In the

SUPREME COURT OF THE UNITED STATES

April Term, 2010

Docket No. 10-1524

DAN COOKS and LOETTA COOKS, individually and as parents of ESTELLA MARIE COOKS,
Petitioners,

v.

CAROLINA LABORATORIES, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Thirteenth Circuit

BRIEF FOR THE RESPONDENT

Team 17
Counsel for Respondent

ORAL ARGUMENT REQUESTED

QUESTIONS PRESENTED

I. Whether the National Childhood Vaccine Injury Act of 1986 preempts state product liability suits for design defects where Congress intended to insulate vaccine manufacturers and injured parties from the expense, unpredictability, and congestion of the fifty-state tort system.

II. Whether the Thirteenth Circuit properly applied the *Twombly* pleading rules when it granted Carolina's motion to dismiss for failure to state a claim where the Complaint simply recited bare allegations and failed to rise to the level of facial plausibility.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

UNITED STATES SUPREME COURT CASES

UNITED STATES COURT OF APPEALS CASES

UNITED STATES DISTRICT COURT CASES

UNITED STATES COURT OF FEDERAL CLAIMS CASES

STATE COURT CASES

CONSTITUTIONAL AND STATUTORY AUTHORITY

LAW REVIEWS AND JOURNALS

OTHER SECONDARY AUTHORITY

OPINIONS BELOW

The opinion of the United States District Court for the District of Grace ("district court"), in the matter of *Cooks v. Carolina Labs., Inc.*, No. 08-cv-04132, dated Mar. 25, 2008, appears in the record at pages 1-8. The decision of the United States Court of Appeals for the Thirteenth Circuit ("Thirteenth Circuit"), *Cooks v. Carolina Labs., Inc.*, No. 09-1032, dated Aug. 6, 2009, appears in the record at pages 9-13.

STATEMENT OF JURISDICTION

In accordance with Rule 2(c) of the Twenty-Third Annual August A. Rendigs, Jr. National Products Liability Moot Court Competition, the Statement of Jurisdiction is waived.

CONSTITUTIONAL AND STATUTORY PROVISIONS

The adjudication of this case involves the application of Article VI, Clause 2 of the United States Constitution. Additionally, the First and Fifth Amendments to the United States Constitution are referenced. The relevant texts of these constitutional provisions are attached in Appendix A. This case predominantly involves the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1, *et seq.* (1986). Other statutory provisions referenced include, Section I of the Sherman Antitrust Act of 1890, Title XXI of the Code of Federal Regulations, and the Rules and Regulations of the Department of Health and Human Services. The relevant texts of these statutory provisions are attached in Appendix B. Furthermore, this case involves Federal Rules of Civil Procedure 1, 8, and 12(b)(6). The relevant texts of these rules are attached in Appendix C.

STATEMENT OF THE CASE

Respondent, Carolina Laboratories, Inc. ("Carolina") is a manufacturer of the Diphtheria, Tetanus Toxoids and Pertussis – Haemophilus influenza type b ("DTP-Hib") combination

vaccine. (R. at 1.) Petitioners, Dan and LoEtta Cooks ("Petitioners") had their daughter vaccinated with three doses of the DTP-Hib vaccine between March 1996 and October 1998. *Id.*

Vaccine Court Proceedings

On September 3, 2001, Petitioners filed a petition for compensation on behalf of their daughter with the National Vaccine Injury Compensation Program ("Vaccine Court") pursuant to 42 U.S.C. § 300aa-1, *et seq.* ("Vaccine Act"). *Id.* at 1-2. Petitioners claimed that the DTP-Hib vaccine impaired their daughter's neurological, gastrointestinal, and immune systems. *Id.* at n.1. Petitioners withdrew from the Vaccine Court on November 5, 2003 and elected to file a civil action. *Id.* at 2.

District Court Proceedings

Petitioners filed their Complaint on March 14, 2007 individually and as parents of their daughter. *Id.* Petitioners' Complaint against Carolina asserted two counts under Grace state law. *Id.* Count I of the Complaint claimed negligence in that Carolina did not sufficiently test a constituent material of the DTP-Hib vaccine, thimerosal ("constituent material"). *Id.* Count II of the Complaint claimed strict products liability for design defects, asserting that a substitute vaccine design existed. *Id.* The Complaint further averred that the constituent material was unsafe and that the harm allegedly experienced by Petitioners' daughter was avoidable. *Id.* at 1, 3. The district court granted Carolina's Motion to Dismiss with prejudice, holding that Petitioners' Complaint gave adequate notice under Grace law, but that the design defect claims were preempted by the Vaccine Act. *Id.* at 4, 7.

Appellate Court Proceedings

The Thirteenth Circuit affirmed the dismissal of Petitioners' case. *Id.* at 13. While it disagreed with the district court's interpretation of the Vaccine Act, the Thirteenth Circuit found

that the Complaint simply stated a formulaic recitation of the elements of a design defect claim and failed to support the claims that Carolina did not sufficiently test the constituent material and that a substitute vaccine design existed. *Id.* at 11-13.

Supreme Court Proceedings

This Court granted Petitioners' writ of certiorari. *Id.* at 14. Carolina now respectfully requests that this honorable Court hold that the Vaccine Act preempts Petitioners' state law design defect claims and that Petitioners' Complaint was properly dismissed under the *Twombly* pleading rules for failure to state a claim.

SUMMARY OF THE ARGUMENT

The Vaccine Act expressly preempts state law design defect claims. Congress' rationale in passing the Vaccine Act was two-fold. First, it intended to protect children from life-threatening diseases by guaranteeing the presence of vaccine manufacturers in the marketplace. Second, Congress intended to provide a simple, speedy, and no-fault avenue for recovery to those injured by vaccines routinely administered to children. Permitting a case-by-case analysis of whether a vaccine was defectively designed would subvert Congressional intent and subject vaccine manufacturers to the expense and uncertainty of the fifty-state tort system. Furthermore, Congress adopted Comment *k* of the Restatement, Second of Torts, Section 402A recognizing that vaccines are unavoidably unsafe as the utility of vaccination heavily outweighs any side effects a vaccine may present. The Thirteenth Circuit, however, misread Congress' application of comment k.

Additionally, the plain language of section 22(b)(1) of the Vaccine Act exhibits Congress' recognition of the three types of product defects – manufacturing, information, and design – and emphasizes the intent to exempt vaccine manufacturers from the latter specifically,

regardless of the cause of action. Moreover, Congress acknowledged that the determination of whether a vaccine is unavoidably unsafe is best left to the expertise of the United States Food and Drug Administration ("FDA"). Furthermore, prior to the Thirteenth Circuit's erroneous decision, only one court had ever interpreted the Vaccine Act to allow for a case-by-case analysis of design defect claims. As such, this Court should reject the flawed construction of the Thirteenth Circuit and adopt the correct reasoning proffered by the United States Court of Appeals for the Third Circuit and the United States District Court for the District of Grace.

As to the second issue, this Court should find that Petitioners failed to state a claim for relief. Petitioners' Complaint merely stated that their daughter received three doses of the DTP-Hib vaccine and that the constituent material led to her alleged injuries. Petitioners failed to establish causation because the Complaint did not state facts related to the administration of each vaccine dose. As such, the connection to the symptoms was purely conclusory. In addition, Petitioners' claim is implausible because it stops short of the line between possibility and plausibility of entitlement to relief. Moreover, as there are two parallel explanations for Carolina's conduct, one lawful and one unlawful, this Court should accept as plausible the lawful explanation that Carolina's vaccine was neither defectively designed nor the cause of the injuries alleged.

Furthermore, Petitioners' Complaint failed to provide Carolina with notice of the grounds upon which Petitioners rest their claims. Specifically, the Complaint did not indicate that a suitable substitute design of the DTP-Hib vaccine was in existence when Petitioners' daughter was vaccinated. Also, the Complaint did not leave open the possibility that Petitioners might later establish some set of undisclosed facts that would support recovery. Finally, this Court should reaffirm the principle in cases such as this, that complaints must be pled with some

specificity in order to avoid an enormous expenditure of time and money where there is no reasonably founded hope that the discovery process will reveal relevant evidence. Therefore, this Court should affirm the Thirteenth Circuit's dismissal of the Petitioners' Complaint.

