UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

EVAN BURKS, by her parents and natural guardians, Rockland Burks and Adrienne Burks, and ROCKLAND BURKS and ADRIENNE BURKS, individually, Plaintiffs, v. ABBOTT LABORATORIES, ABBOTT LABORATORIES ROSS PRODUCTS DIVISION, ABBOTT LABORATORIES, INC., BRISTOL-MYERS SQUIBB COMPANY, and MEAD JOHNSON & CO., Defendants.	Civil No. 08-3414 (JRT/JSM) **MEMORANDUM OPINION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO DISMISS THE FOURTH AMENDED COMPLAINT**

Stephen C. Rathke, **LOMMEN, ABDO, COLE, KING & STAGEBERG, P.A.**, 80 South Eighth Street, Suite 2000, Minneapolis, MN 55402; and Richard H. Taylor, **TAYLOR MARTINO & ZARZAUR**, 51 Saint Joseph Street, Mobile, AL 36601, for plaintiffs.

June K. Ghezzi and Melissa B. Hirst, **JONES DAY**, 77 West Wacker Drive, Suite 3500, Chicago, IL 60601; and Jeannine L. Lee, Robert Bennett, Wendy M. Canaday and Sara H. Daggett, **FLYNN GASKINS & BENNETT, LLP**, 333 South Seventh Street, Suite 2900, Minneapolis, MN 55402, for defendants Abbott Laboratories, Abbott Laboratories Ross Products Division, and Abbott Laboratories, Inc.

Anthony J. Anscombe, **SEDGWICK, DETERT, MORAN & ARNOLD LLP**, 1 North Wacker Drive, Suite 4200, Chicago, IL 60606; Karen E. Woodward, **SEDGWICK, DETERT, MORAN & ARNOLD LLP**, 801 South Figueroa Street, 19th Floor, Los Angeles, CA 90017; and Frederick W. Morris and Jeffrey A. Ehrich, **LEONARD STREET AND DEINARD, PA**, 150 South Fifth Street, Suite 2300, Minneapolis, MN 55402, for defendants Bristol-Myers Squibb Company and Mead Johnson & Co.

Plaintiffs Evan Burks, and Evan's parents Rockland and Adrienne Burks (collectively, "the Burks"), brought this action against defendants Abbott Laboratories, Abbott Laboratories Ross Products Division, Abbott Laboratories, Inc. (collectively, "Abbott"), and Bristol-Myers Squibb Company and Mead Johnson & Company (collectively, "Mead"), alleging products liability claims under the Louisiana Products Liability Act ("LPLA") relating to Evan's consumption of powdered infant formula. On July 24, 2009, this Court granted in part and denied in part defendants' motions to dismiss the Burks' Third Amended Complaint ("TAC") and granted the Burks leave to amend. The case is now before the Court on Abbott and Mead's motions to dismiss the Burks' Fourth Amended Complaint ("FAC") for failure to state a claim. For the reasons set forth below, the Court grants in part and denies in part those motions.

BACKGROUND[1]

On June 19, 2006, Evan Burks was born at the St. Francis Medical Center in the Parish of Ouachita, Louisiana. (Fourth Am. Compl. ("FAC") ¶ 6, Docket No. 111.) Evan was born full term, and for the first 28 days of her life – or the period when Evan was a "neonate" – Evan had a normal immune system for her age. (*Id.* ¶ 7.)

[1] For the purposes of the motions to dismiss, the Court accepts the factual allegations contained in the FAC as true. *Bhd. of Maint. of Way Employees v. Burlington N. Santa Fe R.R.*, 270 F.3d 637, 638 (8th Cir. 2001) (per curiam); *see also Ashcroft v. Iqbal*, --- U.S. ---, 129 S. Ct. 1937, 1949 (2009).

In June 2006, prior to Evan's birth, Abbott sent unsolicited mailings to Rockland and Adrienne Burks at their home address in Louisiana. (*Id.* ¶ 8.) Abbott included in those mailings four packets of infant formula, one of which was a packet of Similac Isomil Advance powdered infant formula ("Similac"). (*Id.*) On or around June 26, 2006, Rockland and Adrienne purchased two cans of Enfamil ProSobee Lipil powdered infant formula ("Enfamil") – which was manufactured by Mead – from a WalMart in Monroe, Louisiana. (*Id.* ¶ 9.) On June 26, 2006, Rockland and Adrienne began feeding Evan the Similac and Enfamil powdered formulas. (*Id.* ¶ 10.) On July 2, 2006, after showing signs of illness, Evan was admitted to the Neonatal Intensive Care Unit of St. Francis Medical Center. (*Id.* ¶ 12.) Evan was diagnosed with neonatal *Enterobacter sakazakii* ("*E. sakazakii*") meningitis, which caused her to suffer severe brain damage. (*Id.*)

Food-borne ingestion of *E. sakazakii* bacteria is the only known cause of neonatal *E. sakazakii* meningitis, and powdered infant formula is the only demonstrated source of neonatal *E. sakazakii* meningitis. (*Id.* ¶ 14.) All but one of the cases of neonatal *E. sakazakii* meningitis documented by the Centers for Disease Control has been associated with powdered infant formula. (*Id.* ¶ 15.) The Burks allege that the Similac and Enfamil powdered infant formulas were the source of the bacteria that caused Evan's neonatal *E. sakazakii* meningitis. (*Id.* ¶ 16.)

The Burks claim that the bacteria that caused Evan's illness originated from "the bacteria colony or its progeny" that contaminated Abbott's and Mead's powdered infant formula facilities, finished product powdered infant formula prior to distribution, and/or

cans of powdered infant formula. (*Id.* ¶¶ 17-18.) The Burks allege that a match between Evan's *E. sakazakii* DNA and DNA found in defendants' factories, manufacturing equipment, raw materials, or finished products, will identify the source of the bacteria that caused Evan's injuries. (*Id.* ¶ 19.) The Burks further allege that after Mead recalled its powdered infant formula on March 29, 2002, because of *E. sakazakii* contamination, the FDA tested samples of powdered infant formula at manufacturing facilities nationwide and determined that 23% of those samples contained *E. sakazakii* bacteria. (*Id.* ¶ 22.) Moreover, the Burks allege "on information and belief" that between March 29, 2002, and July 3, 2006, Abbott's and Mead's facilities, environmental samplings of the raw ingredients in Similac and Enfamil, and samplings of the finished Similac and Enfamil products tested positive for *E. sakazakii* bacteria. (*Id.* ¶¶ 23-28.)

Plaintiffs filed their FAC on August 17, 2009, alleging four claims under the LPLA, alleging that Similac and Enfamil are unreasonably dangerous (1) in composition or construction, (2) in design, (3) because of inadequate warning, and (4) for failure to conform to an express warranty. (Docket No. 111.) Abbott and Mead thereafter filed separate motions to dismiss the FAC pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim.

DISCUSSION

I. STANDARD OF REVIEW

In reviewing a complaint under a Rule 12(b)(6) motion to dismiss, the Court considers all facts alleged in the complaint as true, and construes the pleadings in a light

most favorable to the non-moving party. *See, e.g., Bhd. of Maint. of Way*, 270 F.3d at 638. To survive a motion to dismiss, however, a complaint must provide more than "'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action.'" *Iqbal*, --- U.S. ---, 129 S. Ct. at 1949 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). That is, to avoid dismissal, a complaint must include "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Id.* (internal quotation marks omitted). "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.* "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility," and therefore, must be dismissed. *Id.* (quoting *Twombly*, 550 U.S. at 557) (internal quotation marks omitted).

II. THE LOUISIANA PRODUCTS LIABILITY ACT

The LPLA "establishes the exclusive theories of liability for manufacturers for damage caused by their products." La. Rev. Stat. § 9:2800.52. That is, "[a] plaintiff may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability not set forth in the LPLA." *Jefferson v. Lead Indus. Ass'n, Inc.*, 930 F. Supp. 241, 244-45 (E.D. La. 1996), *aff'd*, 106 F.3d 1245 (5th Cir. 1997) (citing La. Rev. Stat. § 9:2800.52). Under the LPLA, a plaintiff must plead and prove that a "characteristic of the product that renders the product unreasonably dangerous" proximately caused the plaintiff damage and that that damage "arose from a reasonably

anticipated use of the product." La. Rev. Stat. § 9:2800.54(A); *Jefferson*, 930 F. Supp. at 245 (holding that to plead a prima facie LPLA claim, the plaintiff must allege (1) "that the defendant is a manufacturer of the product"; (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"). A plaintiff may show that a product is unreasonably dangerous (1) in construction or composition; (2) in design; (3) because of inadequate warnings; or (4) because of nonconformity to an express warranty. La. Rev. Stat. § 9:2800.54(B)(1)-(4). The Court addresses each theory of liability in turn.

A. The Burks Have Not Adequately Pled that Similac and Enfamil Were Unreasonably Dangerous in Construction or Composition.

Under a heading in the FAC entitled "Defects of Design and Manufacture," the Burks allege that the Similac and Enfamil powdered formulas were unreasonably dangerous in construction or composition. The LPLA provides that "[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. Rev. Stat. § 9:2800.55.

The Burks allege:

> On information and belief and in the alternative, either Defendants' powdered infant formula that Evan consumed deviated in a material way

> from Defendants' specifications and/or performance standards and was, therefore, unreasonably dangerous to the ordinary consumer and/or neonate in composition, or Defendants' specifications and/or performance standards were deficient and caused unreasonably dangerous powdered infant formula to enter the market and be consumed by Evan.

(FAC ¶ 38, Docket No. 111.)

Notwithstanding several other paragraphs alleging facts relating to manufacturing or storage processes, the Burks do not allege a plausible construction or composition defect claim under the LPLA. The Burks do not allege any facts describing or identifying defendants' manufacturing specifications or standards. As a consequence, the Burks are further unable to allege facts describing how defendants' products deviated from such specifications or standards.

The Burks' allegations are limited to a formulaic recitation of the LPLA elements and to legal conclusions, which the Court does not assume as true. *Iqbal*, 129 S. Ct. at 1949. The Burks contend that they would need to conduct discovery to more substantially allege the facts underlying their claims and that allegations of "indirect facts" are sufficient to survive a motion to dismiss for failure to state a claim. The Burks, however, may not offer these "unadorned" claims, *id.*, and merely "le[ave] open the possibility that [plaintiff] might later establish some 'set of undisclosed facts' to support recovery." *O'Neil v. Simplicity, Inc.*, 553 F. Supp. 2d 1110, 1113 (D. Minn. 2008) (quoting *Twombly*, 550 U.S. at 560) (first alteration in original). This claim is not plausible on its face, and the Court accordingly grants defendants' motions, and dismisses

with prejudice[2] the Burks' claims that Similac and Enfamil were unreasonably dangerous in construction or composition.

B. The Burks Have Not Adequately Pled that Similac and Enfamil Were Unreasonably Dangerous as a Result of Design Defect.

The Burks allege that defendants are liable under the LPLA for design defects in Similac and Enfamil powdered infant formulas. A product is unreasonably dangerous in design if at the time it 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 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, if any, of such alternative design on the utility of the product." La. Rev. Stat. § 9:2800.56.

The Burks allege that "manufacturing and storage design defects" introduced *E. sakazakii* bacteria into Similac and Enfamil powdered formulas. (FAC ¶¶ 33-34, Docket No. 111.) Further, the Burks assert that "[t]he likelihood that Defendants' design would cause its products to be unreasonably dangerous outweighed Defendants' burden of adopting alternative manufacturing and storage processes and designs." (*Id.* ¶ 36.) The Burks also allege that "[b]ecause liquid infant formula is sterile, it is a safe

[2] The Court concludes that dismissal with prejudice of the Burks' construction or composition defect claims, design defect claims, and express warranty claims is appropriate given that this is the Burks' **fourth** amended complaint.

alternative for neonates, premature infants and infants with immune problems." (*Id.* ¶ 43.)

1. The Burks Have Not Pled the Availability of an Alternative Design.

Defendants argue that the Burks' design-defect allegations are deficient because they do not identify a suitable alternative design for the powdered infant formulas.

The Burks' FAC alleges that three "alternative" manufacturing or storage processes would "decrease[] the incidence" of *E. sakazakii* bacteria in defendants' powdered infant formula "to a level that would have prevented Evan's infection." (*Id.* ¶ 34.) Those alternatives include "biocidally treating finished powdered infant formula in its end-use containers, storing the product in climate-controlled areas and maintaining the manufacturing and storage facilities in a sufficiently clean condition." (*Id.*) As Mead argues, however, the Burks allege only alternative manufacturing or storage processes, not alternative designs of the product. *See* La. Rev. Stat. § 9:2800.56(1) (stating that a product may be unreasonably dangerous in design if "[t]here existed an alternative design for the **product** that was capable of preventing the claimant's damage" (emphasis added).) Thus, even if defendants implemented the Burks' proposed alternative processes, the design of the powdered infant formula would remain the same. Consequently, the Burks have not adequately pled that such "alternatives" constitute alternative product designs for the purposes of a design-defect claim under the LPLA.

To the extent that the Burks claim that liquid infant formula is a suitable alternative design, the Burks appear to confuse the existence of an alternative "design" with an alternative "product." *See McCarthy v. Danek Med., Inc.*, 65 F. Supp. 2d 410, 412 (E.D. La. 1999) (noting that alternative surgical methods for addressing spinal fusion, as compared to alternative designs for fixation devices, were not alternative designs for the purposes of a design-defect action under the LPLA). On the face of the FAC, it appears that liquid infant formula is a different product entirely than powdered infant formula, with unique qualities and advantages or disadvantages. Indeed, defendants argue that powdered and liquid infant formulas have a variety of dissimilarities. Given that defendants' distinguishing facts fall outside the four corners of the FAC, however, this issue may be more appropriately resolved at summary judgment. The Court need not conclude that liquid infant formula is an altogether different product, as the Burks ultimately fail to properly plead the second prong of the analysis, risk-utility.

2. The Burks Have Not Pled Facts Supporting the Risk-Utility Prong.

Mead contends that the Burks have not characterized the "likelihood" of harm presented by the powdered infant formula, other than to allege that its proposed alternative designs would have "decreased the incidence" of the bacteria in the Similac and Enfamil. Abbott further argues that the Burks have not pled any facts describing the burden on defendants of adopting the alternative designs or the adverse effect any such

alternative design would have on the product.[3] The Court agrees. Although the Burks extensively allege the prevalence of *E. sakazakii* bacteria in powdered infant formula, the Burks do not connect that prevalence to a likelihood of injury. Moreover, the Burks do not offer even conclusory allegations regarding the burden on defendants of adopting the alternative product designs.[4]

Accordingly, the Burks design-defect claims are deficient, and the Court dismisses those claims with prejudice.

C. The Burks Have Pled a Plausible Claim for Inadequate Warning.

The Burks allege that defendants failed to adequately warn them of the dangers of feeding Similac and Enfamil powdered infant formula to Evan. Under the LPLA,

> [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.

La. Rev. Stat. § 9:2800.57(A).

---

[3] Mead also argues that the Burks have not pled that the powdered infant formula was "unreasonably dangerous" because the Enfamil warnings and instructions allowed for safe use. *See Jaeger v. Auto. Cas. Ins. Co.*, 682 So. 2d 292, 297 (La. Ct. App. Cir. 1996) ("A product is not unreasonably dangerous in design where the evidence shows that the product can be safely used if the instructions in the operations manual are followed."). The Court does not address this argument here, as it concludes *infra* that the Burks sufficiently pled claims for inadequate warning under the LPLA.

[4] This analysis further calls into doubt the feasibility of liquid infant formula as an alternative design. The Court notes that it would be particularly challenging for a plaintiff to demonstrate or calculate the burden on defendants of eliminating powdered infant formula from the market in favor of liquid formula.

The LPLA defines an "adequate warning" as

> a **warning or instruction** that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made.

La. Rev. Stat. § 9:2800.53(9) (emphasis added). A manufacturer need not provide a warning when the product "is not dangerous to an extent beyond that which would be contemplated by the ordinary user or handler of the product, with the ordinary knowledge common to the community as to the product's characteristics." La. Rev. Stat. § 9:2800.57(B)(1).

The Burks allege that when Abbott mailed samples of Similac powdered formula to them, the packaging included a document entitled "Directions for Preparation and Use," which stated: "Powdered infant formulas are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor."[5] (FAC ¶ 45, Docket No. 111 (internal quotation marks omitted).) The Burks also allege that the Enfamil they purchased had a label entitled "Instructions for Preparation & Use," which stated "Powdered infant formulas are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor." (*Id.* ¶ 47

[5] The Burks appear to contend that an instruction may not constitute a warning for the purposes of a failure-to-warn claim. The LPLA, however, expressly defines "adequate warning" as a "warning or instruction." La. Rev. Stat. § 9:2800.53(9).

(internal quotation marks omitted).) The Burks further claim that the directions or instructions given by defendants "failed to warn Plaintiffs that Defendants' products were unreasonably dangerous to Evan who was a healthy, full-term neonate with a normal immune system for her age." (*Id.* ¶ 52.) Finally, the Burks allege that "Defendants' inadequate warning and/or lack of warning made their products unreasonably dangerous to all infants and, in particular, to full term neonates with normal immune systems for their age." (*Id.* ¶ 53.)

1. Under the FAC, *E. sakazakii* Bacteria is a Characteristic of Powdered Infant Formula, Including Similac and Enfamil.

Abbott argues that the Burks have not identified a "characteristic" of Similac that could cause damage. According to Abbott, *E. sakazakii* bacteria is at best a "contaminant" of powdered infant formula. Moreover, Abbott asserts that "Powdered infant formulas have been around since the 1890s in this country and are heavily regulated by the FDA. . . . They have safely fed millions of babies in hundreds of millions of feedings over those years." (Abbott's Mem. in Supp. of Mot. to Dismiss at 14, Docket No. 121.)

The FAC alleges that the *E. sakazakii* bacteria that caused Evan's injuries originated from contaminations of defendants' powdered infant formula facilities, of finished powdered infant formula, and of cans of the powdered infant formula. (FAC ¶ 17-18, Docket No. 125.) The FAC also alleges that testing of defendants' facilities, raw ingredients, and finished product will yield positive results for *E. sakazakii*. (*Id.* ¶¶ 20-

28.) Notably, the FAC does not explicitly allege that *E. sakazakii* bacteria is a "characteristic" of Similac or Enfamil. However, the Burks allege that the FDA tested samples of powdered infant formula taken from manufacturing facilities nationwide and concluded that 23% of the samples contained *E. sakazakii*. (*Id.* ¶ 22.)

Initially, the Court declines to take judicial notice of Abbott's proposed facts about the history and efficacy of powdered infant formula. Those facts exist only outside the four corners of the FAC. Further, the Burks allege that defendants' products consistently contained the bacteria, and the allegation of FDA testing offers additional support for the claim that *E. sakazakii* is common in all powdered infant formulas. Accepting all allegations as true and permitting the Burks the benefits of all reasonable inferences, it is this Court's view that the Burks have adequately pled that *E. sakazakii* bacteria is a characteristic of Similac and Enfamil powdered formulas.

2. Under the FAC, Defendants Failed to Exercise Reasonable Care to Provide Adequate Warnings to the Burks.

Defendants also contend that the Burks' pleading is deficient because it does not allege facts sufficient to establish that defendants' instructions or warnings were inadequate.

Defendants' product instructions or warnings, as pled by the Burks, are identical. Defendants argue that the instructions direct consumers to consult with their baby's doctor in certain circumstances. The warning describes two categories of infants for whom a consumer should consult with a doctor: "premature infants" and "infants who

might have immune problems." Noticeably absent from these warnings is any instruction that powdered infant formula should not be fed to neonates, or infants under the age of 28 days, or that parents of neonates, specifically, should consult with their baby's doctor about feeding the neonates powdered infant formula. The Burks plainly and clearly allege that "Evan was a full-term baby," and "[d]uring her first 28 days of life, Evan was a neonate and had a **normal immune system for her age**." (*Id.* ¶ 6-7 (emphasis added).) Moreover, the Burks allege that *E. sakazakii* is commonly found in powdered infant formula and that food-borne ingestion of the bacteria is the only known cause of neonatal *E. sakazakii* meningitis. (*Id.* ¶¶ 14-15.) The Burks further allege that defendants were aware that feeding non-sterile powdered infant formula to neonates posed a risk of danger to that class of infants, but failed to warn consumers of that danger. (*Id.* ¶¶ 49-53.)

Given those allegations, the Burks have properly alleged that defendants did not exercise reasonable care to provide adequate warnings to the Burks that their powdered infant formula should not be fed to Evan or other neonates.

The Court notes that the TAC pled that Evan had an immune problem by virtue of her neonatal condition and alleges that Evan was born "premature." (TAC ¶¶ 25-26, Docket No. 69 ("Premature infants and neonates have immune problems because their immune systems are immature. . . . Evan was a neonate and had immune problems because her immune system was immature."); *id.* ¶ 6 ("Evan E. Burks was delivered by cesarean section on June 19, 2006, slightly more than one week premature . . . .").) Defendants assert that those prior "judicial admissions" contradict the Burks' allegations

in the FAC that Evan was born full-term and with a normal immune system for her age, and argue that the Court should not assume those factual allegations as true for the purposes of these motions. Defendants contend that, if the Court strikes the FAC allegations and instead accepts the allegations in the TAC as true, the instructions accompanying Similac and Enfamil were adequate to notify the Burks that they should have consulted with Evan's doctor prior to feeding Evan powdered infant formula.[6]

In the Eighth Circuit, "[i]t is well-established that an amended complaint supercedes an original complaint and renders the original complaint without legal effect." *In re Wireless Tel. Fed. Cost Recovery Fees Litig.*, 396 F.3d 922, 928 (8th Cir. 2005). As the Ninth Circuit has noted, "there is nothing in the Federal Rules of Civil Procedure to prevent a party from filing successive pleadings that make inconsistent or even contradictory allegations." *PAE Gov't Servs., Inc. v. MPRI, Inc.*, 514 F.3d 856, 860 (9th Cir. 2007); *see also id.* at 859 ("The district court has no free-standing authority to strike pleadings simply because it believes that a party has taken inconsistent positions in the litigation. Rather, the district court's powers are generally limited to those provided by the Federal Rules of Civil Procedure. Though the Federal Circuit reached a contrary

[6] On the same grounds, defendants argue that because the TAC alleged that Evan had "immune problems," feeding her the powdered infant formula was not a reasonably anticipated use of the product under the LPLA. *See Broussard v. Procter & Gamble Co.*, 463 F. Supp. 2d 596, 607 (W.D. La. 2006) ("A manufacturer should not reasonably anticipate that a user will disregard explicit warnings and place herself, in direct contravention of those warnings, in a position of obvious peril."). For the reasons set forth in this discussion, the Burks have properly pled in the FAC that their use of the product was reasonably anticipated.

conclusion in *Bradley v. Chiron Corp.*, 136 F.3d 1317, 1326 (Fed. Cir. 1998), no other court of appeals has followed that decision, and we decline to do so.").

Here, there is no indication that the Burks acted in "bad faith" in pleading their FAC. *See MPRI*, 514 F.3d at 860. Indeed, several intervening circumstances warrant the adjustment of the factual allegations between the TAC to the FAC. After the Burks filed the TAC, defendants sought to introduce into the record the labels that accompanied Similac and Enfamil powdered formula, and which provided the relevant instructions or warnings to consumers. (*See* Docket Nos. 96, 99.) Moreover, as a result of the Court's Order of July 24, 2009, the substantive law in this case changed; the Court dismissed the Burks' Minnesota common law claims and required that the Burks plead claims only under Louisiana substantive products liability law. *Burks v. Abbott Labs.*, 639 F. Supp. 2d 1006, 1015 (D. Minn. 2009). It is reasonable that the Burks would amend their pleadings in accordance with those developments. The Court is also not persuaded that the terms "premature" and "full-term," among the many other technical and medical terms at issue, are necessarily contradictory. The Court expects that even experts will disagree on how to define those terms and whether they are, indeed, contradictory. The Court thus finds that striking the Burks' allegations in the FAC is not warranted.

3. The Burks Have Properly Alleged Causation

Defendants argue that the Burks have not alleged a causal link between the content of defendants' product labels and Evan's illness because the Burks do not allege that they read the label. "A central element of a plaintiff's cause of action for failure to adequately

warn of a product's danger is that there must be some reasonable connection between the omission by the manufacturer and the damage, which the plaintiff has suffered." *Boutte v. Kelly*, 863 So. 2d 530, 545 (La. Ct. App. 2003). The FAC alleges, "As a direct and proximate result of Defendants' liability as manufacturers, and due to . . . Defendants' . . . labeling, . . . Plaintiff Evan E. Burks has suffered considerable damages." (FAC ¶ 63, Docket No. 111.) The Burks also allege earlier in the FAC – albeit in the "express warranty" portion of their claims – that the Burks relied on defendants' instructions when they fed Evan Similac and Enfamil. (*Id.* ¶¶ 57, 59.)

The principles announced in *Iqbal* and in the Eighth Circuit do not support dismissal on these grounds. As the Eighth Circuit recently noted, "the complaint should be read as a whole, not parsed piece by piece to determine whether each allegation, in isolation, is plausible." *Braden v. Wal-Mart Stores, Inc.*, --- F.3d ---, 2009 WL 4062105, at *6 (8th Cir. Nov. 25, 2009). Reading the FAC as a whole, the Burks have properly pled causation and, as a result, have adequately pled their inadequate warning claims to survive a motion to dismiss.

As a result, the Court denies Abbott's and Mead's motions to dismiss those claims. The Court also denies defendants' motions to dismiss Rockland and Adrienne Burks' loss of consortium claims to the extent they are premised on the inadequate warning claims.

D. The Burks' Express Warranty Claims Must Be Dismissed

The LPLA provides for manufacturer liability if the product is unreasonably dangerous because it fails to conform to an express warranty provided by the manufacturer. A product's nonconformance to an express warranty is unreasonably dangerous "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. § 9:2800.58; As the Fifth Circuit reiterated, when bringing an express warranty claim under the LPLA, a plaintiff must prove: "(1) the manufacturer made an express warranty regarding the product, (2) the plaintiff was induced to use the product because of that warranty, (3) the product failed to conform to that express warranty, and (4) the plaintiff's damage was proximately caused because the express warranty was untrue." *Caboni v. Gen. Motors Corp.*, 278 F.3d 448, 452 (5th Cir. 2002). 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 or will meet a specified level of performance." La. Rev. Stat. § 9:2800.53(6).

The Burks pled that Abbott provided two express warranties with its product. First, the Burks allege that Abbott provided documents with Similac that "expressly warranted that its product was beneficial and safe for infants who are not premature and do not have 'immune problems.'" (FAC ¶¶ 54-55, Docket No. 111.) Second, the Burks

allege that Abbott stated in a document entitled "Welcome Addition Club" that the Burks "would be comforted 'to know that no other formula has a higher level of special nutrients to help support baby's developing immune system." (*Id.* ¶ 54.)

The Burks' first allegation does not allege the presence of an express warranty under the LPLA. Under the LPLA, an express warranty is an affirmative statement, promise, or representation about a product. La. Rev. Stat. § 9:2800.53(6). The Burks allege that the instructions that form the basis of their inadequate warning claims constitute express warranties by defendants that Similac was "beneficial and safe for infants who are not premature and do not have 'immune problems.'" (FAC ¶ 54, Docket No. 111.) The instructions, however, do not expressly state that Similac is "beneficial and safe" for infants. Rather, the instructions warn parents that some infants – those who are premature or who may have immune problems – should not be fed Similac unless or until directed to do so by the baby's doctor. A warning, however, does not constitute an express warranty under the LPLA. *Hopkins v. Am. Cyanamid Co.*, 666 So. 2d 615, 623 (La. 1996) ("An express warranty is a guarantee which the manufacturer or seller of a good voluntarily undertakes and extends to its customer. It is not a warning . . . .").

The Burks' second allegation of an Abbott express warranty is also deficient. (*See* FAC ¶ 54, Docket No. 111 (alleging that "no other formula has a higher level of special nutrients to help support baby's developing immune system"). Even if the Court could conclude that Abbott's statement constituted an express warranty under the LPLA, the claim fails because the Burks do not allege that Abbott's product failed to conform to

those statements. That is, the Burks do not allege that Similac lacked nutrients, or that the lack of nutrients caused Evan's injury.

Similar to the claims against Abbott, the allegations against Mead state that Mead represented to the Burks that "its product was suitable and beneficial for all infants who are full term and do not have immune problems." (*Id.* ¶ 55.) That language, which is linked to the instructions that form the basis for the Burks' inadequate warning claims, fails to satisfy the requirements for an express warranty for the reasons discussed *supra* regarding Abbott's instructions.

Accordingly, the Court grants defendants' motions and dismisses with prejudice the Burks' express warranty claims.

III. CONCLUSION

As defendants note, the FAC hints at reviving common law product liability claims, which this Court dismissed with prejudice in its Order on defendants' motion to dismiss the TAC. (*See* Order, Docket No. 104.) To the extent that the Burks allege claims for inadequate testing, (*see, e.g.*, FAC ¶ 40, Docket No. 111), negligent sale, labeling, or marketing of Similac or Enfamil, (*see id.* ¶ 63), or any other Minnesota common law claims, the Court reiterates that those claims are not available.

These motions address the Burks' fifth complaint, and the Court's Order on defendants' motions to dismiss will be filed well over a year after defendants removed this action to federal court. The Court expects that defendants' prompt answers to the

Burks' pleadings of the remaining claims and the commencement of discovery will permit this litigation to advance expeditiously.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that defendants' Motions to Dismiss [Docket Nos. 115 and 119] are **GRANTED in part** and **DENIED in part** as follows:

1. The motions are **DENIED** as to the Burks' claims for inadequate warning and as to the loss of consortium claims to the extent those claims are premised on the Burks' inadequate warning claims.

2. The motions are **GRANTED** in all other respects. Accordingly, the Burks' LPLA claims for construction or composition defect, design defect, and failure to conform to an express warranty are **DISMISSED with prejudice**.

DATED: April 20, 2010
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge