100-391(I), at 691.

In arguing that the Vaccine Act grants it blanket immunity from design defect claims, the Defendant construes the language of Section 22(b) to render any FDA-approved vaccine unavoidably unsafe. *Cooks*, No. 08-cv-4132, slip op. at 2. Again, Defendant has mistakenly considered itself the ultimate and primary beneficiary of the Vaccine Act. By assuming that the FDA approval process is a substitute for manufacturer due diligence, this construction creates incentives for vaccine manufacturers to remain ignorant of potential safety improvements. *Ferrari*, 668 S.E.2d at 242. As one court noted, "a drug manufacturer is in a better position [than the FDA] to monitor the current state of knowledge and technology, as applied to its products. We hesitate to hold that a manufacturer is excused from making changes it knows will improve its product merely because an older, more dangerous version received FDA approval." *Adams v. G.D. Searle & Co.*, 576 So.2d 728, 733 (Fla. App. 1991).

The policy underlying the Vaccine Act bolsters the conclusion that Congress intended for the threat of occasional tort claims to provide manufacturers with an incentive to produce safer vaccines. Therefore, this Court should conclude that the Act only preempts defective design claims against manufacturers where a vaccine was properly prepared and still carried unavoidable side effects.

II. PLAINTIFFS SATISFIED THE PLEADING REQUIREMENT SET OUT IN TWOMBLY BY PLEADING ALL THE REQUIRED ELEMENTS OF A DESIGN DEFECT CLAIM UNDER GRACE LAW AND BY MAKING ALL THE FACTUAL ALLEGATIONS WITHIN THEIR CAPACITY AT THIS STAGE IN THE PROCEEDINGS.

Existing Grace product liability law does not insulate vaccine manufacturers from strict liability for design defects. *Cooks*, No. 08-cv-04132, slip op. at 3. In Grace, a design defect claim is analyzed under a risk-utility analysis that takes numerous factors into account in order to determine if the risks in the product's design outweigh its utility. *Id.* at 3-4. The weighing of these factors is generally a jury question. *Id.* at 4. Plaintiffs, in their Complaint, have pled sufficient facts which would allow one to conclude that the risks inherent in the vaccinations given to young Estella Marie Cooks outweigh the vaccine's benefits.

Federal Rule of Civil Procedure 8(a)(2) only requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). The purpose of a complaint is merely to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Id.* (quoting *Conley*, 355 U.S. at 78). An appellate court is to give *de novo* review to a dismissal of a complaint pursuant to a 12(b)(6) motion. *E.g.*, *Cooks*, No. 09-1032, slip op. at 9-10; *Payne ex rel. Estate of Calzada v. Brake*, 439 F.3d 198, 203 (4th Cir. 2006) *Morrison v. March & McLennan Cos.*, 439 F.3d 295, 299 (Mich. 2006).

Twombly set the current standard under which a motion to dismiss is to be analyzed. *Twombly*, 550 U.S. 544. This Court later held that the *Twombly* "governs the pleading standard 'in all civil actions and proceedings in United States district courts.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1953 (2009) (quoting FED. R. CIV. P. 1). Therefore, this standard applies to Plaintiffs' Complaint.

