

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF LOUISIANA**

**JACOB GUILLOT, ET AL.**

**CIVIL ACTION**

**VERSUS**

**NO: 02-3373**

**AVENTIS PASTEUR, INC., ET AL.**

**SECTION: "S" (5)**

**ORDER AND REASONS**

**IT IS HEREBY ORDERED** that Eli Lilly and Company's Motion for Judgment on the Pleadings (Doc. #49) is **GRANTED**.

**IT IS FURTHER ORDERED** that Sanofi Pasteur Inc., Merck Sharpe & Dohme Corp. and GlascoSmithKlien LLC's Motion to Dismiss (Doc. #51) is **GRANTED**.

**IT IS FURTHER ORDERED** that American International Chemical, Inc.'s Motion to Dismiss (Doc. #55) is **GRANTED**.<sup>1</sup>

**IT IS FURTHER ORDERED** that Plaintiffs' Motion to Strike (Doc. #60) is **DENIED**.

**IT IS FURTHER ORDERED** that Plaintiffs' Motion for Leave to Supplement and Amend the Complaint (Doc. #81) is **GRANTED** as to bringing claims of Jacob Guillot under the Louisiana Products Liability Act ("LPLA"), Louisiana Revised Statutes § 9:2800.51, *et seq.*, for failure to warn against Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc. (Count III of the Proposed Amended Complaint). The motion is **DENIED** as to asserting claims of Jacob under the LPLA for composition and construction, design defects and breach of warranty as to Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc. (Count III of the Proposed Amended Complaint), all proposed claims

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<sup>1</sup> Due to this court's rulings on defendants' motions to dismiss and motion for judgment on the pleadings, it is unnecessary to rule on defendants' motions for summary judgment (Docs. #47, 50 and 53), and those motions are disposed of by this Order and Reasons.

against Sanofi Pasteur Inc., Merck Sharpe & Dohme Corp. and GlaxoSmithKlien LLC's (Counts I through VIII of the Proposed Amended Complaint), and Counts I, II, and IV through VIII of the Proposed Amended Complaint against Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc.

### **BACKGROUND**

On August 15, 2002, Plaintiffs, Dale and Angel Guillot filed this action on their own behalf and on behalf of their minor son, Jacob Guillot, in the Seventeenth Judicial District Court, Parish of Lafourche, State of Louisiana. On November 8, 2002, defendant, Eli Lilly and Company, with the consent of the other defendants, timely removed the action to the United States District Court for the Eastern District of Louisiana alleging diversity subject matter jurisdiction under 28 U.S.C. § 1332.

In the complaint, the plaintiffs allege that Jacob was injured by vaccines that contained Thimerosal, a mercury based preservative. Plaintiffs allege that GlaxoSmithKlien, LLC (f/k/a SmithKlien Beecham Corporation), Sanofi Pasteur Inc. (f/k/a Aventis Pasteur, Inc.), Merck Sharpe & Dohme Corp. (f/k/a Merck & Co., Inc.) (collectively "vaccine defendants") manufactured the vaccines Jacob received, and that American International Chemical Inc., Eli Lilly and Company and Spectrum Laboratory Products, Inc. (collectively "Thimerosal defendants") manufactured the Thimerosal that was a component part of those vaccines.

Plaintiffs allege that Jacob, who was born on February 16, 1998, developed normally until the age of eighteen months, but then he became withdrawn, unable to speak and unresponsive, and lost motor skills. Plaintiffs claim that Jacob's disabilities were caused by the accumulation of

mercury in his body due to the vaccines. In Count I, plaintiffs seek to bring a class action for medical monitoring against all defendants. In Count II, plaintiffs seek an injunction preventing the vaccine defendants from selling vaccines containing Thimerosal. Counts III, V and VII allege claims of negligence, wanton reckless, and outrageous conduct, and breach of warranty for fitness for a specific purpose, respectively, against the vaccine defendants. Counts IV, VI, VIII and IX allege strict liability, intentional infliction of emotional distress, breach of express and implied warranty and civil battery against all defendants. Count X is a claim under the Louisiana Unfair Trade Practices and Consumer Protection Act ("LUTPA"), La. Rev. Stat. § 54:1404, et seq., against all defendants. Count XI is a claim for the parents' mental anguish, loss of consortium, and economic damages for medical and related expenses incurred on Jacob's behalf and Jacob's lost earnings or earning ability.

In 2003, GlaxoSmithKlien, Sanofi Pasteur, Merck, American International Chemical and Eli Lilly<sup>2</sup> moved to dismiss all of plaintiffs' claims that are covered by the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. § 300aa-1, et seq. (Counts III through X, and Count XI as to Dale and Angel Guillot's claims for economic damages for medical and related expenses incurred on Jacob's behalf and Jacob's lost earnings or earning ability), and to stay all remaining claims (Counts I and II, and Count XI as to Dale and Angel Guillot's mental anguish and loss of consortium claims), while plaintiffs pursued remedies in accordance with the Vaccine Act. At oral argument on the motions, plaintiffs' counsel indicated on the record that he did not oppose the court's granting the defendants' motions. On March 31, 2003, the court granted the defendants' motions,

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<sup>2</sup> Spectrum has not filed any motions. However, plaintiffs' claims against Spectrum will be addressed collectively with plaintiffs' claims against the other defendants.

dismissing without prejudice Counts III through X, and Count XI as to Dale and Angel Guillot's claims for economic damages for medical and related expenses incurred on Jacob's behalf and for Jacob's lost earnings or earning ability, and staying the remaining claims pending plaintiffs' pursuit of compensation remedies in the United States Court of Federal Claims under the Vaccine Act.

On April 14, 2003, plaintiffs filed a petition in the Vaccine Court. On March 8, 2012, the special master dismissed plaintiffs' case for failure to prosecute. Judgment was entered on April 11, 2012. Thereafter plaintiffs filed a Motion for Relief from Judgment pursuant to Rule 60(b) of the Rules of the United States Court of Federal Claims<sup>3</sup> and Rule 39 of the Vaccine Rules of the United States Court of Federal Claims.<sup>4</sup> On August 15, 2012, the special master denied plaintiffs' motion, noting that plaintiffs' petition in the Vaccine Court was untimely. Plaintiffs filed a motion for reconsideration, which the special master denied on September 13, 2012. On November 5, 2012, plaintiffs filed an election to proceed with a civil action, thereby purportedly giving them the ability to file a civil action for Jacob's vaccine-related injuries in this court.

On January 16, 2013, Sanofi Pasteur moved this court to reopen this case, arguing that the Vaccine Court “dismissed plaintiffs’ claims for failure to prosecute and for insufficient proof, and because such claims were found to be time barred.” Sanofi Pasteur requested a status conference to discuss whether plaintiffs intend to prosecute the case or dismiss their remaining claims in light of the Vaccine Court’s rulings.

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<sup>3</sup> Rule 60(b) of the Rules of the United States Court of Federal Claims is identical to Rule 60(b) of the Federal Rules of Civil Procedure.

<sup>4</sup> Rule 39 dictates whether a motion for relief from judgment filed under Rule 60 of the Rules of the United States Court of Federal Claims is handled by a judge of the United States Court of Federal Claims or the special master. In this case, the motion was referred to the special master under Rule 39.

At the telephone status conference, plaintiffs' counsel indicated that plaintiffs intended to pursue their remaining claims. The court set dates for the defendants to submit motions to dismiss and motions for summary judgment to address preliminary legal questions before the parties engaged in potentially unnecessary discovery.

GlaxoSmithKlien, American International, Sanofi Pasteur and Merck filed motions to dismiss and motions for summary judgment. Eli Lilly filed a motion for judgment on the pleadings and a motion for summary judgment. Thereafter, plaintiffs filed a motion to continue the motions for summary judgment, arguing that they needed to engage in discovery to adequately respond to the motions. This court denied plaintiffs' motion, noting that the plaintiffs could assert such arguments in opposition to the motions for summary judgment. Plaintiffs also filed a motion to strike documents related to the Vaccine Court and all mention of the Vaccine Court from defendants' motions to dismiss and motions for summary judgment.

Thereafter, the court noted that, in their motions, defendants address the claims asserted by plaintiffs in Counts III through XI of the complaint, which were dismissed without prejudice on March 31, 2003, pursuant to plaintiffs' agreement. "A dismissal without prejudice is a dismissal that occurs without an adjudication on the merits. The dismissal of an action without prejudice leaves the parties as though the action had never been brought." Graves v. Principi, 294 F.3d 1350, 1356 (Fed. Cir. 2002) (citing Bonneville Assocs. Ltd. P'ship v. Barram, 165 F.3d 1360, 1364 (Fed. Cir. 1999) (stating that "[t]he rule in federal courts is that '[t]he effect of a voluntary dismissal without prejudice . . . is to render the proceedings a nullity and leave the parties as if the action had never been brought'"); see also 9 CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2367 (3d ed. 2008)). Thus, Counts III through X, and Count XI as to Dale and Angel

Guillot's claims for economic damages for medical and related expenses incurred on Jacob's behalf and for Jacob's lost earnings or earning ability are not before the court.

On May 1, 2013, plaintiffs moved to amend the complaint to assert the claims that were not properly before the court at the time the defendants' filed their motions. In the Proposed Amended Complaint, plaintiffs reassert their claims for a medical monitoring class action, an injunction and the parents' loss of consortium and mental anguish. They also seek to bring claims under the LPLA, LUTPA, redhibition and breach of warranty. Further, they seek damages for the parents' economic damages for medical and related expenses incurred on Jacob's behalf and for Jacob's lost earnings or earning ability.<sup>5</sup> Defendants oppose plaintiffs' motion to amend the complaint.

## ANALYSIS

### I. Plaintiffs' Motion to Strike

Plaintiffs seek to strike mention of the Vaccine Court from defendants' motions to dismiss and motions for summary judgment. Plaintiffs argue that all such mention should be eliminated because the Vaccine Act does not permit the rulings of the Vaccine Court to be used as evidence in subsequent litigation involving the vaccine-related injury.

Title 42, United States Code, Section 300aa-23(e) "Evidence," provides:

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United

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<sup>5</sup> In the Proposed Amended Complaint, plaintiffs do not specifically seek to re-allege the following claims that were included in the complaint and dismissed without prejudice by consent: negligence and wanton, reckless, and outrageous conduct against the vaccine defendants; and, strict liability, intentional infliction of emotional distress and civil battery against all defendants. As discussed herein, these tort claims are not available against these manufacturer defendants due to the LPLA's exclusivity provision. See LA. REV. STAT. § 9:2800.52; see also Jefferson v. Lead Indus. Ass'n, Inc., 106 F.3d 1245, 1251 (5th Cir. 1997).

States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

42 U.S.C. § 300aa-23(e). The Vaccine Act includes this section to prevent confusion in a civil action because the proceedings in the Vaccine Court are fundamentally different from traditional civil actions. The House Report on the Vaccine Act explains:

Compensation standards, evidence, and proceedings are sufficiently different from civil proceedings in tort that the findings made in compensation are not likely to be based on the more rigorous requirements of tort proceedings and might confuse such civil action.

H. Rep. 908, 99th Cong., 2d Sess. 1, 29, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6370. Section 300aa-23(e) prohibits the introduction into evidence in a civil tort suit of the Vaccine Injury Table and findings of fact or conclusions of law and judgments in the Vaccine Court's proceedings. It does not prohibit the court from considering the fact of the Vaccine Court proceedings to determine whether plaintiffs complied with the Vaccine Act's prerequisites to filing a civil tort suit. See 42 U.S.C. § 300aa-1, et seq.

This court will not consider the prohibited items as evidence in determining liability, but will consider the existence of the record in the Vaccine Court for the appropriate purposes. Thus, plaintiffs' motion to strike is DENIED.

## **II. Defendants' Motions to Dismiss Counts I and II of the Complaint (Docs. #49, 51 & 55)**

Defendants argue that this court lacks subject matter jurisdiction over plaintiffs' class action claim for medical monitoring and claim against the vaccine defendants for an injunction because plaintiffs do not have standing to assert such claims.

### **A. Rule 12(b)(1) of the Federal Rules of Civil Procedure**

"Motions filed under Rule 12(b)(1) of the Federal Rules of Civil Procedure allow a party to challenge the subject matter jurisdiction of the district court to hear a case." Ramming v. United States, 281 F.3d 158, 161 (5th Cir. 2001) (citing FED. R. CIV. P. 12(b)(1)). "Lack of subject matter jurisdiction may be found in any one of three instances: (1) the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." Id. (citing Barrera-Montenegro v. United States, 74 F.3d 657, 659 (5th Cir. 1996)). If the defendant attacks the facts on which the court's subject-matter jurisdiction rests, the court is "free to weigh the evidence and satisfy itself as to the existence of its power to hear the case." Arena v. Graybar Elec. Co., Inc., 669 F.3d 214, 223 (5th Cir. 2012).

In a 12(b)(1) motion, the party asserting jurisdiction bears the burden of proving that jurisdiction does in fact exist. Ramming, 281 F.3d at 161. "The plaintiff must prove by a preponderance of the evidence that the court has jurisdiction based on the complaint and evidence." Ballew v. Cont'l Airlines, Inc., 668 F.3d 777, 781 (5th Cir. 2012) (citing Paterson v. Weinberger, 644 F.2d 521, 523 (5th Cir. 1981)). However, "[a] Rule 12(b)(1) motion 'should be granted only if it appears certain that the plaintiff cannot prove a plausible set of facts that establish subject-matter jurisdiction.'" Battaglia, 495 Fed. Appx. at 441 (quoting Castro v. United States, 560 F.3d 381, 386 (5th Cir. 2008)).

### **B. Standing**

Under Article III of the Constitution of the United States, a litigant must have "standing" to invoke the power of the federal court." Allen v. Wright, 104 S.Ct. 3315, 3324 (1984). "In



essence the question of standing is whether the litigant is entitled to have the court decide the merits of the dispute or of a particular issue.’” Id. (quoting Warth v. Seldin, 95 S.Ct. 2197, 2205 (1975)). The party seeking to have claims redressed by the federal court must establish the elements of standing for each claim that he seeks to press. Lujan v. Defenders of Wildlife, 112 S.Ct. 2130, 2136 (1992); DaimlerChrysler Corp. v. Cuno, 126 S.Ct. 1854, 1867 (2006). Absent Article III standing, a federal court does not have subject matter jurisdiction to address a plaintiff’s claims, and the claim must be dismissed. U.S. CONSTITUTION ART. 3, § 2, cl. 1.

Standing has constitutional and prudential requirements. Standing, at its “irreducible constitutional minimum,” requires a plaintiff to demonstrate that: (1) he has suffered an “injury-in-fact”; (2) the injury is fairly traceable to the defendant’s actions; and (3) that the injury will likely be redressed by a favorable decision. Lujan, 112 S.Ct. at 2136. An “injury-in-fact” is “an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical.” Webb v. City of Dall., Tex., 314 F.3d 787, 791 (5th Cir. 2002).

### **1. Purported Class Action for Medical Monitoring (Count I)**

Defendants argue that the plaintiffs cannot maintain a class action for medical monitoring because Jacob is not an appropriate class representative.

#### **a. Class Action**

Pursuant to Rule 23 of the Federal Rules of Civil Procedure, a class member may sue as a representative party on behalf of all class members if:

- (1) the class is so numerous that joinder of all members is impracticable;
- (2) there are questions of law or fact common to the class;

(3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and

(4) the representative parties will fairly and adequately protect the interests of the class.

FED. R. CIV. P. 23(a). To having standing to pursue a class action, the named plaintiff purporting to represent the class must establish a case or controversy with the defendants, otherwise he may not "seek relief on behalf of himself or any other members of the class." O'Shea v. Littleton, 94 S.Ct. 669, 675-76 (1974) (citations omitted).

If the factors set forth in Rule 23(a) are fulfilled and the named plaintiff has standing, a class action may be maintained if one of the categories provided in Rule 23(b) is satisfied. FED. R. CIV. P. 23(b); see also 5 JAMES WM. MOORE, ET. AL., MOORE'S FEDERAL PRACTICE § 23.40 (3d ed. 2009). If monetary damages are the primary relief sought by a purported medical monitoring class, the standard of Rule 23(b)(3) must be satisfied. Zinser v. Accufix Research Institute, Inc., 253 F.3d 1180, 1195-96 (9th Cir. 2001). However, if the relief sought is a court-supervised program for periodic medical examination, Rule 23(b)(2) applies. Barnes v. Am. Tobacco Co., 161 F.3d 127, 132 (3rd Cir. 1998).

In their purported class action for medical monitoring, plaintiffs primarily seek monetary damages of "funds for medical tests, treatment, periodic evaluations and the establishment of funds to be set aside for scientific research related to mercury neurotoxicity via vaccine exposure." Thus, the standard of Rule 23(b)(3) applies, and to maintain a class action, the court must find "that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." FED. R. CIV. P. 23(b)(3).

## **b. Medical Monitoring under Louisiana Law**

In Bourgeois v. A.P. Green Indus., Inc., 716 So.2d 355, 360-61 (La. 1998) (Bourgeois I), the Supreme Court of Louisiana held that medical monitoring costs are compensable damages under Louisiana Civil Code article 2315 for an asymptomatic plaintiff who experienced significant exposure to a harmful substance and must incur the expense of periodic medical examinations to monitor the effects of that exposure, provided that the plaintiff demonstrates: (1) a significant exposure to a proven hazardous substance; (2) as a proximate result of this exposure, plaintiff suffers a significant risk of contracting a serious latent disease; (3) plaintiff's risk of contracting a serious latent disease is greater than (a) the risk of contracting the same disease had he not been exposed and (b) the chances of members of the public at large of developing this disease; (4) a monitoring procedure exists that makes the early detection of the disease possible; (5) the monitoring procedure has been prescribed by a qualified physician and is reasonably necessary according to contemporary scientific principles; (6) the prescribed monitoring regime is different from that typically recommended in the absence of exposure; and (7) there is some demonstrated clinical value in the early diagnosis and detection of the disease. In so holding, the Supreme Court of Louisiana explained the reasoning behind awarding damages for medical monitoring:

An action for medical monitoring seeks to recover the quantifiable costs of periodic medical examinations necessary to detect the onset of physical harm. The theory behind such recovery is simple. When a plaintiff is exposed to a hazardous substance, . . . , it is often sound medical practice to undergo periodic examinations to ascertain whether the plaintiff has contracted a disease. This is because . . . modern environmental toxins affect[] the body in ways that often do not become manifest for many years. Unlike a car crash, [toxic] exposure is an accident almost always without impact. Nevertheless, it is still an accident that can have consequences every bit as real as those sustained in a head-on collision. In fact, it is precisely because [toxins] can have such deadly consequences that plaintiffs, regardless

of whether or not they are currently suffering from a disease, are often encouraged to submit to regular diagnostic testing.

Id. at 358-59 (internal citations omitted).

On July 9, 1999, Louisiana Civil Code article 2315 was amended to exclude future medical monitoring for asymptomatic plaintiffs. Louisiana Civil Code article 2315(B) states that "[d]amages do not include costs for future medical treatment, services, surveillance, or procedures of any kind unless such treatment, services, surveillance, or procedures are directly related to a manifest physical or mental injury or disease." See also Bonnette v. Conoco, Inc., 837 So.2d 1219, 1230 n. 6 (La. 2003) (explaining that "the amendment effectively eliminated medical monitoring as a compensable item of damage in the absence of manifest physical or mental injury or disease").

Thereafter, in Bourgeois v. A.P. Green Indus., Inc., 783 So.2d 1251, 1260 (La. 2001) (Bourgeois II) the Supreme Court of Louisiana held that the 1999 amendment to Article 2315(B) could not apply retroactively to divest a cause of action that accrued before the effective date of the amendment. Accordingly, to state a claim for damages for medical monitoring following the amendment to Article 2315(B) and Supreme Court of Louisiana's decision in Bourgeois II, a plaintiff must either: (1) have a manifest physical or mental injury or disease as required by Article 2315(B); or, (2) demonstrate that the seven factors forming the Bourgeois I test existed before July 9, 1999. See LA. CIV. CODE art. 2315(B); Crooks v. Metro. Life Ins. Co., 785 So.2d 810, 812 (La. 2001); see also Burmester v. Plaquemines Parish Gov't, 982 So.2d 795, 806 (La. 2008).

Plaintiffs seek to certify a class of:

All children and infants who have received injections of vaccines containing Thimerosal and were exposed to multiple concomitant vaccines or intrauterine exposure through injections to the mother of injectable medications containing Thimerosal, who may develop mercuric neurotoxic disorders.

The complaint alleges that the class consists of "children suffering from mercurialism and later diagnosed generally with ASD, PDD and/or AS,"<sup>6</sup> and repeatedly refers to latent neurological injuries and diseases. In this case, plaintiffs allege that Jacob experienced harmful exposure prior to July 9, 1999, and that he sustained a manifest physical or mental injury. Therefore, both the Bourgeois I and the Article 2315(B) standards may be applicable.

**i. Bourgeois I**

To state a claim for medical monitoring under Bourgeois I, plaintiffs must allege that seven factors forming the Bourgeois I test existed before July 9, 1999. See Crooks, 785 So.2d at 812. Specifically, plaintiffs must allege a harmful exposure to a proven hazardous substance that resulted in a significant risk of contracting a serious latent disease, and that a physician prescribed a monitoring program that is reasonably necessary for early detection and different from that typically recommended in the absence of exposure. See Bourgeois I, 716 So.2d at 360-61.

Plaintiffs have not stated a claim for medical monitoring under Bourgeois I, because they do not allege that Jacob is at significant risk of contracting a latent disease, but rather that he has already manifested neurological injuries. Further, plaintiffs have not alleged that a physician has recommended a monitoring program for Jacob for early detection, rather than continuing care for his manifested issues. Jacob is not an appropriate class representative. Therefore, plaintiffs lack standing to bring a class action claim for medical monitoring under Bourgeois I.

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<sup>6</sup> ASD, PDD and AS refer to Autism Spectrum Disorder, Pervasive Developmental Disorder and Asperger's Syndrome, respectively.

## **ii. Article 2315(B)**

To state a claim for medical monitoring under Article 2315(B), plaintiffs must allege a manifest physical or mental injury or disease that requires medical monitoring. Plaintiffs allege that Jacob has sustained a manifest neurological injury. However, they have not alleged that he requires medical monitoring to prevent a specific potential future disease, as opposed to future medical expenses to treat his manifested issues. There is no allegation that Jacob's condition is progressive or that he could develop a new condition due to exposure to Thimerosal-containing vaccines in 1998 that could be avoided or minimized by medical monitoring. Therefore, Jacob is not an appropriate class representative, and plaintiffs lack standing to bring a class action claim for medical monitoring under Article 2315(B). Thus, plaintiffs' claim for a medical monitoring class action is **DISMISSED WITHOUT PREJUDICE** for lack of subject matter jurisdiction.

## **2. Injunction (Count II)**

The vaccine defendants argue that plaintiffs do not have standing to pursue an injunction preventing them from selling Thimerosal-containing vaccines because plaintiffs do not allege that they are subjected to a real and immediate threat of being exposed to Thimerosal-containing vaccines in the future.

A plaintiff has standing to pursue an injunction when there is a "real and immediate threat of future injury" that is not merely conjectural. K.P. v. LeBlanc, 627 F.3d 115, 122-23 (5th Cir. 2010) (quoting City of L.A. v. Lyons, 103 S.Ct. 1660, 1668 n. 8 (1983)). Thus, "in order to have standing to seek injunctive relief, plaintiffs must demonstrate that they are likely to suffer future injury by the defendant." Id. at 123.

Plaintiffs allege that the vaccine defendants "placed into the marketplace and stream of commerce in Louisiana vaccines destined to be used in infants and children younger than seven years of age that contain Thimerosal as a preservative." They further allege that those vaccines have not been recalled, although Thimerosal-free vaccines are available, and seek an injunction preventing future use of the Thimerosal-containing vaccines. Plaintiffs allege that Jacob is "exposed to potential injection with the stockpiled vaccines containing mercury," but plaintiffs do not demonstrate that there is a real and immediate threat of the proposed future injury. Jacob, who was born in 1998, is more than seven years old. Therefore, he is not a "child younger than seven years of age" on whom the Thimerosal-containing vaccines are "destined to be used." Further, Jacob's parents are unlikely to permit Jacob to receive any Thimerosal-containing vaccine, and he is unlikely to receive it without their consent. Jacob is not likely to suffer the complained of future injury. Thus, plaintiffs do not have standing to pursue the injunctive relief stated in the complaint, and that claim is DISMISSED WITHOUT PREJUDICE for lack of subject matter jurisdiction.

### **III. Defendants' Motions to Dismiss or for Judgment on the Pleadings as to Dale and Angel Guillot's Claims for Mental Anguish and Loss of Consortium in Count XI of the Complaint (Docs. #49, 51, 55)**

#### **A. Legal Standard**

"The standard for dismissal under Rule 12(c) is the same as that for dismissal for failure to state a claim under Rule 12(b)(6)." Chauvin v. State Farm & Cas. Co., 495 F.3d 232, 237 (5th Cir. 2007). To survive a Rule 12(b)(6) motion to dismiss, enough facts to state a claim for relief that is plausible on its face must be pleaded. In re Katrina Canal Breaches Litig., 495 F.3d 191, 205 (5th Cir. 2007) (quoting Bell Atl. v. Twombly, 127 S.Ct. 1555, 1564-65 & 1573 n. 14 (2007)). A claim is plausible on its face when the plaintiff pleads facts from which the court can "draw the reasonable

inference that the defendant is liable for the misconduct alleged.” Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009). “Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” Bell Atl., 127 S.Ct. at 1965. The court “must accept all well-pleaded facts as true and view them in the light most favorable to the non-moving party.” In re S. Scrap Material Co., LLC, 541 F.3d 584, 587 (5th Cir. 2008). However, the court need not accept legal conclusions couched as factual allegations as true. Iqbal, 129 S.Ct. at 1949-50.

In considering a motion to dismiss for failure to state a claim, a district court may consider only the contents of the pleading and the attachments thereto. Collins v. Morgan Stanley Dean Witter, 224 F.3d 496, 498 (5th Cir. 2000) (citing FED. R. CIV. P. 12(b)(6)). However, “[d]ocuments that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff’s complaint and are central to her claim.” Id. at 498-99 (internal citations omitted).

#### **B. Dale and Angel Guillot's Mental Anguish Claims (Count XI)**

Defendants argue that Dale and Angel Guillot cannot maintain bystander claims under Louisiana law for mental anguish due to Jacob's injuries.

Under Louisiana Civil Code article 2315.6(B), claims for mental anguish and emotional distress for injury caused to another person are limited to "persons who view an event causing injury to another person, or who come upon the scene of the event soon thereafter . . ." Further, "the injured person must suffer 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 the



claimant's mental anguish or emotional distress must be severe, debilitating, and foreseeable." LA. CIV. CODE art. 2315.6(B).

In Trahan v. McManus, 728 So.2d 1273, 1279 (La. 1999), the Supreme Court of Louisiana explained that:

bystander damages are intended to provide a remedy when severe mental distress arises directly and immediately from the claimant's observing a traumatic injury-causing event to the direct victim. In order to recover, the claimant who observes the injury-causing event (or soon thereafter comes upon the scene of the injury) must be contemporaneously aware that the event has caused harm to the direct victim. The requirement of temporal proximity has always been at the root of allowing recovery for emotional distress caused by an injury to another, whether recovery is limited to one who actually witnessed a traumatic injury, or whether recovery is extended to one coming upon the traumatic injury, as under the Louisiana rule. Recovery of damages for mental anguish has almost never been extended to one who observed the victim's suffering at a place other than where the injury-causing event occurred or at a time not closely connected to the event.

The requirements of Article 2315.6, when read together, suggest a need for temporal proximity between the tortious event, the victim's observable harm, and the plaintiff's mental distress arising from an awareness of the harm caused by the event. The Legislature apparently intended to allow recovery of bystander damages to compensate for the immediate shock of witnessing a traumatic event which caused the direct victim immediate harm that is severe and apparent, but not to compensate for the anguish and distress that normally accompany an injury to a loved one under all circumstances.

Dale and Angel Guillot allege that they suffered mental anguish as a result of Jacob's receiving Thimerosal-containing vaccines and later developing neurological issues. Their allegations demonstrate that they were not contemporaneously aware of harm to Jacob at the time he received the vaccines. Because they do not allege that they witnessed an event that immediately caused Jacob's injuries, Dale and Angel Guillot cannot maintain bystander claims for mental anguish

under Louisiana law. Therefore, Dale and Angel Guillot's bystander claims for mental anguish are DISMISSED WITH PREJUDICE.

### **C. Dale and Angel Guillot's Loss of Consortium Claims (Count XI)**

Defendants argue that Dale and Angel Guillot's loss of consortium claims are prescribed, because those damage claims arise under the LPLA, which has a one-year prescriptive period.

Louisiana Civil Code article 2315 provides that tort "[d]amages may include loss of consortium, service, and society, and shall be recoverable by the same respective categories of persons who would have a cause of action for wrongful death of an injured person." Pursuant to Louisiana Civil Code article 2315.2(A)(2), the parents of a child who does not have a spouse or children of their own can recover such damages. Jacob Guillot did not have a spouse or children, therefore, his parents, Dale and Angel Guillot, have a claim for loss of consortium due to Jacob's injuries. See LA. CIV. CODE arts. 2315, 2315.2; see also Morrison v. Kappa Alpha Psi Fraternity, 738 So.2d 1105, 1122 (La. Ct. App. 1999) ("Civil Code art 2315 gives parents a cause of action for loss of consortium when their child is injured by the fault of another").

Under Louisiana law, the LPLA, "establishes the exclusive theories of liability for manufacturers for damages caused by their products," and "[a] claimant may not recover from a manufacturer for damage caused by a product on the basis of any [other] theory of liability." LA. REV. STAT. § 9:2800.52. The LPLA defines "damage" as "all damage caused by a product, including survival and wrongful death damages, for which Civil Code Articles 2315, 2315.1 and 2315.2 allow recovery." Thus, Dale and Angel Guillot's loss of consortium damage claims, which arise under Article 2315, are covered by the LPLA.

LPLA claims are subject to the general one-year prescriptive period applicable to delictual actions under Louisiana law. LA. CIV. CODE art. 3492. "The prescription commences to run from the day the injury or damage is sustained." *Id.* In Harvey v. Dixie Graphics, Inc., 593 So.2d 351, 354 (La. 1992), the Supreme Court of Louisiana explained that:

[Louisiana Civil Code article 3492] is rooted in the recognition that a prescriptive period is a time limitation on the exercise of a right of action, and a right of action in tort comes into being only when the plaintiff's right to be free of illegal damage has been violated. When damages are not immediate, the action in damages thus is formed and begins to prescribe only when the tortious act actually produces damage and not on the day that the act was committed.

The damage suffered must at least be actual and appreciable in quality – that is, determinable and not merely speculative. But there is no requirement that the quantum of damages be certain or that they be fully incurred, or incurred in some particular quantum, before the plaintiff has a right of action. Thus, in cases in which a plaintiff has suffered some but not all of his damages, prescription runs from the date on which he first suffered actual and appreciable damage, even though he may thereafter come to a more precise realization of the damages he has already incurred or incur further damage as a result of the completed tortious act.

(citations omitted). Therefore, damage is sustained "when it has manifested itself with sufficiency certainty to support accrual of a cause of action." Bailey v. Khoury, 891 So. 2d 1268, 1283 (La. 2005).

Under Louisiana law, a cause of action accrues when a party has the right to sue, which requires fault, causation, and damages. Ebinger v. Venus Constr. Corp., 65 So.3d 1279, 1286 (La. 2011) (citing Bourgeois II, 783 So. 2d at 1259; Owens v. Martin, 449 So. 2d 448, 451 (La. 1984)). "Further, liberative prescription of one year generally begins to run when the victim knows or should know of the damage, the delict and the relationship between them." Bailey, 891 So.2d at 1283 (citing Branch v. Willis-Kington Med. Ctr., 636 So.2d 211, 212 (La. 1994)). Thus, "prescription

commences when a plaintiff obtains actual or constructive knowledge of facts indicating to a reasonable person that he or she is the victim of a tort.” Id. (quoting Campo v. Correa, 828 So.2d 502, 508 (La. 2002)).

Generally, the party asserting prescription has the burden of proof. Eastin v. Entergy Corp., 865 So.2d 49, 54 (La. 2004). “However, if prescription is evident on the face of the pleadings, . . ., the burden shifts to the plaintiff to show that the action has not prescribed.” Id. In other words, the plaintiff must establish a suspension or interruption of the prescriptive period. Bartucci v. Jackson, 245 Fed. App’x 254, 257 (5th Cir. 2007).

In this case, plaintiffs allege that Jacob was born on February 16, 1998, and sustained noticeable neurological injury at approximately eighteen months of age due to "the accumulation of Mercury in his body" from vaccinations. Plaintiffs allege that prior to eighteen months of age, Jacob "achieved every developmental milestone anticipated of all normally developing children," but thereafter, he "suddenly regressed developmentally, losing milestones of neurological development previously achieved," "becoming withdrawn, unable to speak, unresponsive to his environment, [and] engaging in repetitive behavior." Further, Jacob's medical records state that he developed encephalopathy the day he received a diphtheria, tetanus and pertussis vaccination in May 1999. After the injection he refused to eat or drink, became less involved, lost eye contact and refused to be held or rocked. He also stopped responding to his name, did not acknowledge his siblings and started banging his head on the floor and walls and screaming constantly. The allegations in plaintiffs' complaint establish that Dale and Angel Guillot knew or should have known of the alleged damage caused by the vaccines in 1999. They did not file their complaint until 2002,

more than one year after they knew or should have known of the alleged damage.<sup>7</sup> Thus, their claims for loss of consortium under the LPLA are prescribed, and those claims are **DISMISSED WITH PREJUDICE**.

#### **IV. Plaintiffs' Motion for Leave to File an Amended Complaint (Doc. #81)**

Plaintiffs seek leave of court to supplement and amend the complaint. Plaintiffs reiterate verbatim their claims for a medical monitoring class action, injunction, and for Dale and Angel Guillot's loss of consortium and mental anguish (Proposed Amended Complaint Counts I, II and VIII). All of these claims are discussed above.<sup>8</sup> Additionally, plaintiffs seek to bring claims under the LPLA (Proposed Amended Complaint Count III), redhibition (Proposed Amended Complaint Count IV), breach of the vaccine defendant's warranty of fitness for a specific purpose (Proposed Amended Complaint Count V), breach of express/implied warranty (Proposed Amended Complaint Count VI), and LUTPA (Proposed Amended Complaint Count VII).

##### **A. Legal Standard**

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that “a party may amend its pleading only with the opposing party’s consent or the court’s leave. The court should freely give leave when justice so requires.” The court has discretion on whether to grant or deny leave to

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<sup>7</sup> Article 3492 provides that prescription "does not run against minors or interdicts in actions involving permanent disability and brought pursuant to the Louisiana Products Liability Act or state law governing product liability actions in effect at the time of the injury or damage." LA. CIV. CODE art. 3492. Thus, prescription has not run against Jacob's LPLA claims. However, it has run against Dale and Angel Guillots' personal claims related to Jacob's alleged injuries.

<sup>8</sup> As stated above, plaintiffs cannot prevail on these claims. Because the allegations in the Proposed Amended Complaint regarding these claims are identical to those in the original complaint, the court will not further discuss them, and plaintiffs' motion to amend the complaint is **DENIED** as to Counts I and II and Count VIII, as to Dale and Angel Guillot's loss or consortium and mental anguish claims, of the Proposed Amended Complaint.

amend. Addington v. Farmer's Elevator Mut. Ins. Co., 650 F.2d 663, 666 (5th Cir. 1981). A court may deny leave to amend due to "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment." Wright v. Allstate Ins. Co., 415 F.3d 384 (5th Cir. 2005) (quoting Foman v. Davis, 83 S.Ct. 227, 230 (1962)). "Clearly, if the complaint as amended would still be subject to dismissal" leave to amend should be denied. Addington, 650 F.2d at 667.

### **B. Plaintiffs' Proposed Claims Against the Vaccine Defendants (Proposed Amended Complaint Counts III through VIII)**

In 1986, Congress enacted the Vaccine Act "to achieve optimal prevention of human infectious disease through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. § 300aa-1. "The Vaccine Act is a remedial program designed to provide swift compensation for persons injured by vaccines, while ensuring that the nation's supply of vaccines isn't unduly threatened by the costs and risks of tort litigation." Moss v. Merck & Co., 381 F.3d 501, 503 (5th Cir. 2004). It was enacted "ostensibly as a federal mechanism beyond the traditional tort law paradigm to provide a trust fund for claimants asserting that they had been harmed through the use of childhood vaccines." McDonal v. Abbot Laboratories, 408 F.3d 177, 184 (5th Cir. 2005) (citing Schafer v. Am. Cyanamid Co., 20 F.3d 1, 2 (1st Cir. 1994)).

The Vaccine Act requires a person who has sustained a vaccine-related injury or death,<sup>9</sup> or that person's legal representative, to file a petition against the United States Government in the

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<sup>9</sup> "Vaccine-related injury or death" is defined as "an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except the term does not include illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such vaccine." 42 U.S.C. § 300aa-33(5).

United States Court of Federal Claims, whereupon it is assigned to a special master for adjudication. 42 U.S.C. §§ 300aa-11, 300aa-12. The petition must be filed within "36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." Id. at § 300aa-16(2). The claim must be fully adjudicated in the Vaccine Court prior to the claimant's bringing a civil action in State or Federal court. Id. at § 300aa-11. Section 300aa-11(a)(2)(A) provides:

No person may bring a civil action for damages in an amount greater than \$1,000 or in an unspecified amount against a vaccine administrator or manufacturer<sup>10</sup> in State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than \$1,000 in a civil action for damages for such vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death and - -

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa-12 of this title on such petition, and

(II) such person elects under section 300aa-21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa-21(b) of this title or such petition is considered withdrawn under such section.

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<sup>10</sup> The United States Court of Appeals for the Fifth Circuit has held that Thimerosal, "when used as a preservative is a component of a vaccine rather than an adulterant," but that Thimerosal manufacturers are not vaccine manufacturers under the Vaccine Act. Moss, 381 F.3d at 503-4; see also McDonal, 408 F.3d at 185; see also Holder v. Abbot Laboratories, Inc., 444 F.3d 383, 389 (5th Cir. 2006). Thus, "[t]here is no requirement that redress for vaccine-related injuries against Thimerosal manufacturers be pursued in accordance with section 300aa-11(a)" Holder, 444 F.3d at 389. As a result, plaintiffs were not required to pursue their claims against the Thimerosal defendants in the Vaccine Court prior to bringing civil tort claims against them in federal court.

42 U.S.C. § 300aa-11(a)(2)(A). A vaccine administrator or manufacturer cannot be made a party to any civil action, except one authorized by § 300aa-11(a)(1)(A), for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988. Id. at § 300aa-11(a)(3).

After the United States Court of Federal Claims enters judgment on the petition made under the Vaccine Act, the petitioner must file an election, in writing, with the clerk of that court in accordance with § 300aa-21(a). If the judgment awarded compensation, the petitioner must elect either to receive the compensation or file a civil action for damages. Id. Alternatively, if the judgment did not award compensation, the petitioner must elect to accept the judgment or file a civil action for damages. Id. The election must be filed "not later than 90 days after the date of the court's final judgment with respect to which the election is to be made." Id. If the election is not timely filed, the petitioner "shall be deemed to have filed an election to accept the judgment of the court." Id.

In this case, the United States Court of Federal Claims entered a judgment on plaintiffs' Vaccine Court petition on April 11, 2012. Plaintiffs did not file an election to proceed with a civil action until more than ninety days later, on November 5, 2012. Although plaintiffs filed two Rule 60(b) motions, "the Court of Federal Claims cannot use Rule 60(b) to extend the time of the election under 42 U.S.C. § 300aa-21(a)." Bailiss v. Sec'y of the Dep't of Health and Human Servs., 37 Fed. Cl. 64, 67 (Fed. Cl. 1996). "Just as Federal Rule of Civil Procedure 60(b) cannot be employed to toll, extend, or waive the time period for appeal, so the Court of Federal Claims analog cannot be used to extend the time within which an election must be filed under § 21(a) of the Vaccine Act," because the Vaccine Act does not give the court any "authority to waive the time limits Congress



provided for filing an election." Gilbert v. Sec'y of Health and Human Servs., 51 F.3d 254, 257 (Fed. Cir. 1995) (quotations and citations omitted). Therefore, under § 300aa-21(a), plaintiffs are deemed to have filed an election to accept the judgment dismissing their Vaccine Court petition, and may not proceed with a civil action against the vaccine defendants, because they cannot fulfill the requirements of § 300aa-11(a)(1)(A) for bringing a civil action against the vaccine defendants. As a result, plaintiffs' motion to amend the complaint to bring Counts III through VIII against the vaccine defendants is DENIED because to allow such amendment would be futile.

**C. Plaintiffs' Claims against the Thimerosal Defendants (Proposed Amended Complaint Counts III, IV, VI, VII & VIII)**

Plaintiffs seek to assert claims under the LPLA, LUTPA, redhibition, and breach of express and implied warranties against the Thimerosal defendants.

**1. Louisiana Products Liability Act (Proposed Amended Complaint Count III)**

**a. Exclusivity of the LPLA**

The LPLA, "establishes the exclusive theories of liability for manufacturers for damages<sup>11</sup> caused by their products," and "[a] claimant may not recover from a manufacturer for damage caused by a product on the basis of any [other] theory of liability." LA. REV. STAT. § 9:2800.52. While the methods of establishing an entitlement to recovery under the LPLA "are predicated on principles of strict liability, negligence, or warranty, respectively, neither negligence, strict liability, nor breach of express warranty is any longer available as an independent theory of recovery against a manufacturer." Jefferson v. Lead Indus. Ass'n, Inc., 106 F.3d 1245, 1251 (5th Cir. 1997).

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<sup>11</sup> The LPLA defines "damage" as "all damage caused by a product, including survival and wrongful death damages, for which Civil Code Articles 2315, 2315.1 and 2315.2 allow recovery." Thus, Dale and Angel Guillot's claims for economic damages for medical and related expenses incurred on Jacob's behalf and for Jacob's lost earnings or earning ability under Article 2315 included in Count VIII of the Proposed Amended Complaint are covered by the LPLA.

Moreover, "breach of implied warranty or redhibition is not available as a theory of recovery for personal injury, although a redhibition action is still viable against the manufacturer to recover pecuniary loss." Id.

Because the LPLA is the exclusive remedy for damages caused by a manufacturer's product, except for redhibition for pecuniary loss, plaintiffs cannot assert claims under LUTPA<sup>12</sup> or separate breach of express or implied warranty claims against the Thimerosal defendants. Thus, plaintiffs' motion to amend the complaint is DENIED as to asserting Counts VI and VII of the Proposed Amended Complaint against the Thimerosal defendants.

**b. Elements of a Claim under the LPLA**

A plaintiff must prove the following elements in a products liability cause of action under the LPLA: (1) that the defendant is a manufacturer of the product<sup>13</sup>; (2) that the claimant's damage was proximately caused by a characteristic of the product; (3) that the characteristic made the product unreasonably dangerous in one of the four ways provided in the statute; and (4) that the claimant's damage arose from a reasonably anticipated use of the product by the claimant or someone else. Jefferson, 106 F.3d at 1251(citing generally J. Kennedy, A Primer on the Louisiana

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<sup>12</sup> LUTPA has a one-year preemptive period that runs from the time of the transaction or act that gave rise to the action, and is not subject to suspension, interruption or the doctrine of contra non valentum. Tubos de Acero de Mex., S.A. v. Am. Intern. Inv. Corp., Inc., 292 F.3d 471, 481 n. 4 (2002). The transaction that gave rise to plaintiffs' action was the vaccination that caused Jacob's encephelopathy in 1999. Therefore, if plaintiffs could assert a claim under LUTPA, it would be preempted.

<sup>13</sup> The LPLA defines "product" as "a corporeal movable that is manufactured for placement into trade or commerce, including a product that forms a component part of or that is subsequently incorporated into another product or an immovable." LA. REV. STAT. § 9:2800.53(4). When a plaintiff brings suit against a manufacturer of a chemical that does not, in and of itself, qualify for protection under the Vaccine Act, such as Thimerosal, the plaintiff must prove that the injury was proximately caused by that singular component, rather than the vaccine itself as a whole. Moss, 381 F.3d at 504.

Products Liability Act, 49 LA. L. REV. 565 (1989)); LA. REV. STAT. § 9:2800.54. A plaintiff may prove that a product was “unreasonably dangerous” only under one of four theories:

- (1) The product is unreasonably dangerous in construction or composition as provided in R.S. 9:2800.55;
- (2) The product is unreasonably dangerous in design as provided in R.S. 9:2800.56;
- (3) The product is unreasonably dangerous because of inadequate warning as provided in R.S. 9:2800.57; or
- (4) The product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in R.S. 9:2800.58.

Jefferson, 106 F.3d at 1251 (citing LA. REV. STAT. § 9:2800.54(B)(1-4)).

Rule 8(a)(2) of the Federal Rules of Civil Procedure states that pleadings must contain a short and plain statement of the claim showing that the pleader is entitled to relief. To comply with Rule 8(a)(2) a plaintiff does not need to plead specific facts, but only ““give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.”” Twombly, 127 S.Ct. at 1964-65 (quoting Conley v. Gibson, 78 S.Ct. 99, 103 (1957)). However, “it demands more than an unadorned the-defendant-unlawfully-harmed-me accusation.” Iqbal, 129 S.Ct. at 1949. A pleading must have more than “labels and conclusions” or “a formulaic recitation of the elements of a cause of action.” Id. A complaint will not “suffice if it tenders naked assertions devoid of further factual enhancement.” Id. “Factual allegations must be enough to raise a right to relief above the speculative level.” Twombly, 127 S.Ct. at 1965.

In the Proposed Amended Complaint, plaintiffs seek to bring LPLA claims against the Thimerosal defendants, alleging that they “are liable to the claimants for damage proximately caused by the toxic nature and character of the Thimerosal-containing vaccines that render the vaccines

unreasonably dangerous when such damage arose from the reasonably anticipated use of the vaccines." Plaintiffs then make allegations directed to the LPLA theories under which a product can be unreasonably dangerous.

**i. Construction or Composition**

To prevail on a claim that a product is “unreasonably dangerous” in its “construction or composition” under the LPLA, a plaintiff must show that, “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. REV. STAT. § 9:2800.585; see also Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 261 (5th Cir. 2002). The “construction or composition” provision of the LPLA “provides a remedy for damages caused by a product that is defective due to a mistake in the manufacturing process.” Stahl, 283 F.3d at 263.

Plaintiffs' allegation in the Proposed Amended Complaint directed at a construction or composition claim under the LPLA is:

132. The *vaccines* at issue are unreasonably dangerous in construction or composition as provided in R.S. 9:2800.55 because the *vaccines* deviated in a material way from the manufacturers' specifications or performance standards for the product. Specifically, the FDA mandated that the preservatives used in the vaccines be safe and non-toxic. These *vaccines* deviated from identical products manufactured by the same manufacturer following removal of Thimerosal from the vaccines. At all times material thereto, the *vaccine manufacturers* could have made single dose vials without the use of Thimerosal, or the mercury-based compound.

(emphasis added).

This allegation is insufficient to state a construction or composition claim under the LPLA against the Thimerosal defendants, because it does not allege that the Thimerosal itself used in the

vaccines Jacob received deviated in any material way from the Thimerosal manufacturers' " specifications or performance standards for" Thimerosal, or that there was a mistake in the Thimerosal manufacturing process. Indeed, this allegation is directed at the vaccine defendants, and alleges a design defect claim, by suggesting that the vaccines could have been made in single dose vials without using Thimerosal. Because plaintiffs have not adequately stated a construction or composition claim under the LPLA against the Thimerosal defendants, plaintiffs' motion to amend the complaint is DENIED as to asserting claims under the LPLA for construction or composition against the Thimerosal defendants.

## ii. Design

A plaintiff asserting a design defect claim under the LPLA must show that: (1) an alternative design existed; and (2) "[t]he likelihood that the product's 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 . . . of such alternative design on the utility of the product."

LA. REV. STAT. § 9:2800.56.

Plaintiffs' allegation in the Proposed Amended Complaint directed at a design defect claim under the LPLA is:

133. The vaccines at issue and the Thimerosal preservative at issue [are] unreasonably dangerous in design as provided in R.S. 9:2800.56 because, at the time the *vaccines* left its manufacturer's control: (1) there existed an alternative design for the products that was capable of preventing the plaintiffs' damages, namely *single dose vials without [T]himerosal*; and (2) the likelihood that the products' designs would cause the plaintiffs' damages 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 *vaccines*. The likelihood of damage is great when the manufacturers did not adequately warn prescribing physicians and consumers of the mercury toxicity of the *vaccines*, or

the cumulative effect of multiple injections of the mercury-containing vaccines. This is so when there had been no safety testing of the effects of multiple and cumulative dosages of the mercury-based *vaccines* in adults and children, including pregnant women and infants, with developing organs and brains. The concomitant and aggregated injections of *vaccines manufactured by the VACCINE MANUFACTURERS* exposed him to mercury in excess of all known Federal safe limits. JACOB's total exposure to date exceeds 175 mcg of mercury, this exposure was the cause of his injuries, and *single dose vials without Thimerosal would have prevented the injuries.*

(emphasis added).

This allegation is insufficient to state a design defect claim under the LPLA against the Thimerosal defendants, because it does not allege that an alternative design for Thimerosal existed that would not have affected the utility of the product. Indeed, this allegation is directed at the vaccine defendants in that it alleges an alternative design for the vaccines, i.e single dose vials without Thimerosal. Because plaintiffs have not adequately stated a design defect claim under the LPLA against the Thimerosal defendants, plaintiffs' motion to amend the complaint is DENIED as to asserting a design defect claim.

### **iii. Warning**

La. Rev. Stat. § 9:2800.57(A) provides that a "product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its 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 danger to users and handlers of the product." However, there is no duty to warn if "[t]he user or handler of the product already knows or reasonably should be expected to know of the characteristic of the product that may cause damage and the danger of such characteristic." Id. at § 9:2800.57(B)(2). Louisiana courts have held under the "sophisticated user" exception provided in

§ 9:2800.57(B)(2), and the prior law upon which that section is based, that manufacturers have no duty to warn an end-user of a product's dangers when the product is initially purchased by a sophisticated user that would have the duty to warn the end-user. See Longo v. E.I. Dupont De Nemours & Co., 632 So.2d 1193 (La. Ct. App. 1994); Scallan v. Duriron Co., Inc., 11 F.3d 1249 (5th Cir. 1994); Washington v. Dep't of Transp., 8 F.3d 296 (5th Cir. 1993); Davis v. Avondale Indus., Inc., 975 F.2d 169 (5th Cir. 1992); Bates v. E.D. Bullard Co., 76 So.3d 111 (La. Ct. App. 2011).

Plaintiffs allegations in the Proposed Amended Complaint directed at a failure to warn claim under the LPLA are:

135. The Thimerosal-containing vaccines are unreasonably dangerous because an adequate warning about the products has not been provided as provided in R.S. 9:2800.57.

136. The Thimerosal-containing vaccines are unreasonably dangerous because an adequate warning about the vaccines has not been provided when, at the time the vaccines left the manufacturers' control, the vaccines possessed the unnecessary toxic characteristics that may cause damage and the manufacturers failed to use reasonable care to provide an adequate warning of such mercury toxicity and its danger to users, including infants, and prescribing physicians.

137. The Vaccine Manufacturers and the Thimerosal Manufacturers failed to warn or to adequately warn the prescribing physicians, and the manufacturers' failure to warn or adequately warn was the cause in fact and proximate cause of the plaintiff's injury.

138. If the Vaccine Manufacturers and the Thimerosal Manufacturers had rendered adequate warnings concerning Thimerosal-containing vaccines, prescribers such as Plaintiff's prescriber would not have prescribed Thimerosal-containing vaccines to infants and children, such as the Plaintiff, and would have switched from Thimerosal-containing vaccines to safer vaccines, or would have refrained wholly from any use of Thimerosal-containing vaccines.

141. An adequate warning regarding the mercury toxicity of the vaccines and its cumulative effects in patients and its potential for causing neurological and cognitive damage in patients receiving multiple doses of Thimerosal in excess of EPA "safe levels" would have deterred Jacob's physicians from prescribing multiple and cumulative doses of Thimerosal-containing vaccines to plaintiff.

These allegations are sufficient to state a failure to warn claim under the LPLA against the Thimerosal defendants. The allegations state that the "Thimerosal-containing vaccines" were unreasonably dangerous and that the defendants failed to warn of the dangers of the "Thimerosal-containing vaccines." Clearly, the intent of the allegations is to state that the Thimerosal in the vaccines caused the alleged harm. Further, because there has been no discovery, there is no evidence in the record upon which the court can base a finding that the vaccine manufacturers were "sophisticated users" of Thimerosal who already knew or reasonably should be expected to have known of any characteristics of Thimerosal that may cause damage and the danger of such characteristics. Therefore, plaintiffs have adequately stated a failure to warn claim under the LPLA against the Thimerosal defendants, and plaintiffs' motion to amend the complaint is GRANTED as to asserting claims for failure of the Thimerosal defendants to provide adequate warning.

#### **iv. Express Warranty**

The LPLA provides:

A product is unreasonably dangerous when it 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. REV. STAT. §9:2800.5. The LPLA defines an "express warranty" as:

a representation, statement of alleged fact or promise about a product or its nature, material or workmanship that represents, affirms or promises that the product or its nature, material or workmanship



possesses specified characteristics or qualities that will meet a specified level of performance.

LA. REV. STAT. § 9:2800.53(6).

Plaintiffs allegations in the Proposed Amended Complaint directed at an express warranty claim under the LPLA are:

145. The Thimerosal-containing vaccines are unreasonably dangerous because they do not conform to an express warranty of the manufacturers about the vaccines as provided in R.S. 9:2800.58.

146. This is particular[ly] so where the Vaccine Manufacturers represented to the FDA that the preservatives used in the vaccine were "safe."

147. This representation is, under information and belief, made in each Vaccine Manufacturer's license application.

148. The express warranty put forth in the marketing, distribution, and sale efforts of the Vaccine Manufacturers, Thimerosal Manufacturers, and Distributer Defendants, and their sales teams and representatives, that the vaccines contain a "safe" preservative induced the plaintiffs and the prescribing physician to use the vaccines, and the Plaintiffs' damages were proximately caused because the express warranty was untrue.

These allegations are insufficient to state a breach of express warranty claim under the LPLA against the Thimerosal defendants. Plaintiffs do not allege the existence or content of any specific express warranty about Thimerosal with which the product did not conform. Plaintiffs do not allege any representation or statement of alleged fact or promise made by the Thimerosal defendants about Thimerosal or its nature, material or workmanship that represents, affirms or promises that Thimerosal or its nature, material or workmanship possessed specified characteristics or qualities that met a specified level of performance. Because plaintiffs have not adequately stated a breach of

express warranty claim under the LPLA against the Thimerosal defendants, plaintiffs' motion to amend the complaint is DENIED as to asserting such claims.

## **2. Redhibition (Proposed Amended Complaint Count IV)**

Redhibition is a viable claim against a manufacturer to recover pecuniary loss, but not as a theory of recovery for personal injury. Jefferson, 106 F.3d at 1251. "Redhibition is the avoidance of a sale because of some vice or defect in the thing sold. It requires the seller to return the purchase price and the buyer to return the thing purchased." Capitol City Leasing Corp. v. Hill, 404 So.2d 935, 939 (La. 1981); see also LA. CIV. CODE arts. 2520, 2532. A defect is redhibitory, and gives the buyer the right to obtain rescission of the sale, "when it renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect." LA. CIV. CODE art. 2520. A defect may also be redhibitory, and gives the buyer the right to a reduction in the price, "when, without rendering the thing totally useless, it diminishes its usefulness or its value so that it must be presumed that a buyer would still have bought it but for a lesser price." Id.

In the Proposed Amended Complaint, plaintiffs recite Article 2520, and state that they "are entitled to recover their economic losses where there are redhibitory defects, or vices in the vaccines sold." Plaintiffs do not allege that they are seeking a return of the purchase prices or a reduction in the purchase prices of the vaccines. Instead, the allegations in the proposed amended complaint indicate that they are attempting to collect personal injury damages through a redhibition claim, which is prohibited under the LPLA. Jefferson, 106 F.3d at 1251. Thus, plaintiffs' motion to amend the complaint is DENIED as to asserting Count IV of the Proposed Amended Complaint because it would be futile.

## CONCLUSION

**IT IS HEREBY ORDERED** that Eli Lilly and Company's Motion for Judgment on the Pleadings (Doc. #49) is **GRANTED**.


**IT IS FURTHER ORDERED** that Sanofi Pasteur Inc., Merck Sharpe & Dohme Corp. and GlascoSmithKlien LLC's Motion to Dismiss (Doc. #51) is **GRANTED**.

**IT IS FURTHER ORDERED** that American International Chemical, Inc.'s Motion to Dismiss (Doc. #55) is **GRANTED**.

**IT IS FURTHER ORDERED** that Plaintiffs' Motion to Strike (Doc. #60) is **DENIED**.

**IT IS FURTHER ORDERED** that Plaintiffs' Motion for Leave to Supplement and Amend the Complaint (Doc. #81) is **GRANTED** as to bringing claims of Jacob Guillot under the Louisiana Products Liability Act ("LPLA"), Louisiana Revised Statutes § 9:2800.51, et seq., for failure to warn against Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc. (Count III of the Proposed Amended Complaint). The motion is **DENIED** as to asserting claims of Jacob under the LPLA for composition and construction, design defects and breach of warranty as to Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc. (Count III of the Proposed Amended Complaint), all proposed claims against Sanofi Pasteur Inc., Merck Sharpe & Dohme Corp. and GlascoSmithKlien LLC's (Counts I through VIII of the Proposed Amended Complaint), and Counts I, II, and IV through VIII of the Proposed Amended Complaint against Eli Lilly and Company, American International Chemical, and Spectrum Laboratory Products, Inc.

New Orleans, Louisiana, this 22nd day of August, 2013.

  
MARY ANN VIAL LEMMON  
UNITED STATES DISTRICT JUDGE