IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

THE SECURITY NATIONAL BANK OF SIOUX CITY, IOWA, as Conservator for J.M.K, a Minor,

Plaintiff,

vs.

ABBOTT LABORATORIES,

Defendant.

No. C 11-4017-MWB

MEMORANDUM OPINION AND ORDER REGARDING THE DEFENDANT'S MOTIONS FOR SUMMARY JUDGMENT, TO EXCLUDE PLAINTIFF'S CAUSATION EXPERTS, AND TO STRIKE AFFIDAVIT[1]

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[1] All of the parties' submissions in support of and opposition to the pending substantive motions addressed in this Opinion were filed under seal. Nevertheless, I do not believe that this Opinion discloses any information that should remain under seal, so it will not be filed under seal.

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In this action, plaintiff Security National Bank, as Conservator for a child, JMK, who suffered severe brain damage from bacterial meningitis as a neonate, asserts product defect, breach of warranty, and fraud claims against Abbott Laboratories, the manufacturer of the powdered infant formula (PIF) that was allegedly the source of the bacteria that caused JMK's injuries. Abbott seeks summary judgment on the ground that the Conservator cannot generate genuine issues of material fact on key elements of its claims, including whether Abbott's PIF was even a source of the bacteria that infected JMK. In addition, Abbott seeks to exclude evidence from the Conservator's causation experts pursuant to Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and to strike a "sham" affidavit by JMK's mother, which Abbott argues contradicts her prior deposition

testimony about the onset and progression of JMK's symptoms of infection and, consequently, is submitted for the sole purpose of creating a fact issue where none exists. I must determine whether or not I can consider the challenged affidavit and the challenged experts' opinions, then determine whether or not the Conservator has generated genuine issues of material fact on the challenged elements of its claims in light of admissible evidence.

I. INTRODUCTION

A. Factual Background

As general background,[2] the undisputed record shows that JMK, a baby girl, was the first of non-identical twins born to Megan Surber and Troy Kunkel on April 14, 2008, at St. Luke's Hospital in Sioux City, Iowa. JMK and her twin brother were electively delivered by scheduled Caesarean section, without complications, prior to their estimated due date of May 5, 2008. JMK and her mother remained at the hospital until the morning of April 17, 2008; her twin brother remained in the hospital until April 24, 2008. The parties dispute the precise number and identity of friends and relatives, besides treating physicians, hospital nurses, and hospital staff members, who had physical contact with JMK during her stay at the hospital. The parties agree, however, that while JMK remained at the hospital, she was fed only ready-to-feed (RTF) liquid formula from 2-ounce, single-feeding bottles, with a new bottle used for each feeding, and that she was only fed by Ms. Surber or the nurses.

At the time that JMK and her mother were discharged from the hospital on April 17, 2008, Ms. Surber received a "gift bag" containing several small bottles of Similac

[2] I do not find it necessary to my disposition of any of the pending motions to set out here an exhaustive dissertation of the facts, whether disputed or undisputed, asserted by the parties. Where specific factual disputes become critical, I will address them in my legal analysis to follow.

NeoSure RTF liquid formula, one larger bottle of Similac NeoSure RTF liquid formula, and a 12.8-ounce container of Similac NeoSure PIF, all made by Abbott. The parties dispute whether the bag also contained other information about Similac formulas, and Abbott denies that it ever assembled such "gift bags" or that it provided the Similac in the gift bag in return for any monetary or other consideration from the hospital.

After JMK's discharge from the hospital, Ms. Surber took JMK to the family's residence in Sioux City, Iowa, where JMK remained until April 24, 2008. The parties again dispute the number and identity of family members and other individuals with whom JMK had physical contact during her first week at home. During JMK's first week at home, Ms. Surber only fed JMK the formula that Ms. Surber had received upon her discharge from the hospital.[3] Ms. Surber was the only person to feed JMK. Ms. Surber first fed JMK with single-use bottles of RTF liquid formula, then with RTF liquid formula from the larger bottle, which was refrigerated after opening, and only

[3] Abbott disputes this factual allegation as "misleading/confusing and immaterial," but the basis for Abbott's dispute appears to be the "suggest[ion] that RTF formula cannot be extrinsically contaminated (post-manufacture) while in the possession of a consumer." Defendant's Reply To Plaintiff's Statement Of Additional Material Facts (docket no. 97-1) at ¶¶ 3 and 9. Because the pertinent statement of *fact* is that JMK was only fed the formula from the gift bag during her first week at home, whatever else it may seem to "suggest" to Abbott, the statement is deemed admitted for lack of a proper response. *See* N.D. IA. L.R. 56.d. (the moving party must "expressly admit[ ], den[y], or qualif[y] each of the resisting party's numbered statements of additional fact," and a response that fails to do so is deemed admitted); *see also Habben v. City of Fort Dodge*, 472 F. Supp. 2d 1142, 1147-48 (N.D. Iowa 2007) (concluding that objections to "implications" or "inferences" from facts stated by an opposing party are not properly responsive and the facts stated may be deemed admitted). It does not appear that Abbott's objection is that JMK was fed some other formula. Thus, Abbott could properly have responded by admitting that JMK was not fed anything other than formula from the hospital gift bag, but qualifying the admission by asserting that such formula could have been extrinsically contaminated in storage or handling.

then with PIF, beginning with the evening feeding about 9:00 p.m. on April 23, 2008. The parties dispute whether JMK was already showing symptoms of an infection that evening.

JMK also received PIF feedings at midnight, 4:00 a.m., and 8:30 a.m. on April 24, 2008. At the 8:30 a.m. feeding, JMK was not feeding well and cried throughout the rest of the day. At some point on the morning of April 24, 2008, Ms. Surber took JMK's temperature, which was less than 100 degrees. JMK continued to be fussy, cry, and refuse to eat. When Ms. Surber took JMK's temperature again in the afternoon, it was slightly elevated, so Ms. Surber called JMK's doctor. Ms. Surber took JMK to the pediatrician's office, but was redirected to St. Luke's Hospital, apparently before JMK was examined. JMK was admitted to the hospital shortly after 6:00 p.m. on April 24, 2008. JMK was later transferred to Children's Hospital in Omaha, Nebraska, on April 26, 2008. The parties agree that JMK was diagnosed with meningitis from *Enterobacter sakazakii*, a *Cronobacter*, usually referred to in shortened form as *E. sak* or *C. sak*, but dispute whether the diagnosis was first made at St. Luke's Hospital or Children's Hospital. The Conservator contends that Abbott's PIF was the source of the *C. sak* that infected JMK.

B. Procedural Background

In a Second Amended Complaint (docket no. 46), filed June 27, 2011, the Conservator asserted seven causes of action against Abbott: In **Count 1**, a manufacturing defect claim, premised on the allegation that the presence of *C. sak* in Abbott's PIF was a departure from the intended design of the PIF; in **Count 2**, a design defect claim, premised on allegations that biocidal treatment of the PIF or distribution

of only liquid formula are plausible, reasonable alternative designs to Abbott's PIF;[4] in **Count 3**, a warning defect claim, premised on allegations that Abbott's warning label on its PIF is inadequate in such a manner as to make its PIF not reasonably safe; in **Count 4**, a claim of breach of express warranties; in **Count 5**, a claim of breach of implied warranty of fitness for a particular purpose; in **Count 6**, a claim of breach of implied warranty of merchantability; and in **Count 7**, a claim of fraud. In his February 1, 2012, ruling on Abbott's Motion To Dismiss, however, Senior District Judge Donald E. O'Brien, to whom this case was originally assigned, dismissed the Conservator's claim of breach of the implied warranty of fitness for a particular purpose in **Count 5**. *See* Memorandum Opinion And Order (docket no. 64) at 52-53 & 62, *Security Nat'l Bank of Sioux City, Iowa v. Abbott Labs.*, 2012 WL 327863, *18 & *21 (N.D. Iowa Feb. 1, 2012). A jury trial in this matter is set to begin on September 3, 2013.

On March 20, 2013, Abbott filed its Motion For Summary Judgment (docket no. 86), seeking summary judgment on all of the Conservator's remaining claims, with a request for oral arguments, and its Motion To Exclude Or Limit Plaintiff's Proposed Expert Testimony On Medical And Scientific Causation (Abbott's *Daubert* Motion) (docket no. 87). On May 3, 2013, Abbott filed its Motion To Strike Megan Surber's September 19, 2012, Affidavit (docket no. 99). The Conservator duly resisted each of these motions, and Abbott filed replies in further support of them. On May 14, 2013, the Conservator filed a Request For Oral Argument (docket no. 100), seeking oral arguments on Abbott's Motion For Summary Judgment and Abbott's *Daubert* Motion.

This case was reassigned to me on May 21, 2013. *See* Order (docket no. 102). By Order (docket no. 104), filed May 25, 2013, I requested information from the

[4] The description of this claim indicates the allegations found adequate by Senior District Judge O'Brien in his ruling on Abbott's Motion To Dismiss. *See* Memorandum Opinion And Order (docket no. 64), 33, *Security Nat'l Bank of Sioux City, Iowa v. Abbott Labs.*, 2012 WL 327863, *12 (N.D. Iowa Feb. 1, 2012).

parties concerning Abbott's *Daubert* Motion, including, *inter alia*, whether the parties were requesting an evidentiary hearing or only oral arguments on that motion. In their e-mail responses to my judicial assistant, both parties indicated that they were only requesting oral arguments, not an evidentiary hearing, on Abbott's *Daubert* Motion, but they requested that the oral arguments be "live."[5]

I have decided that it is unnecessary to hear oral arguments on any of the pending motions. First, I find it unnecessary to impose upon the parties the expense of appearing for "live" oral arguments. Second, where the parties do not want an evidentiary hearing on a *Daubert* motion, I do not find that oral arguments are likely to be helpful, at least not where, as here, the parties' positions are well-briefed. An evidentiary hearing is not required prior to a *Daubert* determination on expert evidence; rather, what is required is that the parties "have an adequate opportunity to be heard" before the court makes its decision. *Group Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 761 n.3 (8th Cir. 2003). The parties' written submissions have provided them with such "an adequate opportunity to be heard" on Abbott's *Daubert* Motion. Third, because the parties' briefing on Abbott's other pending motions is thorough, I find it unnecessary to hear oral arguments on those motions, either. Therefore, Abbott's request for oral arguments on its Motion For Summary Judgment (docket no. 86) is denied; the Conservator's May 14, 2013, Request For Oral Argument (docket no. 100), seeking oral arguments on Abbott's Motion For Summary Judgment and Abbott's *Daubert* Motion, is denied; and I will resolve Abbott's pending motions on the parties' written submissions.

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[5] In his e-mail response to my Order (docket no. 102), the Conservator's counsel felt compelled to remind me that there are three motions pending. My Order (docket no. 102) concerned only whether or not the parties wanted an evidentiary hearing or oral arguments on Abbott's *Daubert* Motion, as that is the only motion on which an *evidentiary hearing* would be permissible.

II. LEGAL ANALYSIS

I conclude that Abbott's motions should be considered in the reverse order from their filing. This course is appropriate, because the second and third motions go to the evidence that I may properly consider in deciding the motion for summary judgment.

A. The Challenge To The Affidavit

1. Arguments of the parties

In its May 3, 2013, Motion To Strike Megan Surber's September 19, 2012, Affidavit (docket no. 99), Abbott contends that Ms. Surber's statements to JMK's treating physicians and her mother, as well as her July 5, 2012, deposition testimony, show that JMK was already exhibiting symptoms of bacterial meningitis infection on April 23, 2008, *before* she ever consumed any of Abbott's PIF. Abbott contends, however, that Ms. Surber has done an "about face" in an affidavit dated September 19, 2012—which the Conservator's experts then used as part of the basis for their causation opinions, before it was disclosed to Abbott—by averring that the evening of April 23, 2008, was "routine" and that JMK did not show any unusual behavior, symptomatic of infection, until the morning of April 24, 2008, after JMK had been fed Abbott's PIF. Abbott argues that such a "sham" affidavit cannot generate genuine issues of material fact to preclude summary judgment.

In response, the Conservator argues that Ms. Surber's affidavit does not conflict with or contradict any portion of her own deposition, nor any other deposition or discovery response. Rather, the Conservator contends that the affidavit was prepared to provide its experts with additional information that was not elicited by Abbott during Ms. Surber's deposition. Relying on comparisons of quotations from Ms. Surber's deposition and her affidavit, the Conservator argues that there is no conflict or

contradiction between the deposition and the later affidavit, only elaboration in the affidavit. The Conservator argues that any apparent differences between Ms. Surber's affidavit and the medical records arise from the vagueness of statements in the medical records about the timing of certain events or symptoms. Thus, the Conservator contends that it has either shown the lack of conflicts or adequately explained them, so that Ms. Surber's affidavit is admissible. The Conservator also contends that it was not until after Abbott disclosed its experts in January 2013, well after Ms. Surber's deposition and affidavit, that the Conservator learned that Abbott intended to argue that JMK was already ill before she consumed her first PIF on the evening of April 23, 2008.

In reply, Abbott argues that Ms. Surber's affidavit does not fall within the narrow circumstances in which it would be admissible—such as raising a new matter, explaining vague aspects of prior deposition testimony, or remedying confusion at the deposition—but simply contradicts Ms. Surber's previous unambiguous deposition testimony and her statements to family members and treating physicians.

2. Analysis

The Eighth Circuit Court of Appeals has reiterated, "In *Camfield Tires, Inc. v. Michelin Tire Corp.*, 719 F.2d 1361, 1365 (8th Cir. 1983), this court held where a party creates an issue of fact by filing an affidavit contradicting earlier testimony in order to avoid summary judgment, the party raises a 'sham issue of fact instead of a genuine one.'" *Lykken v. Brady*, 622 F.3d 925, 933 (8th Cir. 2010). The court in *Lykken* noted some exceptions to the "sham issue of fact" rule, including clarification of the prior testimony or explanation of the deponent's confusion. *Id.* I have recognized others, including supplementation that does not contradict factual assertions in a prior deposition, *see Knutson v. AG Processing, Inc.*, No. C01–3015–MWB, 2002 WL 31422858, *11 (N.D. Iowa Oct. 29, 2002), and recent refreshment of the affiant's

memory by photographs that he had not been shown during the deposition, *see Rowson v. Kawasaki Heavy Indus., Ltd.*, 866 F. Supp. 1221, 1229–31 (N.D. Iowa 1994).

Thus, the question is whether any exceptions appear to be applicable here, or whether the affidavit is, instead, an "unexpected revision" to create a fact issue where none existed before, with no attempt to explain the difference. *See Marathon Ashland Petroleum, L.L.C. v. International Bhd. of Teamsters*, 300 F.3d 945, 951 (8th Cir. 2002); *see also Frevert v. Ford Motor Co.*, 614 F.3d 466, 474 (8th Cir. 2010) ("We have previously 'held that the plaintiff did not create a genuine issue of material fact simply by submitting an affidavit that contradicted testimony at a prior deposition, where there were no "legitimate reasons" for the filing of an inconsistent affidavit.' *Roberts v. Park Nicollet Health Serv.*, 528 F.3d 1123, 1126 (8th Cir. 2008) (quoting *Camfield Tires, Inc. v. Michelin Tire Corp.*, 719 F.2d 1361, 1365 (8th Cir. 1983))."); *Bass v. City of Sioux Falls*, 232 F.3d 615, 619 (8th Cir. 1999) ("'Ambiguities and even conflicts in a deponent's testimony are generally matters for the jury to sort out, but a district court may grant summary judgment where a party's sudden and unexplained revision of testimony creates an issue of fact where none existed before. Otherwise, any party could head off a summary judgment motion by supplanting previous depositions ad hoc with a new affidavit, and no case would ever be appropriate for summary judgment.'" (quoting *Wilson v. Westinghouse Elec. Corp.*, 838 F.2d 286, 289 (8th Cir. 1988)). The Eighth Circuit Court of Appeals has also cautioned "that district courts should examine alleged inconsistencies between an affidavit and previous deposition testimony 'with extreme care.'" *Baker v. Silver Oak Senior Living Mgmt. Co., L.C.*, 581 F.3d 684, 690 (8th Cir. 2009) (quoting *Camfield Tires, Inc.*, 719 F.2d at 1366).

Proceeding with the requisite "extreme care" here, *see id.*, I conclude that Abbott has made a colorable "jury argument" that Ms. Surber changed her story about

the progression of JMK's symptoms, *see Bass*, 232 F.3d at 619 ("Ambiguities and even conflicts in a deponent's testimony are generally matters for the jury to sort out. . . ." (internal quotation marks and citations omitted), but has failed to show that there is any unexplained "conflict" or "contradiction" rather than elaboration, clarification, or new matter raised in Ms. Surber's affidavit, as compared to her deposition testimony. *See Marathon Ashland Petroleum, L.L.C.*, 300 F.3d at 951 (considering these factors in determining whether or not to exclude a later affidavit). Indeed, my comparison of the deposition testimony and the affidavit suggests that Abbott too avidly asserts that its interpretations of the deposition testimony are the only possible ones. In contrast, the Conservator has shown, by pointing to specific statements in Ms. Surber's and her mother's depositions, and comparing them with the statements in Ms. Surber's affidavit, that details in the affidavit are either consistent with, clarify, or supplement details in Ms. Surber's deposition in such a way that the affidavit can reasonably be read as consistent with, not contradictory to, Ms. Surber's deposition testimony. *See Lykken*, 622 F.3d at 933 (recognizing that an affidavit need not be excluded where it provides clarification of the prior testimony or explanation of the deponent's confusion); *Knutson*, No. C01–3015–MWB, 2002 WL 31422858 at *11 (recognizing as an exception to the *Camfield* rule an affidavit that supplements but does not contradict factual assertions in a prior deposition).

Furthermore, the Conservator has offered a credible explanation for any apparent conflicts between the more detailed chronology of symptoms (such as the degrees of JMK's "fussiness" and the nature of JMK's crying or whining) that JMK displayed from April 23 to April 24, 2008, in Ms. Surber's affidavit, on the one hand, and her mother's deposition testimony and the much more vague summaries in medical records. Specifically, the Conservator has shown, by pointing to specific statements in Ms. Surber's mother's deposition, and comparing them with the statements in

Ms. Surber's affidavit, that details in the affidavit are either consistent with, clarify, or supplement details in Ms. Surber's mother's deposition testimony, in such a way that the affidavit can reasonably be read as consistent with, not contradictory to, Ms. Surber's mother's deposition testimony. The Conservator also explains that the medical records do not necessarily accurately reflect her statements at the time. *See, e.g., Marathon Ashland Petroleum, L.L.C.*, 300 F.3d at 951 (considering whether the proffering party has attempted to explain apparent inconsistencies between an affidavit and prior deposition testimony).[6] Thus, the Conservator's explanation should be considered by the jury, not by the court, in deciding the truth of the matter.

The apparent differences between Ms. Surber's affidavit and her prior deposition testimony or other evidence, are not only shown to be elaborations or otherwise explained, but can hardly be considered "*unexpected* revisions" simply to attempt to avoid summary judgment. *See, e.g., id.* (emphasis added). Although the allegedly "revisionist" affidavit appeared after Ms. Surber's deposition, and was disclosed to the Conservator's experts before it was disclosed to Abbott, the Conservator points out that the affidavit was disclosed with its experts and their reports on October 24, 2012, well before Abbott disclosed its experts and their reports in January 2013, and well before Abbott filed its Motion For Summary Judgment on May 3, 2013. The affidavit was not created and offered only after and in response to Abbott's Motion For Summary Judgment, nor was the version of the facts in the affidavit in any sense "sudden" or "unexpected" by the time that Abbott filed its Motion For Summary Judgment.

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[6] I am not convinced that any inconsistency between one witness's affidavit and another witness's deposition testimony, or apparent inconsistencies between a witness's affidavit and medical records prepared by a third party, even if the records supposedly reflected the witness's statements at the time, would warrant striking the affidavit. It seems to me that such inconsistency or conflict is the stuff of which genuine issues of material fact are made.

Abbott's May 3, 2013, Motion To Strike Megan Surber's September 19, 2012, Affidavit (docket no. 99) is denied.

B. The Daubert *Challenge To The Conservator's Causation Experts*

I will consider, next, Abbott's May 3, 2013, Motion To Exclude Or Limit Plaintiff's Proposed Expert Testimony On Medical And Scientific Causation (Abbott's *Daubert* Motion) (docket no. 87). This motion is of critical importance to whether or not the Conservator can support any of its claims sufficiently to preclude summary judgment.

1. Arguments of the parties

Abbott seeks to exclude or limit the testimony of the Conservator's three experts—Drs. Catherine Donnelly (a food safety scientist), James Farmer (a microbiologist), and Janine Jason (a pediatrician)—regarding the medical and scientific causation of JMK's bacterial meningitis, on the ground that their testimony fails to meet the standards of admissibility for expert opinions under Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Abbott challenges the reliability of both the experts' "ruling in" methodology, to show that Abbot's PIF was a potential source of the *C. sak* that infected JMK, and their "ruling out" methodology, to eliminate other potential sources of *C. sak*, to demonstrate that the PIF was the most likely source of the *C. sak*.

Somewhat more specifically, as to "ruling in" methodology, Abbott argues that these experts fail to consider evidence that Abbott argues "eliminates" PIF as a potential source of *C. sak*, including testing by the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) that confirmed the absence of *C. sak* in either the container of PIF used to feed JMK or other samples from the same lot of PIF

prepared within minutes of the PIF in the container used to feed JMK; they acknowledge that there is no microbiological, statistical, or other scientific evidence suggesting the presence of *C. sak* in Abbott's PIF or evidence that could otherwise "rule in" Abbott's PIF as a potential source of JMK's illness; they rely, instead, on a supposed epidemiological association between PIF and certain *C. sak* infections, which is insufficient to "rule in" Abbott's PIF in any particular case, such as JMK's infection; and they reason from a desired result backwards to "rule in" Abbott's PIF, assuming the presence of *C. sak* in Abbott's PIF simply because they believe it to be the most likely source of *Cronobacter* in a PIF-fed infant. In addition, Abbott contends that Dr. Jason's "ruling in" methodology is premised on a faulty opinion regarding the incubation period of *C. sak* and a faulty timeline for the progression of JMK's symptoms. Similarly, Abbott argues that these experts used faulty methodology in "ruling out" a host of alternative sources of JMK's *C. sak* infection, where inadequate and limited testing was done to assess whether *C. sak* was present in JMK's environment and whether the source of the bacteria might have been person-to-person contact.

In response, the Conservator argues that its experts' opinions are reliable and relevant and, indeed, their methodology surpasses the *Daubert* standard. The Conservator contends that it is undisputed that PIF can contain *C. sak* and cause bacterial infections in infants. The Conservator argues that it has presented evidence and expert testimony that, despite the testing performed by the CDC and the FDA, JMK was exposed to *C. sak* in Abbott's PIF, based, among other things, on expert opinions that *C. sak* is not necessarily homogeneously distributed throughout PIF, but may be found in clumps and clusters, and, consequently, can evade the kinds of testing done in this case. The Conservator also argues that its experts' opinions are relevant, because those opinions make JMK's infection with *C. sak* from Abbott's PIF more

probable. The Conservator also points out that, while Abbott has relied only on district court decisions excluding its experts' "causation" opinions regarding *C. sak* infections from PIF, Abbott has ignored district court decisions finding that its experts' opinions on these issues met *Daubert* standards. The Conservator argues that, while these cases all involved the same experts and cannot readily be distinguished, the district courts simply reached different results, leaving this court to choose for itself. As to its experts' "ruling in" and "ruling out" methodologies, the Conservator argues that Abbott has simply cherry-picked and distorted the methodologies that they employed. In contrast, the Conservator contends, its experts have directly confronted Abbott's distortions and demonstrated the soundness of their methodologies and opinions. The Conservator contends that mere disagreement among the parties' experts does not mean that its experts should be excluded from the jury's consideration.

In reply, Abbott contends that the Conservator has still not shown any reliable basis for its experts' "ruling in" opinions. As to Dr. Jason, Abbott contends that parts of her "ruling in" methodology are not scientifically valid, but even if they were, there is still no evidence of any kind suggesting that Abbott's PIF contained *C. sak*, which means that her differential diagnosis is fatally flawed. Abbott also argues that Dr. Jason improperly conflates the "ruling in" and "ruling out" steps, simply "ruling in" whatever is left after inadequately "ruling out" other possible causes. Abbott also disputes the validity of and factual basis for Dr. Jason's opinion concerning the incubation period for *Cronobacter* meningitis, the validity of her "ruling out" of RTF formula, her failure to consider the tests by the CDC and FDA showing no *Cronobacter* contamination of Abbott's PIF—and evidence that supposed contaminations with *Cronobacter* in areas unrelated to PIF production were ultimately shown not to be *Cronobacter*—and her non-expert beliefs that *Cronobacter* may not be evenly distributed in PIF. Abbott contends that Dr. Donnelly's opinions remain equally

unrealiable, because she relies on case reports and epidemiological associations between *Cronobacter* and non-Abbott PIF products that are irrelevant to causation in *this* case; her differential diagnosis works backward from the desired result to the desired source of the *C. sak*; she fails to consider probative CDC and FDA test results; and she relies on isolated and irrelevant environmental samples from non-product areas of Abbott's plant where JMK's PIF was manufactured. As to Dr. Farmer, Abbott contends that he offers no explanation of a methodology that characterizes sampling data from a non-production area as a "smoking gun," when the samples were ultimately shown not to be *Cronobacter* and could not be "traced back" to any manufacturing equipment or PIF. Abbott also reiterates its challenge to the Conservator's experts' "ruling out" of numerous plausible causes of JMK's *C. sak* infection on what Abbott calls "the slimmest of pretexts" and the lack of any reliable basis.

2. Analysis

Rule 702 of the Federal Rules of Evidence provides that expert testimony should be admitted if [1] the expert's specialized knowledge "will help the trier of fact to understand the evidence or to determine a fact in issue," [2] it "is based on sufficient facts or data", [3] it "is the product of reliable principles and methods," and [4] "the witness has applied the principles and methods reliably to the facts of the case." FED. R. EVID. 702; *see also General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court explained that the district court must perform a "gatekeeper" function, under Rule 702, so that only expert testimony that is relevant and reliable is admitted. 509 U.S. at 589. The Eighth Circuit Court of Appeals has explained how the district court is to perform its "gatekeeper" function under *Daubert*, as follows:

> First, the trial court must make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that

> reasoning or methodology properly can be applied to the facts in issue." [*Daubert*, 509 U.S. at 592-93, 113 S.Ct. 2786, 125 L.Ed.2d 469]. The Court cautioned that the trial court must focus "on [the] principles and methodology, not on the conclusions that they generate." *Id*. at 595, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469. Second, the court must ensure that the proposed expert testimony is relevant and will serve to aid the trier of fact. *Id*. at 592, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469. Expert testimony assists the trier of fact when it provides information beyond the common knowledge of the trier of fact. *Id*. at 591, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469. The Court, in *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999), clarified that the district court's gatekeeper function applies to all expert testimony, not just testimony based in science. *Id*. at 147, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238.

Kudabeck v. Kroger Co., 338 F.3d 856, 860 (8th Cir. 2003). However, "[a]s the Supreme Court emphasized in *Daubert*, 509 U.S. at 595-96, 113 S.Ct. 2786, 125 L.Ed.2d 469, 'Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" *United States v. Vesey*, 338 F.3d 913, 917 (8th Cir. 2003).

In this case, I am informed—if not actually aided—by three prior district court decisions considering whether or not to exclude essentially the same opinions from the very same experts based on essentially the same methodologies. *See Johnson v. Mead Johnson & Co.*, No. 11-225 (JNE/LIB), 2013 WL 716816 (D. Minn. Feb. 27, 2013) (concluding that Dr. Jason reliably "ruled in" another maker's PIF as a possible source of an infant's *C. sak* infection, but concluding that her "ruling out" methodology was "fundamentally unsound and not supported by any factual basis," and that she unreliably "ruled out" two possible causes; excluding her proposed testimony on her

differential diagnosis and her opinion that the PIF caused the infant's infection; concluding that Dr. Farmer's "ruling out" methodology was flawed for the same reasons as Dr. Jason's, and excluding his proposed testimony on his differential diagnosis and his corresponding opinion that the PIF caused the infant's infection; and excluding Dr. Donnelly's opinions on the cause of the infant's infection for the same reasons); *Burks v. Abbott Labs.*, ___ F. Supp. 2d ___, 2013 WL 101831 (D. Minn. Jan. 8, 2013) (denying Abbott's motion to exclude the same experts' opinions on causation, because Louisiana law would recognize "alternative liability"—which relieves the plaintiff of the burden of proving that it is more likely than not that a particular defendant, either Abbott or another maker of PIF, caused the infant's death, but does require the plaintiff to prove only that it is more likely than not that the contaminated PIF manufactured by one of the defendants caused the infant's illness—and "[p]laintiffs' experts' opinions that it is more likely than not that contaminated PIF manufactured by one of the defendants caused [the infant's] illness has a tend[ency] to make this fact more probable"; and also denying the other PIF manufacturer's motion to exclude these experts, with certain exceptions, because the experts' specific causation opinions were relevant and reliable); *Korte v. Mead Johnson & Co.*, 824 F. Supp. 2d 877 (S.D. Iowa 2010) (granting summary judgment in favor of another PIF manufacturer, because the same three experts (and additional ones) could not reliably show that the PIF caused the infant's illness, where the experts had not adequately "ruled out" other possible causes, even though neither party had requested a *Daubert* hearing on the qualifications of the experts as a part of the summary judgment motion or resistance). As the Conservator suggests, these decisions do not appear to be ultimately reconcilable with or convincingly distinguishable from each other.[7] Thus, I cannot simply adopt the position of the court or courts in one or more prior decisions.

[7] After the Conservator pointed out Abbott's failure to cite *Burks*, and relied on

Turning to my own "preliminary assessment" in this case, from my review of the submissions in support of and resistance to Abbott's *Daubert* Motion, I conclude—albeit with some reluctance and uncertainty—that the reasoning and methodology underlying the challenged opinions are scientifically valid and that the challenged experts' reasoning and methodology can be applied to the facts in issue. *See Daubert*, 509 U.S. at 592-93 (first step in the court's "gatekeeper" function under Rule 702); *Kudabeck*, 338 F.3d at 860 (same). Although Abbott is clearly unhappy with the opinions of the Conservator's causation experts, and has cloaked that unhappiness in challenges to "factual basis" and "reasoning and methodology," I find that the Conservator has shown that its causation experts' reasoning and methodology are appropriate, and apply proper scientific principles. Moreover, I find that the challenged opinions have an adequate factual basis, including those facts identified by

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that case extensively in its resistance to Abbott's *Daubert* Motion, Abbott still only cited *Burks* in a footnote on the final page of its Reply, in which it attempted to demonstrate that *Burks* was "irrelevant," because it involved "alternative liability" under Louisiana law and because the court in that case purportedly did not consider how each of the three experts applied his or her methodology. While Abbott's failure to cite a contrary, but non-controlling decision did not violate any *ethical* obligation, ethical obligations establish only the barest minimum floor for attorney conduct. What attorney would want to be known as a minimally ethical lawyer rather than a highly professional one? Where the pool of decisions considering the same experts and methods is so limited, it is inconceivable to me that reasonably conscientious and highly professional counsel would not cite contrary authority, then meet it head on and attempt to distinguish it, not simply hope neither the opposing party nor the court would notice it—a vain hope, here, where the plaintiffs in *Burks* were represented by the same attorneys who represent the Conservator, and Abbott was represented by the same attorneys who represent Abbott here. Defense counsels' lack of candor is troubling. Hide and seek litigation strategy seldom works and did not work here. As a result, I will find it more difficult to rely on the trustworthiness of defense counsel—a trial lawyer's most important asset. This is not an auspicious beginning for counsel before a judge newly assigned to the case.

the Conservator and the experts in the experts' reports, and that the experts have confronted Abbott's complaints about their methodology and the factual basis for their decisions, such that submission of the experts' opinions to a jury is warranted. I am also convinced that the proposed expert testimony is relevant and will aid the trier of fact. *Daubert*, 509 U.S. at 592 (second step in the analysis); *Kudabeck*, 338 F.3d at 860 (same). Plainly, the Conservator's causation experts will provide information beyond the common knowledge of the trier of fact regarding the circumstances that can—and they believe did, in this case—cause an infant's bacterial meningitis. *See id.* at 591 (explaining that expert testimony assists the trier of fact when it provides information beyond the common knowledge of the trier of fact).

Ultimately, I believe that to exclude the Conservator's causation experts' opinions from this case would "invade the province of the jury, whose job it is to decide issues of credibility and to determine the weight that should be accorded evidence." *Vesey*, 338 F.3d at 916-17. This is a case in which vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are not only traditional, but appropriate means of attacking what Abbott contends are shaky causation opinions by the Conservator's experts. *Daubert*, 509 U.S. at 595-96; *Vesey*, 338 F.3d at 917.

Abbott's May 3, 2013, Motion To Exclude Or Limit Plaintiff's Proposed Expert Testimony On Medical And Scientific Causation (Abbott's *Daubert* Motion) (docket no. 87) is denied, without prejudice to challenges during trial to the jury's consideration of the experts' opinions.

C. Abbott's Motion For Summary Judgment

Having resolved whether I can properly consider either Ms. Surber's affidavit or the opinions of the Conservator's causation experts, I turn to consideration of Abbott's

March 20, 2013, Motion For Summary Judgment (docket no. 86), seeking summary judgment on all of the Conservator's remaining claims. I begin my analysis of this motion with a summary of the standards applicable to motions for summary judgment, then turn to Abbott's arguments for summary judgment on particular claims.

1. Standards for summary judgment

Summary judgment is only appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c) (emphasis added); *see Woods v. DaimlerChrysler Corp.*, 409 F.3d 984, 990 (8th Cir. 2005) ("Summary judgment is appropriate if viewing the record in the light most favorable to the nonmoving party, there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law."); *see generally Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). As the Eighth Circuit Court of Appeals has explained,

> "On a motion for summary judgment, 'facts must be viewed in the light most favorable to the nonmoving party only if there is a genuine dispute as to those facts.'" *Ricci v. DeStefano*, ---U.S. ----, 129 S. Ct. 2658, 2677, 174 L. Ed. 2d 490 (2009) quoting *Scott v. Harris*, 550 U.S. 372, 380, 127 S. Ct. 1769, 167 L. Ed. 2d 686 (2007) (internal quotations omitted). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150, 120 S. Ct. 2097, 147 L. Ed. 2d 105 (2000), quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). The nonmovant "must do more than simply show that there is some metaphysical doubt as to the material facts," and must come forward with "specific facts showing that there is a genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87, 106 S. Ct.

> 1348, 89 L. Ed. 2d 538 (1986). "'Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial.'" *Ricci*, 129 S. Ct. at 2677, quoting *Matsushita*, 475 U.S. at 587, 106 S. Ct. 1348.

Torgerson v. City of Rochester, 643 F.3d 1031, 1042-43 (8th Cir. 2011) (*en banc*). Summary judgment is particularly appropriate when only questions of law are involved, rather than factual issues that may or may not be subject to genuine dispute. *See, e.g., Cremona v. R.S. Bacon Veneer Co.*, 433 F.3d 617, 620 (8th Cir. 2006).

2. The challenge to the causation element for all claims

Abbott argues that each of the Conservator's remaining claims requires proof that Abbott's product was the cause of JMK's alleged injury. Abbott seeks summary judgment on all of these claims, on the ground that there is no evidence that Abbott's PIF was the cause of JMK's injury. Abbott's argument in support of this portion of its motion for summary judgment is, in essence, that the Conservator's causation experts' opinions must be excluded and, consequently, that the Conservator cannot generate genuine issues of material fact on whether Abbott's PIF can be "ruled in" or "ruled out" as a cause of JMK's injury. In response, the Conservator contends, in essence, that its experts' causation opinions are sufficient to generate genuine issues of material fact on the "causation" element of its claims.

I have already determined, above, that the opinions of the Conservator's causation experts should not be excluded. Therefore, I now conclude that, viewing their opinions in the light most favorable to the Conservator, their opinions are sufficient to generate genuine issues of material fact on the element, in each of the Conservator's causes of action, that requires the Conservator to show that Abbott's PIF caused JMK's injury. *Torgerson*, 643 F.3d at 1042-43 (explaining that, on a motion for summary judgment, the non-movant must come forward with specific facts showing

that there is a genuine issue for trial, and the court must consider the evidence in the light most favorable to the non-movant); *see also* FED. R. CIV. P. 56(c); *Woods*, 409 F.3d at 990; *see generally Celotex Corp.*, 477 U.S. at 323-24.

The part of Abbott's Motion For Summary Judgment seeking summary judgment on the ground that the Conservator cannot establish the required causation of injury to support any of its claims is denied.

3. The challenge to the warranty claims

a. Arguments of the parties

Abbott challenges both of the Conservator's remaining warranty claims on the ground that the Conservator has not and cannot present any evidence that Abbott's PIF was "sold" by Abbott to St. Luke's Hospital in exchange for *any* kind of consideration, because the PIF was a gift. Abbott argues that, even after extensive discovery, there is no evidence of any agreement between St. Luke's Hospital and Abbott concerning the PIF, nor any evidence that Abbott assembled or provided any gift bags to St. Luke's Hospital, nor any evidence that Abbott asked or instructed St. Luke's Hospital to make or give gift bags to patients. Abbott also argues that the Conservator has not identified any evidence, in support of its express warranty claim, that St. Luke's Hospital relied on any express affirmation of fact or promise by Abbott. Abbott contends that there is no evidence that, when St. Luke's Hospital received the PIF as a gift, Abbot made or the hospital relied on any representations.

In response, the Conservator argues that one of its experts, Dr. Jason, has opined that Abbott provided the PIF and other formula to St. Luke's Hospital as a marketing tool. The Conservator also contends that, in his ruling on Abbott's motion to dismiss, Judge O'Brien ruled that Abbott's provision of PIF to St. Luke's Hospital was a sale. The Conservator also argues that the label of the PIF, itself, contained express representations that the PIF was safe and suitable for infants of all ages,

including neonates like JMK, and that the hospital relied on these warranties when it supplied the product to its customers, including neonates.

b. Analysis

I conclude that Abbott is entitled to summary judgment on both of the Conservator's remaining breach of warranty claims. First, nothing in Judge O'Brien's ruling on Abbott's motion to dismiss is dispositive of whether or not there was actually a "sale" within the meaning of Iowa law that would support a warranty claim. Rather, Judge O'Brien found that the Conservator's allegations that Abbott provided PIF to St. Luke's Hospital in return for consideration plausibly suggested a "sale" within the meaning of Iowa law, *assuming* that Abbott would ultimately be able to show that it received some type of consideration for providing its product to the hospital. *See* Memorandum Opinion And Order (docket no. 64) at 39-46, *Security Nat'l Bank of Sioux City, Iowa*, 2012 WL 327863 at *14-*16. Abbott now makes a different argument: That there was no "sale," because the formula was given to the hospital as a gift, not for any consideration. Thus, Judge O'Brien's ruling does not bar summary judgment on the remaining warranty claims in this case.

Second, the Conservator has cited no case law, and I have found none, suggesting that a donor's mere anticipation of some economic benefit from a gift, as a matter of marketing strategy, satisfies the "consideration" requirement of a "sale" within the meaning of Iowa law—or any other state's law—sufficient to support a breach of warranty claim. The lack of any legal authority for the Conservator's argument makes summary judgment on the remaining warranty claims particularly appropriate. *See, e.g., Cremona*, 433 F.3d at 620 (explaining that summary judgment is particularly appropriate when only questions of law are involved, rather than factual issues that may or may not be subject to genuine dispute).

Third, the Conservator has not attempted to show that Dr. Jason is qualified to offer expert opinions about marketing strategies of baby formula manufacturers or about marketing strategies behind corporate "gifts," more generally. Thus, I conclude that Dr. Jason's opinion would not generate a genuine issue of material fact on its "marketing strategy as consideration" contention, even if that contention were legally viable. Fourth, the Conservator has not pointed to any factual basis for any assertion that Abbott received any other "consideration" for its "gift" of baby formula to the hospital.

Thus, the Conservator has failed to carry its burden in response to Abbott's motion for summary judgment on the remaining breach of warranty claims to "come forward with specific facts showing that there is a genuine issue for trial." *Torgerson*, 643 F.3d at 1042-43 (internal quotation marks and citations omitted).[8] That part of Abbott's March 20, 2013, Motion For Summary Judgment (docket no. 86) seeking summary judgment on the Conservator's remaining breach of warranty claims is granted.

4. The challenge to the fraud claim

a. Arguments of the parties

Abbott seeks summary judgment on the Conservator's fraud claim on the additional grounds that there is no evidence that JMK's caregiver, Ms. Surber, viewed any advertisements for Abbott's PIF or even the label on the PIF can before preparing PIF feedings, and there is no evidence that Ms. Surber justifiably relied on the labeling when deciding to use the PIF to feed JMK. Indeed, Abbott argues that Ms. Surber testified that she never read any ads, direct mailings, or on-line information regarding

[8] I find it unnecessary to reach Abbott's argument that it is also entitled to summary judgment on the Conservator's express warranty claim on the ground that the Conservator cannot show that the hospital relied on any promise.

Abbott's NeoSure PIF, or any other infant formula, before using the PIF on April 23, 2008; she confirmed that she did not discuss Abbott's NeoSure PIF or PIF in general with anyone before feeding the PIF to JMK; and she testified that she had no recollection of reviewing portions of the label that contained information about the product, warnings about the product's sterility, or warnings to use the product only under the supervision of a doctor. Similarly, Abbott argues that there is no evidence that Ms. Surber relied on the allegedly false statements in any information on Abbott's PIF label, where the Conservator cannot even show that Ms. Surber was aware of the statements on the label; Ms. Surber testified that she had previously used PIF products for her older child and had decided to use PIF for JMK before she was born; she did nothing to assure herself that PIF products were "safe and healthy" before using them; she simply used whatever formula the hospital had sent home with her; she relied on the doctor's prescription instructing her to use NeoSure for JMK; she had no other formula available after exhausting the RTF formula on April 23, 2008; and she had already begun preparing the PIF for a feeding before she ever glanced at any portion of the label.

The Conservator's brief response to these arguments is that Ms. Surber testified that she read the NeoSure PIF label; that she believed that NeoSure PIF was safe for JMK and did not contain harmful bacterial; and that she would not have fed JMK the NeoSure PIF if the label had stated that it was unsuitable for an infant under 28 days of age, that it may contain harmful bacteria, or that liquid formula was safer for JMK.

b. Analysis

The Iowa Supreme Court has made clear that, among other elements, "[t]o bring a fraud claim, the plaintiff must have justifiably relied on the false representation." *Dier v. Peters*, 815 N.W.2d 1, 9 (Iowa 2012) (citing *Spreitzer v. Hawkeye State Bank*, 779 N.W.2d 726, 737 (Iowa 2009)). More specifically, "the plaintiff must not only act

in reliance on the misrepresentation, but the reliance must be justified." *Spreitzer*, 779 N.W.2d at 736 (citing *Gibson v. ITT Hartford Ins. Co.*, 621 N.W.2d 388, 400 (Iowa 2001)). Abbott challenges the Conservator's fraud claim only on the issue of whether Ms. Surber "actually" or "in fact" relied on any alleged misrepresentations, not on whether any reliance was "justified." Abbott's challenge to "actual" reliance has two prongs: Ms. Surber never read any alleged misrepresentation, and Ms. Surber did not rely on any alleged misrepresentation in deciding to use the PIF, because her decision to use the PIF was based entirely on other considerations.

I conclude that, contrary to Abbott's contentions, the Conservator has generated genuine issues of material fact that Ms. Surber did, in fact, read the label of the PIF at the time that she prepared JMK's first PIF feeding. *Torgerson*, 643 F.3d at 1042-43 (explaining that the non-movant must "come forward with specific facts showing that there is a genuine issue for trial" (internal quotation marks and citations omitted)). As the Conservator contends, when asked in deposition, "So when you took out the can [to make JMK's first PIF feeding], did you read the label?", Ms. Surber answered, "Yes." Defendant's Appendix at 313 (Surber Deposition at 348:24—349:1). The extent to which Ms. Surber later recalled the content of any particular statements on the label only generates a fact question on whether or not Ms. Surber was actually aware of those statements at the time that she prepared JMK's first PIF feeding.

Nor am I persuaded that it is "undisputed" that Ms. Surber did not *actually rely* on the statements on the label simply because she did not read it until she was already boiling water to sterilize the bottle for JMK's first PIF feeding or even because the PIF was the only baby formula left in the house at that time, as Abbott seems to suggest. A reasonable jury could conclude that a reasonable parent who discovered information on a baby formula label indicating that use of the formula was inappropriate for their child would not use the formula, no matter how advanced their preparation of the feeding

was, and would make every effort to get other formula, even if the inappropriate formula was the only formula left in the house.

Nevertheless, the Conservator has failed to generate genuine issues of material fact on the "actual reliance" element of its "fraud" claim, because the Conservator has not pointed to *any* evidence that Ms. Surber relied on statements on the label in deciding to use the PIF. This is so, because the portions of Ms. Surber's deposition that the Conservator cites as demonstrating that Ms. Surber "believed the Similac PIF was safe for [JMK] and did not contain harmful bacteria" simply do not support that allegation, where they do not even mention safety or lack of harmful bacteria *at all*. *See* Defendant's Appendix at 282, 288 (Surber Deposition at 174, 198-199); Plaintiff's Appendix at 710-15 (including no amendments to the cited pages of Ms. Surber's deposition, nor any corrections of testimony regarding a belief that PIF was safe and did not contain harmful bacteria). Furthermore, even if the citations supported the allegation about Ms. Surber's beliefs, the Conservator has not cited any evidence that Ms. Surber developed these beliefs from representations on the PIF label. Similarly, although the Conservator has cited a somewhat belated affidavit by Ms. Surber, dated April 12, 2013, that does support allegations that "she would not have fed [JMK] the NeoSure PIF if the label stated it was unsuitable for an infant under 28 days, that it may contain harmful bacteria, or that liquid formula was safer for [JMK]," *see* Plaintiff's Appendix at 620-21, the Conservator has not cited any evidence that Ms. Surber developed a contrary belief from any representation on the label. The lack of such evidence forecloses the Conservator's "fraud" claim, whether that claim is premised on fraudulent misrepresentation or fraudulent non-disclosure.[9]

[9] Indeed, these allegations more readily support a claim that the warnings given were defective than they do a fraud claim. I will turn to Abbott's motion for summary judgment on the Conservator's warning defect claim, next.

Therefore, that part of Abbott's March 20, 2013, Motion For Summary Judgment (docket no. 86) seeking summary judgment on the Conservator's fraud claim is granted.

5. The challenge to the warning defect claim

a. Arguments of the parties

Abbott seeks summary judgment on the Conservator's warning defect claim on the ground that, regardless of the adequacy of Abbott's warning, the warning did not proximately cause JMK's illness. This is so, Abbott contends, again, because JMK's mother's decision to feed JMK the PIF was entirely independent of Abbott's warning. Abbott again asserts that the record shows that Ms. Surber did not read the label warnings nor rely upon them when making the decision to use the PIF. In other words, Abbott contends that the warning language did not enter into Ms. Surber's decision-making process when deciding to feed the PIF to JMK.

In response, the Conservator argues that, in support of what it calls its "negligent failure to warn" claim, it has cited sufficient evidence that an adequate warning would have altered Ms. Surber's conduct and avoided the injury. Indeed, the Conservator argues that, where it has shown that the warning given was inadequate, either in content or presentation, it is entitled to a presumption that Ms. Surber would have heeded an adequate warning, and Abbott has not rebutted that presumption.

b. Analysis

Although the Conservator characterizes its warning claim as a "negligent failure to warn" claim in its resistance to Abbott's Motion For Summary Judgment, the Conservator and Abbott both apparently overlook that, in 2002, the Iowa Supreme Court "adopted the Restatement (Third) of Torts: Products Liability sections 1 and 2 (1998)." *Scott v. Dutton-Lainson Co.*, 774 N.W.2d 501, 504 (Iowa 2009) (citing *Wright v. Brooke Group Ltd.*, 652 N.W.2d 159, 169 (Iowa 2002)). I will refer to the

cited version of the RESTATEMENT as RESTATEMENT (THIRD): PRODUCTS LIABILITY. Although the Iowa Supreme Court has reiterated that "[f]ailure to warn claims cannot be brought under a theory of strict liability," and that, under the RESTATEMENT (THIRD): PRODUCTS LIABILITY, "negligence principles" are "suitable" for warning defect claims, *id.*, "Iowa tort law no longer supports [a] distinction [between strict liability claims and negligence] in the context of design defect and failure to warn claims." *Id.* at 506. Consequently, the proper formulation of a "warning defect" claim under Iowa law is pursuant to RESTATEMENT (THIRD): PRODUCTS LIABILITY § 2(c), and should not identify the claim as a "negligence" claim, but as a "warning defect" claim. *Id.* at 504-06.

Under RESTATEMENT (THIRD): PRODUCTS LIABILITY § 2(c),

> A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:
>
> * * *
>
> (c) is defective because of inadequate instruction or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

RESTATEMENT (THIRD): PRODUCTS LIABILITY § 2(c). Another section of this version of the RESTATEMENT explains the general standard for causation under products liability law:

> One engaged in the business of selling or otherwise distributing products who sells or distributes a defective

> product is subject to liability for harm to persons or property caused by the defect.

RESTATEMENT (THIRD): PRODUCTS LIABILITY § 1. Somewhat more specifically,

> Whether a product defect caused harm to persons or property is determined by the prevailing rules and principles governing causation in tort.

RESTATEMENT (THIRD) § 15.

The "prevailing rules and principles governing causation in tort" under Iowa law were recently clarified in *Thompson v. Kaczinski*, 774 N.W.2d 829 (Iowa 2009). In *Thompson*, the Iowa Supreme Court adopted the "causation" analysis of RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM Ch. 6. *Thompson*, 774 N.W.2d at 836-39. The court first explained,

> *We have held causation has two components: cause in fact and legal cause*. *Faber v. Herman*, 731 N.W.2d 1, 7 (Iowa 2007). *The decisions of this court have established it is the plaintiff's burden to prove both cause in fact and legal (proximate) cause*. *See City of Cedar Falls v. Cedar Falls Cmty. Sch. Dist.*, 617 N.W.2d 11, 17 (Iowa 2000). The latter component requires a policy determination of whether "the policy of the law must require the defendant to be *legally responsible* for the injury." *Gerst v. Marshall*, 549 N.W.2d 810, 815 (Iowa 1996). Causation is a question for the jury, "'*save in very exceptional cases* where the facts are so clear and undisputed, and the relation of cause and effect so apparent to every candid mind, that but one conclusion may be fairly drawn therefrom.'" *Lindquist v. Des Moines Union Ry.*, 239 Iowa 356, 362, 30 N.W.2d 120, 123 (1947) (quoting *Fitter v. Iowa Tel. Co.*, 143 Iowa 689, 693–94, 121 N.W. 48, 50 (1909)).

Thompson, 774 N.W.2d at 836 (emphasis in first two sentences added; other emphasis in the original). The court then noted that "[t]he formulation of legal or proximate cause outlined above has been the source of significant uncertainty and confusion" and

that "[t]his court's adherence to the formulation has been less than consistent." *Id.* Therefore, the court took "the opportunity to clarify this area of law." *Id.* at 837.

In the part of that clarification most pertinent here, the court explained,

> *"Tort law does not impose liability on an actor for all harm factually caused by the actor's tortious conduct."* Restatement (Third) ch. 6 Special Note on Proximate Cause, at 574. *This concept has traditionally been designated "proximate cause."* While this term is used extensively and appropriately by courts, practitioners, and scholars, it causes considerable confusion for juries because it does not clearly express the idea it is meant to represent. *See id.* § 29 cmt. *b*, at 576–77. The confusion arises when jurors understand "proximate cause" as implying "there is but one cause—the cause nearest in time or geography to the plaintiff's harm—and that factual causation bears on the issue of scope of liability." *Id.* § 29 cmt. *b*, at 577. Thus, in an attempt to eliminate unnecessary confusion caused by the traditional vernacular, the drafters of the third Restatement refer to the concept of proximate cause as "scope of liability."
>
> The drafters of the Restatement (Third) explain that the "legal cause" test articulated in the second Restatement included both the "substantial factor" prong and the "rule of law" prong because it was intended to address both factual and proximate cause. *Id.* ch. 6 Special Note on Proximate Cause, at 574. Although the "substantial factor" requirement has frequently been understood to apply to proximate cause determinations, *see Gerst*, 549 N.W.2d at 815–16, the drafters contend it was never intended to do so. Restatement (Third) § 29 cmt. *a*, at 576. *Accordingly, to eliminate the resulting confusion of factual and policy determinations resulting from the Restatement (Second) formulation of legal cause, the drafters have opted to address factual cause and scope of liability (proximate cause) separately.* Restatement (Third) ch. 6 Special Note on Proximate Cause, at 575. *The assessment of scope of liability under the Restatement (Third) no longer includes a determination of whether the actor's conduct was a substantial factor in causing the harm*

> *at issue, a question properly addressed under the factual cause rubric. See id.* § 27 cmt. *j*, at 427–29.

Thompson, 774 N.W.2d at 837-38 (emphasis added). The court expressly adopted the clarification of causation, as consisting of separate questions of scope of liability and factual cause, in the RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM Ch. 6. *Id.* at 839.

Iowa Civil Jury Instruction No. 1000.3 (2012) has been revised to be consistent with *Thompson* and the RESTATEMENT (THIRD): PRODUCTS LIABILITY §§ 1 and 2, because it casts the "factual causation" element of a warning defect claim in terms of whether "[t]he omission of the instruction(s) or warning(s) was a cause of plaintiff's damages," then separately addresses the "legal" or "proximate" causation questions in "scope of liability" elements considering foreseeability and risk. Iowa Civil Jury Instruction No. 1000.3 (2012). This model instruction does not use "proximate cause" at all. The model instruction defining "causation," Iowa Civil Jury Instruction No. 1000.8, is still stated in terms of "proximate cause"—erroneously, in my view, in light of *Thompson*, and inconsistently with the "cause" elements of the other instructions on product defect claims. Nevertheless, with the exception of erroneous inclusion of "proximate," the definition provided in that model is now consistent with the definition of "factual cause" in RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 26. *Compare* Iowa Civil Jury Instruction No. 1000.8 ("A defect in a product is a proximate cause of [damage] when the damage would not have happened except for the defect.") *with* RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 26 ("Conduct is a factual cause of harm when the harm would not have occurred absent the conduct.").

Although Abbott has cast its argument for summary judgment on the Conservator's warning defect claim in terms of lack of any evidence of "proximate

cause," the nature of the challenge is actually to "factual cause." This is so, because Abbott's argument is that the record shows, as a matter of undisputed fact, that Ms. Surber did not read the label warnings nor rely upon them when making the decision to use the PIF.

This argument fails, however, because it misconstrues the nature of "factual causation" in a warning defect case. The question is whether the product was defective because it provided *inadequate* warnings and whether the *omission* of *reasonable* instructions caused the harm. *See* RESTATEMENT (THIRD): PRODUCTS LIABILITY §§ 1 (defining causation) and 2(c) (defining a warning defect); Iowa Civil Jury Instruction No. 1000.3 (2012). Furthermore, nothing in the adoption of RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM Ch. 6 indicates an intent by the Iowa Supreme Court to abrogate its rule that, "'[i]n the context of a failure to warn claim, [factual] cause can be established by showing a warning would have altered the plaintiff's conduct so as to avoid injury.'" *Mercer v. Pittway Corp.*, 616 N.W.2d 602, 624 (Iowa 2000) (quoting *Lovick v. Wil-Rich*, 588 N.W.2d 688, 700 (Iowa 1999)). Indeed, this rule is entirely consistent with RESTATEMENT (THIRD): PRODUCTS LIABILITY § 2(c), which frames the definition of a warning defect, in part, in terms of whether "the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings," and RESTATEMENT (THIRD): PRODUCTS LIABILITY § 1, which frames the causation element in terms of whether the omission of reasonable instructions or warnings caused the harm.

Here, Abbott's assertion that Ms. Surber purportedly did not read the label at all—an issue on which I concluded, above, that the Conservator has generated a genuine issue of material fact—or did not consider the warnings on the label in her decision-making process simply is not dispositive of the Conservator's "warning defect" claim. To the contrary, the Conservator has generated a genuine issue of

material fact on the "causation" element of the "warning defect" claim by pointing to evidence, in the form of the somewhat belated affidavit by Ms. Surber, dated April 12, 2013, in which Ms. Surber avers that she "would not have fed [JMK] the NeoSure PIF if the label stated it was unsuitable for an infant under 28 days, that it may contain harmful bacteria, or that liquid formula was safer for [JMK]." *See* Plaintiff's Appendix at 620-21; *Torgerson*, 643 F.3d at 1042-43 (explaining that the non-movant must "come forward with specific facts showing that there is a genuine issue for trial" (internal quotation marks and citations omitted)). This evidence is sufficient to raise a jury question on the "causation" element. *See Mercer*, 616 N.W.2d at 624; *Lovick*, 588 N.W.2d at 700.

Therefore, that part of Abbott's March 20, 2013, Motion For Summary Judgment (docket no. 86) seeking summary judgment on the Conservator's "warning defect" claim is denied.

III. CONCLUSION

Upon the foregoing,

1. Abbott's request for oral arguments on its Motion For Summary Judgment (docket no. 86) is **denied**;

2. The Conservator's May 14, 2013, Request For Oral Argument (docket no. 100), seeking oral arguments on Abbott's Motion For Summary Judgment and Abbott's *Daubert* Motion, is **denied**;

3. Abbott's May 3, 2013, Motion To Strike Megan Surber's September 19, 2012, Affidavit (docket no. 99) is **denied**;

4. Abbott's May 3, 2013, Motion To Exclude Or Limit Plaintiff's Proposed Expert Testimony On Medical And Scientific Causation (Abbott's *Daubert* Motion)

(docket no. 87) is **denied**, but *without prejudice* to challenges during trial to the jury's consideration of the experts' opinions; and

5. Abbott's March 20, 2013, Motion For Summary Judgment (docket no. 86), seeking summary judgment on the Conservator's fraud claim is **granted in part and denied in part**, as follows:

a. That part of the Motion seeking summary judgment on all of the Conservator's claims on the ground that the Conservator cannot establish the required causation of injury to support any of its claims is **denied**;

b. That part of the Motion seeking summary judgment on the Conservator's remaining breach of warranty claims (**Counts 4** and **6**) is **granted**;

c. That part of the Motion seeking summary judgment on the Conservator's fraud claim (**Count 7**) is **granted**; and

d. That part of the Motion seeking summary judgment on the Conservator's "warning defect" claim (**Count 3**) is **denied**.

THEREFORE, this matter will proceed to jury trial, currently scheduled to begin on September 3, 2013, on the Conservator's product defect claims in **Counts 1** (manufacturing defect), **2** (design defect), and **3** (warning defect).

IT IS SO ORDERED.

DATED this 3rd day of June, 2013.

Mark W. Bennett

MARK W. BENNETT
U.S. DISTRICT COURT JUDGE
NORTHERN DISTRICT OF IOWA