In ruling on a motion to dismiss, the factual allegations made in the complaint are to be taken as true. *Iqbal*, 129 S. Ct. at 1949. The same does not apply to legal conclusions. *Id.* In order for a case to proceed to discovery, a complaint must contain sufficient facts to"state a claim for relief that is plausible on its face." *Id.* at 1949 (quoting *Twombly*, 550 U.S. at 570). This plausibility standard, however, is not a "probability requirement." *Id.* Rather, "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and 'that a recovery is very remote and unlikely.'" *Twombly*, 550 U.S. at 556 (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)). The plausibility requirement merely calls for "enough facts to raise a reasonable expectation that discovery will reveal evidence" to support the plaintiff's cause of action. *Id; see also Iqbal*, 129 S. Ct. at 1949 (stating that the plausibility standard just requires more than a "sheer possibility"). Furthermore, a judge may draw reasonable inferences from the factual allegations to reach his conclusion. *Iqbal*, 129 S. Ct. at 1949; *see also Phillips v. County of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008) (noting that in deciding a 12(b)(6) motion, a court is to "draw all inferences from the facts alleged in the light most favorable to [the non-moving party]"); *Giarratano v. Johnson*, 551 F.3d 298, 302 (4th Cir. 2008) (stating that in reviewing a motion to dismiss, "we 'take the facts in the light most favorable to the plaintiff'") (quoting *E. Shore Mkts. v. J.D. Assocs. Ltd. P'ship*, 213 F.3d 175, 180 (4th Cir. 2000)); *Gregory v. Daly*, 243 F.3d 687, 691 (2d Cir. 2001) (observing that for a

12(b)(6) motion, a court is to "construe the complaint liberally" in favor of the non-moving party).

The appellate court erred in its application of the standard set out *Twombly* and *Iqbal* when it dismissed Plaintiffs' case. Taking all factual allegations from the Plaintiffs' Complaint as true, the court should have reasonably inferred that Defendant's vaccine contained a design defect. From this inference, the court could have expected that discovery would lead to evidence that Defendant's product was in fact defective under Grace's risk-utility analysis.

A. Plaintiffs' pleading alleges sufficient factual allegations to satisfy the plausibility requirement set out in *Twombly* for a design defect claim under Grace law.

This court should find that Plaintiffs pled sufficient facts to make out a claim for defective design under Grace law. The factors considered under Grace's risk-utility analysis for a design defect include the "gravity and severity of the danger caused by the design, the avoidability of the danger, and the ability to eliminate the danger without impairing the product's usefulness." *Cooks*, No. 08-cv-4132, slip op. at 4. Determining whether Plaintiffs have pled enough facts under this analysis to state a plausible claim is a "context-specific task." *Iqbal*, 129 S. Ct. at 1950. In the context of vaccines containing thimerosal, Plaintiffs' Complaint clearly makes sufficient factual allegations regarding all of these risk-utility factors to satisfy the *Twombly* standard for a defective design claim under Grace state law.

1. Plaintiffs have made sufficient factual allegations regarding the gravity and severity of the danger caused by Defendant's design.

The Plaintiffs have made sufficient factual allegations in their Complaint to satisfy the first factor in Grace's risk-utility test. Where a plaintiff pleads sufficient facts to raise a reasonable expectation that discovery will reveal evidence supporting the elements of a claim, dismissal is improper. *Twombly*, 550 U.S. at 556. This reading has been adopted by all but one

of the federal circuit courts that have been asked to interpret this question. *See Phillips v. Bell*, No. 08-1420, 2010 WL 517629, at *4 (10th Cir. Feb. 12, 2010); *Arar v. Ashcroft*, 585 F.3d 559, 617 (2d Cir. 2009); *Fowler v. UPMC Shadyside*, 578 F.2d 203, 213 (3d Cir. 2009); *Nemet Chevrolet, Ltd., v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 262 (4th Cir. 2009); *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 257 (5th Cir. 2009); *In Re Travel Agent Commc'n Antitrust Litig.*, 583 F.3d 896, 902 (6th Cir. 2009); *Brooks v. Ross*, 578 F.3d 574, 581 (7th Cir. 2009); *al-Kidd v. Ashcroft*, 580 F.3d 949, 977 (9th Cir. 2009); *CHS Indus, LLC, v. U.S. Customs and Border Prot.*, 653 F. Supp. 2d 50, 56 (D.C. Cir. 2009); *Phillips v. County of Allegheny*, 515 F.3d 224, 235 (1st Cir. 2008); *Sec. of Labor v. Labbe*, No. 08-12120, 2008 WL 4787133, at *1 (11th Cir. 2008);

Plaintiffs have made numerous factual allegations regarding the grave and severe dangers posed by the Defendant's vaccine. Specifically, the Complaint alleged that the Defendant was aware that the mercury contained in the vaccine given to Estella had "neurotoxic properties." *Cooks*, No. 09-1032, slip op. at 12. Additionally, Plaintiffs' alleged that as a result of the vaccine, Estella now suffers from serious, and likely permanent, neurological injuries. *Cooks*, No. 08-cv-04132, slip op. at 4. Given the current state of litigation and research regarding thimerosal, discovery is very likely to reveal evidence supporting these allegations.

