

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

PATRICK KORTE and MICHELLE L.
KORTE, Individually and as Parents of
D.J.K.,

Plaintiffs,

vs.

MEAD JOHNSON & COMPANY, A
Delaware Corporation, d/b/a MEAD
JOHNSON NUTRITIONALS and
MEAD JOHNSON NUTRITION
GROUP,

Defendants.

No. 4:09-cv-00063-JAJ-CFB

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This matter comes before the Court pursuant to Defendant Mead Johnson & Company, LLC’s (“Mead Johnson”) April 5, 2010 Motion for Summary Judgment. [Dkt. No. 31.] Plaintiffs Patrick Korte and Michelle L. Korte, individually and as Parents of D.J.K. filed a response to Mead Johnson’s motion for summary judgment with the Court on April 29, 2010. [Dkt. No. 44.] The Court granted Mead Johnson’s May 5, 2010 resisted motion for extension of time to file a reply to its motion for summary judgment, which Mead Johnson filed on June 8, 2010. [Dkt. Nos. 47, 48, 49, 50, 51 & 65.]

The Court held a hearing on this matter on May 24, 2010. [Dkt. No. 62.] The Court grants summary judgment in its entirety to Mead Johnson.

I. BACKGROUND AND MATERIAL FACTS¹

A. Manufacturing Enfamil® Human Milk Fortifier

Premature infants often need enhancements or supplements added to breast milk. Breast milk for premature infants can be nutritionally insufficient because they require additional calories, proteins, vitamins, and minerals in order to achieve growth and development comparable to what they would have achieved *in utero*. Mead Johnson’s Enfamil® Human Milk Fortifier (“EHMF”) is one such product used to supplement breast milk. EHMF is a powdered formula that permits supplementation of breast milk without displacing breast milk volume. In other words, a doctor can maximize the amount of breast milk in a feeding because the powdered formula is mixed into the breast milk,

¹Unless otherwise noted, the following facts are undisputed or viewed in the light most favorable to the Plaintiffs.

whereas a liquid formula added to breast milk reduces the volume of breast milk fed to an infant.

The batch of EMHF at issue here, Batch No. BMO05C, was manufactured in late 2006 and early 2007. Beginning in 2002, Mead Johnson had made manufacturing and quality control testing changes to its products in order to make it difficult for bacteria to enter and propagate. But because EHMF is not a sterile product, there is an inherent risk that *Enterobacter sakazakii*² (“*E. sak*”) bacteria will be present and medical professionals must weigh the risk of infection when deciding to use EHMF. To completely sterilize EHMF would otherwise destroy the nutritional quality of the product.

EHMF is made at the Zeeland Specialty Products manufacturing plant in Zeeland, Michigan (“ZSP Plant”). Mead Johnson manufactures EHMF in three phases. The first phase involves a “wet blending” process. In this “wet blending” process, Mead Johnson formulates the base mix by pasteurizing and then drying the milk-based component of the product. In the second phase, other dry ingredients of vitamins and minerals from outside suppliers are blended with the base mix in a dry process and on equipment that curtails microbial growth. These suppliers are audited by Mead Johnson to make sure they have manufactured the ingredients under hygienic conditions. The residual moisture content of the finished product is less than 3%. The blending stage for Batch No. BMO05C was finished by December 27, 2006. Lastly, Mead Johnson packages the EHMF for sale on dedicated equipment in individual tubular sachets. Each sachet weighs .71 gram and every box contains 100 sachets. The total amount of finished product for Batch No. BMO05C was 204.5 kilograms or 204,500 grams.

² *Enterobacter sakazakii* is a gram-negative, rod-shaped bacteria of the family *Enterobacteriaceae*. The subsequent taxonomic relationship of *Enterobacter sakazakii* strains has since resulted in the classification of *Enterobacter sakazakii* as a new genus, *Cronobacter sakazakii*. The Court will continue to refer to *Cronobacter sakazakii* as *Enterobacter sakazakii* because that was the name of the bacteria in 2007, the relevant time period of this suit.

Mead Johnson tests the product during each phase for *E. sak* and Batch No. BMO05C passed all three phases of product testing. If any batch tests positive for *E. sak*, then the entire batch is rejected. In January 2007, Mead Johnson tested 999 grams of Batch No. BMO05C between the base mix, its prepackaged blend, and all the ingredients, and all tests were negative for *E. sak*. Seventy-five grams of Batch No. BMO05C were also tested with a negative result for the more general bacterial family of *Enterobacteriaceae*.³ This testing consisted of three separate tests of twenty-five grams each for the base, blend, and final product of Batch No. BMO05C. According to Mead Johnson, Batch No. BMO05C was manufactured pursuant to its “proper recipe” and was made on equipment that was contemporaneously noted to be clean and in good working order.

Daniel March, Director of Food Safety at Mead Johnson, states that the testing protocols “give a high measure of assurance that even if *E. sak* were to enter the [E]HMF, it would be in very low concentrations, and, to a near statistical certainty, would not exceed one CFU per any one feeding.” If a sample tests positive for *E. sak*, then the results would be “reported as the number of [CFU] per weight of product.” Of course, there is no way to confirm whether amounts not tested did not have *E. sak* present in excess of one CFU per feeding. But product contamination by a bacteria like *E. sak* is a “non-uniform event” and “testing protocols do not exist to confirm the complete absence” of *E. sak* in a finished product. Further, Plaintiffs assert that it is possible for *E. sak* to exist as a biofilm and biofilms, by definition, “can contain many individual cells.”⁴

A pathogen like *E. sak* can also contaminate and become established in powdered

³This was also done on the base mix, prepackaged blend, and all the ingredients in three separate tests of twenty-five grams each.

⁴Mead Johnson disputes that biofilms actually exist in *E. sak* and dispute the number of CFUs Plaintiffs’ experts postulate are in biofilm.

formula manufacturing plants, with such harbourage sites serving as a source of future contamination. *E. sak* may remain in low levels in an otherwise highly hygienic environment if there is an inadequate separation of wet and dry areas and/or by poor control over the movement of employees, equipment and goods.” There is no evidence that Mead Johnson had any harbourage sites in the production area of EHMF. Before January 2007, Mead Johnson had some positive tests for the presence of *E. sak* in certain finished powdered products.⁵

In summary, all samples of Batch No. BMO05C that Mead Johnson tested were negative for *E. sak* and all related documents to Batch No. BMO05C indicate the batch was in compliance with the manufacturing specifications.

B. Microbiological Risks of E. sak

Because powdered infant formulas are not sterile, there is the risk of *E. sak* contamination. Any infection in an infant can have significant consequences. Premature infants have immature or not fully developed gastrointestinal, immune, and blood-brain

⁵Mead Johnson voluntarily recalled powdered formula products in 2002 and 2003 based on the presence of *E. sak*. Mead Johnson recalled Portagen® in 2002 based on “the confirmed presence of [*E. sak*] in unopened cans of the product, and because the [Centers for Disease Control] had concluded that, in combination with time and temperature abuse, had caused illness in a child.” Mead Johnson also voluntarily recalled EnfaCare® in 2003 because the Food and Drug Administration (“FDA”) detected the presence of *E. sak* in unopened cans. Portagen® and EnfaCare® were manufactured at the ZSP Plant although their “ingredients, testing and manufacturing process is different than” than that used for Enfamil®. The only shared stage of the Portagen®, EnfaCare®, and Enfamil® manufacturing processes is at the first phase of base mix production, and not at the blending and packaging equipment phases. Further, there is no evidence that the bacteria strain at issue here matched the *E. sak* strains found in 2002 or 2003. As of December 6, 2006, 40% of batches produced at the ZSP Plant had some type of “non-conformity” to either a Mead Johnson process or Standard Operating Procedures. But these “non-conformities”, according to Daniel March as Director of Food Safety, do not necessarily reflect a deviation from Mead Johnson’s Good Manufacturing Practices or Standard Operating Procedures.

barriers. As a result, neonates are extremely susceptible to rapid and destructive invasion and growth by infections, including *E. sak*. Premature infants do have some defensive physiological and immune mechanisms that can prevent or slow bacterial growth.

