UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Scott Johnson, as guardian ad litem of H.T.P., a minor,

Plaintiff,

v.

Civil No. 11-225 (JNE/LIB)
ORDER

Mead Johnson & Company,

Defendant.

This is an action brought by plaintiff Scott Johnson ("Johnson"), as guardian ad litem of H.T.P., a minor, against defendant Mead Johnson & Company ("Mead"). Johnson claims that H.T.P contracted an infection and consequently suffered severe brain injuries after H.T.P. ingested powdered infant formula manufactured by Mead that was contaminated with *Cronobacter sakazakii* ("*C. sakazakii*").[1] Johnson brings claims of strict liability, negligence, failure to warn, and breach of warranties. This case is before the Court on Mead's motion to exclude or limit the testimony of Johnson's five experts and motion for summary judgment. For the reasons set forth below, the Court grants in part and denies in part Mead's motion to exclude or limit testimony and grants Mead's motion for summary judgment.

I. BACKGROUND[2]

Yvette Nelson ("Nelson") gave birth to H.T.P. on May 4, 2005. After his birth, H.T.P. remained in the hospital for six days for respiratory distress. During his hospital stay, H.T.P. was given ready-to-feed liquid formula. Approximately two days after H.T.P. returned home, around

[1] The parties refer to *C. sakazakii* as *Cronobacter* spp, *Cronobacter sakazakii*, and *E. sakazakii*. For ease of reading, the Court will refer to the organism at issue as *C. sakazakii*, the current name used for the bacterium.

[2] The Court views all facts in the light most favorable to Johnson, the nonmoving party.

May 12, Nelson obtained Enfamil LIPIL with Iron, a powdered infant formula manufactured by Mead, which she fed to H.T.P. Prior to H.T.P.'s feedings, Nelson boiled H.T.P.'s bottles and nipples to sanitize them and cleaned the area in the kitchen where she prepared the formula. She prepared the Enfamil according to the directions on the Enfamil can, mixing the powdered infant formula with municipal water, and then microwaved the bottles of prepared formula. Nelson threw away the prepared formula that was left at the end of a feeding and only prepared one feeding at a time.

On May 13, Nelson took H.T.P. to the doctor because she felt H.T.P. was taking too long to feed. The doctor recommended using a larger nipple on H.T.P.'s bottles.

On May 20, when H.T.P. was 16 days old, H.T.P. was admitted to the hospital for, among other things, poor feeding and a low-grade fever. During his hospital admission, H.T.P. suffered from seizures. His cerebrospinal fluid was collected, and although it bore characteristics suggestive of bacterial meningitis, no organism grew from that fluid. The hospital discharged H.T.P. on June 6 with discharge diagnoses of encephalitis (irritation and swelling of the brain) and a seizure disorder. The hospital also noted that there was a remote possibility of bacterial meningitis. On June 8, H.T.P. was readmitted to the hospital for two days for vomiting. He was discharged with diagnoses of vomiting, probably because of irritation caused by his seizure medication, and possibly viral gastroenteritis.

On June 17, Nelson brought H.T.P. to the hospital because he was fussy, fed poorly, and vomited. A CT scan of H.T.P.'s head revealed hydrocephalus, or a buildup of fluid inside H.T.P's skull that caused brain swelling. H.T.P. was transferred to another hospital, where cerebrospinal fluid was collected for analysis. Three days later, the cerebrospinal fluid culture grew the bacterium *C. sakazakii*.

The hospital contacted the Minnesota Department of Health (MDH) to report H.T.P.'s *C. sakazakii* infection. The MDH collected all of the unopened Enfamil cans Nelson obtained as well as one open Enfamil can she was using. MDH was unable to collect one can of Enfamil that Nelson had completely used and discarded. The MDH gave the cans to the Food and Drug Administration (FDA) for testing, and the FDA tests did not detect any bacteriological contamination.[3] No testing of H.T.P.'s home environment was done.