First, there have been an extraordinary number of lawsuits filed in recent years by parents whose children allegedly suffered neurological injuries after receiving vaccines containing thimerosal. *E.g.*, *Moss v. Merck & Co.*, 381 .F.3d 501 (5th Cir. 2004), *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289 (E.D. Pa. 2007); *Blackmon*, 328 F. Supp. 2d 647. These lawsuits are likely a result of recent studies that have indicated a casual connection between those who received vaccines containing thimerosal and those suffering from neurological disorders. *See* Cynthia E.S. Staats, *The Greater Good: Rethinking Risks and Benefits of*

Childhood Vaccination Programs, 3 J. HEALTH & LIFE SCI. L. 164, 184-86 (2009) (discussing studies by the Center for Disease Control and Prevention and other organizations about the potential harmful effects of thimerosal).

Second, in 1999, the U.S. Department of Health and Human Services urged all vaccine manufacturers "to reduce or eliminate thimerosal from in vaccines as soon as possible." Regina Moreland, *National Vaccine Injury Compensation Program: The Potential Impact of Cedillo for Vaccine-Related Autism Cases*, 29 J. LEGAL MED. 363, 371 (2008). This government department is comprised of numerous agencies including the Food and Drug Administration, that National Institute of Health, and Centers for Disease Control and Prevention, and its opinion carries great weight. *Id.*

Third, in 2004, the Institute of Medicine of the National Academies, the health arm of the National Academy of Sciences, recommended the discontinuance of thimerosal in vaccines for Diphteria, Tetanus, Pertussis, and Haemophilus influenzae type b. IMMUNIZATION SAFETY REVIEW COMM., INST. OF MED. OF THE NAT'L ACADS., IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM 167 (2004).

With respect to these recent developments, the Complaint alleges that Estella received the specific vaccines that were listed in the 2004 report. It also alleged that all of Estella's vaccines contained thimerosal. Given the history and recent notoriety of thimerosal, Plaintiffs' allegations absolutely raise a reasonable expectation that discovery will produce evidence to further support their claims.

2. Plaintiffs have made sufficient factual allegations that the danger in Defendant's vaccine could have been avoided without impairing its utility.

Based on the specific nature of the claims being asserted, this court should also find that Plaintiffs have sufficiently alleged facts regarding the second and third factors of Grace's risk-

utility analysis. Under current 12(b)(6) jurisprudence, reasonable inferences can certainly be drawn from the factual allegations in the Complaint to create a plausible finding that the defendant is liable for the misconduct alleged. *Iqbal*, 129 S. Ct. at 1949.

Plaintiffs claim that the danger posed by the Defendant was in fact avoidable. The Complaint plainly alleges that the Defendant "[f]ailed to conduct adequate safety tests to determine whether thimerosal was safe and nontoxic to . . . infants or small children" at various dosage levels. *Cooks*, No. 08-cv-04132, slip op. at 4. Given the recent recommendations by the U.S. Department of Health and the National Academy of Sciences, it is not difficult to infer that the Defendant would have likely learned about the potential risks of thimerosal had it bothered to conduct further testing. Had the Defendant conducted this additional testing before putting its thimerosal-containing products on the market, it would not have distributed them for use on small children like Estella. This scenario demonstrates just how avoidable these injuries really were. Therefore, Plaintiffs have pled sufficient facts regarding the second factor in Grace's risk-utility analysis.

