Team 7

No. 10-1524

In The

Supreme Court of the United States

April Term 2010

Dan Cooks, *et al.,*

Petitioners,

v.

Carolina Laboratories

Respondent.

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

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BRIEF FOR PETITIONERS

COUNSEL FOR PETITIONERS

QUESTIONS PRESENTED

I. DOES THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986 PERMIT DESIGN DEFECT CLAIMS IN STATE COURT WHERE CONGRESS IS SILENT AND THE STATE PROVIDES A REMEDY UNAVAILABLE UNDER FEDERAL LAW?

II. DID THE APPELLATE COURT PROPERLY APPLY THE TWOMBLY PLEADING RULES ON A MOTION TO DISMISS PURSUANT TO CIVIL RULE OF PROCEDURE 12(B)(6) WHERE THE PETITIONER ALLEGES THAT THE RESPONDENT'S USE OF A TOXIC VACCINE LED TO THE INJURIES PETITIONER SUSTAINED?

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STATEMENT OF THE CASE

Statement of the Facts

In March 1996 Estella Cooks received a toxic dose of a DTP/Hib combination vaccine containing a toxic mercury-laden preservative. (R. at 1.) From March 1996 to October 1998, Estella Cooks received two more doses of this harmful vaccine, resulting in injuries through mercury exposure. (R. at 1.) This mercury exposure caused Estella many injuries, including developmental delays, learning disabilities, social delays and deficits, the impairment of motor skills, gastrointestinal illness, and immune system dysfunction. (R. at 1.)

Carolina Laboratories ("Respondent") is responsible for Estella's injuries because it defectively manufactured the DTP/Hib vaccine by employing a Thimerosal preservative, which primarily contains the toxic metal, mercury. (R. at 1.) Carolina Laboratories failed to conduct adequate safety tests to determine whether was safe and to administer mercury-laden preservatives to infants and small children, including Estella Cooks. (R. at 4.) Additionally, Carolina Laboratories failed to conduct adequate safety tests to determine whether each individual injection of a mercury-containing shot, each single-day administration of multiple mercury-containing shots, or the cumulative administration of multiple shots of mercury would injure children during the first twenty-four months of life. (R. at 4.)

On September 3, 2001 Dan and LoEtta Cooks ("Petitioners") filed a petition for compensation on behalf of their daughter on with the National Vaccine Injury Compensation Program ("Vaccine Program" or "compensation program"). (R. at 1.) Filing a petition under the Vaccine Act tolls the statute of limitations for filing a state tort claim and gives petitioners, like the Cooks, a choice to accept a judgment obtained under the compensation program or to reject the judgment and pursue a civil action for damages. (R. at 2.) On November 5, 2003, after

waiting for relief from the compensation program for 793 days, the Cooks filed a notice of withdrawal from the compensation program. The clerk of the vaccine court entered a judgment on the withdrawal on January 14, 2004. A week later, on January 21, 2004, the Cooks notified the Vaccine Program that they were electing to file a civil action. (R. at 2.)

On March 14, 2007, the Cooks filed a two-count complaint under Grace state law in the Wicked County Court of Common Pleas. (R. at 2.) Petitioners alleged, first, that Carolina Laboratories negligently failed to conduct adequate safety tests to determine whether Thimerosal was safe and nontoxic to humans. (R. at 2.) Second, filed a strict liability claim alleging that the vaccine was defectively designed and a safer alternative existed. (R. at 2.)

Procedural History

On March 25, 2008, the United States District Court for the District of Grace found that in a products liability claim it is difficult to pinpoint a specific source of the defect. (R. at 7.) Because it is so difficult to pin-point the source of a design defect, the District Court ruled that it would be nearly impossible for the Cooks to factually state the causal connection to the claim. (R. at 7.) Therefore, the District Court found the claim was sufficiently pled because the complaint gave the Respondent adequate notice of Petitioners' allegations. (R. at 7.) Despite meeting pleading requirements, the District Court dismissed the claim, deciding that the Vaccine Act impliedly preempted all state claims on design defects. (R. at 7.)

On August 6, 2009, the United States Court of Appeals for the Thirteenth Circuit affirmed the District Court's decision but found that the pleadings were not sufficiently pled. (R. at 13.) However, the court reversed the District Court's decision on the preemption issue. (R. at 11.) The court held that the Vaccine Act allows design defect claims, finding that the Act's language and legislative history support Congress' intent to permit such claims in state court. (R.

at 11.) The Thirteenth Circuit explained that the District Court's interpretation have a perverse effect on the vaccine market by granting "complete tort immunity from design defect liability to an entire industry". (R. at 11.) Subsequently, this Court granted petition for writ of certiorari. (R. at 14.)

STANDARD OF REVIEW

Courts review *de novo* Congressional preemption of state laws, as the question is a matter of law. Horn v. Thoratec Corp., 376 F.3d 163, 165 (3d Cir. 2004). Courts also review *de novo* orders to dismiss under Federal Rule 12(b)(6). Torch Liquidating Trust v. Stockstill, 561 F.3d 377, 384 (5th Cir. 2009).

SUMMARY OF THE ARGUMENT

The Vaccine Act permits children injured by vaccines containing harmful chemicals to bring claims for design defects in state courts. The Act's language and legistlative history are strong evidence of Congress' intent to allow design defect claims to be filed in state courts. Additionally, vaccine-injured individuals may bring claims in state court for avoidably unsafe vaccines. Because Congress did not intend to grant blanket immunity to manufacturers, this Court should find that the Act merely supplements the state tort systems.

The Cooks' complaint is sufficiently pled under the Twombly standard because it explains Petitioners' entitlement to relief. Because the Cooks' complaint is sufficiently pled, the Thirteenth Circuit's dismissal essentially creates an unwarranted heightened pleading standard. Furthermore, Petitioners allege facts sufficient to meet the specific pleading requirements of the circuit courts. The complaint is sufficiently pled because it links Estella Cooks' injuries to Carolina Laboratories' defectively designed DTP/Hib vaccine. Therefore, this Court should find that the complaint survives a Rule 12(b)(6) motion because it is sufficiently pled.

ARGUMENT

III. THE NATIONAL CHILDHOOD VACCINE INJURY ACT'S LANGUAGE AND LEGISLATIVE HISTORY INDICATE CONGRESS' INTENT TO PERMIT CLAIMS FOR DESIGN DEFECTS IN STATE COURTS.

In enacting the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"), Congress sought to promote access—access to vaccines and access to compensation. H.R. Rep. No. 99-908, at 5 (1986). Because the government requires parents to vaccinate their children, a significant number of children have been gravely injured from vaccines containing toxic chemicals. Id. at 4. Therefore, Congress enacted the Vaccine Program to provide an avenue of relief for vaccine-related injuries and deaths. 42 U.S.C. § 300aa-10(a)(2010). Additionally, children injured by chemicals in vaccines can seek relief through the state tort systems. § 300aa-11(a)(2)(A). The Act encourages settlement through the compensation program, but authorizes claims in state courts. H.R. Rep. No. 99-908, at 12. As such, the Act creates an alternative to litigation and provides access to vaccines and access to compensation.

A. Design Defect Claims Protect Individuals Injured by Unsafe Products and, as such, the Vaccine Act Preserves State Claims as an Appropriate Method of Redress for Children Injured by Harmful Vaccinations.

State tort suits can "serve as a catalyst" by exposing new dangers and prompting a manufacturer to address its deficiencies. Bates v. Dow Agrosciences L.L.C., 544 U.S. 431, 451 (2005). To that end, actions for design defects allege that the product poses an unreasonable risk of danger even though the product meets manufacturing specifications. Freeman v. Hoffman-La Roche, 618 N.W.2d. 827, 833 (Neb. 2000). In such cases, manufacturers are liable for their products which cause injury to people using the product. Id. at 834. Because of the importance of design defect claims, Congress expressly rejected a provision shielding manufacturers from liability for failure to develop a safer vaccine. H.R. Rep. No. 100-391(I), at 691 (1987).

Therefore, the Vaccine Act allows for design defect claims in state courts and is intended to be an alternative to the tort system.

1. The Act allows an injured person to bring design defect claims in state court.

The Act specifically provides, "state law shall apply to civil actions brought for damages for vaccine-related injuries". § 300aa-22(a). Furthermore, the Act expressly prohibits states from establishing and enforcing laws which proscribe an individual's right to seek relief against vaccine manufacturers in the tort system. § 300aa-22(e). The Supremacy Clause of the United States Constitution states "the Laws of the United States . . . shall be the supreme Law of the Land". U.S. Const. art. VI, cl. 2. Accordingly, the Supremacy Clause gives rise to express and implied preemption. Silkwood v. Kerr-McGee Corp., 464 U.S 238, 248 (1984).

However, considerations under the Supremacy Clause begin with the basic assumption that Congress did not intend to displace state law. Maryland v. Louisiana, 451 U.S. 725, 746 (1981). Though preemption can be found expressly or impliedly, the Act does not create blanket preemption. The Supreme Court of New Jersey described the issue as "well-settled" when it held that the Vaccine Act did not expressly or impliedly preempt state law claims. Shackil v. Lederle Labs., Div. of Am. Cyanamid, Co., 561 A.2d 511, 527 (N.J. 1989). Because the Act neither expressly nor impliedly preempts state actions, Petitioners may bring claims for design defects.

a. The Act does not express language preempting design defect claims.

Congress' silence on design defects demonstrates it did not expressly prohibit state claims for design defects. When preempting state law, Congress traditionally includes express language in its enactments. Silkwood, 464 U.S at 248; Wyeth v. Levine, 129 S. Ct. 1187, 1200 (2009) (finding that Congress' silence coupled with its awareness of the prevalence of state tort

litigation is powerful evidence that Congress did not intend federal law to be exclusive). For instance, the federal law on medical devices expressly articulates, "no state may establish [a requirement] with respect to a device intended for human use which is different from, or in addition to, any requirement applicable under this Act". 21 USC § 360k(a)(1) (2010).

However, here, Congress did not expressly eliminate state law concerning the design of DTP/Hib or other vaccines. Wack v. Lederle Labs., 666 F. Supp. 123, 127 (N.D. Ohio 1987). In fact, the Act declares "state law shall apply to a civil action brought for damages related to a vaccine-related injury". § 300aa-22(a). Because there is no language regarding design defects and the Act explicitly grants powers to the states, Congress did not expressly eliminate state claims for vaccine design defects.

b. The Act's legislative history reflects Congress' intent to permit state tort claims.

By creating the compensation program, Congress intended to supplement, not supplant, the state tort system. To comport with Congressional intent, courts generally only find preemption to be implied in very limited circumstances. Wack, at 127. As such, courts only imply preemption where the wording of the statute or its legislative history evinces Congress' intent to occupy the field to the exclusion of state law. Silkwood, 464 U.S at 248. Regarding vaccines, Congress began with the assumption that state law would apply generally to design defect claims. Patten v. Lederle Labs., 655 F. Supp. 745, 748 (C.D. Utah 1987). Indeed, the Act was intended to allow easier access to compensation, not to foreclose civil action. Id. at 749. Here, the Act's language indicates its deference to state law. § 300aa-22(a). Similarly, the legislative history reflects Congress' intent to uphold individuals' access to state court on design defect claims. H.R. Rep. No. 99-908, at 12. Consequently, both the language and legislative history are strong evidence of Congress' intent to leave state claims open to injured children.

i. The Act's silence as to design defects indicates Congress' intent to leave state actions open to injured children.

Congressional silence on state claims for design defect is strong evidence of its intent to allow such tort litigation. Indeed, preemption law cautions courts against finding that congressional acts displace state law through silence and even the Supremacy Clause does not extend to every situation in which federal and state laws have similar interests. Maryland, 451 U.S. at 746. Courts generally do not eliminate state actions based on silence because Congress' refusal to speak on a subject may reflect the lack of issues arising under such a matter, the failure of an interested person to pose the problem, or a calculated decision by members of Congress to ignore the issue as to not upset a "carefully crafted compromise". Schafer v. Am. Cyanamid Co., 20 F.3d 1, 6 (1st Cir. 1994). Due to the numerous explanations for why Congress may be silent, and particularly where the state law creates a remedy unavailable under federal law, courts should not displace state claims because Congress has not spoken on the issue. Silkwood, 464 U.S at 251. Even where the federal government extensively regulates a field of law, this Court has found Congress' silence on state matters indicates its tolerance for both federal and state actions and therefore, preemption is improper. Id. at 251, 256.

In Wack, the court found that the Act allows design defect actions in state courts and refused to grant manufacturers immunity for their tortious conduct by creating defective vaccines. Wack, 666 F. Supp. at 127. The court reasoned that Congress' silence on design defect actions takes on added significance when considered in light of the fact that Congress did not provide a substitute for the traditional state court procedures. Id. at 128.

Additionally, the idea that state law should not be discarded through legislative silence was exemplified in Schafer, which concerned the Vaccine Acts' applicability to claims of an injured individuals' family members. Schafer, 20 F.3d at 1. There, the First Circuit rejected a

manufacturer's claim that the Vaccine Act implicitly bars tort claims of family members if the injured person accepts the Vaccine Court's damages award. Id. at 7. The court explained that where the Act's purpose and language do not suggest Congress intended to preempt state action in the field, then the court will not impute such an intent. Id. Therefore, the court refused to conclude that Congress silently intended to deprive families of claims they would be eligible for in the tort system and declined to extend preemption. Id. at 6.

Similar to family member claims in Schafer, federal law provides no remedy for children injured by design defects. Furthermore, Congress' silence on the matter evidences its intent to allow state claims. This Court should find, as did the court in Wack, that the Act allows state claims for design defects, especially where Grace state law provides a remedy for injury in the absence of such a remedy under federal law.

ii. State tort claims for design defects run concurrently with federal vaccine regulations.

Permitting actions for defective design in state courts does not frustrate the Act's purpose. Even where the federal government extensively regulates a field of law, state actions are still permitted as long as they do not frustrate the federal scheme. Silkwood, 464 U.S. at 257. For instance, this Court stated that preemption is only found where a state law directly authorizes acts expressly forbidden by federal law. Mich. Canners & Freezers Assoc. v. Agric. Mktg. & Bargaining Bd., 467 U.S. 461, 478 (1984). In Mich. Canners, farmers challenged the constitutionality of a state law which established an association as the exclusive bargaining agent for farmers. Id. at 468. The state law required service fees and mandatory adherence to an association-negotiated contract for all farmers. Id. Specifically, the state law authorized actions by binding farmers to the association's marketing contracts which directly conflicted with Congress' purposes in enacting the federal law. Id. at 478. The court held that the federal law

preempted the state law because farmers could not physically comply with both federal and state requirements. Id. at 469.

In this case, state tort claims can run concurrently with the Act. Unlike Mich. Canners, Grace state tort law does not authorize actions forbidden by the Vaccine Act. Indeed, Congress recognizes that damages may be recovered through the civil tort system notwithstanding the Food and Drug Administration's ("FDA") exclusive regulatory authority over drug design. Patten, 655 F. Supp. at 748. In Patten, an infant received a DTP vaccination at approximately two months old and died the next day. Id. at 746. The manufacturer alleged implied preemption based on federal regulation of the vaccine industry. Id. However, the court held that Congress did not intend to preempt state law claims even though the federal government regulates the vaccine industry. Id. at 749. Therefore, this Court should find that state tort claims can act in conjunction with the goals of the Vaccine Act.

2. The Vaccine Act supplements the state tort system with a no-fault compensation program.

Congress' enactment of the compensation program supplements the state tort system, allowing for greater access to recovery. Under the Act, state law generally applies to a civil action brought for damages related to a vaccine injuries. § 300aa-22(a). The Act provides an alternative to tort claims, which keeps vaccination costs low by encouraging vaccine-injured individuals to choose the compensation system. Schafer, 20 F.3d at 4. However, legislative history states Congress did not intend to preclude state court actions. H.R. Rep. No. 100-391(I), at 691.

Providing a no-fault compensation program allows greater access to relief for injured children. Here, Congress was concerned that making vaccination virtually obligatory would leave many injured children uncompensated. H.R. Rep. No. 99-908, at 26. Accordingly,

Congress created the Vaccine Program to compensate injured children without requiring the difficult individual determinations of injury causation and without a demonstration that the manufacture was negligent or that the vaccine is defectively designed. Id. at 12. However, though providing a compensation program is important, Congress did not intend for the compensation program to be the sole method of recovery for injured children. Id. Therefore, the compensation system, while a good alternative to litigation, is not a substitute for state claims.

B. The DTP/Hib Combination Vaccine is Avoidably Unsafe.

Though the Vaccine Act permits state claims for design defects, the Act also grants limited protection for unavoidably unsafe vaccines. § 300aa-22(b)(1). Manufacturers are only shielded from liability in civil court if the vaccine-related injury resulted from "side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings". Id. A product is only deemed "unavoidably unsafe" when it is incapable of being made safe for its intended, ordinary use. Restatement (Second) of Torts § 402A cmt. k (1965).

However, comment k does not provide manufacturers blanket immunity from liability. The societal interest in marketing and developing drugs is adequately served through a case-by-case application of the rule espoused in comment k. Freeman, 618 N.W.2d. at 836, 845. For that reason, a majority of jurisdictions adopting comment k apply it on a case-by-case basis. Freeman, 618 N.W.2d. at 836. In fact, even Congress did not intend the codification of comment k to establish as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. H.R. Rep. No. 100-391(I), at 691. Rather, Congress stressed that determination should be left to the courts. Id.

In this case, Grace state law mandates a risk-benefit framework, under which claims for design defect are to be evaluated by weighing the risks inherent in product design against the

utility of the product. A jury must evaluate this risk-benefit analysis in conjunction with the following factors: the usefulness of the product, the gravity and severity of the danger, the efficacy of warnings, the ability to eliminate the danger without impairing the products usefulness, and the user's ability to avoid the danger. Bryant v. Hoffman-La Roche, Inc., 585 S.E.2d 723, 730 (Ga. Ct. App. 2003). In 2000, a Hib vaccine without mercury preservatives was approved by the FDA and by 2001, all vaccines for children under the age of six were mercury-free.[1] In this case, a jury at the trial court level would have sufficient facts to find DTP/Hib as unavoidably unsafe, particularly with its mercury-laden preservative and in light of the available alternatives.

C. Allowing Blanket Immunity for Manufacturers Would Be a Perversion of Congressional Intent.

Unfettered immunity for vaccine manufacturers is contrary to Congressional goals. In Levine, this Court established that powers historically vested in the states are not to be superseded by federal acts unless it is clear Congress intended to do so. Levine, 129 S. Ct. at 1194-95. Furthermore, the promotion of an important federal interest is not to be achieved at any cost. Silkwood, 464 U.S. at 257.

In Levine, the drug industry argued that state actions for improper labeling were preempted because federal laws vested the authority to approve drug labels with the FDA for more than a century. Levine, 129 S. Ct. at 1192. However, this Court held that the drug industry's reliance on preemption was misplaced and the presumption against preemption would stand. Id. at 1195 (emphasis added). Specifically, the Court upheld the presumption against preemption because respect for the states as "independent sovereigns in our federal system"

[1] FDA.gov, Thimersol in Vaccines, http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm#t1 (last visited Mar. 12, 2010).

leads to the assumption that "Congress does not cavalierly preempt state causes of action". Medtronic v. Lohr, 518 U.S. 470, 485 (1996).

Likewise, in Silkwood, the nuclear industry expressed serious concerns over the potentially bankrupting effect of state lawsuits arising out of nuclear incidents. Silkwood, 464 U.S. at 251. However, this Court held that state actions are permitted if Congress is aware of the federal regulation and still declines to preempt. Id. Accordingly, this court refused to find preemption, opting instead to stand by Congress' tolerance of federal and state laws. Id.

Here, vaccine manufacturers are concerned about the effect litigation could have on the industry. Pet. for a Writ of Certiorari, Am. Home Prods. Corp. v. Ferrari, 129 S. Ct. 2786 (2009) (No. 08-1120), 2009 WL 598046. While Congress recognized the importance of the vaccine industry, it did not intend to provide wholesale immunity for manufacturers. H.R. Rep. No. 99-908, at 12. As in Levine, in the absence of specific Congressional intent, this Court should not preempt an area of the law that has traditionally been left to the states. The promotion of childhood vaccinations should not be pursued at any cost, leaving injured children without access to adequate compensation for design defects. Therefore, this Court should not allow blanket immunity for vaccine manufacturers.

Petitioners can bring a state claim for design defects because the Act does not expressly or impliedly preempt such claims. Additionally, because Congress intended the compensation program to be a mere alternative to the state tort system and since DTP/Hib is an avoidably unsafe product, this Court should find that Congress intended to permit state claims for design defects.

IV. THE COOKS' COMPLAINT MEETS THE TWOMBLY PLEADING REQUIREMENTS BECAUSE IT SUFFICIENTLY STATES PETITIONERS' ENTITLEMENT TO RELIEF AND LINKS ESTELLA COOKS' INJURIES TO CAROLINA LABORATORIES DEFECTIVELY DESIGNED VACCINE.

Petitioner's complaint proves entitlement to relief by linking Estella Cooks' injuries to Respondent's defectively designed DTP/Hib vaccine. As such, pleadings are only subject to dismissal under Rule 12(b)(6) where the complaint fails to state a claim for which relief can be granted. Fed. R. Civ. Pro. 12(b)(6).

A. The Thirteenth Circuit Improperly Dismissed Cooks' Complaint, Essentially Applying an Unwarranted Heightened Pleading Standard, Because the Complaint Meets the Twombly Requirements.

Civil actions are generally subjected to simplified pleading requirements. Swierkiewicz v. Sorema, 534 U.S. 506, 512 (2002). This Court has refused to require greater specificity for claims through judicial interpretation where the rules do not require such a standard. Id. at 514. Under Twombly, this Court only requires enough facts to state a claim to relief that is plausible on its face. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). In fact, Twombly does not require heightened pleadings. Id. Rather, Twombly calls for a *flexible plausibility standard*, which obligates plaintiffs to supplement their claims with factual allegations only where further supplements are needed to render the claim plausible. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1944 (2009) (emphasis added).

Though the Federal Rules generally require simple pleadings, there are a few instances where the Rules require a heightened pleading standard. For example, when a party alleges fraud or mistake, or when denying that a condition precedent has occurred, a party must state with particularity the circumstances constituting such allegations or denials. Fed. R. Civ. Pro. 9(b)-(c), 10(b). In this case, the nature of the claim makes it difficult for the Petitioner to know what vaccine defects are present without discovery. By its ruling below, the Thirteenth Circuit

essentially subjected Petitioner's complaint to an unwarranted heightened pleading standard. Therefore, this Court should reverse such a holding and find the complaint is sufficiently pled because it links Carolina Laboratories defective designs to Estella Cooks' injuries.

B. Because Twombly Requires Complaints to Show Plausible Entitlement to Relief, Petitioners' Complaint is Sufficiently Pled to Meet the Twombly Pleading Requirement.

Twombly requires that plaintiffs provide only the grounds for entitlement to relief but do not require detailed factual allegations. Twombly, 550 U.S. at 555. Courts must accept all allegations in the complaint as true even if they seem doubtful to the court unless the allegations are nothing more than legal conclusions disguised as facts. Id. Legal conclusions, however, may serve as the pleading framework as long as the complaint is enhanced by factual allegations. Iqbal, 129 S. Ct. at 1950. Such allegations are required to show that a claim is at least plausible, and requires only enough facts to raise a reasonable expectation that discovery will reveal evidence of wrongful acts. Twombly, 550 U.S. at 556.

The standard pleading continuum is comprised of "possible claims" on one end, which only requires mere speculation and "probable claims" on the other end, which calls for a statement of facts rendering the plaintiff's entitlement to relief likely. Iqbal, 129 S.Ct. at 1949. The "plausible claims" standard falls in the middle and requires only sufficient facts to raise a reasonable expectation that discovery will reveal evidence of wrongful acts. Id. Under the Twombly standard, Petitioners' complaint rises to the level of a plausible pleading, and because the complaint pleads facts showing Petitioners are entitled to relief. Therefore, the complaint survives dismissal.

C. Petitioners' Complaint Meets the Expectations of Both the Limited and Universal Plausibility Standards.

Since Twombly, the federal circuits' interpretations have largely diverged into two fields: the "Limited Plausibility Standard" and the "Universal Plausibility Standard".[2] Petitioners' allegations survive both standards.

1. Petitioners' complaint meets the "Limited Plausibility Standard" because it puts Respondent on notice of the allegations.

The Limited Plausibility Standard espoused by the Sixth, Seventh, Ninth, and D.C. Circuits, requires only a plausibility standard in certain "discovery intensive", cases such as anti-trust and *in terrorem* litigation. Aktieselskabet v. Fame Jeans Inc., 525 F.3d 8, 15-16 (D.C. Cir. 2008) (concluding that Twombly leaves the long-standing fundamentals of notice pleading intact); Kendall v. Visa U.S.A., Inc., 518 F.3d 1042, 1047 (9th Cir. 2008) (finding that a plausibility standard is only necessary in certain cases, such as anti-trust, where discovery frequently causes substantial expenditures and gives the plaintiff the opportunity to extort large settlements even where he does not have much of a case); Limestone Dev. Corp. v. Vill. of Lemont, 520 F.3d 797, 802-03 (7th Cir. 2008) (holding complaints must give enough detail to indicate that plaintiff has a substantial case, otherwise it is unfair to force a defendant to undergo discovery); Rick-Mik Enter., Inc. v. Equilon Enter., 532 F.3d 963, 970 (9th Cir. 2008) (holding that in antitrust matters, factual allegations must raise the plaintiff's right to relief above the speculative level); Midwest Media Prop. L.L.C. v. Symmes Twp., Ohio, 503 F.3d 456, 472 n.3

[2] Robert McGee, Twombly Trumps Conley: Ashcroft v. Iqbal and the Quest for a Standard Pleading Standard, Albany Government Law Review Fireplace, Feb. 27, 2009, http://glrfireplace.albanygovernmentlawreview.org/2009/02/27/twombly-trumps-conley-ashcroft-v-iqbal-and-the-quest-for-a-standard-pleading-standard/.

(6th Cir. 2007) (holding that a plaintiff can satisfy Twombly by coupling its allegations with facts which suggest that defendant committed an illegal act).