ARGUMENT

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

This Court should reverse the decision of the Thirteenth Circuit, holding that the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act") does not preempt Petitioners' state law products liability claims for design defect. (R. at 11.) In 1986, Congress passed the Vaccine Act, under which, "individuals . . . injured by vaccines routinely administered to children" could be compensated for their injuries. H.R. Rep. No. 99-908, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344 [hereinafter *Report*]. The Vaccine Act created the "no-fault" Vaccine Court where persons injured by vaccines were required to bring their claims against vaccine makers. *Id.* Although Congress created the Vaccine Court "to work faster and with greater ease than the civil tort system," *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995), Vaccine Court plaintiffs, nevertheless, were permitted to deny the Vaccine Court's adjudication of their claim or withdraw and bring selected claims in state court under state law. *Wright v. Aventis Pasteur, Inc.*, No. 3861, 2008 WL 4144386, at *5 (Pa. Com. Pl. Aug. 27, 2008) (dismissing plaintiffs' design defect claims against thimerosal-containing vaccine manufacturers as claims were preempted by Vaccine Act).

The Supremacy Clause in Article VI of the United States Constitution makes "the Laws of the United States . . . the supreme Law of the Land." U.S. Const. art. VI, cl. 2. Congress has the authority under the Supremacy Clause to preempt state law. *Cosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). Therefore, any law interfering with federal power is unenforceable. *Maryland v. Louisiana*, 451 U.S. 725, 747 (1981). Federal law may preempt state law in three different ways: (1) express preemption takes place when Congress enacts a statute with language clearly expressing that state law is preempted; (2) field preemption occurs

where Congress passes a statute that allows no space for state law because of a "pervasive regulatory scheme"; or (3) conflict preemption happens when state law conflicts with federal law or its purposes." *Sykes v. Glaxo-Smithkline*, 484 F. Supp. 2d 289, 296 (E.D. Pa. 2007). As Congress expressly preempted state law in specific instances through the Vaccine Act, the latter two modes of preemption are of no concern here. *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 243 (3d Cir. 2009).

Preemption is a question of law, and is therefore, reviewed *de novo*. *Alongi v. Ford Motor Co.*, 386 F.3d 716, 723 (6th Cir. 2004). Likewise, this Court reviews a lower court's construction of a statute *de novo* and grants no deference to the lower court. *United States v. Spinelle*, 41 F.3d 1056, 1057 (6th Cir. 1994). Accordingly, this Court should grant the Thirteenth Circuit no deference and find that Petitioners' design defect claims against Carolina are preempted.

A. Petitioners' Design Defect Claims are Preempted Because Otherwise, the Intent of the Vaccine Act Would be Frustrated as Vaccine Makers Will be Subjected to the Uncertainty and Expense of the State Tort System.

The Vaccine Act expressly preempts state law in several ways. The National Childhood Vaccine Injury Act of 1986 § 22(b)(1), 42 U.S.C. § 300aa-1 *et seq*. (1986) ("subsection (b)(1)"). One such way is that under subsection (b)(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*.

Id. (emphasis added). Put more simply, a vaccine maker is immune from liability for injuries caused by the "unavoidable" side effects of a properly prepared and adequately labeled vaccine. *Id.* Congressional intent is paramount in determining the preemptive effect of a federal law.

Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 604-05 (1991). The proper starting point for finding that intent is the legislative history of the law. *Militrano v. Lederle Labs.*, 810 N.Y.S.2d 506, 508 (N.Y. App. Div. 2006). The legislative history of the Vaccine Act demonstrates Congress' explicit intent to preempt state law.

1. Allowing a Case-by-Case Determination of Whether a Vaccine was Unavoidably Unsafe Would Circumvent Congressional Intent.

The Thirteenth Circuit misread the Congressional intent behind the Vaccine Act. The history of the Vaccine Act reveals Congress' dual-purposes for enacting the legislation. The main function of the Vaccine Act is to guarantee access to childhood vaccines by keeping vaccine manufacturers, such as Carolina, in business. *Report*, *supra*, at 3-4; *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994). Additionally, Congress was frustrated with tort law's ineffectiveness in dealing with vaccine-related injuries. *Report*, *supra*, at 6; *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 843 (N.Y. Sup. Ct. 2003) (dismissing state law design defect claims against DTP-Hib vaccine manufacturer on grounds that Congress clearly intended to preempt all design defect claims). Further, the courts in *Schafer* and *Militrano* noted that Congress enacted the Vaccine Act after hearing testimony that *even* injured plaintiffs criticized the uncertainty of tort law remedies. *Schafer*, 20 F.3d at 2; *Militrano*, 769 N.Y.S.2d at 843.

Moreover, prior to passage of the Vaccine Act, Congress took notice of the costs attributed to defending vaccine lawsuits. *Militrano*, 769 N.Y.S.2d at 842-43. The cost of the DTP vaccine increased by more than 1000% from 1984 to the time the Vaccine Act was passed in 1986. *Id.* at 842. 70% of this increase was credited solely to the cost of insurance. *Id.* High insurance costs also contributed to 60% of the DTP vaccine producers being forced out of the market between 1972 and 1984. *Id.* Consequently, Congress responded to the "instability and

unpredictability" that tort liability posed to injured plaintiffs and vaccine manufacturers alike by passing the Vaccine Act. *Report*, *supra*, at 7.

Congress was clear in its intent to protect children from life-threatening disease by keeping vaccine makers in the market. Therefore, it would be illogical for Congress to then permit "a case-by-case determination as to whether a vaccine was unavoidably unsafe." *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 446 (E.D. Pa. 2007) (dismissing design defect claims sounding in strict liability and negligence against DTP vaccine maker after finding that Vaccine Act preempted all design defect claims). A case-by-case determination would expose vaccine makers to expensive, endless, and arbitrary liability driven by the "inconsistencies of a [fifty]-state tort system," each with its own precedents, particularities, and procedures. *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 665 (S.D. Tex. 2004) (holding that plaintiffs' claim that constituent material in vaccine caused minor to suffer neurological injuries was preempted by Vaccine Act as all design defect claims were barred). Congress was certainly not so careless.

If the liability of vaccine manufacturers differed from state to state and from one jury to another, manufacturers would face conflicting duties. To illustrate, if a jury in one case found the DTP-Hib vaccine's side effects avoidable, but later, a different jury in that same jurisdiction found that same vaccine unavoidably unsafe, the hands of a manufacturer like Carolina would be tied by inconsistent obligations. Likewise, if an Ohio court found the DTP-Hib vaccine's side-effects avoidable, but later, a Kentucky court found that same vaccine unavoidably unsafe, the consequences to vaccine manufacturers would be grave. Outcomes like these would neither keep vaccine prices down, nor maintain a competitive market that encouraged research and development, leaving children without access to life-saving vaccines.

Furthermore, it makes little sense for Congress to subject vaccine manufacturers to the fifty-state tort system after finding it to be so costly, slow, and unpredictable. *Blackmon,* 328 F. Supp. 2d at 665. Ignoring Congressional intent would risk returning to the pre-Vaccine Act era where the number of vaccine manufacturers, and thus, the availability of low-cost vaccines steadily declined. In addition, if, as Congress found, even plaintiffs viewed state law remedies to be uncertain and that sentiment fueled the passage of the Vaccine Act, Congress surely could not have intended to send injured plaintiffs back to such uncertainty for a case-by-case review. Accordingly, the Petitioners in the present case would be better served by keeping state law out of the picture.

Here, the construction given to the Vaccine Act by the Thirteenth Circuit creates a game of chance that could result in high tort awards against vaccine manufacturers, forcing them out of the marketplace. The Thirteenth Circuit's interpretation is at odds with Congressional intent, the wording of the Vaccine Act, and the history of vaccinations in this country, and would allow disease to run rampant. Congress did not intend that the nation's vaccine supply be left to the whim of a jury. It is obvious that Congress considered vaccines "unavoidably unsafe" as a matter of law, and therefore, vaccine manufacturers like Carolina should not be exposed to liability in state courts for design defects.

In a case strikingly similar to the one before this Court, a minor received three doses of a DTP-Hib combination vaccine containing thimerosal. *Sykes*, 484 F. Supp. 2d at 292. Soon after, the minor experienced side effects. *Id.* The minor's parents filed a petition in the Vaccine Court, but later withdrew their petition and filed design defect claims based on state law against the vaccine manufacturers. *Id.* at 294. The plaintiffs alleged that the vaccine was defectively designed and that reasonable alternative designs existed. *Id.* Further, the plaintiffs asserted that

the vaccine maker did not sufficiently test the constituent material to determine whether it was unsafe. *Id.* The *Sykes* court, however, dismissed the plaintiffs' claims holding that all state law design defect claims are preempted by the Vaccine Act. *Id.* at 303. Just as the claims alleged by the plaintiffs in *Sykes* and the Petitioners in the case before this Court are the same, so too should be the result. Accordingly, this Court should find that Petitioners' design defect claims against Carolina are preempted.

2. Congress Adopted Comment *k* of the Restatement, Second of Torts, Section 402A in Order to Absorb Design Defect Claims.

The Thirteenth Circuit's interpretation of Comment *k* is flawed. In adopting subsection (b)(1), Congress echoed the language of Comment *k* of the Restatement, Second of Torts, Section 402A. *Report*, *supra*, at 25-26. Comment *k* states that there are some "products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," but nevertheless, have extraordinary utility. Restatement (Second) of Torts § 402A cmt. k (1965). The comment, therefore, declares that such products, if properly manufactured and sufficiently informative, are unavoidably unsafe and thus, not defectively designed. *Id.* Moreover, Comment *k* expressly acknowledges that it is reasonable to produce a rabies vaccine, which may cause severe harm, because rabies typically results in death. *Id.*; *Sykes*, 484 F. Supp. 2d at 300; *see also Bruesewitz*, 508 F. Supp. 2d at 445 (reasoning that the risks inherent in vaccination are heavily outweighed by the utility of vaccine administration); Mary Beth Neraas, Comment, *The National Childhood Vaccine Injury Act of 1986: A Solution to the Vaccine Liability Crisis?*, 63 Wash. L. Rev. 149, 168 n.3 (1988) (stating that it is tremendously uncommon for children to experience side effects from the DTP vaccine).

Most remarkably, Congress stated that it mirrored "[C]omment [*k*] because it intend[ed] that the principle in Comment K [sic] regarding 'unavoidably' unsafe products . . . apply to the

vaccines covered in the bill and that *such products not be the subject of liability in the tort system*." *Report*, *supra*, at 26 (emphasis added). Comment *k* used a vaccine as an example of an unavoidably unsafe product. Congress subsequently stated that it intended Comment *k* to apply to vaccines covered by the Vaccine Act. Therefore, Congress' aim to preempt design defect claims could not be more unmistakable.

As the Thirteenth Circuit correctly noted, "[c]omment k has been interpreted in a variety of ways and there is a wide range of disagreement regarding its application." (R. at 10.) From there, however, the court's reasoning went astray. Citing *Bryant v. Hoffman-LaRouche, Inc.*, 585 S.E.2d 723 (Ga. Ct. App. 2003), *Freeman v. Hoffman-LaRouche, Inc.*, 618 N.W.2d 827 (Neb. 2000), and *Tansy v. Dacomed Corp.*, 890 P.2d 881 (Okla. 1994), the court continued, "[m]ost of the states that have adopted Comment *k* have applied it in a more limited fashion on a case-by-case basis." (R. at 10.) But those cases dealt with prescription drugs and medical devices. *See Bryant*, 585 S.E.2d at 725, 728 (holding in an action against a heart medication manufacturer, that Comment *k* should be applied on a case-by-case basis); *Freeman*, 618 N.W.2d at 832, 840 (holding that Comment *k* should be applied on case-by-case basis where a patient was injured by acne medication); *Tansy*, 890 P.2d at 883, 886 (holding that Comment *k* should be applied on a case-by-case basis where a patient was injured by penile implant). These examples are easily distinguishable from claims alleging the defective design of vaccines, including the present case.

In the United States, vaccination of children is virtually obligatory. *See* Steve Calandrillo, *Vanishing Vaccinations: Why are so Many Americans Opting Out of Vaccinating Their Children?*, 37 U. Mich. J.L. Reform 353, 383 (2004) (stating that all fifty states require a series of vaccines including vaccination against diphtheria before children may enter school). Further, the scope of the Vaccine Act is restricted to four types of vaccines, which cause a

limited number of enumerated injuries that manifest in a narrow period of time. 42 U.S.C. § 300aa-14(a). Additionally, vaccines are predominantly administered to children. *See* Calandrillo, *supra*, at 440 n. 86 (noting that children should receive fifteen to nineteen immunizations before their second birthday). On the other hand, prescription drugs and medical devices are generally doctor recommended and often voluntary. Also, there are many thousands of different drugs and devices on the market, many of which may cause ailments presently unknown to doctors and scientists, which may not arise until many years into the future. *See* Drugs@FDA, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/ (last visited Mar. 10, 2010 (providing directory of thousands of drugs). Moreover, persons of varied ages take prescription drugs and use medical devices. Quite simply, not everyone needs acne medication and penile implants. Conversely, nearly every child is immunized. Calandrillo, *supra*, at 383. Therefore, vaccine-related injuries present a limited set of facts, whereas injuries resulting from prescription drugs and medical devices are fact specific and deserve a case-by-case review. Accordingly, this Court should not be moved by the number of courts that have applied Comment *k* on a case-by-case basis, as those courts were not operating under like circumstances or under an edict from Congress, as is the case here.

Furthermore, in order to bolster its interpretation of the Vaccine Act and comment k, the Thirteenth Circuit cited *Militrano*. The court stated, "[a]s acknowledged in *Militrano* . . . [the *Report*] 'appears to leave open the possibility of a design defect claim with respect [to] vaccines covered by the Vaccine Act . . . .'" (R. at 11) (third alteration in original) (*quoting Militrano v. Lederle Labs.*, 810 N.Y.S.2d 506, 508 (N.Y. App. Div. 2006)). The court's reliance on *Militrano*, however, is misplaced. The Thirteenth Circuit disregarded the second half of the sentence quoted from that decision, which read, "[however], the balance of the House

Committee's discussion of the issue clearly establishes Congress' determination that the Comment [*k*] defense bars all such claims." *Militrano*, 810 N.Y.S.2d at 508. Thus, this Court should not be enticed by such a disingenuous analysis and should find that Congress adopted Comment *k* in order to preempt design defects claims as a matter of law. Accordingly, this Court should find that Petitioners' design defect claims against Carolina are preempted.

B. Petitioners' Design Defect Claims – Regardless of the Cause of Action – are Preempted Because the Vaccine Act Forecloses Vaccine Manufacturers From Design Defect Claims in Particular.

The Vaccine Act excludes one theory of liability – design defects. There are only three types of product defects: (1) manufacturing defects; (2) information defects, i.e., improper directions or inadequate warnings; and (3) design defects. Restatement (Second) of Torts § 402A (1965). Under subsection (b)(1), "[n]o vaccine manufacturer shall be liable . . . [for] a vaccine-related injury or death . . . result[ing] from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1). Therefore, subsection (b)(1) demonstrates Congress' intent to categorically exempt design defect claims in particular. *Blackmon*, 328 F. Supp. 2d at 664. Certainly, the words of the ninety-ninth Congress said it best: "[Plaintiffs that] cannot demonstrate under applicable law either that a vaccine was *improperly prepared* or that it was accompanied by *improper directions or inadequate warnings* should pursue recompense in the [Vaccine Court], not the tort system." *Report*, *supra*, at 26 (emphasis added). It is difficult to see how Congress could have been any more overt.

In addition, subsection (b)(1) states that "no vaccine manufacturer shall be liable in *a civil action for damages* . . . ." 42 U.S.C. § 300aa-22(b)(1) (emphasis added). Several courts have interpreted this language to mean that Congressional intent was clear that the Vaccine Act

preempted "all design defect claims, regardless of the cause of action." *Sykes*, 484 F. Supp. 2d at 303; *Bruesewitz*, 508 F. Supp. 2d at 440; *Blackmon*, 328 F. Supp. 2d at 666. Accordingly, the use of the words "a civil action for damages" includes both negligence and strict liability claims. *Blackmon*, 328 F. Supp. 2d at 666. Therefore, the Vaccine Act preempts design defect claims sounding in strict liability and negligence alike.

Even a cursory reading of subsection (b)(1) shows that Congress recognized that some side effects were avoidable whereas some were not. Specifically, Congress considered manufacturing and warning-related defects avoidable, whereas design defects were deemed unavoidable: "No vaccine manufacturer shall be liable . . . [for] a vaccine-related injury or death . . . result[ing] from side effects that were unavoidable *even though* the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1) (emphasis added). Thus, Congress envisioned a vaccine properly manufactured and carrying adequate warnings to be exempt from the purview of state law. As there are only three types of product defects, if a vaccine was not defectively manufactured or inadequately labeled,[1] but still caused injury or death, only one theory of liability remains: design defect. Congress, therefore, regarded design defects alone as unavoidable. Thus, the Vaccine Act protects manufacturers from design defects in particular, regardless of the cause of action. Consequently, this Court should find that Petitioners' design defect claims against Carolina, based on negligence and strict liability are preempted.

C. Petitioners' Design Defect Claims are Preempted Because Congress Intended Persons With the Proper Experience and Knowledge, not Juries, to Ensure the Development and Accessibility of Safe Vaccines.

[1] It must be noted that Petitioners do not assert any defect with the manufacture of the vaccine or that the warnings supplied were inadequate. R. at 2 n.5.

Congress intended federal health agencies, not juries, to ensure vaccine safety. *Blackmon*, 328 F. Supp. 2d. at 665. Only the FDA has the power to approve the design of vaccines that will be administered to children. About FDA, Vaccines, Blood, and Biologics, http://www.fda.gov/AboutFDA/Basics/ucm193816.htm (last visited Mar. 7, 2010). The FDA approves vaccine designs based on a "comprehensive scientific evaluation of the product's risks and benefits . . . ." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). Such decisions are made with the knowledge that vaccines are unavoidably unsafe and that in some cases, improving a vaccine's safety would also mean sacrificing some of the vaccine's effectiveness. *Cf. Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) (recounting FDA's weighing of a medical device's risks and utilities).

Moreover, the FDA-vaccine approval process encourages safe and effective vaccines by subjecting vaccine manufacturers to the most stringent of standards. Robin J. Strongin, *U.S. Childhood Vaccine Availability: Legal, Regulatory, and Economic Complexities*, National Health Policy Forum Issue Brief No. 785, 4 (2002); *see* James A. Henderson Jr. & Aaron D. Twerski, *Drug Designs are Different*, 111 Yale L.J. 151, 163-68 (2001) (noting that the development and approval of a new drug usually takes twelve years and nearly a quarter-billion dollars). Furthermore, the Vaccine Act itself calls for "the refinement of . . . vaccines." 42 U.S.C. § 300aa-27(a)(1). This implies that Congress meant to provide vaccine manufacturers with a blanket exemption "under which manufacturers [could] improve the safety of their products while remaining immune from design defect claims." *Bruesewitz*, 561 F.3d at 238.

Permitting juries to decide whether a vaccine is unavoidably unsafe would run counter to the system Congress envisioned and would undercut the broader, "comprehensive regulatory

scheme, administered by the FDA to control the design . . . of vaccines." *Blackmon*, 328 F. Supp. 2d at 665. While juries made up of reasonable-minded individuals drawing on diverse life experiences are effective in most cases, the state tort system is not the proper medium to ensure the production and development of safe vaccines. It is for this reason that Congress acknowledged by way of the Vaccine Act that skilled FDA officials must regulate vaccine designs, with compensation available to injured persons via the Vaccine Court. Moreover, a case-by-case analysis to determine whether a vaccine is unavoidably unsafe would require evidence of a reasonable alternative design. *White v. Wyeth Labs., Inc.*, 533 N.E.2d 748, 753 (Ohio 1988). Given the complexity and expense of vaccine approval, however, the production of a reasonable alternative design is easier said than done. Therefore, it would be unwise to allow a fact finder to pass judgment prematurely on a design that may be several years and millions of dollars away from FDA approval. Thus, in passing the Vaccine Act, Congress entrusted the FDA, rather than judges and juries, with the task of guaranteeing the research and development of increasingly safe vaccines. Accordingly, this Court should find that Petitioners' design defect claims against Carolina are preempted.

D. Petitioners' Design Defect Claims are Preempted Because all but one Court has Held That the Vaccine Act Preempts Design Defect Claims.

Only one court, the Supreme Court of Georgia, has ever held that all design defect claims are not preempted by the Vaccine Act, but rather, that juries are permitted to determine whether a vaccine was unavoidably unsafe on a case-by-case basis. *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 237-38 (Ga. 2008). Subsequently, *Ferrari's* holding was explicitly rejected by the Third Circuit in *Bruesewitz*. *Bruesewitz*, 561 F.3d at 245-46. Unfortunately, however, *Ferrari's* suspect reasoning was later employed by the Thirteenth Circuit in this case. (*See* R. at 11.)

Ferrari involved facts similar to those at issue here. There, the parents of an injured minor sued DTP vaccine and thimerosal manufacturers alleging design defects, specifically, that the constituent material caused the minor's injuries. *Ferrari*, 668 S.E.2d at 237. The *Ferrari* court held that the Vaccine Act did not preempt the plaintiffs' state law design defect claims. *Id.* at 237-38. In so holding, however, the Supreme Court of Georgia, blatantly misconstrued Congress' intent. Therefore, in the dispute between *Bruesewitz* and *Ferrari*, this Court should adopt the holding of the former. The *Ferrari* Court and the Thirteenth Circuit both found that Congress' use of the term "unavoidable" in subsection (b)(1) meant that Congress recognized that some vaccine-related injuries and deaths were avoidable. *Id.* at 240; (R. at 11.) Also, the two courts questioned why Congress would have used the term "unavoidable" at all if it had intended to bar all design defect claims. *Id.* The two courts, nevertheless, were mistaken.

Subsection (b)(2) restricts subsection (b)(1). *Bruesewitz*, 561 F.3d at 246. Subsection (b)(1) bars claims against vaccine manufactures where vaccines are free of manufacturing and warning defects. *Id.* Further, under subsection (b)(2), a vaccine maker is presumed to have provided adequate warnings so long as the warnings conform to FDA regulations. *Id.* That is, there would be no liability unless "the manufacturer engaged in conduct that would subject it to punitive damages under §300aa-23 of the Vaccine Act or there is clear and convincing evidence that the manufacturer failed to exercise due care." *Id.* The *Bruesewitz* court stated that the two subsections taken together confirmed that the *Ferrari* Court, and in turn, the Thirteenth Circuit were incorrect in finding that Congress desired "states to determine what side effects could have been avoided . . . ." *Id.* Were this the case, the Third Circuit maintained, then Congress could have explicitly "preserved" design defect claims caused by avoidable side effects like it

"preserved some warning defect claims" in subsection (b)(2). *Id.* As this was not the case, this Court should find the reasoning of *Bruesewitz* more compelling.

Additionally, the Thirteenth Circuit declared that the district court's, and consequently, *Bruesewitz*' interpretation of the Vaccine Act "would have the perverse effect of granting complete tort immunity from design defect liability to an entire industry." (R. at 11.) What is more perverse, however, is that the Thirteenth Circuit's interpretation flies in the face of the intent of the Vaccine Act as it opens the door to any and all design defect claims. *Bruesewitz*, 561 F.3d at 246. Permitting judges and juries to evaluate whether a vaccine's side effects could have been avoided would mean that "every design defect claim is subject to evaluation by a court." *Id.* This interpretation would render the Vaccine Court meaningless as plaintiffs would be foolish not to claim that they were injured by avoidable side effects. Therefore, this Court should find neither *Ferrari* nor the Thirteenth Circuit persuasive, and instead, adopt the more sound reasoning of *Bruesewitz*.

In sum, subsection (b)(1) plainly demonstrates the intent of Congress to preempt all state law design defect claims against vaccine makers as a matter of law. Given that Congress' intent was clear, as well as the other reasons stated above, this Court should find that Petitioners' design defect claims are preempted and reverse the decision of the Thirteenth Circuit as it pertains to the question of preemption.

II. THE THIRTEENTH CIRCUIT PROPERLY APPLIED THE *TWOMBLY* PLEADING RULES WHEN IT GRANTED CAROLINA'S MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM.

This Court should affirm the decision of the Thirteenth Circuit, dismissing Petitioners' Complaint for failure to properly allege a cause of action for design defect against Carolina. (R. at 13.) The onus is on the plaintiff to adequately present the facts that warrant remedy in language that is more than "a formulaic recitation of the elements of a cause of action." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "A motion to dismiss for failure to state a claim upon which relief can be granted challenges the legal sufficiency of a claim, not the facts supporting it." *Sykes v. Bayer Pharms. Corp.*, 548 F. Supp. 2d 208, 213 (E.D. Va. 2008). "To survive a motion to dismiss, a complaint must contain sufficient factual matter . . . to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). "Factual allegations must be enough to raise a right to relief above the speculative level . . . ." *Twombly*, 550 U.S. at 555. Courts do not need to accept the authenticity of legal conclusions contained in a complaint. *Ashcroft*, 129 S. Ct. at 1949. A complaint will not pass muster "if it tenders naked assertions devoid of further factual enhancement." *Id.*

"Whether . . . [a] complaint states a cause of action on which relief [can] be granted is a question of law . . . ." *Bell v. Hood*, 327 U.S. 678, 682 (1946). Dismissal of a complaint for failure to state a claim upon which relief can be granted is a question of law that this Court should review under a *de novo* standard. *Cooper Indus. v. Leatherman Tool Group*, 532 U.S. 424, 435 (2001); *Morrison v. Marsh & McLennan Cos.*, 439 F.3d 295, 299 (6th Cir. 2006); *Sinay v. Lamson & Sessions Co.*, 948 F.2d 1037, 1039 (6th Cir. 1991).

A. Petitioners' Complaint was Properly Dismissed Because it Simply Recited Conclusory Allegations Against Carolina.

A complaint "must contain something more . . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action . . . ." *Twombly*, 550 U.S. at 555 (alteration in original) (*citing* 5 C. Wright & A. Miller, Federal Practice & Procedure § 1202, at 94, 95 (1969) (hereinafter *Wright*)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft*, 129 S. Ct. at 1949. "[T]he pleading standard [announced by Fed. R. Civ. P. 8(a)] does not require detailed factual allegations, but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id.* at 1950. "A plaintiff . . . must allege sufficient facts to outline the cause of action." *Ellsworth v. City of Ravine*, 774 F.2d 182, 184 (7th Cir. 1985). "[D]ismissal is appropriate if the complaint lacks an allegation regarding a required element necessary to obtain relief." *Ramirez v. Am. Home Prods.*, No. C.A. B-03-155, 2005 WL 2277518, at *8 (S.D. Tex. Sept. 16, 2005) (*citing Blackburn v. City of Marshall*, 42 F.3d 925, 931 (5th Cir. 1995)).

In the present case, the Thirteenth Circuit correctly noted that the district court improperly relied on *Iqbal v. Hasty*, 490 F.3d 143, 155-58 (2d Cir. 2007), *rev'd sub nom.*, *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), in finding that Petitioners' Complaint was sufficiently pled. (R. at 12.) Reversing the district court, the Thirteenth Circuit properly applied the underlying principles of the *Twombly* decision and held that Petitioners' Complaint "must be dismissed [because it did] nothing more than provide a formulaic recitation of the elements of a design defect claim." *Id.* The court also held that Petitioners' Complaint alleged "nothing more than conclusions of law and failed to state any [facts] to support their allegations." *Id.* at 12-13. The principles adhered to by the Thirteenth Circuit and *Ashcroft* are two-fold. *Id.* at 12;

Ashcroft, 129 S. Ct. at 1950. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft*, 129 S. Ct. at 1949. "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 1950.

Here, Petitioners filed their Complaint individually, and as parents of their daughter. (R. at 1-2.) The Complaint against Carolina asserted two counts under Grace state law. *Id.* at 2. Count I of the Complaint claimed negligence in that Carolina did not sufficiently test thimerosal, a constituent material of the DTP-Hib vaccine. *Id.* Count II of the Complaint claimed strict products liability for design defect, asserting that a substitute vaccine design existed. *Id.* The Complaint averred that the constituent material was unsafe and that the harm allegedly experienced by Petitioners' daughter was avoidable. *Id.* at 3. Petitioners' Complaint narrated that their daughter was vaccinated with three doses of the DTP-Hib vaccine between March 1996 and October 1998. *Id.* at 1. It should be noted, however, that Petitioners did not claim that there was a defect with the preparation or manufacture of the vaccine, and they agreed that the warnings supplied were adequate. *Id.* at 2 n.5.

"It is basic hornbook law that legal causation is an essential element of any negligence claim." *Snawder v. Cohen*, 749 F. Supp. 1473, 1479 (W.D. Ky. 1990). In order to properly allege a claim for negligence, a "plaintiff must show that her injury was the "natural and probable result of the defendant's actions." *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983) (*citing Miller v. United States*, 480 F. Supp. 612, 621 (E.D. Mich. 1979). "Plaintiff will need to prove . . . causation as an essential element of her product liability case under any theory of recovery – strict liability [and] negligence . . . ." *Ramirez*, 2005 WL 2277518 at *9 (*citing Mission Petroleum Carriers, Inc. v. Solomon*, 106 S.W.3d 705, 710 (Tex. 2003) (holding that

regardless of recovery theory, causation is essential)). Causation is the "common denominator" that must be established for both counts asserted in Petitioners' Complaint. *See Snawder*, 749 F. Supp. at 1479 ("We need not discuss the various refinements and considerations concerning the application of [the alleged] theories of liability, because all of them have one common denominator, . . . that causation must be established.").

Causation in a products liability suit is established under a two-prong test. *Snawder*, 749 F. Supp. at 1479 (*citing Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1279 (5th Cir. 1974)). The first prong "involves determining whether the defendant's product caused the plaintiff's injuries." *Id.* The second prong considers "whether the plaintiff's injuries resulted from the alleged defect in the defendant's product." *Id.* In the present case, Petitioners' Complaint failed to satisfy both parts of the causation test. The Complaint did not state the specific dates on which Petitioners' daughter was vaccinated and whether the particular doses she was administered were each from single-dose or multi-dose vials.[2] Moreover, the Complaint did not articulate when the alleged symptoms developed in relation to the administering of each dose of the vaccine.[3] Additionally, Petitioners' Complaint made no mention of other vaccinations administered to their daughter

[2] During the relevant period, vaccine manufacturers routinely added thimerosal as a constituent material to multiple-use vials of vaccines to extend each vial's shelf life. *Easter v. Aventis Pasteur, Inc.*, No. 5:03-CV-141 (TJW), 2004 WL 3104610 at *1 n.7 (E.D. Tex. Feb. 11, 2004). This use of thimerosal "satisfies the FDA's requirement that preservatives be added to vaccines distributed in multi-use vials." 21 C.F.R. § 610.15(a) (2005) ("Products in multiple-dose containers shall contain a preservative."); *O'Connell v. Am. Home Prods. Corp.*, No. Civ. A. G-02-184, 2002 WL 31455729 (S.D. Tex. May 7, 2002).

[3] A claim for a vaccine-related injury must be filed in Vaccine Court within three years from the first symptom. 42 U.S.C. §300aa-16(a)(2); National Vaccine Injury Compensation Program, http://www.hrsa.gov/vaccinecompensation/filing_deadlines.htm (last visited Feb. 28, 2010). Petitioners filed their petition for compensation on their daughter's behalf in Vaccine Court on September 3, 2001. Thus, they are time-barred from bringing a cause of action for any alleged injuries that they claim resulted from the two DTP-Hib combination vaccine doses administered to their daughter prior to September 1998. *See Markovich v. Sec'y of the Dep't of Health & Human Servs.*, 69 Fed. Cl. 327, 334 (2005) ("[T]he statute of limitations in Vaccine Act cases begins to run upon the first symptom or manifestation of the onset of injury, even if the petitioner reasonably would not have known at the time that the vaccine had caused an injury.").

during her lifetime, the manufacturers of each of those vaccines, and whether any of those vaccines contained the constituent material alleged to be harmful. Also, the Complaint did not state any facts that would show that Carolina's DTP-Hib vaccine harmed Petitioners' daughter. Furthermore, the Complaint declared that a substitute vaccine design existed, but did not state the name, formulation, or composition of such vaccine and whether it was administered from single-dose or multi-dose vials. As such, Petitioners' Complaint failed to properly plead causation, an essential element of both claims alleged against Carolina. Therefore, this Court should affirm the decision of the Thirteenth Circuit, dismissing Petitioners' Complaint for failure to state a claim.

B. Petitioners' Complaint was Properly Dismissed Because it Failed to Rise to the Level of Facial Plausibility.

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft*, 129 S. Ct. at 1949 (*quoting Twombly*, 550 U.S. at 570). The conclusion that a complaint articulates "a plausible claim for relief [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 1950. An assertion is facially plausible if the plaintiff has pled sufficient facts such that the court could reasonably conclude that the defendant is accountable for the harm alleged. *Id.*

> The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'"

Id. at 1949 (*citing Twombly*, 550 U.S. at 557). When sufficient facts have been alleged, a court should presume their authenticity "and then determine whether they plausibly give

rise to an entitlement to relief." *Id.* at 1950. "But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not "show[n]" – "that the pleader is entitled to relief."" *Id.* (*citing* Fed. R. Civ. P. 8(a)(2)).

Petitioners' Complaint in the present case is analogous to the plaintiff's complaint dismissed by this Court in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009). There, following the September 11, 2001 terrorist attacks, plaintiff Iqbal, a Pakistani Muslim, "was arrested . . . on criminal charges and detained by federal officials" under "maximum security conditions." *Ashcroft*, 129 S. Ct. at 1942-43. He filed a twenty-one-count complaint against several "federal officials, including John Ashcroft, the former Attorney General of the United States, and Robert Mueller, the Director of the Federal Bureau of Investigation ("FBI")." *Id.* Iqbal's "complaint contend[ed] that [the defendants had] designated [him as] a person of high interest on account of his race, religion, or national origin, in contravention of the First and Fifth Amendments to the Constitution." *Id.* at 1944 (citation omitted). Further, the complaint alleged that following the September 11, 2001 attacks, Ashcroft and Mueller discussed and sanctioned "[t]he policy of holding post-September-11th detainees in highly restrictive conditions of confinement until they were 'cleared' by the FBI." *Id.* Additionally, Iqbal posited that Ashcroft and Mueller ""each knew of, condoned, and willfully and maliciously agreed to subject" [him] to harsh conditions of confinement "as a matter of policy, solely on account of [his] religion, race and/or national origin and for no legitimate penological interest."" *Id.* (second alteration in original) (citation omitted). Finally, in his complaint, Iqbal "name[d] Ashcroft . . . the "principal architect" of the policy, and identifie[d] Mueller as "instrumental in [its] adoption, promulgation, and implementation."" *Id.* (fourth alteration in original) (citation omitted).

The *Ashcroft* court examined the complaint and distinguished the conclusory allegations that were "not entitled to the assumption of truth." *Id.* at 1951. First, this Court held that Iqbal's complaint contained "bare assertions . . . [that] amount[ed] to nothing more than a "formulaic recitation of the elements" of a constitutional discrimination claim . . . that . . . [defendants had] adopted a policy "'because of,' not merely 'in spite of,' its adverse effects upon an identifiable group."" *Id.* at 1951 (*citing Pers. Adm'r of Mass. v. Feeney*, 442 U.S. 256, 279 (1979)). Additionally, this Court found that Iqbal "would need to allege more by way of factual content to "nudg[e]" his claim of purposeful discrimination "across the line from conceivable to plausible."" *Id.* at 1952 (*citing Twombly*, 550 U.S. at 570). The *Ashcroft* court emphasized that Iqbal's "bald allegations" were not discarded "on the ground that they were unrealistic or nonsensical." *Id.* at 1951. Instead, it was "the conclusory nature of [Iqbal's] allegations, rather than their extravagantly fanciful nature, that disentitle[d] them to the presumption of truth." *Id.*

Second, the *Ashcroft* court reviewed the facts alleged by Iqbal "to determine if they plausibly suggest[ed] an entitlement to relief." *Id.* This Court found that while Iqbal's allegations were consistent with one theory – that defendants had purposefully designated him a person "of high interest" based on discriminatory intent, there was a more plausible alternative – that his arrest was justified in the wake of the September 11, 2001 attacks in order to investigate an illegal alien present in the United States who had potential terrorism connections. *Id.* The Court stated, "As between the obvious alternative explanation for the arrests, and the purposeful, invidious discrimination [Iqbal] asks us to infer, discrimination is not a plausible conclusion." *Id.* at 1951-52. An inference of discrimination alone would not stand, and to prevent dismissal of his complaint, Iqbal would need to allege "facts plausibly showing that [defendants]

purposefully adopted a policy of classifying post-September 11 detainees as "of high interest" [for discriminatory reasons]." *Id.* at 1952.

The *Ashcroft* court measured the dismissal of the complaint in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) in its analysis. In *Twombly*, this Court considered the sufficiency of a complaint alleging that incumbent telecommunications providers had entered into an agreement not to compete and to forestall competitive entry, in violation of the Sherman Act, 15 U.S.C. § 1. *Twombly*, 550 U.S. 554. The plaintiffs in *Twombly* pled that the defendants had "entered into a contract, combination, or conspiracy to prevent competitive entry" and had "agreed not to compete with one another." *Id.* at 551. The complaint also alleged that the defendants engaged in a "parallel course of conduct . . . to prevent competition." *Id.*

This Court held the complaint in *Twombly* deficient, stating that "an allegation of parallel conduct and a bare assertion of conspiracy will not suffice." *Id.* at 556. This Court observed that the plaintiffs' assertion of an unlawful agreement was "merely [a] legal conclusion[]" and therefore, not entitled to be assumed as true. *Id.* at 564. The Court next addressed "the nub of the complaint" – the allegation of parallel behavior – to determine whether it gave rise to a plausible claim for conspiracy. *Id.* at 565. This Court discussed that while on one hand, parallel behavior could be indicative of an unlawful agreement, on the other hand, the more plausible explanation was simply that the conduct was lawful, uninhibited, free-market behavior. *Id.* at 567-68. The *Twombly* court dismissed the complaint holding that "the plaintiffs . . . have not nudged their claims across the line from conceivable to plausible . . . ." *Id.* at 570.

Under this framework, in the present case, Count I of Petitioners' Complaint simply stated a legal conclusion, that Carolina was negligent and did not sufficiently test the constituent material of the DTP-Hib vaccine. (R. at 2.) Count II posited another legal conclusion, that

Carolina was liable under a strict products liability design defect theory. *Id.* The remainder of the Complaint stated that a substitute vaccine design existed, that the constituent material used was unsafe, and that the harm allegedly experienced by Petitioners' daughter was avoidable. *Id.* at 1, 3.

"The complaint must be liberally construed in favor of the plaintiff, and all facts pleaded in the original complaint must be taken as true." *Oliver v. Scott*, 276 F.3d 736, 740 (5th Cir. 2002); *see also Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984); *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000); *Malina v. Gonzales*, 994 F.2d 1121, 1125 (5th Cir. 1993); *Sykes*, 484 F. Supp. 2d at 296, (*citing Zimmerman v. HBO Affiliate Group*, 834 F.2d 1163, 1164-65 (3d Cir. 1987)); *Benasco v. Am. Home Prods.*, No. Civ. A. 02-3577, 2003 WL 22174270 at *3 (E.D. La. Sept. 10, 2003) (*citing Campbell v. Wells Fargo Bank*, 781 F.2d 440, 442 (5th Cir. 1980)). The facts must be viewed "in the light most favorable to" the plaintiff. *Christopher v. Harbury*, 536 U.S. 403, 406 (2002).

In the present case, viewing the meager facts stated in the Complaint in the light most favorable to Petitioners, and resolving all doubts against Carolina, the Complaint still fails to state a claim for relief. Petitioners need to allege more by way of factual content to raise a reasonable expectation that discovery will reveal evidence of a defect in the design of Carolina's DTP-Hib vaccine or that a substitute vaccine design existed. Further, Petitioners have alleged no facts that would demonstrate that the constituent material was in any way unsafe. Moreover, Petitioners have not clarified the manner in which Carolina could have avoided the alleged harm to their daughter. As such, "the plain statement [of Petitioners' Complaint does not] possess enough heft to show that [they] are entitled to relief. *Twombly*, 550 U.S. at 545. Therefore, this

Court should affirm the decision of the Thirteenth Circuit, dismissing Petitioners' Complaint for failure to state a claim.

C. Petitioners' Complaint was Properly Dismissed Because it Failed Even Under the *Conley* "no set of Facts" Standard.

The Federal Rules of Civil Procedure require "a short and plain statement of the claim" that will give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests. Fed. R. Civ. P. 8(a)(2); *Conley v. Gibson*, 355 U.S. 41, 47 (1957). "Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Ashcroft*, 129 S. Ct. at 1950. "Rule 8(a) contemplates the statement of circumstances, occurrences, and events in support of the claim presented and does not authorize a pleader's bare averment that he wants relief and is entitled to it." *Twombly*, 550 U.S. at 556 n.3. "The question is whether in the light most favorable to the plaintiff, and with every doubt resolved in his behalf, the complaint states any valid claim for relief." *Loge v. United States*, 662 F.2d 1268, 1274 (8th Cir. 1981) (*citing Wright*, *supra*, § 1357 at 601). A court "need not accept as true unsupported conclusions and unwarranted inferences." *Sykes*, 484 F. Supp. 2d at 296 (*citing Doug Grant, Inc. v. Greate Bay Casino Corp.*, 232 F.3d 173, 183-84 (3d Cir. 2000)).

"A district court may . . . dismiss a complaint under Fed. R. Civ. P. 12(b)(6) [where] it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Easter*, 2004 WL 3104610 at *2 n.9 (*citing Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001)). *See also Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514 (2002) (*quoting Hishon*, 467 U.S. at 73); *Neitzke v. Williams*, 490 U.S. 319, 327 (1989); *Baton Rouge Bldg. & Constr. Trades Council AFL-CIO v. Jacobs Constructors, Inc.*, 804 F.2d 879, 991 (5th Cir. 1986); *Sykes*, 484 F. Supp. 2d at 296; *Benasco*, 2003 WL 22174270 at *3. "A

motion to dismiss for failure to state a claim [however,] is viewed with disfavor and is rarely granted." *Kennedy v. Tangipahoa Parish Library Bd. of Control*, 224 F.3d 359, 365 (5th Cir. 2000); *see also Collins*, 224 F.3d at 498; *Easter*, 2004 WL 3104610 at *2 n.9 (*citing Lowrey v. Tex. A & M Univ. Sys.*, 117 F.3d 242, 247 (5th Cir. 1997)); *Benasco*, 2003 WL 22174270 at *3 (*citing Kaiser Aluminum & Chem. Sales v. Avondale Shipyards*, 677 F.2d 1045, 1050 (5th Cir. 1982)).

In *Conley v. Gibson*, 355 U.S. 41 (1957), a unanimous Court held that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley*, 355 U.S. at 45-46. There, black employees brought a class suit under the Railway Labor Act, asking this Court to compel their collective bargaining agent to represent them fairly. *Id.* at 42. The employees alleged, in part, that they were wrongfully discharged from their employment at the Texas and New Orleans Railroad. *Id.* at 43. They further contended that their designated bargaining agent, Local 28 of the Brotherhood, "refused to protect their jobs as it did those of white employees or to help them with their grievances because they were [black]." *Id.* at 43, 46. This Court held that if the plaintiff's "allegations are proven, there has been a manifest breach of the Union's statutory duty to represent fairly and without hostile discrimination, all of the employees in the bargaining unit," and stated that it "had no doubt that [plaintiff's] complaint adequately set forth a claim and gave the [defendants] fair notice of its basis." *Id.* at 46.

The *Twombly* court recognized that under "a focused and literal reading of *Conley's* "no set of facts" [approach,] a wholly conclusory statement of a claim would survive a motion to dismiss whenever the pleadings left open the possibility that a plaintiff might later establish some "set of undisclosed facts" to support recovery." *Twombly*, 550 U.S. at 561. Justice Souter

acknowledged, "[T]his approach to pleading would dispense with any showing of a "reasonably founded hope" that a plaintiff would be able to make a case." *Id.* at 562 (*quoting Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 741 (1975)). The *Twombly* court emphasized that *Conley's* "no set of facts" language "should be understood in light of the opinion's preceding summary of the complaint's concrete allegations, which the Court . . . understood as amply stating a claim for relief." *Id.* at 562-63. This Court then retired the phrase, stating it "is best forgotten as an incomplete, negative gloss on an accepted pleading standard: once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Id.* at 563. "*Conley* . . . described the breadth of opportunity to prove what an adequate complaint claims, not the minimum standard of adequate pleading to govern a complaint's survival." *Id.*

Even under this now-extinct standard, in the present case, the Complaint at issue failed to provide Carolina with fair notice of the bases for Petitioners' claims. The Complaint simply asserted a conclusory claim of negligence in that Carolina did not sufficiently test the constituent material of the DTP-Hib vaccine. (R. at 2.) Additionally, the Complaint articulated that Carolina was strictly liable under a design defect claim because a substitute vaccine design existed. *Id.* These conjectural statements did not give Carolina fair notice of causation or information regarding the substitute vaccine design. As such, Petitioners' Complaint failed even under the retired *Conley* "no set of facts" language. Therefore, this Court should affirm the decision of the Thirteenth Circuit, dismissing Petitioners' Complaint for failure to state a claim.

D. Petitioners' Complaint was Properly Dismissed Because Insistence on Some Specificity Will Avoid the Enormous Expenditure of Time and Money.

Over three decades ago, this Court held that "a district court must retain the power to insist upon some specificity in pleadings before allowing a potentially massive factual

controversy to proceed." *Assoc. Gen. Contractors of Cal., Inc. v. Carpenters*, 459 U.S. 519, 528 n.17 (1983). Since then, this Court has discussed in detail the policy ramifications behind not allowing a barebones complaint to stand. Rule 12(b)(6) "streamlines litigation by dispensing with needless discovery and fact finding." *Neitzke*, 490 U.S. at 326-27. The *Twombly* Court elucidated "the practical significance of the Rule 8 entitlement requirement" when it demanded an allegation of something more than slight chance, "lest a plaintiff with "a largely groundless claim" be allowed to "take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value." *Twombly*, 550 U.S. at 557-58 (*citing Dura Pharms., Inc. v. Broudo*, 544 U.S. 336 (2005).

This Court further stated, "when the allegations in a complaint … [can] not raise a claim of entitlement to relief, "this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court."" *Twombly*, 550 U.S. at 558 (*citing Wright, supra,* § 1216, at 233-34 (*quoting Daves v. Hawaiian Dredging Co.*, 114 F. Supp. 643, 645 (D. Haw. 1953))). "[I]t is only by taking care to require allegations that reach the level suggesting [a cause of action] that we can hope to avoid the potentially enormous expense of discovery in cases with no "reasonably founded hope that the [discovery] process will reveal relevant evidence" to support a . . . claim." *Twombly*, 550 U.S. at 559 (citation omitted). "Because discovery … takes such a high toll on litigants and courts, it has become important to expose pleading deficiencies early in the litigation, before the toll becomes disproportionate to the claim." Andree Sophia Blumstein, *Cover Story: A Higher Standard*, 43 Tenn. B.J. 12, 14 (2007). Additionally, this Court explicitly stated that it was concerned about increasing the caseload of the courts, and that "the threat of discovery [would] push cost-conscious defendants to settle even anemic cases before reaching those proceedings." *Twombly*, 550 U.S. at 559.

Other courts have discussed this concern as well. *See Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 995 (N.D. Ill. 2003) ("some threshold of plausibility must be crossed at the outset before a . . . case should be permitted to go into its inevitably costly and protracted discovery phase"); *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1106 (7th Cir. 1984) ("the costs of modern federal . . . litigation and the increasing caseload of the federal courts counsel against sending the parties into discovery when there is no reasonable likelihood that the plaintiffs can construct a claim from the events related in the complaint.")

Although the *Twombly* decision sounded in antitrust, "the decision was based on [the Court's] interpretation and application of Rule 8." *Ashcroft*, 129 S. Ct. at 1953. "That Rule [sic] in turn governs the pleading standard "in all civil actions and proceedings in the United States district courts."" *Ashcroft*, 129 S. Ct. at 1953 (*citing* Fed. R. Civ. P. 1). As such, Petitioners' Complaint failed to state a claim under the *Twombly* pleadings rules. Therefore, this Court should affirm the decision of the Thirteenth Circuit, dismissing Petitioners' Complaint for failure to state a claim.

CONCLUSION

For the aforementioned reasons, Respondent respectfully requests that this Court reverse the decision of the Thirteenth Circuit and hold that the Vaccine Act preempts all state law claims that a vaccine was defectively designed, and affirm the decision of the Thirteenth Circuit dismissing Petitioners' Complaint for failure to state a claim.

Respectfully submitted,

Team 17, Counsel for Respondent

Date: March 12, 2010

APPENDIX A

U.S. Const. art. VI, cl. 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. amend. I

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

U.S. Const. amend. V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

APPENDIX B

TITLE 15. COMMERCE AND TRADE
CHAPTER 1. MONOPOLIES AND COMBINATIONS IN RESTRAINT OF TRADE

§ 1. Trusts, etc., in restraint of trade illegal; penalty.

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
SUBCHAPTER XIX. VACCINES
PART 2. NATIONAL VACCINE INJURY COMPENSATION PROGRAM

Subpart A. Program Requirements.

§ 300aa-14. Vaccine Injury Table.

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT; Td, or TT)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Brachial Neuritis	2-28 days

	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
II. Vaccines containing whole-cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTaP, DTP, P, DTP-HiB)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Encephalopathy (or encephalitis)	72 hours
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Encephalopathy (or encephalitis)	5-15 days (not less than 5 days and not more than 15 days) for measles, mumps, rubella, or any vaccine containing any of the foregoing as a component.
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
IV. Vaccines containing rubella virus (e.g., MMR, MR, R)	A. Chronic arthritis	7-42 days
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

V. Vaccines containing measles virus (e.g., MMR, MR, M)	A. Thrombocytopenic purpura	7-30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient	6 months
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio -- in a non-immunodeficient recipient -- in an immunodeficient recipient -- in a vaccine-associated community case	 30 days 6 months Not applicable
	B. Vaccine-Strain Polio Viral Infection -- in a non-immunodeficient recipient -- in an immunodeficient recipient -- in a vaccine-associated community case	 30 days 6 months Not applicable
	C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
VII. Vaccines containing polio inactivated virus (e.g., IPV)	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Any acute complication sequela (including death) of an illness, disability, injury, or condition	Not applicable

	referred to above which illness, disability, injury or condition arose within the time period prescribed	
VIII. Hepatitis B. vaccines	A. Anaphylaxis or anaphylactic shock	4 hours
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
IX. Hemophilus influenzae type b polysaccharide vaccines (unconjugated, PRP vaccines)	A. Early-onset Hib disease	7 days
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury or condition arose within the time period prescribed	Not applicable
X. Hemophilus influenzae type b polysaccharide conjugate vaccines	No condition specified	Not applicable
XI. Varicella vaccine	No condition specified	Not applicable
XII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage	No condition specified	Not applicable

§ 300aa-16. Limitations of actions.

(a) General rule. In the case of--

> (2) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this part, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence

of the first symptom or manifestation of onset or of the significant aggravation of such injury . . .

Subpart B. Additional Remedies.

§ 300aa-22. Standards of responsibility.

(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 the effective date of this part [effective Oct. 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. §§ 301 *et seq*.] and section 351 of the Public Health Service Act [42 U.S.C. § 262] (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 2123(d)(2) [42 U.S.C. § 300aa-23(d)(2)(A) or (B)], 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).

§ 300aa-23. Trial.

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, which is not barred by section 300aa-11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa-22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa-22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 301 *et seq*.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in--

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines, which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

Subpart C. Assuring a Safer Childhood Vaccination Program in the United States.

§ 300aa-27. Mandate for Safer Childhood Vaccines.

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall--

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines . . .

CODE OF FEDERAL REGULATIONS
TITLE 21. FOOD AND DRUGS
CHAPTER I. FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER F. BIOLOGICS
PART 610. GENERAL BIOLOGICAL PRODUCTS STANDARDS

Subpart B. General Provisions.

§ 610.15 Constituent materials.

(a) Ingredients, preservatives, diluents, adjuvants. All ingredients used in a licensed product, and any diluent provided as an aid in the administration of the product, shall meet generally accepted standards of purity and quality. Any preservative used shall be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient, and in the combination used it shall not denature the specific substances in the product to result in a decrease below the minimum acceptable potency within the dating period when stored at the recommended temperature. Products in multiple-dose containers shall contain a preservative, except that a preservative need not be added to Yellow Fever Vaccine; Poliovirus Vaccine Live Oral; viral vaccines labeled for use with the jet injector; dried vaccines when the accompanying diluent contains a preservative; or to an Allergenic Product in 50 percent or more volume in volume (v/v) glycerin. An adjuvant shall not be introduced into a product unless there is satisfactory evidence that it does not affect adversely the safety or potency of the product. The amount of aluminum in the recommended individual dose of a biological product shall not exceed:

(1) 0.85 milligrams if determined by assay;

(2) 1.14 milligrams if determined by calculation on the basis of the amount of aluminum compound added; or

(3) 1.25 milligrams determined by assay provided that data demonstrating that the amount of aluminum used is safe and necessary to produce the intended effect are submitted to and approved by the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research (see mailing

addresses in § 600.2 of this chapter).

RULES AND REGULATIONS
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
21 CFR PARTS 201, 314, AND 601
[DOCKET NO. 2000N-1269] (FORMERLY DOCKET NO. 00N-1269)
RIN 0910-AA94
REQUIREMENTS ON CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS
TUESDAY, JANUARY 24, 2006
AGENCY: FOOD AND DRUG ADMINISTRATION, HHS.

ACTION: Final rule.

FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law. Indeed, the Department of Justice (DOJ), on behalf of FDA, has filed a number of amicus briefs making this very point. In order to more fully address the comments expressing concern about the product liability implications of revising the labeling for prescription drugs, we believe it would be useful to set forth in some detail the arguments made in those amicus briefs. The discussion that follows, therefore, represents the government's long standing views on preemption, with a particular emphasis on how that doctrine applies to State laws that would require labeling that conflicts with or is contrary to FDA-approved labeling.

Under the act, FDA is the expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading. Under the act and FDA regulations, the agency makes approval decisions based not on an abstract estimation of its safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling (21 U.S.C. § 355(d)). FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to the use of the product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance. The centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively. FDA carefully controls the content of labeling for

a prescription drug, because such labeling is FDA's principal tool for educating health care professionals about the risks and benefits of the approved product to help ensure safe and effective use. FDA continuously works to evaluate the latest available scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate.

Changes to labeling typically are initiated by the sponsor, subject to FDA review, but are sometimes initiated by FDA. Under FDA regulations, to change labeling (except for editorial and other minor revisions), the sponsor must submit a supplemental application fully explaining the basis for the change (§§ 314.70 and 601.12(f) (21 CFR 314.70 and 601.12(f))). FDA permits two kinds of labeling supplements: (1) Prior approval supplements, which require FDA approval before a change is made (§§ 314.70(b) and 601.12(f)(1)); and (2) "changes being effected" (CBE) supplements, which may be implemented before FDA approval, but after FDA notification (§§ 314.70(c) and 601.12(f)(2)). While a sponsor is permitted to add risk information to the FPI without first obtaining FDA approval via a CBE supplement, FDA reviews all such submissions and may later deny approval of the supplement, and the labeling remains subject to enforcement action if the added information makes the labeling false or misleading under section 502(a) of the act (21 U.S.C. § 352). Thus, in practice, manufacturers typically consult with FDA prior to adding risk information to labeling. As noted in response to comment 5, however, a sponsor may not use a CBE supplement to make most changes to Highlights.

Since the proposed rule was published, FDA has learned of several instances in which product liability lawsuits have directly threatened the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the act. In one case, for example, an individual plaintiff claimed that a drug manufacturer had a duty under California State law to label its products with specific warnings that FDA had specifically considered and rejected as scientifically unsubstantiated. In some of these cases, the court determined that the State law claim could not proceed, on the ground that the claim was preempted by Federal law, or was not properly before the court by operation of the doctrine of primary jurisdiction. In some cases, however, the court has permitted the claim to proceed.

State law actions can rely on and propagate interpretations of the act and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate. For example, courts have rejected preemption in State law failure-to-warn cases on the ground that a manufacturer has latitude under FDA regulations to revise labeling by adding or strengthening warning statements without first obtaining permission from FDA. In fact, the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act. A manufacturer may, under FDA regulations, strengthen a labeling warning, but in practice manufacturers typically consult with FDA before doing so to avoid

implementing labeling changes with which the agency ultimately might disagree (and that therefore might subject the manufacturer to enforcement action). (citations and footnotes omitted).

APPENDIX C

Federal Rule of Civil Procedure 1. Scope of Rules.

These rules govern the procedure in all civil actions and proceedings in the United States district courts, except as stated in Rule 81. They should be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding.

Federal Rule of Civil Procedure 8. General Rules of Pleading.

(a) Claims for Relief.

A pleading that states a claim for relief must contain:

(1) a short and plain statement of the grounds for the court's jurisdiction, unless the court already has jurisdiction and the claim needs no new jurisdictional support;
(2) a short and plain statement of the claim showing that the pleader is entitled to relief; and
(3) a demand for the relief sought, which may include relief in the alternative or different types of relief.

(b) Defenses; Admissions and Denials.

(1) In General.

In responding to a pleading, a party must:

(A) state in short and plain terms its defenses to each claim asserted against it; and

(B) admit or deny the allegations asserted against it by an opposing party.

(2) Denials — Responding to the Substance.

A denial must fairly respond to the substance of the allegation.

(3) General and Specific Denials.

A party that intends in good faith to deny all the allegations of a pleading — including the jurisdictional grounds — may do so by a general denial. A party that

does not intend to deny all the allegations must either specifically deny designated allegations or generally deny all except those specifically admitted.

(4) Denying Part of an Allegation.

A party that intends in good faith to deny only part of an allegation must admit the part that is true and deny the rest.

(5) Lacking Knowledge or Information.

A party that lacks knowledge or information sufficient to form a belief about the truth of an allegation must so state, and the statement has the effect of a denial.

(6) Effect of Failing to Deny.

An allegation — other than one relating to the amount of damages — is admitted if a responsive pleading is required and the allegation is not denied. If a responsive pleading is not required, an allegation is considered denied or avoided.

Federal Rule of Civil Procedure 12. Defenses and Objections: When and How Presented; Motion for Judgment on the Pleadings; Consolidating Motions; Waiving Defenses; Pretrial Hearing.

(b) How to Present Defenses.

Every defense to a claim for relief in any pleading must be asserted in the responsive pleading if one is required. But a party may assert the following defenses by motion:

(6) failure to state a claim upon which relief can be granted.

A motion asserting any of these defenses must be made before pleading if a responsive pleading is allowed. If a pleading sets out a claim for relief that does not require a responsive pleading, an opposing party may assert at trial any defense to that claim. No defense or objection is waived by joining it with one or more other defenses or objections in a responsive pleading or in a motion.