No. 10-1524

In the

Supreme Court

of the United States

April Term, 2010

Dan Cooks, et al.,

Petitioner, Cross-Respondent,

v.

Carolina Laboratories, Inc.,

Respondent, Cross-Petitioner.

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

Brief for the Respondent

Team # 14R
Counsel for the Respondent

Questions Presented

I. Does the National Childhood Vaccine Injury Act of 1986 preempt state design defect claims when (a) the specific language in section 22(b) of the National Childhood Vaccine Injury Act expressly preempts state design defect claims; (b) the relevant legislative history reflects Congress's intent to preempt state design defect claims; and (c) the structure of the National Childhood Vaccine Injury Act demonstrates that Congress intended to remove design defect claims from the state court system?

II. Does a complaint for a design defect claim fail to survive a Fed. R. Civ. P. 12(b)(6) motion to dismiss when it (a) does not allege any facts necessary to satisfy the elements of a design defect claim; and (b) provides only legal conclusions?

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The opinion of the United States District Court for the District of Grace, and the opinion of the United States Court of Appeals for the Thirteenth Circuit are unpublished. A copy of the opinion of the United States District Court for the District of Graces is attached as Appendix A, and a copy of the opinion of the United States Court of Appeals for the Thirteenth Circuit is attached as Appendix B.

Statutes Involved

This case involves the interpretation of Section 22(b) of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 *et. seq*. (2006). The relevant provisions of the National Childhood Vaccine Injury Act of 1986 are attached as Appendix C. This case also involves the interpretation of Fed. R. Civ. P. 12(b)(6) and Fed. R. Civ. P. 8(a)(2). The relevant provisions of Fed. R. Civ. P. 12(b)(6) and Fed. R. Civ. P. 8(a)(2) are attached as Appendix D.

Statement of the Case

A. Statement of the Facts

The Respondent, Carolina Laboratories Inc., ("Carolina" or "Respondent"), is a vaccine manufacturer incorporated in the state of Delaware, but its primary operations are based in the state of New Jersey. (R. at 1-2). In March of 1996, and October of 1998, Estella Marie Cooks ("Petitioner") received three does of Carolina Laboratories Diphtheria, Tetanus Toxoids, and Pertussis ("DTP"). *Id*. at 1. Each DTP dose given to the Petitioner contained the vaccine preservative thimerosal. *Id*. Thimerosal is a preservative that prevents microbial growth in vaccines during and after the manufacturing process. *Owens v. American Home Products Corp.*,

203 F. Supp. 2d 748, 755 (S.D. Tex. 2002). Carolina used thimerosal to comply with the Food and Drug Administration's ("FDA") requirement that a preservative be used in all multi-dose vaccine vials such as DTP. *See* 21 C.F.R. § 610.15. The Petitioner agrees that all of the DTP doses were properly manufactured and supplied with adequate warning labels. *Id*. at 1.

At an unspecified point following the three vaccinations, Estella's parents, Dan and LoEtta Cooks ("Petitioners"), claimed that their daughter began to develop neurological injuries. *Id*. The Petitioners alleged that these injuries resulted from the three DTP vaccinations she received between 1996 and 1998. *Id*. The Petitioners' claim is based on the unsupported allegation that the thimerosal was toxic and that its use led to their daughter's injuries. *Id*. The Petitioners also allege that Carolina failed to conduct the proper safety tests on the thimerosal even though it has been safely used as a vaccine preservative since the 1930s. *Id*. at 2. The record lacks any evidence indicating that the Petitioners investigated other possible reasons for their daughter's illness. *Id*. at 1-2. Nevertheless, the Petitioners filed a claim with the National Vaccine Injury Compensation Program ("NVICP"), in compliance with the National Childhood Vaccine Injury Act, ("NCVIA") on September 3, 2001, just before their claim passed the statute of limitations. *Id*. at 1.

B. Course of Proceedings and Disposition in the Courts Below

On November 5, 2003, the Petitioner filed a notice of withdrawal in the NVICP, and after judgment was subsequently entered, an election to commence a civil action was filed on January 21, 2004. (R. at 2). On March 14, 2007, the Petitioner filed a two-count complaint in the Wicked County Court of Common Pleas, and the Respondent removed the case to the United States District Court for the District of Grace based on diversity of citizenship. *Id*. The first count in the complaint alleged that Carolina Laboratories negligently failed to conduct adequate

safety tests on thimerosal, and the second count asserted a strict products liability design defect claim. *Id*. The Respondent made a motion to dismiss the complaint on grounds that the Petitioner's claims were barred by Section 22(b)(1) of the NCVIA, and that the Petitioner's complaint failed to allege facts sufficient to state a claim for design defect under Grace state law. *Id*. at 3-4. Even though the district court ruled that the complaint gave sufficient notice of a claim, it determined that the Petitioner's claims were barred by the NCVIA and granted the Respondent's motion to dismiss. *Id*. at 7-8. The Petitioner timely filed a notice to appeal the district court's ruling with the United States Court of Appeals for the Thirteenth Circuit. *Id*. at 9.

On appeal, the Petitioner argued that their claims against the Respondent were not barred by the NCVIA, and the Respondent maintained that the Petitioner's complaint did not contain factual allegations sufficient to survive a motion to dismiss under Rule 12(b)(6). *Id*. at 9-10. The Thirteenth Circuit disagree with the district court's ruling on both issues, and held that while the Petitioner's claims were not preempted by Section 22(b)(1) of the NCVIA, their claim failed to contain any facts that would allow it survive a 12(b)(6) motion to dismiss. *Id*. at 10, 13.

The Petitioners appealed the Thirteenth Circuit's decision to dismiss the case because the complaint failed to allege facts sufficient to state a claim for relief, and the Respondent cross-appealed the court's decision that the NCVIA did not preempt the state design defect claim under the NCVIA. *Id*. at 14. The Supreme Court of the United States granted certiorari to consider these two issues. *Id*.

C. Standard of Review

The appropriate standard of review for a question concerning federal preemption of a state law claim is *de novo*. *Hesling v. CSX Transportation*, *Inc*., 396 F.3d 632 (5th Cir. 2005). While a *de novo* review of a preemption issue must be performed in the light most favorable to the non-moving party, this Court owes no deference to the lower court's determination that the National Childhood Vaccine Injury Act of 1986 did not preempt the Petitioner's design defect claim.

The appropriate standard of review for a court's dismissal of a complaint pursuant Fed. R. Civ. P. 12(b)(6) is also *de novo*. *Reger Development, LLC v. National City Bank*, 592 F.3d 759 (7th Cir. 2010) (noting that *de novo* is the appropriate appellate standard of review for a district court's ruling on a 12(b)(6) motion to dismiss). Even though a *de novo* review of this type requires the court to construe a complaint in the light most favorable to plaintiff, it is only required to accept the complaint's well-pleaded facts as being true. *Id*. Because the Petitioner's complaint lacks any well-pleaded facts, this Court should affirm the Thirteenth Circuit's decision to dismiss under Rule 12(b)(6).

Summary of the Argument

This case presents two issues that have been subjected to conflicting opinions in the courts below. First, the Thirteenth Circuit incorrectly reversed the district court when it held that the Petitioner's state design defect claims were not preempted by the NCVIA. Second, the Thirteenth Circuit was correct when it ruled that the Petitioner's complaint failed to allege any facts necessary for a design defect claim in Grace. These issues are addressed in turn.

The United States Court of Appeals for the Thirteenth Circuit incorrectly concluded that state design defect claims are permitted under the NCVIA. The specific language in the NCVIA, legislative history found in the NCVIA's Committee Report, and its structure all indicate that Congress passed it in order to preempt state design defect claims. The Thirteenth Circuit incorrectly concluded that the NCVIA allows state design defect claims because it did not read all of the language included in Section 22(b) of the NCVIA. Specifically, the Thirteenth Circuit disregarded the language that states that a vaccine manufacturer that properly prepares and labels a vaccine is not liable for vaccine-related injuries or deaths so long as the injuries or deaths resulted from unavoidable side effects. 42 U.S.C. § 300aa-22(b)(1) (2006). Because the Thirteenth Circuit overlooked this language, it incorrectly held that the Petitioners could proceed with their design defect claim even though Carolina properly prepared and labeled the vaccine. (R. at 2).

Furthermore, the Thirteenth Circuit also ignored language in the NCVIA's Committee Report that indicated that Congress wanted to limit vaccine manufacturers' liability. In the Committee on Energy and Commerce's 1986 House Report 99-908 ("Committee Report")

Congress relied on Comment K of § 402A of the Restatement (Second) of Torts[1] to state why further tort claims against vaccine manufacturers is a threat to future vaccine investment. H.R. Rep. No. 99-908 at 26 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6367. In addition, the Committee Report also states that all state tort claims against vaccine manufacturers should be preempted unless a plaintiff can demonstrate that a vaccine was improperly prepared or accompanied by improper labeling. *Id*. The Thirteenth Circuit did not address this language in its opinion, and because of this omission it wrongfully concluded that the NCVIA permitted design defect claims.

The Thirteenth Circuit also overlooked the fact that the NCVIA's structure places decisions regarding design defect claims in the hands of federal experts and not state juries. In its opinion, the Thirteenth Circuit indicated that design defect claims should be handled by state juries on a case by case basis. (R. at 11). This conclusion disregards the section in the NCVIA that places the Secretary of Health and Human Services ("Secretary of HHS") in charge of vaccine safety and oversight. 42 U.S.C. § 300aa-27(a)(1) (2006). This section is counter to the Thirteenth Circuit's holding that design defect claims could be handled by a jury on a case by case basis. Therefore, the structure of the NCVIA, and the NVICP, makes it clear that Congress wanted to provide a new method for settling vaccine design defect claims, and leave issues involving vaccine safety in the hands of federal experts.

In the event this Court finds that the Petitioner's design defect claim is not preempted by the NCVIA, the Petitioner's case should still be dismissed because the complaint fails to allege any facts necessary to state a design defect claim in Grace. In accordance with this Court's ruling in *Twombly*, which was reaffirmed in *Iqbal* and has been applied in other products liability

[1] Relevant provisions of §402A of the Restatement (Second) of Torts are found in Appendix G.

claims, a plaintiff must allege enough facts to support the grounds for a particular claim in order for the complaint to survive a motion to dismiss under Rule 12(b)(6). Furthermore, this Court also said in *Twombly* that mere legal conclusions, or formulaic recitations of the elements of a cause of action, will not suffice the factual burden required. The Petitioner's complaint only provides conclusory, legal statements that merely recite the elements of a design defect claim. The Petitioner stated no facts showing that the Respondent failed to adequately test thimerosal, that thimerosal is unreasonably dangerous or that its usage was a substantial, contributing cause of the injuries. Therefore, because the Petitioner has failed to allege any facts in their complaint to establish a design defect claim, their case should be dismissed pursuant to Fed. R. Civ. P. 12(b)(6).

Argument

I. The National Childhood Vaccine Injury Act of 1986 Expressly Preempts Design Defect Claims.

The Constitution of the United States gives Congress the power to preempt state statutes, regulations and common laws. *See* U.S. Const. Art. VI, cl. 2. In *Lorillard*, this Court held that Congress's intention to preempt state law with a federal statute may be determined by reviewing the statute's text, legislative history and structure. *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 542-546 (2001). The specific language in the National Childhood Vaccine Injury Act of 1986 at issue is found in Section 22 (b). In addition, the relevant legislative history may be found in the Committee on Energy and Commerce's 1986 House Report 99-908, and the structure of the NCVIA may be understood by reviewing the additional statutes that support Section 22 (b).

Under the *Lorillard* analysis, this Court should first consider the plain language found in Section 22 (b) of the NCVIA. The language in Section 22 (b) specifically insulates vaccine manufacturers from civil liability for injuries or deaths that may result from the use of a vaccine so long as the injuries or deaths were unavoidable, and the vaccine was properly prepared and labeled. 42 U.S.C. § 300aa-22(b)(1) (2006). The Petitioners conceded that Carolina properly prepared and labeled the DTP, and based on this concession, their design defect claim should be preempted. (R. at 2).

The next step in the *Lorillard* analysis looks at the federal statute's legislative history. The legislative history on the NCVIA is found in the Committee on Energy and Commerce's 1986 House Report 99-908 ("Committee Report"). H.R. Rep. No. 99-908 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344. This committee report captures Congress's intent to preempt state design defect claims through its reliance on Comment K of § 402A of the Restatement (Second) of Torts. The reliance on Comment K makes it clear that Congress wanted to preempt state design defect claims in order to protect vaccine manufacturers from mounting litigation that threatened to cut off the supply of their vital products.

The final factor that should be considered in the *Lorillard* analysis is the structure of the NCVIA. Various sections of the NCVIA clearly indicate that issues dealing with the regulation and promotion of safer vaccinations should be handled by federal experts, and not state judicial systems. This additional federal oversight, which adds to existing vaccine regulations mandated by the FDA, makes it obvious that Congress wanted decisions regarding vaccine design safety to be handled by the federal government and not lay juries.

The decision of the Thirteenth Circuit is based on a limited *Lorillard* analysis. It only considered a small portion of the language in Section 22 (b), and ignored the Petitioner's

concession that Carolina properly manufactured and labeled the DTP. (R. at 2, 11). Furthermore, the Thirteenth Circuit also failed to consider the Committee Report's reliance on Comment K of § 402A of the Restatement (Second) of Torts, and by doing so it incorrectly concluded that the NCVIA left open the possibility for state design defect claims. Finally, the Thirteenth Circuit ignored the entire structure of the NCVIA, and its emphasis on leaving decisions regarding vaccine safety in the hands of federal experts. Because of these oversights, this Court should reverse the Thirteenth Circuit's decision regarding state design defect claims.

A. The Plain Language in the NCVIA Preempts Design Defect Claims.

In *Medtronic, Inc.*, this Court held that the specific language of a federal statute must be examined to determine if it preempts state law. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996). The specific language in the NCVIA that shows Congress intented to preempt state design defect claims is in Section 22(b)(1). Section 22(b)(1) of the NCVIA states that a vaccine manufacturer that properly prepares and labels a vaccine is not liable for vaccine-related injuries or deaths so long as the injuries or deaths resulted from unavoidable side effects. 42 U.S.C. § 300aa-22(b)(1) (2006). The Petitioners conceded that Carolina properly prepared the vaccine and accompanied it with the appropriate warning labels. (R. at 2). However, the Thirteenth Circuit incorrectly concluded that Section 22(b)(1) left open the possibility for state design defect claims because it did not analyze all of statute's language, and because it misconstrued the holding in *Militrano v. Lederle*, 810 N.Y.S.2d 506 (N.Y. App. Div. 2006).

The Thirteenth Circuit concluded that design defect claims are permitted under the NCVIA because it considered only the language that stated that a vaccine manufacturer is not civilly liable "if the [vaccine-related] injury or death resulted from side effects that were

unavoidable." (R. at 11). However, the Thirteenth Circuit ignored the remaining language in Section 22(b)(1) that states that vaccine manufactures are not civilly liable for unavoidable side effects, "even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1) (2006). This language means that a vaccine manufacturer is not civilly liable for unavoidable side effects that lead to injury or death so long as it properly manufactured, prepared and labeled the vaccine. By ignoring the rest of the language in Section 22(b)(1), the Thirteenth Circuit disregarded this Court's ruling in *Bates v. Dow Agrosciences LLC*, which concluded that reading words out of a statute will only amputate the meaning of the statute and not reveal its purpose. 544 U.S. 431, 448-449 (2005). This amputation of language in Section 22(b)(1) allowed the Thirteenth Circuit to wrongfully conclude that design defect claims are permitted by the NCVIA. This conclusion destroys the purpose of the NCVIA and ignores Congress's goal of protecting vaccine manufacturers from mounting state tort claims.

