UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

ROCKLAND BURKS and ADRIENNE LAWRENCE, *individually, and as parents and natural guardians of E.B.*,	Civil No. 08-3414 (JRT/JSM)
Plaintiffs,	**MEMORANDUM OPINION AND ORDER**
v.	
ABBOTT LABORATORIES and MEAD JOHNSON & CO.,	
Defendants.	

Stephen C. Rathke, Kate G. Westad, and Nicholas A. Dolejsi, **LOMMEN, ABDO, COLE, KING & STAGEBERG, PA**, 80 South Eighth Street, Suite 2000, Minneapolis, MN 55402, for plaintiffs.

June K. Ghezzi, **JONES DAY**, 77 West Wacker Drive, Suite 3500, Chicago, IL 60601, and William J Tipping and Sara H. Daggett, **GASKINS, BENNETT, BIRRELL, SCHUPP, LLP**, 333 South Seventh Street, Suite 2900, Minneapolis, MN 55402 for defendant Abbott Laboratories.

Anthony J. Anscombe, **SEDGWICK LLP**, One North Wacker Drive, Suite 4200, Chicago, IL 60606; and Frederick W. Morris, **LEONARD STREET AND DEINARD, PA**, 150 South Fifth Street, Suite 2300, Minneapolis, MN 55402, for defendant Mead Johnson & Company.

Rockland Burks and Adrienne Lawrence ("plaintiffs") bring this failure to warn action against Abbott Laboratories ("Abbott") and Mead Johnson & Company ("Mead") individually and on behalf of their minor child, E.B. Plaintiffs allege that defendants' powdered infant formula ("PIF") was contaminated with Cronobacter sakazakii (C. sak),

that E.B. became ill after being fed defendants' PIF, and that the PIF was unreasonably dangerous because defendants failed to provide an adequate warning of the risks of C. sak infection.

In July 2009, the Court held that Louisiana law would govern the present action and dismissed plaintiffs' claims that were not brought under the Louisiana Products Liability Act ("LPLA") with prejudice. *See Burks v. Abbott Labs.*, 639 F. Supp. 2d 1006, 1014-15 (D. Minn. 2009). The Court denied defendants' motion to dismiss plaintiffs' LPLA failure to warn claim and the parents' derivative loss of consortium claims, dismissed without prejudice plaintiffs' LPLA claims premised on manufacturing defect, design defect, and express warranty, and allowed plaintiffs to file an amended complaint. *See id.* at 1015-20. In April 2010, the Court again denied defendants' motions to dismiss plaintiffs' LPLA failure to warn claim and the parents' derivative loss of consortium claims, but dismissed plaintiffs' remaining LPLA claims with prejudice. *See Burks v. Abbott Labs.*, Civ. No. 08-3414, 2010 WL 1576779 (D. Minn. Apr. 20, 2010). Accordingly, plaintiffs' sole surviving claim is for failure to warn under the LPLA, along with the parents' derivative loss of consortium claims.

Defendants move for summary judgment and assert, among other things, that plaintiffs' failure to warn claim fails because there is no direct evidence that defendants' PIF was contaminated and because plaintiffs' experts cannot opine that it is more likely than not that one particular defendant caused E.B.'s illness. Defendants assert that they are entitled to summary judgment on the parents' derivative loss of consortium claims because Plaintiffs filed the action after the statute of limitations expired. The Court will

deny defendants' motion with respect to the failure to warn claim and grant the motion to dismiss the parents' loss of consortium claim. A reasonable jury could find that both defendants failed to use reasonable care to provide an adequate warning of a dangerous characteristic of their PIF and that it is more likely than not that the tortious conduct of one of the defendants caused E.B.'s illness. As the Court will explain below, the doctrine of alternative liability is applicable and plaintiffs' failure to warn claim survives summary judgment for that reason. Defendants also bring several motions to exclude plaintiffs' expert witnesses, which the Court will deny because it finds that the experts' opinions are reliable and relevant.

BACKGROUND

I. FACTS

E.B. was born on June 19, 2006. (Decl. of Melissa B. Hirst in Support of Abbott's Motion, Ex. 1 (Dep. of Adrienne Lawrence ("Lawrence Dep. A") 60:19-20), May 21, 2012, Docket No. 323.) She was a healthy, full term baby. (Aff. of Stephen C. Rathke in Opposition, Ex. B (Dep. of Adrienne Lawrence ("Lawrence Dep. B") 172:13-16), June 8, 2012, Docket No. 351-2.) On July 2, E.B. had a fever and plaintiffs took her to the emergency room where she was diagnosed with C. sak[1] meningitis. (*Id.* 188-91; Aff. of Stephen C. Rathke in Opposition, Ex. A (Decl. of Janine Jason, M.D. ("Jason Decl.") ¶ 277), Docket No. 351-2.)

[1] Prior documents in this action have referred to the bacteria as Enterobacter sakazakii or

A. E.B.'s Feedings

During the first week of E.B.'s life, she ate milk-based, ready-to-feed liquid formula at the hospital and at home. (Jason Decl. ¶ 250; Lawrence Dep. B 142-43.) On or about June 27, E.B. showed signs of an upset stomach and Lawrence decided, upon the advice of a physician, to feed E.B. soy-based formula instead of milk-based formula. (Lawrence Dep. B 157-58:16-4.) The only soy-based formula Lawrence had was a sample of Abbott's Similac PIF that she had received in an unsolicited mailing two or three weeks before E.B. was born. (Lawrence Dep. B 155:6-8.) Lawrence fed E.B. a packet of Abbott's PIF on the morning of June 28. (*Id.* 158:6-11.) That same day, Lawrence purchased two cans of Mead's Enfamil ProSobee Lipil PIF. (*Id*. 159:14-22.) Between the afternoon of June 27 or 28 and the evening of June 30, Lawrence fed E.B. Mead's PIF three times. (*Id*. 169:17-24.) Each time Lawrence fed E.B. PIF, she mixed it with Music Mountain bottled water, which was delivered to her home on a weekly basis. (*Id*. 158-65.) Lawrence testified at length regarding the cleanliness of her home, the care she took in sanitizing E.B.'s bottles and storing E.B.'s food, and the care she took to ensure that her hands and the surrounding surfaces were sanitary when she fed E.B. (*See, e.g., id*. 108-25.)

B. The PIF Warning Labels

Mead and Abbott's PIF featured nearly identical instructions and warnings. Mead's label included "Instructions for Preparation & Use," which began as follows:

> Your baby's health depends on carefully following the instructions below. Proper hygiene, preparation, dilution, use and storage are important when preparing infant formula. [PIFs] 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. Ask your baby's doctor which formula is appropriate for your baby.

(Decl. of David J. Grycz in Support, Ex. 12, May 18, 2012, Docket No. 312.) Following the instructions, Mead's label stated that "[f]ailure to follow these instructions could result in severe harm." *Id*. The only use of the word "warning" on the label was a warning that using a microwave to warm the formula could cause serious burns. *Id*.

C. C. sak, PIF, and Neonates

As the labels indicate, PIF is not sterile. According to Mead, this is because it cannot undergo a terminal heat process without destroying the powder. (Mead's Memo in Support at 4-5, May 18, 2012, Docket No. 311.) C. sak is an enteric bacterium that is frequently isolated in PIF, but it has also been isolated in other environments. (Jason Decl. ¶¶ 19, 63, 77.) Although C. sak infections are rare,[2] C. sak outbreaks have historically been linked to PIF. (*Id*. ¶¶ 85-95.) For these reasons, the World Health Organization ("WHO") has convened expert panels on three occasions over the past decade to assess the risks of PIF and identify ways to make PIF safer. (*Id*. ¶ 54.)

The PIF labels suggest that PIF may not be safe for infants who are particularly susceptible to infection, such as premature infants and infants with immune problems.

