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 JMK, a Minor,	
Plaintiff,	**No. 11-CV-4017-DEO**
v.	
ABBOTT LABORATORIES,	**Memorandum and Opinion Order**
Defendant.	

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I. INTRODUCTION AND BACKGROUND

This matter is before the Court due to the unfortunate infection of a newborn, J.M.K., with *Enterobacter sakazakii* meningitis, resulting in severe brain damage. Docket No. 46. On March 16, 2011, Plaintiff, Court appointed conservator[1] for J.M.K., The Security National Bank of Sioux City, Iowa (hereinafter Plaintiff), filed an Amended Complaint alleging

[1]The Iowa District Court for Woodbury County appointed Plaintiff, Security National Bank, conservator pursuant to a January 7, 2011, Order. Probate No.GCPRO052050.

eleven separate causes of action against Abbott Laboratories (hereinafter Defendant). Docket No. 9. On April 18, 2011, Defendant filed a motion to dismiss Plaintiff's Amended Complaint; and on June 20, 2011, this Court held a hearing to consider Defendant's Motion. Docket Nos. 30 and 44. In a subsequent Order, this Court gave Plaintiff permission to file a Second Amended Complaint, which they did on June 27, 2011. Docket Nos. 45 and 46. This matter is currently before the Court on Defendant's Motion to Dismiss Amended Complaint and Defendant's Motion to Dismiss Plaintiff's Second Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). Docket Nos. 30 and 47.

II. FACTUAL ALLEGATIONS

Plaintiff arranged its factual allegations so that general allegations are first presented and only then followed by other allegations related to their specific causes of action. For simplicity, this Court will present Plaintiff's factual allegations in a similar manner.

A. General Allegations

J.M.K. was born at the St. Luke's Regional Medical Center in Sioux City, Iowa, on April 14, 2008. Id. at 2. J.M.K. was a full-term, healthy new born. Id. Upon discharge from the

hospital, "J.M.K.'s mother was given an unsolicited gift bag" containing Similac powder infant formula (hereinafter PIF) and "liquid infant formula also manufactured by [Defendant]." Id. at 3. The gift bag was provided due to an "agreement wherein [Defendant] supplied gift bags to the hospital containing Similac PIF in exchange for consideration from the hospital." Id. at 2.

From April 17, 2008, to April 24, 2008, J.M.K.'s mother fed J.M.K. only the liquid infant formula. Id. at 3. When the liquid infant formula ran out, J.M.K.'s mother began feeding J.M.K. the Similac PIF. Id. J.M.K. was 10 days old at this time. Id. at 3. Prior to preparing the PIF, "J.M.K.'s mother boiled the water, utensils, bottles and all bottle parts she used with the PIF" and "prepared the PIF in her kitchen" in compliance with Defendant's product label recommendations. Id. at 3 and 4.

"On April 24, 2008, after being fed the Similac PIF, J.M.K. began showing signs of a possible infection and J.M.K.'s mother took her to the emergency department at St. Luke's Regional Medical Center of Sioux City . . . ." Id. at 3. Two days later, J.M.K. was flown to the Children's Hospital and Medical Center in Omaha, Nebraska, where she "was

admitted and diagnosed with neonatal *Enterobacter sakazakii* meningitis," resulting "in severe brain damage . . . ." Id. Subsequently, the Federal Drug Administration (FDA) tested for and did not find *Enterobacter sakazakii* in the kitchen where J.M.K.'s PIF

was prepared, suggesting an alternate source of contamination. Id. at 4.

From J.M.K.'s date of birth through the time she suffered her injuries, J.M.K. was a neonate, "an infant younger than 28 days." Id. at 2. Plaintiff contends Defendant's Similac PIF, was not and is not "reasonably safe for . . . neonates, whether or not the neonate is full term and whether or not the neonate is healthy . . . ." Id. at 5. "The only known cause of neonatal *Enterobacter sakazakii* meningitis is food-borne ingestion," and "PIF is the only known source of neonatal *Enterobacter sakazakii* meningitis." Id. at 5. The Center for Disease Control has associated PIF with every documented case of neonatal *Enterobacter sakazakii* except one." Id. at 5. In the one exception, "it is believed that the infant may have been fed its twin's PIF because of an admitted crib card switch resulting in misidentification." Id. at 5.

The Food and Drug Administration has "tested samples of

PIF taken at PIF manufacturing facilities and . . . found that 23 percent contained *Enterobacter sakazakii*." Id. at 6. The Plaintiff claims, "[o]n information and belief," that "between March 29, 2002 and September 19, 2006, environmental sampling" from Defendant's "facilities tested positive for *Enterobacteriaceae* (Eb) which is the family containing *Enterobacter sakazakii* . . . ." Id. at 6. In addition, during the above mentioned time period, Plaintiff alleges, again on information and belief, that both raw ingredient and finished product sampling from Defendant's product tested positive for *Enterobacter sakazakii*. Id. at 6.

PIF is susceptible to contamination with *Enterobacter sakazakii* "because it is not manufactured as commercially sterile." Id. at 7. "Upon information and belief," Plaintiff contends Defendant "has testing procedures in place (although inadequate) . . . and discards batches of PIF found to contain the bacteria." Id. at 7. This alleged practice demonstrates that the "presence of *Enterobacter sakazakii* is not part of the intended design of Abbott's PIF." Id. at 7.

From the above alleged facts, Plaintiff concludes the "source of bacteria that caused J.M.K.'s neonatal *Enterobacter sakazakii* meningitis was Defendant's Similac PIF;" and

Enterobacter sakazakii originated in Defendant's "facilities, and/or [Defendant's] finished product PIF prior to distribution, and/or PIF consumed [by J.M.K.] prior to the diagnosis of *Enterobacter sakazakii* infection." Id. at 5-6. Plaintiff intends to demonstrate the source of the *Enterobacter sakazakii* that infected J.M.K. by matching its DNA with "isolate found in [Defendant's] factory, manufacturing equipment, raw materials, finished product (before or after distribution) or with one found in another baby following ingestion of [Defendant's] PIF . . . ." Id. at 6.

B. Specific Allegations

Plaintiff asserts seven causes of action: (1) manufacturing defects (2) design defects, (3) failure to warn, (4) breach of express warranties, (5) breach of implied warranty of fitness for a particular purpose, (6) breach of implied warranty of merchantability, and (7) fraud. Id. at 11-20.

1. Manufacturing and Design Defect

Though two separate causes of action, Plaintiff's manufacturing and design defect claims are closely related. Plaintiff contends *Enterobacter sakazakii* must have entered

J.M.K.'s PIF from either a manufacturing or a design defect; that is, either J.M.K.'s PIF was contaminated due to a deviation in Defendant's "specifications and/or performance standards" in a manner that was "not reasonably safe to the ordinary consumer" (manufacturing defect) or Defendant's "specifications and/or performance standards were deficient" (design defect). Id. at 11. Plaintiff also contends that J.M.K.'s parents used the PIF in an ordinary, normal, and expected manner, in comportment with the actions of a reasonable consumer. Id. at 8.

Plaintiff also alleges a number of potential sources for the manufacturing defect, as well as potential alternative designs. In terms of the proposed alternative designs, Plaintiff alleges Defendant's failure to implement them made Defendant's PIF not reasonably safe. Id. at 14. If implemented, the "alternative design(s) would have reduced or avoided the foreseeable risks of harm posed by the PIF by decreasing the incidence of *Enterobacter sakazakii*" and would have prevented J.M.K.'s damages. Id. at 13 and 14. Finally, Plaintiff alleges the manufacturing and/or design defects in Defendant's product amounted to willful and wanton disregard of J.M.K.'s safety and rights. Id. at 12,13, and 14.

2. Failure to Warn

Plaintiff alleges the PIF J.M.K. was given was labeled with an express warranty "that its product was beneficial and safe for infants, including neonates. More specifically, the label" consisted of a "large type . . . statement that the product was suitable for infants '0-12 months' of age." Id. at 3. "The label also contained a statement that the product was not sterile and should not be fed to an infant who was premature and had immunity problems." Id. Before feeding J.M.K. the PIF, J.M.K.'s mother read the label and determined that the warning language "did not apply to J.M.K." Id. According to Plaintiff,

> J.M.K.'s mother would not have fed J.M.K. Similac PIF had [the] label stated:
>
> (1) the product was unsuitable for an infant under 28 days, (2) the product may contain a bacteria that, if present, would cause serious harm to J.M.K., or (3) that liquid formula was safer for J.M.K.