In Fame Jeans, the plaintiff alleged that the defendant committed trademark infringement with the intent to use the trademark. Fame Jeans Inc., 525 F.3d at 11. There, the D.C. Circuit interpreted Twombly as a new threshold under which to clarify the basis of each claim, but which leaves the notice-pleading requirements intact. Id. at 15. The court reasoned that since heightened pleading standards require an amendment to the rules, Twombly is not intended to change the notice standard. Id. at 16. Therefore, the court found that the plaintiff's pleading requirement sufficiently put defendant on notice, and thus, was sufficiently pled. Id. at 12.

Similarly, in Midwest Media, the Sixth Circuit held that notice pleading is generally sufficient to plead the claim. Midwest Media, 503 F.3d at 472. There, a company brought an action against a town for violating the company's speech rights because the town denied the company's petition to place signs outside. Id. at 458-59. The court reasoned that the company met the pleading standard because the complaint sufficiently placed the defendant on notice of the injury alleged. Id. at 472. The court found that Twombly did not apply because the plaintiff coupled its allegations with facts suggesting the defendant engaged in illegal conduct. Id.

Furthermore, in Rick-Mik, the plaintiff claimed the defendant engaged in anti-trust behaviors by requiring the plaintiff to use the defendant's credit card processing but did not link the use of credit cards with the alleged illegal behavior. Rick-Mik, 532 F.3d at 967. The Ninth Circuit affirmed dismissal of the claim because the complaint merely speculated as to illegal behavior. Id. at 972.

Under the Limited Plausibility Standard, plausibility pleading is not required in this case. Here, Petitioner is only required to plead facts to suggest Respondent engaged in the alleged

conduct. Petitioner's complaint includes the following facts: (1) between March 1996 and October 1998, Plaintiff Estella Cooks received three doses of DTP/Hib combination vaccine; (2) the vaccine Estella Cooks received was manufactured by Respondent, Carolina Laboratories; (3) DTP/Hib combination vaccine contains a Thimerosal preservative; (4) Thimerosal's primary component is derived from the toxic metal, mercury; and (5) as a result of the mercury exposure, Estella Cooks suffers from many injuries which are likely to be permanent. These allegations give Respondent sufficient notice and suggest Respondent engaged in conduct leading to Estella Cooks' injuries. As such, this Court should find that Petitioner meets the Limited Plausibility Standard.

2. Petitioners' Complaint even rises to meet the "Universal Plausibility Standard" because it states plausible entitlement to relief.

Under the Universal Plausibility Standard, the Third, Fourth, Fifth, and Eleventh Circuits require plaintiffs in all cases to plead facts that demonstrate a reasonable expectation that evidence of the alleged conduct will be revealed during discovery. Davis v. Coca-Cola Bottling Co., 516 F.3d 955, 974 (11th Cir. 2008) (finding that pleadings must give the defendant fair notice of what the claim is and the grounds upon which it rests, providing enough factual matter to suggest that plaintiff is entitled to relief); Giarratano v. Johnson, 521 F.3d 298, 302 (4th Cir. 2008) (stating that all complaints must allege enough facts to state a claim for relief that is plausible on its face); Umland v. Planco Fin. Serv. Inc., 542 F.3d 59, 64 (3d Cir. 2008) (finding that complaints must allege facts suggestive of illegal conduct); Katrina Canal Breaches Litig., 495 F.3d 191, 205 (5th Cir. 2007) (finding that plaintiffs must state an entitlement to relief that is plausible on its face to survive a Rule 12(b)(6) motion to dismiss).

In Umland, the plaintiff filed an action for unjust enrichment against the defendant. Umland, 542 F.3d at 67. The complaint alleged only that the defendant required the plaintiff to

pay a tax but did not stipulate any facts linking the action of paying the tax to the alleged illegal conduct. Id. at 62. The Third Circuit found that the plaintiff did not satisfy Twombly because the complaint did not allege sufficient facts to support the contention that the defendant engaged in illegal conduct. Id. at 69.

In Davis, the plaintiffs alleged the defendant promoted a hostile work environment through pay, hiring, and promotion practices subject to racial discrimination. Davis, 516 F.3d at 961. The complaint alleged the plaintiffs were treated differently than employees because they were denied promotions. Id. at 974. The Eleventh Circuit upheld dismissal, explaining that merely alleging adverse action is insufficient, and the complaint must demonstrate the reasons why the plaintiff is entitled to relief. Id. at 978.

Here, Petitioners facts and allegations plausibly claim an entitlement to relief. Petitioner alleges that Estella Cooks' injuries were a direct result of Respondent's actions because Carolina Laboratories not only negligently failed to determine whether Thimerosal was safe and nontoxic to humans; but Carolina Laboratories also 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, including Estella Cook. Specifically, the Respondent failed to determine the safety of each individual injection of a Thimerosal-containing shot, each single-day administration of multiple Thimerosal-containing shots, and the cumulative administration of multiple shots during the first twenty-four months of a child's life. As a result of both Carolina Laboratories' negligent failure to conduct safety tests and defective design by failing to utilize a safer alternative, Estella Cooks suffers from neurological injuries including developmental delays, learning disabilities, social delays and deficits, the impairment of motor skills, gastrointestinal illness and immune system dysfunction. Consequently, Petitioners' complaint

satisfies the Universal Plausibility Standard because the complaint alleges facts demonstrating the reasons why Petitioners are entitled to relief.

D. The Cooks' Complaint Survives a Motion to Dismiss Because the Allegations are Sufficiently Pled.

Courts must review complaints on a case-by-case basis to determine whether a complaint is sufficiently pled to render the claim plausible. Bryant, 585 S.E.2d at 726. To conduct this review, courts should first determine which allegations are entitled to an assumption of truth; and second, decide whether the allegations state a plausible entitlement to relief. In making both of these determinations, courts should draw on their judicial experience and common sense. Iqbal, 129 S. Ct. at 1947, 1949, 1950, 1951. Review of Petitioner's allegations will show that Petitioners' complaint sufficiently demonstrates entitlement to relief.

1. The Cooks' allegations are entitled to an assumption of truth because the Complaint enhances its legal conclusions with factual assertions.

Courts should first identify the allegations in the complaint that are entitled to an assumption of truth. Id. at 1951. Even factual statements that a judge does not believe are presumed to be true. Neitzke v. Williams, 490 U.S. 319, 327 (1989). The rules of procedure do not require complaints to list every evidentiary detail but require plaintiffs to allege a factual predicate concrete enough to warrant further proceedings. DM Research v. Coll. of Am. Pathologists, 170 F.3d 53, 55 (1st Cir. 1999). In Iqbal, this Court found that bare assertions stating that the defendants knew of and agreed to subject plaintiff to harsh conditions solely on the account of race was insufficient. Iqbal, 129 S. Ct. at 1951. There, the plaintiff also alleged that one defendant was the "architect" of a policy and that another defendant was "instrumental" in carrying out the policy. Id. As such, this Court ruled that the plaintiff was not entitled to the

assumption of truth because the allegations were not factual but were merely legal conclusions. Id.

Here, Petitioner shows entitlement to assumption of truth by setting out facts that enhance the legal conclusions. For example, Petitioner alleges that Carolina Laboratories manufactured the defective DTP/Hib vaccine given to Estella Cooks and that her injuries are a result of that defective design. These facts are sufficiently concrete to warrant further proceedings. Unlike the complaint in Iqbal, Petitioners assert Respondent manufactured a defective design which caused the ultimate harm to Estella Cooks. These allegations use factual assertions to enhance Petitioners' legal conclusions and are, therefore, entitled to an assumption of truth.

2. Petitioners' claim states a plausible entitlement to relief.

Next, the court should consider the factual allegations in the complaint to determine if they plausibly suggest an entitlement to relief. Iqbal, 129 S.Ct. at 1949. Petitioners' complaint should be considered in light of the nature of products liability claims. The allegations in this complaint comport with complaints courts have previously found to be sufficiently pled.

a. In light of the nature of products liability claims, Petitioners' Complaint is as sufficiently pled as possible before discovery.

The nature of a products liability action is such that the source of a product's defect is not obvious to the consumer. Bailey v. Janssen Pharmaceutica, Inc., 288 F. App'x 597, 605 (11th Cir. 2008). Therefore, actions for products liability make it difficult for plaintiffs to pinpoint the specific source of a defect prior to discovery. Id. Additionally, courts give plaintiffs room to support their claims with discovery as long as the discovery is not a fishing expedition. Stockstill, 561 F.3d 377, 392 (5th Cir. 2009).

For example, in Bailey, the court found that the claimant could not be in a position to know with specificity what the likely source of the product defect was before discovery. Bailey

v. Janssen Pharmaceutica, Inc., 288 F. App'x at 605. Therefore, the complaint was sufficiently pled and dismissal for procedural deficiencies was inappropriate. Id. at 606. Here, Petitioners complaint regarding a products liability design defect is sufficiently pled because it demonstrates that Estella Cooks was harmed by the defective design of the DTP/Hib vaccine. Through discovery, Petitioners will be able to pin-point the design defect with more certainty. A premature dismissal, however, will prevent Petitioners from identifying the exact source of the design defect that caused severe harm to Estella Cooks.

b. Petitioners' Complaint falls in line with complaints found to be sufficiently pled.

Petitioners' complaint is consistent with other complaints found to sufficiently statie an entitlement to relief. For instance, in Bailey, the plaintiff died after being prescribed a seventy-two hour pain killing patch that released a narcotic. Id. at 599. There, the plaintiff alleged that the patch malfunctioned and delivered the entire dose of medicine at one time, causing deadly injury to plaintiff. Id. at 599-600. The Eleventh Circuit found that such allegations were sufficiently pled. Id. at 610.

In Beraglia, the plaintiff was injured due to asbestos exposure. Beraglia v. Owens-Corning Fiberglas Corp., 606 So. 2d 1213, 1214 (Fla. Dist. Ct. App. 1992). Plaintiff's complaint alleged that defendant's asbestos products contained design defects at the time they were manufactured and at the time plaintiff was exposed to the asbestos fibers from those products. Id. The court upheld such allegations as sufficient to state a cause of action. Id. Similarly, in Markel, plaintiff's boat was severely damaged by an engine fire. Markel Am. Ins. Co. v. Pac. Asian Enters, Inc., 2008 WL 5102400, at *1 (N.D. Cal. 2008). There, the plaintiff alleged damage to the boat was caused by an electrical malfunction because the electrical components were

defective. Id. The court found that the allegations were specific enough because the defendant could defend the action on the merits based on the complaint. Id. at *2.

In this case, like in Bailey, Petitioners allege that Carolina Laboratories created a vaccine that was defective due to its use of a mercury-preservative. Similar to Beraglia and Markel, Petitioners also allege that the mercury laden product was defective in its design when administered to Estella Cooks and that such defects are the cause of her injuries. Because Petitioners complaint closely resembles complaints that have been upheld as sufficiently pled, this Court should find that the complaint at hand is sufficiently pled and survives a motion to dismiss under Rule 12(b)(6).

c. Petitioners' allegations are contrasted from complaints subject to dismissal.

The complaint in this case is markedly different from complaints dismissed by this Court. In Iqbal, this Court concluded that the allegations, even if taken as true, were not sufficient to support a plausible entitlement to relief. Iqbal, 129 S. Ct. at 1951. There, the plaintiff alleged that defendants illegally adopted a policy of classifying post-September 11th detainees as "high-interest" on the basis of race, religion or national origin. Id. at 1952. However, the complaint suggested only that "the policy of holding post-September 11th detainees in highly restrictive conditions of confinement was 'approved' by the defendants". Id. at 1951. Therefore, this Court found that the complaint did not sufficiently plead a plausible entitlement to relief. Id. at 1952. However, the Court pointed out that the complaint did not link defendants' acts of approving a policy to race discrimination and, thus, was subject to a Rule 12(b)(6) dismissal. Id.

This Court found the pleadings in Harbury did not sufficiently state grounds on which relief could be granted because the complaint failed to identify the underlying cause of action and only alleged that the defendant gave false information that foreclosed the plaintiff from

effectively seeking adequate legal redress. Christopher v. Harbury, 536 U.S. 403, 418 (2002). Thus, this Court explained that the pleadings were insufficient because the courts and the defendant were left to guess as to the unstated cause of action and the remedy being sought. Id. Additionally, in Car Carriers, the complaint was dismissed because it did nothing more than state plaintiff's disappointment in defendant's actions, which did not entitle the plaintiff to relief. Car Carriers v. Ford Motor Co., 745 F.2d 1101, 1110 (7th Cir. 1984).

In the present case, Petitioners state a plausible entitlement to relief. Unlike Iqbal, Petitioners' complaint includes allegations linking Estella Cooks' many injuries to her mercury exposure from vaccines manufactured by Carolina Laboratories. Petitioners' complaint contrasts with the complaint in Harbury because it expresses the underlying cause of action that Carolina Laboratories was negligent in its failure to conduct adequate safety tests to determine whether Thimerosal was safe and nontoxic. Additionally, the Petitioners' complaint alleged a defective design of the vaccine and that a safer alternative exists. Unlike Car Carriers, the Petitioner's allege more than simple disappointment in Carolina Laboratories. Petitioners' complaint is a marked contrast from complaints previously dismissed because the complaint pleads facts sufficient to show Petitioners are entitled to relief. Accordingly, this Court should find that the complaint survives a Rule 12(b)(6) motion to dismiss.

E. If Necessary, this Court Can Remand to Give Petitioners an Opportunity to Amend the Complaint.

Courts can remand a complaint subject to a Rule 12(b)(6) dismissal for the opportunity to amend. Iqbal, 129 S. Ct. at 1954. When the original complaint alone is dismissed, the litigation is not terminated and the plaintiff still retains the right to amend once as a matter of course under Rule 15(a). Car Carriers, 745 F.2d at 1111. Even if Petitioners do not have the right to amend as a matter of course, courts freely give leave to amend when "justice so requires". Fed. R. Civ.

Pro. 15(a)(2). Under that rule, courts consider equitable factors such as undue delay, bad faith, dilatory motive on the part of the movant, repeated failure to cure deficiencies by previously allowed amendments, and futility of the amendment. Stockstill, 561 F.3d at 391.

Estella Cooks suffers serious injuries due to exposure to vaccines containing mercury manufactured by Defendant, including social delays and deficits, neurological problems, impairment of fine motor skills, and other symptoms of mercury poisoning. If necessary, Petitioners can amend as matter of course since only the complaint is at risk of dismissal. Otherwise, this Court should grant leave because Estella Cooks was egregiously harmed and unable to obtain relief from the compensation system. Here, there is no evidence of bad faith on Petitioners' behalf. Rather, the Cooks family seeks relief for the harm imposed on Estella by the Respondent. Where the Cooks have not been given the opportunity to amend below, it is likely that a chance to amend now would be fruitful. Therefore, this Court can remand to give Petitioners the opportunity to amend the complaint. To categorically dismiss a claim in which a child is seriously injured and unable to receive compensation from the Vaccine Program would undermine not only the purpose of the civil tort system but also the goals of the Vaccine Act.

In this case, because Petitioners' complaint is only required to state a plausible entitlement to relief, the Thirteenth Circuit improperly applied the Twombly pleading rules to the Cooks' complaint. Consequently, this Court should reverse the decision below, finding that the Cooks' complaint stands as a plausible entitlement to relief.

CONCLUSION

Therefore, this Court should reverse the decision of the Thirteenth Circuit, finding that the Vaccine Act permits state claims for design defects and that Petitioners' complaint is sufficiently pled.

Respectfully Submitted,
Team 7

CERTIFICATE OF SERVICE

We hereby certify that a copy of this brief has been delivered to the Rendigs Moot Court Competition and other teams on March 12, 2010.

Respectfully Submitted,
Team 7