In 2002, the FDA informed health care professionals of certain precautions they should take when using powdered infant formulas:

As background information for health professionals, FDA wants to point out that powdered infant formulas are not commercially sterile products. Powdered milk-based infant formulas are heat-treated during processing, but unlike liquid formula products they are not subjected to high temperatures for sufficient time to make the final packaged product commercially sterile.

Additionally, the Food and Agricultural Organization and the World Health Organization (“FAO/WHO”) convened panels of experts in 2004, 2006, and 2008 to “evaluate and develop strategies to reduce risks of infection due to *E. sak* and other bacteria.” In its studies, the FAO/WHO determined that *E. sak* in formula has caused illness and that epidemiological evidence associates powdered infant formula with *E. sak*. But the FAO/WHO literature does not conclude that every *E. sak* case can be causally linked to powdered infant formula, or more specifically, EHMF.

The Codex Alimentarius Commission, associated with the WHO, issued guidelines in 2008 for the “manufacture, testing, and use of powdered formulas in a manner to reduce the risks of *E. sak* infection.” The American Dietetic Association also updated its recommendations for infant feedings of powdered formula to reduce *E. sak* risks. Mead Johnson’s manufacturing process and testing protocols for EHMF conformed to the recommendations of the FAO/WHO and the Codex Alimentarius Commission.

Beginning in 2005, Mead Johnson labeled EHMF with the following statement:

Warning: Your baby’s health depends on carefully following the instructions below. Use only as directed by a medical professional. Improper hygiene, preparation, dilution, use or

storage may result in severe harm. Although this powder is formulated for premature infants, nutritional powders are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by a physician.

This label appeared on Batch No. BMO05C. Mead Johnson also provided Mercy Medical Center (“MMC”) from 2002 to 2007, with educational products related to EHMF and the microbiological inherent risk. MMC adopted the following protocol related to powdered infant formula in 2004:

In light of the epidemiological findings and the fact that powdered infant formulas are not commercially sterile products, FDA recommends that powdered infant formulas not be used in neonatal intensive care settings unless there is no alternative available. If the only option available to address the nutritional needs of a particular infant is a powdered formula, risks of infection can be reduced by [special handling precautions].

The precise incubation period for an *E. sak* infection is unknown. Scientists cannot definitively establish the period of time between the pathogen exposure and the onset of disease symptoms, such as sepsis. There is also a dispute between the parties as to the incubation period. Defendant’s expert, Dr. Robert Baltimore, has opined that it is impossible for an infant first exposed to *E. sak* at 2 pm to develop a “rampant infection” by 10 pm, or within eight hours of initial exposure. Conversely, plaintiffs’ expert, Dr. Janine Jason, has stated that such an infection in a relatively short time period is biologically possible because “[n]eonates’ gastrointestinal, immune, and blood-brain barrier immaturities make them extremely susceptible to rapid and destructive invasion and growth by” *E. sak*. The parties agree that factors influencing the incubation period would include “the number of colony forming units in the dose, the biological activity of the bacteria, its doubling time in the human body, its matrix, the route of exposure, and other

factors.” Such host and pathogen factors can influence incubation time. The doubling time of *E. sak* in premature infants, or how rapidly a bacteria can propagate, is also unknown. There is also no definitive data that states a minimum infectious dose needed to cause an infection in a neonate. There is currently no established epidemiologic data that can estimate *E. sak*’s incubation period, particularly because organizations such as the Centers for Disease Control (“CDC”) only recently began collecting data. The CDC has also never identified *E. sak* in a batch of powdered human milk fortifier. *E. sak* has, to date, only been found in powdered infant formula. It is commonly understood due to the FDA letter and FAO/WHO studies, that extended periods of feeding times, or improper use of the product, could also influence the infectious levels of *E. sak* bacteria. Mead Johnson’s own directions for use also stress the importance of proper use because it is not a sterile product.

C. D.J.K. ’s Illness and Investigation

D.J.K. and his twin were born by cesarian section on April 23, 2007. From birth, the infants both suffered from multiple episodes of apnea, a secession of breathing, and bradycardia, a slowing of the heart rate as a result of the apnea. Apnea and bradycardia episodes are typical for premature infants. MMC medical personnel treated D.J.K.’s apnea and bradycardia episodes with medicine and oxygen delivered through a nasal tube. He was fed both by intravenous—or “parenteral” nutrition—delivered through a catheter and breast milk and/or liquid premature baby formula through a naso-gastric tube.

On May 5, 2007, at a gestational age of thirty weeks or twelve days after birth, D.J.K.’s physician and neonatologist, Dr. Terri Whalig, decided that D.J.K. needed to receive more calories to encourage better growth. Nursing staff understood her direction to increase calories to mean that D.J.K. should receive EHMF. At approximately 9:30 am, Dr. Whalig noted on D.J.K.’s chart that she was increasing his flow of oxygen to be

doubled from 1 to 2 liters/minute because of his increased episodes of apnea and bradycardia. The increased oxygen flow had previously ameliorated his apnea and bradycardia spells. After the increase in oxygen flow, D.J.K. still suffered from additional spells of apnea at 1:23 pm, 4:45 pm, 6:20 pm, and 7:20 pm.

Beginning at 2 pm on May 5, D.J.K. received breast milk fortified with EHMf. At MMC, only a physician⁶ could order EHMf and MMC only permitted trained medical personnel to prepare EHMf pursuant to strict guidelines intended to prevent the growth of potentially harmful bacteria. MMC did not allow parents to bring EHMf home after discharge.

Each feeding to D.J.K. was approximately 20 milliliters (or four teaspoons) with a caloric concentration of 24 cal/oz. A feeding consisted of 50% fortified breast milk (10 mls) and 50% premature liquid infant formula (10 mls). It takes approximately .28 gram of a .71 gram packet to reach a caloric density of 24 cal/oz for each 20 ml serving D.J.K. received. D.J.K. also received breast milk fortified with EHMf again at 5 pm and 8 pm. Overall, it is likely that D.J.K. received no more than two packets of EHMf.

As the day progressed, nurses noted that D.J.K. continued to have apnea and bradycardia spells. Nurses noted that he looked as if he were not feeling well and there were several signs of emerging sepsis⁷, such as the spells, skin discoloration, fussiness, and an elevated temperature. Nurses noted another spell paired with crying at 4:45 pm,

⁶In 2007, Enfamil® was available for direct sale to customers through Mead Johnson's website because Enfamil® was available at that time without a prescription. Mead Johnson asserts that there is no retail market for EHMf "and in those rare instances where a consumer sale occurs, it occurs under circumstances where it is reasonable to infer that a physician has ordered it [sic]." Mead Johnson also asserts that "[t]he vast majority of uses of [EHMF] occur in controlled hospital settings, where it is administered by a health care professional in accordance with . . . guidelines, and only after a physician has made a clinical determination that the benefits of [EHMF] outweigh risks of the use of a non-sterile product."

⁷Sepsis is a pre-meningitis blood infection.

and at 5 pm, a “pain index” of 3, and signs of him being “fussier than usual”. At 6 pm, nurses changed D.J.K.’s diaper in an attempt to calm him, but he had another apnea and crying spell at 6:20 pm and another spell of apnea at 7:20 pm. D.J.K.’s skin also appeared pale, dusky, and slightly mottled at 7:20 pm. Nurse Stephanie Pollard made her last reading of the day for D.J.K. at 6:20 pm and informed the next nurse on-call, Melody Hutton, that D.J.K. was “fussier than usual” and of his apnea/brady episodes. By 8 pm, D.J.K.’s temperature had increased from 99.3 degrees to 99.6 degrees, he had irregular breathing, a pain index of 3, and seemed to be irritable and crying. The nurse reported that D.J.K. still appeared neurologically normal, had unlabored breathing, a regular heartbeat, soft abdomen, and normal bowel sounds. D.J.K.’s nurse called Dr. Whalig at 10 pm to report “his presentment over the course of the afternoon” and Dr. Whalig ordered a full septic work up. Lab samples taken at 10:45 pm indicated that D.J.K. had a very low white blood cell count, which is “strong evidence of a severe, disseminated bacterial infection, also known as sepsis.” At 11:30 pm, a cerebrospinal fluid sample revealed “clear evidence” of a meningitis infection that later grew a positive *E. sak* culture.

Following the confirmed presence of *E. sak*, MMC involved, among others, the University Hygienic Laboratory (“UHL”) at the University of Iowa and the CDC for testing. The CDC did not find *E. sak* in any of the twenty-six packets of remaining EHMF taken from the same box used for D.J.K. There was a similar negative finding when the UHL tested 190 grams of EHMF from Batch No. BMO05C and when the FDA tested at least half of 710 grams of EHMF obtained directly from Mead Johnson.

Because it did not find *E. sak* in any of the EHMF samples, the Iowa Department of Public Health then conducted epidemiological tests in D.J.K.’s hospital room on May

10, 2007.⁸ Epidemiological tests can be used to support the finding of a source of infection. D.J.K.'s hospital room had been cleaned on a daily basis since May 5. All the samples taken from the hospital room were negative.⁹ MMC also tested Michelle Korte's expressed breast milk and stools of nine infants who received EHMf from the same box as D.J.K. Mrs. Korte's tested breast milk had not been fed to D.J.K. on May 5, because she expressed it on May 5 at 4:30 pm and on May 6 at 8:00 am. This was after the breast milk was mixed with the implicated EHMf packets and fed to D.J.K. None of the infants who had received EHMf tested positive for *E. sak*; infants who had not received EHMf were not tested.¹⁰ The one to two packets of EHMf D.J.K. consumed were not ingested by any of the other nine tested premature infants. D.J.K.'s twin did not receive any EHMf and did not become ill. Tests could not be performed on the one to two packets D.J.K. consumed because there was none left to test.

⁸D.J.K. was diagnosed with the meningitis infection late in the evening on May 5, 2007, and he had been fed EHMf that day at 2 pm, 5 pm, and 8 pm.

⁹Mead Johnson argues that it was an insufficient epidemiological investigation for the following reasons:

The investigation did not examine areas of the hospital other than his room. It did not test any personnel who came in contact with him. It did not look for signs of colonization in infants who had not received HMF, but who might have been exposed to other sources of the bacteria. It did not verify the underlying classification of the bacteria as *Cronobacter*, and it did not follow up on information suggesting that there were bacteria in Mrs. Korte's breast milk. There was no testing of the nasogastric tubes of DJK and other infants. The limitations of the investigation render it absolutely insufficient to rule out other possible sources for the infection.

The Plaintiffs, however, disagree with the conclusion that the epidemiological investigation does not rule out these possible sources. They assert that it is not possible for the alternative sources to be the actual source of the *E. sak*.

¹⁰The average population in the neonatal intensive care unit varied from 35-45 infants.

The Iowa Department of Public Health concluded that: “This is a sporadic case of undetermined origin. No definitive conclusions can be made as all additional clinical, environmental, and product samples tested by Hospital A Laboratory or UHL were negative for *Enterbacter sakazakii*.” Lastly, the FDA did not recall Batch No. BMO05C and allowed Mead Johnson to sell the remaining EHMf from that batch.

II. SUMMARY OF ARGUMENTS

Plaintiffs claim that the EHMf D.J.K. ingested was contaminated with *E. sak*, and that EHMf was the source of D.J.K.’s subsequent illness. Because the EHMf was contaminated, the Plaintiffs argue that the EHMf had a manufacturing defect or that the sale of EHMf containing *E. sak* is a breach of warranty. Further, Plaintiffs claim that EHMf manufactured with *E. sak* constitutes negligence per se or negligence. They assert Mead Johnson had a duty to manufacture the EHMf without contaminants, Mead Johnson breached that duty, there is medical causation, and D.J.K. was damaged as a result. Lastly, Plaintiffs assert a loss of consortium claim.

First, in Mead Johnson’s motion for summary judgment, it asserts that Plaintiffs cannot prove medical causation, such that the EHMf D.J.K. ingested was contaminated with *E. sak* and led to his bacterial meningitis. Mead Johnson states that it is temporally impossible for EHMf to be the cause of D.J.K.’s illness based on the timing of his breast milk-enhanced EHMf feedings. Mead Johnson’s experts opine that any *E. sak* possibly in EHMf would be in a “dessicated form” and there would be an inherent “lag time” needed before the bacteria could even begin proliferating. Further, Mead Johnson asserts that Plaintiffs cannot eliminate other potential sources of the infection. The epidemiological investigation did not establish that the breast milk, environmental exposure, person to person exposure, or parenteral feedings, were not alternative sources of the *E. sak* bacteria. For these reasons, Mead Johnson asserts that there is insufficient

evidence to demonstrate that D.J.K.'s illness was caused by the EHMF he ingested.

Plaintiffs, however, assert that the EHMF was the most likely source for D.J.K.'s infection. Contrary to Mead Johnson's medical experts' opinions, Plaintiffs assert that it is possible that the EHMF feeding was the cause as "[n]eonates' gastrointestinal, immune, and blood-brain barrier immaturities make them extremely susceptible to rapid and destructive invasion and growth by" bacteria. Further, D.J.K. only became ill after ingestion of the EHMF. Additionally, Plaintiffs assert that EHMF was the specific cause of D.J.K.'s infection because the epidemiological investigation did not uncover any other source of infection. Plaintiffs assert that as *E. sak* has previously been "epidemiologically and microbiologically linked to ingestion of powdered infant formula intrinsically contaminated with" *E. sak*, that EHMF is the most likely infectious source.

III. SUMMARY JUDGMENT STANDARD

A motion for summary judgment may be granted only if, after examining all of the evidence in the light most favorable to the nonmoving party, the court finds that no genuine issues of material fact exist and that the moving party is entitled to judgment as a matter of law. *HDC Med., Inc., v. Minntech Corp.*, 474 F.3d 543, 546 (8th Cir. 2007) (citation omitted); *see also Kountze ex rel. Hitchcock Found. v. Gaines*, 536 F.3d 813, 817 (8th Cir. 2008) ("[S]ummary judgment is appropriate where the pleadings, discovery materials, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to summary judgment as a matter of law.").

Once the movant has properly supported its motion, the nonmovant "may not rest upon the mere allegations or denials of [its] pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." FED. R. CIV. P. 56(e). "[A]n issue of material fact is genuine if the evidence is sufficient to allow a reasonable jury verdict for the nonmoving party." *Great Plains Real Estate Dev., L.L.C. v. Union Cent. Life Ins. et*

al., 536 F.3d 939, 944 (8th Cir. 2008) (citation omitted). “A genuine issue of fact is material if it ‘might affect the outcome of the suit under the governing law.’” *Saffels v. Rice*, 40 F.3d 1546, 1550 (8th Cir. 1994) (citation omitted). The nonmoving party is entitled to all reasonable inferences that can be drawn from the evidence without resort to speculation. *Sprenger v. Fed. Home Loan Bank of Des Moines*, 253 F.3d 1106, 1110 (8th Cir. 2001). “[A]lthough [the non-moving party] does not have to provide direct proof that genuine issues of fact exist for trial, the facts and circumstances that she [or he] relies ‘upon must attain the dignity of substantial evidence and not be such as merely to create a suspicion.’” *Taylor v. White*, 321 F.3d 710, 715 (8th Cir. 2003) (citation omitted). The mere existence of a scintilla of evidence in support of the plaintiff’s position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff. *Sprenger*, 253 F.3d at 1110.

IV. PLAINTIFFS CANNOT ESTABLISH MEDICAL CAUSATION

Mead Johnson asserts that Plaintiffs’ claims must fail because Plaintiffs cannot prove that the EHMf D.J.K. ingested caused his illness. The parties disagree as to whether it was temporally possible for *E. sak* bacteria to generate an infection from a desiccated state and whether Plaintiffs have eliminated other potential sources of infection. Plaintiffs assert that they have established general causation because *E. sak* has been found in other powdered formulas and can be found in EHMf. Plaintiffs also assert that they can show specific causation because the EHMf D.J.K. consumed was infected with *E. sak*. Plaintiffs can only succeed on their claims through submission of legally sufficient evidence that would permit a fact finder to find that D.J.K.’s ingestion of EHMf more likely than not caused an *E. sak* bacterial infection that resulted in D.J.K.’s illness.

Under Iowa law, the burden of proving proximate cause is on the plaintiff. *Banks v. Harley-Davidson, Inc.*, 73 F.3d 213, 215 (8th Cir. 1996). “In products liability, the plaintiff must prove his or her injuries were proximately caused by an item manufactured

or supplied by the defendant.” *Spaur v. Owens-Corning Fiberglas Corp.*, 510 N.W.2d 854, 858 (Iowa 1994); *Lovick v. Wil-Rich*, 588 N.W.2d 688, 700 (Iowa 1999) (must be a causal relationship between the product and resulting injury). The plaintiff also must show that the manufacturing defect was a “substantial factor” and that the injury would not have occurred “but for” that defect. *Id.* (citing *Jones v. City of Des Moines*, 355 N.W.2d 49, 50 (Iowa 1984) (defining proximate cause as the substantial factor and but for cause)).

When plaintiffs put forth circumstantial evidence to prove proximate cause, “that evidence ‘must be sufficient to make plaintiffs’ theory asserted reasonably probable, not merely possible, and more probable than any other theory based on such evidence.’” *Banks*, 73 F.3d at 215 (quoting *Oak Leaf Country Club, Inc. v. Wilson*, 257 N.W.2d 739, 746 (Iowa 1977)). Plaintiffs must use the testimony of medical experts to prove medical causation. *In re Baycol Litig.*, 596 F.3d 884, 889 (8th Cir. 2010). The trier of fact usually determines whether circumstantial evidence establishes proximate cause. *Oak Leaf Country Club, Inc.*, 257 N.W.2d at 746. Proximate cause “will be decided as a matter of law only in extraordinary cases”, *Boham v. City of Sioux City*, 567 N.W.2d 431, 435 (Iowa 1997), or when “reasonable minds can come to no other conclusion.” *Peters v. Howser*, 419 N.W.2d 392, 394 (Iowa 1988).

A plaintiff must prove general causation, such that a product causes a “particular injury or condition in the general population”. *Junk v. Terminix*, 2008 WL 5142193, at *3 (S.D. Iowa Nov. 3, 2008) (citing *Knight v. Kirby Inland Marine, Inc.*, 482 F.3d 347, 351 (5th Cir. 2007)); *see also Meister v. Med. Eng’g Corp.*, 267 F.3d 1123, 1132 (D.C.Cir. 2001) (affirming judgment as a matter of law where plaintiffs’ experts were unable to show that breast implants caused scleroderma and epidemiological evidence failed to show a causal relationship). Likewise, a plaintiff must show specific causation, in that the product actually caused the injury. *Colon v. Abbott Labs.*, 397 F. Supp. 2d 405, 416–17 (E.D.N.Y. 2005) (in a summary judgment motion, holding that expert’s

opinion as to specific causation was too “speculative” to prove that Similac formula caused Type 1 juvenile diabetes). “Mere use of the product and subsequent injury . . . are not a sufficient basis from which to infer causation.” *Id.* (quoting *Gilks v. Olay Co.*, 30 F. Supp. 2d 438, 443 (S.D.N.Y. 1998)). Thus, in a products liability suit, a plaintiff must show that both general and specific causation is present. *See, e.g., Barrett v. Rhodia, Inc.*, 606 F.3d 975, 983–85 (8th Cir. 2010) (applying Nebraska law, court concluded that experts’ opinions stating that symptoms were “consistent with” exposure to hydrogen sulfide gas was insufficient to establish causation; while experts could establish general causation, experts could not establish specific causation); *Hendrix ex rel. G.P. v. Evenflo Co., Inc.*, — F.3d —, 2010 WL 2490760, at *11 (11th Cir. 2010) (quoting *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999) (explaining that “[t]he underlying predicates of any cause-and-effect medical testimony are that medical science understands the physiological process by which a particular disease or syndrome develops and knows what factors cause the process to occur”)); *Doe v. Baxter Healthcare Corp.*, 380 F.3d 399, 405–07 (8th Cir. 2004) (on a summary judgment motion for a hemophiliac child infected with human immunodeficiency virus (HIV) through infusions of blood factor concentrates, plaintiffs failed to prove proximate cause; plaintiffs could only narrow the potential dates of infection and show the products used on those dates, but evidence could not distinguish which product was actually infected with HIV); *Nelson v. Am. Home Prods. Corp.*, 92 F. Supp. 2d 954, 972–73 (W.D. Mo. 2000) (on a summary judgment motion, patient unable to prove proximate cause that ingesting 400 mg of Amiodarone for treatment of ventricular arrhythmia led to loss of vision because “[t]he differential diagnostic analyses that some of the [plaintiff’s] experts performed were tainted by unreliable assumptions on the temporal association between [plaintiff’s] Amiodarone therapy and his ophthalmic problems . . . [therefore,] such opinions and distinctions are no more than untested hypotheses; they are not causal conclusions”); *Allen v. Penn. Eng’g Corp.*, 102 F.3d 194, 199 (5th Cir. 1999) (concluding that “[s]cientific knowledge of the harmful level of exposure to a

chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiffs' burden in a toxic tort case"); *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1350–53 (6th Cir.), *cert. denied*, 113 S.Ct. 84 (1984) (court affirmed grant of summary judgment motion for manufacturer based on insufficiency of evidence to allow a jury to find that Bendectin, an anti-nausea drug for pregnant women, caused minor plaintiff's birth defects; lack of epidemiological proof tying Bendectin to birth defects was fatal to causation).

In *Wheat v. Pfizer, Inc.*, the Fifth Circuit Court of Appeals affirmed judgment as a matter of law in favor of Pfizer, Inc. because the plaintiff failed to show specific causation. *Wheat v. Pfizer, Inc.*, 31 F.3d 340, 341 (5th Cir. 1994). In *Wheat*, a physician prescribed Feldene to Margaret Gordon, a drug manufactured by Pfizer, for her chronic neck pain in July 1989. *Id.* Approximately five weeks later her physician also prescribed Parafon Forte DSC for pain management. *Id.* The pharmacy used the generic drug Chlorzoxazone to fill Mrs. Gordon's prescription. *Id.* During Thanksgiving week of 1989, Mrs. Gordon became "violently ill" and her physician ordered her to cease taking Feldene on November 28, 1989. *Id.* at 342. Lab tests showed "serious liver dysfunction, and her condition was diagnosed as hepatitis." *Id.* Mrs. Gordon tested negative for the viral hepatitis strains A and B, without any test at the time capable of testing for hepatitis C. *Id.* Mrs. Gordon later lapsed into a coma and died December 13. *Id.* Plaintiffs then sued, claiming that the Feldene and Parafon caused her hepatitis. *Id.* The court affirmed the district court's holding¹¹ because plaintiffs failed to show that Feldene was the most probable cause of her death. *Id.* at 342–43. For example, Mrs. Gordon had been in contact with a hepatitis-infected family member; plaintiffs presented no evidence excluding the possibility that she "contracted hepatitis C, a form of viral hepatitis unrelated to

¹¹The district court had granted summary judgment to another defendant in the suit, McNeil Lab, because it found that there was insufficient evidence to create a material issue that Mrs. Gordon ever actually used Parafon Forte DSC. *Wheat*, 31 F.3d at 343–44.

medication”; and there was no evidence to show that Feldene caused the hepatitis, rather than Chlorzoxazone. *Id.* at 343. For these reasons, the court found that there was insufficient “evidence from which a reasonable jury could have concluded that Feldene was the most probable cause of Mrs. Gordon’s hepatitis.” *Id.*

Likewise, in *Sorensen v. Shaklee Corp.*, 31 F.3d 638 (8th Cir. 1991), the Eighth Circuit affirmed a district court’s grant of summary judgment in favor of the manufacturer. The court found that the plaintiffs failed to prove both general and specific causation because the plaintiffs failed to prove that consumption of ethylene oxide (EtO) residue causes mental retardation or that their consumption of chemically treated alfalfa tablets caused mental retardation in their children. *Sorensen*, 31 F.3d at 651.