Id. at 4.

Plaintiff alleges that, at the time J.M.K. consumed the PIF, the average consumer was unaware of the risks associated with PIF. Id. at 14. Since there was no adequate warning, Defendant's PIF was "not reasonably safe" for J.M.K., and was a cause of J.M.K.'s damages. Id. at 15-16. Finally,

Defendant's failure to adequately warn its customers of the danger of its products amounted to willful and wanton disregard of their rights and safety. Id. at 16.

3. Breach of Express Warranty

Plaintiff alleges Defendant has made several express warranties over the years. For instance, the product J.M.K.'s parents received from the hospital was accompanied by a "label that expressly warranted that its product was beneficial and safe for infants, including neonates." Id. at 16. Defendant also expressly states that its "formula is microbiologically safe on its website" and that "'infant formula is the only safe, nutritious, and recommended alternative' to breastfeeding . . . ." Id. at 16. On December 23, 2008, Defendant "issued a press release stating that its infant formulas were "'completely safe . . . .'" Id. at 17. Defendant also advertises that its products nurture and fortify the immune systems of infants. Id. at 17.

Plaintiff contends J.M.K.'s parents fed J.M.K. PIF in reliance on Defendant's express warranties; specifically, Defendant's warranty that its "PIF is both safe and beneficial for neonates with normal immune systems . . . ." Id. at 17. Since the PIF did not conform to Defendant's express

warranties, they breached those warranties. Id. at 17. Finally, the making and breaching of their express warranties amounted to "willful and wanton disregard for J.M.K.'s rights or safety . . . ." Id. at 18.

4. Implied Warranty of Fitness for a Particular Purpose

Plaintiff alleges Defendant knew their product was used to feed babies, and their sale, advertising, and distribution of their PIF included an implied warranty that their product "was beneficial and safe for infants . . . ." Id. at 18. Further, Defendant "had reason to know J.M.K. was relying on its skill or judgment to furnish the PIF." Id. at 19. For instance, their advertising indicates their product was designed for healthy balance, and "'[m]oms can count on Similac for trusted nutrition and the formula that's right for their babies.'" Id. at 19. However, according to Plaintiff, the PIF was not fit for its particular purpose, and this failure "was a cause of J.M.K.'s damage." Id. at 19. Further, Plaintiff contends Defendant's breach of the implied warranty of fitness for a particular purpose amounted to "willful and wanton disregard of J.M.K.'s rights or safety . . . ." Id. at 19.

5. Implied Warranty of Merchantability

Plaintiff alleges Defendant "was a merchant at the time the PIF was distributed to J.M.K." Id. at 19. "The PIF Defendant distributed to J.M.K. was not merchantable in that it was not in fair average quality because it contained *Enterobacter sakazakii*," and Defendant's failure to provide a merchantable product "was a cause of J.M.K.'s damage." Id. at 19. Finally, Defendant's breach of the implied warranty of merchantability was in "willful and wanton disregard of J.M.K.'s safety . . . ." Id. at 20.

6. Fraud

Plaintiff, providing specific examples, alleges Defendant has repeatedly and "expressly stated that its infant formula is microbiologically safe . . . ." Id. at 20. J.M.K.'s parents gave the PIF to J.M.K. in justifiable reliance upon such express statements. Id. at 21. Defendant failed to inform its consumers of facts they knew would prevent them from being mislead. Id. at 21. Finally, Defendant's failure to disclose certain facts was "in willful and wanton disregard of J.M.K.'s rights or safety . . . ." Id. at 22.

III. LAW AND ANALYSIS

A. Legal Standard

Rule 12(b)(6) provides that a defendant may assert a defense for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Rule 8(a)(2) requires a plaintiff to plead "a short plain statement of the claim showing" they are "entitled to relief." F.R.C.P. 8(a)(2). Rule 8(e) requires courts to construe pleadings "so as to do justice." Fed. R. Civ. P. 8(e).

In Bell Atlantic Corporation v. Twombly, the Supreme Court revisited the standard for a 12(b)(6) motion. 550 U.S. 544 (2007). The Court upheld the traditional concept of notice pleading, whereby the primary purpose of pleading in the federal system is to give a defendant "'fair notice what the claim is and the grounds upon which it rests.'" 550 U.S. at 555 (citing Conley v. Gibson, 355 U.S. 41 (1957)). A complaint need not include detailed factual allegations but "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action . . . ." Id. "[F]acts and allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if

doubtful in fact)." Id. Overall, the Court did not "require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face."[2] 550 U.S. at 570.

In Ashcroft v. Iqbal, the Court identified two principles underlying its decision in Twombly. 129 S. Ct. 1937, 1950-51 (2009). First, a court need not accept allegations which constitute mere legal conclusions as true. Id. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. (citing Twombly, 550 U.S. at 556). "Second, only a complaint that

[2]Though attorneys, when their client's needs demand, are apt to portray the Supreme Court's rulings in Twombly as a profound change in motion to dismiss jurisprudence, a post-Twombly Supreme Court decision, Erickson v. Pardus, clearly reiterates the basic principles of liberal pleading in federal district courts. 551 U.S. 89 (2007). The Court noted,

> Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief.' Specific facts are not necessary; the statement need only 'give the defendant fair notice of what the claim is and the grounds upon which it rests.' Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 . . . (2007) (quoting Conley v. Gibson, 355 U.S. 41, 47 . . . (1957)). In addition, when ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint.

551 U.S. at 93-94.

states a plausible claim for relief survives a motion to dismiss." Id. (citing 550 U.S. at 556). A determination of whether a claim is plausible "requires the reviewing court to draw on its judicial experience and common sense." Id. (citing Iqbal v. Hasty, 490 F.3d 143, 157-58 (2nd Cir. 2007).

B. Manufacturing Defect

Iowa has adopted § 2 of the Restatement (Third) of Torts: Product Liability for manufacturing defects. Wright v. Brooke Group Ltd., 652 N.W.2d 159, 168 (Iowa 2002). A product contains a "manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product." Restatement (Third) of Torts § 2 (1997). The rule is one of strict liability: a showing of fault on the part of the manufacturer is not required.[3] Id. at cmt. a. Manufacturing

[3] There are several policy considerations behind strict liability for manufacturing defects: (1) strict liability "encourages greater investment in product safety than" a fault based regime; (2) it "discourages the consumption of defective products by" increasing the cost of defective products; (3) it "reduces . . . transaction costs involved in litigating" product defect claims by eliminating proof of fault; (4) it compensates victims clearly harmed by products, who, under a negligence regime, would face an insuperable burden of proof; and (5) it forces companies who profit form the sale of their product and unharmed "consumers who benefit from" the product to share, through increased prices, "injury costs." Restatement (Third) of Torts: Products Liability, § 2, cmt. a.

defect claims often arise when a product is obviously "physically flawed," though a plaintiff lacks crucial information necessary to demonstrate the manufacturer is at fault. Id. at cmt. c. In this sense, it serves a function similar to the doctrine of res ipsa loquitur[4] in negligence. Id. at cmt. a.

Defendant argues Plaintiff's complaint fails to state a claim upon which relief can be granted for two reasons: (1) Plaintiff fails to plead Similac PIF's intended design, and (2) Plaintiff fails to plead how Similac PIF deviated from its intended design. Docket No. 47-1, 7. These arguments are closely related. If something is not part of the intended design of a product, then the presence of the unintended thing, if harmful, will likely constitute a defect.

1. Allegations of Defendant's Intended Design

"[U]nder Iowa law, an essential element of any manufacturing defect claim is the intended design of the product." Depositors Ins. Co. v. Wal-Mart Stores, Inc., 506 F.3d 1092, 1095 (8th Cir. 2007). A recent decision by a

[4] "The doctrine providing that, in some circumstances, the mere fact of an accident's occurrence raises an inference of negligence that establishes a prima facie case." Black's Law Dictionary (9th ed. 2009).

federal District Court in Minnesota, considering a complaint with allegations almost identical to the case at bar in which Abbott Laboratories was the defendant and the plaintiff was represented by the same attorneys as in the case at bar, ruled that plaintiffs failed to "allege any facts describing or identifying defendants' manufacturing specifications or standards." Burks v. Abbott Labs, et. al., No. 08-3414, 2010 U.S. Dist. Lexis 38616, at 9-10 (D. Minn. April 20, 2010) (hereinafter "Burks II"). According to the Burks II Court, plaintiffs' allegations were "limited to a formulaic recitation of the . . . elements and . . . legal conclusions," and, therefore, were not in compliance with the Supreme Court's decision in Iqbal and failed to state a claim upon which relief could be granted. 2010 U.S. Dist. Lexis 38616, at 9. This Court respectfully disagrees.

In the Complaint at issue here, Plaintiff alleges "[t]he presence of *Enterobacter sakazakii* is not part of the intended design of Defendant's PIF." Docket No. 46, 7. This is not a legal conclusion, such as "Abbott's PIF contained a manufacturing defect," this is a straight forward allegation of fact which clearly references Abbott's intended design. As previously noted, for purposes of a motion to dismiss, a

plaintiff's plausible allegations must be accepted as true, and this particular allegation is highly plausible. Any assertion that Defendant's intended design included the presence of *E. sakazakii* strains credulity.

In addition, while, under Iowa law, a plaintiff does have to allege a product's intended design, the allegations in relation thereto need not be exhaustive. The base rule requires only that a plaintiff show how a "product departs from its intended design" and does not require the pleading of a product's detailed specifications. Restatement (Third) of Torts: Products Liability, § 2. Again, Plaintiff alleges *E. sakazakii* is not part of Similac PIF's intended design. Docket No. 46, 7. To Require Plaintiff to plead more, unrelated aspects of Defendant's intended design would be superfluous, overly burdensome, and contrary to the spirit of notice pleading.

If Defendant wishes to argue the presence of *E. sakazakii* or other potentially harmful bacteria are, in fact, included in their intended design, they may do so at later stages in the proceeding. For now, this Court must accept Plaintiff's plausible allegations as true; and, as noted, the allegation that Defendant's intended design did not include the presence

of *E. sakazakii* seems highly plausible, and constitutes a sufficient allegation of Defendant's intended design.

2. Allegations of a Deviation from Defendant's Intended Design

Defendant claims Plaintiff has failed to allege the PIF J.M.K. consumed deviated from Defendant's intended design. In support of this argument, Defendant cites another federal District Court of Minnesota decision in which Abbott Laboratories was again the Defendant under similar facts to the case at bar. Burks v. Abbot Laboratories, 639 F. Supp. 2d 1006, 1016 (D. Minn. 2009) (hereinafter "Burks I"). The Burks I Court ruled that because PIF is a non-sterile product and is "expected . . . [to] be contaminated," the plaintiff failed to show that Abbott's product deviated from its intended design. Id. Again, this Court respectfully disagrees.

It is clear from Plaintiff's complaint that the presence of *E. sakazakii* is the alleged deviation from Defendant's intended design, and this Court does not think the presence of harmful bacteria in baby formula is "expected" by the average, reasonable consumer. The Plaintiff in fact alleges, and this Court must accept as true, that the risks associated with PIF were not "generally known" by the public at the time of J.M.K.'s illness. Docket No. 46, 15.

The Burks I ruling seems to rely on the fact that, since the Food and Drug Administration in 2003 reported that *E. sakazakii* was present in 23% of PIF tested, *E. sakazakii*'s presence is somehow common knowledge and/or acceptable. In a similar vein, Defendant notes the general rule that a "manufacturing defect . . . 'exists only where an item is substandard when compared to other identical units off the assembly line.'" Docket No. 56, 3 (quoting Wright v. Brooke Group, Ltd., 652 N.W.2d 159, 178-79 (Iowa 2002). Though Defendant does not draw this citation to its logical conclusion, the implication is clear: their product is intended to contain *E. sakazakii*, as well as other potentially harmful bacteria. First, if 75% of a product does not contain a bacteria and 25% of a product does, elementary statistics dictates that the 75% without the bacteria constitutes the norm while the 25% with the bacteria constitutes a deviation therefrom. Second, a common defect, such as the persistent contamination of a food product with bacteria, if generally unknown and proven harmful, should increase a manufacturer's total liability, rather than eliminate it.

As previously noted, Plaintiff also alleges, on "information and belief," that Defendant "has testing

procedures in place (although inadequate) to test for the presence of *Enterobacter sakazakii* and discards batches of PIF found to contain the bacteria." Docket No. 46, 7. Clearly, if Defendant is screening for and disposing of batches of formula containing *E. sakazakii*, the presence of *E. sakazakii* is not part of Similac PIF's intended design, and its presence constitutes a deviation therefrom.

Plaintiff further alleges specific quality control lapses which caused Defendant's PIF to be defective, i.e., storing PIF in areas with improper climate control, failure to biocidally treat the finished product, failure to keep manufacturing and storage facilities sufficiently clean, and inadequate testing procedures; thus, Plaintiff alleges not only Similac PIF's departure from its intended design but the potential sources of that departure. Docket No. 46, 12-13.

Finally, both the Burks I Court and the Defendant ignore the primary test for determining whether a product has deviated from its intended design; that is, a determination of whether the average, reasonable consumer, rather than government regulators or industry insiders, would expect a product to have the alleged defect. Restatement (Third) of Torts: Products Liability, § 2, cmt. 3. While expressly

rejecting consumer expectations as a test for whether a product has a design defect, the Restatement (Third) of Torts: Products Liability, notes the importance of consumer expectations in relation to manufacturing defects and, more specifically, food product defects; it provides:

> On occasion it is difficult to determine whether a given food component is an inherent aspect of a product or constitutes an adulteration of the product. Whether, for example, a fish bone in commercially distributed fish chowder constitutes a manufacturing defect within the meaning of §2(a) is best determined by focusing on reasonable consumer expectations.

Restatement (Third) of Torts: Products Liability, § 2, cmts. g and h.

The Plaintiff alleges "[n]either J.M.K.'s parents . . . nor the ordinary consumer would reasonably expect [Defendant's] food product to contain" *E. sakazakii*. Docket No. 46, 4. This Court agrees. Though Defendant makes no secret that its product is not sterilized, the average consumer would not, from that, infer that its baby formula contains life-threatening bacteria.

For the above reasons, this Court is convinced that, under Iowa law, Plaintiff has pled facts sufficient to establish that Similac PIF deviated from its intended design.

3. Conclusion

Plaintiff's narrative is clear and plausible: Defendant did not intend to incorporate *E. sakazakii* into its PIF, and the presence of *E. sakazakii* in the PIF J.M.K. consumed constituted a deviation from Defendant's intended design. **Therefore, Defendant's motion to dismiss Plaintiff's manufacturing defect claim is denied**.

C. Design Defect

Iowa has also adopted the Restatement (Third) of Torts for design defect causes of action. Wright, 652 N.W.2d at 169. A product has a defective design when:

> the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.

Restatement (Third) Torts: Products Liability, § 2(b) (1997).

A design defect claim differs from a manufacturing defect claim in that a manufacturing defect arises from a deviation from a products design, whether or not that design be reasonable, whereas a design defect arises directly from a products unreasonable design. Id. at cmt. a. In addition, while manufacturing defects claims are based in strict

liability, design defect claims require a "risk-utility" analysis, similar to a determination of negligence, in which the foreseeable danger of a product is weighed against the desirability of altering its features. Id.

Defendant argues Plaintiff's design defect claim should be dismissed because they have failed to: (1) allege the existence of an alternative design, and (2) allege how any of their "proposed 'alternatives' would, at a reasonable cost, reduce or avoid the alleged risk of harm from powdered infant formula." Docket No. 47-1, 10.

1. Failure to Allege Alternative Designs

Plaintiff identified the following alternative designs: (1) storing PIF in proper climate controlled areas, (2) maintaining the manufacturing and storage facilities in a sufficiently clean condition, (3) biocidally treating PIF, (4) implementation of adequate product testing procedures, and (5) distribution of only liquid infant formula. Docket No. 46, 13.

Defendant maintains that storage, maintenance, testing, and biocidal treatment do not alter the design of Abbott's PIF, but only its manufacturing and storage procedures. Docket No. 47-1, 8-9. The Burks II Court ruled that "even if

defendants implemented the [plaintiff's] proposed alternative processes, the design of the powdered infant formula would remain the same." 2010 U.S. Dist. LEXIS 38616 10, 12.

