No. [redacted]

IN THE

[redacted]

APRIL TERM [redacted]

[redacted] *et al.*,

Petitioners,

v.

[redacted],

Respondent.

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

[redacted]

TEAM 9

Attorneys for Petitioners

I. Whether the National Childhood Vaccine Injury Act of 1986 allows state court design defect claims arising from avoidably unsafe side effects resulting from vaccine manufacturers' use of the preservative, thimerosal.

II. Whether the district court may dismiss a products liability complaint for failing to state a claim upon which relief can be granted when the complaint was filed in state court and only reached federal court after the defendant removed the case.

Page

APPENDICES:

Page(s)

CASES:

CONSTITUTIONAL PROVISIONS:

STATUTORY PROVISIONS:

LEGISLATIVE MATERIALS:

LAW REVIEWS:

OTHER MATERIALS:

I

Dan and LoEtta Cooks, plaintiffs in the United States District Court for the District of Grace, Appellants in the United States Court of Appeals for the Thirteenth Circuit and Petitioners here, file this brief on the merits in support of their request that this Court reverse the court of appeals' judgment and remand the case for a trial on the merits.

IV

The opinion of the United States District Court for the District of Grace is unreported but appears on pages 1–8 of the record. The decision of the United States Court of Appeals for the Thirteenth Circuit also is unreported but appears on pages 9–13 of the record.

V

This case involves Article VI, Clause 2 of the United States Constitution, which is reproduced in Appendix "A," and provisions of the National Childhood Vaccine Injury Act of 1986, codified in 42 U.S.C. § 300aa (1986) and reproduced in Appendix "B." This case also involves Rules 1, 8, 11, 12(b)(6) and 81 of the Federal Rules of Civil Procedure, which are reproduced in Appendix "C."

VI

This is a personal injury suit arising from the neurological injuries suffered by Estella Marie Cooks following the administration of three doses of thimerosal, a vaccine produced by Carolina Laboratories. (R. at 1.) Dan and LoEtta Cooks, Petitioners, on behalf of their daughter Estella Marie, filed suit to recover damages for the vaccine's indelible effects. (R. at 2.)

The Victim. During the first few years of Estella Marie's life, between March 1996 to October 1998, she received three doses of Carolina's Diphtheria, Tetanus Toxoids, and Pertussis

("DTP") and Haemophilus influenzae type b ("Hib") combination vaccine, containing the preservative thimerosal, half of which is ethyl mercury. (R. at 1.) Petitioners alleged that the mercury-laden preservative caused Estella Marie's injuries. (R. at 1.) By the time her parents filed this action, Estella Marie was twelve years old, and she already had a host of injuries to show for the vaccine's efficacy—including, developmental delays, learning disabilities, social delays and deficits, the impairment of motor skills, gastrointestinal illness, and immune system dysfunction. (R. at 1 n.1.) As a result of the litany of illnesses, her suffering is bound to continue for the rest of her life.

The Vaccine Act. The National Vaccine Injury Compensation Program ("NVICP"), established by the National Childhood Vaccine Injury Act of 1986 ("NCVIA" or "Vaccine Act"), serves to compensate individuals who have sustained vaccine-related injury or death. 42 U.S.C. § 300aa (1986). In an effort to curtail protracted, expensive litigation for those who have been affected and to protect the much needed vaccine industry from instability and the constant threat of litigation, Congress passed the Vaccine Act to insure the continued presence of a market for vaccine development.[1] H.R. Rep. 99-908, at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345. An injured party must file a petition for compensation with the NVICP, and upon receiving a judgment, the party may then choose to either accept the judgment or pursue recovery through civil action. *See* 42 U.S.C. § 300aa-11, -21 (1986). However, recovery by way of the civil courts is not without its limitations, as the Vaccine Act has refined common tort law

[1] *See* Whitney S. Waldenberg & Sarah E. Wallace, *When Science Is Silent: Examining Compensation of Vaccine-Related Injuries When Scientific Evidence of Causation Is Inconclusive*, 42 Wake Forest L. Rev. 303, 305 (2007) (stating that, with pressure coming from both sides, from victims of vaccine-related injuries and from vaccine manufacturers alike, Congress sought to provide a no-fault, streamlined system for compensation to create a method for recovery for those injured but also to ensure a market for vaccine manufacturers, so as to avoid the possible resurgence of preventable diseases).

for vaccine-related injury or death. *See, e.g.*, 42 U.S.C. § 300aa-22(c) (1986) (providing that no vaccine manufacturer may be held liable for warnings defects that may have accompanied the vaccine). This case involves § 22(b) of the Vaccine Act, the limitations on available tort claims Congress intended to provide, and the individuals the Act most affects—consumers like young Estella Marie.

Petitioners' State Court Filing. Initially filing suit with the National Vaccine Injury Compensation Program under 42 U.S.C. § 300aa, the Cooks Family subsequently withdrew the action with the program and filed suit in the Wicked County Court of Common Pleas. (R. at 2.) With a two-count complaint, the family alleged that (1) Carolina Laboratories negligently failed to conduct adequate safety tests when determining the effect the vaccine would have on humans, and (2) Carolina Laboratories was strictly liable for the vaccine's defective design under products liability law, as a safer alternative existed. (R. at 2.) Seeking all costs, punitive damages, and other equitable relief, the Cooks Family's action would have been governed by Grace state law; however, Carolina Laboratories removed the action to federal court based on diversity of citizenship. (R. at 2.)

The District Court. Soon after removing the case, Carolina Laboratories moved to dismiss the action under Rule 12(b)(6), asserting that the family had failed to state a claim for design defect and, alternatively, that Petitioners' claims were barred by the National Childhood Vaccine Injury Act. (R. at 2–3.) Relying on its interpretation of what amounts to legal sufficiency in light of what is necessary to support a motion to dismiss, Carolina Laboratories asserted that the complaint failed to surpass the requisite threshold. (R. at 2–3.) In addition, Carolina Laboratories contended that Congress intended to preempt such products liability claims against childhood vaccines when it passed the Act in 1986. (R. at 2.) The Cooks Family, on the other

hand, argued that not only does the Vaccine Act plainly allow for such design defect claims—finding that defectively designed, avoidably unsafe vaccines are not preempted by the Vaccine Act—but that its complaint more than adequately meets the federal pleading standard, considering what is possible for such claims. (R. at 3.)

The district court, ultimately deciding in favor of Carolina Laboratories and dismissing the Cooks Family's suit, found that while the complaint included sufficient factual allegations to survive a 12(b)(6) motion to dismiss, section 22(b)(1) of the Vaccine Act preempted the claims. (R. 4, 7.) Specifically, the district court, in part, relied heavily on the legislative history behind the Vaccine Act to support its decision, concluding that vaccine-related injuries must derive from a manufacturing or warning defect in order to recover damages. (R. at 7.) Additionally, to support its order further, the district court found the Vaccine Act's particular resemblance to the language of comment k to the Restatement (Second) of Torts § 402A to be instructive. (R. at 7.) Since the Cooks Family never alleged Carolina Laboratories' failure to deviate from FDA regulations in its design of the vaccine, its claims for design defect under a pure products liability theory were barred. (R. at 7.) Even in light of the Carolina Laboratories' knowledge of the dangerous levels of mercury in the vaccine, its failure to accurately test the product in the variety of ways that it might be administered to humans, and the difficulty of citing the specific cause of injury in pharmaceutical products liability litigation prior to discovery, as alleged by Petitioners, the district court found the sufficiency of pleading futile. (R. at 4.) Using *Blackmon v. American Home Products Corp.*, 328 F. Supp. 2d 659 (S.D. Tex. 2004), as support, the district court dismissed both claims, asserting that the scope § 22(b) of the Vaccine Act was broader than that of comment k and, thus, Petitioners' negligent design defect claim had been preempted, as well as their strict liability claim. (R. at 7.)

The Court of Appeals. Despite affirming the district court's judgment, the court of appeals held differently for both the pleading standard required for 12(b)(6) motions to dismiss and the permissibility of design defect claims against avoidably unsafe vaccines under the Vaccine Act. (R. at 11, 13.) Taking up the Vaccine Act first, the court construed § 22(b) of the Vaccine Act differently. (R. at 10–11.) By noting the importance of the conditional clause within § 22(b)(1)—mainly, "if the [vaccine-related] injury or death resulted from side effects that were unavoidable . . ."—the court found the statute's plain meaning comported with the majority understanding of comment k: if the vaccine's side effects were avoidable, then the manufacturer may be civilly liable. (R. at 11.) Moreover, the court of appeals construed the same committee report the district court relied so heavily upon and discovered Congress intended for the Vaccine Act to have a different effect. (R. at 11.) The Court found that if the injuries were avoidable, as determined on a case-by-case basis, a vaccine manufacturer could be held liable, both strictly and negligently. (R. at 11.)

However, the Thirteenth Circuit Court of Appeals determined the factual allegations fell short of what was required under Rule 8. (R. at 12.) In stating that the district court misapplied *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), the court restated the standard used in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). (R. at 11.) Despite not explaining the crux of *Twombly*—what is required to amount to a "plausible claim" for relief—the court summarily concluded that whatever facts had been alleged merely tracked the elements for any design defect claim. (R. at 11.) Finding that Cooks Family's recitation of testing deficiencies and the toxic nature of ethyl mercury were nothing more than conclusions of law, the court dismissed the claims, collectively, declaring that even the generous pleading standard required under Fed. R.

Civ. P. 8 does not "unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." (R. at 12.)

[redacted]

I

Despite the Thirteenth Circuit Court of Appeals' ultimate dismissal of the Cooks Family's claims, it correctly found that the Vaccine Act does not absolve Carolina Laboratories of responsibility for the preservative, thimerosal, causes. The vaccine manufacturer must answer for the harm resulting from this product.

First, the Vaccine Act does not apply to lawsuits dealing with the toxic effects of vaccine components. Thimerosal is not a vaccine within the meaning of the Vaccine Act. It is a component of a vaccine and, as a result, the preservative does not invoke the statutory protections otherwise available to vaccine manufacturers.

Second, the federal statute does not expressly or impliedly preempt all state claims against vaccine manufacturers. Through an examination of the statute's language, the plain meaning allows for design defect claims when a vaccine is shown to have avoidably unsafe side effects. Moreover, the committee report explaining the focus of the statute supports the notion that the compensation program under the Vaccine Act was meant to serve merely as an appealing alternative, not a mandatory avenue for recourse against vaccine manufacturers. As both the Vaccine Act and the committee report only single out manufacturing and warning defect claims, to conclude that design defect claims are also barred, despite the lack of any provision providing as such, would undermine the very presumption to be employed when construing an express preemption clause—the presumption against preemption.

While Carolina Laboratories and the district court have based their arguments on the statute's similarities to Section 402A of the Restatement (Second) of Torts, it has been widely held that Section 402A does not, in fact, foreclose all design defect claims. Even statements from a subsequent committee report are congruent with the Cooks Family's argument, design defect claims against avoidably unsafe vaccines are permissible. Additionally, the Vaccine Act may not be construed to preempt all design defect claims, as that would constitute field preemption, something which the FDA and this Court have routinely rejected when the field is related to health and safety. Either way, Carolina Laboratories has caused substantial injury for which there should be an opportunity for restitution, as intended by Congress, allowed by courts of this nation, and determined by the Thirteenth Circuit.

I

The court of appeals, however, erred in dismissing the Cooks Family's complaint for failure to state a claim. First, the Federal Rules of Civil Procedure do not apply to complaints filed in state court and subsequently removed to federal court. When the Cooks Family drafted and filed its pleading, it did so in state district court and the complaint conformed with state law. As a result, the *Twombly* and *Iqbal* decisions are inapplicable, as they define the effect of Fed. R. Civ. P. 8, a rule does not retroactively apply to complaints filed in state court.

Additionally, in light of public policy and the core principles of the Federal Rules, the heightened pleading standard of *Twombly* is inapplicable to products liability cases. The Rules were developed to offer a liberal standard, so the burdens placed on those asserting claims would be minimal. In products cases, under the *Twombly* standard, it would be oppressive to require such explicit factual allegations from the filing party when the information necessary to support such a claim is exclusively known by the defendant. Without such information, a plaintiff can

only help to be conclusory. Moreover, the "plausibility" threshold laid down by the *Twombly* decision is hardly definitive, especially when most plaintiffs would be hard-pressed to proffer the requisite factual allegations without any discovery.

However, should the *Twombly* standard is held to apply to the Cooks Family's complaint, the allegations support a plausible claim to relief. The complaint, as filed, provides sufficient notice for the claims being made, the product they concern, the suspected defects in the product, and the distinct injuries for which compensation is sought. Considering the principles bolstering the Federal Rules of Civil Procedure, the Cooks Family has propounded claims with the very specificity that Rule 8 demands; therefore, to preclude recovery at this point would be to undermine the very opportunity our justice system was meant to provide.

Even if this Court determines that dismissal of the complaint was appropriate, then this Court should provide the Cooks Family with an opportunity to replead its case. This is particularly true where, as here, the plaintiff crafted its pleading in state court with state court. Fundamental fairness demands that before an appeal is dismissed, the plaintiff should be given the opportunity to replead her claim.

This Court should reverse-in-part and affirm-in-part to allow the Cooks Family to pursue its claims.

■

The district court resolved this case by granting Carolina Laboratories' motion to dismiss for failing to state a claim upon which relief could be granted. This Court reviews a district court's decision to dismiss under a de novo standard of review. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1952 (2009); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (recognizing reviewing court considers preemption question under a de novo standard of review).

I THE NATIONAL CHILDHOOD VACCINE ACT OF 1986 DOES NOT ABSOLVE CAROLINA LABORATORIES FROM ALL RESPONSIBILITY FOR INJURIES THAT RESULTED FROM ITS DECISION TO INCLUDE THE PRESERVATIVE, THIMEROSAL, IN VACCINES.

Carolina Laboratories contends that it cannot be sued under state law because of the provisions of the National Childhood Vaccine Act of 1986. Through the Act, Congress established a scheme for compensation for vaccine-related injuries or death. 42 U.S.C. § 300aa-11 (1988 ed., as amended 2002). In passing the Vaccine Act, Congress recognized that the "[v]accination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken. Use of vaccines has prevented thousands of children's deaths each year and has substantially reduced the effects resulting from disease." H.R. Rep. No. 99-908, at 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345. However, although most children benefit greatly from immunization programs, "a small but significant number have been gravely injured." *Id.* at 3. Estella Marie is just such a child and Congress never intended for the Act to wipe out her ability to make Carolina Laboratories answer for injuries it caused when it chose to include the mercury-laden preservative, thimerosal, in a vaccine.

A [redacted]

The Cooks Family's claims relate to the inclusion of thimerosal in a vaccine that was administered to Estella Marie. The family does not allege any defect with the vaccine itself, but rather, with Carolina Laboratories' decision to introduce the mercury-laden preservative, thimerosal, into the vaccine. These allegations do not fall within the parameters of the Vaccine Act because the complaint does not assert a vaccine-related claim against a vaccine manufacturer. *Moss v. Merck & Co.*, 381 F.3d 501, 505 (5th Cir. 2004) ("[Thimerosal's] status

as a vaccine component no more makes Thimerosal a 'vaccine' than does the inclusion of a piston under the hood of an automobile make that object an 'engine.'").

The Vaccine Act defines "vaccine manufacturer" as "any corporation, organization or institution, whether public or private (including Federal, state and local departments, agencies or instrumentalities), which manufactures, imports, processes or distributes under its label any vaccine as set forth by the Vaccine Injury Table." 42 U.S.C. § 300aa-33(3). Thimerosal is not listed on the Vaccine Injury Table. Thus, under the Vaccine Act, a manufacturer of a vaccine component or vaccine ingredient is not a vaccine "manufacturer." A "manufacturer" must manufacture, import, process, or distribute the vaccine as a whole.

For a short time, the term "manufacturer" would have included a component manufacturer. In a 2003 amendment to the nearly 500-page Homeland Security Act, Congress added three sections amending the Vaccine Act. The Homeland Security Act, Pub. L. No. 107-296 §§ 1714-1717, 116 Stat. 2135 (adding "including any component or any ingredient of such vaccine" to definition of "manufacturer"). These modifications were met with outrage. *See, e.g.*, Bob Herbert, *Whose Hands Are Dirty?*, N.Y. Times, Nov. 25, 2002, at A21 ("Buried in this massive bill, snuck into it in the dark of night by persons unknown (actually, it's fair to say by Republican persons unknown), was a provision that—incredibly—will protect Lilly and a few other big pharmaceutical outfits from lawsuits by parents who believe their children were harmed by thimerosal."). Soon afterwards, Congress repealed the language. H.R.J. Res. 2, 108th Cong. § 102 (2003), Pub. L. 108-7, at 518.

The Fifth Circuit Court of Appeals recognized the distinction between thimerosal and the underlying vaccine in the case of *Holder v. Abbott Laboratories, Inc.*, 444 F.3d 383 (5th Cir. 2006). There, the parents of two children suffering from neurological damage brought suit

against several pharmaceutical companies for the vaccines they believed caused their children's injuries. *Id.* at 385–86. Some defendants were manufacturers of the preservative thimerosal and others were responsible for making the vaccines themselves. *Id.* at 386. On appeal, the court was asked to determine which defendants the parents were able to pursue without having to file initially with the Court of Federal Claims, as required by the Vaccine Act. *Id.* at 387–88 (citing 42 U.S.C. § 300aa-11(a)(1) (1986)). The Fifth Circuit Court of Appeals concluded that the parents' claims against the thimerosal manufacturers did not have to be initially filed with the Court of Federal Claims, as the Vaccine Act requires, because thimerosal is but a component, not the vaccine itself. *Holder*, 444 F.3d at 389 n.25 (quoting *Moss*, 381 F.3d at 503–04). Because the parents did not initially file suit with the Court of Federal Claims, the court determined that it could only pursue the thimerosal manufacturers, as the Vaccine Act afforded them no protection. *Id.* at 389–90.

B [redacted]

Upon removing this case to federal court, Carolina Laboratories moved to dismiss the lawsuit, asserting that § 22(b) of the Vaccine Act imposes a total bar against all design defect claims, as long as the vaccine at issue was produced in accordance with FDA-approved specifications. (R. at 2.) Specifically, Carolina Laboratories contends that "the plain language of the Vaccine Act reflects the intent of Congress to preempt state law claims for design defects"—a construction which would provide all vaccine manufacturers with "broad immunity, not subject to case-by-case review in the courts." (R. at 2.) However, the express language of the statute expressly *permits* such design defect claims—only barring those claims for vaccine-related injuries caused by "unavoidable" side effects.

The Supremacy Clause of the Constitution provides Congress' power to preempt state law through the passage of federal statutes, but Congress' intent to exercise such power must be "*explicitly* stated in the statute's language or *implicitly* contained in its structure and purpose." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (citing U.S. Const. art. VI, cl. 2) (emphasis added). For express preemption, Congress' intention to supersede state law must be stated in "express terms." *Hillsborough County v. Automated Med. Labs.*, 471 U.S. 707, 713 (1985). While a court may look to the legislative history to supplement the court's understanding, "it cannot alter the plain meaning of the text." *Brown v. Earthboard Sports USA, Inc.*, 481 F.3d 901, 912 (6th Cir. 2007). Alternatively, in the absence of express language, preemption may be found impliedly in two ways: (1) where there is a conflict between state and federal law; or (2) where federal law completely occupies the field in question, leaving no room for additional state regulation. *Pac. Gas & Elec. Co. v. Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 204 (1983). Despite Congress' ability to supplant state law by enacting a federal statute, there remains a pervasive presumption against preemption. *Medtronic, Inc.*, 518 U.S. at 485. Especially for areas such as health and safety, the presumption against preemption ensures that the delicate balance between state and federal interests "will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones*, 430 U.S. at 525.

1 [redacted]

Carolina Laboratories contends that the Vaccine Act expressly preempts all of the Cooks Family's claims. When construing an express preemption clause, a reviewing court must necessarily begin its construction of the statute by examining the "plain wording of the clause," as this "necessarily contains the best evidence of Congress' preemptive intent." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62–63 (2002). While keeping in mind two guiding principles, in

step two, the reviewing court must then "identify the domain expressly preempted." *Medtronic*, 518 U.S. at 484–85. The first of the guiding principles is congressional purpose—"the ultimate touchstone of [the court's] inquiry." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001). The second, and most importantly, is the assumption under which the court must operate—"that the historic police powers of the States [a]re not to be superseded by the Federal Act unless that [is] the clear and manifest purpose of Congress." *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997). It is from this second principle that this Court has deduced the main pillar underlying all preemption cases—the presumption against preemption. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). In context, "when faced with two equally plausible readings of statutory text, [courts] 'have a duty to accept the reading that *disfavors preemption*.'" *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 240 (3d Cir. 2009) (quoting *Bates v. Dow Agrosciences*, 544 U.S. 431, 449 (2005)) (emphasis added).

a. The plain meaning of section 22(b)(1) of the Vaccine Act precludes only those claims against vaccines with side effects first shown to be "unavoidable."

Section 22 relates to those state law claims Congress intended to preempt by way of its passage of the Vaccine Act. *See* 42 U.S.C. § 300aa-22 (1986). Specifically, subsection (a) states that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death,' except as provided in subsections (b), (c), and (e). 42 U.S.C. § 300aa-22(a) (1986). In following, subsection (b), entitled "Unavoidable side effects; warnings," states:

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

42 U.S.C. § 300aa-22(b) (1986). Subsection (b)(2) proceeds by further qualifying paragraph (1); however, it only speaks to manufacturing and warning defects, not design defects. 42 U.S.C. § 300aa-22(b)(2) (1986). As paragraph (2) reads in full,

> For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 301 *et seq.*] and section 351 of the Public Health Service Act [42 U.S.C. § 262] (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which civil action was brought unless the plaintiff shows—
>
> (A) that the manufacturer engaged in the conduct set forth in 42 U.S.C. § 300aa-23(d)(2)(A) or (B), or
> (B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

42 U.S.C. § 300aa-22(b)(2) (1986).

Construing the language of each subsection, paragraph by paragraph as they relate to each other, subsection (a) provides that federal law will trump state law in the cases outlined in sections (b), (c), and (e). As subsections (c) and (e) are not at issue, the court must only construe subsection (b). Consequently, the only language that could purport to preempt design defect claims is that which is located in subsection (b)(1), and, assuming *arguendo* that subsection (b)(1) contains the express preemption language, there is nothing that speaks to preempting design defect claims for vaccine-related injuries that are determined to have been avoidable. *See* 42 U.S.C. § 300aa-22(b)(1) (1986); *see also Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664 (S.D. Tex. 2004) (recognizing the drafters' failure to name design defect claims specifically, despite plainly identifying manufacturing and warning defect claims—thus, making section 22(b) hardly an *express* preemption clause).

Congress intended to use the term "unavoidable" so as to purposefully omit those claims which involve avoidable vaccine-related injury or death from the preemptive domain. To disregard this clause and especially the term "unavoidable," as the district court did (R. at 7), would render the entire clause superfluous, *see Duncan v. Walker*, 533 U.S. 167, 174 (2001) ("We are thus 'reluctant to treat statutory terms as surplusage' in any setting. We are especially unwilling to do so when the term occupies so pivotal a place in the statutory scheme.").

Section 22(b) allows for three types of legal recourse against vaccine manufacturers. Subsection (b)(1) permits design defect claims where the side effects were avoidable, and subsection (b)(2) allows for manufacturing and warning defect claims where the complainant alleges the vaccine manufacturer departed from FDA regulations. The Cook Family is not the first to assert this understanding of the statute's plain meaning.[2] Of the courts that have taken up this issue regarding the scope of preemption of section 22(b), the most notable include: one federal circuit court, two federal district courts and two state courts.[3] In *Sykes*, *Bruesewitz*, and *Militrano*, despite finding both readings to be plausible, both courts ultimately ruled that section

[2] *See Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 299 (E.D. Pa. 2007) (conceding that plaintiff's interpretation of section 22(b), only barring those design defect claims against side effects deemed "unavoidable," was equally as plausible as defendant's contrary assertion); *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 843–44 (Sup. Ct. 2003) ("[T]he section could be read as barring defective design claims only where the injury was unavoidable, with a finding of unavoidability being determined on a case-by-case basis."), *aff'd*, 810 N.Y.S.2d 506 (App. Div. 2006); *Ferrari v. Am. Home. Prods. Corp.*, 650 S.E.2d 585, 590 (Ga. Ct. App. 2007) (explaining not only are there two plausible readings of the statute but that a reviewing court has a duty to accept the one that disfavors preemption pursuant to this Court's decision in *Bates*, 544 U.S. 431).

[3] Third Circuit: *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233 (3d Cir. 2009); Eastern District of Pennsylvania: *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430 (E.D. Pa. 2007); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289 (E.D. Pa. 2007); Southern District of Texas: *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659 (S.D. Tex. 2004); Georgia Supreme Court: *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008).

22(b) bars all preemption claims; the Georgia Supreme Court, however, underwent a similar analysis, examining the plain meaning as well as employing the statute's legislative history, and ruled that section 22(b) does not bar design defect claims for vaccine-related injuries caused by avoidable side effects. *See Am. Home. Prods. Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008).

Of the language contained in section 22, only that of subsection (b)(1) could have any remote bearing on design defect claims; however, the statute plainly qualifies its effect on design defect claims using the very same language it uses to broach the issue 42 U.S.C. § 300aa-22(b)(1) (1986) ("No vaccine manufacturer shall be liable in a civil action for vaccine-related injury or death . . . , *if the injury or death resulted from side effects that were unavoidable*.") (emphasis added). Therefore, only those claims involving injuries due to unavoidable side effects are precluded. The Cooks Family has alleged injuries due to side effects that could have been easily avoided had Carolina Laboratories taken the proper measures to test its product.

b. The legislative history confirms Section 22(b)(1)'s plain language.

This Court has explained that courts should not embark on an exhaustive examination of legislative intent when the statute sufficiently manifests Congress' intention. *See, e.g.*, *Conroy v. Aniskoff*, 507 U.S. 511, 518 (1993) (Scalia, J., concurring) ("The greatest defect of legislative history is its illegitimacy . . . . But not the least of the defects of legislative history is it indeterminacy. If one were to search for an interpretive technique that, *on the whole*, was more likely to confuse than to clarify, one could hardly find a more promising candidate than legislative history.") (emphasis in original). However, even the legislative history confirms that Congress did not intend to supplant state causes of action for harm resulting from avoidable side effects associated with vaccines.

i [redacted]

The district court and the court of appeals used the committee report to shed light on Congress' intent. (R. at 5–7, 11). However, by using such language as "the Committee intends to make clear," H.R. Rep. No. 99-908, at 26 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6367, the report only serves to mislead those parties in Carolina Laboratories' position or those courts deciding in its favor. Despite this notion and the unnecessary nature of parsing the report's language, Petitioners contend the committee report still bolsters their ultimate argument—that the Vaccine Act allows for design defect claims against vaccines with avoidably unsafe side effects.

The critical language in the committee report provides, "[v]accine-injured persons will now have an appealing alternative to the tort system." *Id.* In the following sentence, the committee proceeds by stating the presumption offered by the Act, which *pertains only to manufacturing and warning defect claims*—not design defect claims. *Id.* For purposes of subsection (b), the presumption provides that all vaccines covered by the Act are presumed to include proper directions and warnings when a manufacturer shows it complied with all FDA regulations. *Id.* However, as stated by the committee, the presumption only applies to manufacturing and warning defect claims. *Id.* ("In establishing this presumption, the Committee intends to make clear its view that only those significant failures to warn or provide directions that clearly pertain to vaccine safety and that clearly arise from substantial wrongdoing on the part of the manufacturer ought to result in liability."). If the Committee intended to expressly preempt all design defect claims, besides being unmistakably clear in the statute's text, the Committee could have at least offered an explanation of its intention to do so in the report, as it did for both

manufacturing and warning defect claims. Since it did not do so, courts should not import additional meaning to legislation that never was.

i [redacted]h

In the committee report, the corresponding explanation for subsection 22(b) offers comment k to the Restatement (Second) of Torts § 402A as the basis for the subsection's purpose. Comment k attempts to explain "unavoidably unsafe products" in relation to the "unreasonably dangerous" language in Section 402A. However, like the effect of section 22(b) of the Vaccine Act here, there has been much disagreement as to the effect of comment k for those states that have adopted it. See Jeffrey D. Winchester, Note, *Section 8(c) of the Proposed Restatement of Torts: Is It Really What the Doctor Ordered?*, 82 Cornell L. Rev. 644 (1997). In fact, comment k is something less than a paradigm of clarity, as it has been more of a "model of confusion" than an illuminating explanation. Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 Geo. Wash. L. Rev. 76, 79 (1994). In the context of design defect claims, such claims should be reviewed on a case-by-case basis, employing the following method of analysis to determine:

> (1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable;
> (2) whether the then-existing risk posed by the product was both substantial and *unavoidable*; and
> (3) whether the interest in availability outweighs the interest in promoting enhanced accountability through strict liability design defect review.

Kearle v. Lederle Labs., 218 Cal. Rptr. 453, 464 (Ct. App. 1985) (emphasis added); *see also Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8 (1st Cir. 1995); *Patten v. Lederle Labs.*, 676 F. Supp. 233 (D. Utah 1987).

The aspect of "unavoidability" is crucial to the statute's effect, similar to the majority of states who have applied comment k in other products liability cases. (R. at 10–11); *Ferrari*, 668 S.E.2d 236. Even the committee report speaks to the essential nature of "unavoidability" in the context of the statute, by stating, "[the committee] intends that the principle of comment k regarding 'unavoidably unsafe' products . . . apply to the vaccines covered in the bill . . . ." H.R. Rep. No. 99-908, at 26 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6367. If a majority of states differentiate between those products that are avoidably and unavoidably unsafe in the context of comment k, as stated above, it is unconscionable to think the committee intended to employ the minority's "blanket immunity" for vaccine manufacturers with such a succinct explanation. According to the majority, comment k is an affirmative defense, and the manufacturer must prove that its product is commensurate with the current state of the art. *Patten*, 676 F. Supp. at 237. Accordingly, if comment k's principle is the foundation of subsection 22(b), then the same requirement should transfer—vaccine manufacturers should not be granted blanket immunity but should have to prove their product is incapable of being made safe "in the present state of human knowledge." *Id.* (quoting Restatement (Second) of Torts § 402A cmt. k (1964)).

i [redacted]

While the Vaccine Act was initially passed in 1986, it did not take effect until Congress created a tax levy to fund the Vaccine Act's compensation program. H.R. Rep. No. 100-391(I), at 690 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-364. Acting pursuant to the recommendations of the House Committee on Energy and Commerce, the Budget Committee, in its own committee report, clarified the scope of the Vaccine Act, stressing "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 [state] law." *Ferrari*, 668 S.E.2d at 241 (quoting H.R. Rep. No. 100-391(I), at 691 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365). Moreover, as the subsequent committee report states, an amendment was offered during the original consideration of the Act, stating that "a manufacturer's failure to develop [a] safer vaccine [would not be] grounds for liability." H.R. Rep. No. 100-391(I), at 691 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365. However, the amendment was rejected. *Id.*

In *Bruesewitz*, the court dismissed this legislative action—saying, it is unclear as to which committee was speaking by the way the word "committee" was used interchangeably for both the Energy and Commerce Committee and the Budget Committee in the report. 561 F.3d at 250. The court also complained of the lack of a record to confirm that the Energy and Commerce Committee had in fact considered and rejected any amendments related to design defects. *Id.* Ultimately, the court concluded that it would be in error to consider the Budget Committee's report "as an accurate reflection of what transpired." *Id.* Besides the first page of the report including "Report to accompany recommendations from the Energy and Commerce Committee," the Budget Committee plainly stated that the rejected amendment was initially examined during the Act's *original* consideration. H.R. Rep. No. 100-391(I), at 691 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365. The Energy and Commerce Committee, as relayed by the Budget Committee, never intended for the Vaccine Act to preempt *all* design defect claims, and it is preposterous to think the Budget Committee offered explanations *sua sponte*. The explanations offered were only pursuant to what the Energy and Commerce Committee had recommended.

2 [redacted]

Carolina Laboratories' preemption claim fares no better under the doctrine of implied preemption. Implied preemption comes in two varieties, commonly known as "conflict preemption" and "field preemption." *See Cal. Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272, 281 (1987) (field preemption); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (conflict preemption). Conflict preemption stands for when a state law is preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Because there is no law being called for any citizen or entity to abide by, there can be no conflict preemption. Alternatively, though it is feasible for there to be field preemption in this circumstance, there is not. Either way, this Court has consistently refused to confer immunity from liability under the guise of implied preemption.[4]

For field preemption, courts have found congressional intent to preempt state law where Congress and the states occupy the same field. *Guerra*, 479 U.S. at 281. But those have all considered this issue in light of express preemption; however, with the way most have chosen to apply comment k to the Restatement (Second) of Torts § 402A, providing vaccine manufacturers with blanket immunity, such an application could arguably amount to field preemption for vaccine design. *Ferrari*, 668 S.E.2d at 243 (explaining that "construing subsection 22(b)(1) as set forth in *Bruesewitz*, *Sykes*, *Blackmon*, and *Militrano* would have the perverse effect of granting complete tort immunity from design defect liability to an entire industry") (citations

[4] *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 894 (2000) (Stevens, J., dissenting) (speaking to instances of implied preemption, Justice Stevens wrote, "the Supremacy Clause does not give unelected federal judges *carte blanche* to use federal law as a means of imposing their own ideas of tort reform on the States."); *see also United Constr. Workers v. Laburnum Constr. Co.*, 347 U.S. 656, 663–64 (1954).

omitted). Nonetheless, this sort of field preemption for pharmaceutical companies has been routinely rejected by this Court. *See, e.g., Hillsborough*, 471 U.S. 707 (declaring that the Court will seldom infer an intent to preempt, in its entirety, a field related to health and safety). Consequently, the Act does not impliedly preempt all design defect claims against vaccine manufacturers.

I THE COOKS FAMILY STATED A CLAIM UPON WHICH RELIEF COULD BE GRANTED.

The court of appeals dismissed the Cooks Family's lawsuit because the complaint—drafted and filed in Grace state court according to state pleading rules—did not comply with the Federal Rules. Rule 12(b)(6) challenges the legal sufficiency of a complaint and requires that it state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). A complaint must allege conduct in violation of law, which, at a minimum, must contain enough information to identify each element of a claim for relief. Fed. R. Civ. P. 8. Only in this manner does notice pleading meet the constitutional dictates of due process by providing adequate notice to allow for a meaningful opportunity to be heard. *See Mullane v. Cent. Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950).

Three years ago, this Court addressed the demands of Rule 8. In *Bell Atlantic Corp. v. Twombly*, a group of subscribers to local telephone and Internet services challenged the conduct of several local exchange carriers, claiming that they had conspired to inflate charges for local telephone and high-speed Internet services. 550 U.S. 544, 550 (2007). The plaintiffs there filed a complaint alleging that the defendant-companies, by way of their parallel conduct, coordinated and agreed to force other independent carriers out of the market. *Id.* The defendant challenged the sufficiency of the complaint because the plaintiffs merely alleged parallel conduct among the defendant-companies but propounded nothing more to support its antitrust claims. *Id.* at 552. In

dismissing the complaint, this Court explained that "stating such [an antitrust] claim requires a complaint with enough factual matter (taken as true) to suggest that an agreement was made." *Id.* at 556. In addition to factual sufficiency, the allegations made must "call[] for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal agreement," so suggestive that the alleged conspiracy is plausible. *Id.*

Two years later, this Court revisited the pleading rules in the case of *Ashcroft v. Iqbal*. 129 S. Ct. 1937 (2009). There, the plaintiff filed a *Bivens* action alleging that various law enforcement officials, ranging from day-to-day correctional officers to the U.S. Attorney General and the Director of the Federal Bureau of Investigation, were responsible for his unreasonably harsh treatment while confined as person "of high interest" for his suspected involvement with the terrorist attacks of September 11th as a Muslim of Pakistani origin. *Id.* at 1943–44. The government challenged the complaint's legal sufficiency on the grounds that plaintiff failed to state sufficient allegations to show defendants' involvement clearly established unconstitutional conduct. *Id.* at 1944. In dismissing the complaint, this Court reasoned plaintiff failed to plead the necessary facts "plausibly showing that [defendants] purposefully adopted a policy of classifying post-September-11 detainees as 'of high interest' because of their race, religion, or national origin." *Id.* at 1952. In so holding, this Court announced that the *Twombly* standard was not exclusive to antitrust matters but extends to all civil actions, "antitrust and discrimination suits alike." *Id.* at 1953.

Since these holdings, courts have held that the heightened pleading standards do not apply in certain circumstances. *See, e.g., Ciomber v. Coop. Plus, Inc.*, 527 F.3d 635 (7th Cir. 2008) (explaining that state law standards, not federal pleading standards, applied to pre-removal pleadings). This case presents another circumstance. In the court of appeals' estimation,

however, the Cooks Family had to, and did not, meet the heightened pleading requirements announced in *Twombly* and *Iqbal*. But, in reaching this conclusion, the court not only analyzed the standard incorrectly but it also applied the standard where it did not apply. Thus, the court of appeals erred in determining that the Cooks Family failed to state a claim upon which relief could be granted.

A [redacted]

The Cooks Family filed its complaint in the Wicked County Court of Common Pleas, and conformed with the pleading requirements for the State of Grace. The case only reached federal court when Carolina Laboratories subsequently removed the case to federal court based on diversity. (R. at 2.) Nonetheless, Carolina Laboratories sought a retrospective application of the Federal Rules. In dismissing the claim for failing to comply with Rule 8(a)(2), the court of appeals improperly held that the Cooks Family had to comply with these federal pleading requirements even though the complaint was drafted and filed as a state-court pleading.

1 [redacted]

The Federal Rules of Civil Procedure only apply to a civil action only after it is removed from state court. Rule 81 specifically provides that "[t]hese rules apply to a civil action after it is removed from a state court." Fed. R. Civ. P. 81(c)(1). As a result, a complaint filed in state court that was drafted as a state court pleading must be gauged against the state procedural requirements that were applicable at the time the pleading was filed. This approach makes sense because, as one court explained, "[n]o federal interest in a case arises until the date of removal, and there is no reason why federal procedural rules should be thought to apply until such an interest arises." *Alber v. Ill. Dep't of Mental Health & Developmental Disabilities*, 786 F. Supp. 1340, 1376 (N.D. Ill. 1992). Not only is Rule 8(a)(2) inapplicable to state court pleadings, but a

federal court, sitting in diversity, cannot use Rule 11 to retrospectively sanction one who signs a state court pleading. *Tompkins v. Cyr*, F.3d 770, 787 (5th Cir. 2000); *see also Ciomber*, 527 F.3d at 644 ("Normally, we are guided by the Federal Rules of Civil Procedure when addressing the sufficiency of pleadings, but because Ciomber's complaint and Cooperative Plus's answer were filed in Illinois state court before this action was removed, we must apply Illinois's standards.").

2 *Twombly* & *Iqbal*

The district court determined that *Twombly* and *Iqbal* controlled but, in doing so, the court ignored critical distinctions—those cases arose under federal law and the plaintiffs there filed pleadings in federal court. Those distinctions make a difference. *Twombly* involved a putative class' allegations under the Sherman Antitrust Act that were filed in the United States District Court for the Southern District of New York. 550 U.S. at 550. Likewise, *Iqbal* dealt with a civil rights plaintiff's claims that federal government officials violated his constitutional rights and those *Bivens* claims were brought in the United States District Court for the Eastern District of New York. 129 S. Ct. at 1943. In both cases, each action was originally filed in federal court, so the Federal Rules of Civil Procedure were applicable from the outset. Thus, the federal interest was implicated from the moment the case began. Under these circumstances, federal procedural rules would undoubtedly apply. *Twombly* and *Iqbal* cannot be equated to the situation involved here where the challenged complaint originated in state court.

B *Twombly*'s

Petitioners alleged everything they knew. They did not file against a litany of defendants, nor did they include a host of claims. Instead, they targeted a specific product, thimerosal, known by Carolina Laboratories to have neurotoxic properties and used by Carolina Laboratories to preserve its DTP/Hib combination vaccine. Citing the injuries thimerosal is known to cause,

the injuries shown by Estella Marie, and the fact that the suspect vaccine contained thimerosal, Petitioners' complaint can hardly be called a threadbare recitation of the elements for a products liability action. The rationale and spirit of the *Twombly* decision does not translate to the products liability context. The heightened pleading requirements should not be used as a means of depriving products liability plaintiffs of their day in court.

1 *Twombly* and *Iqbal*

Twombly and *Iqbal* arose in unique contexts. Though this Court determined that, if the plaintiffs there had a legitimate claim, they would have alleged additional facts, the holding was a function of the nature of the plaintiffs' prima facie burden, the type of evidence available to them, and what was included in their complaints. The Seventh Circuit Court of Appeals emphasized this point by stating, "how many facts are enough will depend on the type of case. In a complex antitrust or RICO case a fuller set of factual allegations than found in the sample complaints in the civil rules' Appendix of Forms may be necessary to show that the plaintiff's claim is not largely groundless." *Limestone Dev. Corp. v. Village of Lemont, Ill.*, 520 F.3d 797, 803 (7th Cir. 2008).

A products liability claim is fundamentally different. To prove a product-liability claim, the moving party needs to show: (1) the product was defectively manufactured or designed; (2) the defect was the cause of the plaintiff's injury; and (3) damages. *See* Restatement (Second) of Torts § 402A. As the district court explained, "[t]he very nature of a products liability action—where the cause or source of the defect is not obvious to the consumer—makes it difficult for a plaintiff to pinpoint a specific source of defect against one entity along the chain of distribution prior to discovery." (R. at 4) (citing *Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 605 (11th Cir. 2008)). Many products liability claims may hinge on subjective motivations,

states of mind, or concealed activities that the consuming public will not know without discovery. *See EEOC v. Concentra Health Servs., Inc.*, 496 F.3d 773, 780 (7th Cir. 2007) ("[A] plaintiff might sometimes have a right to relief without knowing every factual detail supporting its right; requiring the plaintiff to plead those unknown details before discovery would improperly deny the plaintiff the opportunity to prove its claim.").

Applying the heightened pleading requirements in the products liability context not only undermines the societal goals in restricting dangerous products but it does so in a way that has no relationship to the personal merit of a particular case. That is because, in many instances, consumers will not have access to the factual information needed to comply with these pleading standards. Enforcing those standards to effectively foreclose an injured consumer's ability to seek redress violates the letter and spirit of the Federal Rules of Civil Procedure.

2 *Twombly*

Chief Justice John Marshall recognized the importance of access to justice in *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 163 (1803) ("The very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury. One of the first duties of government is to afford that protection."). The Federal Rules were written in a fashion to underscore this duty—establishing a liberal pleading system in which the burdens placed on those asserting claims were minimal. A. Benjamin Spencer, *Plausibility Reading*, 49 B.C. L. Rev. 431, 469 (2008). However, to require so much of the products liability plaintiff from the very outset, as *Twombly* suggests, would contradict the liberal pleading system the Federal Rules intended to create.

As this Court has previously emphasized, "other provisions of the Federal Rules of Civil Procedure are inextricably linked to Rule 8(a)'s simplified notice pleading standard."

Swierkiewicz v. Sorema N.A., 534 U.S. 506, 513 (2002). Therefore, Rule 8(a) may not be read alone but only as a component to a larger set of rules. And as Rule 8(e) requires, highlighting the backbone of the Rules' overall purpose, "pleadings must be construed so as to do justice." Fed. R. Civ. P. 8(e). The purpose of Rule 8(e) is to ensure that judges make every effort to read a complaint in the light most favorable to the plaintiff, liberally construing it to state a claim unless it is clear that the plaintiff will be unable to make out a claim. *See Jenkins v. McKeithen*, 395 U.S. 411, 421 (1969); *see also Conley v. Gibson*, 355 U.S. 41, 48 (1957) ("The Federal Rules reject the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept the principle that the purpose of pleading is to facilitate a proper decision on the merits."). Consequently, if the *Twombly* Court's reading of Rule 8(a)(2) required the rejection of *Conley*'s "no set of facts" language in products liability cases, then plausibility pleading either implicitly repudiates or is simply incompatible with the liberal construction duty of Rule 8(e) on which *Conley*'s statement was based.

Rule 11 also favors generalized, notice pleading. Under Rule 11, attorneys certify that the claims presented in a complaint are warranted by law and that the allegations "have evidentiary support or, if specifically so identified, *are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery*." Fed. R. Civ. P. 11(b)(3) (emphasis added). If the claims asserted are baseless, having no evidentiary support or violating any of the conditions stated by the Rule, then sanctions may be filed. Fed. R. Civ. P. 11(c). This argument of Rule 11 favoring a generalized, notice pleading standard is not novel, as both this Court and lower federal courts have linked the flexibility of Rule 11 with the liberal notice pleading standard as well. *See Rotella v. Wood*, 528 U.S. 549, 560 (2000) (citing how Rule 11(b)(3) "allow[s] for pleadings based on evidence reasonably anticipated after further investigation or

discovery"); *see also Frantz v. U.S. Powerlifting Fed'n*, 836 F.2d 1063, 1068 (7th Cir. 1987) ("Rule 11 neither modifies the 'notice pleading' standard approach of the federal rules nor requires counsel to prove the case in advance of discovery."). The Federal Rules envisioned a liberal pleading standard that would allow for injured products liability plaintiffs to have access to justice, not bar the door to the necessary discovery some plaintiffs need to fully justify their claims.

C [illegible]*wombly*

The *Twombly* standard, though inappropriate here, was still met by the Cooks Family's complaint. As this Court explained,

> Rule 8(a)(2) does not contemplate a court's passing on the merits of a litigant's claim at the pleading stage. Rather, the "simplified notice pleading standard" of the Federal Rules "relies on liberal discovery rules and summary judgment motions to define disputed facts and issues and to dispose of unmeritorious claims."

Twombly, 550 U.S. at 585 (quoting *Swierkiewicz*, 534 U.S. at 512).

1 [illegible]

The first step of *Twombly* analysis requires an examination of the alleged facts and whether specific factual statements support the allegations. 550 U.S. at 570. In its complaint, the Cooks Family alleged that Carolina Laboratories

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

(R. at 4.) The family also alleged that "[a]s 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 his injuries are likely to be permanent." (R. at 4 n.7.) *Twombly* forbids a "formulaic recitation of the elements" because the intended purpose of a complaint is not merely to give fair notice but also to provide the grounds on which the complaint rests. 550 U.S. at 555. The complaint gives Carolina Laboratories fair notice of the claim being asserted, for what reasons, the defective product at issue, and the precise harm the product has caused.

These allegations are no different from what the Eleventh Circuit Court of Appeals said were sufficient in *Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597. There, the estate of a patient sued the manufacturer of a time-released pain control patch, which failed, releasing the entire dose to the decedent and ultimately causing his death. *Id.* at 599. Despite the inclusion of multiple defect theories of strict liability and multiple defendants, the Eleventh Circuit found plaintiff's complaint sufficiently met the *Twombly* pleading standard. *Id.* at 609. The plaintiff in *Bailey* asserted that the company was involved in designing, manufacturing, testing, and selling of the product; therefore, the court found the defendant-company had derived revenue from the product's sale.[5] *Id.* at 607. The complaint there also suggested several possible defects by identifying the suspected source of death—the medical patch, itself. *Id.* The Eleventh Circuit Court of Appeals found plaintiff had adequately alleged the suspected defect, which would allow the defendant-company to frame a responsive pleading to a defect in the product's design. *Id.* at 608. Lastly, in *Bailey*, the court found plaintiff had sufficiently pleaded causation, as the

[5] The Cooks Family necessarily had to make a connection between the vaccine and Carolina Laboratories because Carolina Laboratories seeks refuge under its construction of the Vaccine Act, which it claims affords it total immunity. However, the record is silent as to whether the family specifically alleged that Carolina Laboratories was involved in the designing, manufacturing, testing, and selling of the product. Nothing reflects that Carolina Laboratories claimed that it was not involved in any of the above areas of involvement. Only the allegations pertaining to Carolina Laboratories' inadequate testing procedures are mentioned. (R. at 4.)

complaint stated the proximity of the injuries sustained (death) to the time the patch was provided to the decedent. *Id.*

Looking to what has been proffered by the Cooks Family, the factual allegations that conform to the elements for a products liability suit and are far from a threadbare recitation. Thus, the complaint made specific factual allegations consistent with this Court's holding in *Twombly*. There can be no mistake at to the provided notice, and as argued, there can be no question of the grounds on which the complaint rests. The court must accept all factual allegations as being true, *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984), and the reviewing court must examine the complaint in a light most favorable to the plaintiff, *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), what the Cooks Family has alleged meets the liberal pleading standard the Federal Rules intended to provide. As the *Twombly* Court conceded, "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and 'that a recovery is very remote and unlikely.'" 550 U.S. at 556 (quoting *Scheuer*, 416 U.S. at 236).

2 [illegible]n

The second step of *Twombly* analysis requires an examination of the alleged facts and whether or not they state a claim to relief that is "plausible" on its face. 550 U.S. at 570. The plausibility standard "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence supporting the plaintiff's allegations." *Id.* at 556.

The complaint alleged that Carolina Laboratories manufactures thimerosal for incorporation into other products. (R. at 2.) The vaccine manufacturers' products, as alleged in the Cooks Family's complaint, incorporate thimerosal in amounts which, at the recommended vaccine dosage, are alleged to be toxic to the recipient infants and young children. (R. at 2.) As

found by the Autism Research Institute and published in the journal of *Laboratory Medicine*, "there exist striking similarities between autism and mercury poisoning" because of the same set of nervous system autoantibodies seen in both mercury poisoning and autism. Bernard Rimland & Woody McGinnis, *Vaccines and Autism*, 33 Laboratory Med. 708, 713 (2002). As a result, Drs. Rimland and McGinnis recommended, "[g]iven current available data, thimerosal would stand no chance of approval as a new injectable medication by modern standards, and because thimerosal alternatives exist for all the scheduled childhood vaccines, we call for its summary removal and safe disposal from every repository in this country." *Id.* at 716.

The Cooks Family's claims are plausible under *Twombly*. The complaint has not alleged the vaccine pleading equivalent of the world is flat, the moon is made of green cheese, or the earth is the center of the solar system. The alleged injuries—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—are all consistent with harm caused by thimerosal. Beyond the suspicion of a defective testing procedure, what they know about thimerosal, and the harm they can see in the injuries their daughter has sustained, much more information is necessary for Petitioners to prove up each claim before a trier of fact. However, to declare that their claims are implausible would be an extreme departure from what our justice system has intended to provide—access to recovery for unwarranted injuries.

D

Regardless of whether the complaint was deficient, the district court should not have dismissed the complaint. Rule 15(a) provides that a district court should "freely give[]" leave to amend when there is no "undue delay, bad faith[,] . . . dilatory motive on the part of the movant, . . . undue prejudice to the opposing party by virtue of . . . the amendment, [or] futility of [the]

amendment . . . ." *Foman v. Davis*, 371 U.S. 178, 182 (1962) (quoting Fed. R. Civ. P. 15(a)); *see also DeSoto v. Yellow Freight Sys., Inc.*, 957 F.2d 655, 658 (9th Cir. 1992) (recognizing leave generally granted unless deficiencies could not be cured by amendment). Thus, if the Court determines that the Cooks Family was required to meet heightened federal pleading requirements and its state-court complaint did not do so, the case should be remanded to the district court to allow an opportunity to cure the deficiency.

CONCLUSION

This Court should affirm-in-part and reverse-in-part. Specifically, this Court should affirm the Thirteenth Circuit's finding that the Vaccine Act provides for design defect claims against vaccine manufacturers for vaccines with avoidably unsafe side effects. However, this Court should reverse the Thirteenth Circuit's judgment as to Respondent's motion to dismiss, since the Federal Rules and the *Twombly* pleading standard do not apply to complaints initially filed in state court.

Respectfully submitted,

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ATTORNEYS FOR PETITIONERS

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

[illegible]

[illegible]

§[illegible]

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

(b) Unavoidable adverse side effects; warnings.

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

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [*21 USCS §§ 301* et seq.] and *section 351* of the Public Health Service Act [*42 USCS § 262*] (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows--

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 2123(d)(2) [*42 USCS § 300aa-23(d)(2)(A)* or (B)], or

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

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

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

(e) Preemption. No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle [*42 USCS §§ 300aa-10* et seq.].

* * *

§

For purposes of this subtitle [*42 USCS §§ 300aa-10* et seq.]:

(1) The term "health care provider" means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

(2) The term "legal representative" means a parent or an individual who qualifies as a legal guardian under State law.

(3) The term "manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 2128 [*42 USCS § 300aa-28*], such term shall include the manufacturer of any other vaccine covered by that section. The term "manufacture" means to manufacture, import, process, or distribute a vaccine.

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(5) The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

(6)

(A) The term "Advisory Commission on Childhood Vaccines" means the Commission established under section 2119 [*42 USCS § 300aa-19*].

(B) The term "Vaccine Injury Table" means the table set out in section 2114 [*42 USCS § 300aa-14*].

(7) [Repealed]

[redacted]

[redacted]

[redacted]

Scope and Purpose

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

[redacted]

General Rules of Pleading

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

(b) Defenses; Admissions and Denials.
(1) *In General.* In responding to a pleading, a party must:
(A) state in short and plain terms its defenses to each claim asserted against it; and
(B) admit or deny the allegations asserted against it by an opposing party.
(2) *Denials--Responding to the Substance.* A denial must fairly respond to the substance of the allegation.
(3) *General and Specific Denials.* A party that intends in good faith to deny all the allegations of a pleading--including the jurisdictional grounds--may do so by a general denial. A party that does not intend to deny all the allegations must either specifically deny designated allegations or generally deny all except those specifically admitted.
(4) *Denying Part of an Allegation.* A party that intends in good faith to deny only part of an allegation must admit the part that is true and deny the rest.
(5) *Lacking Knowledge or Information.* A party that lacks knowledge or information sufficient to form a belief about the truth of an allegation must so state, and the statement has the effect of a denial.
(6) *Effect of Failing to Deny.* An allegation--other than one relating to the amount of damages--is admitted if a responsive pleading is required and the allegation is not denied. If a responsive pleading is not required, an allegation is considered denied or avoided.

(c) Affirmative Defenses.

(1) *In General.* In responding to a pleading, a party must affirmatively state any avoidance or affirmative defense, including:

. accord and satisfaction;
. arbitration and award;
. assumption of risk;
. contributory negligence;
. discharge in bankruptcy;
. duress;
. estoppel;
. failure of consideration;
. fraud;
. illegality;
. injury by fellow servant;
. laches;
. license;
. payment;
. release;
. res judicata;
. statute of frauds;
. statute of limitations; and
. waiver.

(2) *Mistaken Designation.* If a party mistakenly designates a defense as a counterclaim, or a counterclaim as a defense, the court must, if justice requires, treat the pleading as though it were correctly designated, and may impose terms for doing so.

(d) Pleading to Be Concise and Direct; Alternative Statements; Inconsistency.

(1) *In General.* Each allegation must be simple, concise, and direct. No technical form is required.

(2) *Alternative Statements of a Claim or Defense.* A party may set out two or more statements of a claim or defense alternatively or hypothetically, either in a single count or defense or in separate ones. If a party makes alternative statements, the pleading is sufficient if any one of them is sufficient.

(3) *Inconsistent Claims or Defenses.* A party may state as many separate claims or defenses as it has, regardless of consistency.

(e) Construing Pleadings. Pleadings must be construed so as to do justice.

[redacted]

Signing Pleadings, Motions, and Other Papers; Representations to the Court; Sanctions

(a) Signature. Every pleading, written motion, and other paper must be signed by at least one attorney of record in the attorney's name--or by a party personally if the party is unrepresented.

The paper must state the signer's address, e-mail address, and telephone number. Unless a rule or statute specifically states otherwise, a pleading need not be verified or accompanied by an affidavit. The court must strike an unsigned paper unless the omission is promptly corrected after being called to the attorney's or party's attention.

(b) Representations to the Court. By presenting to the court a pleading, written motion, or other paper--whether by signing, filing, submitting, or later advocating it--an attorney or unrepresented party certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances:

(1) it is not being presented for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation;

(2) the claims, defenses, and other legal contentions are warranted by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law or for establishing new law;

(3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery; and

(4) the denials of factual contentions are warranted on the evidence or, if specifically so identified, are reasonably based on belief or a lack of information.

(c) Sanctions.

(1) *In General.* If, after notice and a reasonable opportunity to respond, the court determines that Rule 11(b) has been violated, the court may impose an appropriate sanction on any attorney, law firm, or party that violated the rule or is responsible for the violation. Absent exceptional circumstances, a law firm must be held jointly responsible for a violation committed by its partner, associate, or employee.

(2) *Motion for Sanctions.* A motion for sanctions must be made separately from any other motion and must describe the specific conduct that allegedly violates Rule 11(b). The motion must be served under Rule 5, but it must not be filed or be presented to the court if the challenged paper, claim, defense, contention, or denial is withdrawn or appropriately corrected within 21 days after service or within another time the court sets. If warranted, the court may award to the prevailing party the reasonable expenses, including attorney's fees, incurred for the motion.

(3) *On the Court's Initiative.* On its own, the court may order an attorney, law firm, or party to show cause why conduct specifically described in the order has not violated Rule 11(b).

(4) *Nature of a Sanction.* A sanction imposed under this rule must be limited to what suffices to deter repetition of the conduct or comparable conduct by others similarly situated. The sanction may include nonmonetary directives; an order to pay a penalty into court; or, if imposed on motion and warranted for effective deterrence, an order directing payment to the movant of part or all of the reasonable attorney's fees and other expenses directly resulting from the violation.

(5) *Limitations on Monetary Sanctions.* The court must not impose a monetary sanction:

(A) against a represented party for violating Rule 11(b)(2); or

(B) on its own, unless it issued the show-cause order under Rule 11(c)(3) before voluntary dismissal or settlement of the claims made by or against the party that is, or whose attorneys are, to be sanctioned.

(6) *Requirements for an Order*. An order imposing a sanction must describe the sanctioned conduct and explain the basis for the sanction.

(d) Inapplicability to Discovery. This rule does not apply to disclosures and discovery requests, responses, objections, and motions under Rules 26 through 37.

[redacted]

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

(1) lack of subject-matter jurisdiction;
(2) lack of personal jurisdiction;
(3) improper venue;
(4) insufficient process;
(5) insufficient service of process;
(6) failure to state a claim upon which relief can be granted; and
(7) failure to join a party under Rule 19.

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

[redacted]

Applicability of the Rules in General; Removed Actions

(c) Removed Actions.

(1) *Applicability.* These rules apply to a civil action after it is removed from a state court.

(2) *Further Pleading.* After removal, repleading is unnecessary unless the court orders it. A defendant who did not answer before removal must answer or present other defenses or objections under these rules within the longest of these periods:

(A) 21 days after receiving--through service or otherwise--a copy of the initial pleading stating the claim for relief;

(B) 21 days after being served with the summons for an initial pleading on file at the time of service; or

(C) 7 days after the notice of removal is filed.

* * *

(d) Law Applicable.

(1) *"State Law" Defined.* When these rules refer to state law, the term "law" includes the state's statutes and the state's judicial decisions.

(2) *"State" Defined.* The term "state" includes, where appropriate, the District of Columbia and any United States commonwealth or territory.

(3) *"Federal Statute" Defined in the District of Columbia.* In the United States District Court for the District of Columbia, the term "federal statute" includes any Act of Congress that applies locally to the District.

[redacted]

[redacted]

§[redacted]

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

[redacted]

k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to 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.