The Thirteenth Circuit also ignored additional language in the statute that supported the language in Section 22(b)(1). Section 22(b)(2) indicates that unless the Petitioners can demonstrate that Carolina failed to follow the manufacturing and labeling requirements under the Federal, Food, Drug, and Cosmetic Act, the vaccine shall be considered properly manufactured and protected from civil liability. 42 U.S.C. § 300aa-22(b)(2) (2006). The Petitioners conceded that the DTP given to their daughter met the standards in Section 22(b)(2), therefore their claim should be preempted. However, the Thirteen Circuit ignored this language, and improperly allowed the Petitioner's claim to proceed despite the fact that Section 23(d) only allows state judicial systems to award certain damages under instances of fraud, intentional withholding of

safety information, or criminal activity. 42 U.S.C. § 300aa-23(d)(2) (2006). As a result of this limited reading, the Thirteenth Circuit misinterpreted the language in the NCVIA.

The Thirteenth Circuit also incorrectly relied on *Militrano v. Lederle*, 810 N.Y.S.2d 506 (N.Y. App. Div. 2006) to support its interpretation of Section 22(b). The Thirteenth Circuit cited the section of the *Militrano* opinion that states that the language [in the NCVIA] "appears to leave open the possibility of a design defect claim with respect to vaccines covered by the Vaccine Act…" *Id*. at 508. This interpretation of *Militrano* ignores the rest of that court's decision, which held that when the language of the NCVIA is read in its entirety, along with the Congressional Committee Report, it is clear that Congress intended it to preempt state design defect claims. *Id*. at 508–509.

This conclusion regarding the language in the NCVIA is also supported by numerous court decisions. *See Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009) (ruling that the language of Section 22(b), when combined with the legislative history, clearly preempts design defect claims.); *Sykes v. Glaxo-Smithkline*, 484 F. Supp. 2d. 289 (E.D. Pa. 2007) (holding that strict liability design defect claims and negligent design defect claims are expressly preempted by the NCVIA); *Blackmon v. American Home Products Corporation*, 328 F. Supp. 2d. 659 (S.D. Tex. 2004) (determining that when reading Section 22(b) against the background of products liability law it is clear that all design defect claims against vaccine manufacturers are barred). Because the Thirteenth Circuit only read a limited portion of Section 22(b), misinterpreted the holding in *Militrano*, and ignored numerous court opinions regarding the language in the NCVIA, this Court should conclude that it preempts state design defect claims.

B. The Legislative History of the NCVIA Demonstrates that Congress Intended to Preempt Design Defect Claims.

In *Medtronic, Inc.*, this Court held that statute interpretation cannot take place in a contextual vacuum. 518 U.S. 470, 484-485. Instead, a court must also consider the legislative history and the statutory structure. *Lorillard Tobacco Co.*, 533 U.S. 525, 542-546 (2001). The specific report that provides the legislative history on the NCVIA is the Committee on Energy and Commerce's 1986 House Report 99-908. H.R. Rep. No. 99-908 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344. The language in this report demonstrates that Congress intended to preempt design defect claims in order to protect vaccine manufacturers. Specifically, it shows that the language used to draft the NCVIA relied heavily on Comment K of Section 402A of the Restatement (Second) of Torts, and it is the Committee Report's reliance on Comment K that supports the conclusion that NCVIA preempts design defect claims.

1. The language in the Committee Report supports preemption.

In *Garcia v. United States*, this Court concluded that the record of Congressional intent can be found in the committee report on the bill that became law. 469 U.S. 70, 76 (1984). In the NCVIA's Committee Report, Congress indicated that all state tort claims against vaccine manufacturers should be preempted unless a plaintiff can demonstrate that a vaccine was improperly prepared or labeled. H.R. Rep. No. 99-908 at 26 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6367. If a plaintiff cannot prove that one of these reasons caused their injuries, then they should seek relief in the NCVIA's compensation system, and not the tort system. *Id*. This unambiguous statement in the Committee Report bolsters the conclusion that the Petitioners must seek relief through the NVICP if they cannot show that Carolina improperly manufactured or labeled the DTP.

Several courts have reviewed the Committed Report and agreed with this conclusion. In *Blackmon*, the United States District Court in the Southern District of Texas concluded that when the Committee Report is read in context with the specific language of the NCVIA, it is clear that Congress intended to bar all design defect claims and only allow potential plaintiffs to move forward with manufacturing defect and improper labeling claims. 328 F. Supp. 2d. 659, 664 (S.D. Tex. 2004).

Three other federal courts also reached this conclusion. *See Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009) (ruling that the Committee Report states in precise terms that design defect claims are barred by the language in Section 22(b) of the Act); *Sykes v. Glaxo-Smithkline*, 484 F. Supp. 2d. 289 (E.D. Pa. 2007) (holding that the legislative history contained in the Committee Report clearly supports the conclusion that Congress intended to preempt all design defect claims); *Militrano v. Lederle*, 810 N.Y.S.2d 506 (N.Y. App. Div. 2006) (finding that the portion of the Committee Report that deals with Section 22(b) clearly establishes Congress's intent to preempt such claims). When the language of the Committee Report is considered, along with these court's conclusions, it is clear that Congress intended to preempt all design defect claims.

2. The reliance on Comment K in the Committee Report supports preemption.

Further evidence of Congress's intent to preempt design defect claims is found in the Committee Report's adoption of Comment K of Section 402A of the Restatement (Second) of Torts. Comment K deals with unavoidably unsafe products, and states that products that are incapable of being made safe in their intended and ordinary use should not be considered unreasonably dangerous or defective so long as the product is properly manufactured and

accompanied by the appropriate warning labels. Restatement (Second) of Torts § 402A cmt. K (1965). This section also states that if a manufacturer properly prepared and marketed these products it should not be held strictly liable for injuries that result from the use of these products because it chose to supply the public with useful products that come with a known and reasonable risk. *Id*.

The Committee Report relied on the language in Comment K to change state laws after the NCVIA's enactment. H.R. Rep. No. 99-908 at 26 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6367. This change meant that the NCVIA and the NVICP would protect vaccine manufacturers from endless state tort claims. *Id*. The fact that Congress chose to rely on Comment K to bring about this change clearly indicates that it intended to preempt all state tort claims against vaccine manufacturers, except those based on manufacturing or labeling defects.

The courts have also reached this conclusion regarding the Committee Report's reliance on Comment K; *See Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009); *Sykes v. Glaxo-Smithkline*, 484 F. Supp. 2d. 289 (E.D. Pa. 2007); *Militrano v. Lederle*, 810 N.Y.S.2d 506 (N.Y. App. Div. 2006); *Blackmon v. American Home Products Corporation*, 328 F. Supp. 2d. 659 (S.D. Tex. 2004). In addition, numerous legal scholars on tort and products liability have concluded that Comment K protects manufacturers of reasonably unsafe products so long as the product was properly manufactured and labeled.

See David G. Owen, *Products Liability Law*, §8.10 at 553 (2d ed. 2005) (concluding that drugs as understood under Comment K are different from other products and that most courts properly exempt useful and unavoidable unsafe drugs from strict product liability); Dan B. Dobbs, *The Law of Torts* § 359 at 989 (2001) (writing that Comment K protected unavoidably dangerous products from strict liability if a proper warning was given); 2 David G. Owen, et al.,

Madden & Owen on Product Liability, §23:4 at 608 (3d ed. 2000) (stating that Comment K prevents subjecting manufacturers of prescription drugs and medical devices from strict liability for unfortunate consequences attending to their use because they supply society with a useful product with a known risk); 2 M. Stuart Madden, *Products Liability*, §23.8 at 360 (2d ed. 1988) (stating that under Comment K manufacturers of valuable, efficacious, but concededly dangerous products should not be found strictly liable where it provided adequate warnings of all potential adverse reactions, which it knew of as an expert in the field).

These conclusions by the courts and legal experts support the fact that Congress relied on Comment K in the Committee Report because it wanted to protect vaccine manufacturers from state design defect claims. If Congress wanted to leave open an exception to Comment K it would have stated this exception in the Committee Report, however it makes no mention of a possible exception that will allow the Petitioners to move forward with their state design defect claim.

The Thirteenth Circuit reached its conclusion on design defect claims by relying on a narrow portion of the Committee Report. (R. at 11). In its opinion, it ignored the Committee Report's reliance on Comment K and the protection it extends to manufacturers of reasonably unsafe products. *Id*. It also ignored the court opinions and legal treatises that concluded that Comment K's protects manufacturers from most state tort claims. *Id*. Due to these omissions, this Court should reverse the Thirteenth Circuit's decision on state design defect claims.

C. The Structure of the NCVIA Supports Preemption of State Design Defect Claims.

The final step in the *Lorillard* analysis looks at a statute's structure and if its structure supports federal preemption. The Thirteenth Circuit concluded that state design defect claims are not preempted by the NCVIA, and that decisions regarding design defect claims should be handled by a jury on a case by case basis. (R. at 11). This conclusion undermines the purpose of the NCVIA, and takes the power to make decisions about vaccine safety out of the hands of the expert agencies, and places it in the hands of lay juries who may reach conflicting conclusions about vaccine safety. This conclusion by the Thirteenth Circuit destroys the purpose of the NCVIA, and to find otherwise could lead to devastating consequences for future vaccine development.

Congress passed the NCVIA to ensure that the vital and necessary vaccine production market remained stable, and to ensure that there are no shortages of these necessary vaccines in the future. H.R. Rep. No. 99-908 at 26 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6346. The NCVIA is structured so vaccine manufactures may freely produce and distribute vaccines without the fear of facing massive litigation that would make investments in vaccine production unprofitable. *Id*. The Thirteenth Circuit wants to undermine this purpose by disregarding the NCVIA's structure and allowing juries to make conclusions about vaccine safety requirements. (R. at 11). This would annihilate the NCVIA, and empower state juries to determine which vaccines are safe on a case by case basis, thus making investments in vaccine production undesirable to manufacturers.

The Thirteenth Circuit ignored the language in the NCVIA that designated the Secretary of HHS as the primary promoter of vaccine safety. (R. at 11). Section 27 of the NCVIA states

that the Secretary of HHS is responsible for promoting childhood vaccines that result in fewer injuries, and make improvements in the licensing, labeling, processing, testing, manufacturing, warning and research of vaccines in order to reduce adverse reactions in children. 42 U.S.C. § 300aa-27(a)(1) (2006). This language in Section 27 is counter to the Thirteenth Circuit's conclusion that the NCVIA leaves open the possibility for juries to regulate design defect claims on a case by case basis. (R. at 11). Instead, Section 27 makes it clear that Congress intended to leave these decisions in the hands of federal experts so vaccine manufacturers that have struggled in the face of mounting tort claims, particularly ones involving DTP, would continue to invest in these vital and necessary vaccinations. H.R. Rep. No. 99-908 at 26 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 6344, 6347.

Furthermore, by entrusting the Secretary of HHS with vaccine oversight and regulation, the NCVIA builds upon the federal law that currently regulates the vaccine industry. Specifically, the NCVIA expands federal oversight of vaccine production that requires a vaccine manufacturer to seek a license to distribute a new vaccine, and to comply with guidelines and safety standards set forth by the FDA before it is approved for use. *See* 21 U.S.C. § 301 *et seq*.; 42 U.S.C. § 262(a); 21 C.F.R. § 600 *et seq*. Because the NCVIA's structure built upon existing federal regulation and expanded federal oversight, it is clear that Congress wanted to avoid a situation that allows lay juries to make case by case determinations about vaccine safety.

In conclusion, the specific language, legislative history and structure of the NCVIA demonstrate that Congress wanted to preempt state design defect claims. The language in Section 22(b) makes it clear that the Petitioners cannot move forward with their state design defect claim because it is not a permitted cause of action under the NCVIA. Furthermore, the legislative history in the Committee Report indicates that the NCVIA's purpose is to protect

vaccine manufacturers from mounting tort claims that threaten future investments in vaccine development. Finally, the NCVIA's structure makes it clear that Congress wanted federal experts to make decisions about vaccine safety. Because of these three factors, it is obvious that Congress wanted the NCVIA to preempt state design defect claims. Therefore, this Court should reverse the Thirteenth Circuit's decision on this matter.

II. The Petitioner's Claim Should be Dismissed Because it Fails to Plead Any Factual Allegations in Accordance with *Twombly*.

Federal Rule of Civil of Procedure 8(a)(2) requires that a complaint contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In *Conley v. Gibson*, this Court established that Rule 8(a)(2) should be construed broadly so that a complaint only needs to give a defendant fair notice of a particular claim and the grounds upon which it is brought forth. 355 U.S. 41 (1957). In *Conley*, it was held that a complaint should not be dismissed under Rule 12(b)(6) "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Id*. at 45-46.

Later, this court further clarified the outer boundaries of this broad construction by requiring that while complaints need not provide detailed factual allegations, they must contain enough facts to support the grounds for a particular claim, and that mere legal conclusions or formulaic recitations of the elements of a cause of action will not suffice. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007). This Court reaffirmed the holding in *Twombly*, and further refined the requirements for notice pleading in *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009), by requiring a complaint to contain enough facts so that a claim for relief is facially plausible. Recent refining of the requirements for a complaint to survive a 12(b)(6) motion to dismiss show

that the Petitioner's complaint should fail because it lacks any factual content to show a plausible design defect claim, and it only contains conclusions of law that recite the elements of a design defect claim.

Carolina agrees that some plaintiffs may not have all the facts necessary to prove every element of a design defect claim at the time a complaint is drafted. Furthermore, it understands that discovery may be the only viable means for a plaintiff to obtain all the facts sufficient to prove a claim. However, all plaintiffs must have at least some, minimal facts related to one or more elements of a claim in order for their complaint to withstand a motion to dismiss. *See Twombly*, 550 U.S. at 552-553. Even in instances where the discovery process may be minimally intrusive and could theoretically be controlled by careful case management, allowing a plaintiff who alleges no factual allegations in their complaint to proceed beyond this stage is not justified. *Iqbal*, 129 S. Ct. at 1953. Therefore, since the complaint in this case lacks any factual allegations to prove a design defect claim, the Petitioner's should not be permitted to proceed to discovery in attempt to gather such facts.

A. The Petitioner's Complaint Does Not Provide Sufficient Facts to Plausibly State a Design Defect Claim.

The Supreme Court of Grace determined a framework for establishing a design defect claim against a product manufacturer that is consistent with the majority of jurisdictions in the United States. (R. at 3-4). In Grace, design defect claims are to be evaluated through a risk-utility analysis where the risks inherent in the product design are weighed against the utility of the product. *Id*. at 4. Factors that may be considered in the risk-utility analysis include the gravity of danger caused by the design, the ability of the manufacturer to avoid the danger, as well as the ability to eliminate the danger without impairing the product's usefulness. *Id*.

Because Grace's framework for design defect claims tends to follow the majority of jurisdictions, it sheds further light on this case if some similar ways of expressing this analysis in other jurisdictions are considered. Other jurisdictions incorporate a standard which requires that a product be "unreasonably dangerous"; a standard which contemplates whether risks posed by a product are unreasonably higher than what the ordinary consumer would expect, or whether the risks are so great that a reasonable seller would not place the product on the market. Kristine Cordier Karnezis, Annotation, *Products Liability: Modern Cases Determining Whether Product is Defectively Designed*, 96 A.L.R. 3d 22 (1979). In this case, the Petitioner has failed to provide any facts in their complaint that show the Respondent failed to safely design thimerosal under the frameworks established for Grace or other majority jurisdictions.

In *Twombly*, a group of plaintiffs filed a complaint alleging that the defendant cable companies had violated anti-trust laws by creating monopolies in their own local markets. 550 U.S. at 550-551. The complaint stated upon information and belief that the local cable companies had entered into a contract, conspiracy, or both, to prevent competition in each company's respective markets. *Id*. at 551. The plaintiff's factual basis for violation of the anti-trust laws consisted of the mere absence of competition, and the fact that the local companies conducted business in a parallel manner. *Id*. No facts to show that the companies had entered into a contract, conspiracy or other type of agreement essential to proving an anti-trust violation were offered, nor were any facts provided that might show the defendants' parallel business conduct stemmed from anything but independent, self-interest. *Id*. at 552. This Court held that because the plaintiff's complaint contained only legal conclusions and did not contain any facts for the anti-trust violation claim to be facially plausible, it must be dismissed. *Id*. at 570.

In *Iqbal*, a Muslim plaintiff was detained in federal prison as part of a massive effort to

investigate potential perpetrators of the September 11 terrorist attacks. 129 S. Ct. at 1942. Mr. Iqbal claimed that while he was detained in federal prison, he was mistreated, and that his constitutional rights were violated by discriminatory policies purposefully put in place by former Attorney General, John Ashcroft, and FBI Director, Robert Mueller. *Id*. However, in Iqbal's complaint he offered only conclusory statements regarding the motives of Ashcroft and Mueller, and no factual allegations were provided to show that Iqbal's detention was for discriminatory purposes rather than legitimate law enforcement concerns. *Id*. at 1952. Accordingly, this Court determined that because Iqbal's complaint lacked any factual allegations to state a claim for purposeful unlawful discrimination, it must be dismissed pursuant Rule 12(b)(6). *Id*. at 1954.

Recently, in *Gainer v. Mylan Bertek Pharmaceuticals, Inc.*,[2] application of the refined pleading standards set forth in *Twombly* and *Iqbal* were applied in the context of a design defect case involving a drug. No. 09-690, 2010 U.S. Dist. LEXIS 2018 (D. Minn. Jan. 11, 2010). In *Gainer*, the plaintiff took a generic version of Dilantin which contained the active ingredient Phenytoin. *Id*. at 1. After continued use of Phenytoin, Gainer was diagnosed with two medical conditions that caused her to suffer notable pain and be subjected to lengthy medical treatments. *Id*. at 1-2. The defendants, Mylan Pharmaceuticals, along with several other pharmaceutical companies that manufactured drugs containing Phenytoin, were named as defendants in Gainer's complaint that asserted a design defect claim. *Id*. This action was adjudicated under Ohio law which raised an accrual date issue for claims involving drugs. *Id*. at 2. Under Ohio law, a claim for bodily injury that stems from usage of an ethical drug was considered to have accrued when a medical authority informs a plaintiff of the relationship between a medical condition and the usage of a drug, or when a plaintiff should have reasonably known that such a relationship

[2] A copy of this decision is found in Appendix E.

existed. *Id*. Claims that accrued before April 7, 2005, were abrogated by Ohio Revised Code and thus considered invalid. *Id*. In Gainer's complaint, there were no factual allegations that indicated when she was told of, or should have been aware of a relationship between her conditions and the usage of Phenytoin. *Id*. Because her complaint failed to provide any factual allegations regarding the accrual date of claim, her complaint was dismissed pursuant to a Rule 12(b)(6) motion. *Id*. at 3. While Gainer was afforded the opportunity to file an amended complaint, her original complaint was nonetheless considered insufficient by the district court that relied upon the holdings in *Twombly* and *Iqbal*. *Id*. at 2.

When the Petitioner's complaint is considered in the light of the pleading standards set forth in *Twombly* and reaffirmed in *Iqbal*, and is compared to recent application in similar product liability claims, it is clear that it provides no factual allegations to plausibly state a design defect against Carolina. The Petitioner makes no factual allegations about Carolina's failure to perform adequate safety tests of thimerosal, offers no facts regarding a safer alternative to thimerosal that may have existed, and, imperative to the design defect claim standards of Grace, makes no factual allegations pertaining to the risk inherent with thimerosal when balanced against its utility. Absent any factual allegations, the Petitioner's complaint sets forth mere possibilities of defective design, and fails to allege any facts to make a facially plausible design defect claim. Therefore, the Petitioner's complaint should be dismissed.

B. The Petitioner's Complaint Only Provides Conclusions of Law to State a Design Defect Claim.

While the absence of factual allegations to make a plausible design defect claim justifies dismissal of the Petitioner's claim through a 12(b)(6) motion, the fact that the complaint only sets forth mere conclusions of law further justifies this type of dismissal in accordance with *Twombly* and *Iqbal*. A plaintiff's complaint for relief requires more than conclusions of law and mere formulaic recitation of the elements of a cause of action in order to survive a motion to dismiss. *Twombly*, 550 U.S. at 555. While courts will accept as true the factual allegations stated in a complaint, the same is not true for legal conclusions. *Iqbal*, 129 S. Ct. at 1949. Furthermore, mere conclusory statements that simply recite the elements of a cause of action, with no supporting factual allegations, will not suffice to establish a plausible claim. *Id*. This Court's stance on the viability of complaints consisting of mere conclusions of law is clearly enunciated in *Iqbal*, where the opinion reads, "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged --but it has not "show[n]" -- "that the pleader is entitled to relief." " *Id*. at 1950.

In a recent Louisiana case, a plaintiff filed a complaint against the manufacturer of a smoking cessation drug called Chantix for various products liability causes including design defect. *Ivory v. Pfizer, Inc.*, No. 09-0072, 2009 U.S. Dist. LEXIS 90735 (D. La. Sept. 30, 2009).[3] Under Louisiana law, the plaintiff had to show there existed an alternative design for the product which would have prevented the plaintiff's injuries, and the risk of injuries by the current design would outweigh the burden of adopting the alternative. *Id*. at 3. The plaintiff's complaint did not provide any facts relating to an alternative design of Chantix, and it only

[3] A copy of this decision is found in Appendix F.

provided mere conclusions that the likelihood and gravity of harm presented by Chantix outweighed an unspecified alternative design. *Id*. Because this complaint lacked facts from which the court could draw an inference of a plausible design defect claim, it was dismissed. *Id*.

All of the statements in the Petitioner's complaint that serve to establish the design defect claim are mere conclusions of law. First, the complaint simply concludes that Carolina failed to conduct adequate safety tests of thimerosal, however no factual allegations exist regarding its tests on thimerosal or its testing processes. (R. at 12-13). Next, the complaint states that thimerosal was dangerously defective because it contained dangerous levels of ethyl mercury, and that Carolina knew about potential side effects. (R. at 12). Because Grace follows a risk-utility analysis for design defect claims, mere knowledge of potential side effects without any facts regarding the drug's utility is a conclusory statement that does not justify relief. (R. at 4). Thirdly, the Petitioner's complaint states that the unreasonably dangerous and defective products described were a substantial contributing cause of the plaintiff's neurodevelopmental injuries. (R. at 13). However, the Petitioner provides no factual allegations to link usage of thimerosal to the neurodevelopmental injuries that have been sustained. *Id*. Therefore, because the Petitioner's complaint only contains legal conclusions, and presents only the mere possibility of a design defect claim it should be dismissed.

C. The Petitioner May Not Use the Discovery Process to Obtain Facts Necessary to Construct a Viable Complaint.

The provision for a motion to dismiss pursuant to Rule 12(b)(6) gives courts the ability to expeditiously discharege complaints that lack proper foundation before it proceeds to the discovery process. *See Twombly*, at 558-560; *See also Smith v. Duffey*, 576 F.3d 336, 340 (7th Cir. 2009) (expounding on *Twombly's* analysis that discovery may force expensive settlement

even in cases where a plaintiff's claim is very weak, and upholding a dismissal even when the discovery process would not be burdensome for a defendant). Furthermore, the purpose of discovery is to provide the parties of a dispute the opportunity to become aware of evidence and facts that will promote the just resolution of a claim, and not to serve as a vehicle of convenience in drafting a complaint. *See Id*. The Petitioner contends that the reason his complaint lacks factual detail is because discovery is necessary to garner such facts. (R at 3.) While this may be true, forcing Carolina to participate in a potentially expensive and exhausting discovery process is contrary to the natural civil litigation process and the very essence of why mechanisms such as the civil complaint and motions to dismiss under Rule 12(b)(6) exist. Furthermore, the potential expense of a purely expeditious discovery may unjustly force Carolina to offer a settlement based solely on the desire to avoid discovery. Allowing plaintiff's to enter the settlement arena without alleging any facts to state a plausible claim establishes very dangerous policy that could have far reaching impact upon the United State's economy.

This Court enunciated in *Iqbal* that minimally intrusive and controlled discovery processes are not merited when a plaintiff's complaint fails to adequately plead a cause of action. 129 S. Ct. at 1953. Furthermore, exposing a defendant to a potentially expensive discovery process when a claim is merely conceivable or possible, is contrary to the purpose of Rules 8(a)(2) and 12(b)(6). Finally, by allowing a fact gathering expedition to occur under the guise of discovery could force manufacturers to unjustly suffer monetary loss through early settlement simply to avoid the process of discovery. Therefore, this Court should dismiss the Petitioner's complaint because it is devoid of facts, contains only conclusions of law and may potentially expose Carolina to an unjustified, speculative discovery.

Conclusion

The Thirteenth Circuit incorrectly held that state design defect claims are permitted under the NCVIA. In its decision it did not account for the language in Section 22(b)(1) that expressly preempts all tort claims, except those for manufacturing and labeling defects. In addition, the Thirteenth Circuit also disregarded additional sections in the NCVIA that support the preemption language in Section 22(b)(1). This failure to interpret all of the language in Section 22(b)(1) amputated the statute, and allowed the Thirteenth Circuit to incorrectly conclude that Congress intended to permit design defect claims under the NCVIA. Furthermore, the Thirteenth Circuit also limited its interpretation of the NCVIA's legislative history, and by doing so, it failed to recognize vital language in the Committee Report that clearly stated Congress's intention to preempt most tort claims under the NCVIA. Finally, the Court also disregarded the NCVIA's structure, and wrongfully stated that Congress wanted design defect claims to be handled by state juries on a case by case basis. Therefore, the Respondent respectfully requests this Court to reverse the Thirteenth Circuit's regarding design defect claims.

The Thirteenth Circuit correctly held that the Petitioner's complaint should be dismissed in accordance with the factual pleading standard set forth by this Court in *Twombly*. The Petitioner's complaint does not allege any facts regarding any of the elements necessary to obtain relief via a design defect claim in Grace. Furthermore, the Petitioner's complaint only provides conclusions of law that recite the elements of a design defect claim. Therefore, the Respondent respectfully requests this Court to affirm the Thirteenth Circuit's decision on this issue.

Respectfully Submitted,

_____
Team 14R
Counsel for the Respondent

Appendix A

Decision of United States District Court for the District of Grace

Cooks v. Carolina Laboratories, Inc., No. 08-cv-04132, (U.S. Dist. Grace Mar. 25, 2008)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF GRACE

Dan Cooks, *et al.*,

Plaintiffs

-V-

Carolina Laboratories, Inc.,

Defendant

No. 08-cv-04132

March 25, 2008, Decided

OPINION

SCARLET, *District Judge*

Presently before the Court is Defendant's Motion to Dismiss pursuant to Civil Rule of Procedure 12(b)(6). For the reasons that follow, the Court finds Plaintiffs' claims are barred by the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"), 42 U.S.C. § 300aa-1 *et seq.* Accordingly, Defendant's Motion will be **GRANTED**.

I. Background

A. Factual Background

Twelve-year old Estella Marie Cooks suffers from neurological injuries which her parents believe were caused by a product made by the Defendant.[1] Between March 1996 and October 1998 Estella Marie received three doses of Carolina Laboratories' thimerosal-containing Diphteria and Tetanus Toxoids and Pertussis ("DTP") – Haemophilus influenzae type b ("Hib") combination vaccine.[2] Thimerosal is an organic compound which is approximately 50% mercury by weight. According to the Complaint, the mercury contained in the thimerosal preservative was toxic and led to Estella Marie's injuries.

B. Procedural Background

Dan and LoEtta Cooks filed a timely petition for compensation on Estella Marie's behalf with the National Vaccine Injury Compensation Program ("NVICP") on September 3, 2001,

---

[1] The Complaint alleges Estella Marie's neurological injuries include developmental delays, learning disabilities, social delays and deficits, the impairment of motor skills, gastrointestinal illness, and immune system dysfunction.

[2] The parties do not dispute that the product administered to Estella Marie is a vaccine under the Vaccine Act. *See* 42 C.F.R. § 100.3 (Vaccine Injury Table).

pursuant to 42 U.S.C. § 300aa-1 *et seq.*[3] On November 5, 2003, the Cooks 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). The Cooks filed an election to file a civil action on January 21, 2004, pursuant to 42 U.S.C. § 300aa-21(a).

On March 14, 2007, Plaintiffs filed their Complaint with this Court, individually and as parents of Estella Marie Cooks. The Complaint proceeds with two counts under Grace law against the vaccine manufacturer Carolina Laboratories.[4] Count I alleges Carolina Laboratories negligently failed to conduct adequate safety tests to determine whether thimerosal was safe and nontoxic to humans in the doses administered. Count II asserts strict products liability for design defect, in that the vaccine was defectively designed and a safer alternative existed.[5] Plaintiffs are suing for damages to Estella Marie, costs, punitive damages, and other legal or equitable relief the Court deems just and proper.

Plaintiffs initially filed their Complaint in the Wicked County Court of Common Pleas. Defendant removed the case to this Court based on diversity of citizenship, pursuant to 28 U.S.C. § 1332.[6]

II. Parties' Contentions

A. Defendant

Defendant moves to dismiss Plaintiffs' causes of action, first, on the grounds that Plaintiffs' design defect claims against it are barred by § 22(b) of the Vaccine Act. Defendant construes this section of the Vaccine Act to impose a total bar on design defect claims arising from vaccine-related injuries so long as the vaccine was produced in accordance with FDA-approved specification. According to Defendant, the plain language of the Vaccine Act reflects the intent of Congress to preempt state law claims for design defects. Defendant argues that this is a broad immunity, not subject to case-by-case review in the courts.

In addition, even if Congress did not intend to preclude design defect claims, Defendant maintains that Plaintiffs fail to allege facts sufficient to

---

[3] The filing of a petition under the NVICP stays the running of state statutes of limitations. *See* 42 U.S.C. § 300aa-16(c). The NVICP then gives a petitioner the choice to accept the judgment obtained under the program and surrender his tort rights or to reject that judgment and pursue a civil action for damages. *See* 42 U.S.C. § 300aa-21(a).

[4] The parties do not dispute that, absent preemption, Grace law will apply in this case.

[5] Plaintiffs do not assert that there was any defect with the preparation or manufacture of the vaccine and the warnings supplied were adequate.

[6] Carolina Laboratories is incorporated in Delaware, but has always had its principal place of business in New Jersey. Plaintiffs are domiciled in the State of Grace.

state a claim for design defect under Grace state law.

B. Plaintiffs

Plaintiffs disagree with Defendant's construction of the Vaccine Act and argue that the Vaccine Act only bars design defect claims if the side effects are determined, on a case-by-case basis, to be "unavoidable." Plaintiffs claim their defective design claims are permitted because the injuries suffered by Estella Marie were avoidable.

Plaintiffs further contend that they have sufficiently pled all of the elements of a cause of action for design defect. In support of their design defect claims, Plaintiffs allege that Defendant marketed a drug whose risks were not known to the general public and should have manufactured children's vaccines without thimerosal prior to their daughter's vaccination. Plaintiffs assert that they cannot plead their specific allegations more particularly without conducting discovery.

III. Standard for Rule 12(b)(6) Motion to Dismiss

A motion to dismiss for failure to state a claim upon which relief can be granted challenges the legal sufficiency of a claim, not the facts supporting it. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). In ruling on a Rule 12(b)(6) motion, a court must regard as true all of the factual allegations in the complain, *Erickson v. Pardus*, 551 U.S. 89, 94 (2007), as well as any facts that could be proved that are consistent with those allegations, *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984), and view those facts in the light most favorable to the plaintiff, *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). The court may grant a Rule 12(b)(6) motion only if it "appears beyond doubt" that the party bringing the claim cannot prove any facts that would entitle it to relief. *Conley*, 355 U.S. at 46. But, the court does not have to accept legal conclusions that are couched as factual allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Under established precedent, a district court is not obligated *sua sponte* to provide a plaintiff with an opportunity to amend her complaint prior to dismissing it with prejudice. *See Wagner v. Daewoo Heavy Inds. Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002) (en banc) ("A district court is not required to grant a plaintiff leave to amend his complaint *sua sponte* when the plaintiff, who is represented by counsel, never filed a motion to amend nor requested leave to amend before the district court.").

IV. Discussion

A. Adequacy of the Pleadings

Plaintiffs' design defect claims are sufficient to present claims for design defect under Grace state law. Grace law recognizes three types of product liability claims: (1) defective design, (2) defective manufacture, and (3) inadequate warning or failure to warn.

Existing Grace product liability law does not encompass the minority rule insulating vaccine manufacturers from strict liability. Rather, the risk-benefit analysis comports with the Supreme Court of Grace's determination

that claims for design defect are to be evaluated under a risk-utility analysis balancing the risks inherent in product design against the utility of the product designed. The factfinder may consider a number 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. Further, the weighing of these factors is generally a question for the jury.

The standard on a motion to dismiss is normally generous. *See Iqbal v. Hasty*, 490 F.3d 143, 157-58 (2d Cir. 2007) (noting that specific factual allegations are generally only necessary to make a claim plausible). Plaintiffs' Complaint plainly alleges that Defendant:

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

Moreover, the section of Plaintiffs' Complaint discussing Plaintiffs' general factual allegations sheds light on the nature of the risks allegedly posed by dangerous levels of ethyl mercury, a substance known by Defendant to have neurotoxic properties.[7]

The very nature of a products liability action—where the cause or source of the defect is not obvious to the consumer—makes it difficult for a plaintiff to pinpoint a specific source of defect against one entity along the chain of distribution prior to discovery. *Bailey v. Janssen Pharmaceutica, Inc.*, 288 Fed. App'x 597, 605 (11th Cir. 2008). It is difficult for a plaintiff at such an early stage in the litigation to know the source of the defect that was responsible for the harm caused. *Id.* Thus, it would be difficult at this stage of the litigation for the Cooks to particularly allege the exact deficiencies in Carolina Laboratories' testing procedures, despite Defendant's insistence that Plaintiffs specifically plead the source of the defect.

Because Plaintiffs' Complaint gives adequate notice of the Plaintiffs' accusations, Plaintiffs' design defect claims have been sufficiently pled.

B. National Childhood Vaccine Injury Act of 1986

1. Vaccine Act in General

[7] "As a result of the mercury exposure, Estella Marie suffered neurological injuries, including developmental delays, learning disabilities, social delays and deficits, the impairment of fine motor skills, gastrointestinal illness, immune system dysfunction, and other symptoms of mercury poisoning. Some of his injuries are likely to be permanent."

While most children derive a great benefit from childhood vaccination, "a small but significant number have been gravely injured." *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 663-66 (S.D. Tex. 2004). Vaccine-related injuries raise two concerns: (1) the inconsistency, expense, delay, and unpredictability of the tort system in compensating claims of vaccine-injured children; and (2) the instability and uncertainty of the childhood vaccine market inevitably caused by the risks of tort litigation. *Id.* With the passage of the Vaccine Act, Congress hoped to prevent manufacturers from ceasing vaccine production or significantly increasing their prices, while at the same time hoping to compensate victims of vaccine-related injuries quickly. *See Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994).

"The Vaccine Act reflects a congressional determination that the disappearance or unavailability of childhood vaccines would cause far greater harm than the inevitable but limited injuries caused by the vaccines themselves." *Blackmon*, 328 F. Supp. 2d at 663-66 (citing *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995)). In effect, the Act "ensures that all children who are injured by vaccines have access to sufficient compensation for their injuries." H.R. Rep. No. 99-908 at 4 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6345. A person alleging a vaccine-related injury can obtain compensation by filing a petition with the Vaccine Court. The petitioner need not prove fault nor causation; he only needs to show that he received the vaccine and then suffered certain symptoms within a defined period. *See* 42 U.S.C. §§ 300aa-13, 300aa-14.

In the event a plaintiff seeking compensation for vaccine-related injuries does not accept the judgment of the Vaccine Court and elects to pursue claims in state or federal court, the Vaccine Act includes certain limitations on state tort claims designed to "free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufacturers in the market." *Schafer*, 20 F.3d at 4. The limitations are stated in 42 U.S.C. § 300aa-21, and convey Congress's intent to supersede, or preempt, state tort law standards and create legal protections that apply in any civil action brought against a vaccine manufacturer.

The pertinent part of the Vaccine Act that modifies state tort law, and is at issue in this case, provides:

> (a) General Rule
>
> Except as provided in subsections (b), (c), and (e) of this section 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 October 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 U.S.C.A. § 301 *et seq.*] and *section 262* of this title (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 plaintiffs shows--

(A) that the manufacturer engaged in the conduct set forth in *subparagraph (A)* or *(B)* of *section 300aa-23(d)(2)* of this title, 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

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 part.

42 U.S.C. § 300aa-22.

As the words of the statute indicate, the Vaccine Act provides that

"[s]tate law shall apply to a civil action" for "vaccine-related injury," except in certain situations including if a plaintiff's vaccine-related injury resulted from side effects that were unavoidable even though the vaccine was properly prepared.

2. Plaintiffs' Defective Design Claims against Defendant Are Barred

Plaintiffs' defective design claim against Carolina Laboratories, based on a strict liability theory is barred. The purpose of the Vaccine Act would not be served if defective design claims could be tried before juries. A case-by-case determination of whether a vaccine was unavoidably unsafe would defeat the protection the Act was intended to provide vaccine manufacturers.

The legislative history of § 22(b) clearly supports the conclusion that Congress intended to protect vaccine manufacturers from liability for defective design claims. If a vaccine-injured person "cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system." 1986 U.S.C.C.A.N. at 6367.

In addition, product liability law and comment k to the Restatement (Second) of Torts § 402A aid this holding. The Vaccine Act mirrors this established area of tort law for unavoidably unsafe products and limits the strict liability of vaccine manufacturers for vaccine-related injuries to claims that the vaccine deviated from its FDA-approved design or it was not accompanied by proper warnings (and thereby eliminates strict liability defective design claims). Here, Plaintiffs do not claim that Defendant deviated from the FDA-approved design for the vaccines and the warnings supplied were adequate. Accordingly, Plaintiffs' strict liability design defect claim is preempted by the Vaccine Act.

Significantly, the Vaccine Act limits a manufacturer's liability for design defects regardless of the cause of action. Therefore, Plaintiffs' defective design claim based on negligence is preempted for the same reasons as the strict liability claim. The text of the Vaccine Act that limits a manufacturer's liability is not directed toward any particular cause of action. Section 22(b)(1) states broadly that no manufacturer "shall be liable in a civil action for damages arising from a vaccine-related injury or death." "A civil action for damages" includes a product liability claim based on strict liability as well as negligence. *See Blackmon*, 328 F. Supp. 2d at 666 ("While comment k is restricted to strict liability claims, § 22(b) is not."). Thus, Plaintiffs' negligent design defect claim is also barred by the Act.

V. Conclusion

For the reasons discussed above, all claims against vaccine defendant Carolina Laboratories are dismissed with prejudice. An appropriate Order follows.

ORDER

AND NOW, this 25th day of March, 2008, upon consideration of all outstanding motions filed, and all

responses thereto, it is hereby **ORDERED**:

1.) Defendant Carolina Laboratories' Motion to Dismiss is **GRANTED**. All defective design claims against Carolina Laboratories are preempted and dismissed for the reasons set forth in the preceding opinion.

Appendix B

Opinion of the United States District Court for the District of Grace

Cooks v. Carolina Laboratories, Inc., No. 09-1032, (U.S. 13th Cir. 2009) (unpublished)

and

Writ of Certiorari

UNITED STATES COURT OF APPEALS
FOR THE THIRTEENTH CIRCUIT

Dan Cooks, *et al.*,

Appellants

-V-

Carolina Laboratories, Inc.,

Appellee

No. 09-1032

August 6, 2009, Decided

Before MUSTARD, PEACOCK, and PLUM, Circuit Judges

PLUM, *Circuit Judge*

Plaintiffs-Appellants appeal from the district court's decision dismissing their claims for design defect against the Defendant-Appellee.

For the following reasons, we **AFFIRM**.

I. Introduction

Appellants Dan and LoEtta Cooks, individually and on behalf of their minor daughter, brought suit against Appellee Carolina Laboratories, a vaccine manufacturer, alleging that their daughter suffered neurological damage caused by a vaccine made with the preservative thimerosal, which contained the toxic substance mercury. Appellants' claims under Grace law included strict liability and negligence. They alleged Defendant failed to conduct adequate tests to determine whether thimerosal was safe and that a safer alternative existed.

The district court granted Defendant's motion to dismiss, ruling that Appellants' design defect claims were preempted by the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"), 42 U.S.C. § 300aa-1 *et seq*. Appellants filed a timely notice of appeal.

II. Jurisdiction

This Court has jurisdiction of Appellants' appeal pursuant to 28 U.S.C. § 1291, as the district court's order granting the Defendant's motion to dismiss is an appealable final decision.

III. Standard of Review

We review *de novo* the district court's order granting a motion to

dismiss for failure to state a claim under Rule 12(b)(6). *E.g.*, *Morrison v. Marsh & McLennan Cos.*, 439 F.3d 295 (6th Cir. 2006). We may affirm dismissal on any basis supported by the Rule 12(b)(6) record. *E.g.*, *Torch Liquidating Trust v. Stockstill*, 561 F.3d 377, 384 (5th Cir. 2009).

A motion to dismiss pursuant to Rule 12(b)(6) operates to test the sufficiency of the complaint. The first step in testing the sufficiency of the complaint is to identify any conclusory allegations. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* at 1949 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "[A] plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (citations and quotation marks omitted). Although the court must accept well-pleaded factual allegations of the complaint as true for purposes of a motion to dismiss, the court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Id.*

After assuming the veracity of all well-pleaded factual allegations, the second step is for the court to determine whether the complaint pleads "a claim to relief that is plausible on its face." *Iqbal*, 129 S. Ct. at 1949, 1950 (citing *Twombly*, 550 U.S. at 556, 570 (rejecting the traditional 12(b)(6) standard set forth in *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957))). A claim is facially plausible when the plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S. Ct. at 1949 (citing *Twombly*, 550 U.S. at 556). The standard for plausibility is not akin to a "probability requirement," but it requires "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 129 S. Ct. at 1949 (citing *Twombly*, 550 U.S. at 556).

IV. Discussion

Appellee contends that the allegations against it are insufficiently pled. Therefore, it is necessary to determine (1) whether it is legally possible to assert design defect claims under the Vaccine Act and (2) given the relevant legal standards, whether Appellants' show a possible cause of action.

A. National Childhood Vaccine Injury Act of 1986

The district court erred in holding that 42 U.S.C. § 300aa-22(b)(1) preempts all claims that a vaccine was defectively designed.

Congress modeled subsection (b)(1) after comment k to § 402A of the Restatement (Second) of Torts. Comment k has been interpreted in a variety of ways and there is a wide range of disagreement regarding its application. *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 835 (Neb. 2000). Most of the states that have adopted comment k have applied it in a more limited fashion and on a case-by-case basis. *See, e.g.*, *Bryant v. Hoffman-La Roche, Inc.*, 585 S.E.2d 723, 726 (Ga. Ct. App. 2003); *Tansy v. Dacomed*

Corp., 890 P.2d 881, 886, n.2 (Okla. 1994).

The text of subsection (b)(1) is most consistent with the majority understanding of comment k. Under that subsection, a vaccine manufacturer is not civilly liable "if the [vaccine-related] injury or death resulted from side effects that were unavoidable...." The conditional nature of this clause contemplates the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable.

This construction of 42 U.S.C. § 300aa-22(b)(1) is bolstered by the 1986 committee report that states:

> The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding "unavoidably unsafe" products, i.e., those products which in the present sense of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.

H.R. Rep. 99-908, at 26, as reprinted in 1986 U.S.C.C.A.N. 6344, 6367. As acknowledged in *Militrano v. Lederle Laboratories*, this wording "appears to leave open the possibility of a design defect claim with respect [to] vaccines covered by the Vaccine Act...." 810 N.Y.S.2d 506, 508 (N.Y. App. Div. 2006). Further, the committee report does not use language which indicates that use of the compensatory system is mandatory. The report provides that "[v]accine-injured persons will now have an appealing alternative to the tort system." H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367. Accordingly, Congress defended the new compensation system by assuming that it would attract even vaccine-injured persons who may be able to prove that the vaccine was not made as safe as reasonably possible.

This analysis is consistent with the structure and purpose of the Vaccine Act as a whole. Having thoroughly examined both the text of 42 U.S.C. § 300aa-22(b)(1) and the congressional intent behind that subsection and the entire Act, we hold that subsection (b)(1) clearly does not preempt all design defect claims against vaccine manufacturers, but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe.

The district court erred when it concluded that § 22(b)(1) protects vaccine manufacturers from all suits. Although the Act provides for limited no-fault compensation, the district court's construction of subsection (b)(1) would have the perverse effect of granting complete tort immunity from design defect liability to an entire industry. In the absence of any clear and manifest congressional purpose to achieve that result, we must reject such a far-reaching interpretation of the Vaccine Act.

B. Adequacy of the Pleadings

Having determined that the Vaccine Act does not preempt all design defect claims against vaccine manufacturers, it remains to determine whether Appellants' allegations are sufficient to satisfy the necessary pleading standard.

The district court erred in holding that Appellants' design defect claims have been sufficiently pled. Initially, it should be noted that the district court's reliance on *Iqbal v. Hasty*, 490 F.3d 143, 155-58 (2d Cir. 2007), *rev'd*, *Iqbal*, 129 S. Ct. at 1954, was misguided. Although some predicted earlier than others that the enhanced pleading requirements established in *Twombly* would apply to pleading in all actions, with its recent decision in *Iqbal*, the Supreme Court has removed all doubt.

In *Bell Atlantic Corporation v. Twombly*, the Supreme Court clarified the 12(b)(6) standard. Specifically, the Court "retired" the language contained in *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 which would entitle him to relief." *Twombly*, 550 U.S. at 561 (quoting *Conley*, 355 U.S. at 45-46). Instead, the factual allegations set forth in a complaint "must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. This "does not impose a probability requirement at the pleading stage," but instead "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of" the necessary element. *Id.* at 556.

In *Ashcroft v. Iqbal*, the Supreme Court affirmed that *Twombly* standards apply to all motions to dismiss. 129 S. Ct. at 1949. Two working principles underlie the Court's decision in *Twombly*. *Id.* First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. *Twombly*, 550 U.S. at 555. Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. *Id.* at 556. Determining whether a complaint states a plausible claim for relief requires the reviewing court to draw on its judicial experience and common sense. *Iqbal*, 129 S. Ct. at 1950.

Applying the sufficiency standard set forth in *Twombly* and affirmed in *Iqbal*, Appellants' claims for design defect against Appellee must be dismissed pursuant to Rule 12(b)(6). Appellants' Complaint does nothing more than provide a formulaic recitation of the elements of a design defect claim. Significantly, Appellants' Complaint alleges nothing more than conclusions of law[8] and fails to state any scientifically

[8] For example:

> The vaccine product injected into [Minor Name] was unreasonably and dangerously defective because it contained dangerous levels of ethyl mercury, a substance known to the defendants to have neurotoxic properties.
>
> Defendants failed to conduct adequate safety

reliable evidence to support their allegations that Appellee failed to conduct adequate tests to determine whether thimerosal was safe and that a safer alternative existed.

Civil Rule of Procedure 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions. *Iqbal*, 129 S. Ct. at 1950. After *Iqbal*, we expect that tort complaints would become more fact-inclusive and less rhetoric.

Because they have not alleged any facts that would permit the Court to conclude that there was a defect in the design of the vaccine in question and that the defect was the proximate cause of Estella Marie's alleged injuries, Appellants' claims for design defect must be dismissed.

V. Conclusion

For the foregoing reasons, we **AFFIRM** the district court's dismissal of the case.

---

tests to determine whether thimerosal was safe and nontoxic to humans in the doses administered to pregnant women, 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.

The unreasonably dangerous and defective products described were a substantial contributing cause of plaintiff's neurodevelopmental injuries.

THE SUPREME COURT OF
THE UNITED STATES

Dan Cooks, *et al.*,

Petitioners,

-V-

Carolina Laboratories, Inc.,

Respondent

No. 10-1524

This petition for writ of certiorari to the United States Court of Appeals for the Thirteenth Circuit is hereby granted that this Court may hear and consider the following issues:

1. Does the National Childhood Vaccine Injury Act of 1986 preempt state product liability suits for design defects?

2. Did the appellate court properly apply the *Twombly* pleading rules when it granted Respondent's motion to dismiss pursuant to Civil Rule of Procedure 12(b)(6)?

Appendix C

Relevant Provisions of the National Childhood Vaccine Injury Act 1986

LEXSTAT 42 USC 300AA-1

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*** CURRENT THROUGH PL 111-144, APPROVED 3/2/2010 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
NATIONAL VACCINE PROGRAM

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42 USCS ß 300aa-1

ß 300aa-1. Establishment

The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

LEXSTAT 42 U.S.C. 300AA-22

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*** CURRENT THROUGH PL 111-144, APPROVED 3/2/2010 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
NATIONAL VACCINE INJURY COMPENSATION PROGRAM
ADDITIONAL REMEDIES

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42 USCS ß 300aa-22

ß 300aa-22. Standards of responsibility

(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 ßß 301* et seq.] and *section 351* of the Public Health Service Act [*42 USCS ß 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 ß 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 ßß 300aa-10* et seq.].

LEXSTAT 42 U.S.C. 300AA-23

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TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
NATIONAL VACCINE INJURY COMPENSATION PROGRAM
ADDITIONAL REMEDIES

Go to the United States Code Service Archive Directory

42 USCS ß 300aa-23

ß 300aa-23. Trial

(a) General rule. A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part [effective Oct. 1, 1988] which is not barred by section 2111(a)(2) [*42 USCS ß 300aa-11(a)(2)*] shall be tried in three stages.

(b) Liability. The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 2122 [*42 USCS ß 300aa-22*].

(c) General damages. The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 2122 [*42 USCS ß 300aa-22*] shall be required to pay.

(d) Punitive damages.
(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 2122 [*42 USCS ß 300aa-22*] shall be required to pay.
(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in--

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 351 [*42 USCS ß 262*],

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence. In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Claims Court [United States Court of Federal Claims] or a special master in a proceeding on a petition filed under section 2111 [*42 USCS ß 300aa-11*] and the final judgment of the United States Claims Court [United States Court of Federal Claims] and subsequent appellate review on such a petition shall not be admissible.

LEXSTAT 42 U.S.C. 300AA-27

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*** CURRENT THROUGH PL 111-144, APPROVED 3/2/2010 ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A. THE PUBLIC HEALTH SERVICE
VACCINES
NATIONAL VACCINE INJURY COMPENSATION PROGRAM
ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

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42 USCS ß 300aa-27

ß 300aa-27. Mandate for safer childhood vaccines

(a) General rule. In the administration of this subtitle [*42 USCS ßß 300aa-10* et seq.] and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall--

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on the effective date of this part [effective Dec. 22, 1987] and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force.

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report. Within 2 years after the effective date of this part [effective Dec. 22, 1987], and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and

Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

Appendix D

Relevant Provisions of the Federal Rules of Civil Procedure

LEXSTAT FED. R. CIV. P. 8

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FEDERAL RULES OF CIVIL PROCEDURE
TITLE III. PLEADINGS AND MOTIONS

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Rule 8. 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.

LEXSTAT USCS FED RULES CIV PROC R 12

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Rule 12. Defenses and Objections: When and How Presented; Motion for Judgment on the Pleadings; Consolidating Motions; Waiving Defenses; Pretrial Hearing

(a) Time to Serve a Responsive Pleading.
(1) *In General.* Unless another time is specified by this rule or a federal statute, the time for serving a responsive pleading is as follows:
(A) A defendant must serve an answer:
(i) within 21 days after being served with the summons and complaint; or
(ii) if it has timely waived service under Rule 4(d), within 60 days after the request for a waiver was sent, or within 90 days after it was sent to the defendant outside any judicial district of the United States.
(B) A party must serve an answer to a counterclaim or crossclaim within 21 days after being served with the pleading that states the counterclaim or crossclaim.
(C) A party must serve a reply to an answer within 21 days after being served with an order to reply, unless the order specifies a different time.
(2) *United States and Its Agencies, Officers, or Employees Sued in an Official Capacity.* The United States, a United States agency, or a United States officer or employee sued only in an official capacity must serve an answer to a complaint, counterclaim, or crossclaim within 60 days after service on the United States attorney.
(3) *United States Officers or Employees Sued in an Individual Capacity.* A United States officer or employee sued in an individual capacity for an act or omission occurring in connection with duties performed on the United States' behalf must serve an answer to a complaint,

counterclaim, or crossclaim within 60 days after service on the officer or employee or service on the United States attorney, whichever is later.

(4) *Effect of a Motion.* Unless the court sets a different time, serving a motion under this rule alters these periods as follows:

(A) if the court denies the motion or postpones its disposition until trial, the responsive pleading must be served within 14 days after notice of the court's action; or

(B) if the court grants a motion for a more definite statement, the responsive pleading must be served within 14 days after the more definite statement is served.

(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.

(c) Motion for Judgment on the Pleadings. After the pleadings are closed--but early enough not to delay trial--a party may move for judgment on the pleadings.

(d) Result of Presenting Matters Outside the Pleadings. If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.

(e) Motion for a More Definite Statement. A party may move for a more definite statement of a pleading to which a responsive pleading is allowed but which is so vague or ambiguous that the party cannot reasonably prepare a response. The motion must be made before filing a responsive pleading and must point out the defects complained of and the details desired. If the court orders a more definite statement and the order is not obeyed within 14 days after notice of the order or within the time the court sets, the court may strike the pleading or issue any other appropriate order.

(f) Motion to Strike. The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter. The court may act:

(1) on its own; or
(2) on motion made by a party either before responding to the pleading or, if a response is not allowed, within 21 days after being served with the pleading.

(g) Joining Motions.

(1) *Right to Join.* A motion under this rule may be joined with any other motion allowed by this rule.

(2) *Limitation on Further Motions.* Except as provided in Rule 12(h)(2) or (3), a party that makes a motion under this rule must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion.

(h) Waiving and Preserving Certain Defenses.

(1) *When Some Are Waived.* A party waives any defense listed in Rule 12(b)(2)-(5) by:

(A) omitting it from a motion in the circumstances described in Rule 12(g)(2); or

(B) failing to either:

(i) make it by motion under this rule; or

(ii) include it in a responsive pleading or in an amendment allowed by Rule 15(a)(1) as a matter of course.

(2) *When to Raise Others.* Failure to state a claim upon which relief can be granted, to join a person required by Rule 19(b), or to state a legal defense to a claim may be raised:

(A) in any pleading allowed or ordered under Rule 7(a);

(B) by a motion under Rule 12(c); or

(C) at trial.

(3) *Lack of Subject-Matter Jurisdiction.* If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action.

(i) Hearing Before Trial. If a party so moves, any defense listed in Rule 12(b)(1)-(7)--whether made in a pleading or by motion--and a motion under Rule 12(c) must be heard and decided before trial unless the court orders a deferral until trial.

Appendix E

Gainer v. Mylan Bertek Pharmaceuticals, Inc.
No. 09-690, 2010 U.S. Dist. LEXIS 2018 (D. Minn. Jan. 11, 2010)

LEXSEE 2010 U.S. DIST. LEXIS 2018

Bernice Gainer, Plaintiff, v. Mylan Bertek Pharmaceuticals, Inc.; Mylan Pharmaceuticals, Inc.; Actavis Mid-Atlantic, LLC; Actavis Group; Morton Pharmaceutical, Inc.; Taro Pharmaceuticals, Inc.; Vistapharma, Inc.; Barr Pharmaceuticals, Inc.; Hospira Worldwide, Inc.; and Baxter Healthcare Corporation, Defendants.

Civil No. 09-690 (JNE/JSM)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA

2010 U.S. Dist. LEXIS 2018

January 11, 2010, Decided
January 11, 2010, Filed

COUNSEL: [*1] For Bernice Gainer, Plaintiff: Amy Lynn Ewald, LEAD ATTORNEY, Victoria, MN; W Lewis Garrison, Jr, PRO HAC VICE, Heninger Garrison & Davis LLC, Birmingham, AL; William L Bross, PRO HAC VICE, Heninger Garrison Davis, LLC, Birmingham, AL.

For Mylan Bertek Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., Defendants: John J Wackman, LEAD ATTORNEY, Halleland Lewis Nilan & Johnson, PA, Mpls, MN; Clem C Trischler, PRO HAC VICE, Pietragallo Gordon Alfano Bosick & Raspanti, Pittsburgh, PA.

JUDGES: JOAN N. ERICKSEN, United States District Judge.

OPINION BY: JOAN N. ERICKSEN

OPINION

ORDER

Plaintiff Bernice Gainer brought this federal diversity action on March 25, 2009. The Complaint named numerous pharmaceutical companies, including Mylan Bertek Pharmaceuticals, Inc., and Mylan Pharmaceuticals, Inc. (collectively, Mylan). Mylan was served on July 20, 2009. [1] Mylan filed a Motion to Dismiss shortly thereafter. Plaintiff filed no memorandum opposing Mylan's motion, but two days before the scheduled hearing on the motion, "[o]ut of an abundance of caution," Plaintiff moved to continue the hearing because of "circumstances which prevent[ed] either of Plaintiff's Counsel from appearing at [the] [h]earing." In light of Plaintiff's [*2] failure to respond to Mylan's motion, the Court treated the matter as submitted without oral argument, cancelled the hearing, and denied Plaintiff's motion as moot. The Court now considers the merits of Mylan's motion.

1 No other Defendant has been served.

I. BACKGROUND

Mylan manufactures, packages, markets, distributes, promotes, and sells the generic equivalent of the prescription drug Dilantin, which contains the active ingredient Phenytoin.

[2] While living in Ohio in 2002, Plaintiff was prescribed Phenytoin to treat seizures. Plaintiff was diagnosed with Stevens Johnson Syndrome (SJS) in March 2003. After continued use of Phenytoin, Plaintiff was again diagnosed with SJS in addition to Toxic Epidermal Necrolysis (TEN) in June 2004. These conditions required lengthy and painful treatment, including a skin graft, and left Plaintiff with permanent hair loss, dry skin, and scarring. Plaintiff alleges that Phenytoin caused her SJS and TEN. Plaintiff's Complaint asserts claims for failure to warn, defective design or manufacture, fraud, breach of implied warranty, breach of express warranty, negligence, and gross negligence. Plaintiff seeks compensatory and punitive damages. Mylan maintains [*3] that Plaintiff's Complaint fails to state a claim.

2 The Court uses Phenytoin to denote Dilantin and its generic equivalents.

II. DISCUSSION

When ruling on a motion to dismiss for failure to state a claim pursuant to *Rule 12(b)(6) of the Federal Rules of Civil Procedure*, a court must accept the facts alleged in the complaint as true and grant all reasonable inferences in favor of the plaintiff. *Crooks v. Lynch, 557 F.3d 846, 848 (8th Cir. 2009)*. Although a complaint is not required to contain detailed factual allegations, "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009)* (quoting *Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007))*. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly, 550 U.S. at 570*). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

Under Ohio law, [3] "all common law product [*4] liability claims or causes of action" accruing after April 7, 2005, are abrogated by *Ohio Revised Code ßß 2307.71-.80* (2009). *See Doty v. Fellhauer Elec., Inc., 175 Ohio App. 3d 681, 2008 Ohio 1294, 888 N.E.2d 1138, 1142 (Ohio Ct. App. 2008)* (holding claims accruing before April 7, 2005, not abrogated even if action commenced after that date). A claim for bodily injury caused by "ethical drugs" [4] accrues when "the plaintiff is informed by competent medical authority" that a relationship exists between an injury suffered by the plaintiff and the drugs, or when the plaintiff should have known of such a relationship through the exercise of reasonable diligence. *Ohio Rev. Code ß 2305.10(B)(1)* (2009).

3 Mylan argues that Ohio law applies to Plaintiff's claims. Plaintiff has waived any argument to the contrary by not responding to Mylan's motion. *Cf. P & O Nedlloyd, Ltd. v. Sanderson Farms, Inc., 462 F.3d 1015, 1017 n.3 (8th Cir. 2006)* ("[C]hoice of law is waived if not timely raised."). Nevertheless, even under a traditional choice-of-law analysis, Ohio law would apply because all of the relevant conduct occurred in Ohio and the only connection this litigation has to Minnesota is Mylan's general sale of its products in the state. [*5] *See Nesladek v. Ford Motor Co., 46 F.3d 734, 738-41 (8th Cir. 1995)* (identifying Minnesota's choice-of-law analysis and refusing to apply Minnesota law largely due to a lack of meaningful contacts with the state); *Schmelzle v. ALZA Corp., 561 F. Supp. 2d 1046, 1048-50 (D. Minn. 2008)* (same).

4 "'Ethical drug' means a prescription drug that is prescribed or dispensed by a physician or any other person who is

> legally authorized to prescribe or dispense a prescription drug." *Ohio Rev. Code ßß 2305.10(F)(2)*, *2307.71(A)(4)*.

In this case, all of Plaintiff's claims are common law product liability claims. [5] *See, e.g., McAuliffe v. W. States. Imp. Co., 72 Ohio St. 3d 534, 1995 Ohio 201, 651 N.E.2d 957, 961 (Ohio 1995)* (gathering cases recognizing common law product liability claims for defective manufacture, defective design, inadequate warning, and failure to conform to representation); *Freas v. Prater Constr. Corp., 60 Ohio St. 3d 6, 573 N.E.2d 27, 30 (Ohio 1991)* (identifying elements for product liability claim based upon negligence); *Lonzrick v. Republic Steel Corp., 6 Ohio St. 2d 227, 218 N.E.2d 185, 192-94 (Ohio 1966)* (recognizing breach of implied warranty claim in product liability context); *Rogers v. Toni Home Permanent Co., 167 Ohio St. 244, 147 N.E.2d 612, 615-16 (Ohio 1958)* [*6] (recognizing breach of express warranty claim in product liability context); *Saylor v. Providence Hosp., 113 Ohio App. 3d 1, 680 N.E.2d 193, 195-96 (Ohio Ct. App. 1996)* (dismissing "products liability claim for misrepresentation" because of failure to allege any misrepresentations). Thus, these claims are valid only if they accrued before April 7, 2005. The Complaint, however, contains no allegations related to when Plaintiff was told of or should have been aware of a relationship between SJS, TEN, and Phenytoin. Therefore, because the Complaint does not contain sufficient factual detail to permit a reasonable inference that the alleged claims accrued before April 7, 2005, dismissal of Plaintiff's claims against Mylan is warranted. This dismissal is without prejudice, and Plaintiff is granted leave to file an amended complaint to assert cognizable claims under Ohio law. [6] The Court does not address Mylan's other arguments.

> 5 Mylan argues only that the fraud, breach of warranty, and negligence claims are common law product liability claims. Plaintiff, however, has alleged no statutory basis for her failure to warn and defective design or manufacture claims, and the Court treats those claims as common law [*7] product liability claims.
>
> 6 If Plaintiff chooses to file an amended complaint, the Court admonishes her counsel that the dilatoriness with which this matter has been prosecuted thus far will not be tolerated. Full knowledge of and obedience to this District's Local Rules is expected. The failure to meet such requirements will be cause for dismissal of this action.

III. CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

> 1. Mylan's Motion to Dismiss [Docket No. 3] is GRANTED.
>
> 2. Plaintiff's claims against Mylan are DISMISSED WITHOUT PREJUDICE.
>
> 3. Plaintiff is granted leave to file an amended complaint on or before February 10, 2010.
>
> 4. Pursuant to *Rule 4(m) of the Federal Rules of Civil Procedure*, the Court notifies Plaintiff that it will dismiss this action without prejudice as to all remaining Defendants unless Plaintiff effects proper service on those Defendants no later than February 17, 2010.

Dated: January 11, 2010

/s/ Joan N. Ericksen

JOAN N. ERICKSEN

United States District Judge

Appendix F

Ivory v. Pfizer, Inc.
No. 09-0072, 2009 U.S. Dist. LEXIS 90735 (D. La. Sept. 30, 2009)

LEXSEE 2009 U.S. DIST. LEXIS 90735

JIMMIE IVORY and JAMES IVORY VERSUS PFIZER INC.

CIVIL ACTION NO. 09-0072

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF LOUISIANA, SHREVEPORT DIVISION

2009 U.S. Dist. LEXIS 90735*; *CCH Prod. Liab. Rep. P18,316

September 30, 2009, Decided
September 30, 2009, Filed

SUBSEQUENT HISTORY: Transferred by *In re Chantix Prods. Liab. Litig., 655 F. Supp. 2d 1346, 2009 U.S. Dist. LEXIS 92169 (J.P.M.L., Oct. 1, 2009)*

PRIOR HISTORY: *Brennon v. Pfizer, Inc., 2009 U.S. Dist. LEXIS 72511 (W.D. La., Aug. 16, 2009)*

COUNSEL: [*1] For Jimmie Ivory, James Ivory, Plaintiffs: Kevin D Alexander, LEAD ATTORNEY, Guerriero & Guerriero, Monroe, LA; Philip Bohrer, Bohrer Law Firm, Baton Rouge, LA; Ramon Rossi Lopez, PRO HAC VICE, Lopez McHugh, Newport Beach, CA.

For Pfizer Inc, Defendant: John W Sinnott, Quentin F Urquhart, Jr, Irwin Fritchie et al, New Orleans, LA.

JUDGES: S. MAURICE HICKS, JR., UNITED STATES DISTRICT JUDGE. MAGISTRATE JUDGE HORNSBY.

OPINION BY: S. MAURICE HICKS, JR.

OPINION

MEMORANDUM RULING

Before the Court is a Motion to Dismiss Pursuant to *Federal Rule of Civil Procedure 12(b)(6)* [Record Document 7], filed on behalf of Defendant, Pfizer Inc. Defendant seeks dismissal of Counts I-V and VII of the Complaint and James Ivory's request for damages. Plaintiffs oppose this motion. For the reasons stated herein, Defendant's Motion to Dismiss is **GRANTED in part** and **DENIED IN PART**.

FACTUAL BACKGROUND

This case involves the prescription medication Chantix, a smoking-cessation aid, made by Defendant Pfizer Inc. ("Pfizer"). Plaintiff Jimmie Ivory ("Mrs. Ivory") began using Chantix in December 2007 for its indicated use, to stop smoking. Mrs. Ivory alleges that unbeknownst to her, her prescribing physicians, or the medical community in general, [*2] Chantix presented a definite risk of serious injury and death, including suicide. She asserts seven causes of action based on injuries purportedly associated with her use of Chantix: Construction or Composition Defect (Count I); Design Defect (Count II); Inadequate Warning (Count III); Breach of Express

Warranty (Count IV); Breach of Implied Warranty (Count V); Redhibition (Count VI); and a "Punitive Damage Claim" (Count VII). [Doc. 1, Petition]. Additionally, although her husband, James Ivory ("Mr. Ivory"), did not ingest Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 2 of 16 Chantix or plead any independent causes of action, he seeks damages on his own behalf for loss of consortium and negligent infliction of emotional distress. Id.

With the exception of Plaintiffs' redhibition claim, Defendant contends Plaintiffs' causes of action fail as a matter of law and seeks dismissal of Counts I-V and VII of Plaintiffs' Complaint, including Mr. Ivory's request for damages, pursuant to *Federal Rule of Civil Procedure 12(b)(6)*. [Docs. 7, 9]. Defendant argues that Mrs. Ivory's composition defect, design defect, failure to warn, and express warranty claims, as well as Mr. Ivory's [*3] claim for damages, all fail to satisfy the basic pleading standard set forth in *Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)*. Additionally, with respect to the design defect and failure to warn claims, Defendant contends Mrs. Ivory (i) failed to plead the existence of an alternative design, and (ii) improperly pled that Pfizer owed a duty to warn consumers generally, notwithstanding that under Louisiana's "learned intermediary" doctrine such a duty to warn runs only to Mrs. Ivory's prescribing physician. As for Mrs. Ivory's breach of implied warranty and punitive damages claim, Defendant asserts that these claims are neither recognized nor permitted under Louisiana law under the circumstances presented in this case. [Docs. 7, 9].

LAW AND ANALYSIS

1. Motion to Dismiss Standard

Federal Rule of Civil Procedure 12(b)(6) allows for dismissal of an action "for failure to state a claim upon which relief can be granted." While a complaint attached by a *Rule 12(b)(6)* motion does not need detailed factual allegations, in order to avoid dismissal, the plaintiff's factual allegations "must be enough to raise a right to relief above the speculative Case 5:09-cv-00072-SMH-MLH Document 19 Filed [*4] 09/30/2009 Page 3 of 16 level." *Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 127 S.Ct. 1955, 1964-65, 167 L.Ed.2d 929 (2007)*; see also, *Cuvillier v. Sullivan, 503 F.3d 397, 401 (5th Cir. 2007)*. A plaintiff's obligation "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. The Supreme Court recently expounded on the Twombly standard, explaining that a complaint must contain sufficient factual matter to state a claim to relief that is plausible on its face. *Ashcroft v. Iqbal, -- U.S. --, 129 S.Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009)*. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id.

It is well-established that the Court must construe the complaint in the light most favorable to the plaintiff and accept all well-pleaded factual allegations as true. *Id., 129 S.Ct. at 1949-50*; *In re Katrina Canal Breaches Litig., 495 F.3d 191, 205 (5th Cir. 2007)*. The tenet that a court must accept all allegations contained in a complaint as true, however, is applicable only to *factual* allegations and does not [*5] apply to legal conclusions. *Id., 129 S.Ct. at 1949*. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. "*Rule 8* marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than more conclusions." Id. While legal conclusions may provide the framework for a complaint, they must be supported by factual allegations demonstrating the plausibility of

plaintiff's "entitlement to relief." Id. Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 4 of 16

2. Construction Defect, Design Defect, Inadequate Warning (Counts I, II, III)

Defendant seeks dismissal of Counts I, II, and III on the ground that Plaintiffs merely restated the statutory language of the Louisiana Products Liability Act ("LPLA"), *La. R.S. ß 9:2800.51 et seq*., untethered from any meaningful, underlying factual allegations. [Doc. 9, pp. 2-3]. A review of Plaintiff's petition reveals that each count, when read alone, is simply a formulaic recitation of the elements from the LPLA. See Petition, PP 110-42 . However, Counts I, II, [*6] and III must be read in context with the entire petition, including the one hundred and four factual averments immediately preceding Counts I-VII. Id.

A. Construction Defect (Count I)

To prevail on a construction or composition defect claim under Louisiana law, a plaintiff must show that: (1) the defendant is a manufacturer of the product; (2) the product proximately caused the plaintiff's damage; (3) the damaging characteristic of the product rendered it "unreasonably dangerous in construction or composition "; and (4) the plaintiff's damages arose from a reasonably anticipated use of the product. See *Rollins v. St. Jude Med., Daig Div., Inc., 583 F. Supp. 2d 790, 800 (W.D.La. 2008)* (citing *Gomez v. St. Jude Med. Daig Div., Inc., 442 F.3d 919, 932 (5th Cir. 2006))*. "A product is unreasonably dangerous in construction or composition if, at the time the product left its manufacturer's control, the product deviated in a material way from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer." *La. R.S. ß 9:2800.55*.

Mrs. Ivory alleges numerous facts in her petition in support of her claim that Chantix is unreasonably [*7] dangerous in construction or composition, including the following: (1) Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 5 of 16 Chantix, indicated for use as an aid to quit smoking, is designed to work by specifically inhibiting nicotine receptors in the human brain [Petition, PP 17, 20]; (2) in theory, Chantix is supposed to work by blocking dopamine so that the cravings for nicotine are diminished and the psychological pleasure derived from smoking is reduced [P 28]; (3) Defendant failed to adequately study the mechanism of action and the effects thereof [P 30]; (4) Defendant failed to adequately study Chantix to determine the risk of serious injury and/or death associated with its use, as evidenced by Defendant's exclusion of certain patients from clinical trials and intentionally ignoring any proper evaluation of depression or suicidal thoughts [PP 31-32]; (5) Defendant knew or should have known that Chantix increases the risk of causing serious injuries and/or death, including suicide, based on (i) medical reports documented as early as 1972 linking cytosine (the active ingredient in Chantix) to cases of suicide and attempted suicide [PP 36-37], (ii) the numerous adverse [*8] event reports from the FDA concerning suicide and attempted suicide after patients initiated Chantix treatment [PP 38-43], (iii) regulatory action and reviews from the FDA indicating increased risk of depression, agitation, suicidal ideation and suicidal behavior [PP 44-47], (iv) known risks associated with other drugs with similar mechanisms of action [P 48], (v) results of clinical trials demonstrating the increased risk of serious injury and/or death [PP 49-52], and (vi) data indicating the efficacy of Chantix is no better than a placebo or the nicotine patch [PP 53-57]. Additionally, Ms. Ivory avers that she was prescribed Chantix for its intended use, that she used Chantix in a proper and reasonably foreseeable manner, that Chantix

caused her to suffer past, present, and future damages, including suicidal thoughts and behavior, and that she would not have used Chantix had she been aware of the risks associated with or caused by Chantix. [PP 6-16]. Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 6 of 16

The Count finds that these factual averments are more than sufficient "to raise a right to relief above the speculative level" for an alleged construction or composition [*9] defect. See *Twombly, 550 U.S. at 555, 127 S.Ct. at 1964-65*. Accordingly, Defendant's motion to dismiss Count I is DENIED.

B. Design Defect (Count II)

To establish a design defect under the LPLA, a plaintiff must show that at the time the product left the manufacturer's control, (1) "[t]here existed an alternative design for the product that was capable of preventing the claimant's damage," and (2) "[t]he likelihood that the products design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product." *La. R.S. ß 9:2800.56*. However, plaintiffs' petition, read in its entirety, is completely devoid of *any* reference to an alternative design. Plaintiffs fail to even allege that an alternative design existed, much less that any such design would have reduced the adverse effects or that the burden of adopting such design was less than the likelihood and gravity of damages associated with Chantix as designed. Therefore, in the absence of any allegation regarding a required element necessary to obtain relief, Defendant's motion [*10] to dismiss Count II is GRANTED. See *Rios v. City of Del Rio, Tex., 444 F.3d 417, 420-21 (5th Cir. 2006)* ("the complaint must contain either direct allegations on every material point necessary to sustain a recovery...or contain allegations from which an inference fairly may be drawn that evidence on these material points will be introduced at trial") (quoting 3 Wright & Miller, Fed. Prac. & Proc.: Civil 2d ß 1216 at 156-59); see also, *Guidry v. Aventis Pharms., Inc., 418 F. Supp. 2d 835, 842 (M.D.La. 2006)* (recognizing that an "alternative Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 7 of 16 design" capable of preventing the plaintiff's damage is an "essential element" of a design defect claim under *La. R.S. ß 9:2800.56*); *Green v. BDI Pharms., 803 So. 2d 68, 72 (La.App. 2 Cir. 2001)* (same).

C. Inadequate Warning (Count III)

To maintain a failure to warn or inadequate warning claim under the LPLA, a plaintiff must prove that, at the time the product left the manufacturer's control, "the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its dangers to users and [*11] handlers of the product." *Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 261 (5th Cir. 2002)* (quoting *La. R.S. ß 9:2800.57*). Plaintiffs' inadequate warning claim arises, in part, from the alleged lack of inadequate information on the label and package insert for Chantix concerning the risk for serious injury and/or death. [Petition, P 67]. Specifically, Plaintiffs state that *21 C.F.R. ß 201.57* requires the following information on every drug label:

> 1) *Contraindications*: "Under this section heading, the labeling shall describe those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. These situations include administration of the drug to patients known to have a hypersensitivity to it . . ." *21 C.F.R. ß 201.57(d)*

> 2) *Warnings*: "Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. . . ." *21 C.F.R. ß 201.57(e)* [*12] Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 8 of 16
>
> 3) *Precautions*: "This subsection of the labeling shall contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug." *21 C.F.R. ß 201.80(f)(1)*
>
> 4) *Adverse Reactions*: "An adverse reaction is an undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." *21 C.F.R. ß 201.57(g)*. For clarification the section further reads: "*The 'Warnings' section of the labeling or, if appropriate, the 'Contraindications' section of the labeling shall identify any potentially fatal adverse reaction*." Id. (emphasis supplied).

[P 70].

Plaintiffs further aver that:

> The information contained in the product label and package insert is insufficient for many reasons, including but not limited to the following: a) the label fails to explicitly warn of increased risk for serious injury and/or death; and, b) the label fails to reference the severity of such serious injuries; and/or c) the label fails to provide adequate information advising consumers of appropriate action if [*13] certain adverse events are experienced.

[P 73].

Based on these allegations, the Court can reasonably infer that Defendant failed to provide an adequate warning of the dangers associated with the use of Chantix. See *Ashcroft v. Iqbal, -- U.S. --, 129 S.Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009)* ("A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.").

Defendant contends Count III should nevertheless be dismissed to the extent Plaintiffs contend Pfizer had a duty to warn anyone other than Mrs. Ivory's prescribing physician. [Doc. 9, p.10]. Louisiana applies the "learned intermediary doctrine" to product Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 9 of 16 liability claims involving prescription drugs. Under this doctrine, a drug manufacturer discharges its duty to consumers by *reasonably* informing prescribing physicians of the dangers of harm from a drug. *Stahl, 283 F.3d at 265*. Plaintiffs allege, however, that Defendant failed to "advise instruct or warn plaintiff *or* prescribing *or* administering physicians" of Chantix's risk of harm and adverse effect, and failed [*14] to "adequately warn prescribing doctors *and*

users." [Petition, PP 91, 117]. Therefore, because Plaintiffs pleaded the requisite factual allegations to state a claim for inadequate warning under *La. R.S. ß 9:2800.57*, Defendant's argument based on the "learned intermediary doctrine" is premature at this stage of the proceedings. Accordingly, Defendant's motion to dismiss Count III is DENIED.

3. Breach of Express Warranty (Count IV)

In addition to the theories of liability discussed above, the LPLA imposes liability on a manufacturer when a product "does not conform to an express warranty made at any time by the manufacturer about the product if the express warranty has induced the claimant or another person or entity to use the product and the claimant's damage was proximately caused because the express warranty was untrue." *La. R.S. ß 9:2800.58*. In the petition, Plaintiffs allege that Defendant represented to consumers and the medical community that Chantix was "safe, efficacious, and fit for its intended purposes, that it was of merchantable quality, that it did not produce any unwarned-of dangerous side effects, and that it was adequately tested." [Petition, P 120]. Defendant allegedly [*15] made such representations "through its labeling, advertising, marketing materials, detail persons, Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 10 of 16 seminar representations, publications, notice letters, and regulatory submissions," and fraudulently concealed information about the safety and efficacy of the drug. [P 121].

Defendant contends Count VI should be dismissed because Plaintiffs failed to state the "explicit words" that purportedly create the express warranty made by Defendant. [Doc. 9, pp. 4-5]. But the Court does not believe that Twombly requires the plaintiff to set forth such precise, detailed allegations. See *Twombly, 550 U.S. at 555, 127 S.Ct. at 1964-65*. Plaintiffs' factual allegations concerning Defendant's alleged breach of express warranty are more than enough at the pleading stage "to raise a right to relief above the speculative level." Accordingly, Defendant's motion to dismiss Count IV is DENIED.

4. Mr. Ivory's Damages

At the conclusion of Plaintiffs' petition, Mr. Ivory seeks damages for "loss of consortium" and as a person "within the zone of danger and a participant" in Mrs. Ivory's suicide attempt. [Petition, PP 145-46]. Defendant contends [*16] Mr. Ivory failed to "identify any meaningful basis for the damages sought," and that the claims "are untethered from any factual allegations, and rely only on terse legal conclusions." [Doc. 9, pp.6-7].

A. Loss of Consortium

It is well-settled that Louisiana law recognizes a cause of action for loss of consortium. *Ferrell v. Fireman's Fund Ins. Co., 696 So.2d 569, 573 (La. 1997)*; see also, *De Atley v. Victoria's Secret Catalogue, LLC, 876 So.2d 112, 116 n.2 (La.App. 4 Cir. 2004)* ("Damages recoverable under the LPLA include pain and suffering, medical expenses, damage to property, other than to the product itself, and loss of consortium, to name a few.") (citing *John Kennedy, A Primer on the Louisiana Products Liability Act, 49 La.L.Rev 565*. Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 11 of 16 565, 579-80 (1989)). A loss of consortium claim is "derivative" of the predicate tort claim; in other words, it is a "secondary layer of tort liability inuring to the benefit of a person whose relationship with the primary tort victim has been diminished as a result of the defendant's negligence." *Scott v. Istar Real Estate Servs., Inc., 2005 U.S. Dist. LEXIS 1676, 2005 WL 287151, *2 (E.D.La. Feb. 3, 2005)* (citing [*17] *Ferrell, 696 So.2d at 574*). The compensable elements of a spouse's loss of

consortium claim include (1) loss of love and affection; (2) loss of companionship; (3) loss of material services; (4) loss of support; (5) impairment of sexual relations; and (6) loss of felicity. *Id.* (citing *Ferrell, 696 So.2d at 573 n.4*).

In the petition, Plaintiffs allege that as a result of consuming Chantix, Mrs. Ivory suffered from depression, aggressive behavior, erratic behavior, mood swings, panic attacks, and that on December 21, 2007, Mrs. Ivory attempted suicide by exiting a moving vehicle operated by Mr. Ivory. [Petition, P 15]. Mr. Ivory further avers that, at all times pertinent hereto, he was married to and living with Mrs. Ivory and, as such, "suffered damages, past, present and future, for loss of consortium." [P 145]. Taking the factual allegations relating to Mrs. Ivory's injuries as true, and recognizing that Mr. Ivory's claim derives from his wife's injuries, the Court finds Mr. Ivory's allegations sufficient to state a claim for damages for loss of consortium. Accordingly, Defendant's motion to dismiss Mr. Ivory's allegations for loss of consortium is DENIED.

B. Negligent Infliction of [*18] **Emotional Distress**

Mr. Ivory alleges he "was in the zone of danger and a participant in the event" and is therefore entitled to all damages by law. [P 146]. Construing the petition liberally and in the light most favorable to Plaintiffs, the Court will construe Mr. Ivory's allegations as a request for damages for negligent infliction of emotional distress. Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 12 of 16

Louisiana law allows "persons who view an event causing injury to another person" to recover damages for negligent infliction of emotional distress if (i) the injured person "suffer[s] such harm that one can reasonably expect a person in the claimant's position to suffer serious mental anguish or emotional distress from the experience," and (ii) the claimant's mental anguish or emotional distress is "severe, debilitating, and foreseeable." *La. C.C. art. 2315.6(A)*, *(B)*. "In order to recover, the claimant who observes the injury-causing event...must be contemporaneously aware that the event has caused harm to the direct victim." *Trahan v. McManus, 728 So.2d 1273, 1279 (La. 1999)*. The Louisiana Supreme Court has held, however, that a negligent omission (such as a failure [*19] to adhere to a prescribed duty) is not an injury-causing event by which a claimant is contemporaneously aware that the event caused harm to the direct victim. *Id. at 1280*. In Trahan, the state's highest court refused to allow the claimant to recover bystander damages resulting from a physician's negligent conduct:

> Even [if] the injury-causing event was the doctor's negligent discharge of the patient, that event was not a traumatic event likely to cause severe contemporaneous mental anguish to an observer, even though the ultimate consequences were tragic indeed. There was no observable harm to the direct victim that arose at the time of the negligent failure to treat, and no contemporaneous awareness of harm caused by the negligence. The doctor's negligent discharge of the patient, accompanied by mistaken assurances that the patient would soon recover, was not itself an emotionally shocking event....

Id.

Here, Mr. Ivory does not allege that he witnessed Mrs. Ivory ingest Chantix or that he was aware, at that precise time, that the Chantix caused Mrs. Ivory harm. Rather, Mr. Ivory asserts that Mrs. Ivory's injuries came to light

in the months following the Case 5:09-cv-00072-SMH-MLH Document [*20] 19 Filed 09/30/2009 Page 13 of 16 vaccinations. See e.g., *Maurice v. Eli Lilly & Co., 2005 U.S. Dist. LEXIS 36534, 2005 WL 3542902, *5 (E.D.La. Nov. 7, 2005)* (finding that parents of minor child failed to state a claim for negligent infliction of emotional distress where they did not witness the vaccinations of the minor child and were not aware, at the time of vaccination, that the minor child suffered harm). Accordingly, the Court concludes that the allegations in Plaintiffs' petition are insufficient to state a claim for negligent infliction of emotional distress.

Furthermore, even if the allegations set forth in Plaintiffs' petition were sufficient to state a claim, the LPLA does not allow recovery of damages for negligent intentional of emotional distress. Because the LPLA provides the exclusive remedy for injuries allegedly caused by Defendant, see infra, this claim must be dismissed.

5. Breach of Implied Warranty (Count V)

Defendant contends Mrs. Ivory's claim for breach of implied warranty falls outside the purview of the LPLA and must be dismissed. [Doc. 9, p.11]. The LPLA "establishes the exclusive theories of liability for manufacturers for damages caused by their products," and a plaintiff "may not recover [*21] from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth" in this Act. *La. R.S. ß 9:2800.52*. In *Jefferson v. Lead Ind. Ass'n, Inc., 106 F.3d 1245, 1251 (5th Cir. 1997)*, the Fifth Circuit explained that:

> While the statutory ways of establishing that a product is unreasonably dangerous are predicated on principles of strict liability, negligence or warranty, respectively, neither negligence, strict liability, nor breach of express warranty is any longer viable as an independent theory of recovery against a manufacturer. Further, *breach of implied warranty* or redhibition *is no longer available as a theory of recovery for personal injury*, although a redhibition action is still viable against the manufacturer to recover pecuniary loss.

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Id. (emphasis added) (internal citations omitted).

It is apparent that Plaintiffs' allegations of breach of implied warrant fail to state a claim against Defendant under the LPLA and must be dismissed. Furthermore, to the extent Plaintiffs' contend a claim for breach of implied warranty is a form of redhibition for which Plaintiffs may [*22] recover damages for economic loss, Plaintiffs' breach of implied warranty claim is duplicative of their claim for redhibition (Count VI). See *Dawson Farms, LLC v. BASF Corp., et al., 2008 U.S. Dist. LEXIS 100784, 2008 WL 5220517, *2 (W.D.La. Dec. 12, 2008)* (a claim for breach of implied warranty "arises under the Redhibition chapter and allows recovery for damage to the product itself and economic loss"). Accordingly, Defendant's motion to dismiss Count V is GRANTED.

6. Punitive Damage Claim (Count VII)

It is well-settled under Louisiana jurisprudence that punitive or other penalty damages are not allowable unless expressly authorized by statute. *International Harvester Credit Corp. v. Seale, 518 So. 2d 1039, 1041 (La. 1988)*. The LPLA, which provides the exclusive theories of liability against a manufacturer, does not authorize punitive damages. *Bladen v. C.B. Fleet Holding, Co.,*

487 F.Supp.2d 759, 770 (W.D.La. 2007) (citing *La. R.S. ßß 9:2800.51-.59*). Plaintiffs even acknowledge that Louisiana law precludes recovery of such damages in their petition, instead arguing that "provisions of other state laws are applicable here" and that "plaintiff is therefore entitled to...punitive and/or exemplary damages based on the willful, [*23] reckless, wanton and/or egregious nature of the conduct of the defendants that occurred in other states." [Petition, P 144].

Plaintiffs request this court apply *article 3546 of the Louisiana Civil Code*, a general choice of law provision that allows punitive damages to be awarded when authorized: Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 15 of 16

> (1) By the law of the state where the injurious conduct occurred and by either the law of the state where the resulting injury occurred or the law of the place where the person whose conduct caused the injury was domiciled; or
>
> (2) By the law of the state in which the injury occurred and by the law of the state where the person whose conduct caused the injury was domiciled.

However, *Article 3546* expressly excludes products liability claims for its scope and does not apply to Plaintiff's claim for punitive damages. See *La. C.C. art. 3545 cmt. (a)*. Rather, Plaintiffs' claim is governed by *Article 3545*, which unambiguously provides that Louisiana law governs "liability for injury caused by a product, as well as damages, whether compensatory, special, or punitive," when the injury is sustained in Louisiana by a Louisiana domiciliary [*24] or resident or when the product was manufactured or acquired in this state and caused injury to a Louisiana domiciliary. See *La. C.C. art. 3545*.

Plaintiffs allege that Mrs. Ivory acquired Chantix in Louisiana, that she was injured in Louisiana, and that both she and her husband were domiciliaries of the state. Consequently, *Article 3545* governs Plaintiffs' claim for punitive damages. Therefore, because Louisiana law expressly prohibits recovery of punitive damages for product liability claims, see supra, Defendant's motion to dismiss Count VII is GRANTED.

CONCLUSION

For the reasons stated herein, Defendant's Motion to Dismiss [Record Document 7] is **GRANTED in part** and **DENIED IN PART**. Plaintiffs' claims for design defect (Count II), breach of implied warranty (Count V), punitive damages (Count VII), and Mr. Ivory's claim for damages for negligent infliction of emotional distress are **DISMISSED WITH PREJUDICE**, while Plaintiffs claims for construction or composition defect (Count I), Case 5:09-cv-00072-SMH-MLH Document 19 Filed 09/30/2009 Page 16 of 16 inadequate warning (Count III), breach of express warranty (Count IV), and Mr. Ivory's claim for damages for loss of consortium survive.

THUS [*25] **DONE AND SIGNED** in Shreveport, Louisiana, this 30th day of September, 2009.

/s/ S. Maurice Hicks, Jr.

S. MAURICE HICKS, JR.

UNITED STATES DISTRICT JUDGE

Appendix G

Relevant Provisions of the Restatement (Second) of Torts

Restatement of the Law, Second, Torts
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Case Citations

Rules and Principles

Division 2 - Negligence

Chapter 14 - Liability of Persons Supplying Chattels for the Use of Others

Topic 5 - Strict Liability

Restat 2d of Torts, ß 402A

ß 402A Special Liability of Seller of Product for Physical Harm to User or Consumer

(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.

CAVEAT: Caveat:

The Institute expresses no opinion as to whether the rules stated in this Section may not apply

(1) to harm to persons other than users or consumers;

(2) to the seller of a product expected to be processed or otherwise substantially changed before it reaches the user or consumer; or

(3) to the seller of a component part of a product to be assembled.

COMMENTS & ILLUSTRATIONS: Comment:

a. This Section states a special rule applicable to sellers of products. The rule is one of strict liability, making the seller subject to liability to the user or consumer even though he has

exercised all possible care in the preparation and sale of the product. The Section is inserted in the Chapter dealing with the negligence liability of suppliers of chattels, for convenience of reference and comparison with other Sections dealing with negligence. The rule stated here is not exclusive, and does not preclude liability based upon the alternative ground of negligence of the seller, where such negligence can be proved.

b. History. Since the early days of the common law those engaged in the business of selling food intended for human consumption have been held to a high degree of responsibility for their products. As long ago as 1266 there were enacted special criminal statutes imposing penalties upon victualers, vintners, brewers, butchers, cooks, and other persons who supplied "corrupt" food and drink. In the earlier part of this century this ancient attitude was reflected in a series of decisions in which the courts of a number of states sought to find some method of holding the seller of food liable to the ultimate consumer even though there was no showing of negligence on the part of the seller. These decisions represented a departure from, and an exception to, the general rule that a supplier of chattels was not liable to third persons in the absence of negligence or privity of contract. In the beginning, these decisions displayed considerable ingenuity in evolving more or less fictitious theories of liability to fit the case. The various devices included an agency of the intermediate dealer or another to purchase for the consumer, or to sell for the seller; a theoretical assignment of the seller's warranty to the intermediate dealer; a third party beneficiary contract; and an implied representation that the food was fit for consumption because it was placed on the market, as well as numerous others. In later years the courts have become more or less agreed upon the theory of a "warranty" from the seller to the consumer, either "running with the goods" by analogy to a covenant running with the land, or made directly to the consumer. Other decisions have indicated that the basis is merely one of strict liability in tort, which is not dependent upon either contract or negligence.

Recent decisions, since 1950, have extended this special rule of strict liability beyond the seller of food for human consumption. The first extension was into the closely analogous cases of other products intended for intimate bodily use, where, for example, as in the case of cosmetics, the application to the body of the consumer is external rather than internal. Beginning in 1958 with a Michigan case involving cinder building blocks, a number of recent decisions have discarded any limitation to intimate association with the body, and have extended the rule of strict liability to cover the sale of any product which, if it should prove to be defective, may be expected to cause physical harm to the consumer or his property.

c. On whatever theory, the justification for the strict liability has been said to be that the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public has the right to and does expect, in the case of products which it needs and for which it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.

d. The rule stated in this Section is not limited to the sale of food for human consumption, or other products for intimate bodily use, although it will obviously include them. It extends to any product sold in the condition, or substantially the same condition, in which it is expected to reach

the ultimate user or consumer. Thus the rule stated applies to an automobile, a tire, an airplane, a grinding wheel, a water heater, a gas stove, a power tool, a riveting machine, a chair, and an insecticide. It applies also to products which, if they are defective, may be expected to and do cause only "physical harm" in the form of damage to the user's land or chattels, as in the case of animal food or a herbicide.

e. Normally the rule stated in this Section will be applied to articles which already have undergone some processing before sale, since there is today little in the way of consumer products which will reach the consumer without such processing. The rule is not, however, so limited, and the supplier of poisonous mushrooms which are neither cooked, canned, packaged, nor otherwise treated is subject to the liability here stated.

f. Business of selling. The rule stated in this Section applies to any person engaged in the business of selling products for use or consumption. It therefore applies to any manufacturer of such a product, to any wholesale or retail dealer or distributor, and to the operator of a restaurant. It is not necessary that the seller be engaged solely in the business of selling such products. Thus the rule applies to the owner of a motion picture theatre who sells popcorn or ice cream, either for consumption on the premises or in packages to be taken home.

The rule does not, however, apply to the occasional seller of food or other such products who is not engaged in that activity as a part of his business. Thus it does not apply to the housewife who, on one occasion, sells to her neighbor a jar of jam or a pound of sugar. Nor does it apply to the owner of an automobile who, on one occasion, sells it to his neighbor, or even sells it to a dealer in used cars, and this even though he is fully aware that the dealer plans to resell it. The basis for the rule is the ancient one of the special responsibility for the safety of the public undertaken by one who enters into the business of supplying human beings with products which may endanger the safety of their persons and property, and the forced reliance upon that undertaking on the part of those who purchase such goods. This basis is lacking in the case of the ordinary individual who makes the isolated sale, and he is not liable to a third person, or even to his buyer, in the absence of his negligence. An analogy may be found in the provision of the Uniform Sales Act, ß 15, which limits the implied warranty of merchantable quality to sellers who deal in such goods; and in the similar limitation of the Uniform Commercial Code, ß 2-314, to a seller who is a merchant. This Section is also not intended to apply to sales of the stock of merchants out of the usual course of business, such as execution sales, bankruptcy sales, bulk sales, and the like.

g. Defective condition. The rule stated in this Section applies only where the product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him. The seller is not liable when he delivers the product in a safe condition, and subsequent mishandling or other causes make it harmful by the time it is consumed. The burden of proof that the product was in a defective condition at the time that it left the hands of the particular seller is upon the injured plaintiff; and unless evidence can be produced which will support the conclusion that it was then defective, the burden is not sustained.

Safe condition at the time of delivery by the seller will, however, include proper packaging, necessary sterilization, and other precautions required to permit the product to remain safe for a normal length of time when handled in a normal manner.

h. A product is not in a defective condition when it is safe for normal handling and consumption. If the injury results from abnormal handling, as where a bottled beverage is knocked against a radiator to remove the cap, or from abnormal preparation for use, as where too much salt is added to food, or from abnormal consumption, as where a child eats too much candy and is made ill, the seller is not liable. Where, however, he has reason to anticipate that danger may result from a particular use, as where a drug is sold which is safe only in limited doses, he may be required to give adequate warning of the danger (see Comment *j*), and a product sold without such warning is in a defective condition.

The defective condition may arise not only from harmful ingredients, not characteristic of the product itself either as to presence or quantity, but also from foreign objects contained in the product, from decay or deterioration before sale, or from the way in which the product is prepared or packed. No reason is apparent for distinguishing between the product itself and the container in which it is supplied; and the two are purchased by the user or consumer as an integrated whole. Where the container is itself dangerous, the product is sold in a defective condition. Thus a carbonated beverage in a bottle which is so weak, or cracked, or jagged at the edges, or bottled under such excessive pressure that it may explode or otherwise cause harm to the person who handles it, is in a defective and dangerous condition. The container cannot logically be separated from the contents when the two are sold as a unit, and the liability stated in this Section arises not only when the consumer drinks the beverage and is poisoned by it, but also when he is injured by the bottle while he is handling it preparatory to consumption.

i. Unreasonably dangerous. The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from over-consumption. Ordinary sugar is a deadly poison to diabetics, and castor oil found use under Mussolini as an instrument of torture. That is not what is meant by "unreasonably dangerous" in this Section. The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fusel oil, is unreasonably dangerous. Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous. Good butter is not unreasonably dangerous merely because, if such be the case, it deposits cholesterol in the arteries and leads to heart attacks; but bad butter, contaminated with poisonous fish oil, is unreasonably dangerous.

j. Directions or warning. In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger.

Likewise in the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required.

But a seller is not required to warn with respect to products, or ingredients in them, which are only dangerous, or potentially so, when consumed in excessive quantity, or over a long period of time, when the danger, or potentiality of danger, is generally known and recognized. Again the dangers of alcoholic beverages are an example, as are also those of foods containing such substances as saturated fats, which may over a period of time have a deleterious effect upon the human heart.

Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.

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.

l. User or consumer. In order for the rule stated in this Section to apply, it is not necessary that the ultimate user or consumer have acquired the product directly from the seller, although the rule applies equally if he does so. He may have acquired it through one or more intermediate dealers. It is not even necessary that the consumer have purchased the product at all. He may be a member of the family of the final purchaser, or his employee, or a guest at his table, or a mere donee from the purchaser. The liability stated is one in tort, and does not require any contractual relation, or privity of contract, between the plaintiff and the defendant.

"Consumers" include not only those who in fact consume the product, but also those who prepare it for consumption; and the housewife who contracts tularemia while cooking rabbits for her husband is included within the rule stated in this Section, as is also the husband who is opening a bottle of beer for his wife to drink. Consumption includes all ultimate uses for which the product is intended, and the customer in a beauty shop to whose hair a permanent wave solution is applied by the shop is a consumer. "User" includes those who are passively enjoying the benefit of the product, as in the case of passengers in automobiles or airplanes, as well as

those who are utilizing it for the purpose of doing work upon it, as in the case of an employee of the ultimate buyer who is making repairs upon the automobile which he has purchased.

Illustration:

1. A manufactures and packs a can of beans, which he sells to B, a wholesaler. B sells the beans to C, a jobber, who resells it to D, a retail grocer. E buys the can of beans from D, and gives it to F. F serves the beans at lunch to G, his guest. While eating the beans, G breaks a tooth, on a pebble of the size, shape, and color of a bean, which no reasonable inspection could possibly have discovered. There is satisfactory evidence that the pebble was in the can of beans when it was opened. Although there is no negligence on the part of A, B, C, or D, each of them is subject to liability to G. On the other hand E and F, who have not sold the beans, are not liable to G in the absence of some negligence on their part.

m. "Warranty." The liability stated in this Section does not rest upon negligence. It is strict liability, similar in its nature to that covered by Chapters 20 and 21. The basis of liability is purely one of tort.

A number of courts, seeking a theoretical basis for the liability, have resorted to a "warranty," either running with the goods sold, by analogy to covenants running with the land, or made directly to the consumer without contract. In some instances this theory has proved to be an unfortunate one. Although warranty was in its origin a matter of tort liability, and it is generally agreed that a tort action will still lie for its breach, it has become so identified in practice with a contract of sale between the plaintiff and the defendant that the warranty theory has become something of an obstacle to the recognition of the strict liability where there is no such contract. There is nothing in this Section which would prevent any court from treating the rule stated as a matter of "warranty" to the user or consumer. But if this is done, it should be recognized and understood that the "warranty" is a very different kind of warranty from those usually found in the sale of goods, and that it is not subject to the various contract rules which have grown up to surround such sales.

The rule stated in this Section does not require any reliance on the part of the consumer upon the reputation, skill, or judgment of the seller who is to be held liable, nor any representation or undertaking on the part of that seller. The seller is strictly liable although, as is frequently the case, the consumer does not even know who he is at the time of consumption. The rule stated in this Section is not governed by the provisions of the Uniform Sales Act, or those of the Uniform Commercial Code, as to warranties; and it is not affected by limitations on the scope and content of warranties, or by limitation to "buyer" and "seller" in those statutes. Nor is the consumer required to give notice to the seller of his injury within a reasonable time after it occurs, as is provided by the Uniform Act. The consumer's cause of action does not depend upon the validity of his contract with the person from whom he acquires the product, and it is not affected by any disclaimer or other agreement, whether it be between the seller and his immediate buyer, or attached to and accompanying the product into the consumer's hands. In short, "warranty" must be given a new and different meaning if it is used in connection with this Section. It is much simpler to regard the liability here stated as merely one of strict liability in tort.

n. Contributory negligence. Since the liability with which this Section deals is not based upon negligence of the seller, but is strict liability, the rule applied to strict liability cases (see ß 524) applies. Contributory negligence of the plaintiff is not a defense when such negligence consists merely in a failure to discover the defect in the product, or to guard against the

possibility of its existence. On the other hand the form of contributory negligence which consists in voluntarily and unreasonably proceeding to encounter a known danger, and commonly passes under the name of assumption of risk, is a defense under this Section as in other cases of strict liability. If the user or consumer discovers the defect and is aware of the danger, and nevertheless proceeds unreasonably to make use of the product and is injured by it, he is barred from recovery.

Comment on Caveat:

o. Injuries to non-users and non-consumers. Thus far the courts, in applying the rule stated in this Section, have not gone beyond allowing recovery to users and consumers, as those terms are defined in Comment *l*. Casual bystanders, and others who may come in contact with the product, as in the case of employees of the retailer, or a passer-by injured by an exploding bottle, or a pedestrian hit by an automobile, have been denied recovery. There may be no essential reason why such plaintiffs should not be brought within the scope of the protection afforded, other than that they do not have the same reasons for expecting such protection as the consumer who buys a marketed product; but the social pressure which has been largely responsible for the development of the rule stated has been a consumers' pressure, and there is not the same demand for the protection of casual strangers. The Institute expresses neither approval nor disapproval of expansion of the rule to permit recovery by such persons.

p. Further processing or substantial change. Thus far the decisions applying the rule stated have not gone beyond products which are sold in the condition, or in substantially the same condition, in which they are expected to reach the hands of the ultimate user or consumer. In the absence of decisions providing a clue to the rules which are likely to develop, the Institute has refrained from taking any position as to the possible liability of the seller where the product is expected to, and does, undergo further processing or other substantial change after it leaves his hands and before it reaches those of the ultimate user or consumer.

It seems reasonably clear that themere fact that the product is to undergo processing, or other substantial change, will not in all cases relieve the seller of liability under the rule stated in this Section. If, for example, raw coffee beans are sold to a buyer who roasts and packs them for sale to the ultimate consumer, it cannot be supposed that the seller will be relieved of all liability when the raw beans are contaminated with arsenic, or some other poison. Likewise the seller of an automobile with a defective steering gear which breaks and injures the driver, can scarcely expect to be relieved of the responsibility by reason of the fact that the car is sold to a dealer who is expected to "service" it, adjust the brakes, mount and inflate the tires, and the like, before it is ready for use. On the other hand, the manufacturer of pigiron, which is capable of a wide variety of uses, is not so likely to be held to strict liability when it turns out to be unsuitable for the child's tricycle into which it is finally made by a remote buyer. The question is essentially one of whether the responsibility for discovery and prevention of the dangerous defect is shifted to the intermediate party who is to make the changes. No doubt there will be some situations, and some defects, as to which the responsibility will be shifted, and others in which it will not. The existing decisions as yet throw no light upon the questions, and the Institute therefore expresses neither approval nor disapproval of the seller's strict liability in such a case.

q. Component parts. The same problem arises in cases of the sale of a component part of a product to be assembled by another, as for example a tire to be placed on a new automobile, a brake cylinder for the same purpose, or an instrument for the panel of an airplane. Again the

question arises, whether the responsibility is not shifted to the assembler. It is no doubt to be expected that where there is no change in the component part itself, but it is merely incorporated into something larger, the strict liability will be found to carry through to the ultimate user or consumer. But in the absence of a sufficient number of decisions on the matter to justify a conclusion, the Institute expresses no opinion on the matter.