Finally, plaintiffs clearly allege in the Complaint that "a safer alternative existed." If true, this means that the utility of the Defendant's vaccines would not have been impaired if the danger was eliminated. *Cooks*, No. 08-cv-04132, slip op. at 4. Today, in fact, "thimerosal is no longer used in most U.S. vaccines." *Hennessey v. Sec'r of the Dep't of Health and Human Servs.*, No. 01-190V, 2009 WL 1709053, at *4 n.2 (Fed. Cl. May 29, 2009). This fact readily supports the assertion that the vaccines given to Estella would not have surrendered their utility had the Defendant refrained from using thimerosal. As a result, Plaintiffs have also pled sufficient facts regarding the third design defect factor under Grace law.

B. Post-*Twombly* decisions support the conclusion that Plaintiffs have made sufficient factual allegations to survive a motion to dismiss.

Based on various recent complaints alleging similar design defects to the one currently asserted, this court should find that Plaintiffs' Complaint is sufficient to survive a motion to dismiss. A complaint is not insufficient under *Twombly* merely because it fails to specifically allege that a product's risks outweigh its benefits; it is enough that the complaint gives rise to a fair inference that the product's unsafe aspects outweigh its benefits. *Boroff v. Alza Corp.*, No. 3:09CV1595, 2010 WL 395211, at *4 (N.D. Ohio Jan. 27, 2010).

In *Boroff*, the plaintiff's complaint alleged that her husband was prescribed and used the drug Duragesic, which was administered through a skin patch. *Id.* at *1. The complaint further alleged that the patch had been recalled for causing the deaths of several users by leaking a certain type of medication into the skin. Not surprisingly, the complaint alleged that this defect had killed plaintiff's husband. *Id.* at *5. The jurisdiction in which the claim was filed applied a risk-benefit analysis to claims for design defects, similar to the one used under Grace state law. *Id.* In applying the *Twombly* plausibility standard, the court found that since the complaint alleged that the patch had been recalled for leakage, and that it was the leakage that caused the death, this was sufficient to support an inference that the product's risks outweighed its benefits. *Id.* at *5. The court found this sufficient to survive a 12(b)(6) motion, despite that fact that complaint did not even specifically allege that the risks of the design outweighed its benefits. As the court reasoned "there would appear to be little benefit to forcing a plaintiff, as a matter of pleading, to assert legal conclusions" which corresponded to the "complicated multi-factor" risk benefit analysis that was applied to design defect claims. *Id.*

The allegations in the Complaint and the substantive law regarding design defects in this case parallel those in *Boroff*. Both jurisdictions employ the risk-benefit analysis in deciding

whether a product has been defectively designed. Like the complaint in *Boroff*, the Complaint here makes fairly limited factual allegations of a design defect and of an injury caused by that defect. Specifically, the *Boroff* plaintiff alleged that the drug "has been recalled for causing death to users due to an excessive leak of fentanyl, a dangerous narcotic medication," and that this leakage caused the death of plaintiff's husband. Complaint at ¶¶ 20-21, *Boroff*, 2010 WL 395211 (No. 3:09CV1595). Here, the Cooks allege that the vaccine given to their daughther "contained dangerous levels of mercury, a substance known to the defendants to have neurotoxic properties," which caused her injuries. *Cooks*, No. 09-1032, slip op. at 12, n.8.

This court should apply the reasoning of the *Boroff* court and find that Plaintiffs' complaint is sufficient under *Twombly*. Under this formulation, there is no need for Plaintiffs to explicitly allege that the risks of the vaccine outweigh its benefits. There would be little benefit in forcing Plaintiffs to plead a "legal conclusion" that corresponds to the factors of Grace's multifactor risk-utility test. It is sufficient that Plaintiffs' Complaint gives rise to a fair inference that the risks of including thimerosal in vaccines outweigh any corresponding benefits.

Given that the allegations in the Complaint plainly state that Defendant knew thimerosal had dangerous neurotoxic properties, that this danger caused extensive neurological damage, and that a safer alternative existed, it can be inferred that the risks outweighed its benefits. *See also Jozwiak v. Stryker Corp.*, No. 6:09-cv-1985-Orl-19GJK, 2010 WL 743834, at *6 (M.D. Fla. Feb. 26, 2010) (denying defendant's motion to dismiss where plaintiff alleged merely that "Defendants knew or should have known that" the relevant product was toxic); *Krywokulski v. Ethicon, Inc.*, No. 8:09-VC-980-T-30MAP, 2010 WL 326166, at *2-*3 (M.D. Fla. Jan. 21, 2010) (observing that a bare allegation that the product, " malfunctioned, thus making [it] unsafe and dangerous for use" was sufficient to plead a design defect claim); *Gilbert v. Watson Labs., Inc.*,

No. 07-CV-2023, 2008 WL 4532168, at *3 (S.D. Cal Oct. 9, 2008) (finding that plaintiff met his burden under *Twombly* by pleading simply that the drug "was not properly prepared," "was not accompanied by warnings of its dangerous side-effects," and that defendants "were aware" that the drug caused certain injuries); *Horne v. Novartis Pharms. Corp.*, 541 F. Supp. 2d 768, 784 (W.D.N.C. 2008) ("While these allegations leave much to be desired to demonstrate…that they reflect more than mere speculation that the Plaintiff hopes she has a claim, (citation omitted) these allegations are sufficiently factual to state a cognizable claim for negligence and to give the Defendant" fair notice of the claims alleged.)

Under this line of decisions, courts have recognized that specific facts may not always be available in cases of defectively designed medical devices and drugs. Because of the highly technical nature of these products, plaintiffs have been permitted to plead their factual conclusions with limited specificity to create a reasonable and plausible inference. To demand more would ignore the reality of these claims.

C. Dismissing the Complaint would impose an improperly heightened pleading standard that would compel Plaintiffs to produce evidence prior to discovery.

Without evidence obtained through routine discovery, it is impossible for Plaintiffs to plead any further factual allegations. *Twombly* expressly provides that a complaint requires just enough facts "to raise a reasonable expectation that *discovery will reveal evidence*" to support a valid claim. *Twombly*, 550 U.S. at 556 (emphasis added). "To require more under Rule 8 [of the Federal Rules of Civil Procedure] would be to impose a heightened pleading standard that would require the plaintiff to produce evidence before discovery has commenced." *Woodcock v. Mylan, Inc.*, 661 F. Supp. 2d 602, 612 (S.D. W. Va. 2009).

In *Woodcock v. Mylan, Inc.*, 661 F. Supp. 2d 602 (S.D. W. Va. 2009), the plaintiff alleged the defendant's product contained a design defect that caused her husband's death. *Id.* at

604, 611. The governing law required a plaintiff to prove "that a safer, practical, alternative design was available to the manufacturer at the time the product was manufactured." *Id.* at 611. To make this determination, the court employed a multi-factor risk-utility analysis similar to the one used in Grace. *Id.* at 611-12. In her complaint, the plaintiff simply stated that the defendant's product contained a toxic chemical that could have been replaced with a safer alternative, and that this design defect caused her husband's death. *Id.* at 612. The court found that these allegations were sufficient to satisfy the *Twombly* standard. *Id.* To require more, the court held, would place an undue burden on the plaintiff. *Id.*

The circumstances surrounding defendant's 12(b)(6) motion in *Woodcock* closely mirror those presented in this case. Plaintiffs here must consider nearly identical factors under Grace's risk-benefit analysis. *See Cooks*, No. 08-cv-4132, slip op. at 4. Both plaintiffs pled merely that products contained a dangerous design defect, that a safer alternative existed, and that the defect proximately caused an injury. Specifically, the Cooks alleged that the Defendant marketed a dangerous product without conducting adequate testing, which caused severe neurological injuries to their daughter. *See id.* at 2-4; *Cooks*, No. 09-1032, slip op. at 12-13.

Like the *Woodcock* court, this Court should conclude that Plaintiffs' Complaint satisfies the *Twombly* standard despite its relative simplicity. Requiring more out of Plaintiffs would impose a heightened pleading requirement that would require them to produce evidence before discovery had commenced. This Court previously stated that it did wish to "apply any 'heightened pleading standard,'" nor did it seek "to broaden the scope of [the] Federal Rules," in general. *Twombly*, 550 U.S. at 569 n.14 (quoting *Swierkiewicz v. Sorema N.A.*, 550 U.S. 544, 515 (U.S. 2002); *see also Oak Lawn Pavillion v. United States Dep't of Health and Human Servs.*, No. 98C614, 1999 WL 1023920, at *5 (N.D. Ill. 1999) ("It is axiomatic that a plaintiff is

not required to produce evidence in support of its allegations of harm; notice pleading is the standard.").

At this point in the litigation, Plaintiffs have made every factual allegation that their knowledge permits. Anything beyond this would require at least minimal discovery. In determining whether Plaintiffs' Complaint satisfies *Twombly*, it does not matter if the court thinks the claims are "unrealistic or nonsensical." *Iqbal*, 129 S. Ct. at 1951. The federal pleading standard "relies on liberal discovery rules and summary judgment motions . . . to dispose of unmeritorious claims." *Swierkiewicz*, 534 U.S. at 512.

Furthermore, in the context of products liability litigation, a plaintiff will often be unable to plead detailed factual allegations. As the Eleventh Circuit pointed out, "[t]he very nature of a products liability action—where the cause or source of the defect is not obvious . . . make it very difficult for a [plaintiff] to pinpoint a specific source of defect . . . prior to discovery." Relying on judicial experience and common sense, this court should find that Plaintiffs have pled all the allegations within their capacity. In a products liability action involving highly technical knowledge, these pleadings satisfy the standard set forth in *Twombly*.

D. Dismissing Plaintiffs' Complaint at this stage in the proceedings would controvert the purposes of products liability law.

Granting Defendant's 12(b)(6) motion would run contrary to the main purposes behind products liability law. This body of law exists generally to encourage the design of safer products, and to socialize the losses caused by defective products. *See Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 185 (Mich. 1984); *Williams v. Weiler & Co.*, 498 F. Supp. 917, 920 (S.D. Iowa).

Dismissing the Plaintiff's Complaint prior to discovery would essentially remove any economic motivation for manufacturers to produce optimally safe vaccines. This Court recently

agreed that tort liability "creates an incentive to act with greater care." *Herring v. United States*, 129 S. Ct. 695, 702 (2009) (quoting *id.* at 708 (Ginsburg, J., dissenting)). In their Complaint, Plaintiffs have made every allegation they were capable of making at this stage in the litigation. Requiring more would essentially signal to vaccine manufacturers that they are immune from civil suit so long as they maintain confidential production records.

Additionally, dismissing Plaintiff's Complaint at this stage would prevent the socialization of loss for injuries caused by thimerosal-containing vaccines. The potential dangers associated with thimerosal are now well-publicized. *See, e.g.*, IMMUNIZATION SAFETY REVIEW COMM., INST. OF MED. OF THE NAT'L ACADS., IMMUNIZATION SAFETY REVIEW: VACCINES AND AUTISM 167 (2004). Given these dangers, and the fact that ruling on a motion to dismiss is such a "context-specific" task, this court should not deny countless potential victims the chance to recover for a thimerosal-related injury. *Iqbal*, 129 S. Ct. at 1950.

CONCLUSION

For the reasons stated herein, Petitioners Dan Cooks, *et al.*, respectfully request that the Order dismissing all defective design claims against Respondent Carolina Laboratories, Inc. be reversed.

APPENDIX

National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 *et seq.*
§ 300aa-22: Standard of Responsibility

(a) General rule
Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows--

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings
No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

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

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

42 U.S.C. § 300aa-22 (2006).