Docket No. 10-1524

IN THE
SUPREME COURT OF THE UNITED STATES

DAN COOKS, *ET AL.*,
Petitioner,

v.

CAROLINA LABORATORIES, INC.,
Respondent.

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

---

BRIEF FOR PETITIONERS

TEAM 6

Counsel for Petitioners

ORAL ARGUMENT REQUESTED

STATEMENT OF THE ISSUES

1. Whether the Court of Appeals for the Thirteenth Circuit was correct in holding that the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1, *et seq*. (2009) does not preempt all design defect claims as a matter of law where the Act does not contain such preemptive language and where a finding of preemption would frustrate the intent of Congress to facilitate the compensation of childhood injuries caused by vaccines.

2. Whether the Court of Appeals for the Thirteenth Circuit erred when it held that the Cooks' civil complaint should have been dismissed under Fed. R. Civ. P 12(b)(6), where the complaint made specific factual allegations and pleaded a claim for relief that was plausible on its face, as required by *Bell Atl. Corp. v. Twombly*, 550 U.S. 554 (2007).

TABLE OF CONTENTS

TABLE OF AUTHORITIES

United States Supreme Court Cases

United States Courts of Appeals Cases

United States District Court Cases

United States Court of Federal Claims Cases

State Supreme Court Cases

State Courts of Appeals Cases

Constitutional Provisions

Statutory Provisions

Federal Rules of Civil Procedure

Restatements

Legislative Materials

Law Review Articles

Miscellaneous Sources

STATEMENT OF THE CASE

A. Nature of the Case

Estella Marie Cooks is nearly fourteen years old but she has suffered from severe neurological disorders almost her entire life. Her symptoms are consistent with mercury poisoning and appeared after she was injected with a DTP-Hib vaccine developed and manufactured by the Respondent, Carolina Laboratories, Inc. The vaccine contained the preservative thimerosal, which is 50% mercury by weight.

This Court is being asked to consider two issues in a civil vaccine design defect case. First, whether the Vaccine Act preempts all design defect claims as a matter of law, thereby giving blanket tort immunity to the entire vaccine manufacturing industry. Second, whether the Cooks' detailed civil complaint met the pleading standard recently announced by this Court in *Bell Atl. Corp. v. Twombly*, 550 U.S. 554 (2007).

The Cooks respectfully request that this Court affirm the Court of Appeals' holding that the Vaccine Act does not preempt all design defect claims as a matter of law. The Cooks further request that this Court reverse the Court of Appeals' holding that the civil complaint merited dismissal under Rule 12(b)(6).

B. Course of the Proceedings and Disposition of the Courts Below

On September 3, 2001, Estella Marie's parents, Dan and LoEtta Cooks, filed a petition for compensation under the Vaccine Act as required by 42 U.S.C. § 300aa-11. Despite the fact that § 300aa-12(d)(3)(A)(ii) requires a special master to decide on such petitions within 240 days, and that § 300aa-21(b)(2) requires the court to enter judgment within 420 days, the Cooks waited more than two years with no progress. On November 3, 2003, the Cooks filed a notice of withdraw of their petition pursuant to § 300aa-21(b). It took another two months before the judgment of withdrawal was entered on January 14, 2004.

Dan and LoEtta Cooks filed a civil complaint individually and on behalf of Estella Marie in federal district court on March 14, 2007. The complaint alleged in two counts that the Respondent defectively designed the DTP-Hib vaccine administered to Estella Marie, and that the defective design caused her severe injuries. The first count of the complaint alleged that the Respondent was negligent in failing to adequately test the vaccine to ensure that the amount of thimerosal was safe in the doses administered. The second count alleged strict products liability for design defect because the Respondent failed to use a reasonable alternative design.

At trial, the Respondent filed a motion to dismiss under Rule 12(b)(6) claiming that the complaint failed to adequately plead a cause of action, and that the Cooks' tort claims were preempted as a matter of law by the Vaccine Act. The district court denied the 12(b)(6) motion as to the adequacy of the pleadings but granted it on the preemption ground.

The Cooks appealed to the Court of Appeals for the Thirteenth Circuit, arguing that the district court erred in granting 12(b)(6) dismissal on federal preemption grounds. The Respondent raised the pleading issue and argued that the district court should also have granted its motion on the grounds of inadequate pleading. In an August 6, 2009 opinion, the Court of Appeals reversed both of the district court's rulings but affirmed the judgment of dismissal. The Court of Appeals felt that the complaint did not allege enough particular facts to meet the *Twombly* pleading standard. On the preemption issue, the Court of Appeals held that an analysis of the language, history, and intent behind the Vaccine Act revealed that it does not preempt all design defect claims as a matter of law. This Court granted the Cooks' writ of certiorari.

C. Statement of Facts.

Between March 1996 and October 1998, when Estella Marie Cooks was an infant, she received a mandatory three-dose DPT vaccination as required by state law. (R. at 1.) The precise vaccine administered was a DTP-Hib compound developed by the Respondent, which

contained the preservative thimerosal which is approximately 50% mercury by weight. (R. at 1.) Soon after receiving these injections, Estella Marie began to exhibit serious neurological problems including developmental delays, learning disabilities, social delays and deficits, the impairment of fine motor skills, gastrointestinal illness, and immune system dysfunction. (R. at 1.) These and other injuries suffered by Estella Marie are common symptoms of mercury poisoning. (R. at 1.) Many of these afflictions will likely be permanent. (R. at 4.)

Carolina Laboratories knew that thimerosal had "neurotoxic properties" when it designed its DTP-Hib vaccine. (R. at 3 to 4.) Yet it still chose to disseminate the mercury-containing product to infants and young children. (R. at 3.) Carolina Laboratories "failed to conduct adequate safety tests to determine that the [vaccine] was safe and nontoxic" in the doses given to Estella Marie and children like her. (R. at 4.) Individually and on behalf of their daughter, Dan and LoEtta are now seeking compensatory damages for Estella Marie's grave injuries. (R. at 2.)

SUMMARY OF THE ARGUMENT

Congress passed the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act") in response to two concerns: the difficulty experienced by those trying to obtain recovery for injuries caused by vaccines and the fear that excess tort litigation could drive vaccine manufacturers from the market. The Vaccine Act addressed these dual concerns by creating a no-fault compensation program that was intended to generously compensate injured victims while simultaneously diverting civil lawsuits. The Vaccine Act was not primarily a tort reform statute, nor was its purpose to grant tort immunity to vaccine manufacturers.

The Cooks' design defect claims are not preempted by the Vaccine Act. Congress has not expressed an intent for the Vaccine Act to preempt all design defect claims as a matter of law. Congress merely intended to bar claims arising from "unavoidable" side effects, a determination it expected to be made by the courts on a case-by-case basis. Moreover, Congress intended the

Vaccine Act to facilitate claims for compensation, even those from claimants who would not be able to prevail in court. Since Congress intended to lower the bar to encompass claims that would be meritless in the tort system, it would frustrate the purposes of Congress to hold as a matter of law that claimants may not bring meritorious design defect claims in civil court.

Because the Vaccine Act does not expressly preempt the Cooks' design defect claims and because non-preemption is consistent with the intention and purposes of Congress, we respectfully request that this Court affirm the Court of Appeals' judgment that the Vaccine Act does not preempt the Cooks' civil claims.

Although the Thirteenth Circuit was correct in holding that the Vaccine Act does not preempt the Cooks' claims, it erred in dismissing the complaint under Rule 12(b)(6). The Court of Appeals misinterpreted this Court's recent opinions and applied a standard requiring more factual specificity than what this Court has ever required. There is no support in law or logic for the Thirteenth Circuit's proposed reading of Rule 8's pleading standard. Additionally, the Federal Rules, absent the lower court's embellishments, plainly rebut the contention that the Cooks' failed to plead enough factual detail to support their allegations of a design defect claim. Had the Cooks' complaint not been unjustly dismissed, additional evidence of Respondent's liability would have been readily discoverable.

A complaint should not be dismissed unless it fails to satisfy Rule 8(a)(2), whose requirements are articulated through the plausibility standard set forth in *Twombly* and *Iqbal*. Specifically, the two-prong pleading standard mandates that a pleading contain "factual particulars" and assert a claim that is "plausible on its face." Having met the requisite burden, the Cooks' complaint should not have been dismissed. Accordingly, we respectfully request that this Court reverse the the Thirteenth Circuit's dismissal of the Cooks' complaint.