Here, the hypotheses presented by plaintiffs’ experts follow no scientific principles. Those opinions reason that, because Kristofer and Katrina sustained birth defects (mental retardation) and their parents used Shaklee’s alfalfa tablets, and because some alfalfa tablets had contained an EtO residue, the parents must have ingested the EtO residue tablets. That inference turns scientific analysis on its head. Instead of reasoning from known facts to reach a conclusion, the experts here reasoned from an end result in order to hypothesize what needed to be known but what was not. While it may be that this sort of reasoning could pass muster in some cases where the obvious result explains the etiology (for example, where a fractured bone accompanied by bruised outer skin and flesh demonstrate that some type of physical contact caused the injury) such reasoning cannot apply here where several possible causes could have produced one effect.

Id. at 649.

Mead Johnson asserts that Plaintiffs cannot prove medical causation. While the Court views the facts in the light most favorable to Plaintiffs, the Plaintiffs still must show that there is a genuine issue of material fact as to whether EHMf can be causally related to D.J.K.’s infection. For general causation, the issue is whether EHMf can contain *E. sak*; Mead Johnson concedes that it can. Thus, the Court primarily focuses on whether the

EHMF ingested by D.J.K. was *actually* contaminated with *E. sak*. This is the narrower issue of specific causation. The record must demonstrate to the Court that there is no genuine issue of material fact that EHMF caused the injury to D.J.K.

Here, Plaintiffs' evidence has failed to generate a genuine issue of material fact. The record does not demonstrate to the Court that there is not a causal relationship between the alleged defective EHMF and the *E. sak* infection D.J.K. sustained. *McCleary v. Wirtz*, 222 N.W.2d 409, 414 (Iowa 1974). The Court finds there is not medical causation on the basis of the following.

A. Expert Testimony

The parties have secured and deposed multiple experts. In determining the issue of causation, Iowa has long recognized the necessity of "opinion testimony if it is of a nature which will aid the jury and is based on special training, experience, or knowledge [as] to the issue in question." *Yates v. Iowa West Racing Ass'n*, 721 N.W.2d 762, 774 (Iowa 2006) (citing *Iowa Power & Light Co. v. Stortenbecker*, 334 N.W.2d 326, 330 (Iowa Ct. App. 1983)). If not within the realm of laypersons, "[b]efore [medical] testimony can be considered competent, there must be sufficient data upon which the expert judgment can be made," without the facts being "mere conjecture or speculation." *Id.* (citing *Stortenbecker*, 334 N.W.2d at 330–31). In this case, the Defendant's evidence on the issue of causation consists of four expert opinions. The Plaintiffs present five experts in support of medical causation. Neither party requested a *Daubert* hearing on the qualifications of these witnesses as a part of the summary judgment motion and resistance. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591 (1993).

1. Plaintiffs' Experts Causation Evidence

a. John Farmer, III, Ph.D.

In Dr. John Farmer's¹² opinion, D.J.K. suffered from a "sporadic case of [*E. sak*] meningitis, culture-positive, in which the implicated vehicle (the two packets of [EHMF] that he was fed) was not available for culture or testing." Dr. Farmer states that it is "possible, but not probable" that there were any other possible causes of the *E. sak* infection. Dr. Farmer disputes Dr. Baltimore's opinion that the incubation period was not long enough for the EHMF to be the source of the bacteria. Dr. Farmer cites to rat studies that show a different, virulent, strain of *E. sak* with an infectious dose of 1000 to 10,000 cells of *E. sak* can rapidly multiply and appear in the brain within six hours. He admits that the infectious dose of *E. sak* is unknown in humans, but speculates that a "biofilm" of *E. sak* form large masses of cells.¹³ He theorizes that these biofilm masses would not be distributed evenly in the production batch. He also states that the "[i]ngestion of contaminated powdered infant formula has been implicated as the cause in every reported case of neonatal meningitis in which the cause was identified". Lastly, in Dr. Farmer's opinion, Mead Johnson cannot prove that the EHMF D.J.K. ingested did not contain *E. sak*.

¹²John Farmer, III, Ph.D. earned his Ph.D. in Microbiology from the University of Georgia in 1968. He then spent three years at the U.S. Public Health Service in Bethesda, Maryland before eventually joining the CDC. Since 2000, he has been the Scientist Director, U.S. Public Health Service (Retired). Dr. Farmer has authored more than 150 papers and has discovered and named bacterial species, including *E. sak*. He has also been involved in numerous international and national committees and working groups, including the International Subcommittee on the Taxonomy of *Enterobacteriaceae*. Dr. Farmer has been involved in the scientific study of *E. sak* for about thirty years and was one of the first to document that *E. sak* can grow "an unusually tough colony", called a biofilm. Dr. Farmer based his opinion on D.J.K.'s medical records, certain published articles, emails, and his extensive knowledge of the bacteria. He concludes that more likely than not D.J.K. suffered a case of *E. sak* from the "implicated vehicle" of EHMF.

¹³In his opinion, Dr. Farmer states "that a piece of biofilm about the size of the head of a pin would contain about 1,000,000 cells."

b. Kathleen Harriman, Ph.D.

It is the opinion of Dr. Kathleen Harriman¹⁴ that the EHMF is the most likely source of the *E. sak* because the subsequent CDC investigation did not identify *E. sak* from any other source; the hospital followed protocol for handling and storage of the EHMF; and D.J.K.'s twin was not infected. In Dr. Harriman's opinion, it was "not an unexpected finding" that the CDC failed to isolate *E. sak* from Batch No. BMO05C because less than ten grams of the implicated lot were available for testing, thus not allowing for a robust test to be performed. As Dr. Harriman states, the "CDC and the FDA [identified] no other likely cause". Additionally, Dr. Harriman compares the characteristics of *E. sak* to that of *Salmonella* outbreaks, in which low-level contamination of foods by *Salmonella* caused disease. She also states that although *E. sak*'s incubation period is unknown, other bacteria are known to have shorter incubation times and this could also be the case with *E. sak*.

c. Janine Jason, M.D.

In Dr. Janine Jason's¹⁵ opinion, the immunopathophysiology of an *E. sak* infection

¹⁴Dr. Kathleen Harriman obtained her Ph.D. in Environmental Health (Infectious Disease) from the University of Minnesota in 2004 and her Masters of Public Health in Epidemiology from the University of Sydney (Australia) in 1981. Since 2007, she has been Chief of the Vaccine Preventable Disease Epidemiology Section in the Immunization Branch of the California Department of Public Health. Before this, she worked for fifteen years in infectious disease epidemiology at the Minnesota Department of Health (MDH) Acute Disease Investigation and Control Section. While at the MDH, she led the investigations of *E. sak* outbreaks in infants. Dr. Harriman has also served as a consultant to the World Health Organization. Based on her review of medical literature, D.J.K.'s medical records, and reports from MMC and the CDC, Dr. Harriman concludes that it is more likely than not that there is a strong association between D.J.K.'s ingestion of EHMF and his *E. sak* infection.

¹⁵Dr. Janine Jason obtained her M.D. from Harvard Medical School in 1975. She did her internship and residency in Pediatrics at the Children's Hospital of Los Angeles, University of Southern California from 1975-1977. She was then a fellow in the Department of Immunology at the Hospital for Sick Children, University of Toronto, before serving as a

will differ in infants because infants do not have “gut immunity.” She disputes Dr. Baltimore’s opinion, stating that “[a] premature infant’s immunologic immaturity makes that infant relatively less able to control a pathogenic organism when it enters the gastrointestinal tract-and when it breaches the intestinal wall and enters the blood stream.” Infants also have a “leaky” blood-brain barrier and are at heightened risk for blood stream infections. Dr. Jason cites to Dr. Baltimore’s research, as well as other studies, that show how lag times and incubation periods can be “as low as a matter of hours” for some strains of *E. sak*. She states that there is a strong epidemiological link between EHMF and *E. sak* because *E. sak* has only been isolated from powdered infant formula or human growth formula. Lastly, Dr. Jason’s opinions of D.J.K.’s medical records show that a “precipitous change” occurred at around 9:30 pm after D.J.K. ingested EHMF and that the “only notable change in [his] clinical care” was the EHMF feeding.

d. Gregory Pincar

In the opinion of Mr. Gregory Pincar¹⁶, the audits of the ZSP Plant indicate that the

research assistant at the Howard Hughes Medical Institute and Yale University School of Medicine until 1980. Dr. Jason served for twenty-three years as an officer in the Commissioned Corps of the U.S. Public Health Service and as a medical scientist at the CDC. She specializes in epidemiologic, immunologic, and infectious diseases research and has authored a series of publications concerning pediatrics and diseases in infants. Dr. Jason’s opinion is based on CDC’s records related to D.J.K.’s case, information about other infants infected with *E. sak*; and medical and scientific literature. In Dr. Jason’s opinion, it is more probable than not that EHMF caused D.J.K.’s *E. sak* infection.

¹⁶Gregory Pincar has worked for the past fifteen years in the area of food safety in manufacturing plants. He obtained his Bachelor of Science in Microbiology from Oregon State University in 1988. He then worked as a research specialist at the Food Research Institute on the University of Wisconsin (Madison) campus and then as a client services manager at Silliker Laboratories in Madison, Wisconsin. Mr. Pincar later became a business partner at Kornacki Food Safety, LLC. To form his opinion, Mr. Pincar reviewed industry information; general CDC/FDA information; Dr. Doyle and Forsythe’s reports; and documents from Mead Johnson’s production of Batch No. BMO05C.

plant was not in compliance with Good Manufacturing Procedures (“GMPs”). He states that it is likely that contamination came from the ZSP Plant because conditions at the plant were conducive for cross-contamination. Mr. Pincar did not personally visit the plant.

e. Robert Behling

In Mr. Robert Behling’s¹⁷ opinion, Mead Johnson was not in compliance with GMPs at its ZSP Plant. His review of the records indicate that there is a “pattern and culture . . . of non compliance with both Mead Johnson internal and FDA standards.” Mr. Behling also disputes Mr. Doyle’s conclusion that the facility was “well maintained” in 2009 because Mr. Doyle’s opinion does not reach the state of the plant from 2005, 2006, and 2007. Mr. Behling also disputes Dr. Forsythe’s opinion that *E. sak* in milk fortifiers has not been proven, because “[w]hile no published scientific data may exist, microbiological contamination of milk based products is well known in industry. Simply because data is not published does not meant an issue does not exist.”

2. Defendant’s Experts Causation Evidence

a. Robert Baltimore, M.D.

At his deposition in this case, Dr. Robert Baltimore¹⁸ testified to his general belief

¹⁷Robert Behling has a Bachelor of Science in Business Management from Pepperdine University. Mr. Behling has been a quality control analyst, production manager, and plant manager at various manufacturing facilities. From 1990 to 1999, he was Vice President of Operations at a company acquired by Nestle USA, and then served as a Vice President of Global Operations at Wyeth Pharmaceuticals until 2005. He has developed and implemented global programs for handling *E. sak* and has fifteen years of experience in the manufacturing and quality management of infant formulas. Mr. Behling looked at similar items as Mr. Pincar in order to form his opinion.

¹⁸Dr. Robert Baltimore, M.D. is a Professor of Pediatric Medicine and Epidemiology at Yale University Medical School, where his specialties are diseases of children and neonates, as well as director of the infection control program at Yale New Haven Children’s Hospital. Dr. Baltimore graduated from the State University of New York at Buffalo School of Medical in

that D.J.K.'s illness could not have been caused by his 2 pm consumption of EHMf. He arrived at this opinion primarily through reviewing D.J.K.'s medical records, depositions of other experts, and reports from official bodies, such as the FDA. Dr. Baltimore gives several reasons for why the EHMf cannot be the cause of D.J.K.'s illness: the timeline for D.J.K.'s feeding of EHMf and the onset of his illness is too brief to cause the infection; the *E. sak* bacteria could not have multiplied that rapidly¹⁹ in the blood stream and penetrated²⁰ the blood-brain barrier that quickly; transferrin and other bacteriostatic proteins in the blood would have inhibited the transmission of *E. sak*; and it is likely nurses missed earlier warning signs of illness as apnea episodes, irritability, and low-grade fever had been occurring. Dr. Baltimore also points out that Drs. Jason and Farmer attempt to link the infection to the EHMf on the basis of "there being no other plausible explanation", rather than on the basis of a "positive connection".

b. Michael Doyle, Ph.D.

1968 and interned for three years in Pediatrics at the University of Chicago Hospitals and Clinics/Wyler Children's Hospital. Following this, he was a medical officer and infectious diseases fellow at the Walter Reed Army Institute of Research and served for three years as a Major in the U.S. Army Medical Corps. Dr. Baltimore then spent two years as a postdoctoral fellow and instructor in Pediatrics at the Harvard Medical School before joining the faculty at Yale in 1976. Dr. Baltimore has published close to two hundred articles on a variety of topics, including infectious diseases in neonates.

¹⁹Dr. Baltimore opined that it takes approximately 100,000 CFU/ml before a microscope can identify gram negative rod organisms, like *E. sak*, on a gram stain.

²⁰According to Dr. Baltimore's declaration, after the bacteria emerges from its lag phase, it would then need to:

pass from the stomach to the intestines; multiply in the infant's intestines; penetrate into the bowel wall by translocation; enter into the bloodstream; multiply in the bloodstream which would be inhibited by transferrin and other bacteriostatic proteins; cross the blood-brain barrier and multiply in the cerebrospinal fluid to produce the symptoms and profoundly abnormal lab results taken later that evening.

Dr. Michael Doyle²¹ opines that *E. sak* is ubiquitous in the environment. As such, it is not feasible to produce EHMF “absolutely free of risk” of *E. sak* contamination because current manufacturing technology cannot treat the formula without degrading the nutritional content. Dr. Doyle states that production conditions of EHMF followed recommended guidelines and ranks the overall ZSP Plant facility in the top 5% of the more than 500 food manufacturing plants he has visited worldwide. He states that the ZSP Plant employs state of the art industry practices with traffic control of personnel for restricted areas; aggressive environmental hygiene monitoring; control of dust-borne contamination; and effective cleaning and sanitation procedures. His review of the product testing results of the EHMF and inspections by the FDA demonstrate that there were no deviations that could adversely effect the microbial safety of the products. If any *E. sak* were present in a batch, it would be evenly distributed. Further, Dr. Doyle reviewed in-depth internal audits and discussed the content with Daniel March, Director of Food Safety at Mead Johnson.

c. Stephen Forsythe, Ph.D.

It is Dr. Stephen Forsythe’s²² opinion that D.J.K.’s illness was not caused by

²¹Dr. Michael Doyle, Ph.D. has been at the University of Georgia since 1991 and is currently the Director of the Center for Food Safety. Dr. Doyle has for the past thirty years researched better detection, control, and killing methods for foodborne pathogens. He has advised the CDC on foodborne disease topics and has advised on food safety issues for the World Health Organization, Food and Agriculture Organization of the United Nations, U.S. FDA, U.S. Department of Agriculture, U.S. Department of Defense, and the National Academy of Science, among other groups. Dr. Doyle has over 250 published peer-reviewed articles. Dr. Doyle was the first food microbiologist to study *E. coli* O157:H7 as a foodborne pathogen in 1983 and developed the first procedure to detect *E. coli* in foods. To arrive at his conclusions, Dr. Doyle personally visited the ZSP Plant facility on August 12, 2009, reviewed the GMPs and HACCP plans at the ZSP Plant, and the product testing results of the EHMF.

²²Dr. Stephen Forsythe, Ph.D. is a Professor of Microbiology at Nottingham Trent University in Nottingham, England. Dr. Forsythe has published twenty-five papers on *E. sak*

intrinsic contamination of EHMF, based on his review of the microbiological aspects of D.J.K.'s case and of literature on *E. sak*. He states that there is no evidence to make it more likely than not that EHMF was the source of D.J.K.'s infection. In Dr. Forsythe's opinion, the time from exposure to onset of symptoms is too short to have been caused by EHMF. He opines that there is a "lag time" before a bacteria in a desiccated state can begin to multiply, which can vary from 1.6 to 4.6 hours. Dr. Forsythe cited Dr. Baltimore's description of the route the bacteria would have to take before reaching D.J.K.'s brain and states the time sequence is "not microbiologically possible." Further, in Dr. Forsythe's opinion, the investigation after the incident did not rule out the following possible alternative sources: breast milk, environmental sources, personnel, and parenteral feedings. He also states that he is not aware of epidemiological evidence establishing a causal link between *E. sak* and intrinsic contamination of formula on an individual basis, as here with D.J.K.'s infection.

d. Nancy Nevin-Folino, R.D.

In Nancy Nevin-Folino's²³ opinion, there are multiple sources of possible *E. sak* contamination. For example, there was the potential of cross-contamination in D.J.K.'s room as the feeding area was in close proximity to the formula preparation area; other equipment used on D.J.K. may have been contaminated; the refrigerator may not have

specifically and has spent approximately the last eight years studying the bacteria. He has co-authored a WHO risk assessment of the bacteria on three separate occasions (2004, 2006, and 2008) and has written a book on the subject.

²³Nancy Nevin-Folino, R.D. has been a registered and licensed dietician who has practiced in the area of neonatal intensive care for twenty years. She is Board Certified in Pediatric Nutrition and Family and Consumer Sciences. She was the Chief Editor of the American Dietetic Association ("ADA") Pediatric Manual of Clinic Dietetics in 2003 and part of an advisory committee in 2004 for another ADA publication. In forming her opinion, Nevin-Folino reviewed depositions of D.J.K.'s nurses, Dr. Harriman's deposition, and records from MMC.

been cold enough to inhibit bacterial growth; there is no documentation on how long the breast milk mixed with the EHMF was stored or handled; and D.J.K.'s indwelling nasogastric tube was not tested.

B. Temporal Relationship

The parties dispute whether the temporal relationship between the feedings of EHMF to D.J.K. indicates the EHMF contained the disease-causing *E. sak* bacteria. "Under some circumstances, a strong temporal connection is powerful evidence of causation." *Bonner v. ISP Techs., Inc.* 259 F.3d 924, 931 (8th Cir. 2001); Federal Judicial Center, *Reference Guide on Toxicology* 422 (2000) (hereinafter "*Toxicology*"). For example, the court in *Bonner* found strong evidence of causation "'if a person were doused with chemical X and immediately thereafter developed symptom Y'". *Bonner*, 259 F.3d at 931 (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 154 (3d Cir. 1999)). Temporal proximity from the ingestion of a substance to a resulting illness can depend on the biology of the body, such as the absorption rate of the substance, among other factors.²⁴

²⁴For example, the Federal Judicial Center's "Reference Manual on Scientific Evidence" states that,

[o]nce a compound is absorbed into the body through the skin, lungs, or gastrointestinal tract, it is distributed throughout the body through the bloodstream. Thus, the rate of distribution depends on the rate of blood flow to various organs and tissues. Distribution and resulting toxicity are also influenced by other factors, including the dose, the route of entry, tissue solubility, lymphatic supplies to the organ, metabolism, and the presence of specific receptors or uptake mechanisms within body tissues. . . . In acute toxicity, there is usually a short time period between cause and effect. However, in some situations, the length of basic biological processes necessitates a longer period of time between initial exposure and the onset of observable disease. For example, in acute myelogenous leukemia, the adult form of acute leukemia, at least one to two

But courts have long held that a differential diagnosis based only on the assumption of causation due to a temporal relationship is “entitled to little weight in determining causation.” *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 278 (5th Cir. 1998); *Bland v. Verizon Wireless (VAW) L.L.C.*, 2007 WL 5681791, at *10 (S.D. Iowa Aug. 9, 2007), *aff’d*, 538 F.3d 893 (8th Cir. 2008) (holding that doctor’s hypothesis as to “temporal relationship between [plaintiff’s] exposure to the difluoroethane-containing Freon (cleaning solution) and the onset of her reported asthma symptoms” was insufficient to establish causation); *Willert v. Ortho Pharm. Corp.*, 995 F. Supp. 979, 981–82 (D. Minn. 1998) (court granted motion for summary judgment in favor of manufacturer because the temporal proximity was insufficient between the plaintiff suffering from the diseases, autoimmune hemolytic anemia and Guillain-Barre Syndrome, and the ingestion of Floxin, an antimicrobial medication; the court noted, “[u]ltimately, the theory devolves into the thesis that because “B” came after “A,” “A” caused “B.” While this may be phenomenologically and temporally accurate, it does not prove causation, which is the issue at hand.”). This is especially true where the bacteria is known to exist in a variety of places.

Here, the issue is whether the feedings of EHMF are sufficiently temporally related to D.J.K.’s subsequent infection to create a genuine issue of material fact on the issue of causation. It is an uncontroverted fact that D.J.K. first consumed EHMF at his 2 pm feeding, followed by additional feedings at 5 pm and 8 pm. Lab results at 10:45 pm indicated severe sepsis and cerebrospinal fluid taken at 11:30 pm revealed a meningitis

years must elapse from initial exposure to radiation, benzene, or cancer chemotherapy before the manifestation of a clinically recognizable case of leukemia. A toxic tort claim alleging a shorter time period between cause and effect is scientifically untenable. . . .

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infection. Plaintiffs' expert, Dr. Jason, opines there was a "precipitous change" in D.J.K.'s condition by 9:30 pm. Thus, the time frame between D.J.K.'s first consumption of EHMF at 2 pm to the time of his "precipitous change" occurs over 7.5 hours.²⁵ The evidence presents the Court with a finite time period in which it can review the evidence to determine whether Mead Johnson has presented sufficient evidence to suggest it was temporally impossible for EHMF to cause D.J.K.'s meningitis infection.

It is Dr. Baltimore's opinion that it was impossible for EHMF to cause D.J.K.'s infection because the time window is too narrow. *E. sak* would need to traverse the intestinal system, pass through the bowel walls, enter the bloodstream, multiply in the blood, cross the blood-brain barrier, and multiply in the cerebrospinal fluid to cause the meningitis detected at 11:45 pm. Dr. Forsythe concurs in Dr. Baltimore's findings that the time from exposure to the bacterial meningitis infection is "not microbiologically possible." Dr. Jason, however, testifies that a bacteria like *E. sak* could result in a devastatingly quick infection because infants' stomachs cannot control or prevent, to the degree capable in adults, bacteria in the stomach from crossing into the bloodstream. Likewise, infants have a "leaky" blood-brain barrier and it is easier for bacteria to enter the brain. In her opinion, it can take only a "matter of hours" for a severe infection to arise. Dr. Harriman agrees that such short incubation periods are possible.

The Court must still consider the time needed for a desiccated form of *E. sak* to regenerate and multiply. *E. sak* in EHMF would be in a dry and desiccated form; it is not biologically active and cannot become infectious until after a "lag time" has passed. In Dr. Forsythe's opinion, this lag time can vary from 1.6 to 4.6 hours, but Dr. Farmer opines that the lag time can be much shorter. The lag time for this specific strain of *E. sak* is unknown; more broadly, scientists also do not know the lag time for *E. sak* in

²⁵Alternatively, if the second packet had been contaminated with *E. sak*, the time window could start from the 5 pm or 8 pm feedings, with only 4.5 or 1.5 hours elapsing from the feeding to the "precipitous change."

general. Plaintiffs' expert, Dr. Farmer, opines that it is possible the incubation period, even with the lag time, was long enough to cause a rampant infection. He suggests that rat studies using another *E. sak* strain led to bacteria piercing the blood-brain barrier within six hours. Additionally, he suggests that *E. sak* is a bacteria capable of forming "sticky masses" or biofilms of hundreds of thousands of cells. Dr. Farmer's opinion, then, suggests that one CFU could actually consist of a biofilm and be sufficient to inundate a neonate's immune system. There is no other scientific data on *E. sak* that confirms, or even suggests, that bacteria could proliferate that quickly or can form "biofilm". The experts do agree that scientific studies have not established the infectious dose needed to cause an infection in a human.

Plaintiffs attempt to point to specific symptoms that indicate EHMF in fact caused a change in D.J.K.'s condition. Plaintiffs attempt to bolster the temporal proximity with other evidence of D.J.K.'s condition that day. However, D.J.K. suffered these symptoms before and after the EHMF feedings. There is evidence that increased oxygen flow from that morning (which usually alleviated episodes) did not help because D.J.K. had another spell before his first EHMF feeding. According to Nurse Stephanie Pollard's deposition, D.J.K. had five episodes of apnea on May 4th, two on May 5th before the EHMF feeding, and then three episodes after the feeding. [Pollard Dep., Def.'s Appx. 000451, 000454.] Dr. Wahlig's deposition indicates that doctors look for many factor in order to diagnose sepsis, including apnea, vital signs, and the baby's behavior. She states that the "vital signs may have shown some early changes at approximately 8 pm, but very clearly by 10 pm." [Wahling Dep., Def.'s Appx. 000434-37.] The Court finds that the evidence relating to temporal proximity does not assist the Plaintiffs in creating a genuine issue of material fact on causation. *Bonner*, 259 F.3d at 931. In fact, the Court finds the temporal evidence presented here is more akin to the situation noted in *Willert*, where Plaintiffs assert that because bacterial meningitis occurred and it came after the EHMF feedings, that the EHMF feedings caused the bacterial meningitis. *Willert*, 995 F. Supp. at 981-82.

This is not a case where there is indication that the *E. sak* came from the EHMF and immediately caused illness. *Bonner*, 259 F.3d at 931 (quoting *Heller*, 167 F.3d at 154). Based on the record, there is simply an insufficient temporal relationship for EHMF to be the medical cause of D.J.K.'s illness and there is not a genuine issue of material fact created here.

However, the Court examines the other possible sources of the *E. sak* to see if the Plaintiffs can meet their burden. *Bland*, 2007 WL 5681791, at *10.

C. Other Possible Sources

The parties dispute whether it is possible for other sources to have been the cause of the *E. sak* bacterial infection. “[E]pidemiology addresses whether an agent can cause a disease, not whether an agent did cause a specific plaintiff’s disease.” Federal Judicial Center, *Reference Guide on Epidemiology* 382 (2000). As a result, a plaintiff must rule out other possible causes for injury, in order to support specific causation:

[A] differential diagnosis in a proper specific causation analysis assumes the toxin at issue is capable of causing the outcome under consideration. . . . A differential diagnosis involves “ruling in” specific causes, followed by a process of elimination, and ‘the final suspected “cause” remaining after this process of elimination must actually be *capable* of causing the injury.’

Ranes v. Adams Labs., Inc., 778 N.W.2d 677, 695 (Iowa 2010) (quoting *Cavallo v. Star Enter.*, 892 F. Supp. 756, 771 (E.D.Va. 1995), *aff’d in relevant part*, 100 F.3d 1150, 1159 (4th Cir. 1996)) (emphasis in original). *But see Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1201, 1208 (8th Cir. 2000) (physician’s differential diagnosis opinion for causation inadmissible because physician “was clearly more concerned with identifying and treating [defendant’s] condition than he was with identifying the specific substance that caused her condition.”).

“A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.” *Westberry v. Gislaved Gummi A.B.*, 178 F.3d 257, 265 (4th Cir. 1999) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 758–61 (3d Cir. 1994)). For example, without experts excluding other disease-causing alternatives, it then becomes difficult for an expert to pinpoint the actual disease-causing factor and as a result, there can be “competing causes” of a disease. *See, e.g., Bland*, 2007 WL 5681791, at *8 (expert could only conclude there was a “possibility” alleged product caused asthma, as expert could not exclude other factors such as plaintiff’s home, environment, or other possible causes) (citing *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 758 (8th Cir. 2006)).

Here, to create a genuine issue of material fact on causation, Plaintiffs must be able to present evidence from which a jury can determine that they have excluded other potential sources of the *E. sak* infection. Dr. Forsythe and Ms. Nevin-Folino identified several areas in which the investigation following D.J.K.’s diagnosis was deficient: the breast milk, environmental sources, hospital personnel, and parenteral feedings (the tube inserted in D.J.K.). In their opinion, it is possible any one of these sources could be the cause, especially as both sides concede *E. sak* is “ubiquitous” in the environment. Plaintiffs’ expert, Dr. Farmer, states that the following sources have been ruled out and the EHMF was most likely caused by the EHMF: hospitalization; incubation period; infectious dose; cohort of nine other infants; cohort of other infants; twin cohort; new *E. sak* strain; MMC and CDC initially thought EHMF cause; *E. sak* is a well-documented pathogen; Mead Johnson had past recalls; EHMF sample tested was very small; and epidemiological study did not include the “implicated vehicle.” Dr. Harriman’s opinion endorses Dr. Forsythe’s opinion as to the exclusion of the sources, and further speculates that the CDC may have failed to detect *E. sak* in its sample of EHMF because the sample size was too small.

However, in order for Plaintiffs to succeed in their differential diagnosis, they must

“rule out” potential causes. *Ranes*, 778 N.W.2d at 695. Here, it is unfortunate that the Plaintiffs cannot rule out all the other possible sources, but the fact remains that they cannot do so. *Westberry*, 178 F.3d at 265. For example, the room was cleaned on multiple occasions after May 5, there is not a record of hospital personnel visits to the room, and there was no expressed breast milk to test from the same feedings D.J.K. received on May 5. Contrary to Plaintiffs’ assertion, the investigation by the Iowa Department of Health did not conclude that EHMF was the most likely cause; rather, it stated that it could not “draw definitive conclusions.” The Court refers to Dr. Baltimore’s report, in which he asserts that Drs. Jason and Farmer come to their conclusion on the basis of

there being no other plausible explanation. . . . Among infectious diseases specialists we teach that diagnosis is made by making a positive finding and not by elimination . . . [The logic of just because it] has happened in the past [means] it must have happened this time ignores the demonstrated evidence that other causes of transmission have occurred and the true specificity of the connection with powdered formula has been deemed unclear in the literature by experts.

Plaintiffs’ experts cite EHMF as the cause, but cannot produce evidence that excludes other likely sources. This situation is not unlike the situation in *Turner*, where an expert was so focused on identifying the condition, that he failed to identify the substance causing the condition. *Turner*, 229 F.3d at 1208. Here, when Plaintiffs’ experts identify EHMF as the source of the *E. sak*, they cannot, by a process of elimination, “rule out” other specific causes. *Ranes*, 778 N.W.2d at 695. For example, Dr. Harriman’s opinion as to other environmental sources in the hospital, such as cross-contamination in the room, states that because the hospital followed its protocol for handling EHMF, then that source must be eliminated. Likewise, Dr. Harriman also endorses the finding that the absence of *E. sak* in the tests the CDC performed do not rule out the possibility that *E. sak* was in the packets D.J.K. consumed. Dr. Farmer’s methodology for eliminating

alternative sources follows a similar vein. He states that EHMf is the likely source because D.J.K. was hospitalized the entire time and it was only after he was fed the EHMf, that he became sick. Or that because D.J.K.'s twin remained well (a "twin cohort" study) and EHMf was the only appreciable difference in treatment, that EHMf was the cause.

Plaintiffs are not able to rule out alternative sources. There is not evidence in the record that either proves or disproves that these sources were the "implicated vehicle" for the *E. sak*.

V. CONCLUSION

The Court finds that Plaintiffs fail to offer sufficient proof that genuine issues of material fact exist as to the question of medical causation. Plaintiffs cannot demonstrate that D.J.K.'s ingestion of EHMf caused his bacterial meningitis. Accordingly, the Court finds in favor of Mead Johnson and grants Mead Johnson's motion for summary judgment in its entirety.

Upon the foregoing,

IT IS ORDERED

Defendant Mead Johnson's Motion for Summary Judgment is granted in its entirety. The Clerk shall enter judgment for the Defendant.

DATED this 30th day of July, 2010.



JOHN A. JARVEY
UNITED STATES DISTRICT JUDGE
SOUTHERN DISTRICT OF IOWA