[2] One of plaintiffs' experts believes there have been only ninety-two reported cases of pediatric C. sak infection between 1958 and 2008. (Jason Decl. ¶ 105.)

But the labels do not explicitly refer to healthy, full term infants. Healthy, full term infants that are less than four weeks old – neonates – do not have fully developed enteric (gut) immunity. (*Id*. ¶ 32.) The root of plaintiffs' failure to warn claim is that healthy, full term neonates are particularly susceptible to C. sak infection (like premature infants and infants with immune problems) and the label should have included a warning about this category of infants as well. (*Id*. ¶ 55.)

D. Investigations Following E.B.'s Diagnosis

Following E.B.'s diagnosis, the Food and Drug Administration ("FDA") and Center for Disease Control ("CDC") commenced an investigation. (Decl. of David J. Grycz in Support, Ex. 4 (Dep. of Adrienne Lawrence ("Lawrence Dep. C") 203-07) May 18, 2012, Docket No. 312.) The FDA obtained the remaining Mead PIF from Lawrence; an unopened can from the same batch, which it purchased at the same store that Lawrence purchased the PIF; and thirty cans from the same batch, which it collected from a distributor's warehouse. (Decl. of David J. Grycz in Support, Ex. 13, May 18, 2012, Docket No. 312.) Testing by the FDA and CDC did not identify C. sak in the samples.[3] The FDA did not conduct any testing of the Burks' home because E.B.'s grandmother had sanitized the home after E.B.'s diagnosis. (*Id*.) The FDA also did not analyze the Music Mountain water dispenser because the investigator believed the jug

[3] C. sak was also not identified in a sample of Abbott's PIF from the batch that included the PIF E.B. consumed. (Decl. of Melissa B. Hirst in Support of Abbott's Motion, Ex. 1 (Dep. of Janine Jason ("Jason Dep.") 303, 350), May 21, 2012, Docket No. 323.)

used for E.B.'s feedings was no longer available. (*Id.*) Plaintiffs' experts contend that the negative tests do not establish that the PIF did not contain C. sak and advance various theories to support their opinions. (*See, e.g.*, Jason Decl. ¶¶ 155-57, 311-14; Aff. of Stephen C. Rathke in Opposition, Ex. C (Decl. of John (Jim) Farmer ("Farmer Decl."), ¶¶ 125-28), June 8, 2012, Docket No. 351-2.)

ANALYSIS

I. MOTIONS FOR SUMMARY JUDGMENT

A. Standard of Review

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party can demonstrate that it is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). A fact is material if it might affect the outcome of the suit, and a dispute is genuine if the evidence is such that it could lead a reasonable jury to return a verdict for either party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A court considering a motion for summary judgment must view the facts in the light most favorable to the non-moving party and give that party the benefit of all reasonable inferences that can be drawn from those facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

B. Failure to Warn

In order to prevail on an LPLA claim, a plaintiff must establish that (1) "the defendant is a manufacturer of the product;" (2) "the product [was] unreasonably dangerous in one of the four ways provided in the statute;" (3) plaintiff's "damage was

proximately caused by [the] characteristic of the product;" and (4) plaintiff's "damage arose from a reasonably anticipated use of the product." *See Jefferson v. Lead Indus. Ass'n, Inc.*, 106 F.3d 1245, 1251 (5th Cir. 1997). With respect to the second element, plaintiffs allege that the PIF was unreasonably dangerous because an adequate warning was not provided. More specifically, 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). The LPLA defines "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). A manufacturer is not required to provide a warning when "[t]he 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" or when "[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." La. Rev. Stat. § 9:2800.57(B)(1)-(2).

The burden of proving each element is on the plaintiff. *See* La. Rev. Stat. Ann. § 9:2800.54(D). In the motions before the Court, defendants do not dispute that they are

manufacturers of the PIF, that C. sak contamination is a "characteristic" of PIF that may cause damage, or that plaintiffs' use of the PIF was a reasonably anticipated use. Mead moves for summary judgment on the basis that it had no obligation to warn of "remote risks," that it took reasonable care to provide adequate warnings, and that plaintiffs cannot establish by a preponderance of the evidence that Mead's PIF, or any company's PIF, caused E.B.'s illness. Abbott moves for summary judgment on the basis that plaintiffs cannot establish by a preponderance of the evidence that Abbott's PIF, or any company's PIF, caused E.B.'s illness, and that plaintiffs cannot establish that Abbott's warning, if it was inadequate, proximately caused E.B.'s illness. There is substantial overlap between the defendants' motions for summary judgment and the Court will distinguish between the defendants only where necessary.

1. Duty to Warn

The Court must first determine whether "duty" is a question for the Court and or the jury in an LPLA failure to warn action. Mead contends that under Louisiana law, manufacturers have no obligation to warn of remote risks. On the one hand, Mead's proposition could mean that **the court** must determine whether a manufacturer has a duty to warn of a particular risk in light of the risk's remoteness and if so, the jury merely decides whether such a warning was adequately provided. On the other hand, Mead's proposition could mean that **the jury** decides whether particular risks warrant warnings and also whether adequate warnings were provided, but that the court may find in certain

cases that no reasonable jury could find that a particular risk is sufficient to warrant a warning. The Court concludes that the latter framework is correct under Louisiana law.

Whether a manufacturer has a duty to warn consumers of a particular danger posed by its product appears to be a question for the jury under Louisiana law. *See Manuel v. Am. Bank & Trust Co.*, No. Civ. A. 88-3562, 1990 WL 728, at *1 (E.D. La. Jan. 2, 1990) (citing *Boudreaux v. Jack Eckerd Corp.*, 854 F.2d 85 (5th Cir. 1988)).[4] For example, there are certain situations where a manufacturer has no duty to warn, such as "when the purchaser has particular knowledge of or experience with the inherent dangers in the use of a product," *see* La. Rev. Stat. § 9:2800.57(B)(2), and the jury determines whether a case presents such a situation. *See Mozeke v. Int'l Paper Co.*, 933 F.2d 1293, 1297 (5th Cir. 1991). Additional Louisiana cases and jury instructions also suggest that it is the jury's responsibility to determine whether a product possesses a characteristic that may cause damage and whether the defendant used reasonable care to provide an adequate warning of the characteristic. *See, e.g.*, *Lozano v. Touro Infirmary*, 778 So. 2d 604, 613 (La. Ct. App. 2000); *Simon v. Am. Crescent Elevator Co.*, 767 So. 2d 64, 74 (La. Ct. App. 2000); *see also* 18 La. Civ. L. Treatise, Civ. Jury Instructions § 11:3 (3d

[4] The Court notes that in *Perez v. Michael Weinig, Inc.*, No. Civ. A. 304CV0448, 2005 WL 1630018, at *6 (W.D. La. July 7, 2005), a United States Magistrate Judge stated that "[w]hether defendant owes plaintiff a duty to warn is a question of law." However, the court formulated the "duty" as a general "duty to warn of the known risks of using its product." *Perez* is not controlling and even if it were, it would not change the Court's analysis because in the present case, like in *Perez*, there is no dispute that defendants owe a general duty to warn consumers about dangerous characteristics of their product. *Perez* does not suggest that the Court, not the jury, makes more subtle determinations about the scope of the duty and whether a defendant breached its duty.

ed.). In other words, the jury is charged with determining both the contours of a defendant's duty to warn and whether defendants breached the duty.

Mead cites several cases in which courts have held, as a matter of law, that certain risks were so remote that no warnings were required. All of the cases were decided prior to the enactment of the LPLA or were decided after the enactment but applied pre-LPLA law. *See, e.g., Blalock v. Westwood Pharms., Inc.*, Civ. No. 89-2117, 1990 WL 10557, at *2 (E.D. La. Jan. 30, 1990) (holding that manufacturers are not obligated to warn against the possibility of "a rare or idiosyncratic reaction"); *Thomas v. Gillette Co.*, 230 So. 2d 870, 875 (La. Ct. App. 1970) ("[T]he possibility of danger from an allergic reaction to [the product] was so remote and unlikely that defendant was under no duty to warn purchasers or users of such a possibility."). To the extent that these cases hold that the Court, not the jury, is responsible for determining whether a manufacturer has a duty to warn consumers of a particular risk, the Court concludes that they are no longer good law in light of the LPLA.

The LPLA expressly provides two exceptions in which a manufacturer is not required to provide an adequate warning. *See* La. Rev. Stat. § 9:2800.57(B)(1)-(2). The LPLA does not include a third exception for remote risks. The omission of an exception for remote risks indicates that the remoteness of the risk is simply a factor for the jury to weigh in determining whether the manufacturer exercised "reasonable care to provide an

adequate warning," not a categorical exception to a manufacturer's duty to warn.[5] *See Watt v. GMAC Mortg. Corp.*, 457 F.3d 781, 783 (8th Cir. 2006) ("A standard axiom of statutory interpretation is *expressio unius est exclusio alterius*, or the expression of one thing excludes others not expressed."); *Filson v. Windsor Court Hotel*, 907 So. 2d 723, 728 (La. 2005) (discussing and applying the same rule of construction). It bears noting, though, that even if there were a third categorical exception where manufacturers had no obligation to provide an adequate warning, it would be for the jury to determine whether a case fell within the exception because Louisiana law appears to charge juries with determining whether a case falls within an exception to a manufacturer's duty to warn.

In the present case, the practical impact of the Court's conclusion is that it is not for the Court to determine whether defendants had a specific duty to warn consumers of the risk that potential C. sak contamination in PIF poses for healthy, full term neonates. Defendants' duty under the LPLA is to use reasonable care to provide an adequate warning of a characteristic of their product that may cause damage. It is for the jury to determine whether such a characteristic exists, and if so, whether defendants took reasonable care to provide an adequate warning.

[5] A Louisiana commentator reached the same conclusion. *See* John Kennedy, *A Primer on the Louisiana Products Liability Act*, 49 La. L. Rev. 565, 616 (1989) ("Among the factors that should be considered in ascertaining whether a manufacturer has exercised such reasonable care [is] . . . [t]he likelihood and gravity of the danger.").

2. Reasonable Care to Provide Adequate Warnings

Defendants' primary contentions regarding the reasonableness and adequacy of the warning are (1) that the risk of E.B.'s illness was so remote that they did not need to provide a warning regarding it and (2) that a more detailed warning including an explicit reference to C. sak and an explicit reference to neonates would be unreasonable because it would contribute to public health risks rather than alleviate them.

Mead cites a number of cases to suggest that it did not need to provide a warning because the risk of E.B.'s illness was remote. The Court concluded above that these cases, to the extent that they created a categorical "remoteness" exception to a manufacturer's duty to warn, are inconsistent with the LPLA. However, the facts of these cases are still somewhat relevant to determining what findings a jury could reasonably make on the basis of the facts of the present case. For example, in *Blalock*, 1990 WL 10557, the plaintiff suffered severe burns in places where she applied sunscreen and the defendant had sold nearly one million units without receiving a similar complaint. *Id.* at *2. The court noted that even the plaintiff's own expert described the reaction as "idiosyncratic in its severity" and held that the defendants were not liable for failure to warn. *Id.*; *see also Guilbeau v. W.W. Henry Co.*, 85 F.3d 1149, 1169 (5th Cir. 1996) (holding that "a single injury" cannot support liability for failure to warn when the product "has been used by thousands of people without any other reported injuries").

Here, plaintiffs' experts offer substantial evidence suggesting that although C. sak infection is rare, there is a well-documented connection between PIF and C. sak infection and E.B.'s severe illness was not one-of-a-kind. For example, an expert meeting

convened by the World Health Organization and the Food and Agriculture Organization of the United Nations to analyze the risks of C. sak contamination in PIF concluded that "intrinsic contamination of [PIF] with [C. sak] . . . has been a cause of infection and illness in infants" and "[a]mong infants those at greatest risk for [C. sak] infection are neonates (first 28 days), particularly pre-term infants, low birth-weight infants or immunocompromised infants." (Aff. pf Stephen C. Rathke, Ex. F, June 4, 2012, Docket No. 347.)

As for the potential consequences of a more detailed warning, defendants contend that other than breast feeding, no alternatives to PIF present lower overall risks, and a more detailed warning would "send consumers in the direction of feeding sources that were substantially less safe than formula, such as cow's milk, goat's milk and homemade concoctions." (Memo. in Support of Mead's Motion for Summ. J. at 27, May 18, 2012, Docket No. 311.) Plaintiffs contend that there is no basis for defendants' concern and that a more detailed warning would provide consumers opportunity to make an informed choice, which they are entitled to under the LPLA. Specifically, plaintiffs argue that defendants already provided a warning that PIF is not sterile and referred to premature infants or infants who might have immune problems, but the warnings are insufficient because they do not explicitly refer to healthy, full-term neonates.

Whether it is reasonable for a manufacturer to omit a warning regarding a particular risk is a factually specific inquiry for the jury to decide. *See, e.g., Wood v. SubSea Intern., Inc.*, 766 So. 2d 563, 569 (La. Ct. App. 2000) ("What actions are reasonable under the circumstances is a question of fact to be determined by the fact

finder."); *Williams v. Super Trucks, Inc.*, 842 So. 2d 1210, 1217-18 (La. Ct. App. 2003) ("Whether a particular warning on a product is adequate is a question for the trier of fact."). The Court finds that genuine issues of material fact remain regarding the reasonableness of defendants' warnings. The parties dispute the remoteness of the risk and what consequences might flow from a more detailed warning, among other things. A jury could find that Mead and Abbott struck a reasonable balance with their warnings after considering a number of factors such as the likelihood of the risk, the gravity of the risk, the feasibility of providing an effective warning, and the consequences of providing a more detailed warning. On the other hand, given the severity of the potential harm, the known association between C. sak and PIF, and the heightened risk posed to neonates, a jury could reasonably conclude that Mead and Abbott failed to exercise reasonable care to provide an adequate warning because their warnings seemingly suggested that their PIF posed risks for premature infants and infants with immune problems, but not for healthy, full-term neonates.

3. Causation

a. Alternative Liability

Defendants' primary argument regarding why plaintiffs cannot establish causation is that they are entitled to summary judgment because plaintiffs' experts cannot opine that a particular defendant's PIF was more likely than not the cause of E.B.'s illness and plaintiffs therefore have failed to meet their burden of proof with respect to causation. Plaintiffs' experts opine that contaminated PIF manufactured by one of the defendants

was more likely than not the cause of E.B.'s illness, but cannot opine that either company's PIF was more likely than not the cause. (*See* Jason Decl. ¶ 432; Farmer Decl. ¶ 64; Aff. of Stephen C. Rathke in Opposition, Ex. B (Decl. of Catherine Donnelly, Ph.D ("C. Donnelly Decl.") ¶ 15), June 8, 2012, Docket No. 351.) Plaintiffs argue that the doctrine of alternative liability allows their claim to proceed.

Whether a plaintiff may invoke the doctrine of alternative liability in an action under the LPLA appears to be an unresolved question of Louisiana law. When confronted with a novel or unresolved issue of state law, this Court's duty is to predict how the state supreme court would resolve the issue.[6] *See Spine Imaging MRI, L.L.C. v. Country Cas. Ins. Co.*, 2011 WL 379100, at *6 (D. Minn. Feb. 1, 2011) (citing *Midwest Oilseeds, Inc. v. Limagrain Genetics Corp.*, 387 F.3d 705, 715 (8th Cir. 2004)). The Court will first outline the doctrine of alternative liability, then explain why the present case satisfies the requirements of the doctrine, then predict whether the Louisiana Supreme Court would apply the doctrine.