ARGUMENT

I. THIS COURT SHOULD AFFIRM THE COURT OF APPEALS' RULING THAT THE COOKS' DESIGN DEFECT CLAIMS ARE NOT PREEMPTED BY THE NATIONAL CHILDHOOD VACCINE INJURY ACT.

The doctrine of federal preemption derives from the Constitution, which declares that the "Laws of the United States . . . shall be the supreme Law of the Land." U.S. CONST. amend. VI, cl. 2. Consequently, state statutes and common law causes of action are preempted insofar as they "interfere with, or are contrary to the laws of Congress." *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824). In determining the scope of federal preemption of state law in a particular case, "[t]he purpose of Congress is the ultimate touchstone." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). Thus, federal law does not preempt state law unless Congress intended it to do so.

The Supreme Court has recognized three ways in which Congressional intent to preempt state law can be manifested. *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985). First, express preemption exists where Congress "preempt[s] state law by so stating in express terms." *Id*. (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). Second, "field preemption" is inferred either where a federal regulatory scheme is so comprehensive as to preclude the existence of supplementary state regulation in that field, or where the federal interest in the field is so strong that enforcement of state laws on the subject must be presumed to be precluded. *Hillsborough County*, 471 U.S. at 713. Lastly, conflict preemption exists where state law actually conflicts with federal law, either because compliance with both is physically impossible or because state law claims would frustrate the purposes of the federal law. *Id*.

Under none of these analyses are the Cooks' design defect claims[1] preempted by the

[1] The Cooks alleged the DTP-Hib vaccine was defectively designed in two counts, one based on

National Childhood Vaccine Injury Act, 42 U.S.C. § 300a-1 *et seq*. (2010). Express preemption does not defeat the Cooks' design defect claim because the Vaccine Act does not contain language indicating the clear and manifest intent of Congress to preempt all vaccine design defect claims as a matter of law, as Respondent contends. Field preemption is likewise inapplicable because the Vaccine Act, far from supplanting state regulation, was intended merely to supplement existing state regulation. *See, e.g.,* 42 U.S.C. § 300a-22(a) (stating the "general rule" that "State law *shall* apply" to vaccine-related civil actions) (emphasis added). Finally, conflict preemption does not bar design defect claims such as the Cooks' because such claims do not frustrate the purpose of the Vaccine Act. The Vaccine Act was intended to make it *easier* for injured children to receive compensation, not to give blanket tort immunity to an entire industry. Because the high bar of federal preemption is not met, the Court of Appeals for the Thirteenth Circuit was correct in holding that the Cooks' design defect claims are not preempted as a matter of law.

A. State law concerning public health and safety is subject to a presumption against preemption.

Whenever the Court analyzes preemption claims, it must "start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). This presumption against preemption is particularly strong in arenas that have historically been the subject of state or local regulation. *Lohr*, 518 U.S., at 485; *Hillsborough County*, 471 U.S. at 715. Public health and safety is recognized as one field in which the presumption against preemption applies with particular force. *Lohr*, 518 U.S. at 485. As a result, whenever a

negligence and the other in strict products liability. The courts below did not distinguish between these theories in their opinions. Because the preemption analysis applies equally to both negligence and strict liability design defect theories, they will be treated together here.

preemption clause has more than one plausible reading, the Court has "a duty to accept the reading that disfavors pre-emption." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005). The Respondent therefore must overcome the "considerable burden" of the presumption that the Vaccine Act does not preempt the Cooks' claims. *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997) (citing *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654 (1995)).

B. Respondent cannot demonstrate preemption under any of the three methods.

1. The Vaccine Act does not expressly preempt all design defect claims because Congress did not intend to give the vaccine industry tort immunity.

For state law to be preempted under an "express preemption" analysis, Congress must communicate in "clear and manifest" terms that the federal law is intended to preempt state law. *Good*, 129 S. Ct. at 543; *Rice*, 331 U.S. at 230. Respondent's reading of the statute would have the perverse effect of "granting complete tort immunity from design defect liability to an entire industry," and in the absence of any evidence that Congress intended this result, the Court of Appeals was correct to "reject such a far-reaching interpretation of the Vaccine Act." (R. at 11.)

The preemption provision of the Vaccine Act at issue states: "No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper warnings and directions." 42 U.S.C § 300aa-22(b)(1). The Vaccine Act provides no guidance regarding when a side effect is "unavoidable" and a split among courts considering the question has revealed two ways to read this provision.

The first interpretation, adopted by the district court below and advanced by the Respondent here, is that FDA approval is the *sine qua non* of unavoidability and that all vaccine

side effects are "unavoidable" as long as the vaccine was manufactured according to its FDA-approved design. (R. at 7); *see also Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 303 (E.D. Pa. 2007) (finding preemption where vaccine produced according to FDA-approved specifications).

The second interpretation, endorsed by the Thirteenth Circuit, is that injured plaintiffs ought to be given the opportunity to actually show, on a case-by-case basis, that the suffered side effects were in fact avoidable before their claims are summarily rejected. (R. at 11); *see also Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 237-38 (Ga. 2008) (holding that the Vaccine Act only preempts design defect claims where it is shown on a case-by-case basis that the side effects were unavoidable).

Even assuming the Respondent's proposed interpretation is plausible, the presumption against preemption demands that it must be rejected in favor of an equally plausible reading that disfavors preemption. *Good*, 129 S. Ct. at 543; *Bates*, 544 U.S. at 449. Beyond the presumption, there are two reasons why the latter reading is correct. First, the text of the statute is devoid of congressional intent to preempt. Second, a case-by-case analysis is more consistent with the legislative history indicating congressional intent not to provide blanket tort immunity from design defect claims.

a. The text of the statute does not indicate a "clear and manifest" intent to preempt all design defect claims.

The starting point for any judicial analysis of a disputed statute is in the plain language of the text. *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 475 (1992). The Court is to give the words their "ordinary, contemporary, common meaning" unless Congress intended them to have some other meaning. *Williams v. Taylor*, 529 U.S. 420, 431 (2000) (citing *Pioneer Inv. Servs. Co. v. Brunswick Assocs. Ltd. P'ship*, 507 U.S. 380, 388 (1993)). An interpretation of a

statute should be adopted if it can be determined without "psychoanalyzing those who enacted it." *Carter v. United States*, 530 U.S. 255, 271 (2000) (quoting *Bank One Chicago, N.A. v. Midwest Bank & Trust Co.*, 516 U.S. 264, 279 (1996) (Scalia, J., concurring in part and concurring in judgment)). Interpreting a statute according to its plain meaning allows the Court to "avoid the pitfalls [of the] controversial realm of legislative history." *Lamie v. U.S. Tr.*, 540 U.S. 526, 536 (2004).

The plain meaning of 42 U.S.C. § 300aa-22(b)(1) compels the conclusion that courts should determine on a case-by-case basis what side effects are "unavoidable." The statute provides that tort claims are preempted "if the injury . . . resulted from side effects that were *unavoidable*" even though the product was manufactured properly and adequate warnings were provided. *Id.* (emphasis added). If Congress had intended to preempt all design defect claims, it would have been unnecessary to include the language limiting its application to *unavoidable* side effects. Blanket preemption of design defect claims could have been achieved simply by saying that a vaccine manufacturer will not be liable for any injury if the vaccine was manufactured properly and adequate warnings were given. *Ferrari*, 668 S.E.2d at 390. But the Act specifically limits its application to *unavoidable* side effects, which necessarily means that the Act was not intended to preempt cases arising out of *avoidable* side effects. *Id*. To read this provision as a blanket ban of design defect claims is therefore to read the word "unavoidable" right out of the statute.

The Third Circuit recently provided an unsettling example of the linguistic gymnastics required to circumvent this result. In *Bruesewitz v. Wyeth, Inc.*, the court acknowledged that subsection (b)(1) preempts *some* claims, and recognized that whatever claims might be barred would be design defect claims. 561 F.3d 233, 245 (3d Cir. 2009). But then the court looked at subsection (e), which prevents states from *prohibiting* any claim not barred by the rest of the

section, and from this it somehow concluded that subsection (b)(1) must therefore be "an outright bar" to *all* design defect claims. *Id.* The court considered and rejected the *Ferrari* opinion, holding that if Congress had intended to allow a case-by-case determination of side effect avoidability, it should have done so with an explicit exception like the ones contained in subsection (b)(2). *Bruesewitz*, 561 F.3d at 246. In essence, the *Bruesewitz* court concluded that the victim's claims were preempted because Congress had not sufficiently manifested its intent *not* to preempt them. In so doing, the court turned the *Bates* mandate and the presumption against preemption entirely on their heads.[2]

The reading employed by the *Bruesewitz* Court is strained and cumbersome. Under a natural and straightforward reading of the statute, cases arising from unavoidable side effects are preempted whereas cases arising out of avoidable side effects are not. The limiting clause in subsection (b)(1) referring to proper manufacturing and warnings was necessary to restrict this preemptive effect to only those injuries that could not have been avoided by the use of a reasonable alternative design. *Ferrari*, 668 S.E.2d at 390. No other portion of the Vaccine Act even hints that the doors to the courthouse should be closed to the victim who would prove that her suffering could have been avoided by such a reasonable alternative design.

The case for preemption is not bolstered by a reading of subsection (b)(1) that would replace the word "unavoidable" with "FDA-approved," as the district court below did. (R. at 7); s*ee also Sykes*, 484 F. Supp. 2d at 303. If Congress had intended FDA approval to be determinative of the issue of side effect avoidability, it could certainly have done so. In fact, the very next paragraph of the statute, subsection (b)(2) provides that proper warnings and instructions will be presumed where the manufacturer complied with FDA requirements. 42

[2] Perhaps the clearest indication of the Third Circuit's backwards analysis is the court's observation that the case-by-case reading "does not foreclose the preemption of some claims." *Bruesewitz*, F.3d at 246. Whereas this Court has repeatedly instructed that preemption must only be found where Congress clearly and manifestly intended, *Bruesewitz* found preemption when the contrary reading failed to "foreclose" the possibility of preemption.

U.S.C. § 300aa-22(b)(2). Clearly, Congress knew how to achieve the preemptive result sought by the Respondent and chose not to do so. It must therefore be presumed that Congress did not intend that result. "[Congress'] silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009).

The plain language of the Vaccine Act does not clearly and manifestly indicate congressional intent to preempt the Cooks' design defect claims. The reading disfavoring preemption "is at once the only one that makes sense of each phrase in [§ 300aa-22(b)(1)] and the one favored by our canons of interpretation." *Bates*, 544 U.S. at 449. Accordingly, this Court should affirm the Court of Appeals' ruling that the Cooks' claims are not preempted as a matter of law.

b. Legislative history indicates that Congress did not intend for the Vaccine Act to preempt all design defect claims.

Even if this Court is not inclined to adopt our reading of the text, the legislative history surrounding the passing and enabling of the Vaccine Act shows no "clear and manifest" congressional intent to preempt all design defect claims. To the contrary, the legislative history shows that Congress intended *not* to bar claims as a matter of law.

Legislative history should be considered only if the words of a statute are ambiguous or a plain reading would lead to an absurd result. *Lamie*, 540 U.S. at 534; *Blum v. Stenson*, 465 U.S. 886, 896 (1984). The fact that a statute may be "awkward" and "ungrammatical" does not make it ambiguous for this purpose. *Lamie*, 540 U.S. at 534. Relying on legislative history to discern the intent of Congress is a step that should be taken cautiously. *Piper v. Chris-Craft Indus., Inc.*, 430 U.S. 1, 26 (1977).

The legislative history of the Vaccine Act indicates that Congress intended to make it easier for injured children to obtain quick, fair judgments, not to give vaccine manufacturers blanket immunity from civil litigation arising out of defective and dangerous vaccine formulas. Speaking of the Act generally, the Committee on Energy and Commerce stated: "While the bill *does not prohibit a vaccine-injured person who has completed compensation proceedings from going on to court*, the system is intended to lessen the number of lawsuits against manufacturers." H.R. Rep. No. 99-908, at 12 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6353 (emphasis added). The Committee anticipated that the reduction of lawsuits would result from "the speed of the compensation program, the low transaction costs of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the system's awards." 1986 U.S.C.C.A.N. at 6354. Thus Congress intended to create a no-fault compensation system that would reduce lawsuits not by barring certain claims as matter of law, but by making the new system more attractive to injured victims. *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994); 1986 U.S.C.C.A.N. at 6367 ("Vaccine-injured persons will now have an appealing alternative to the tort system.").

Congress was guided by the Restatement (Second) of Torts, § 402A cmt. k (1965) while structuring the compensation program. In fact, Congress codified Comment k in § 300aa-22(b)(1) of the Act. "[Subsection (b)(1)] sets forth the principle contained in Comment k . . . that a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects even though the vaccine was properly prepared and accompanied by proper directions and warnings." 1986 U.S.C.C.A.N. at 6366-67. Congress therefore intended that subsection (b)(1) operate in the same fashion as Comment k.

Comment k provides that, in the case of "products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," the seller

of such products should "not . . . be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." Restatement (Second) of Torts, § 402A cmt. k.

A majority of jurisdictions hold that under Comment k, the question whether a product is "incapable of being made safe" is determined on a case-by-case basis. *See, e.g., Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 726 (Ga. Ct. App. 2003); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 836 (Neb. 2000) (collecting cases) ("The majority of jurisdictions that have adopted comment *k.* apply it on a case-by-case basis, believing that societal interests in ensuring the marketing and development of prescription drugs will be adequately served without the need to resort to a rule of blanket immunity."); *Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 n.2 (Okla. 1994) (observing that most states require a risk-utility analysis must be performed before Comment k bars recovery). Even the district court in *Bruesewitz* acknowledged that "whether a particular vaccine is unavoidably unsafe – and therefore subject to the immunity from suit posited by comment k – is a question of fact for the jury to determine." *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 445 (E.D. Pa. 2007).

Courts favoring preemption have singled out for special attention another excerpt from the committee report that states: "[I]f [vaccine-injured persons] cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] *should* pursue recompense in the compensation system, not the tort system." 1986 U.S.C.C.A.N. 6344, 6367 (emphasis added). The Third Circuit in *Bruesewitz* seized on this suggestion, but declared it "precise and certain" evidence that Congress intended to grant "immunity for liability for all design defects, whether liability rests on theories of strict liability or negligence." 561 F.3d at 248. A Texas federal

district court likewise read in this language "intent to relegate design defect claims to the compensation system." *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 665 (S.D. Tex. 2004). The *Sykes* court even read this statement to "protect[] vaccine manufacturers from tort liability for making a product in accordance with FDA specifications." 484 F. Supp. 2d at 302.

Such conclusions are neither justified by the language nor consistent with the report as a whole. The most that can be said of this sentence is that Congress preferred design defect claimants to avail themselves of the compensation system. To go any further and consider this language "clear and manifest" intent to grant blanket tort immunity as a matter of law is to convert the invitation ("should") to an imperative ("must"). *See Militrano v. Lederle Labs.*, 810 N.Y.S.2d 506, 508 (N.Y. App. Div. 2006) (conceding that the language used in the report "appears to leave open the possibility of a design defect claim with respect to vaccines covered by the Vaccine Act"). As the foregoing discussion of the committee report demonstrates, Congress did not intend to close the doors of the courthouse to injured victims but rather sought to make it *easier* for them to recover by providing an enticing alternative.

The lack of congressional intent to bar all design defect claims can be clearly seen in the legislative history of the bill that actually implemented and funded the Vaccine Act in 1987. As originally passed in 1986, the compensation program in the Vaccine Act did not take effect until 1988 and it had no funding until 1987. In its report in connection with the implementation and funding bill, the Budget Committee cautioned:

> It is important to note that both at the time of original enactment and in passing *this* legislation, the Committee acted with the understanding that tort remedies were and are available. Without this understanding, such provisions of the Act as those allowing rejection of compensation, trifurcation of trial, and limitation of punitive damages would be meaningless. It is not the Committee's intention to preclude court actions under applicable law. The Committee's intent at the time of considering the Act and in these amendments was and is to leave otherwise applicable

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

H.R. Rep. No. 100-391(I), at 691, *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365 (1987) (emphasis added).

Consistent with the 1986 committee report, this report explicitly states that Congress intended merely to create an attractive option for litigants, not to replace the civil court system. More importantly, this report clearly and manifestly states that Congress did not intend to preempt *any* claims as a matter of law, and that the question whether a vaccine is unavoidably unsafe should be determined in the courts on a case-by-case basis. *Id.*

The report also indicates that the committee responsible for drafting the bill considered and rejected an amendment which would have explicitly preempted design defect claims. The fact that limiting language is deleted from a bill prior to enactment gives rise to a presumption that the limitation was not intended. *Russello v. United States*, 464 U.S. 16, 23–24 (1983) (citing *Arizona v. California*, 373 U.S. 546, 580-81 (1963)). Because Congress specifically rejected language that would have preempted design defect claims, the Court must conclude that Congress did not intend the result advanced by the Respondent.

The excerpt from the Budget Committee report should be given considerable weight despite the Court's general disinclination towards *ex post facto* legislative history. *United States v. Price*, 361 U.S. 304, 313 (1960). As this Court recently recognized, disfavor of "post-enactment legislative history" is based on the fact that statements made after a congressional vote

cannot be said to have affected the outcome of that vote. *District of Columbia v. Heller*, 128 S. Ct. 2783, 2805 (2008). But this is an atypical case. The 1987 Budget Committee report was issued *before* the congressional vote that implemented and funded the compensation program in the Vaccine Act. As originally passed in 1986, the portions of the Act at issue here did not "include a source of payment for such compensation and made the compensation program and accompanying tort reforms contingent on the enactment of a tax to provide funding for the compensation." 1987 U.S.C.C.A.N. at 2313-364. The excerpt quoted above was issued before the vote on the bill that implemented the compensation program and the provision at issue, section 300aa-2(b)(1). Therefore, even if the comments could not be considered in determining the intent of Congress in authoring the Vaccine Act, they certainly should be considered in determining the intent of Congress in making the Act effective.

The Respondents bear the "considerable burden" of showing that Congress expressed a "clear and manifest" intent to preempt state law. *Good*, 129 S. Ct. at 543; *De Buono*, 520 U.S. at 814; *Rice*, 331 U.S. at 230. Here, no such showing can be made. The text of the statute does not support the reading the Respondents would have it bear, and the legislative history positively indicates that Congress did not intend it to have that reading. The Cooks are entitled to a presumption against preemption and this Court recognizes a "duty to accept the reading that disfavors pre-emption." *Bates*, 544 U.S. at 449. For these reasons, the Court of Appeals below was correct in holding that the Cooks' claims are not expressly preempted by 42 U.S.C. § 300aa-22(b)(1) and this Court should affirm the decision of the Thirteenth Circuit.

2. The Cooks' design defect claims are not defeated by field preemption because the Vaccine Act was not intended to "occupy the field" of civil liability for defective vaccines.

Preemption cannot be implied in this case because the Vaccine Act was intended to supplement, not supplant, state tort systems. Since field preemption is only appropriate where Congress intended to supplant state involvement, field preemption does not apply here.

In the absence of an express preemption, congressional intent to preempt state law may sometimes be inferred where federal predominance in a particular field precludes concurrent state or local involvement. *Hillsborough County*, 471 U.S. at 713. Field preemption can be demonstrated where a federal regulatory scheme is so comprehensive that it precludes the existence of supplementary state regulation in that field, or where the federal interest in the field is so strong that enforcement of state laws on the subject must be presumed to be precluded. *Rice*, 331 U.S. at 230. Neither rationale applies to the facts of this case.

Although the federal government has enacted an impressive and complex regulatory scheme relating to the development and distribution of childhood vaccinations, this scheme cannot be said, as a matter of law, to preclude the possibility of civil litigation in state courts. Quite the contrary, this Court continues to recognize that the protection of public health and safety, to include civil lawsuits, is "primarily, and historically, a matter of local concern." *Hillsborough County*, 471 U.S. at 719. The states therefore have "great latitude" to occupy this field. *Lohr*, 518 U.S. at 475 (quoting *Met. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985)).

Regarding the strength of the federal interest, this Court has subdivided the field preemption inquiry. This Court explained that a dominating federal interest that presumes the preclusion of state involvement can be found either in the Constitution itself, or where the subject matter is "intimately blended and intertwined with responsibilities of the national

government." *Hillsborough County*, 471 U.S. at 719 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 66 (1941)). Applying its own test, this Court concluded that health care regulation (in that case, plasmapheresis regulation) obviously did not fit these categories, reiterating that public health and safety is primarily a matter for state regulation. *Hillsborough County*, 471 U.S. at 719.

The impropriety of applying a field preemption analysis to the facts of this case is made evident by considering the fields that fall properly under that rubric. *Zschernig v. Miller*, 389 U.S. 429 (1968) (international treaties); *Hines*, 312 U.S. 52 (foreign relations); *Pa. R. Co. v. Pub. Serv. Comm'n of Commonwealth of Pa.*, 250 U.S. 566, 568 (1919) (railroad regulation).

Field preemption would be especially inappropriate here because the the statute's plain text and legislative history clearly indicate that Congress did not intend to supplant the state tort system. The Act itself declares that, in general, "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). In the subsection headed "preemption," the Act actually *prohibits* states from closing the courthouse doors to victims of vaccine-related injuries, provided that the action is not already barred by other provisions of the Act. § 300aa-22(e).[3]

Far from displacing state court litigation, the Vaccine Act is self-consciously intended to supplement it. Section 300aa-21(a) provides that while injured victims must initially pursue their claims in the Vaccine Court, they are free to reject the award and pursue their claims in civil court. Section 300aa-21(b) allows claimants to withdraw their petitions and file a civil action if the compensation process is too slow, as was the situation in this case.

Congress was clearly aware of the prevalence of state tort litigation in this field and

[3] This subsection appears to be aimed at those states which, in the years leading up to the Vaccine Act, had already barred certain strict liability claims in prescription drug cases. *See Bruesewitz*, 561 F.3d at 246 n.7 (citing *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 128 (9th Cir. 1968); *Lewis v. Baker*, 413 P.2d 400, 404 (Or. 1966)). This may explain what the Committee report means when it states that in "some cases," the provisions of § 300aa-22 would "change most State laws." 1986 U.S.C.C.A.N. at 6366. Far from indicating that Congress intended to "change most State laws" by *barring* all design defect claims, this language equally supports the conclusion that Congress intended to allow *more* cases to be heard in civil courts, as subsection (e) indicates.

carefully drafted the Vaccine Act to work in tandem with the civil court system. "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989) (internal quotation marks omitted). Accordingly, the Cooks' claim should not be barred under a field preemption analysis.

3. The Cooks' claims are not barred by conflict preemption because litigating their claim in a civil court would not conflict with the Vaccine Act or stand as an obstacle to its purposes.

The third and final basis for federal preemption exists when a state law actually conflicts with a federal law. *Hillsborough County*, 471 U.S. at 713. This can be demonstrated in either of two ways. First, in the case of legislative acts, state and federal laws are considered to conflict where it is physically impossible to comply with both. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). Second, a state law or cause of action conflicts with federal law to the extent that it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines*, 312 U.S. at 67. Here, the Cooks' design defect claim neither conflicts with nor frustrates the purposes of the Vaccine Act.

The primary purpose of the Vaccine Act's compensation program is to make certain that children who are injured by vaccinations are compensated for their injuries. 42 U.S.C. § 300aa-10(a). Congress created the compensation program to ensure that "awards can be made to vaccine-injured persons quickly, easily, and with certainty and generosity." 1986 U.S.C.C.A.N. at 6344. Indeed, the first "overriding concern" that led to the creation of the compensation program was "the inadequacy – from both the perspective of vaccine-injured persons as well as vaccine manufacturers – of the current approach to compensating those who have been damaged by a vaccine." 1986 U.S.C.C.A.N. at 6348. The courts have also recognized compensation as

the primary aim of the Vaccine Act. *See, e.g., Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995) (stating that the compensation program is "designed to work faster and with greater ease than the civil tort system"); *Avera v. Sec'y of Health and Human Servs.*, 515 F.3d 1343, 1352 (Fed. Cir. 2008) ("[O]ne of the underlying purposes of the Vaccine Act was to ensure that vaccine injury claimants have readily available a competent bar to prosecute their claims."); *Brice v. Sec'y of Health and Human Servs.*, 240 F.3d 1367, 1368 (Fed. Cir. 2001) (Congress intended to compensate many who could not obtain recovery in tort system).

To be sure, Congress was also concerned about the effect of tort litigation on the vaccine market. 1986 U.S.C.C.A.N. at 6347-48 (opining that the loss of even one vaccine manufacturer could threaten the vaccine market). But as the discussion in section I.B.1.b *supra* indicates, Congress addressed both of these concerns not by barring civil suits but by creating an "attractive alternative" to the tort system, trusting that fewer lawsuits would result and more victims could be compensated.

Unfortunately, the program has failed to live up to its laudable goals. Since the program began in 1988, only 18% of victims who filed claims received any form of compensation under the program. U.S. Dep't of Health and Human Servs., National Vaccine Injury Compensation Program – Claims Filed and Compensated or Dismissed by Vaccine 1 (2009), http://www.hrsa.gov/vaccinecompensation/Docs/ClaimsFiledCompenDismiss.pdf (reprinted in Appendix A). Thirty-eight percent had their claims dismissed by the Vaccine Court and the remaining petitioners either withdrew their petitions to try their luck in the tort system or are still pending. *Id.* The rate of dismissal is even higher for claimants like Estella Marie Cooks who were injured by the DTP-Hib vaccine. Nearly 80% of DTB-Hib recipients have had their claims denied by the Vaccine Court. *Id.* In the twenty years since the program's inception, only three victims of the DTP-Hib vaccine have ever been compensated. *Id.*

Congress intended to create a program that would quickly and fairly compensate injured children, especially those who could not prove any wrongdoing by the vaccine manufacturer. 1986 U.S.C.C.A.N. at 6367. The program calls for a special master to make a decision on the petition within eight months and for the court to enter a judgment within 14 months. 42 U.S.C. § 300aa-22(b). Instead, the program allowed the Cooks' claim to languish for more than 26 months without taking any action. (R. at 1-2.) Even after the Cooks filed their notice of withdrawal, it took the court more than two months just to enter the judgment of withdrawal. (R. at 2.) The Cooks simply want their day in court.

Because Congress intended to facilitate the compensation of injured children even when the vaccine manufacturer was not at fault, allowing the Cooks the opportunity to establish manufacturer wrongdoing[4] in court would not stand as an obstacle to Congress' objectives. If the Cooks are unable to meet their burden in a civil design defect lawsuit, there is no reason to fear that this vaccine manufacturer will be forced from the market. If the Cooks can meet their burden, it would offend the very notion of justice itself to claim that Congress intended to insulate them from liability.

The text of the statute and the legislative history are devoid of a "clear and manifest" intent to bar all design defect suits as a matter of law. To the contrary, Congress intended the vaccine compensation program to supplement the operation of state tort law, not replace it. Moreover, the overriding concern of Congress was to facilitate, increase, and maximize the compensation made to children injured by vaccines, whether the manufacturer was negligent or

[4] The Cooks' negligence claim is strong on the merits. It alleged that the Respondent did not perform adequate tests to determine whether the levels of thimerosal it used in its DTP-Hib vaccine were safe. Despite being a preservative once commonly used in vaccinations, thimerosal is a "very toxic" compound which presents significant health risks, especially when inhaled or put in contact with the skin. Merck, Safety Data Sheet - Thiomersal Ph Eur, BP, USP (2010), http://www.merck-chemicals.com/documents/sds/emd/int/en/8170/817043.pdf. When metabolized by the body, thimerosal degrades to ethyl-mercury. U.S. Food and Drug Adminisration – Thimerosal in Vaccines (2010), http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228#act. Thimerosal was linked to acute mercury poisoning in humans as early as 1972 and in animals as early as 1931. *Id.*

not. Based on the foregoing, we respectfully request that this Court affirm the judgment of the Court of Appeals for the Thirteenth Circuit that the Vaccine Act does not preempt the Cooks' civil design defect claims.

II. THE COURT OF APPEALS INCORRECTLY HELD THAT THE COOKS' COMPLAINT WAS INADEQUATELY PLED.

The Thirteenth Circuit Court of Appeals erred when it held that the Cooks' complaint failed to plead sufficient facts to survive dismissal under Fed. R. Civ. P. 12(b)(6). This is true for three reasons. First, the Cooks' complaint conformed to the historical development and underlying goals and objectives of the Federal Rules of Civil Procedure ("The Rules" or "The Federal Rules"). Second, the Cooks' complaint satisfied the current two-prong pleading standard, which necessitates that a pleading contain more than the "mere recitation of the elements of a cause of action" and assert a claim that is "plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007). Finally, the Court of Appeals misinterpreted the requirements for a 12(b)(6) motion, imposing that pleadings satisfy discovery and summary judgment objectives.

Pleading requirements (and the Rules in general) were adopted with the overarching goal of allowing litigants their day in court. Rule 8(a)(2) speaks directly to the issue, mandating that a plaintiff's complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." With this rule, Congress intended to remove, or at least relax, the procedural technicalities litigants fell victim to under past regimes.

A. The Cooks' complaint comports with the underlying goals and purposes embodied in the Rules as well as the overall historical development of pleadings.

Throughout its history, Rule 8 has been somewhat of a chameleon. True, it has served as the centerpiece for pleadings since it came into existence, but common law and the Field Code

("the Code") placed much more emphasis on pleadings than have the Rules. The common law pleading system was best known for setting procedural "hoops" that litigants must jump through in hopes of reducing a claim to a sole material issue. Christopher M. Fairman, *Heightened Pleading*, 81 TEX. L. REV. 551, 554 (2002). In practice, this led to undue delay, complexity, and expense, which brought about the Code regime. *Id.* at 555. The Code, commonly called the "fact pleading" era, was adopted in 1848 and prefaced as being simple, because it merely required that the complaint include "a plain and concise statement of the facts constituting each cause of action." Code Civ. Proc. S.S. Sec. 163. But this standard based a pleading's sufficiency on "hyper-technical" distinctions that ultimately disposed of many meritorious cases and created conflicting precedent. Note, *Plausible Pleadings: Developing Standards for Rule 11 Sanctions*, 100 HARV. L. REV. 630, 646 (1987). Courts moved from common law and code pleading regimes because they were weighted down with technicalities which dismissed more cases than necessary.

In 1938, the Federal Rules of Civil Procedure were drafted. The drafters envisioned a system that was uniform, trans-substantive,[5] and above all, straightforward. *Id.* at 623. Consequently, the Rules were constructed to promote determination on the merits. This result was only possible if pleadings were not forced to shoulder the extensive list of burdens[6] that common law and the Code required, thereby allowing pleadings to better serve the system as a whole. Accordingly, the Rules specified that pleadings need only provide the function of serving notice, per Rule 8(a)(2). *Id.* at 556.

Under this paradigm, providing notice merely directed the pleader to present a "short and plain statement of a claim entitling one to relief." Fed. R. Civ. P. 8(a)(2). Although a seemingly

[5] "Trans-substantive" means that, regardless of the claim's substantive nature, a uniform system is workable.

[6] In particular, past pleading regimes mandated that pleadings carry out the following functions: 1) to provide notice of a claim or defense, (2) to state facts, (3) to narrow the issues for litigation, and (4) to allow for quick disposition of sham claims and defenses.

simple phrase, courts have struggled with its application. Giving content to this phrase has been the focus of four notable Supreme Court decisions.

Conley v. Gibson marked the first of the succession of pleading cases. 355 U.S. 41 (1957). There, Negro railroad workers brought a class action suit under the Railway Labor Act. *Id.* at 42. The district court and Fifth Circuit Court of Appeals dismissed the claim on 12(b)(6) grounds, but this Court granted *certiorari* to clarify whether the complaint adequately set forth a claim upon which relief could be granted. *Id.* at 41. To determine adequacy, the Court had to compare allegations of the complaint to underlying substantive law.

The Court noted that petitioners' complaint alleged employment discrimination and wrongful discharge based on race. *Id.* at 46. The Court rejected the respondent's argument that the complaint failed to put forth "specific enough facts" to support its general allegations of discrimination and held that petitioners' allegations were sufficient. *Id.* at 47. Justice Black wrote for the Court 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." *Id.* at 45 (emphasis added). This *de minimis* showing was premised on the liberal discovery theory, which allows defendants to enrich fact development and more precisely discover the basis of the claim. *Plausible Pleadings*, 100 HARV. L. REV. at 636.

For nearly fifty years, *Conley*'s "no set of facts" standard held sway. That changed in 2007 with *Twombly*. In *Twombly*, the complaint alleged potential antitrust violations under the Sherman Act, which prohibited certain types of anti-competitive conduct. *Id.* at 573. The only facts alleged in the complaint were "a parallel course of conduct" between the defendant and other companies. *Id.* at 564. The district court dismissed the complaint, *Twombly v. Bell Atl. Corp.*, 313 F. Supp. 2d 174 (S.D.N.Y. 2003), and the Second Circuit reversed, *Twombly v. Bell Atl. Corp.*, 425 F.3d 99 (2d Cir. 2005).

Upon review, this Court reversed, affirming the district court's dismissal. *Twombly*, 550 U.S. at 553. In so doing, it effectively ushered out *Conley*, noting: "[*Conley*'s] famous observation has earned its retirement." *Id.* at 563. In its place, the Court substituted a plausibility standard, stating that a complaint must include "enough facts to state a claim to relief that is plausible on its face." *Id.* at 547. The Court suggested without further elaboration, that a "plausible" claim is not akin to a *probable* one, but it must be more than a mere *possibility* that unlawful conduct has occurred. *Id.* at 557. Nevertheless, the Court reiterated that when analyzing a complaint's sufficiency, "detailed factual allegations" are not required. *Id.* at 555; *see Conley*, 355 U.S. at 47.

But *Twombly* was not the lone pleading case decided during the 2007 Term. In *Erickson v. Pardus*, a *pro se* prisoner filed a complaint alleging that prison officials violated his constitutional rights by withholding medicine he needed as part of ongoing treatment for hepatitis. 551 U.S. 89, 90 (2007). The district court dismissed the complaint, and the Tenth Circuit affirmed, noting that the allegations were fatally "conclusory." *Id.* at 90. In a *per curium* opinion, this Court reversed, holding that the Tenth Circuit significantly departed "from the pleading standard mandated by the Federal Rules of Civil Procedure." *Id.* at 94. Importantly, the *Twombly* standard was cited only for the principle that a complaint simply needs to "give the defendant fair notice of what the claim is and the grounds upon which it rests." *Id.* at 93. Noticeably absent was the notion that any type of heightened pleading was required.

Less than two years later, this Court again accepted a pleading case. In *Ashcroft v. Iqbal*, a Pakistani who was detained after the 9/11 terrorist attacks alleged that the former Attorney General and FBI Director authorized an unconstitutional detention policy. 129 S. Ct. 1937, 1942 (2009). Applying the *Twombly* plausibility standard, the Court explained that "facial plausibility" exists when a plaintiff pleads factual content which allows drawing a "reasonable

inference" of the defendant's liability. *Id.* at 1949.

The detainee acknowledged that, in a qualified immunity context, he was required to "plead sufficient factual matter" showing the government actors imposed the detention polices for discriminatory purposes rather than for any neutral, investigative reason. *Id.* at 1948. Finding that he failed to do so, a splintered 5-4 majority held that the detainee had not "nudged his claims . . . across the line from *conceivable* to *plausible*." *Id.* at 1951 (emphasis added).

At least two important principles can be gleaned from the *Iqbal* decision. First, "threadbare recitals of the elements of a cause of action" will not suffice; factual particulars are a must. *Id.* at 1949. Second, the plausibility standard applies in *all* civil cases. *Id.* at 1953.

B. The Court of Appeals erred in holding that the Cooks' complaint did not meet the plausibility standard.

This Court charged lower federal courts to use their "judicial experience and common sense" to give content to Rule 8 and further flesh out the *Twombly* pleading standard. *Iqbal*, 129 S. Ct. at 1950. Here, the Cooks' complaint met *Twombly*'s two-fold burden because it pled "factual particulars" of a design defect claim that was "plausible on its face."

1. The Cooks' complaint did more than recite the elements for the cause of action.

Respondent mistakenly places too much emphasis on *Twombly*'s "heightened" pleading requirements. Even the *Twombly* Court stressed that Rule 8's burden does not demand "detailed factual allegations." 550 U.S. at 555. Quite to the contrary, *Twombly* explained that Rule 8 merely calls for pleadings to contain more than "unadorned, the-defendant-unlawfully-harmed-me accusations," legal conclusions, or a mechanical recitation of the elements to the cause of action that would raise a right to relief above the speculative level." *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 268 (1986)). The Cooks' complaint has satisfied this prong.

In large part, the Court of Appeals rested its decision as to the pleadings' adequacy on the

premise that they were mere legal conclusions. (R. at 12.) It also thought the complaint should be dismissed because it, regrettably, failed to "state any scientifically reliable evidence" as support. (R. at 12.) In particular, the court criticized the Cooks' complaint, opining that it "did nothing more than provide a formulaic recitation of the elements of a design defect claim." (R. at 12.)

Twombly counsels, and *Iqbal* affirms, that well pleaded factual allegations are different than mere legal conclusions couched as factual allegations. *Iqbal*, 129 S. Ct. at 1949 (citing *Twombly*, 550 U.S. at 555)). Factual allegations *must* be accepted as true for motion to dismiss purposes, while mere conclusions do not warrant such protection. *Id.* Surely the Cooks' complaint specified more than the conclusions on which the Court of Appeals focused. Indeed, the pleadings in this case alleged more particular facts than did the complaints in *Twombly* or *Iqbal*. The Cooks' pleadings more than survive any increased burden.

As civil complaints go, neither *Twombly* nor *Iqbal* were short on ink. Rather, they were short on the "right facts." To be trite, it's not the length of the complaint, it's the quality of the facts pled. The complaint in *Twombly* merely stated that the defendants "engaged in a contract, combination, or conspiracy to prevent competitive entry" in their respective markets. 550 U.S. 554. Similarly, in *Iqbal* the detainee stockpiled his complaint with "legal conclusions" that were "not entitled to a presumption of truth" as previously set forth in *Twombly*. *Iqbal*, 129 S. Ct. at 1951. The complaint was essentially a play-back for a discrimination claim, merely stating that the government actors "knew of, condoned, and willfully and maliciously agreed to subject" the detainee to harsh conditions of confinement "as a matter of policy, *solely* on account of religion, race, and/or national origin." *Id.* (emphasis added). It also suggested that Attorney General Ashcroft was the alleged conspiracy's "principal architect," and proffered FBI Director Mueller as being "instrumental in [the] adoption, promulgation, and implementation" of the

discriminatory policy. *Id.* The complaint further asserted that the governmental actors undertook the course of action "because of," not merely "in spite of," the policy's adverse effects upon the Respondent. *Id.* Even if these assertions in the complaint were taken as true, they merely recited the elements to the cause of action. Considering the "allegations" in *Twombly* and *Iqbal*, a casual observer could have duplicated those pleadings by simply plugging the defendants' names into the hornbook formula for the same causes of action.

Statements such as these are mere legal conclusions held out as factual allegations, and as such, insufficient to survive 12(b)(6) dismissal under *Twombly* and *Iqbal*. But conclusions and elements are significant to provide context to facts pled in the complaint that the court should consider. Put differently, the remaining statements are not mere legal conclusions and should therefore be taken as true. *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984) ("facts that could be proved that are consistent with factual allegations" must also be taken as true); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002) (instructing that factual allegations must be "viewed in the light most favorable to the plaintiff").

Design defect claims in the products liability arena, by their very nature, make it difficult for a plaintiff to pinpoint a specific source of defect against one entity along the chain of distribution prior to discovery. *Bailey v. Janssen Pharmaceuticals, Inc.*, 288 Fed. App'x 597, 605 (11th Cir. 2008). Nevertheless, the Cooks' complaint still managed to provide many more factual particulars than did the defective complaints in *Twombly* and *Iqbal*.[7]

Instead of merely stating that "Carolina Laboratories sold the DTP-Hib Vaccine in a defective condition unreasonably dangerous to Estella Marie Cooks," the Cooks' complaint specifically alleged that the vaccine was defective because it "contained dangerous levels of ethyl mercury, a substance known to the defendants to have neurotoxic properties." (R. at 4.)

[7] Appendix B contains a chart comparing the relevant allegations from the Cooks' complaint with those at issue in *Twombly* and *Iqbal*.

Instead of merely concluding that the defective product "physically harmed" Estella Marie, the Cooks' complaint alleged:

> As a result of the mercury exposure, Estella Marie suffered neurological injuries, including developmental delays, learning disabilities, social delays and deficits, the impairment of fine motor skills, gastrointestinal illness, immune system dysfunction, and other symptoms of mercury poisoning. Some of [her] injuries are likely to be permanent. [DTP-Hib] was the substantial contributing cause of [Estella Marie's] neurodevelopmental injuries.

(R. at 4.) And instead of merely stating that the product was unsafe, the Cooks' complaint explained that Carolina Laboratories

> 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 twenty-four (24) months of a child's life, pursuant to the recommended pediatric immunization schedule.

(R at 4.) Such factually particularized statements plainly pass the threshold that allegations are not mere legal conclusions, and therefore the Cooks' complaint should have survived a 12(b)(6) motion under the *Twombly* plausibility standard.

Other recent cases demonstrate that pleadings as detailed as the Cooks' complaint should survive 12(b)(6) dismissal. *See, e.g., Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 595 (8th Cir. 2009) (pleading satisfied *Twombly* standard even without specific allegations of defendant's conduct); *Rouse v. Berry*, No. 06-2088, 2010 WL 325569, at *1 (D.D.C. Jan. 29, 2010) (pleading satisfied *Iqbal* where it alleged facts indicating independent corroboration of claims); *Chao v. Ballista*, 630 F. Supp. 2d 170, 178 (D. Mass. 2009) (plaintiff alleged sufficient facts to state claim despite possibility that discovery would "reveal an alternative picture"); *Purcel v. Adv. Bionics Corp.*, No. 3:07-CV-1777-M, 2008 WL 3874713 (N.D. Tex. 2008) (surviving dismissal when complaint alleged that a particular malfunction causing plaintiff's injury was the result of

an unapproved supplier's modification of the regulated medical device); *Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790 (W.D. La. 2008) (holding sufficient a complaint that alleged a violation of pre-marketing packing requirements applicable to the particular medical device at issue).

The Court of Appeals did correctly note that Rule 8 substantially altered the pleading landscape compared to the code pleading system, but cautioned that even the Federal Rules' relaxed approach does not "unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." (R. at 13.) Here, the Cooks' complaint contains more than mere legal conclusions. It alleged particular facts that far exceed the *Twombly* standard. Therefore, the Court of Appeals' judgment should be reversed. To hold otherwise would signal a reversion to the hyper-technical era of code pleading and the unjust dismissal of meritorious cases.

2. The Cooks' complaint nudged the claim across the line from conceivable to plausible.

Due to the newness of the recent pleading opinions, there is not yet much guidance as to what plausibility means in practice. It is clear, however, that courts base plausibility on a continuum. One side marks pleadings that satisfy the plausibility standard, while claims that fail to meet the standard are located at the opposite pole. The problem lies in the middle ground. What "in-between" cases meet the standard's burden? This Court should seize the opportunity to further define plausibility through this case.

Only limited guidance was given in *Iqbal*. It stated that plausibility is not "akin to [a] probability" that defendants acted unlawfully, but simply must get past illustrating the "sheer possibility" of defendant's liability. *Iqbal*, 129 S. Ct. at 1949. Specifically, though, when does a complaint pass the line from possible to plausible? This Court has advised that a complaint demonstrating "mere consistency" with a defendant's liability "stops short of the line between

possibility and plausibility" entitling the pleader to relief. *Id.* (quoting *Twombly*, 550 U.S. at 557). The *Iqbal* Court has further directed lower federal courts that the "context-specific task [ ] requires the reviewing court to draw on its judicial experience and common sense" as a guideline when determining whether a complaint is plausible. *Id.* at 1950.

The Respondent's position is that the plausibility standard effectively supplanted *Conley*'s notice pleading standard with some "heightened" form of fact-pleading. (R. at 10.) This is contradicted by *Twombly*'s notation that "once a claim has been stated adequately, it may be supported by showing *any* set of facts consistent with the allegations in the complaint." *Dobyns v. United States*, No. 08-700C, 2010 WL 391510, at *9 (Fed. Cl. 2010) (citing *Twombly*, 550 U.S. at 561) (emphasis added). Of course this could not be accurate if the standard required pleading every fact "consistent with the allegations in the complaint" from the beginning. To say otherwise negates *Erickson*, a case this Court decided only weeks after *Twombly*. There, this Court made clear that Rule 8 does not require specific facts, but that the pleadings only need "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Erickson*, 551 U.S. at 93-94 (citing *Twombly*, 550 U.S. at 555 (quoting *Conley*, 355 U.S. at 41)). *Erickson* also rejected the Court of Appeals' "heightened" pleading application, stating that it "depart[ed] in stark . . . manner from the pleading standard mandated by the Federal Rules of Civil Procedure."[8] *Id.* at 90. This, the Court opined, was a "grand somersault backwards toward" code pleading which the Rules were intended to replace. *Dobyns*, 2010 WL 391510,D at *9. The upshot of *Erickson was* a lowering and clarification of *Twombly*'s burden that this Court has yet to override.

Simply because *Iqbal* made the plausibility standard applicable to all civil actions does

[8] For other post-*Twombly* decisions that reaffirm the notice pleading standard, *see Iqbal*, 129 S. Ct. at 1940; *Bridge v. Phoenix Bond & Indem. Co.,* 553 U.S. 639, n.1 (2008); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319 (2007); *see also Thomas v. Rhode Island,* 542 F.3d 944, 948 n.4 (1st Cir. 2008); *Petro-Hunt, LLC v. United States*, 90 Fed. Cl. 51, 71 (2009).

not mean that it will foreclose the majority of claims at the pleading stage. The uniform plausibility standard is workable, because different application is necessary in different contexts. In other words, not all civil cases are created equal and the level of plausibility will differ in each area.[9] For instance, qualified immunity cases pose a severe risk of governmental intrusion. Whereas, antitrust and securities regulation are tremendously complex. These types of cases may require greater factual detail than the ordinary run-of-the-mill civil action. In stark contrast, these concerns are not present here.

In allowing circuit courts to flesh out the standard, a notable Seventh Circuit Court of Appeals opinion has provided content to plausibility post-*Iqbal*. Just months after *Iqbal*, the Seventh Circuit decided *Smith v. Duffey*, 576 F.3d 336 (7th Cir. 2009). Judge Posner authored the opinion and placed particular emphasis on reeling back *Iqbal*'s effect. *Id.* at 340. He hypothesized that *Iqbal* was unique since it involved a defense of qualified immunity, which is meant to limit the litigation burden on officials. *Id.* As suggested earlier, and reiterated by Judge Posner, the plausibility standard is context-specific. *Id.* Because discovery costs are high in antitrust cases (under *Twombly*) and burdensome in qualified immunity cases (under *Iqbal*), these contexts require a higher level of factual specificity than does the ordinary civil dispute, such as a tort claim. *Id.* According to Judge Posner, in ordinary cases, the plausibility threshold is easier to meet. *Id.*

Because Estella Marie's injuries were so distinctive, they were not "merely consistent with" liability on the Respondent's part. Nor can it fairly be said that it was only a "sheer possibility" that Respondent's were to blame for Estella Marie's injuries. Were this Court to mandate that the Cooks' complaint do more contravenes the Federal Rules' intent. As *Conley*

[9] The Federal Forms serve as good examples regardless of the claims. The notice contemplated should allow opposing parties to glean the grounds for the claim and basic type of litigation which underlies a general understanding of the claim as a whole. Fairman, 81 TEX. L. REV. at 554. By comparison, the Cooks' complaint provides far more than the bare bones pleading requirements of the Federal Forms.

stated many years ago, and *Twombly* and *Iqbal* have so recently affirmed, the Cooks' need only "give the defendant fair notice of what the claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555 (quoting *Conley*, 355 U.S. at 41). Never has this Court mandated "detailed factual particulars" as the standard. *Id.*; *see Conley*, 355 U.S. at 47.

Importantly, discovery in this type of situation does not allow plaintiffs, such as the Cooks, to discover if *pure speculations* are true. This is not a proper basis to file a pleading. Rather, Rule 11 explains that factual statements must be supported by evidence known to the pleader, or in the alternative, "will likely have evidentiary support" after discovery. Fed. R. Civ. P. 11(b)(3). A sufficient complaint cannot rest on mere hope that events happened in a particular way. Rule 8(a)(2)'s "short and plain statement" entitling the pleader to relief must minimally "chart a factual path" towards the defendant's liability. *Schultea v. Wood,* 47 F.3d 1427, 1430 (5th Cir. 1995) (en banc). When that happens, a court may allow limited discovery to fill in the factual gaps. *Id.* at 1433.

Tellingly, the Cooks' complaint charted a factual path directly to the Respondent's liability. First, the complaint correctly named Carolina Laboratories as the manufacturer of the DTP-Hib Vaccine and as defendant in the action. (R. at 1.) Second, the complaint alleged that the vaccine contained a substantial amount of ethyl-mercury, so much that it was at a toxic level. (R. at 1.) Third, the complaint alleged that Estella Marie was injected with three vaccine doses from infancy, which implicated that physical side effects could be more prevalent and severe in infants and young children. (R. at 4.) Fourth, the complaint alleged that Estella Marie suffered extensive injuries. (R. at 1.) And finally, the complaint inferred that Respondents were motivated by financial gain, because a reasonable alternative existed that was more expensive to produce than the one Respondent manufactured. (R. at 4.) While it is true that the Cooks' may have to "prove up" their case later, the specific facts they alleged were well founded, non

conclusory statements and entitled to a presumption of truth.

In sum, what can be gleaned from *Twombly*, *Erickson*, *Iqbal*, and post-*Iqbal* opinions in the circuit courts is that *Twombly*, in fact, was not the revolutionary tool that some anticipated. To be sure, the plausibility standard was never intended by this Court as a vehicle for swiftly doing away with 12(b)(6) motions. Or as a means for courts to terminate legislation at the outset, as the Thirteenth Circuit would have it with its requirement that "scientifically reliable evidence" must be pled as support to survive dismissal. (R. at 12.) The mechanism for that objective is summary judgment.

CONCLUSION

This Court should affirm the Court of Appeals and hold that the Vaccine Act does not preempt all design defect claims as a matter of law. The Cooks are entitled to a heavy presumption against preemption and the Respondent cannot meet the considerable burden of overcoming that presumption. Congress has not "clearly and manifestly" expressed an intent to preempt all design defect claims as a matter of law, and this intent cannot be inferred from the notion of "field preemption." The Vaccine Act is carefully crafted to work hand in hand with state tort law and expressly provides that state law *shall* apply to vaccine-related injuries. Furthermore, there is absolutely no conflict between the Vaccine Act and design defect claims. Congress intended the Vaccine Act compensation program to grant recovery where tort law could not; it did not intend to withhold recovery where tort law was able to provide recovery. Accordingly, the Cooks respectfully request this Court to affirm the Court of Appeals' decision that their design defect claims are not preempted by the Vaccine Act.

The Court of Appeals incorrectly read a "heightened" pleading requirement into *Twombly*'s plausibility standard. It was wrong to determine that the Cooks' complaint rested on "mere legal conclusions," and it should be further faulted for requiring the complaint to provide

"scientifically reliable evidence to support its allegations." (R. at 12-13.) This likens a 12(b)(6) motion to a motion for summary judgment. The Cooks' complaint, moreover, conformed with the historical development and underlying goals and objectives of the Federal Rules. Based on the foregoing, the District Court was correct in holding that the Cooks' complaint satisfied the current two-prong pleading standard. We ask this Court to reverse the judgment of the Thirteenth Circuit Court of Appeals.

Respectfully Submitted,

_____

Counsel for the Petitioners

Team 6
Attorneys at Law

APPENDIX A

National Vaccine Injury Compensation Program (VICP)

Claims Filed and Compensated or Dismissed by Vaccine[1]

November 3, 2009

Vaccines Listed in Claims as Reported by Petitioners

Vaccine(s)	Filed			Compensated	Dismissed
	Injury	Death	Total		
DT (diphtheria-tetanus)	63	9	72	20	48
DTP (diphtheria-tetanus-whole cell pertussis)	3,282	696	3,978	1,265	2,676
DTP-HIB	16	8	24	3	19
DTaP (diphtheria-tetanus-acellular pertussis)	277	69	346	92	113
DTaP-Hep B-IPV	34	16	50	8	9
DTaP-HIB	6	1	7	4	0
DTaP-IPV-HIB	1	0	1	0	0
Td (tetanus-diphtheria)	146	2	148	56	54
Tdap	18	0	18	1	0
Tetanus	63	2	65	26	31
Hepatitis A (Hep A)	20	1	21	3	5
Hepatitis B (Hep B)	540	46	586	154	266
Hep A- Hep B	6	0	6	4	1
Hep B-HIB	6	0	6	2	2
HIB (*Haemophilus influenzae* type b)	19	3	22	6	6
HPV (*human papillomavirus)*	25	2	27	0	0
Influenza (Trivalent)	360	22	382	111	33
IPV (Inactivated Polio)	261	14	275	7	265
OPV (Oral Polio)	279	27	306	157	147
Measles	143	19	162	54	107
Meningococcal	8	0	8	1	0
MMR (measles-mumps-rubella)	800	52	852	295	335
MMR-Varicella	13	1	14	2	1
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	5	3	8	2	6
Pneumococcal Conjugate	25	3	28	5	14
Rotavirus	37	1	38	20	11
Rubella	189	4	193	70	123
Varicella	48	3	51	27	14
Nonqualified[2]	68	9	77	0	76
Unspecified[3]	5,390	6	5,396	2	630
TOTAL	**12,173**	**1,019**	**13,192**	**2,404**	**5,010**

[1] The number of claims filed by vaccine as reported by petitioners since the VICP began on October 1, 1988, and how many of those have been compensated or dismissed by the U.S. Court of Federal Claims (Court). Claims can be compensated by a settlement between parties or a decision by the Court.

[2] Claims filed for vaccines which are not covered under the VICP.

[3] Insufficient information submitted to make a determination. The majority of these claims are part of the Omnibus Autism Proceedings

SOURCE: U.S. Dep't of Health and Human Servs., National Vaccine Injury Compensation Program – Claims Filed and Compensated or Dismissed by Vaccine 1 (2009), http://www.hrsa.gov/vaccinecompensation/Docs/ClaimsFiledCompenDismiss.pdf

APPENDIX B

Comparison of the Cooks' Pleadings to *Twombly* and *Iqbal*

Case	Elements of COA	Facts Pled in Complaint
Twombly Antitrust	1) *Contract, conspiracy or combination* among defendants 2) Unreasonable restraint of trade 3) Conduct pursuant to contract or conspiracy were illegal 4) Injury to plaintiff's business and property as a result of conspiracy 5) Damages that are capable of reasonable ascertainment and not speculative	• Agreed not to compete with one another • Parallel course of conduct that each engaged in to prevent competition
Iqbal Qualified Immunity	1) *Adopted* detention policies 2) *Implemented* detention policies 3) Not for *neutral, investigative* purpose 4) But for purpose of *discrimination on account of race, religion, or national origin*	• Plaintiff designated "high interest" due to his *race, religion, or national origin* • Petitioners directed FBI to arrest and detain thousands of Arab Muslim men . . . as part of 9/11 investigation. • The policy of holding post 9/11 detainees in highly restrictive conditions of confinement until they were "cleared" by the FBI was approved by defendants in discussions the weeks after September 11.
Cooks Products Liability	1) One who sells 2) Any product 3) In *defective condition* 4) *Unreasonably dangerous* 5) To user (is liable for) 6) Physical harm caused to ultimate user if:	• Defendants (Carolina Laboratories, Inc.) • DTP-Hib vaccine, thimerosal-containing shots • Contained ethyl mercury, a substance defendant knew had neurotoxic properties • Contained dangerous levels of ethyl mercury, and defendant failed to conduct adequate safety tests to determine whether 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 twenty-four (24) months of a child's life, pursuant to the recommended pediatric immunization schedule. • Child Cooks • As a result of mercury exposure, vaccine was a contributing cause of neurodevelopmental injuries, i.e., developmental delays, learning disabilities, social delays and deficits, impairment of fine motor skills, gastrointestinal illness, immune system dysfunction, and other symptoms of mercury poisoning. Some injuries are likely permanent • Vaccine product, thimerosal-containing shots • Vaccine product injected into Child Cooks