A *C. sakazakii* infection in an infant can have serious consequences. An infant who is younger than 28 days—a neonate, in other words—has less fully developed gastrointestinal and immune systems than an older infant and is therefore more susceptible to a *C. sakazakii* infection than an older infant. But *C. sakazakii* infections in infants of any age are rare. According to one of Johnson's experts, there were only 92 reported cases of pediatric *C. sakazakii* infections—without any apparent underlying genetic, chronic, immune disorder—worldwide from 1958 to 2008.[4] *C. sakazakii* has been found in powdered infant formulas; in vacuum cleaner bags; in food factories producing chocolate, cereal, potato flour, spices, and pasta; and in the stomachs of

[3] The Centers for Disease Control and Prevention (CDC) also became involved, but it is unclear from the record whether the CDC did any testing of the Enfamil.

[4] In 2008 alone, over 4 million births occurred to United States residents. Mead requests that this Court take judicial notice of five National Vital Statistics Reports from the Centers for Disease Control that chronicle data on births from 2004 to 2008. Mead cites the reports for the total number of births each year. "The court may judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). "The court must take judicial notice if a party requests it and the court is supplied with the necessary information." Fed. R. Evid. 201(c)(2). The Court determines that the information in the reports is not subject to reasonable dispute and that it has been supplied with the necessary information. Therefore, the Court takes judicial notice of the five National Vital Statistics Reports referenced in Docket No. 61.

certain flies. Mead produced a study published in 2012 that found *C. sakazakii* in 26.9% of domestic kitchens.

In 2011, Johnson commenced this action against Mead, alleging that the Enfamil H.T.P. consumed when he was a neonate caused H.T.P.'s *C. sakazakii* infection and that Mead failed to warn consumers that the Enfamil was unreasonably dangerous for neonates. The matter is now before the Court on Mead's motions to exclude or limit the testimony of Johnson's experts and for summary judgment.[5]

II. DISCUSSION

A. Motion to Exclude or Limit Expert Testimony

Mead seeks to exclude or limit large portions of the proposed testimony of five of Johnson's experts. The Court, however, will only focus on the causation testimony of Dr. Janine Jason, Dr. John Farmer, and Dr. Catherine Donnelly because that testimony bears on the Court's analysis of Mead's summary judgment motion.

Federal Rule of Evidence 702 governs the admission of expert testimony and requires courts to act as gatekeepers to ensure that proffered expert testimony is both relevant and reliable. *Vasquez v. Colores*, 648 F.3d 648, 653 (8th Cir. 2011) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993)). Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

[5] The Court did not request supplemental briefing on the question of whether Johnson's strict liability claim, based on an injury that occurred in 2005, was precluded by Minn. Stat. § 541.05, subd. 2 (2012), which sets a four-year statute of limitations on "any action based on the strict liability of the defendant and arising from the manufacture, sale, use or consumption of a product."

> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

"Courts should resolve doubts regarding the usefulness of an expert's testimony in favor of admissibility." *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 758 (8th Cir. 2006). "As 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 (8th Cir. 2001) (quotation omitted). However, an expert's opinion must be excluded if it "is so fundamentally unsupported that it can offer no assistance to the jury." *Id.* at 929–30 (quotation omitted). For example, courts may determine that an expert's proffered opinion is inadmissible because the connection between the opinion and the data is connected "only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 519 (1997).[6] The proponent of the proffered expert testimony must show by the preponderance of the evidence that the expert is qualified and the expert's proffered opinion is reliable. *Khoury v. Philips Med. Sys.*, 614 F.3d 888, 892 (8th Cir. 2010).

1. Dr. Janine Jason

Dr. Jason received her M.D. from Harvard Medical School; completed a pediatric residency and a fellowship in pediatric immunology; and participated in pediatric, immunology, and infectious diseases clinical activities. Dr. Jason worked for 23 years at the CDC as a medical scientist and epidemiologist, and while at the CDC, she was also a member of the clinical faculty at Emory University School of Medicine in the Department of Pediatric Infectious Diseases,

[6] *Ipse dixit* means "he himself said it." Bryan A. Garner, *A Dictionary of Modern Legal Usage* 468 (2d ed. 1995).

Immunology, and Epidemiology. Now Dr. Jason is the chief executive officer of Jason & Jarvis Associates, LCC, a private consulting firm.

