IN THE SUPREME COURT OF THE UNITED STATES

April Term 2010

DAN COOKS, *ET AL.*,

Petitioners

-V-

CAROLINA LABORATORIES, INC.

Respondent

ON WRIT OF CERTIORARI TO THE

UNITED STATES COURT OF APPEALS

FOR THE THIRTEENTH CIRCUIT

Team 8

Attorneys for Petitioners

QUESTIONS PRESENTED FOR REVIEW

1. Did the Circuit Court of Appeals properly rule that state products liability suits for design defects are not preempted by the National Childhood Vaccine Injury Act of 1986?
2. Did the appellate court properly apply the *Twombly* pleading rules when it granted Respondent's motion to dismiss under Federal Rule of Civil Procedure 12(b)(6)?

TABLE OF CONTENTS

TABLE OF CITED AUTHORITIES iv

CONSTITUTIONAL PROVISIONS, TREATIES, STATUTES, ORDINANCES, AND REGULATIONS INVOLVED IN THIS CASE vi

STATEMENT OF THE CASE 1

SUMMARY OF ARGUMENT 4

ARGUMENT 7

I. THE VACCINE ACT DOES NOT PRE-EMPT ALL DESIGN DEFECT CLAIMS AGAINST VACCINE MANUFACTURERS BECAUSE THE PLAIN LANGUAGE OF THE ACT RUNS CONTRARY TO THIS PROPOSITION, CONGRESS DID NOT INTENT SUCH A PREEMPTION WHEN IT ADOPTED COMMENT K OF RESTATEMENT (SECOND) OF TORTS §402A INTO THE ACT, AND THE LEGISLATIVE HISTORY OF THE ACT DEMONSTRATES CONCURRENT FEDERAL AND STATE JURISDICTION. 7

A. *Introduction* 7

B. *Properly interpreted through canons of statutory interpretation and with an understanding that Congress does not cavalierly pre-empt traditional areas of state law, the plain text of the Act allows state tort claims for design defects* 9

C. *Proper application of the majority rule regarding comment K requires that the Act allow products liability suits for products that can be made reasonable safe, to be determined on a case-by-case basis.* 13

D. *The plain language of the 1986 committee report demonstrates congress' contemplation of concurrent federal and state litigation under the Act.* 16

II. THE APPELLATE COURT ERRED IN APPLYING THE *TWOMBLY* PLEADING RULES TO THE COOKS' COMPLAINT AND SHOULD NOT HAVE GRANTED RESPONDENT'S MOTION TO DISMISS UNDER RULE 12(B)(6) OF THE FEDERAL RULES OF CIVIL PROCEDURE. 19

A. *The recent Supreme Court decisions of* Twombly *and* Iqbal *are limited in scope to their individuals facts and therefore do not overrule fifty years of Supreme Court precedent in determining a Rule(12)(b)(6) motion to dismiss for an unrelated factual dispute.* 19

B. *The Cooks' complaint sufficiently states a claim upon which relief can be granted and is not susceptible to the same deficiencies of parallel conduct and conclusory allegations as the complaints in* Twombly *and* Iqbal, *respectively.* 26

C. .....*The Cooks' complaint should not be dismissed for failure to state a claim because public policy dictates that any factual inadequacies be resolved through judicial oversight of the discovery process, not the grant of a motion to dismiss.* 28

CONCLUSION.....32

TABLE OF CITED AUTHORITIES

CASES:

Abbot v. American Cyanamid Co., 844 F.2d 1108 (4th Cir. 1988).....16

Am. Home Products Corp. v. Ferrari, 284 Ga. 384 (2008).....7, 8, 10, 17

Ashcroft v. Iqbal, --- U.S. ---, 129 S. Ct. 1937 (2009).....5-6, 19-31

Bailey v. Janssen Pharmaceutica, Inc., 288 Fed. App'x 597 (11th Cir. 2008).....30

Ballard v. Wall, 413 F.3d 510 (5th Cir.2005).....20

Bates v Dow AgroSciences, L.L.C., 544 U.S. 431 (2005).....9, 16, 17

Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007).....3-5, 19-29, 31

Blackman v. Am. Home Products Corp., 328 F. Supp. 2d. 659 (S.D. Tex. 2004).....7, 14

Bruesewitz v. Wyeth, Inc., 561 F.3d 233 (3rd Cir. 2009).....7, 12, 13, 15, 18

Caminetti v. United States, 242 U.S. 470 (1917).....9-11, 15, 16

Carcieri v. Salazar, --- U.S. ---, 129 S. Ct. 1058 (2009).....9

Cooks v. Carolina Laboratories, No. 09-1032 (13th Cir Aug 6, 2009).....7, 11

Conley v. Gibson, 355 U.S. 41 (1957).....4, 5, 20, 21, 26

Connecticut National Bank v. Germain, 503 U.S. 249 (1992).....9

Continental Colleries v Shober, 130 F.2d 631 (3d Cir. 1942).....20

In re Digitek Products Liability Litigation, 2009 WL2433468 (S.D. W.Va. Aug. 3, 2009) ...30

Dioguardi v. Durning, 139 F.2d 774 (2d Cir.1944) 20

Graham v. Wyeth, 666 F. Supp. 1483 (Kan. 1987) 16

Iqbal v. Hasty, 490 F.3d 143 (2d Cir. 2007) 24

Leimer v. State Mutual Life Assur. Co., 108 F.2d 302 (8th Cir. 1940).....20

Medtronic v. Lohr, 518 U.S. 470 (1996) 10

Militrano v. Ledere Laboratories, 810 N.Y.S.2d. 506 (2006) 7, 14

Morris v. Parke, Davis & Co., 667 F. Supp. 1332 (C.D. Ca. 1987) 12

Priester v. Lowndes County, 354 F.3d 414 (5th Cir. 2004).....20

Swierkiewicz v Sorema N.A., 534 U.S. 506 (2002).....20

Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289 (E.D. Pa. 2007).....7, 14

United States v. Gonzales, 520 U.S. 1 (1997). 9

Williams v. Pfizer, Inc., 2009 WL 1362783 (W.D. La., 2009) 30

FEDERAL RULES:

Fed. R. Civ. P. 8(a)(2)..... 19-21

Fed. R. Civ. P. 12(b)(6)..... 1, 5, 19, 20, 23-26

Fed. R. Civ. P. 12(e) 21

Fed. R. Civ. P. 12(f).....21

Fed. R. Civ. P. 15.....21

Fed. R. Civ. P. 16.....21

Fed. R. Civ. P. 26-37.....21

Fed. R. Civ. P. 56.....21

ARTICLES AND TREATISES

Erika L. Amarante, New Pleading Standards in Federal Court:
Will They Impact Franchise Cases? 29(2) Franchise L. J.
(Fall 2009), available at http://www.wiggin.com/db30/cgi-
bin/pubs/New%20Pleading%20Standards%20in%20
Federal%20Court,%20FLJ,%2010.09.pdf.....19, 20, 23, 28, 29

5 Wright & Miller, Federal Practice and Procedure: Civil 3d § 1216 (Supp. 2009).....19, 23

CONSTITUTIONAL PROVISIONS, TREATIES, STATUTES, ORDINANCES, AND REGULATIONS INVOLVED IN THIS CASE

National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-1 *et seq.*

STATEMENT OF THE CASE

A. Preliminary Statement

This is an appeal from a judgment of the United States Court of Appeals for the Thirteenth Circuit, decided August 6, 2010. Appellants Dan and LoEtta Cooks initially filed a timely petition for compensation on the minor daughter's behalf with the National Vaccine Injury Compensation Program ("NVICP") on September 3, 2001. The Cooks filed a notice of withdrawal in the NVCIP, and the Clerk of the U.S. Court of Federal Claims entered judgment on January 14, 2004, under 42 U.S.C. § 300aa-21(b). Thereafter, the Cooks filed an election to file a civil action on January 21, 2004, under 42 U.S.C. §300aa-21(a).

The Cooks filed their initial complaint in the Wicked County Court of Common Pleas, and thereafter the Court granted Appellee-Defendant's filing for removal to the United States District Court for the District of Grace. On March 14, 2007, the Cooks filed their complaint with the District Court, to which Appellee-Defendant responded with a Motion to Dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. On March 25, 2008, the District Court granted Appellee-Defendant's motion to dismiss.

Thereafter, the Cooks filed an appeal to the United States District Court of Appeals for the Thirteenth Circuit. On August 6, 2009, the Appeals Court affirmed the District Court's opinion granting Appellant-Defendant's motion to dismiss. In response, the Cooks filed a Writ of Certiorari with this court, which was granted.

B. Statement of Facts

Dan and LoEtta Cooks come before this Court on behalf of themselves and their developmentally disabled twelve-year old daughter, Estella Marie Cooks. Like millions of children every year, Estella Marie was vaccinated as a child. Between March 1998 and October 1998, she received three doses of Carolina Laboratories' Diphtheria and Tetanus Toxoids and Pertussis ("DTP") – Haemophilus influenzae type b ("Hib") combination vaccine. (R.1.). But after receiving this vaccine, Estella Marie developed a host of neurological injuries. (R.1). The many injuries from which young Estella Marie suffers include developmental delays, learning disabilities, social delays and deficits, motor skill impairment, gastrointestinal illness, and immune system dysfunction. (R.1.).

Appellant-Defendant's vaccine contains a preservative, known as thimerosal, made up of about fifty percent by weight of the toxic substance mercury. (R.1.). The Cooks allege that Appellant-Defendant's vaccine is toxic and directly caused Estella Marie's neurological injuries. (R.1.).

Originally, the Cooks filed a timely petition for compensation of Estella Marie's vaccine-caused injuries with the NVICP on September 3. 2001. (R.1.) But on November 5, 2003, the Cooks filed a notice of withdrawal, electing instead to file a civil action to vindicate their tort rights under 42 U.S.C. § 300aa-21(a). (R.2.)

First, they allege that Appellee-Defendant negligently failed conduct adequate safety tests to determine whether the level of the thimerosal preservative containing toxic mercury was safe and non-toxic to humans in the vaccine doses administered to children. (R.2.). And in Count II, the Cooks assert strict products liability for design defect because the vaccine was defectively

designed and a safer alternative existed. (R.2.). The Cooks seek damages to care for their developmentally disabled daughter, included compensation for the damage done to Estella Marie, costs, punitive damages, and any other relief that the court deems appropriate. (R.2.).

After the District court granted Appellee-Defendant's motion to dismiss, the Cooks appealed to the United States Court of Appeals for the Thirteenth Circuit. The Thirteenth Circuit held that the Vaccine Act "does not preempt all design defect claims against vaccine manufacturers" such as Appellee-Defendant. (R.12). However, the court inappropriately applied the sufficiency rule established in *Bell Atl. Corp. v. Twombly* to this case and upheld the lower court's motion to dismiss on this ground only. 550 U.S. 544, 555 (2007). (R.13.).

SUMMARY OF THE ARGUMENT

A. Design Defect Products Liability Claims are Not Preempted By the Vaccine Act

The Vaccine Act does not expressly preclude state tort products liability design defect claims. Canons of statutory interpretation require that the Court give full effect to the plain language of a statute in order to properly effectuate Congress's intent. And in situations where a question of federal preemption of laws traditionally left to the purview of the states occurs, absent any specific decree to the contrary, a stature must be read to disfavor preemption. The plain language of the Vaccine Act thus contemplates the possibility of state products liability design defect claims because it does not expressly preempt such cases.

Moreover, Congress' adoption of comment k from the Restatement Second of Torts §402(A) evidences their intent to allow individual state lawsuits for products that can, through some reasonable alternative design, be made safe. The language of comment k specifically exempts vaccine manufacturers for products that are "unavoidably unsafe." This court should adopt the holding of the majority of states in this country that comment k's language leaves open the possibility of products liability design defect claims.

Finally, even if the Court is disinclined to adopt the language of the statute on its face, the legislative history of the Act demonstrates Congress's understanding that the Act contemplates concurrent federal and state jurisdictions.

B. The *Twombly* Pleading Rules Were Improperly Applied in Dismissing This Complaint

Decided in 1957, *Conley v. Gibson* has long served as the standard for determining the sufficiency of a complaint in the face of a motion to dismiss for failure to state a claim under

Federal Rule of Civil Procedure 12(b)(6). In 2007, when the Supreme Court decided *Bell Atl. Corp. v. Twombly*, it was suggested that the *Conley* formulation had been replaced with an enhanced pleading standard that required plausibility and the absence of the possibility of legal parallel conduct. Two years later, *Iqbal v. Ashcroft* took the pleading standards a step farther, stating that the pleading standards advanced in *Twombly* applied to all civil cases and that conclusory allegations were insufficient to survive a motion to dismiss. However, both of these cases should be applied narrowly and construed to require heightened pleading for only their specific contexts, alleged antitrust violations and prisoner civil rights violations, respectively. This narrow interpretation is required as recognition of the unique factual contexts presented by *Twombly* and *Iqbal*. Furthermore, this motion to dismiss should be denied in accordance with the acceptance of *Conley* in 16 prior Supreme Court writings and 26 state's (plus the District of Columbia's) formulations of pleading standards in order to comply with a long-established legal standard and to provide predictability and stability within the courts' pleading system.

In addition, even if this Court were to apply broadly the enhanced pleading standards of *Twombly* and *Iqbal* to this entirely distinct case, the pleading deficiencies present in those cases are not present here. Whereas *Twombly* faced the possibility of legal parallel conduct and *Iqbal* confronted conclusory allegations, neither of those problems are presented here. In contrast, Carolina Laboratories can present no evidence to suggest that it was engaged in legal parallel conduct that caused a failure to adequately test the Hib vaccine, as alleged in the complaint. Additionally, the Cooks have been able to provide both specific and general allegations that contain information about the type of drug involved, its contents, its dosage, and the timeline of the distribution of its dosage that are sufficient to survive a Rule 12(b)(6) motion to dismiss. In so doing, the Cooks have sufficiently called attention to the potentially dangerous levels of ethyl

mercury, a substance known by the Defendant to have neurotoxin properties, contained in the Hib vaccine. Therefore, these claims are sufficiently specific to give notice to Carolina Laboratories of the claims presented and the factual basis for these claims so that Carolina Laboratory may be expected to defend its interests pertaining to these claims.