A 1948 case, *Summers v. Tice*, 199 P.2d 1 (Cal. 1948), is crediting with giving birth to alternative liability. The doctrine has gained widespread acceptance and has been adopted by the Restatement, which defines the doctrine as follows:

> When the plaintiff sues all of multiple actors and proves that each engaged in tortious conduct that exposed the plaintiff to a risk of harm and that the

[6] This approach is not followed in all circuits. *See, e.g., Thompson v. Johns-Manville Sales Corp.*, 714 F.2d 581, 583 (5th Cir. 1983) (refusing to consider applying market share liability in a case governed by Louisiana law because no Louisiana court had adopted the doctrine and "[s]uch departures are for the Louisiana courts, not for us").

> tortious conduct of one or more of them caused the plaintiff's harm but the plaintiff cannot reasonably be expected to prove which actor or actors caused the harm, the burden of proof, including both production and persuasion, on factual causation is shifted to the defendants.

Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 28(2) (2010).[7] Alternative liability has been rejected by only two states and only in one instance by a state supreme court. *See* Restatement (Third) of Torts § 28, Reporters' Note.[8] As the Restatement explains, to prevail a plaintiff must prove that each defendant's conduct was tortious and that the tortious conduct of one or more of the defendants caused the plaintiff's harm. Further, the doctrine applies only if "all persons whose tortious acts exposed the plaintiff to a risk of harm [are] joined as defendants." *See* Restatement (Third) of Torts § 28 cmt. h; *see also Doe v. Baxter Healthcare Corp.*, 380 F.3d 399, 408 (8th Cir. 2004) (explaining that alternative liability imposes a "much stiffer burden" on plaintiffs than market share liability, because plaintiffs "must target all the companies that might have been liable and prove that each had a duty of care that it breached"). "The rationale for shifting the burden of proof to defendants whose tortious conduct

[7] The Restatement (Second) of Torts § 433B(3) (1965) also included alternative liability, and it defined the doctrine similarly:

> Where the conduct of two or more actors is tortious, and it is proved that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm.

[8] Minnesota is one of the two jurisdictions reported as rejecting alternative liability. *See* Restatement (Third) of Torts § 28, Reporters' Note (citing *Leuer v. Johnson*, 450 N.W.2d 363 (Minn. App. 1990)). However, the Reporters' Note describes *Leuer* as unpersuasive, and Minnesota commentators note that the Minnesota Supreme Court has not categorically rejected alternative liability. *See* Michael K. Steenson *et al.*, Minn. Prac., Products Liability Law § 3.19 (2012).

exposed the plaintiff to a risk of harm is that, as between two culpable defendants and an innocent plaintiff, it is preferable to put the risk of error on the culpable defendants." Restatement (Third) of Torts § 28 cmt. g.

At the summary judgment stage, the present case meets the requirements of alternative liability. As the Court explained above, a jury could reasonably find that both Abbott and Mead's conduct was tortious – that is, that both Abbott and Mead breached a duty to plaintiffs by manufacturing a product that "possessed a characteristic that may cause damage and . . . fail[ing] 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). Additionally, all potentially liable parties are before the Court because E.B. did not consume PIF manufactured by any other companies. Finally, a reasonable jury could find, on the basis of plaintiffs' experts' opinions, that "one or more of the[] [defendants] caused the plaintiff's harm but the plaintiff cannot reasonably be expected to prove which actor or actors caused the harm." Restatement (Third) of Torts § 28(2).

Defendants contend that alternative liability cannot apply in the present case because plaintiffs' experts have not ruled out potential environmental causes other than PIF with 100% certainty. In the classic alternative liability case, *Summers*, there were no potential causes other than the two defendants' who fired their shotguns in the plaintiff's direction. *See Summers*, 199 P.2d at 2. While the present case is distinguishable from *Summers* because environmental sources other than the defendants' PIF could have caused E.B.'s illness, the Court concludes that alternative liability is applicable if a plaintiff proves by a preponderance of the evidence that one of the defendants caused the

harm. The Court has located very little authority on this specific question, but some courts agree that a preponderance of the evidence is the appropriate standard. *See, e.g.*, *Anderson v. Anderson*, 959 N.E.2d 1167, 1173-74 (Ill. App. Ct. 2011) ("The plaintiff must still prove that the manufacturers failed to provide adequate warnings and that the injuries suffered by her husband were, in fact, caused by [the drug]. Thus, . . . alternative liability does not shift the burden of proof for causation . . . onto the defendants until plaintiff has proven its case by a preponderance of the evidence."). According to the Restatement, the causation element of alternative liability is satisfied if the plaintiff "**proves** that . . . the tortious conduct of one or more of the[] [defendants] caused the plaintiff's harm." Restatement (Third) of Torts § 28(2) (emphasis added). The Restatement does not suggest that "proves" refers to something greater than the typical burden of proof for civil cases, which is a preponderance of the evidence. If a plaintiff establishes that both defendants' engaged in tortious conduct, that the harm was more likely than not caused by one of the defendants' tortious conduct, and that all potentially liable defendants are joined in the action, the policies underlying alternative liability are served by applying the doctrine.

Having established that plaintiffs' case satisfies the requirements of alternative liability, the Court must determine whether the Louisiana Supreme Court would apply the doctrine in the present case. Louisiana courts have neither accepted nor rejected alternative liability, but they have accepted a somewhat analogous burden-shifting doctrine called the "guest passenger presumption." *See, e.g.*, *Richardson v. Aldridge*, 854 So. 2d 923, 935 (La. Ct. App. 2003) (on rehearing). The guest passenger presumption

provides that when "'an innocent party is injured through the concurrent acts of two parties under circumstances where one or the other must be at fault, the burden is upon these parties to exculpate themselves from negligence.'" *Id.* (quoting *Eason v. Hartford Accident & Indem. Co.*, 327 So. 2d 187, 190 (La. Ct. App. 1976)). Under the guest passenger presumption, the plaintiff is relieved of the burden of proving which of two drivers was negligent if "the circumstances of the accident compel a finding that either one or both drivers in a two-car collision must be at fault." *Eason*, 327 So. 2d at 191. Under alternative liability, on the other hand, the plaintiff is relieved of proving that a particular defendant caused the harm, but must prove that all defendants' conduct was tortious. While the doctrines are distinct, the consistent willingness of Louisiana courts to apply the guest passenger presumption and relieve plaintiffs of the burden of proving that a specific defendant was negligent provides some indication that the Louisiana Supreme Court would apply alternative liability in the present case and relieve plaintiffs of the burden of proving that a specific defendant caused the harm.

Defendants argue that even if alternative liability were generally available under Louisiana law, it is unavailable in LPLA actions because the LPLA makes no reference to alternative liability and the statute states that it "establishes the **exclusive theories of liability** for manufacturers for damage caused by their products." La. Rev. Stat. Ann. § 9:2800.52 (emphasis added). The Court concludes, however, that the LPLA's "theories of liability" are the four causes of action outlined in the LPLA, not more specific tort doctrines that relate to certain elements of the four causes of action. *See id.* § 9:2800.54(B)(1)-(4); *see also* John Kennedy, *A Primer on the Louisiana Products*

Liability Act, 49 La. L. Rev. 565, 571 (1989) ("[T]he LPLA 'establishes the exclusive theories of liability for manufacturers for damage caused by their products.' **There are four such theories available under the act**[.]") (footnote omitted) (emphasis added)). The LPLA provides that a manufacturer shall be liable if a product is "unreasonably dangerous in one of four ways: (1) in construction or composition; (2) in design; (3) because an adequate warning has not been provided; or (4) because it does not conform to an express warranty. *Id.* Because plaintiff proceeds on an inadequate warning theory, plaintiffs' claim is within the "exclusive theories of liability" established by the LPLA.[9]

Alternative liability is widely accepted and supported by a sensible rationale; the policies underlying the doctrine would be advanced by applying the doctrine in the present case; Louisiana courts have shown willingness to apply analogous burden-shifting doctrines in tort cases; and the LPLA does not prevent the application of

[9] The Court draws slight support for its conclusion from *George v. Housing Auth. of New Orleans*, 906 So. 2d 1282 (La. Ct. App. 2005). In that case, the court considered whether a plaintiff could utilize the doctrine of market share liability in an LPLA action. *Id.* at 1286-87. Market share liability is somewhat similar to alternative liability, but the two are distinct doctrines. *See Doe v. Baxter Healthcare Corp.*, 380 F.3d 399, 407-09 (8th Cir. 2004). The court in *George* declined to allow plaintiffs to rely on market share liability because the products in question "cannot be deemed fungible[,]" but not because allowing market share liability would necessarily run afoul of the LPLA's exclusive theories of liability. *See George*, 906 So. 2d at 1287.

alternative liability. For all of these reasons, the Court predicts that the Louisiana Supreme Court would allow plaintiffs to proceed relying on alternative liability.[10]

b. Lack of Direct Evidence

Defendants contend that even if alternative liability applies, plaintiffs cannot prove that either defendant's PIF caused E.B.'s illness because there is no direct evidence that the PIF was contaminated and there are other potential environmental sources of C. sak. Plaintiffs acknowledge that there is no direct evidence that the PIF was contaminated. Plaintiffs' experts' method of proof is a "differential etiology," which is a process where

[10] The Court is not alone in predicting that the Louisiana Supreme Court would apply a burden-shifting tort doctrine. *See In re MTBE Prods. Liab. Litig.*, 379 F. Supp. 2d 348, 405-09 (S.D.N.Y. 2005) (noting, in a product liability action, that "Louisiana courts have been silent regarding collective liability theories" and predicting that "Louisiana would be likely to find market share liability applicable").

A remaining question is what burden defendants will face in disproving that they caused E.B.'s illness. The Oregon Supreme Court cited this difficult question as one reason it rejected alternative liability. *See Senn v. Merrell-Dow Pharm., Inc.*, 751 P.2d 215, 223 (Or. 1988) ("In a two defendant situation . . . [a]s to either defendant it is exactly as likely as not that that defendant caused plaintiff's harm. In theory, one of the defendants can escape liability altogether by presenting some scintilla of exculpatory evidence greater than that the other defendant produces, so that the evidence preponderates against the other defendant. Where there are three or more possible defendants, however, the necessary quantum of exculpatory evidence cannot be easily articulated. . . . What lesser degree of likelihood would a defendant have to prove to escape liability?"). In a two defendant situation, like the present case, it seems too arbitrary to allow one defendant to escape liability by merely presenting "some scintilla of exculpatory evidence greater than the other defendant produces." On the other hand, requiring a defendant to prove that it "could not possibly have caused the harm," as one commentator suggests, is too steep a burden. *See* Mark A. Geistfeld, *The Doctrinal Unity of Alternative Liability and Market-Share Liability*, 155 U. Pa. L. Rev. 447, 466 (2006). In the present case, if plaintiffs successfully carry their burden as described above such that the burden shifts to the defendants to prove that they did not cause E.B.'s illness, the Court concludes that an appropriate middle ground is to allow either defendant to avoid liability by proving that it was substantially less likely than the other defendant to have caused E.B.'s illness.

experts determine the most likely cause of a disease by eliminating other potential causes rather than by providing direct evidence that a particular product caused the harm. *See Wagoner v. Exxon Mobil Corp.*, 813 F. Supp. 2d 771, 804 (E.D. La. 2011).

The Court concludes that neither the lack of direct evidence that the PIF was contaminated nor the possibility an environmental source other than PIF caused E.B.'s illness means that plaintiffs' have failed to prove causation as a matter of law. As one Louisiana court explained:

> The plaintiff's burden is to prove causation by a preponderance of the evidence. This burden may be met by direct or by circumstantial evidence. Taken as a whole, circumstantial evidence must exclude other reasonable hypotheses with a fair amount of certainty. This does not mean, however, that it must negate all other possible causes. Otherwise, the mere identification by the record of another possibility, although not shown to be causally active, would break the chain of causation.

Llewellyn v. Lookout Saddle Co., 315 So. 2d 69, 71 (La. Ct. App. 1975).

Plaintiffs' experts claim to have considered all possible causes of E.B.'s illness and opine that contaminated PIF was more likely than not the cause. They reach this opinion after considering a wide range of relevant information, including the fact that C. sak is present in environmental sources other than PIF and that none of the tests of the batches of PIF from which E.B. ate were positive for C. sak. A jury is not required to accept an expert's opinion, and defendants' experts present different opinions, but a jury could reasonably find, on the basis of plaintiffs' experts' opinions, that it is more likely than not that one of defendants' PIFs was contaminated and caused E.B.'s illness.

c. Would Lawrence Have Heeded a Different Warning?

A final issue the Court must consider relating to causation is whether defendants are entitled to summary judgment on the basis that a different warning would not have changed Lawrence's decision to feed PIF to E.B.. Abbott in particular argues that Lawrence decided to feed PIF to E.B. solely because she wanted to switch to a soy-based formula and that the warnings, which she had read weeks prior, did not enter into her mind at the time she made the decision.

Under Louisiana law, "'when a manufacturer fails to give adequate warnings or instructions, a presumption arises that the user would have read and heeded such admonitions.'" *Wagoner v. Exxon Mobil Corp.*, 813 F. Supp. 2d 771, 797 (E.D. La. 2011) (quoting *Bloxom v. Bloxom*, 512 So. 2d 839, 850 (La. 1987)). "The presumption may be rebutted 'if the manufacturer produces contrary evidence which persuades the trier of fact that an adequate warning or instruction would have been futile under the circumstances.'" *Id.* (quoting *Bloxom*, 512 So. 2d at 797). Although *Bloxom* predated the LPLA, Louisiana courts have continued to apply this rebuttable presumption since the enactment of the LPLA. *See, e.g., Grayson v. State ex rel. Dept. of Health and Hosps.*, 837 So. 2d 87, 93 (La. Ct. App. 2002).

In the present case, Lawrence testified that she read the warnings, that she was unaware PIF posed risks to E.B., and that she would not have fed PIF to E.B. had she known the risks. (*See* Lawrence Dep. B 172:6-10.) Lawrence's testimony creates a genuine issue of material fact regarding whether "an adequate warning or instruction would have been futile." A jury might conclude that Abbott has successfully rebutted the

presumption that Lawrence would have heeded an adequate warning, but a reasonable jury could certainly conclude that the presumption applies. For all of the reasons explained above, the Court will deny defendants' motions for summary judgment on plaintiffs' failure to warn claim.

C. Parents' Derivative Loss of Consortium Claims

The Court must next decide whether to grant defendants' motion for summary judgment on E.B.'s parents' derivative loss of consortium claims. Although plaintiffs filed the claims after Louisiana's one year statute of limitations for tort actions had expired, *see* La. Civ. Code Art. 3492,[11] plaintiffs urge the Court to utilize the "escape clause" in the Minnesota Uniform Conflict of Laws-Limitations Act, which provides that "[i]f the court determines that the limitation period of another state . . . is substantially different from the limitation period of this state and has not afforded a fair opportunity to sue upon . . . the claim, the limitation period of this state applies." Minn. Stat. § 541.33.

The escape clause should "rarely be employed" and only "extreme cases" justify deviating from the statute of limitations of the state whose law governs the case. Unif. Conflict of Laws-Limitations Act § 4, cmt. "It is not enough that the forum state's limitation period is different than that of the state whose substantive law is governing." *Id.* In its 2009 Order, the Court withheld judgment on the escape clause issue because "additional discovery [wa]s needed to determine whether the Burks had a fair opportunity

[11] The statute of limitations does not apply to a minor's claims relating to permanent disability under the LPLA. *See* La. Civ. Code Art. 3492.

to litigate their claims under the Louisiana prescriptive period." *Burks*, 639 F. Supp. 2d at 1020. The Court stated that discovery may provide a reasonable factual basis to conclude that the parents "encountered any kind of substantial barriers to instituting the suit within one year." *Id*. at 1019-20 (internal quotation marks omitted).

Discovery has ended and plaintiffs have not produced evidence that the present action is an extreme case warranting application of the escape clause. While Minnesota's six-year statute of limitations is substantially different from Louisiana's one-year statute of limitations, plaintiffs have made very little effort to establish that the one-year statute of limitations deprived them of a fair opportunity to sue upon their claim. Plaintiffs seemingly believed the burden was on defendants to establish that the escape clause should not apply, which several courts have held is incorrect. *See, e.g.*, *Vicknair v. Phelps Dodge Indus., Inc.*, 794 N.W.2d 746, 753 (N.D. 2011). Plaintiffs point to the fact that they contacted an attorney well within the one year statute of limitations and the attorney failed to file the action, but, if anything, this fact suggests that the parents did have a fair opportunity to litigate under Louisiana's one-year statute of limitations and that it was the attorney, not an unfair statute of limitations, that deprived them of the opportunity. Because plaintiffs have not produced evidence suggesting Louisiana's one-year statute of limitations deprived them of a fair opportunity to litigate their derivative loss of consortium claims, the Court will grant the defendants' motions for summary judgment as to the parents' derivative claims and dismiss the claims with prejudice.

II. MOTIONS TO EXCLUDE

Having resolved defendants' motions for summary judgment, the Court will now address defendants' motions to exclude plaintiffs' expert witnesses.

A. Standard of Review

Under Federal Rule of Evidence 702, expert testimony must satisfy three prerequisites to be admitted:

> First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy. Second, the proposed witness must be qualified to assist the finder of fact. Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires . . . .

Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001) (citations and internal quotation marks omitted). The district court has a gate keeping obligation to make certain that all testimony admitted under Rule 702 satisfies these prerequisites and that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). The proponent of the expert testimony has the burden of establishing by a preponderance of the evidence that the expert is qualified, that his methodology is scientifically valid, and that "the reasoning or methodology in question is applied properly to the facts in issue." *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 758 (8th Cir. 2006).

The Supreme Court in *Daubert* outlined particular factors for courts to consider in assessing reliability, such as (1) whether the opinion is based on scientific knowledge, is

susceptible to testing, and has been tested; (2) whether the opinion has been subjected to peer review; (3) whether there is a known or potential rate of error associated with the methodology; and (4) whether the theory has been generally accepted by the scientific community. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149-50 (1999) (summarizing *Daubert* factors). However, in *Kumho Tire*, the Court explained that "the test of reliability is 'flexible,' and *Daubert*'s list of specific factors neither necessarily nor exclusively applies to all experts in every case. Rather, the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." *Id*. at 141-42. The reliability inquiry is designed to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Marmo*, 457 F.3d at 757 (quoting *Kumho Tire*, 526 U.S. at 152).

"Courts should resolve doubts regarding the usefulness of an expert's testimony in favor of admissibility." *Id.* at 758; *see also Kumho Tire*, 526 U.S. at 152 ("[T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable."). "Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001) (quoting *Hose v. Chi. Nw. Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1996)).

B. Abbott's Motion to Exclude Plaintiffs' Warnings/Labeling Expert

Abbott first moves to exclude plaintiffs' proposed warnings expert, Dr. Gerald M. Goldhaber. Dr. Goldhaber has a masters in Communication Theory and a Ph.D. in Organizational/Interpersonal Communication. (Aff. of Stephen C. Rathke, Ex. D, June 4, 2012, Docket No. 347.) He has published many books and articles on communications and the effectiveness of warnings, and he runs a company that designs and evaluates warnings. (*Id.*) After familiarizing himself with the risks of C. sak contamination in PIF, Dr. Goldhaber arrived at his central opinion, which is that defendants' warnings were inadequate because they did not specifically refer to C. sak and its consequences and because they did not convey that healthy, full term neonates are at risk. (Decl. of Melissa B. Hirst, Ex. 6 (Expert Report of Gerald M. Goldhaber ("Goldhaber Report") at 6), May 21, 2012, Docket No. 329.) Among other things, Dr. Goldhaber also opines that average consumers would not know about the risks of C. sak in PIF and would assume the risks do not apply to neonates on the basis of the warnings provided.[12] (*Id.* at 2, 5.)

Abbott attacks Dr. Goldhaber's report on numerous grounds. Abbott contends that he is unqualified and that his opinions are not based on sufficient facts and data because he is not an expert on infant feeding practices or the science of C. sak and PIF. Abbott

[12] Dr. Goldhaber's report opines that the following warning would be more appropriate: "DANGER! Powdered infant formulas are not sterile products and may be contaminated with E. Sakazakii, a highly virulent bacterium that may cause meningitis, brain and other serious injury or death to infants, especially neonates, low birth weight and premature infants as well as infants whose immunity systems may be compromised. Parents and caregivers should avoid giving powdered infant formulas to infants at risk without consulting their doctor and carefully following preparation and use instructions on this package." (Goldhaber Report at 6.)

also argues that his opinions are unreliable and speculative because he did not conduct testing or surveys regarding the current warnings or of his proposed alternative warning. For the following reasons and with the following qualifications, the Court will deny Abbott's motion.

The Court finds that as a warnings and human factors[13] expert, Dr. Goldhaber is qualified to opine on whether the risks posed by PIF are the type that an average consumer would understand without a warning and whether the warnings provided would effectively communicate the risks of PIF to consumers. *See, e.g., Wolfe v. McNeil-PPC, Inc.*, Civ. No. 07-348, 2011 WL 1673805, at *10 (E.D. Pa. May 4, 2011) ("[A]fter reviewing substantial literature on the association between SJS and ibuprofen . . . [the witness] concluded that the warning in this case was inadequate to communicate the nature of the risk. Based on her years of studying human interaction with packaging, she is qualified to make that determination."). Dr. Goldhaber's opinions about the adequacy and effectiveness of the warnings provided are based on well-established theories regarding how humans interact with warning labels. His experience and expertise allow him to provide reliable and useful opinions regarding the effectiveness of the provided warnings and alternative warnings. *See Michaels v. Mr. Heater, Inc.*, 411 F. Supp. 2d 992, 999-1000 (W.D. Wis. 2006) ("It is undisputed that [the witness] is an expert i[n]

[13] "Human factors analysis . . . 'is a recognized analytical approach that is applied in a variety of contexts and may yield legitimate insights as to the hazards that particular products and situations . . . may pose in light of predictable human behavioral patterns.'" *Michaels v. Mr. Heater, Inc.*, 411 F. Supp. 2d 992, 999 (W.D. Wis. 2006) (quoting *Mihailovich v. Laatsch*, 359 F.3d 892, 919 (7th Cir. 2004)).

human factors engineering. Although he performed no studies or tests in conjunction with this case, the theories and methods upon which he relies are recognized by the engineering community. [The witness'] credentials are impressive, and his knowledge of warnings and their proper design may be helpful to the jury.").

The Court notes that Dr. Goldhaber's opinions must be carefully confined to remain within his area of expertise and to avoid invading the province of the jury. First, Dr. Goldhaber may opine regarding whether PIF poses the **type of risks** average consumers would comprehend in the absence of a warning, but he is not qualified to opine on the **scope of the risk** posed by PIF or the likelihood that PIF caused E.B.'s illness. Second, Dr. Goldhaber will not be permitted to invade the province of the jury by opining on whether defendants' acted reasonably. *See, e.g., Hutto v. McNeil-PPC, Inc.*, 79 So. 3d 1199, 1211 (La. Ct. App. 2011) ("Whether a product is unreasonably dangerous due to an inadequate warning is a question for the trier of fact.") Rather, Dr. Goldhaber will be permitted to opine on issues such as (1) whether C. sak contamination is the type of risk an average consumer would understand in the absence of a warning, (2) how an average consumer would interpret and react to the warnings provided and to alternative warnings, and (3) how Lawrence would have responded to alternative warnings. Dr. Goldhaber's opinions and explanations will help the jury determine whether the defendants had an obligation to provide a warning and whether they took reasonable care to provide an adequate warning. Although the Court denies Abbott's motion to exclude Dr. Goldhaber, the Court will entertain objections to specific

aspects of Dr. Goldhaber's testimony if it falls outside the witness' expertise or invades the province of the jury.

C. Abbott's Motion to Exclude Plaintiffs' Causation Experts

Abbott also moves to exclude plaintiffs' three proposed causation experts, Dr. Janine Jason, Dr. John Farmer, and Dr. Catherine Donnelly. The three experts opine that it is more likely than not that PIF contaminated with C. sak caused E.B.'s illness. Abbott contends that the experts' reports lack relevance and are likely to confuse the jury because none of the experts could opine that it was more likely than not that Abbott's PIF caused E.B.'s illness and none offer direct evidence that Abbott's PIF was contaminated.

The Court held above that plaintiffs may rely on the doctrine of alternative liability, which means that plaintiffs can potentially be relieved of the burden of proving that it is more likely than not that a particular defendant – Abbott or Mead – caused E.B.'s illness. If plaintiffs successfully establish the other prerequisites for applying alternative liability, plaintiffs' burden with respect to cause-in-fact will be to establish that it is more likely than not that contaminated PIF manufactured by one of the defendants caused E.B.'s illness. The Court also held that a lack of direct evidence is not fatal to plaintiffs' claims, which means that plaintiffs may prove cause-in-fact on the basis of circumstantial evidence.

Under Federal Rule of Evidence 402, evidence is relevant if "(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Because of the Court's holding

on alternative liability, whether contaminated PIF manufactured by one of the defendants' was more likely than not the cause of E.B.'s illness is a fact that is of consequence in determining the action. Plaintiffs' experts' opinions that it is more likely than not that contaminated PIF manufactured by one of the defendants caused E.B.'s illness has a tending to make this fact more probable. Therefore, the Court will deny Abbott's motion to exclude plaintiffs' causation experts on the basis of relevance.

D. Mead's Motion to Exclude Plaintiffs' Causation Experts

Mead separately moves to exclude Dr. Jason, Dr. Farmer, and Dr. Catherine Donnelly, as well as Dr. Scott Donnelly. Mead challenges the experts' qualifications, as well as the reliability and relevance of their opinions.

1. Dr. Jason

Dr. Jason is a "pediatrician, . . . epidemiologist, clinical pediatric infectious diseases physician, and board-eligible immunologist." (Aff. of Janine Jason, M.D. ("Jason Aff.") ¶ 2, June 11, 2012, Docket No. 361.) Dr. Jason's central opinion is that it is more probable than not that E.B.s' illness was caused by PIF contaminated with C. sak. (Jason Decl. at 7.) Mead attacks Dr. Jason's report on numerous grounds, relating to both reliability and relevance. For example, Mead contends that Dr. Jason's reliance on case reports and cross-sectional analysis to predict the likelihood that PIF caused E.B.'s illness is unreliable because of various methodological biases. Mead also contends that Dr. Jason's opinions regarding the tests conducted on the batches of PIF at issue and regarding other possible sources of C. sak are speculative and lack foundation.

Additionally, Mead contends that Dr. Jason is unqualified to opine on the adequacy of Mead's product testing and that evidence relating to Mead's plant is irrelevant because it is not direct evidence that the batch in question was contaminated.

The Court finds that Dr. Jason is qualified to opine on potential causes of C. sak infection and on the potential effectiveness of various methods of testing for C. sak and preventing C. sak contamination. The Court also finds that her methodology – identifying the most likely cause of E.B.'s illness by performing a differential etiology – is reliable enough to assist the jury. *See, e.g., Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) ("[A] reliable differential diagnosis provides a valid foundation for an expert opinion."). Dr. Jason's qualifications allow her to reliably opine on potential causes of C. sak infection on the basis of the scientific literature on C. sak, to which she has contributed. Dr. Jason's experience also allows her to assess, with sufficient reliability, the potential effectiveness of various methods of testing for C. sak contamination. While case reports and cross-sectional analysis may not be as reliable or persuasive as other methods of assessing risk, such as prospective cohort studies, the Court does not find that Dr. Jason's opinion "is so fundamentally unsupported that it can offer no assistance to the jury." *See Bonner*, 259 F.3d at 929–30.

Crucially, "'[a]s a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination.'" *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929-30 (8th Cir. 2001) (quoting *Hose v. Chicago NW Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1996)). "Vigorous cross-examination, presentation of contrary

evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. Mead will have ample opportunity to attempt to undermine the factual basis of Dr. Jason's opinion through cross-examination and its own experts' opinions. Mead may attempt to expose on cross-examination the potential weaknesses and biases in the case reports and cross-sectional analysis on which Dr. Jason relies. The Court will also entertain specific objections to Dr. Jason's testimony at a later juncture should the testimony stray beyond the narrow question on which she was asked to opine – whether it is more likely than not that E.B.'s illness was caused by contaminated PIF manufactured by one of the defendants. To the extent that Dr. Jason opines on unrelated matters, such as the effectiveness of the warning labels, the Court will not allow them into evidence.

2. Dr. Farmer

Dr. Farmer is a former CDC director who specializes in enteric diseases. (Aff. of Stephen C. Rathke, Ex. L, June 12, 2012, Docket No. 363.) In 1980, he identified and named the bacteria at issue in the present case. (Aff. of John J. Farmer III, Ph.D. ¶ 4, June 11, 2012, Docket No. 360.) Like Dr. Jason, Dr. Farmer opines that E.B.'s illness was more likely than not caused by contaminated PIF manufactured by one of the two defendants. (Aff. of Stephen C. Rathke, Ex. C, (Decl. of John J. Farmer III, Ph.D. ("Farmer Decl.") ¶ 64), June 8, 2012, Docket No. 351.) In reaching his opinion, Dr. Farmer considered, among other things, the likelihood that E.B.'s illness was caused by sources other than contaminated PIF, the likelihood that conditions at defendants'

plants could lead to contaminated PIF, and the significance of the negative testing of the batches of PIF in the present case.

Much of Mead's attack on Dr. Farmer overlaps with its attack on Dr. Jason and is the proper subject of cross-examination, but not a basis for the Court to exclude Dr. Farmer as a witness. Dr. Farmer has significant experience analyzing the causes of infectious diseases. (Farmer Aff. ¶ 4.) The Court finds that Dr. Farmer is qualified to assess the effectiveness of product testing at defendants' plants and the testing that was done on the specific batches at issue and the Court finds that his opinions are sufficiently reliable. (*Id.* ¶ 6.) Dr. Farmer relies on a body of peer-reviewed scientific literature to reach his opinion despite the fact that none of the tests of the batches of PIF at issue were positive C. sak. The Court does not find that Dr. Farmer's opinion "is so fundamentally unsupported that it can offer no assistance to the jury." *See Bonner*, 259 F.3d at 929–30. To the extent that Mead sees flaws in the methodologies and scientific theories upon which Dr. Farmer relies or believes alternative methodologies and scientific theories are more reliable and persuasive, it may raise these issues through cross-examination and the testimony of its own experts.

Dr. Farmer, like Dr. Jason, was asked to provide an opinion on a specific question and his testimony must be limited to that specific question. Thus, Dr. Farmer will not be allowed to offer opinions on the adequacy of defendants' warning labels. Additionally, the Court will not allow Dr. Farmer to opine on the financial incentives that may have led defendants to adopt what Dr. Farmer believes are inadequate safety measures. Dr. Farmer will be allowed to describe the safety measures and explain why he believes

they are inadequate because such testimony is relevant to the likelihood that defendants' PIF was contaminated, but the company's financial incentives are not directly relevant to the issue on which Dr. Farmer is asked to testify.

3. Dr. Catherine Donnelly

Dr. Catherine Donnelly is a food microbiologist with experience investigating infectious disease outbreaks. (Aff. of Catherine Donnelly, Ph.D. ¶ 2, June 11, 2012, Docket No. 357.) Her central opinion is the same as that of Dr. Jason and Dr. Farmer – that it is more likely than not that E.B.'s illness was caused by contaminated PIF manufactured by one of the defendants. (Aff. of Stephen C. Rathke, Ex. E, (Decl. of Catherine W. Donnelly, Ph.D. ¶ 15), June 8, 2012, Docket No. 351.) [14] Her opinion is premised on the likelihood that other sources might have caused E.B.'s illness, the conditions and testing at defendants' plants, and the testing of the specific batches conducted in the present case, among other topics.

Mead attacks Dr. Catherine Donnelly's qualifications, the foundation of her opinions, and her methodology. The Court will deny Mead's motion for reasons similar to those described above. Dr. Catherine Donnelly is qualified to opine on possible sources of E.B.'s illness and to analyze the potential effectiveness of PIF testing. Mead's

[14] The Court has previously rejected Abbott's attempt to strike Dr. Catherine Donnelly and Dr. Scott Donnelly. (*See* Order Adopting the R. and Recommendation of the Magistrate J., Sept. 30, 2012, Docket No. 407.) The order contains additional description of the two experts' reports.

doubts about various aspects of her analysis can be brought to light through cross-examination and the testimony of Mead's experts.

4. Dr. Scott Donnelly

Dr. Scott Donnelly is a food microbiologist who worked for Wyeth, another manufacturer of PIF, for over 20 years. (Aff. of Stephen C. Rathke, Ex. N, June 12, 2012, Docket No. 363.) Mead's primary contention regarding Dr. Scott Donnelly is that his report is irrelevant because he was retained to provide an opinion on the design, construction, and composition of defendants' PIF and those issues relate to plaintiffs' dismissed claims, not to their failure to warn claim. The Court rejected this argument when it was raised by Abbott in a separate motion. (*See* Order Adopting the R. and Recommendation of the Magistrate J., Sept. 30, 2012, Docket No. 407.) The Court held then, as it does now, that Dr. Scott Donnelly's report analyzing the conditions at defendants' plants was relevant to two aspects of plaintiffs' failure to warn claim: whether C. sak contamination constitutes a "characteristic" of PIF and whether E.B.'s illness was caused by contaminated PIF. (*See id.* at 8-10.) Mead also contends that Dr. Scott Donnelly lacks foundation for his assessment of their plant and that his report contains irrelevant attacks on Mead personnel. The Court finds that Dr. Scott Donnelly is qualified to assess the conditions and policies of a PIF plant and opine on the likelihood that the plant would produce contaminated PIF. The Court also finds that his opinions are sufficiently reliable and that his opinions regarding policies and personnel at the plant may be relevant to the likelihood that contaminated PIF was manufactured. As with each

of the other experts, the Court will entertain specific objections if the witness's testimony strays beyond the specific areas in which it is relevant or runs afoul of other evidentiary principles such as the need to avoid unfair prejudice.

As outlined above, and with the exceptions noted above, the Court will deny Mead's motion because it finds that plaintiffs' experts' opinions are relevant and reliable.

III. MISCELLANEOUS MOTIONS

A. Mead's Motion to Strike Dr. Jason's Supplemental Declaration

On July17, 2012, plaintiffs submitted an affidavit of Dr. Jason indicating that an article she authored that she relies upon in her expert report was accepted for publication by *Pediatrics*.[15] Mead moves to strike the supplemental exhibits on the grounds that it was procedurally improper for plaintiffs to submit them without moving the Court to extend the briefing deadline. Mead also contends that it is unfair for the Court to accept Dr. Jason's affidavit because Dr. Jason has not turned over documents relating to earlier attempts to publish the article in other journals, a revised copy of the article, or the peer review comments she received from *Pediatrics*.

"District courts have broad discretion in establishing and enforcing deadlines." *In re Baycol Prods. Litig.*, 596 F.3d 884, 888 (8th Cir. 2010). Neither the federal rules nor the local rules explicitly prohibit plaintiffs' provision of a newly discovered fact after the

[15] Plaintiff also submitted an excerpt of deposition transcript from another action involving Mead, in which one of Mead's experts stated that "Pediatrics would be a journal thought to have significant impact."

end of briefing and the fact that Dr. Jason's article was accepted by *Pediatrics* has relevance because it bolsters the reliability of her opinions. Further, because Dr. Jason avers that the methodology of the revised version of the article is identical to the methodology in the draft she has already provided to defendants (Aff. of Janine Jason, M.D. ¶¶ 6, 8, July 7, 2012, Docket No. 387), defendants seemingly suffer no prejudice in their attempts to undermine Dr. Jason's methodologies by virtue of not being able to review the revised version of the article. For these reasons, the Court will deny Mead's motion to strike Dr. Jason's supplemental declaration.[16]

B. Defendants' Motion to Supplement Record

Defendants also move to supplement the record with newly received materials that they contend could not reasonably have been produced earlier. The materials consist of (1) a recently published article relating to the prevalence of C. sak in home kitchens and (2) five pages of email correspondence between Dr. Jason and a CDC doctor relating to Dr. Jason's article discussed above.[17] Plaintiffs do not object to defendants' experts relying upon the article discussing C. sak in home kitchens and the Court will allow experts on both sides to discuss and rely upon the article. Plaintiffs oppose

[16] If, in light of this opinion and order, defendants still wish to review the revised version of Dr. Jason's article, they may move the Court to order plaintiffs to provide the revised version under seal for the limited purpose of defendants reviewing the article to ensure that its methodology is unchanged, as Dr. Jason avers.

[17] The correspondence between Dr. Jason and the CDC doctor were produced in response to an order by a United States Magistrate Judge in a separate action involving Mead.

supplementing the record with Dr. Jason's email correspondence, but the Court will allow the supplementation as the email correspondence contains information that may be of some relevance to defendants' attempts to undermine the strength of Dr. Jason's publication.

This case will be placed on the Court's next available trial calendar.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Mead's Motion for Summary Judgment [Docket No. 309] and Abbott's Motion for Summary Judgment [Docket No. 321] are **GRANTED in part** and **DENIED in part**, as follows:

   a. The motions are **GRANTED** as to plaintiffs' derivative loss of consortium claims and those claims are **DISMISSED with prejudice**.

   b. The motions are **DENIED** as to plaintiffs' failure to warn claim under the LPLA.

2. Abbott's Motion to Exclude Plaintiffs' Proposed Labeling Expert [Docket No. 327] is **DENIED**.

3. Abbott's Motion to Exclude Plaintiffs' Proposed Causation Experts [Docket No. 332] is **DENIED**.

4. Mead's Motion to Exclude Expert Testimony Pursuant to Fed. R. Evid. 702 [Docket No. 338] is **DENIED**.

5. Mead's Motion to Strike the Supplemental Declaration of Dr. Janine Jason [Docket No. 392] is **DENIED**.

6. Defendants' Motion to Supplement the Record [Docket No. 397] is **GRANTED**.

DATED: January 8, 2013
at Minneapolis, Minnesota.

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