Mead seeks to exclude Dr. Jason's opinion that the Enfamil was the cause of H.T.P.'s *C. sakazakii* infection. Mead objects to Dr. Jason's opinion, arguing that the methodology Dr. Jason used to reach her opinion is unreliable.

Dr. Jason arrived at her opinion that the Enfamil was the cause of H.T.P.'s *C. sakazakii* infection by conducting a differential diagnosis. A differential diagnosis is a process whereby an expert rules in all scientifically plausible causes of a plaintiff's injury (the "ruling-in stage") and then systemically rules out the least plausible causes (the "ruling-out stage") until the most likely cause of the plaintiff's injury remains. *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001). The parties do not dispute that a differential diagnosis is a reliable methodology. *See Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000) (noting that an opinion on causation based on a proper differential diagnosis is "sufficiently reliable"). However, Mead argues that Dr. Jason did not conduct a scientifically valid differential diagnosis. Courts may exclude differential diagnoses that are not scientifically valid at either the ruling-in stage or the ruling-out stage. *See Glastetter*, 252 F.3d at 989. A differential diagnosis can fail at the ruling-in stage if an expert relies on inadequate or incomplete data to rule in a cause of the plaintiff's injury. *Id.* A differential diagnosis can fail at the ruling-out stage if the expert uses "subjective beliefs or unsupported speculation" rather than "scientific methods and procedures" to rule out a potential cause. *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1197 (11th Cir. 2010); *see Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010) (stating that for a differential etiology to be reliable, the expert must "reliably rule in the possible causes" and "reliably rule out the rejected causes"); *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1058 (9th Cir. 2003)

("The expert must provide reasons for rejecting alternative hypotheses using scientific methods and procedures and the elimination of those hypotheses must be founded on more than subjective beliefs or unsupported speculation." (quotation omitted)). In her differential diagnosis, Dr. Jason ruled in the Enfamil, the water used to reconstitute the Enfamil, and the environment as possible sources of H.T.P.'s *C. sakazakii* infection. She then ruled out the water and the environment and concluded that it was more probable than not that the Enfamil caused H.T.P.'s infection.

Turning first to the ruling-in stage of Dr. Jason's differential diagnosis, Mead argues that Dr. Jason relied on improper data—specifically, case reports—to rule in the Enfamil as a potential cause of H.T.P.'s infection. "A case report is simply a doctor's account of a particular patient's reaction to a drug or other stimulus, accompanied by a description of the relevant surrounding circumstances." *Glastetter*, 252 F.3d at 989. Case reports, however, have several flaws: they "make little attempt to screen out alternative causes" and "frequently lack analysis." *Id.* at 989–90. Consequently, case reports demonstrate a temporal association between a stimulus and a disease, but such an association is not scientifically valid proof of causation. *Id.* at 990. For example, a case report on a patient who contracts food poisoning might list all the meals the patient ate over the past 48 hours, but that report would only show an association between the meals the patient ate and the disease and would not be valid proof that a specific meal caused the patient's disease. Dr. Jason does rely in part on case reports to rule in the Enfamil.[7] However, Dr. Jason also cites instances where infants were fed powdered infant formula, the infants became infected with *C. sakazakii*, and the *C. sakazakii* was actually isolated from the powdered infant

[7] In her report, Dr. Jason relies on the contents a preliminary version of an article that had not been published as of the date of her report. In that report, she allegedly reviewed all reported cases of pediatric *C. sakazakii* infections worldwide. She summarizes that article for the Court in her report. A copy of that article, however, was not produced for the Court, so the Court does not know the breadth, strength, or content of Dr. Jason's conclusions in that article.

formula. In fact, the parties do not dispute that powdered infant formula can contain *C. sakazakii* and that *C. sakazakii* can cause infections in infants. Therefore, the Court concludes that Dr. Jason reliably ruled in the Enfamil as a possible source of H.T.P.'s *C. sakazakii* infection.

Turning to the ruling-out stage, Mead argues that Dr. Jason unreliably ruled out the water and the home environment. Dr. Jason ruled out the water by observing that during the relevant time period, the municipal water was "tested in some fashion" monthly for "total coliforms," which is a broad group of bacteria found in the environment, and "fecal *e. coli*" and those tests were negative. (Dkt. 124 at 58.) But nowhere in her report does Dr. Jason state that testing for total coliforms or fecal *E. coli* would identify the presence of *C. sakazakii*. Dr. Jason does not provide any information regarding how the municipality tests its water. Dr. Jason did admit, however, in her deposition that municipal water testing "is really not terribly good" for *C. sakazakii*. (Dkt. 66, Exh. 3 at 58.) Further, it is undisputed that the water from the pipes in H.T.P.'s home and faucet was never tested at all. This fact is especially important in light of the fact that, as Dr. Jason states, *C. sakazakii* can clump together and form biofilms. According to Dr. Jason, *C. sakazakii* is not homogenously distributed and can periodically cause sporadic, localized contamination, which would not be detected through routine testing. Given the absence of any information regarding the method and timing of the municipal water testing, and the undisputed fact that the water in H.T.P.'s home was not tested, Dr. Jason had no reliable basis upon which to rule out the water as a possible source. This is particularly true in light of the characteristics of *C. sakazakii* that Dr. Jason so thoroughly described, indicating this bacterium's particular ability to evade detection and cause localized contamination. Dr. Jason's ruling out of the water was not based on a reliable methodology and is so fundamentally unsupported that it would offer no assistance to the jury.

Dr. Jason also ruled out the home environment. Dr. Jason asserted that when H.T.P.'s mother prepared the Enfamil, she used "correct sanitary techniques," such as washing her hands, cleaning the area where she mixed the formula, feeding H.T.P. immediately after preparing the formula, and discarding any formula left in H.T.P.'s bottles. (Dkt. 124 at 57–58.) But nowhere in her report does Dr. Jason assert that "correct sanitary techniques" would prevent *C. sakazakii* contamination. Further, in her deposition, Dr. Jason acknowledged that she did not know what was in the cleaning product H.T.P.'s mother used and so she had no basis to conclude that the product would eradicate any *C. sakazakii* that was present. Without evidence that good housekeeping has any effect on the bacterium, the fastidiousness of H.T.P.'s mother is not relevant. Further, Dr. Jason's admission that she did not know what was in the cleaning product is especially problematic considering Dr. Jason's contention that *C. sakazakii* can form biofilms that can be highly resistant to disinfectants. There was no testing performed of H.T.P.'s home. The cabinet where his feeding supplies were kept was not tested, nor was the kitchen sink or any other part of H.T.P.'s environment. There was some evidence in the record that H.T.P.'s mother might have used a water filter, and that filter was not tested. H.T.P.'s family members were not tested for the presence of *C. sakazakii*. Dr. Jason's ruling out of the home environment is based on no ascertainable methodology, let alone a methodology that satisfies the requirements of Fed. R. Evid. 702(c).

Dr. Jason's ruling-out methodology is fundamentally unsound and not supported by any factual basis. Because Dr. Jason unreliably ruled out the water and the home environment, the Court excludes Dr. Jason's proposed testimony on her differential diagnosis and her opinion that the Enfamil caused H.T.P.'s infection.

2. Dr. John Farmer

Dr. Farmer holds a Ph.D. in microbiology. He described *C. sakazakii* in 1980 and is responsible for giving the organism its name. He has spent his career at the CDC.

Mead seeks to exclude Dr. Farmer's opinions that the Enfamil was the cause of H.T.P.'s *C. sakazakii* infection and that the strain of *C. sakazakii* that infected H.T.P. was genetically related to *C. sakazakii* strains isolated from other infants who were also fed powdered infant formula manufactured by Mead. Mead argues that the methodologies Dr. Farmer used to reach his opinions are unreliable.

Dr. Farmer reached his opinion that the Enfamil was the cause of H.T.P.'s infection by conducting a differential diagnosis. In his differential diagnosis, Dr. Farmer does not engage in the primary step of ruling in the Enfamil. Rather, Dr. Farmer jumps directly to ruling out potential causes of the infection. Once at the ruling out stage, however, Dr. Farmer's analysis suffers from the same fatal flaws as Dr. Jason's.

Like Dr. Jason, Dr. Farmer also rules out the water because municipal water testing never identified the presence of *C. sakazakii*. But he does not indicate that the municipal water testing would have, or even could have, identified *C. sakazakii*. He lacked information regarding how and where the water was tested. He agrees that *C. sakazakii* is not spread homogenously and can form clumps and biofilms that cause sporadic localized contamination. But he ignores the fact that the water H.T.P. consumed—the water flowing through the pipes in H.T.P.'s home—was never tested. Like Dr. Jason, Dr. Farmer does not use any reliable methodology to rule out the water.

Dr. Farmer also ruled out the home environment as a source of H.T.P.'s *C. sakazakii* infection. He did so by stating that "[n]othing in the record documents or even suggests the presence of [*C.*] *sakazakii*" in the home environment. (Dkt. 125 at 42.) But he admitted in his deposition that H.T.P.'s home was never tested for *C. sakazakii*; the lack of testing does not support Dr. Farmer's conclusion that *C. sakazakii* did not exist in the home environment. He also rules out H.T.P.'s mother introducing *C. sakazakii* into the Enfamil when she prepared it because she was a good housekeeper. But Dr. Farmer never asserts that good housekeeping practices would preclude the presence of *C. sakazakii*. And in his deposition, Dr. Farmer admitted that he did not know which disinfectants H.T.P.'s mother used to clean her house and was unable to state that those disinfectants would eradicate *C. sakazakii*. Because Dr. Farmer failed to use reliable methods to rule out the water and the home environment, the Court excludes Dr. Farmer's proposed testimony on his differential diagnosis and his corresponding opinion that the Enfamil caused H.T.P.'s infection.

Mead also objects to Dr. Farmer's opinion that the *C. sakazakii* strain that infected H.T.P. was related to the strains that infected other infants fed powdered infant formula manufactured by Mead. Before discussing the methodology Dr. Farmer used to reach his conclusion, the Court first turns to what Dr. Farmer actually said in his report. Dr. Farmer states that the CDC received two strains of *C. sakazakii* that had been isolated from two different batches of Enfamil and that those strains were a "match" with strains isolated from two particular infants (not H.T.P.). (*Id.* at 54.) He then states that the *C. sakazakii* isolated from H.T.P. was a "match" to the *C. sakazakii* strains isolated from *other* infants fed powdered infant formula manufactured by Mead. (*Id.*) Notably, Dr. Farmer does not state that the strain isolated from H.T.P. matched either of the two strains isolated from the two batches of Enfamil. He also never states that H.T.P.'s *C. sakazakii*

strain matched strains that were ever found in powdered infant formula, only strains that were found in "other infants" who were fed powdered infant formula. (*Id.*) Therefore, Dr. Farmer's analysis does not suggest that H.T.P.'s *C. sakazakii* strain matched strains that were found in formula manufactured by Mead, only that H.T.P.'s strain matched strains found in other infants who were fed Mead's formula.

Dr. Farmer reached his conclusion about the relatedness of *C. sakazakii* strains by conducting a pulsed-field gel electrophoresis (PFGE) analysis. PFGE is a method scientists use to create a DNA fingerprint for a bacterium. A DNA fingerprint is created by slicing a small piece out of a bacterium's DNA, digesting that piece with a restriction enzyme, placing the piece onto a slab of gelatin, and sending electricity through the gelatin so that the piece separates. The separation of the piece creates a banding pattern—a DNA fingerprint. A digital image of the DNA fingerprint is taken and in some cases is stored on a CDC database. In his report, Dr. Farmer analyzes what he calls "CDC PFGE dendrogram 1," a document that he says contains the PFGE patterns—in other words, the DNA fingerprints—of over 100 *C. sakazakii* isolates in the CDC database. (*Id.*) He states that that document shows that the *C. sakazakii* strain that infected H.T.P. was a "PFGE match"—in other words, genetically related—to *C. sakazakii* strains isolated from other infants who were fed powdered infant formula manufactured by Mead. (*Id.*) Mead argues that Dr. Farmer's PFGE analysis is unreliable and submits for support the declaration and report of Dr. Garth Ehrlich. In his report, Dr. Ehrlich argues that the CDC's published method for PFGE testing states that if a PFGE analysis using one restriction enzyme shows that two bacterial strains are indistinguishable, then a second and third restriction enzyme

should be used to determine if the strains come from a common source.[8] He asserts that the PFGE analyses in "CDC PFGE dendrogram 1" were done with only one restriction enzyme, so under the CDC's published method, any comparison between strains cannot establish that the strains came from a common source or match. In Dr. Farmer's responsive affidavit to Dr. Ehrlich's critiques, Dr. Farmer only states that he "took great pains not to over-interpret the PFGE findings" (Dkt. 81 at 9) but does not dispute that the PFGE test was only done with one enzyme. Dr. Farmer does not rebut Dr. Ehrlich's argument regarding the unreliability of the PFGE method Dr. Farmer employed. As the proponent of the proffered expert testimony, Johnson carries the burden of showing by the preponderance of the evidence that Dr. Farmer's proposed PFGE testimony is reliable. *Khoury,* 614 F.3d at 892. Johnson has not carried that burden here, where he has failed to substantively respond to an argument that places the reliability of Dr. Farmer's methodology in question.

Federal Rule of Evidence 703 provides that under some circumstances an expert's opinion may be based on information that is not admissible. Dr. Farmer opines that the test for whether *C. sakazakii* strains are a "PFGE match" is whether they meet the "Arduino criteria." (Dkt. 125 at 3–4, 12.) The "Arduino criteria" seems, in fact, to be a single criterion, but more relevantly is a phrase coined by Dr. Farmer following communications he had with a CDC colleague named Arduino. Dr. Arduino supposedly told Dr. Farmer that strains were related if their similarity was 80% or higher. Dr. Farmer does not point to any publications or anything

[8] The CDC's PFGE method is published in Efrain M. Ribot et al., *Standardization of Pulsed-Field Gel Electrophoresis Protocols for the Subtyping of* Escherichia coli *O157:H7,* Salmonella*, and* Shigella *for PulseNet,* 3 FOODBORNE PATHOGENS & DISEASE 59, 63 (2006) (Dkt. 90, Exh. 8). As published the Ribot article applies only to the PFGE method of testing *E. coli*, *Salmonella*, and *Shigella*. But Dr. Farmer admitted in his deposition that to his knowledge the CDC only uses one PFGE method, and that is the method published in the Ribot article. He proffers no scientific justification for any other method.

else establishing that the "Arduino criteri[on]" has ever been referred to outside the context of this litigation, much less that it is generally accepted or commonly relied on by experts in the relevant field. It does not satisfy Rule 703.

Because Dr. Farmer's analysis is not based on application of reliable principles and methods, the Court excludes Dr. Farmer's proffered testimony on the PFGE analysis.

3. Dr. Catherine Donnelly

Dr. Catherine Donnelly has an M.S. and a Ph.D. in food science and is a full professor of nutrition and food science at the University of Vermont. The main focus of her study since 1983 has been the detection and prevention of *Listeria monocytogenes*, a bacterium that thrives in dairy products and deli meats.

Mead seeks to exclude Dr. Donnelly's opinion that the Enfamil was more likely than not the cause of H.T.P.'s *C. sakazakii* infection. Mead objects to Dr. Donnelly's opinion, arguing that the methodology Dr. Donnelly used to reach her opinion is unreliable.

Dr. Donnelly appears to reach her opinion that the Enfamil was the cause of H.T.P.'s infection by conducting a differential diagnosis. She does not first rule in the Enfamil, but she rules out contamination during preparation by H.T.P.'s mother as well as the water. Like Dr. Jason and Dr. Farmer, Dr. Donnelly rules out the home environment and contamination by H.T.P.'s mother because H.T.P.'s mother had a "clean and sanitary home environment" and was a "self-described germaphobe." (Dkt. 126 at 6.) But Dr. Donnelly does not state that having a clean home environment would preclude the existence of *C. sakazakii*. She acknowledges that *C. sakazakii* forms biofilms that are resistant to disinfectants. She also was aware that she not seen any environmental testing data for H.T.P.'s home. Dr. Donnelly makes no assertion that the municipal water testing would have identified the presence of *C. sakazakii*, and she admits that

C. sakazakii had been isolated from tap water. She also admits that the municipal water department did not test for *C. sakazakii*. For the same reasons as Dr. Jason and Dr. Farmer, Dr. Donnelly failed to use a reliable methodology to rule out other possible sources of H.T.P.'s infection. The Court therefore excludes Dr. Donnelly's proposed testimony that the Enfamil caused H.T.P.'s infection.[9]

B. Motion for Summary Judgment

Summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). To support an assertion that a fact either cannot be or is genuinely disputed, a party must cite "to particular parts of materials in the record," show "that the materials cited do not establish the absence or presence of a genuine dispute," or show "that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A)–(B). In determining whether summary judgment is appropriate, a court must look at the record and any inferences to be drawn from it in the light most favorable to the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

Johnson sued Mead for strict liability, negligence, failure to warn, and breach of warranties. The failure to warn[10] and breach of warranties claims require proof that the Enfamil

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[9] The Court is aware that in a similar case, the causation testimony of Dr. Jason, Dr. Farmer, and Dr. Donnelly was not excluded. *Burks v. Abbott Labs.*, Civil No. 08-3414, 2013 WL 101831 (D. Minn. Jan. 8, 2013). However, in that case, the court did not discuss the methodology the experts used to rule out other possible sources of infection, so the Court declines to follow that order.

[10] After the hearing on this matter, the Court asked the parties to submit supplemental memoranda on whether Johnson's failure to warn claim was preempted by federal law. Because the Court has already excluded the causation testimony of Johnson's experts, Johnson's failure to warn claim fails on the merits, and the Court deems it unnecessary to determine whether Johnson's claim would be preempted. The Court appreciates the parties' efforts in submitting timely and thorough supplemental memoranda.

caused H.T.P.'s injuries. *See In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161, 1166 (8th Cir. 2012) (in failure to warn cases, plaintiff must show that the lack of an adequate warning caused plaintiff's injuries); *Minn. Mining & Mfg. Co. v. Nishika Ltd.*, 565 N.W.2d 16, 23 (Minn. 1997) (in breach of warranty cases, plaintiff must "prove that there was a warranty, that it was breached, and that a loss was caused by the breach"). Because the Court has excluded the causation testimony of Johnson's experts, Johnson cannot prove that the Enfamil caused H.T.P.'s injuries. Therefore, the Court grants summary judgment to Mead on Johnson's failure to warn and breach of warranties claims.

Johnson's strict liability and negligence claims are analyzed under the law that pertains to defective food products. In a defective food products case where a plaintiff does not have direct proof of the injury-causing substance, the plaintiff can survive summary judgment if he establishes by reasonable inference from circumstantial evidence that

> (1) the injury-causing event was of a kind that would ordinarily only occur as a result of a defective condition in the food product; (2) the defendant was responsible for a condition that was the cause of the injury; and (3) the injury-causing event was not caused by anything other than a food product defect existing at the time of the food product's sale.

Schafer v. JLC Food Systems, Inc., 695 N.W.2d 570, 576 (Minn. 2005). Without the causation testimony of Johnson's experts, Johnson cannot show that Mead was responsible for the *C. sakazakii* that injured H.T.P. or that the *C. sakazakii* infection was not caused by anything other than the Enfamil. Furthermore, the parties do not dispute that other populations that do not consume powdered infant formula—elderly adults and non-formula fed infants—acquire *C. sakazakii* infections, so Johnson cannot show that H.T.P.'s contraction of a *C. sakazakii* infection after consuming powdered infant formula would ordinarily only occur as a result of a defective

condition in the formula. Therefore, the Court grants summary judgment to Mead on Johnson's strict liability and negligence claims.

III. CONCLUSION

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

1. Defendant's Motion to Exclude Expert Testimony [Docket No. 62] is GRANTED IN PART and DENIED IN PART in accordance with this Order.
2. Defendant's Motion for Summary Judgment [Docket No. 50] is GRANTED.
3. The Plaintiff's Complaint is DISMISSED.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: February 27, 2013

s/Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge