Docket No. 10-1524

In the Supreme Court of the United States

April Term 2010

Dan Cooks, *et al.*

Petitioners

v.

Carolina Laboratories, Inc.

Respondent

On Writ of Certiorari to the United States Court of Appeals,

Thirteenth Circuit

BRIEF FOR THE PETITIONER

Team #1P

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QUESTIONS PRESENTED

I. Whether the National Childhood Vaccine Injury Act of 1986 Preempts All State Product Liability Suits for Design Defects Against Vaccine Manufacturers When Both the Plain Language and the Legislative History of the Act Clearly Show Congress Intended To Only Preempt Claims Involving Unavoidably Unsafe Vaccines.

II. Whether the Appellate Court Properly Applied the *Twombly* Pleading Rules When it Granted Respondent's Motion to Dismiss Pursuant to Civil Rule of Procedure 12(b)(6) Even Though Petitioners Pled Enough Factual Content To Plausibly State Causes of Action for Design Defect.

STATEMENT OF THE CASE

Dan and LoEtta Cooks ("Petitioners") are parents of twelve-year old, Estella Marie Cooks, who unfortunately suffers from serious neurological injuries, including developmental delays, learning disabilities, social delays and deficits, the impairment of motor skills, gastrointestinal illness, and immune system dysfunction. (R. at 1.) Estella Marie will likely suffer some of these injuries for the rest of her life. (R. at 4.)

Between March 1996 and October 1998, Estella Marie received three doses of thimerosal-containing Diphteria and Tetanus Toxoids and Pertussis ("DTP") - Haemophilus influenzae type b ("Hib") combination vaccine, manufactured by Carolina Laboratories, Inc. ("Respondent") (R. at 1.) Thimerosal is an organic compound with a high content of 50% mercury by weight. (R. at 1.) Petitioners believe the mercury contained in the thimerosal preservative was toxic and led to Estella Marie's injuries. (R.at 1.) Neither party disputes that the product administered to Estella Marie is a vaccine under the National Vaccine Injury Compensation Program ("Vaccine Act"). (R. 1.)

On September 3, 2001, Petitioners filed a timely petition for compensation on behalf of Estella Marie with the National Vaccine Injury Compensation Program ("NVICP") pursuant to 42 U.S.C. § 300aa-1 *et-seq*. (R. at 1.) More than two years later, Petitioners filed a notice of withdrawal in the NVICP and judgment was entered on the withdrawal by the Clerk of the U.S. Court of Federal Claims on January 14, 2004, pursuant to 42 U.S.C. § 300aa-21(b). (R. at 2.) As expressly permitted by 42 U.S.C. § 300aa-21(a), Petitioners filed an election to file a civil action on January 21, 2004. (R. at 2.) On March 14, 2007, Petitioners filed their Complaint in state court, individually and as parents of Estella Marie. (R. at 2.)

Petitioners' Complaint alleges two counts under Grace law against Respondent. (R. at 2.) Count I alleges Respondent negligently failed to conduct adequate safety tests to determine whether thimerosal was safe and nontoxic to humans in the dose administered. (R. at 2.) Count II alleges strict liability products liability for design defect, in that the vaccine was defectively designed and a safer alternative existed. (R. at 2.)

Petitioners originally filed their Complaint in the Wicked County Court of Common Pleas. (R. at 2.) Respondent removed the case to the United States District Court for the District of Grace based on diversity of citizenship, pursuant to 28 U.S.C. § 1332. (R. at 2.) Respondent is incorporated in Delaware, but has always had its principal place of business in New Jersey. (R. at 2.) Petitioners are domiciled in the State of Grace. (R. at 2.)

Respondent subsequently filed a motion to dismiss Petitioners' causes of action on two grounds. First, Respondent contends Petitioners' design defect claims are barred by § 300aa-22(b)(1) of the Vaccine Act. (R. at 2.) In the alternative, Respondent alleges that Petitioners failed to allege facts sufficient to state a claim for design defect under Grace state law. (R. at 2-3.) On March 25, 2008, the United States District Court for the District of Grace issued its decision, granting Respondent's motion to dismiss with prejudice. (R. at 7.) The Court found that although the Petitioners' Complaint sufficiently pled design defect, the Vaccine Act preempted Petitioners' claims against Respondent. (R. at 4, 7.)

Petitioners appealed from the District Court's decision dismissing their claims for design defect against Respondent. (R. at 9.) On August 6, 2009, the United States Court of Appeals for the Thirteenth Circuit affirmed the lower court's decision. (R. at 9.) However, its reasoning was in stark contrast with the District Court. The Court of Appeals, after thoroughly examining both

the text of § 300aa-22(b)(1) as well as the legislative history behind the Vaccine Act, concluded that the District Court erred when it found that state tort law claims were preempted under the Act. (R. at 11.) More specifically, the Court of Appeals found that § 300aa-22(b)(1) does not preempt all design defect claims against vaccine manufacturers, but rather provides that a immunity from liability, if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe. (R. at 11.) Nonetheless, the Court of Appeals affirmed the District Court's dismissal with prejudice on the grounds that Petitioners failed to allege facts sufficient to state a claim for design defect. (R. at 12.)

SUMMARY OF THE ARGUMENT

This Court should reverse the United States Court of Appeals decision and hold that (1) Petitioners' claims are not preempted by the Vaccine Act; and (2) that Petitioners have sufficiently pled both negligence and strict liability causes of action in accordance with the *Twombly* pleading standard.

Respondent mistakenly construes § 300aa-22(b)(1) of the Vaccine Act as mandating broad preemption against state tort law claims in all instances. However, the plain language of the Act undoubtedly shows that Congress did not intent to preempt all state law claims. Instead, it was Congress's intent to insulate vaccine manufacturers from liability, and thus preempt state tort law claims, when the side effects of the vaccine in question are first shown to be unavoidable. Even assuming the plain language does not clearly evidence Congress's intent, the legislative history of the Vaccine Act does not show a clear and manifest intention to preempt all state law claims against vaccine manufacturers. In addition, when faced with ambiguous statutory text, a court has the duty to adopt the reading that disfavors preemption.

Moreover, the Court of Appeals incorrectly applied *Twombly* when it dismissed Petitioners' Complaint for failure to state a claim under Federal Rules of Civil Procedure 12(b)(6). Petitioners have pled enough factual content to allow the Court to draw the reasonable inference that Respondent is liable for both negligent failure to conduct adequate safety tests as well as strict liability for design defect. The Court of Appeals incorrectly held that Petitioners pled nothing more than legal conclusions. In addition, the Court of Appeals also erred when it misinterpreted *Twombly* as requiring plaintiffs to provide scientific evidence at the pleading stage. Because the Petitioners have pled facts that suggest plausible claims for design defect, they have satisfied the standard articulated in *Twombly*.

Furthermore, the Court of Appeals also erred when it affirmed the District Court's dismissal of Petitioners' Complaint with prejudice. Since the Court did not specifically articulate that allowing the Petitioners leave to amend would be futile, it should have remanded to the District Court with instructions to grant leave to amend. Denial of leave to amend would not have been warranted. Therefore, Petitioners ask this Court, in the event it finds Petitioners' Complaint insufficient, to remand to the District Court with instructions granting Petitioners leave to amend.

ARGUMENT

I. THE VACCINE ACT DOES NOT AUTOMATICALLY PREEMPT ALL STATE TORT LAW CLAIMS, BUT INSTEAD, CALLS FOR A CASE-BY-CASE APPROACH TO THE DETERMINATION OF PREEMPTION.

In an attempt to balance the need for compensation to victims of vaccine-related injuries and the cost of litigation to manufacturers, Congress enacted the National Childhood Vaccine Injury Act of 1986. *Am. Home Prods. Corp. v. Ferrari,* 668 S.E.2d 236, 242 (Ga. 2008). In

doing so, Congress created an alternative to the traditional tort system, where persons injured by vaccines would not need to prove fault or causation. *Id*. at 241. Instead, such individuals would only have to establish that they received a vaccine and suffered symptoms contained on the vaccine injury table. 42 U.S.C. § 300aa-11(c)(1)(A). While the Vaccine Act created an alternative to the tort system, it nonetheless also contemplated the availability of state tort actions. *Ferrari*, 668 S.E.2d at 241. Under the Vaccine Act, an individual is not completely precluded from bringing a state tort action against a vaccine manufacturer. *Ferrari*, 668 S.E.2d at 241-42; 42 U.S.C. § 300aa-11(a)(2)(A). Rather, the Vaccine Act only requires that an individual first initiate a proceeding in the Court of Federal Claims. 42 U.S.C. § 300aa-11(a)(2)(A). If the individual chooses to reject the judgment of the Court of Federal Claims or withdraw his petition, he is then free to initiate a state court proceeding. *Id*. Additionally, subject to certain exceptions, the Vaccine Act clearly provides that "[s]tate 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 particular, one of the relevant exceptions to this provision provides: "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 warning." 42 U.S.C. § 300aa-22(b)(1). While this exception certainly preempts state law to the extent stated, it does not, however, completely foreclose all such claims against vaccine manufacturers. Respondent mistakenly construes § 300aa-22(b)(1) as stating that any injury caused by a covered vaccine is unavoidable as a matter of law provided that the vaccine was produced in accordance with FDA-approved specification. However, this interpretation is misguided as the plain language of § 300aa-22(b)(1), as well as

the legislative history of the Vaccine Act, indicate a contrary interpretation. It is clear that it was Congress's intent for § 300aa-22(b)(1) to bar design defect claims in the limited instance where it is first shown that the side effects in question were unavoidably unsafe. If such is not shown, the exception does not apply and § 300aa-22(a) mandates the application of state law to a civil tort action.

A. The Vaccine Act Does Not Preempt All Claims Brought Under State Law As It Was Not Congress's Intent to Provide Automatic Blanket Immunity For Vaccine Manufacturers

Pursuant to the Supremacy Clause of the United States Constitution, the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. Under the Supremacy Clause, federal law may supersede state law in three different ways: express preemption, field preemption, and implied conflict preemption. *Brueswitz v. Wyeth Inc.*, 561 F.3d 233, 238 (3d Cir. Pa. 2009). Express preemption occurs when a federal enactment contains language expressly supplanting state law. *Id*. In the absence of express language, Congress's intent to preempt state law may be inferred "when the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation." *Hillsborough County v. Automated Medical Labs., Inc.*, 471 U.S. 707, 713 (1985) (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Preemption may also be inferred where the field is one in which "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Rice,* 331 U.S. 218, 230 (citing *Hines v. Davidowitz*, 312 U.S. 52 (1941)). In addition, "[e]ven where Congress has not completely displaced state regulation in a specific area, state law is nullified to

the extent that it actually conflicts with federal law." *Hillsborough*, 471 U.S. at 712 (citing *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143, (1963)).

When interpreting a preemption clause, a court must "start with the assumption that the historic police powers of the states [are] not to be superseded by [any] Federal Act unless that [is] the clear and manifest purpose of Congress." *Rice*, 331 U.S. at 230. Therefore, "the purpose of Congress is the ultimate touchstone" in preemption analysis. *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963). Congressional intent can be determined from the explicit language of the statute or from the implicit structure and purpose of the Act. *In Re Blue Flame Energy Corp.*, 871 N.E.2d 1227, 1242 (Ohio Ct. App. 2006). Here, Petitioners concede that the provision in question is an express preemption clause that precludes certain state tort claims. More specifically, § 300aa-22(b)(1) only expressly preempts state tort claims involving vaccines with side effects that are first shown to be unavoidable. Accordingly, in cases where Congress has included an express preemption provision in the statute, the first focus must be on the plain wording of the provision, "which necessarily contains the best evidence of Congress's preemptive intent." *Blue Flame*, 871 N.E.2d at1242 (quoting *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62-63 (2002)). Even though a federal law contains an express preemption clause, "it does not immediately end the inquiry because the question of the substance and scope of Congress' displacement of state law still remains." *Brueswitz*, 561 F.3d at 239 (quoting *Altria Group, Inc. v. Good*, 129 S. Ct. 538, 543 (2008)). Additionally, if the express provision is unambiguous, the court need not go any further than the statutory language to determine whether the state law is preempted. *Blue Flame*, 871 N.E.2d at 1242 (citing *Exxon Corp. v. Hunt*, 475 U.S.355, 362 (1986))

1. The plain language of the express preemption provision of the Vaccine Act clearly indicates that Congress did not intend to preempt all state tort law claims against vaccine manufacturers.

An analysis of the plain meaning of the text of § 300aa-22(b)(1) clearly and unambiguously supports the contention that Congress did not intend to provide blanket immunity to vaccine manufacturers. The provision is written in a conditional structure: No vaccine manufacture shall be liable *if* the injury or death resulted from side effects that were unavoidable. *Ferrari,* 668 S.E.2d at 237. This demonstrates that Congress only intended to grant manufacturers limited immunity under the Vaccine Act, and, therefore preempt contradicting state law, when the side effects of the vaccine are first shown to be unavoidable. *Id.* at 237-38. If it was Congress's intent for the Vaccine Act to preempt all state tort law claims brought against vaccine manufacturers, it surely would not have conditioned immunity on a showing that the injury or death resulted from side effects that were unavoidable. *Id.* at 240.

In addition, under accepted canons of statutory interpretation, the court "must interpret statutes as a whole, giving effect to each word and making every effort not to interpret a provision in a manner that renders other provisions of the same statute inconsistent, meaningless or superfluous." *Boise Cascade Corp. v. United States EPA*, 942 F.2d 1427 (9th Cir. 1991). The court certainly cannot adopt Respondent's interpretation as this would render the conditional phrase, "if the injury or death resulted from side effects that were unavoidable," superfluous. *Id.* If Congress truly intended to provide broad immunity, as Respondent contends, it would have omitted the conditioning clause and this would have transformed the provision to completely preclude any liability under state law against vaccine manufacturers. *Ferrari,* 668 S.E.2d at 240. Thus, Congress had the opportunity to explicitly preempt all state tort law claims against vaccine manufacturers but failed to do so. Therefore, § 300aa-22(b)(1) must be construed in a

manner consistent with the deliberate inclusion of the conditional phrase, thereby mandating a narrow and limited interpretation of preemption under the Vaccine Act.

Furthermore, since Congress has expressly reserved a role for state courts under other provisions of the Vaccine Act, it would be inconsistent with such provisions to interpret § 300aa-22(b)(1) as completely barring all state law claims against vaccine manufacturers. By its very own terms, the Vaccine Act contemplates state tort action as an alternative to resolving vaccine-related injury. *Shadie v. Pasteur*, 254 F. Supp. 2d 509, 516 (M.D. Pa. 2003). The Vaccine Act requires plaintiffs to first pursue their claim through the Court of Federal Claims prior to instituting a civil action. However, this certainly does not suggest that plaintiffs are barred from bringing a state law action against vaccine manufacturers. It only suggests that the state tort system is not available until the plaintiff has exhausted its administrative remedy under the Vaccine Act. The notion that Congress intended the Vaccine Act to supplant state law in all circumstances is inconceivable, when the Act itself, allows plaintiffs to bring their vaccine-related claims in the state tort system. After all, the coexistence of federal and state regulation is inconsistent with the assertion that Congress intended to preempt state law claims in all circumstances. If Congress truly intended for the Vaccine Act to be the only remedy for vaccine-injured plaintiffs, it would not have expressly provided the option to sue civilly for vaccine related injuries.

As such, the plain meaning of the text supports the contention that Congress only intended to preempt state law liability against vaccine manufacturers if the injury or death resulted from side effects that were unavoidable. In situations where this is not shown, the Vaccine Act permits liability against vaccine manufacturers pursuant to state products liability

law. 42 U.S.C. § 300aa-22(a). Accordingly, the court cannot grant Respondent immunity pursuant to the Vaccine Act before a determination is made regarding the avoidability of harm. Furthermore, since the scope of the express preemption provision is clear, the court need not go any further in its inquiry to determine whether the state law is preempted.

2. Even if the Court finds that the express preemption provision is ambiguous and does not clearly evidence Congress's intent, the Court must nonetheless find against broad preemption.

When confronted with ambiguous statutory text, a court may turn to legislative history to determine congressional intent. *Brueswitz*, 561 F.3d at 244 (citing *Bedroc Ltd., LLC v. United States*, 541 U.S. 176, 187 (2004)). Since states traditionally have had greater latitude under their police powers to protect the health and safety of their citizens, courts will not find preemption unless the legislative history shows a "clear and manifest" congressional intent to supplant state law. *Medtronic Inc. v. Lohr*, 518 U.S. 470, 474 (1996). The legislative history of the Vaccine Act does not indicate any "clear and manifest" intention to preempt state law. *Ferrari*, 668 S.E.2d at 242. On the contrary, an examination of the legislative history shows that Congress could not have been clearer in its intention *not* to preempt all design defect claims brought under state law. *Id.*

Furthermore, when faced with an ambiguous preemption clause, the court has the duty to accept the reading that disfavors preemption. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 432 (2005). This is true even with an express preemption clause. *Brueswitz*, 561 F.3d at 240. As such, even if the plain language of § 300aa-22(b)(1) gives rise to two plausible interpretations, the court must nonetheless adopt Petitioners' interpretation of limited preemption. *Ferrari*, 688 S.E.2d at 242 (citing *Bates*, 544 U.S. at 449).

a. The legislative history of the Vaccine Act does not show a "clear and manifest" intention to preempt all state law claims.

The 1986 committee report indicates that the Vaccine Act should be interpreted as barring liability for vaccine manufacturers only for injuries arising from unavoidable side effects. H.R. REP. NO. 99-908, at 26 (1986). The committee report states that the Vaccine Act established a "no fault compensation system," allowing individuals injured by vaccines to receive compensation regardless if the manufacturer made the vaccine as safe as possible. *Id.* Hence, it was Congress's intent to create an arena, outside of the tort system, where vaccine-injured victims would be entitled to compensation without having to prove, under applicable law, whether the vaccine was improperly prepared. *Ferrari*, 668 S.E.2d at 241. Nothing in the committee reports suggest that the acceptance of the award from the "no fault compensation system" is mandatory. *Id*. In fact, the committee report also does not suggest that individuals who can prove that a safer alternative vaccine existed, such as Petitioners, should accept the award under the Vaccine Act's compensatory system. Therefore, the legislative history does not show any intent to preclude individuals, such as Petitioners, from pursuing their claims against Respondent under Grace state law.

Additionally, a subsequent committee report issued in 1987 undoubtedly supports Petitioners' contention of limited preemption. Although the Vaccine Act was passed in 1986, its compensation program and accompanying tort reforms were contingent on the enactment of a tax to provide the funding for the compensation. *Brueswitz* at 249 (quoting H.R. REP. NO. 100-391(I), at 690 (1987)). One year later, in 1987, Congress passed legislation to fund the

compensation program. *Brueswitz*, 561 F.3d at 249. As part of the funding legislation, the House Committee on the Budget issued its own report which provides:

> 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 a safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act.

Id. This language illustrates that Congress explicitly rejected an amendment that would have provided blanket immunity to manufacturers. This proposed amendment would have insulated manufacturers from liability even when the manufacturer could have developed a safer vaccine. By rejecting this amendment, Congress could not have made it clearer that it intended to grant immunity to vaccine manufacturers and preempt state law only when the side effects of the vaccine are first shown to be unavoidable.

Moreover, as the Court of Appeals correctly noted, Congress modeled § 300aa-22(b)(1) after comment k to Section 402A of the Restatement (Second) of Torts. *Ferrari* 668 S.E.2d at 239. Comment k provides:

> Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quire incapable of being made *safe* for their intended and ordinary use. These are especially common in the field of drugs. . . . 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. . . . 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.

Restatement (Second) of Tort § 402A, cmt. k (1965). Although comment k itself has been the subject of two interpretations, the majority of jurisdictions adopting comment k have interpreted it narrowly – as an exception to strict liability for unavoidably unsafe products. *Id*. at 240. In their determination, these courts have paid particular attention to the plain language of the comment itself. For example, the Supreme Court of Idaho, in *Toner v. Lederle Labs*, relying on the wording of comment k, concluded that it only immunizes certain products from strict liability claims based on an alleged design defect. 732 P.2d 297, 307 (Idaho 1987). The Court explained that comment k only refers to "*some*" products which are unavoidably unsafe and states that such products are "especially *common* in the field of drugs." Based on such wording, it is clear that comment k's bar on strict liability does not apply to *all* drugs. *Id.* As such, the majority of jurisdictions adopting comment k apply it on a case-by-case basis and only after taking evidence related to the determination of whether the product in question was unavoidably unsafe. *Id.*

Similarly, § 300aa-22(b)(1) should also be applied in the same limited fashion. Since the legislative history demonstrates Congress wrote § 300aa-22(b)(1) to reflect the principle of comment k, it is evident that Congress intended for the Vaccine Act to only selectively grant immunity to vaccine manufacturers. In fact, the 1987 committee report of the Vaccine Act itself supports a case-by-case approach to determine unavoidability. The report provides:

> [t]he 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.

Ferrari, 668 S.E.2d at 241 (citing H.R. REP. NO. 100-391 (I), at 691 (1987) *as reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-365). This language explicitly refutes the contention that a vaccine is unavoidably unsafe as a matter of law provided that the vaccine was properly prepared and accompanied by proper warnings. Instead, as the committee report demonstrates, it was Congress's intention to leave the determination of unavoidability to the courts to determine on a case-by-case basis. As such, Respondent may only avail itself of the Vaccine Act's immunity after showing that the vaccine in question was unavoidably unsafe.

b. In the event of an ambiguous preemption clause, the Court has a duty to accept the reading that disfavors preemption.

As mandated by the United States Supreme Court in *Bates v. Dow Agrosciences, LLC.*, if an express preemption provision is ambiguous, a court has the duty to accept the reading that disfavors preemption, particularly in the areas of health and safety. 544 U.S. at 449. While the Petitioners construe the express preemption provision narrowly, the Petitioners nonetheless acknowledge that other courts have interpreted the provision to grant broad immunity so long as the vaccine was produced in accordance with FDA-approved specification. Nevertheless, applying the rules mandated by *Bates*, the court has the duty to follow the reading that disfavors preemption, and thus, must adopt Petitioners' interpretation of limited preemption.

In fact, the Georgia Supreme Court, in a case involving similar facts, acknowledged the duty set forth by the Court in *Bates*. *Ferrari,* 668 S.E.2d at 237. In *Ferrari*, parents of a minor

child brought suit against several vaccine manufacturers alleging that their child suffered neurological damage caused by vaccines made with the preservative thimerosal, which contained the toxic substance mercury. *Id*. After thoroughly examining both the text of § 300aa-22(b)(1) and the legislative history, the court unequivocally held that the Vaccine Act does not preempt all design defect claims, but instead allows the court to determine, on a case-by-case basis, whether the side effects of a particular vaccine were unavoidable *before* granting immunity to the manufacturer of the vaccine. *Id.* at 242 (emphasis added). More notably, the court, following the guidance of *Bates*, recognized that even if defendants/appellants had offered a plausible alternative reading of § 300aa-22(b)(1), the court would nevertheless have a duty to accept the reading that disfavors preemption. *Id.* The court also explained that the "long history of tort litigation against manufacturers adds force to the basic presumption against preemption." *Id.* at 293. After all, "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Bates*, 544 U.S at 449. Thus, because Congress did not express any clear intention to preempt all state law claims, there is a presumption against preemption.

Since the United States Supreme Court's explicit guidance in *Bates* cannot be ignored, this Court should adopt an interpretation of limited preemption, thereby requiring the Respondent to prove that the side effects of the vaccine were unavoidable, before granting it immunity under the Vaccine Act.

3. Adopting a case-by-case approach to preemption will not undermine Congress's purpose in enacting the Vaccine Act.

To determine Congress's intent regarding the scope of preemption, the purpose of the statute itself is also relevant. *Medtronic*, 518 U.S. at 486. In enacting the Vaccine Act,

Congress's purpose was to shield manufacturers of vaccines that could not be made entirely safe. *Brueswitz*, 561 F.3d at 247-248 (citing H.R. REP. NO. 99-108 (1986)). Congress was worried about situations where "innocent children would be 'badly injured or killed' by a vaccine, but in which a jury would likely impose liability on the manufacturer 'even if the defendant manufacturer may have made as safe a vaccine as anyone reasonably could expect.'" *Brueswitz*, 561 F.3d at 248 (citing H.R. REP. NO. 99-908 at 26). Thus, Congress was not concerned about insulating all manufacturers from liability. Instead, Congress was only concerned about liability imposed on those vaccine manufacturers whose products were unavoidably unsafe. Under a case-by-case approach, if a manufacturer could prove that its vaccine was unavoidably unsafe, the court would grant it immunity under the Vaccine Act and preempt state law claims. As contemplated by Congress, the manufacturer would not have to face a jury and would justifiably be shielded from liability. Therefore, the adoption of a case-by-case approach to the determination of preemption would not undermine Congress's concerns.

B. Interpreting The Vaccine Act To Provide Broad Immunity Will Jeopardize The Production Of Safer Drugs To The Public.

The tort system provides important incentives for the safe manufacture and distribution of vaccines. *Schafer v. American Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. Mass. 1994). If the Court was to adopt Respondent's interpretation of broad preemption, these important incentives to continually design and distribute safer drugs for the public would be completely wiped out. Without the fear of liability in the tort system, manufacturers would have very little reason to exercise due care to ensure the safety of their products. Surely, it was not the intention of Congress to preempt state remedies in an entire industry, which would essentially have the

perverse effect of immunizing all vaccine manufacturers from liability. *Medtronic*, 518 U.S. at 487.

Furthermore, allowing manufacturers to use FDA approval as a defense to causing harm that could have been avoided, especially to a child, cannot be justified. The mere fact that the FDA has approved a drug or vaccine does not mean that a manufacturer is excused from continually testing its design. After all, advancements in the medical field are constantly occurring and an older drug with FDA approval may not always be the safest alternative. *See Ferrari*, 668 S.E.2d at 242. Consequently, a broad interpretation of the preemption clause in the Vaccine Act will jeopardize the continued production of safer drugs.

II. THIS COURT SHOULD REVERSE THE RULING OF THE COURT OF APPEALS BECAUSE THE PETITIONERS' COMPLAINT COMPORTS TO THE REQUIREMENTS OF FEDERAL RULE OF CIVIL PROCEDURE 8(a)(2).

Under Federal Rule of Civil Procedure 8(a)(2), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). This standard does not require "detailed factual allegations," but demands more than unfounded allegations of defendant's unlawful behavior. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). When a court is faced with a motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted, its function is not to weigh the evidence that might be presented at trial, but merely to determine whether the complaint itself is legally sufficient. *Bio-Technology Gen. Corp. v. Genentech, Inc.*, 886 F. Supp. 377, 380 (S.D.N.Y. 1995). Indeed, a motion to dismiss for failure to state a claim on which relief can be granted is a disfavored motion and is rarely granted. *Gilligan v. Jamco Dev. Corp.*, 108 F.3d 246, 249 (9th Cir. Cal. 1997).

A. The Court of Appeals Incorrectly Applied Twombly Because Petitioners Have Pled Enough Factual Allegations To Make It More Than Plausible That They Have A Legally Cognizable Right Of Action

In 2007, the United States Supreme Court, in *Bell Atlantic Corp. v. Twombly*, directly addressed the pleading requirements under Federal Rules of Civil Procedure 8(a)(2). 550 U.S. at 555-571. While this case involved allegations of an antitrust conspiracy, the Supreme Court, in a subsequent case, extended the reach of *Twombly* to all civil actions filed in federal court. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1953 (U.S. 2009).

In *Twombly*, plaintiffs asserted that defendants, local telephone and internet service providers, were engaging in parallel billing and contracting misconduct designed to discourage competition, in violation of § 1 of the Sherman Act. *Twombly*, 550 U.S. at 551. While the second circuit held that the allegations of parallel conduct alone were sufficient to state a claim of unlawful conspiracy, the Supreme Court reversed and held that the complaint should be dismissed. *Id*. at 553. The Court found that plaintiffs did not plead enough facts to state a claim that was plausible on its face. *Id.* at 570. Additionally, the Court retired the language from *Conley v. Gibson* 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 that would entitle him to relief." *Id.* at 557. In doing so, however, the Court did not apply or mandate a heightened pleading standard nor did it "require heightened fact pleading of specifics." *Id.* at 570. The Court simply articulated a standard whereby plaintiffs would be required to allege sufficient facts to "nudge their claims across the line from conceivable to plausible." *Id*. According to the Court, to achieve plausibility, a plaintiff must merely plead

factual content that allows the court to draw the reasonable inference that the defendant is liable for the alleged unlawful behavior. *Twombly*, 550 U.S. at 556-57.

In 2009, the Supreme Court, in *Ashcroft v. Iqbal*, re-examined its reasoning in *Twombly*. 129 S. Ct. at 1949. The Court confirmed that the pleading standard under F.R.C.P. 8 does not require detailed factual allegations. *Id*. Furthermore, the Court found that its *Twombly* decision turned on two principles: one, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions" and second, "only a complaint that states a plausible claim for relief survives a motion to dismiss." *Id.* at 1949-50. In keeping with these principles, a court considering a motion to dismiss must begin its analysis by identifying mere conclusions in the complaint as those are not entitled to assumption of the truth. *Id*. at 1951. Next, the court must assume the veracity of the remaining well-pleaded factual allegations, and then determine whether they plausibly give rise to an entitlement of relief. *Id*. at 1950. The Supreme Court indicated that the determination of plausibility is context-specific and requires the reviewing court to draw on its judicial experience and common sense. *Id*. However, this "plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft*, 129 S. Ct. at 1949. As set forth below, in applying this two-pronged test, it is clear that both counts in Petitioners' Complaint meet the plausibility standard articulated in *Twombly*.

1. Count I of Petitioners' Complaint for negligent failure to conduct adequate safety tests is sufficiently pled.

A claim for negligent design falls within the framework of common law negligence. *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 263 (Ill. 2007). Thus, in alleging negligent design, the plaintiff must establish the existence of a duty of care owed by the defendant, a

breach of that duty, proximate cause, and damages. *Id*. A manufacturer has a duty "to design a product so that it will be reasonably safe for its intended use and for any reasonably foreseeable use." *Flaugher v. Sears, Roebuck & Co.*, 378 N.E.2d 337, 340 (Ill. App. Ct. 5th Dist. 1978). Moreover, the "crucial question in a negligent-design case is whether the manufacturer exercised reasonable care in the design of the product." *Calles*, 864 N.E.2d at 264. To determine whether the manufacturer's conduct was reasonable, the question is "'whether in the exercise of ordinary care the manufacturer should have foreseen that the design would be hazardous to someone.'" *Id*. Additionally, to show that the manufacturer acted unreasonably based on the foreseeability of harm, "the plaintiff must show the manufacturer knew or should have known of the risk posed by the product design at the time of manufacturer." *Id*.

Petitioners have set forth several factual allegations that support their claim for negligent design against Respondent. Notably, Petitioners have pled that Respondent was aware of mercury's neurotoxic properties. Yet, despite the knowledge of the potential danger of mercury, Respondent not only failed to conduct adequate safety tests to determine whether mercury-containing thimerosal was safe and nontoxic, but also designed its vaccine to include a very high content of mercury. Additionally, Petitioners have pled that the exposure of the mercury caused their daughter's numerous injuries. Accordingly, following the guidance of *Twombly*, these factual assertions should be afforded the assumption of truth. The Court of Appeals erred in mistakenly construing all of Petitioners' allegations as conclusory. On the contrary, Petitioners have laid out nothing but facts to support their negligent design defect claim. The *Twombly* court was concerned about plaintiffs providing a mere formulaic recitation of the elements of a cause of action. *Twombly*, 550 U.S. at 555. Here, however, Petitioners have not simply pled the

elements of duty, breach, causation, and injury. Instead, Petitioners have pled enough factual content to support each of the elements for negligent design.

Since the Court of Appeals erred in its finding that Petitioners' allegations were conclusory, it failed to consider the factual allegations in its plausibility analysis. It is clear, given the assumption of the veracity of these assertions, Petitioners have undoubtedly stated a plausible claim for relief. Through their well-pleaded facts, Petitioners have shown that Respondent knew of the risk posed by the product design and yet failed to act reasonably, such as conduct safety tests at the very least, to ensure the safety of its product. By pleading Respondent's failures, Petitioners have shown that Respondent breached its duty of making its product safe for its intended safe. This breach, in turn, caused severe injuries to Petitioners' daughter. Accordingly, these factual allegations create more than a suspicion of negligent design defect. In fact, these factual allegations are more than enough to raise a right to relief above the speculative level. Thus, Petitioners have pled factual content that allows the court to draw the reasonable inference that the defendant is liable for the alleged unlawful behavior and have met the plausibility standard articulated in *Twombly*.

2. Count II of Petitioners' Complaint for strict liability design defect is sufficiently pled.

Under Grace product liability law, vaccine manufacturers are not insulated from strict liability; instead, claims for design defect are evaluated under a risk-utility analysis balancing the risks inherent in the product design against the utility of the product designed. Under this risk-utility analysis, the fact finder may consider a variety of factors, including the gravity and severity of the danger caused by the design, the avoidability of the danger, and the ability to eliminate the danger without impairing the product's usefulness.

Although the Court of Appeals held that Petitioners have pled nothing more than a formulaic recitation of the elements of a design defect claim, this is simply not true. *Cooks, et al v. Carolina Laboratories, Inc.*, No. 09-1032, slip op. at 12 (13th Cir. Aug. 6, 2009). Petitioners' allegations are not conclusory as the Complaint details facts, not conclusions, of Respondent's failure and the consequences of such failure. Namely, the allegations in the Complaint present facts to indicate that the Petitioners' daughter has suffered neurodevelopmental injuries as a result of Respondent's failure to test the mercury contained in the thimerosal prior to administering the vaccine. Petitioners concede that there are minor legal conclusions intertwined in with some of the allegations, such as the vaccine was "unreasonably and dangerously defective," which was a "substantial and contributing cause." However, the inclusion of legal conclusions is appropriate to provide the legal framework as long as it is supported by factual allegations and Petitioners have supported any legal conclusion asserted by facts. *Ashcroft*, 129 S. Ct. at 1950. For example, the Petitioners have clearly explained that the product was unreasonably and dangerously defective based on the fact that it had dangerous levels of ethyl mercury. It appears the Court of Appeals only took a cursory look at Petitioners' allegations and failed to adequately recognize the factual content in these allegations. Consequently, the Court of Appeals incorrectly applied *Twombly* when it ignored the factual allegations and proceeded to conclude that Petitioners' Complaint alleges nothing more than conclusions of law.

Petitioners' factual allegations plausibly show that the risks inherent in Respondent's vaccine greatly outweigh its benefits, if any. Notably, Petitioners have pled that Respondent failed to adequately conduct safety tests, thereby exposing their daughter to mercury. Because of such exposure, their daughter has suffered various neurological injuries as well as gastrointestinal illness, immune system dysfunction, and other symptoms of mercury poisoning.

As the District Court correctly noted, these factual allegations shed light on the nature of the risks allegedly posed by dangerous levels of ethyl mercury. *Cooks, et al v. Carolina Laboratories, Inc.*, No. 08-cv-04132, slip op. at 4 (D. Grace Mar. 25, 2008). Thus, Petitioners have undoubtedly presented the gravity and severity of the danger caused by Respondent's vaccine. Because design defect claims are subject to a risk-benefit balancing under Grace law, these allegations, taken as true, make it more than plausible for the Court to draw the reasonable inference that Respondent's vaccine is susceptible to design defect.

In *Twombly*, the Court concluded that the mere allegation of parallel conduct was not enough to plausibly suggest an unlawful conspiracy as such an allegation was not only also compatible with, but more likely explained, by lawful, free-market behavior. *Twombly,* 550 U.S. at 567. Moreover, the Court acknowledged that monopoly was in fact the norm in telecommunications; hence, a bare allegation of parallel conduct, in that specific context, could not plausibly suggest unlawful conduct. *Id*. at 568. In the present case, however, Petitioners' allegation that their daughter was severely injured after receiving a vaccine with dangerous levels of mercury, taken as true, cannot be explained by lawful conduct. Taking the context into consideration, a vaccine severely injuring a child is not the norm, nor is it consistent with lawful conduct. Therefore, Petitioners' well-pleaded facts plausibly suggest that the risks inherent in Respondent's vaccine outweigh its benefits, thereby showing that the Petitioners have sufficiently pled a cause of action for design defect.

Moreover, the lack of an allegation in Petitioners' Complaint specifically asserting that the risks of the vaccine exceed the benefits is not significant. After all, such an allegation would only amount to a legal conclusion. In an analogous case, involving a motion to dismiss a cause

of action for design defect, the District Court of Northern Ohio held that "[i]t is enough that the well-pled factual material in the complaint gives rise to a fair inference that the foreseeably unsafe aspects of the drug's design or formulation outweigh the benefits … ." *Boroff v. Alza Corp.*, 2010 U.S.Dist. LEXIS 6654. In the present case, Petitioners have pled that Respondent knew of the neurotoxic properties of mercury, and yet, failed to conduct adequate safety tests. This fact coupled with Estella Marie's injuries gives rise to a fair inference that the risks of Respondent's vaccine outweigh any benefits, thereby plausibly supporting a cause of action for design defect under Grace state law

3. *Twombly* does not require scientific evidence at the pleading stage.

The Court of Appeals mistakenly focused on Petitioners' failure to state scientifically reliable evidence to support the allegations that Respondent is liable for design defect. *Cooks, et al*, No. 09-1032, slip op. at 12-13. While the standard set in *Twombly* undoubtedly requires more than just mere conclusions of law, the notion that the Petitioners must plead scientific evidence prior to discovery to support their factual allegations is misguided. In *Twombly,* the Supreme Court clearly held that a pleading does not require detailed factual allegations, but rather, simply requires a plausible claim. *Twombly,* 550 U.S. at 555-56. It is unclear how the Court of Appeals construed plausible to suggest a requirement of scientific evidence. There is nothing in the Supreme Court's opinion to suggest the requirement of such evidence at the pleading stage.

Furthermore, requiring scientifically reliable evidence during the pleading stage is in contrast with the Supreme Court's emphasis that F.R.C.P. 8(a)(2) does not require a heightened fact pleading. *Twombly,* 550 U.S. at 570. The purpose of F.R.C.P. 8(a)(2) is to simply provide each defendant adequate notice of what the plaintiff's claims are and the grounds upon which

each claim rests. *Id*. at 555. This purpose does not mandate detailed factual allegations. *Id.* Here, the Petitioners have provided defendants more than adequate notice as they have specifically pled each of their daughter's injuries, the source/vaccine that may have caused it, and the reasons as to why they believe the particular vaccine was defectively designed. To require more would be unfounded as well as highly impracticable. This is particularly true in cases involving products liability where the cause or source of the defect is not obvious to the consumer and would make it difficult for an appellant to pinpoint a specific source of defect prior to discovery. *Bailey v. Janssen Pharmaceutica, Inc.*, 288 Fed. Appx. 597, 605 (11th Cir. Fla. 2008). Because of the very nature of design defect allegations, it would be unduly burdensome to require Petitioners to plead scientific evidence that supports their allegations.

It appears the Court of Appeals incorrectly extended the reach of *Twombly* and *Iqbal*. Surely, the Supreme Court, in articulating a plausibility standard, did not intend to wipe out years of precedent and require scientific evidence in the pleading stage. Such a heightened standard would essentially foreclose on a plaintiff's opportunity to bring a legally cognizable claim as it would be virtually impossible, without conducting discovery, to present scientific evidence. Indeed, the Supreme Court itself expressly articulated it did not intend to require a heightened pleading standard. *Twombly,* 550 U.S. at 570. On the contrary, it was the Supreme Court's intention to only interpret F.R.C.P. 8 as requiring plausibility, a standard the Petitioners have clearly met.

B. <u>In The Event The Court Finds That The Petitioners' Complaint Is Not Sufficiently Pled, This Court Should Nonetheless Reverse, In Part, The Court of Appeal's Dismissal With Prejudice and Remand To The District Court With Instructions To Grant Leave to Amend</u>

Under Federal Rules of Civil Procedure 15(a)(2), leave to amend shall be freely given "when justice so requires". FED. R. CIV. P. 15(a)(2). This rule should be applied with extreme liberality. United States v. Webb, 655 F.2d 977, 979 (9th Cir. Ariz. 1981). Moreover, denial of leave to amend is warranted where there is "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment . . . " *Foman v. Davis*, 371 U.S. 178, 182 (1962). Since none of these issues are present here, the District Court could not have justified denial of leave to amend. Thus, if the Court of Appeals had properly remanded to the District Court, Petitioners would have been granted leave to amend. Consequently, Petitioners' request for leave to amend is not moot and the Court of Appeals' failure to provide leave to amend was in error. Therefore, in the event this Court finds that Petitioners' Complaint fails to state a claim, this Court should remand to the District Court with instructions to grant the Petitioners leave to amend their Complaint.

1. Instead of affirming the dismissal with prejudice, the Court of Appeals should have remanded to the District Court with instructions to grant leave to amend.

Courts have held that, in dismissing for failure to state a claim, a district court should grant leave to amend, even if no request to amend the pleading was made, unless the court determines that the pleading could not possibly be cured by the allegation of other facts. *Doe v. United States (In re Doe)*, 58 F.3d 494, 497 (9th Cir. Cal. 1995); *See also Phillips v. County of Allegheny*, 515 F.3d 224, 236 (3d Cir. Pa. 2008) ("It does not matter whether or not a plaintiff seeks leave to amend. We have instructed that if a complaint is vulnerable to a *12(b)(6)* dismissal, a district court must permit a curative amendment, unless an amendment would be inequitable or futile."). Here, the District Court granted Respondent's motion to dismiss with

prejudice when it found that the Vaccine Act preempted Petitioners' claims. The Court of Appeals affirmed the decision, but on the grounds that Petitioners had not sufficiently pled their design defect claims. In doing so, however, the Court of Appeals did not determine that Petitioners' Complaint could not possibly be cured by the allegation of other facts. Thus, in affirming the grant of the motion to dismiss, the Court of Appeals should not have dismissed with prejudice. Instead, the Court of Appeals should have remanded to the District Court with instructions allowing the Petitioners to amend. For example, in *Doe v. United States*, the United States Court of Appeals for the Ninth Circuit found that the record did not indicate that the district court had determined that the pleading could not have possibly been cured by the allegation of other facts. 58 F.3d at 497. The court ultimately held that because the district court did not determine, nor was the court itself able to conclude, that the allegation of other facts could not cure the deficiencies in the complaint, the district court erred in dismissing the claims without leave to amend. *Id*. Similarly, since the Court of Appeals did not indicate that an amendment would be futile, it committed error when it affirmed the dismissal of Petitioners' Complaint with prejudice. Consequently, this Court should reverse, in part, the Court of Appeals dismissal and remand to the District Court with instructions to allow Petitioners leave to amend.

2. The Court of Appeal's failure to remand was not harmless error since Petitioners would have been granted leave to amend.

A trial court may deny leave to amend if permitting amendment would prejudice the opposing party, produce undue delay in the litigation, or result in futility for lack of merit. *Foman*, 371 U.S. at 182. The most important factor, in the determination of whether leave to amend should be granted, is the consideration of prejudice to the opposing party. *Jackson v. Bank of Hawaii*, 902 F.2d 1385, 1387 (9th Cir. Haw. 1990). Courts have refused to grant leave to

amend based on prejudice in instances where the parties are past the discovery stage or have filed a motion for summary judgment. *Foman*, 371 U.S. at 178; *See Kendall v. Visa U.S.A., Inc*., 518 F.3d 1042, 1051-52 (9th Cir. Cal. 2008). For example, in *Jackson v. Bank of Hawaii*, the Court justified its denial of leave to amend on the fact that it would unfairly result in additional discovery for the opposing party and the necessity to re-litigate on issues not addressed in the original complaint. *Id.* at 1388. In the present case, discovery has not yet occurred and Respondent has not filed a motion for summary judgment. Respondent would not have to re-litigate or incur additional discovery costs to respond to Petitioners' newly-pleaded facts. Therefore, if the Court of Appeals had properly remanded to the District Court, the Petitioners would have been granted leave to amend.

Furthermore, also pertinent in evaluating whether denial of leave to amend is warranted, is the issue of undue delay to the opposing party. Here, Petitioners were put on notice of the alleged deficiencies in their Complaint only after the Court of Appeals granted Respondent's motion to dismiss for failing to state a claim. Even if this amounts to an undue delay, "[m]ere delay, however, absent a showing of bad faith or undue prejudice, does not provide a basis for a district court to deny the right to amend." *State Teachers Retirement Bd. v. Fluor Corp.*, 654 F.2d 843, 856 (2d Cir. N.Y. 1981). There are no facts to support the contention that Petitioners purposefully delayed their request to amend their pleading. On the contrary, Petitioners were under the impression that their Complaint was sufficiently pled as this was explicitly affirmed by the District Court. *Cooks, et al*, No. 08-cv-04132, slip op. at 4. Therefore, since no undue delay would be imposed on Respondent, the District Court could not have justified denial of leave to amend.

Lastly, an amendment may be denied as futile when it would be subject to immediate dismissal. *Jones v. New York State Div. of Military & Naval Affairs*, 166 F.3d 45, 50-55 (2d Cir. N.Y. 1998). For example, an amendment would be futile where the additional allegations would be barred under an applicable statute of limitations. See *Jablonski v. Pan American World Airways, Inc.*, 863 F.2d 289, 292 (3d Cir. Pa. 1988). An amendment, however, would not be futile if the complaint was dismissed for mere factual insufficiency such as an error that can be fixed by alleging additional facts. Here, the Court of Appeals merely dismissed Petitioners' Complaint for pleading nothing more than legal conclusions. *Cooks, et al*, No. 09-1032, slip op. at 12. Accordingly, because Petitioners could amend their Complaint to sufficiently plead more facts, leave to amend would not be futile.

CONCLUSION

For the foregoing reasons, Petitioners respectfully request that this Court find that their claims for design defect are not preempted under the Vaccine Act. Furthermore, Petitioners ask this Court to reverse the Court of Appeals order dismissing their Complaint with prejudice.

Respectfully Submitted,

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Attorneys for Petitioners