Finally, public policy dictates that the motion to dismiss should be denied because the costs of discovery in this action will not be overly burdensome because the Cooks are only seeking information on the testing of one drug, presumably a minor portion of Carolina Laboratories overall testing program. Additionally, the information that the Cooks seek pertaining to the vaccine's defects is proprietary to Carolina Laboratories and could not be known by the Cooks through any other means than disclosure from Carolina Laboratories via discovery. Lastly, whereas the Court in *Iqbal* worried that allowing the case to proceed would hinder the Federal Government's ability to respond to a national security crisis, here the Cooks' case should be allowed to proceed to discovery in order to promote public health and deter failures to adequately test vaccines before their public use.

ARGUMENT

I. THE VACCINE ACT DOES NOT PRE-EMPT ALL DESIGN DEFECT CLAIMS AGAINST VACCINE MANUFACTURERS BECAUSE THE PLAIN LANGUAGE OF THE ACT RUNS CONTRARY TO THIS PROPOSITION, CONGRESS DID NOT INTENT SUCH A PREEMPTION WHEN IT ADOPTED COMMENT K OF RESTATEMENT (SECOND) OF TORTS §402A INTO THE ACT, AND THE LEGISLATIVE HISTORY OF THE ACT DEMONSTRATES CONCURRENT FEDERAL AND STATE JURISDICTION.

A. *Introduction*

Appellants Dan and LoEtta Cooks, individually and on behalf of their minor daughter, have come to this Court to guarantee their rights to sue Carolina Laboratories, Inc. for design defect claims under the laws of the State of Grace. Hiding behind the veil of the National Childhood Vaccine Act of 1986, Appellee-Defendant Carolina Labs attempts to shield itself from liability for its failure to conduct adequate tests to determine whether vaccines made with thimerosal were safe or a safer alternative existed. The court below overturned the District Court's ruling and recognized Appellant's right to bring a design defect claim against Carolina Labs, noting that to determine otherwise would "have the perverse effect of granting complete tort immunity from design defect liability to an entire industry." *Cooks v. Carolina Laboratories*, No. 09-1032 (13th Cir. Aug 6, 2009). Appellants ask this Court to uphold their right to bring a state tort claim.

There exists little published case law considering whether the Act preempts all vaccine design defect claims. *See e.g.*, *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233 (3d Cir. 2009), *cert. granted*, 2010 U.S. Lexis 2266 (U.S. Mar 8. 2010.); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289 (E.D. Pa 2007); *Blackmon v. Am. Home Products Corp.*, 328 F. Supp. 2d. 659 (S.D. Tex. 2004); *Am. Home Products Corp. v. Ferrari*, 284 Ga. 384 (2008); *Militrano v. Ledere Laboratories*, 810 N.Y.S.2d 506 (2006). But even from this dearth of published case law rise two distinct interpretations of the Act – either the Act allows limited state tort suits for design defect

claims, or it fully preempts all state tort claims. The majority of published decisions have incorrectly agreed with the latter position. Appellants argue to the contrary and urge this court to apply the reasoning of the Georgia Supreme Court in *Ferrari* and hold Appellees liable in tort for their defectively designed vaccines.

Appellants adopt the argument of the *Ferrari* Court as their own. In *Ferrari* the Georgia Supreme Court gave three distinct reasons for their ruling allowing state design defect tort claims under the Act: 1) A full examination of the text of the statute demonstrates that total preemption is not proper under the statute; 2) A proper application of Comment K of the Second Restatement of Torts §402A bars liability only for vaccine side effects that are unavoidable; and 3) Congress intended that the Act not act as a complete bar to state tort suits, as evidenced by the 1986 House Committee reports accompanying the Act.. 284 Ga. at 386, 390.

Accordingly, Appellants request that this court uphold the Thirteenth Circuit Appeals Court's ruling that the Act does not preclude all state tort claims. First, the language of the Act itself expressly notes that it does not preempt state tort claims for design defects. Next, because the act draws upon Comment K of Section 402A of the Restatement of Torts, products liability tort claims based upon products that can be made reasonably safe must be allowed under state law. Finally, not only does the language of the act expressly provide for state tort claims for design defect, but the committee reports behind the Act demonstrate that Congress intended to specifically allow such state tort claims for design defect. Accordingly, this Court should uphold the Appeals Court's ruling that the Act allows Appellants to bring a products liability design defect claim against Carolina Labs under the laws of the State of Grace.

B. *Properly interpreted through canons of statutory interpretation and with an understanding that Congress does not cavalierly pre-empt traditional areas of state law, the plain text of the Act allows state tort claims for design defects.*

Lending most credence to Appellants' argument is the plain text of the Act itself. The National Childhood Vaccine Act of 1986 expressly precludes claims state tort claims for injury or death resulting from "side effects that [are] unavoidable." 42 U.S.C. §300aa-22(b)(1) (1986). Applying proper and well-established canons of statutory interpretation to this and other sections of the Act, this Court shall recognize that the Act does not preclude all state tort claims, but rather contemplates concurrent state and federal jurisdiction.

A Court's analysis of the meaning of a statute begins with an examination of the statutory text. *Unites States v. Gonzales*, 520 U.S. 1, 4 (1997). It is indeed elementary that the meaning of a statute must be sought in the language in which it is drafted. *Caminetti v. United States*, 242 US. 470, 485 (1917). "[F]ull effect must be given to the intention of Congress as gathered from the words of the statute," because "they give meaning to the act, and it is neither the duty nor the privilege of the courts to enter speculative fields in search of a different meaning." *Id* at 485, 490. *Accord Carcieri v. Salazar*, 129 S. Ct 1058, 1063-64 (2009) "When the words of a statute are unambiguous, then, [the] first canon is also the last: 'judicial inquiry is complete'" *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 254 (1992), and "no reasons exist to resort to legislative history." *Gonzales*, 520 U.S. at 6.

In this case, because the issue of federal preemption of state laws exists, it is especially important that the Court understands Congress does not "cavalierly pre-empt state-law causes of action" because states are "independent sovereigns" in the federal system. *Bates v. Dow AgroSciences, L.L.C.*, 544 U.S. 431, 449 (2005). Rather, in areas of tradition state regulation, such as tort law, a federal statute does not supplant state law unless Congress clearly voices its

intent to do so. *Id.* The Vaccine Act's text speaks to its own limits, and no broad declaration of Congress's intent to supplant all state tort law can be found therein; the Act is not meant to pre-empt all state tort claims.

To begin, some review of the Act's provisions is required. Subsection 300aa-22(a) of the act reads "[e]xcept as provided in subsections (b), (c), and (e) of [this Act,] State law shall apply to a civil action brought for damages for a vaccine-related injury or death. 42 U.S.C. § 300aa-22(a). And in this case, subsection (b)(1) of the Act is crucial to determine that state tort design defect claims are allowed. "Thus, in construing subsection (b)(1), [a court] is presented with the task of interpreting a statutory provision that expressly pre-empts state law." *Ferrari* at 286 citing *Medtronic v. Lohr,* 518 U.S. 470, 484 (1996) (internal quotations omitted). With an understanding of Congress' express intent to have subsection (b)(1) pre-empt state law, one must then look the language of subsection (b)(1) to determine its limits. Where Congress intends to preempt some state law, a Court must "identify the domain pre-empted" by the language. *Medtronic,* 518 U.S. at 484. A review of subsection (b)(1) is crucial in this inquiry because "full effect must be given to the intention of Congress as gathered from the words of [a] statute," as the words "give meaning to the act, and it is neither the duty nor the privilege of the courts to enter speculative fields in search of a different meaning." *Caminetti*, 242 U.S. at 490.

Subsection (b)(1) reads:

> 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 . . . *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 (emphasis added).

Giving each of Congress's words full effect "used in their ordinary sense and with the meaning commonly attributed to them," *Caminetti*, 242 U.S. at 485, the Act limits subsection (a)'s decree of federal preemption to only those cases in which injury or death results from *unavoidable side effects*. Conspicuously absent from the act is any mention of civil immunity for manufacturers whose vaccines cause side effects that are *avoidable* due to design defect. In rejecting the District court's holding to the contrary, the Appeals Court below noted the absence of congressional intention to create blanket products liability immunity for the entire industry, and specifically wrote that the District Court's holding would "have the perverse effect of granting complete tort immunity from design defect liability to an entire industry." (*Cooks v. Carolina Laboratories*, No. 09-1032 (13th Cir. Aug 6, 2009).

Further language demonstrating Congress's intent to allow state tort law claims can be found in subsection (e) of the act, which explicitly forbids states from precluding individuals from bringing products liability claims against a manufacturer in state court.

Subsection (e) provides:

> Preemption – No State may establish or enforce a law which prohibits an individual from brining 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(e).

This language demonstrates that Congress contemplated concurrent federal and state jurisdiction for claims against vaccine manufacturers. In a contemporaneous ruling by the Central District of California looking at the whole of the newly-enacted Vaccine Act, the court wrote that the statue's language demonstrated that "state law had not previously been, and would not be, preempted by the pertinent [sic] federal statutes and regulations except as expressly provided."

Morris v. Parke, Davis & Co., 667 F. Supp. 1332, 1339 (1987). As explained above, the only suits expressly barred by subsection (b)(1) of the Act are those where an injury or death results from unavoidable side effects. Thus subsections (a) and (e), together, demonstrate Congress' understanding the Act does not preempt state law except as expressly provided. *Morris* at 1440.

Appellee-Defendant's argument must concede the issue that there is a presumption against preemption in areas of traditional state regulation. *Bruesewitz*, 561 F.3d at 240. Regardless, Appellee will probably contend that they possess evidence clear enough to overcome this presumption. *Id.* Likely, Appellee will use the reasoning of the Third Circuit Court's decision in *Bruesewitz* and argue that the Act, read as a whole, clarifies Congress' intent to completely bar all products liability claims against vaccine manufacturers. This is made all the more likely because *Bruesewitz*'s reasoning directly addresses that of the *Ferrari* court, upon which much of Appellant's argument must rely. The *Bruesewitz* court determined, virtually through speculation, that a "clear and manifest" expression of Congressional intent, but then noted that their own interpretation of the Act "does not indicate whether subsection (b) preempts all design defect claims or only strict liability design defect claims." *Id.* at 246-47. But Appellee cannot rely only on the text of the statute itself to support this claim, but must instead support it with multiple references to the legislative history of the Act itself. Such an argument flies in the face of statutory construction. The wording of the Act, as written, does not lend itself to an absurd result, as the *Bruesewitz* claimed. Instead, the Act creates a system whereby those who are able to specifically allege design defect claims and prove a reasonable alternative design to the unreasonably dangerous vaccine preservative thimerosal may avail themselves of the state tort system. Those who are not able to prove this claim then have the

"appealing alternative" of the compensation system. H.R. Rep. 99-908 at 25, as reprinted in 1986 U.S.C.C.A.N. 6344, 6366

Despite Appellee's likely claims to the contrary, the language of the Act, read in full and understood under the canons of statutory interpretation, provides a clear and workable system in which injured parties have options on how to best remedy the damages caused by dangerous vaccines, whether the vaccine is unreasonable dangerous or unavoidably unsafe. This is the most reasonable decision within the framework of presumption against pre-emption.

C. *Proper application of the majority rule regarding comment K requires that the Act allow products liability suits for products that can be made reasonable safe, to be determined on a case-by-case basis.*

Section 402A of the Second Restatement of Torts applies strict liability to sellers of an unreasonably dangerous product in a defective condition. The familiar comment K to this section provides an exception from strict liability to the seller of unavoidably unsafe products, those which "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." *Restat 2d Torts § 402A cmt. k.* Such products may include vaccines. *Id.* However true this general exception may be, comment K itself does not foreclose the possibility of a case-by-case determination of whether a certain side-effect is unavoidable. In fact, as noted by the Third Circuit in *Bruesewitz v. Wyeth,* "a majority of states permit some design defect claims under comment k[.]" 561 F.3d at 247, n.9. *See also Ferrari* 284 Ga. at 389.[1] Because comment k is embodied in the act, there is wide disagreement regarding its application, and since most states utilize a limited, case-by-case application, this Court should rule that

[1] Though the Third Circuit Court agreed with *Ferrari*'s assertion that most states applied comment k on a limited "case by case" basis, it disagreed with the relevance of that fact to the ultimate determination of whether its application barred state tort claims under the Vaccine Act. *Bruesewitz,* 561 F.3d at 247, n.9.

comment k does not stand for the concept that all vaccines are unavoidably unsafe; accordingly, Appellants should be allowed to proceed with their design defect claim.

The cases that analyze subsection (b)(1) of the Act have all correctly recognized that Congress modeled the subsection after comment K to §402A of the Restatement (Second) of Torts. *Ferrari*, 284 Ga. at 388. *Accord Sykes* 484 F.Supp.2d. at 300 ("Congress modeled § 22(b) after comment k in § 402A of the Restatement (Second) of Torts."); *Blackmon*, 328 F.Supp.2d. at 664; *Militrano*, 769 N.Y.S.2d at 844. Congress expressly indicated this fact in the Committee Report accompanying the Vaccine Act, writing "[subsection b] sets forth the principle contained in Comment K of Section 402A of the Restatement of Torts (Second) that a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects[.]" H.R. Rep. 99-908 at 25, as reprinted in 1986 U.S.C.C.A.N. 6344, 6366. The bone of contention is the proper application of comment k within the realm of the Act.

This Court should adopt the reasoning of the *Ferrari* court as its own. The *Ferrari* court noted widespread disagreement in the application of comment k, stating "[m]ost of the states . . . that have adopted Comment k have applied it in a [] limited fashion and on a case-by-case basis." *Ferrari*, 284 Ga. at 389. In fact, "[t]he majority of courts . . . have applied a case-by-case approach in which they consider Comment *k* an affirmative defense and apply a risk/utility balancing test in which the availability of other drugs addressing the same problem is considered in determining whether the particular drug at issue is unavoidably unsafe." *Militrano*, 796 N.Y.S.2d at 532. Since 1985, only "a minority of courts have held that any prescription drug is deemed unavoidably unsafe for purposes of application of Comment *k*, and thus, that defective design claims with respect to such drugs--at least those premised upon strict liability--are barred." *Id.*

Thus, it follows that Congress' incorporation of much of comment k into the Act should allow the majority understanding of comment k to apply to Act. As discussed earlier, subsection (b)(1) holds a vaccine manufacturer immune from civil liability only if a vaccine-related injury is unavoidable. the *Ferrari* court aptly stated, "[t]he conditional nature of this clause contemplates the occurrence of side effects [that] are avoidable, and for which a vaccine manufacturer may be civilly liable." *Ferrari* 284 Ga. at 390. Congress could have simply removed this clause from the Act and made the bar to civil liability conditional on only proper preparation and warnings – making subsection (b)(1) bar civil liability if a vaccine was properly prepared and accompanied by proper direction and warnings. *See id.* Remembering that it is elementary that the meaning of a statute must be sought in the language in which it is drafted, this Court should not simply discount Congress's decision to leave the conditional operator within subsection (b). *Caminetti*, 242 U.S. at 485. As written, the statute bars liability "only for those side effects [that] were unavoidable by means other than proper manufacturing and packaging." *Ferrari* 284 Ga. at 390.

Defendant-Appellee's strongest argument to the contrary arises from the Third Circuit's ruling in *Bruesewitz*, decided after *Ferrari. Bruesewitz* directly attacked the reasoning of the Georgia court – reasoning that (1) a significant minority of courts reject all products liability design defect claims for FDA approved drugs under comment k; (2) "the current state of affairs with regard to the interpretation of comment k tells us little about what Congress knew in 1986 when it passed the Vaccine Act;" and (3) the Court believed that Congress made clear its intentions in invoking comment k. *Bruesewitz*, 561 F.3d at 247, n.9. These arguments do not directly address the specific text of the Act, which when read under general conventions of English grammar belies the Third Circuit's arguments. Certainly, a significant minority of courts reject design defect claims, but the reverse of this argument is also true – the majority of courts

still allow such claims.[2] Moreover, Congress's knowledge in 1986 is irrelevant to an understanding of a statute that plainly contemplates the possibility of a design defect claim. Finally, regardless of the Court's beliefs regarding Congress' intentions, a court's function when interpreting a statute "is to enforce it according to its terms," *Caminetti* at 485, not to substitute its own judgment for that of Congress. If Congress truly intended for the statute to have the effect claimed by the Third Circuit, it surely can amend the Act to state that fact with greater specificity. But such an amendment is conspicuously absent.

Accordingly, this Court should rule that comment k, as applied in the Act by Congress, allows for a case-by-case inquiry into state tort products liability claims, and does not act as a bar to all civil design defect products liability suit against vaccine manufacturers.

D. *The plain language of the 1986 committee report demonstrates congress' contemplation of concurrent federal and state litigation under the Act.*

Appellants' arguments regarding the interpretation of plain language of the Act are sufficient to stand alone. However, further support of Appellants' position can be found in the 1986 committee report on the Act. The legislative history of the Act clarifies that at the time of the Act's passage, Congress expressly intended for state law actions to remain available. *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1113 (4th Cir. 1988). And where Congress intends to deprive injured parties of a long available form of compensation, such as the state tort system, it is assumed that Congress would express that intent clearly. *Bates*, 544 U.S. at 449. Thus even assuming that the language of 42 U.S.C. §300aa-22(b)(1) is ambiguous, the legislative history of

[2] See, e.g. *Graham v. Wyeth*, 666 F.Supp. 1483, 1496 (Kan. 1987) (holding that comment k does not stand for the rule that *all* prescription drugs are unavoidably unsafe as a matter of law).

the act shows no "clear and manifest congressional purpose to supplant state tort law with respect to claims of defective design." *Ferrari*, 284 Ga. at 393. Rather, as there is no express intent to deprive injured parties of their long-standing tort rights, it follows that this Court should leave open the possibility of products liability state tort claims.

The Committee Report first addresses the application of comment k:

> The Committee has set forth Comment K in this bill because it intends that the *principle in Comment K 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. . . .* Governing the existence of the compensation system in this bill, the Committee strongly believes that Comment K is appropriate as necessary as the policy for seeking civil damages in tort. Vaccine-injured persons will now have *an appealing alternative* to the tort system. (emphasis added).

H.R. Rep. 99-908 at 26, as reprinted in 1986 U.S.C.C.A.N. 6344, 6367.

Two brief but important issues arise from this short excerpt; (1) the report notes that comment k's principle regarding "unavoidably unsafe" vaccines should make only "such products," i.e. unavoidably unsafe vaccines, not subject to tort liability; and (2) Congress' recognition that the vaccine compensation system acts as an "alternative" to the tort system.

First, the Report clears ambiguity regarding the proper application of comment k to the act. The construction of the language, even in the Report, is precise and indicates that that only "unavoidably unsafe" vaccines are covered by the bill and not subject to the liability of the tort system. Additionally, the Report speaks of the compensation system as an "appealing alternative" to, rather than a replacement for, the tort system. And where plausible alternative readings of a text exist, the Court has a duty to accept a reading that disfavors preemption. *Bates*, 544 U.S. at 449.

Further investigation of the report reveals the following:

> [Subsection a] establishes certain standards of responsibility with respect to civil actions brought for damages for vaccine-related injuries or death. *In some cases, the standards will be the same or similar to existing state law; in others, the standards will change most State laws.* The committee believes that the establishment of these standards of responsibility is appropriate in light of the availability of a comprehensive and fair compensation system. *However, the establishment of these standards are the only new requirements that affect state law regarding actions for vaccine-related injuries or death; all other aspects of State law remain unchanged.* (emphasis added)

H.R. Rep. 99-908 at 26, as reprinted in 1986 U.S.C.C.A.N. 6344, 6367.

This language obviously contemplates the effect that the Act will have on state law – with the exception of the details specifically outlined by the Act, "all other aspects of State law" regarding actions for injuries or death "remain unchanged." By simply mentioning the concept of state law, Congress shows its intent to preempt only those areas of law that the act specifically mentions. Considering that the majority of the states allow products liability design defect claims for vaccines, and the express preemption of design defect claims for all vaccines never appears, this Court should be bound to interpret the report in a manner that disfavors preemption.

Naturally, using language from this same report, Appellee will argue that Congress "clearly" intended to preempt this area of tort law because "each of the objectives extolled by the Commerce Report would be undermined if design defect claims were permitted under the statute." Bruesewitz, 561 F.3d at 249. But absent specific language from Congress to the contrary, this Court may not favor preemption of state laws.

This Court should rule accordingly and hold that even relying only on Congressional intent via the committee report, subsection (b)(1) does not preempt all design defect claims for

manufacturers, but provides instead that a manufacturer can be held liable for defective design if a case-by-case determination shoes that the particular vaccine was not "unavoidably unsafe."

Congress intended to allow state products liability design defect claims when it ratified the Vaccine Act. Congress' efforts to assist those who have been injured and allow them to avail themselves of the no-fault compensation system have undoubtedly assisted many who were without the resources to file a products liability lawsuit against vaccine manufacturers. However, if this Court allows the Act to foreclose the possibility of all state design defect products liability suits, this country will be left with the perverse after effect of an entire industry completely immune from design defect liability.

II. THE APPELLATE COURT ERRED IN APPLYING THE *TWOMBLY* PLEADING RULES TO THE COOKS' COMPLAINT AND SHOULD NOT HAVE GRANTED RESPONDENT'S MOTION TO DISMISS UNDER RULE 12(B)(6) OF THE FEDERAL RULES OF CIVIL PROCEDURE.

A. *The recent Supreme Court decisions of* Twombly *and* Iqbal *are limited in scope to their individuals facts and therefore do not overrule fifty years of Supreme Court precedent in determining a Rule(12)(b)(6) motion to dismiss for an unrelated factual dispute.*

Federal Rule of Civil Procedure 8(a)(2) states that a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." From its inception, this rule was designed to both simplify the federal pleading standard and remove the harshness of the rigid and aged code-pleading system. *See* Erika L. Amarante, *New Pleading Standards in Federal Court: Will They Impact Franchise Cases?* 29(2) Franchise L. J. (Fall 2009), *available at* http://www.wiggin.com/db30/cgi-bin/pubs/New%20Pleading%20Standards%20in%20Federal%20Court,%20FLJ,%2010.09.pdf (hereinafter "Amarante"); 5 Wright & Miller, Federal Practice and Procedure: Civil 3d § 1216, at 207–08 (Supp. 2009). In so doing, the rule

simply intends to provide a defendant with "fair notice" of the allegations it faces, thereby providing the defendant with an opportunity to respond to the stated claims. *See* Amarante at 1; *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 512 (2002) (*citing Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

To regulate the validity of the notice provided under Federal Rule of Civil Procedure 8(a)(2), the drafters of these rules crafted Federal Rule of Civil Procedure 12(b)(6) as a means of ensuring that improper notice would lead to dismissal of the claim. Accordingly, Rule 12(b)(6) states that a defendant may present a motion to dismiss the claim for "failure to state a claim upon which relief may be granted." However, motions to dismiss under Rule 12(b)(6) are disfavored and are rarely granted. *Priester v. Lowndes County*, 354 F.3d 414, 418 (5th Cir.2004). Moreover, when judging the merits of a Rule 12(b)(6) motion, a court must accept all of the plaintiff's allegations as true. *Ballard v. Wall*, 413 F.3d 510, 514 (5th Cir.2005). This review is best explained by the Supreme Court in *Conley v. Gibson* where the Court stated "the accepted rule [is] 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." 355 U.S. at 45-46. In making this statement, the Supreme Court was merely recognizing case law that had existed throughout the United States Circuit Courts of Appeals for many years. *See e.g.*, *Leimer v. State Mutual Life Assur. Co.*, 8th Cir. 108 F.2d 302 (1940); *Dioguardi v. Durning*, 2d Cir. 139 F.2d 774 (1944); *Continental Colleries v. Shober*, 3d Cir. 130 F.2d 631 (1942).

Additionally, in reversing and remanding the decision of the United States Court of Appeals for the Fifth Circuit, the *Conley* Court reinforced the intention of the drafters of the Rules in that "the Federal Rules of Civil Procedure do not require a claimant to set out in detail

the facts upon which he bases his claim." *Conley*, 355 U.S. at 47. While reiterating the requirement of Rule 8(a)(2) that the plaintiff provide a "short and plain statement of the claim," the Court added that such simplified pleading requirements are both allowable and encouraged by the ability to liberally utilize discovery as a means of filling the gaps in imprecise claims. *Id.* Furthermore, the Court reasoned, other pretrial procedures have been implemented within the Federal Rules of Civil Procedure to "define more narrowly the disputed facts and issues." *Id*; *see e.g.*, Fed. R. Civ. P. 12(e) (motion for a more definite statement); Fed. R. Civ. P. 12(f) (motion to strike portions of the pleading); Fed. R. Civ. P. 16 (pre-trial procedure and formulation of issue); Fed. R. Civ. P. 26-37 (depositions and discovery); Fed. R. Civ. P. 56 (summary judgment); Fed. R. Civ. P. 15 (right to amend). In so doing, "[t]he Federal Rules reject the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept the principle that the purpose of pleading is to facilitate a proper decision on the merits." *Conley*, 355 U.S. at 48.

Since *Conley* was decided in 1957, the Supreme Court has cited it favorably in a dozen decisions and four separate writings. *See, e.g.*, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 577–78 (2007) (Stevens, J., dissenting). None of these opinions "questioned, criticized, or explained away" the validity of *Conley*'s "no set of facts" language as the test for determining when a motion to dismiss should be granted. *Id.* Moreover, 26 States and the District of Columbia adopted the same standard for dismissal of a complaint. *Id* at 578.

When *Bell Atlantic Corp. v. Twombly* was decided in 2007, some 50 years after *Conley* adopted the "no set of facts" standard that had already become an accepted standard in the Circuit Courts of Appeals, the Court expressed its first doubts as to the *Conley* formulation. *Id.* In *Twombly*, the Court considered the sufficiency of a complaint alleging that incumbent local

exchange carriers (ILECs) had violated § 1 of the Sherman Act by engaging in parallel conduct designed to hinder competition and inflate local telephone and Internet service charges. *See id* at 549-551. In particular, it was asserted by a class of subscribers to the local services that the ILECs had coordinated efforts to restrain trade by entering into non-compete agreements amongst themselves and by inhibiting the growth of upstart competitive local exchange carriers (CLECs) by "making unfair agreements with the CLECs for access to the ILEC networks, providing inferior connections to the networks, overcharging, and billing in ways designed to sabotage the CLECs' relations with their own customers." *Id* at 550-551.

In reversing the opinion of the Second Circuit, Justice Souter began the *Twombly* Court's opinion by stating:

> Liability under § 1 of the Sherman Act, 15 U.S.C. § 1, requires a "contract, combination ..., or conspiracy, in restraint of trade or commerce." The question in this putative class action is whether a § 1 complaint can survive a motion to dismiss when it alleges that major telecommunications providers engaged in certain parallel conduct unfavorable to competition, absent some factual context suggesting agreement, as distinct from identical, independent action. We hold that such a complaint should be dismissed.

Id at 548-549. From there, the Court continued to analyze the pleading standards within this narrow framework of a § 1 claim, holding that "[i]n applying these general standards to a § 1 claim…stating such a claim requires a complaint with enough factual matter (taken as true) to suggest that an agreement was made." *Id* at 556. In reliance upon the specific nuances involved with a § 1 claim, the Court deemed it necessary to require that allegations of parallel conduct (the ILECs all acting in the same manner to restrain trade) be accompanied by a factual context that plausibly suggested a preceding agreement between the parallel actors. *See id* at 557. Finding that this contextual background was lacking from the complaint in *Twombly*, the Court reasoned

that the parallel conduct may not have been the result of concerted efforts, but merely coincidentally similar independent actions. *See id.*

Nonetheless, the Court was careful to emphasize that it was not requiring "heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face." *Id* at 570. Since the Court reasoned that the plaintiffs had not "nudged their claims across the line from conceivable to plausible," their complaint was dismissed. *Id.*

Since *Twombly*, the federal district and appeals courts have struggled to reconcile their well-settled and previously undisputed formulation for determining the sufficiency of a complaint and the validity of a corresponding motion to dismiss under Rule 12(b)(6) with the enhanced (but specifically stated in *Twombly* to not be heightened) pleading standards. *See* Amarante at 3; *see also* 2 James Wm. Moore, Moore's Federal Practice 3d § 8.04[1][a] at 8-27 ("The courts of appeals have acknowledged that the *Twombly* opinion creates considerable uncertainty about pleading standards."); 5 Wright & Miller, Federal Practice and Procedure: Civil 3d § 1216, at 39 (Supp. 2009) (noting that "courts continue to struggle with the meaning of 'plausibility'").

Two years later, the Supreme Court attempted to resolve this confusion when it decided *Ashcroft v. Iqbal*. In *Iqbal*, the plaintiff was a Pakistani Muslim arrested on criminal charges and detained by federal officials following the September 11, 2001 terrorist attacks. *See Ashcroft v. Iqbal*, --- US ---, 129 S.Ct. 1937, 1942 (2009). Claiming that he was deprived of various constitutional protections during his detainment, Iqbal filed suit against a number of federal officials, including John Ashcroft, the former Attorney General of the United States, and Robert Mueller, the Director of the Federal Bureau of Investigation. *See id.* Of the allegations made in the complaint, only those made against Ashcroft and Mueller were presented to the Supreme

Court. In these portions of the complaint, Iqbal asserted that Ashcroft and Mueller designated him "a person of high interest" based on his race, religion, or national origin. *Id* at 1944.

Moreover, Iqbal alleged, "the [FBI], under the direction of Defendant MUELLER, arrested and detained thousands of Arab Muslim men ... as part of its investigation of the events of September 11." *Id.* (*citing Iqbal* Complaint ¶ 47, at 164a). Iqbal also claimed "[t]he policy of holding post-September-11th detainees in highly restrictive conditions of confinement until they were 'cleared' by the FBI was approved by Defendants ASHCROFT and MUELLER in discussions in the weeks after September 11, 2001." *Id.* (*citing Iqbal* Complaint ¶ 69, at 168a). Finally, the complaint asserts that Ashcroft and Mueller "each knew of, condoned, and willfully and maliciously agreed to subject" Iqbal to these conditions "as a matter of policy, solely on account of [his] religion, race, and/or national origin and for no legitimate penological interest." *Id.* (*citing Iqbal* Complaint ¶ 96, at 172a-173a). Here, it should also be noted that the complaint refers to Ashcroft as the "principal architect" of the policy, (*Id* (*citing Iqbal* Complaint ¶ 10, at 157a), and Mueller as "instrumental in [its] adoption, promulgation, and implementation." *Id.* (*citing Iqbal* Complaint ¶ 11, at 157a).

After the District Court for the Eastern District of New York overruled a Rule 12(b)(6) motion to dismiss, the Second Circuit affirmed this decision, noting that specific factual allegations are generally only necessary to make a claim plausible. *See Iqbal v. Hasty*, 490 F.3d 143, 157-58 (2d. Cir. 2007). In overruling the Second Circuit, Justice Kennedy adopted two principles from *Twombly*:

> First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions… Second, only a complaint that states a plausible claim for relief survives a motion to dismiss.

Iqbal, 129 S.Ct. at 1949-50. As for the legal conclusions, the Court found the complaint deficient because it lacked facts that plausibly showed that Ashcroft and Mueller acted with a discriminatory intent. *Id* at 1942. Finding nothing in the complaint to suggest this legal conclusion possessed a basis in fact, the Court assumed that this was merely a "threadbare [recital] of the elements of a cause of action, supported by mere conclusory statements [which did] not suffice" to sufficiently state a cause of action that would survive a Rule 12(b)(6) motion to dismiss. *Id* at 1949 (*citing Twombly*, 550 U.S. at 555).

In reaching this decision, the *Iqbal* Court purportedly expanded *Twombly* to "all civil actions." *Id* at 1953. However, it should be noted that Justice Souter, the author of *Twombly* wrote the dissent in *Iqbal*, because *Iqbal* was not simply a proper expansion of the *Twombly* holdings to other areas of law. Instead, the standard advanced in *Iqbal* requires an impermissible determination of fact, a question that should be left to the fact-finder, in deciding whether a complaint is sufficient to survive a motion to dismiss. *See id* at 1959. As explained by Justice Souter, "*Twombly* does not require a court at the motion-to-dismiss stage to consider whether the factual allegations are probably true. We made it clear, on the contrary, that a court must take the allegations as true, no matter how skeptical the court may be." *Id.* Consequently, as explained by the author in *Twombly*, the *Iqbal* court incorrectly interpreted *Twombly*'s meaning.

Furthermore, whereas the complaint in *Twombly* was encumbered by allegations that may have been entirely consistent with legal conduct, the *Iqbal* complaint does not suffer from this same malady. *See id* at 1959. Thus while the naked assertion of conspiracy in *Twombly* was not deemed sufficient to state a claim without some factual enhancements, even Justice Souter believes the claims in *Iqbal* should have been deemed sufficient because they gave Ashcroft and

Mueller "fair notice of what the ... claim is and the grounds upon which it rests." *Id* at 1961 (*citing Twombly,* 550 U.S., at 555 (*quoting Conley* 355 U.S. at 47)).

Thus, having shown that the Court in *Iqbal* improperly expanded the holding in *Twombly* to all other civil actions, it stands to reason that *Twombly* should be limited strictly to cases pertaining to the same type of Sherman Act § 1 violation, as was questioned by the federal district and appeals courts prior to *Iqbal*. Consequently, since this case does not fall within the *Twombly* fact pattern (or the improper *Iqbal* pattern for that matter), the Cooks should not be subjected to the enhanced pleading standards. Such consistency and deference to established Supreme Court case law from 1957 on is necessary to promote predictability and consistency within the courts. Therefore, since the Cooks have given Appellee fair notice of their claims of (1) negligent failure to conduct adequate safety tests to determine whether thimerosal was safe and nontoxic to humans in the doses administered and (2) strict products liability for design defect in that the vaccine was defectively designed and a safer alternative existed, their complaint has sufficiently plead the allegations charged and Appellee' Rule 12(b)(6) motion to dismiss should be denied.

B. *The Cooks' complaint sufficiently states a claim upon which relief can be granted and is not susceptible to the same deficiencies of parallel conduct and conclusory allegations as the complaints in* Twombly *and* Iqbal, *respectively.*

Even if the enhanced pleading requirements of *Iqbal* and *Twombly* were applied to this case, the Cooks' complain is nonetheless sufficient. According to *Iqbal,* the sufficiency of a complaint is to be determined by first identifying and removing all conclusory allegations. *See Iqbal,* 129 S.Ct. at 1950. Then, after assuming the veracity of all well-pleaded factual allegations, the second step is to determine whether the complainant pleads "a claim to relief that

is plausible on its face." *Id* at 1949-50 (*citing Twombly*, 550 U.S. at 570). Here, the Cooks have not stated any conclusory allegations in their complaint. First of all, the Cooks have specifically alleged that their causes of action stem from Appellee' failure to conduct adequate safety tests not just in general, but on a specific vaccine in specific dosages administered during a specific period in a child's life. (R.4.) Thus, an allegation that states Appellee:

> Failed to conduct adequate safety tests to determine whether the thimerosal was safe and nontoxic to humans in the dose administered to infants or small children with each individual injection of a thimerosal-containing shot, with each single-day administration of multiple thimerosal-containing shots, or with the cumulative administration of multiple shots during the first 24 months of a child's life, pursuant to the recommended pediatric immunization schedule

is more than specific enough to constitute a sufficient cognizable claim rather than a mere conclusory allegation. (R.4.). Moreover, even the Cooks' general factual allegations advance the sufficiency of their claims by explaining "the nature of the risks allegedly posed by dangerous levels of ethyl mercury, a substance known by [Appellee] to have neurotoxic properties." (R.4.). Consequently, the Cooks are not susceptible to the dismissal of their claim for stating conclusory allegations similar to those contained in Iqbal's pleading where there was no factual context for suggesting that Ashcroft and Mueller had a discriminatory intent.

As for the plausibility of the Cooks' claims, there is nothing in the record to suggest that their claims are not plausible. Whereas the allegations in *Twombly* could be explained away by a showing of entirely legal parallel conduct, that simply cannot be the case here. In this situation, Appellee either acted negligently by failing to conduct adequate safety testing or they complied with industry standards and conducted the proper tests. There is no middle ground. Thus, this case is not subject to the difficulties of having to prove a negative. While the telecommunication companies in *Twombly* would have to attempt to show a lack of an agreement, here Appellee can

simply disclose their testing results and procedures and it can then be determined as a matter of fact, by a jury, whether they complied with industry standards.

C. *The Cooks' complaint should not be dismissed for failure to state a claim because public policy dictates that any factual inadequacies be resolved through judicial oversight of the discovery process, not the grant of a motion to dismiss.*

In both *Twombly* and *Iqbal*, strong public policy arguments existed for refusing to allow the cases to proceed to discovery, but that is not the case here, where public policy dictates that the Cooks deserve to conduct discovery not just for their own well-being, but also for the health and safety of society. Twombly was a dismissal of 50 years of Supreme Court precedent decided upon the basis of discovery cost concerns pertaining to the investigation of highly-nuanced and secretive business dealings that allegedly precipitated anti-trust violations perpetrated by major telecommunications companies against 90% of subscribers to local telephone or high-speed Internet service over a prolonged period of 7 years. As explained in Justice Stevens' dissent:

> Two practical concerns presumably explain the Court's dramatic departure from settled procedural law. Private antitrust litigation can be enormously expensive, and there is a risk that jurors may mistakenly conclude that evidence of parallel conduct has proved that the parties acted pursuant to an agreement when they in fact merely made similar independent decisions.

550 U.S. at 573.

Moreover, even in dismissing a complaint that the Court deemed not to be plausible, the Court still relied heavily upon its observation that "proceeding to antitrust discovery can be expensive." *Id* at 546; *see also* Amarante at 2. To emphasize that point, the Court noted:

> That potential expense is obvious here, where plaintiffs represent a putative class of at least 90 percent of subscribers to local telephone or high-speed Internet service in an action against America's largest telecommunications firms for unspecified

> instances of antitrust violations that allegedly occurred over a 7-year period.

Id. Additionally, the Court cites its concern that case management and judicial oversight of discovery may not alleviate these expenses and that "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases." Amarante at 2 (*citing Twombly*, 550 U.S. at 559).

Meanwhile, the *Iqbal* Court dismissed the notion proposed by the Second Circuit that Ashcroft and Mueller could be insulated from the heavy costs of discovery through court-supervised and limited discovery. *See id*. Thus, the Court again focused more on the costs involved rather than the pleadings presented, as it stated that litigation against government officials "exacts heavy costs in terms of efficiency and expenditure of valuable time and resources that might otherwise be directed to the proper execution of the work of the Government." *Id.* Furthermore, the Court noted its concern for the "concept of qualified immunity" and the need for high-ranking Government officials to not be "deterred nor detracted from the vigorous performance of their duties." *Id* at 1954.

In contrast, this case concerns a simple complaint filed by one family in regard to one child who received one drug. (R.1) Although the injuries inflicted upon Estella Marie, consisting of neurological injuries that include developmental delays, learning disabilities, social delays and deficits, the impairment of motor skills, gastrointestinal illness, and immune system dysfunction are both debilitating and tragic, the complaint drafted to seek redress of these injuries is quite ordinary in terms of both costs and other burdens. (R.1) In order to solve this dispute, only one family needs to obtain records on one discrete set of testing that occurred over a finite period before the vaccine was put into commercial use. Presuming that Appellee

conducted any testing, the results of this testing would be on record and readily available to Appellee, and could be easily produced at minimal photocopying and digital reproduction costs. Additionally, unlike the burden to be placed upon national security and the Federal Government's ability to respond to a national crisis if Ashcroft and Mueller were forced to proceed through lengthy discovery and court appearances in *Iqbal*, no such crippling effect exists here. Not only is there nothing in the record to indicate that Appellee would be unable to effectively continue its day-to-day functions without any interruption if required to produce documents pertaining to its testing of the Hib vaccine, but surely the hindrance of one laboratory's interests pales significantly in comparison to the importance of the Attorney General and the Director of the FBI to be able to fully perform their daily duties without interruption.

Lastly, and perhaps most importantly, it should be noted that "the very nature of a products liability action—where the cause or source of the defect is not obvious to the consumer—makes it difficult for a plaintiff to pinpoint a specific source of defect against one entity along the chain of distribution prior to discovery." (*Cooks v. Carolina Laboratories,* No. 09-1032 (13th Cir Aug 6, 2009) (*citing Bailey v. Janssen Pharmaceutica, Inc.*, 288 Fed. App'x 597, 605 (11th Cir. 2008)). Recognizing this problem, courts confronted with motions to dismiss in the pharmaceutical industry (an industry quite similar to the vaccine industry in terms of its impact on public health) have been willing to accept pleadings that do not meet the enhanced pleading standards, accepting that this information will be determined as discovery is conducted. *See e.g., Williams v. Pfizer, Inc.*, 2009 WL 1362783 at *4 (W.D. La., 2009) (noting that although the complaint was "understandably lean on specific factual allegations" the plaintiff had alleged a characteristic of the disputed drug that could prove unreasonably dangerous upon the revealing of evidence during discovery); *In re Digitek Products Liability Litigation,* 2009 WL2433468

(S.D. W.Va. Aug. 3, 2009). In so doing, the strong public policy of encouraging public health is advanced by letting the discovery progress to determine if the plaintiff's claim is legitimate, not only to provide a remedy to the plaintiff, but also to prevent these products from harming others in the future.

Here, although Estella Cook is the only potential victim identified in the record, there is certainly the possibility that others may have already been harmed by this vaccine or may be harmed by its future use. Plus, if Appellee is granted a motion to dismiss and allowed to keep its records secretive, this will only incentivize further concealment of potentially dangerous drugs that may or may not be adequately tested. Consequently, public policy favors the further investigation of the Cooks' claim through discovery in order to promote public health and deter unsafe testing practices. Therefore, unlike the concerns of cost and governmental burdens weighing against the continuance of litigation in *Iqbal* and *Twombly*, here public policy strongly supports the survival of the litigation until it can be determined via discovery whether additional facts support the Cooks' claims. Thus, public policy dictates that the motion to dismiss should not have been granted and the decision of the United States Court of Appeals for the Thirteenth Circuit should be reversed and this dispute remanded to the United States District Court for the District of Grace so that the parties may proceed with discovery.

CONCLUSION

For the foregoing reasons, this court should overturn the United States Court of Appeals for the Thirteenth Circuit's decision to grant Appellee's motion to dismiss and hold that Appellants be able to proceed with their state tort products liability claim.

Respectfully Submitted,

Team 8