This Court agrees that Plaintiff's proposed storage, maintenance, and product testing alternatives do not constitute alternative designs. The McGraw-Hill Science & Technology Dictionary defines "product design" as "[t]he determination and specification of the parts of a product and their interrelationship so that they become a unified whole." *Answers.com*, Product Design, available at http://www.answers.com/topic/product-design, last visited January 31, 2012. In other words, product design refers to the conception of a product's component parts and how those parts are put together, rather than how those parts or the finished product are stored, maintained, and tested.

Furthermore, the Restatement (Third) notes that "a product asserted to have a defective design" is one asserted to have "specifications"[5] that create "unreasonable risks."

[5] The American Heritage Dictionary defines specifications as a "detailed, exact statement of particulars, especially a statement prescribing materials, dimensions and quality of work for something to be built, installed, or manufactured." *The Free Dictionary*, specification, available at http://www.thefreedictionary.com/specification, last visited November 10, 2011.

Restatement (Third) of Torts: Products Liability § 2, cmt. d. As commonly understood, storage, facility maintenance, and testing procedures, do not comprise a product's specifications, but are quality control measures.

Because questions of quality control involve conduct that a Defendant can easily rectify prior to discovery and often turns on company information unavailable to consumers, the Restatement (Third) wisely provides they are better addressed through the strict liability regime of manufacturing defect law. On the other hand, because design/specification issues are often readily apparent to the general public, such issues are best dealt with through design defect law's risk-utility analysis, which, as previously noted, more closely resembles traditional negligence. A lesser burden of proof for claims relating to a manufacturer's quality control measures is further justified because quality control measures are less costly to alter and more easily manipulated than the underlying design of a product. See Restatement (Third) of Torts: Products Liability, § 2, cmt a. ("the element of deliberation in setting appropriate levels of design safety is not directly analogous to the setting of levels of quality control by the manufacturer."). A manufacturer's quality

control measures, such as product storage, facility maintenance, and product testing procedures may be relevant in a manufacturing defect claim; but they cannot serve as a basis for a design defect claim. They simply do not touch upon a products' design.

However, this Court is persuaded that biocidal treatment does constitute an alternative design. Defendant contends that, as with the storage, maintenance, and testing alternatives, biocidal treatment would not change the end product. Docket No. 47-1, 11. The American Heritage Science Dictionary defines "biocide" as "[a] chemical agent, such as a pesticide or herbicide, that is capable of destroying living organisms." *The Free Dictionary*, Biocide, Available at http://www.thefreedictionary.com/biocide, last visited January 31, 2012. Thus, biocide is a substance that would be added to Defendant's PIF, thus altering the conception of its component parts as well as the finished product, rather than a mere quality control measure.

Finally, Defendant contends Plaintiff's suggested alternative design of liquid formula would create an entirely different product and so cannot constitute an alternative design. Docket No. 47-1, 10. In support of this argument,

Defendant again cites Burks II. The Court in Burks II noted that "liquid infant formula is a different product entirely than powdered infant formula, with unique qualities and advantages and disadvantages," but Defendant conveniently omits that the Burks II Court did not make a decision based on this opinion and went on to state that the issue "may be more appropriately resolved at summary judgment." 2010 U.S. Dist. Lexis 38616 at 13. Of course, any alternative design which alters a products specifications will have "unique qualities and advantages and disadvantages" as compared to the initial product; whether those differences are superior to the design of the original product is what risk-utility analysis is all about. This Court is unaware of any controlling precedent suggesting there is a magic line of demarcation whereby suggested alterations constitute an alternative product rather than an alternative design. While such a line of demarcation may prove practicable in some rare instances, this is not one of them. The only difference between liquid infant formula and powdered infant formula is water; the end result is still baby food.[6]

[6] In their reply, Defendant claims Plaintiff's pronouncement that liquid infant formula is an alternative design to powdered infant formula "is akin to arguing that beer is just an alternative design to bread because both

On the one hand, Defendant argues something must be added or taken away from the component parts of a product to create an alternative design; on the other hand, Defendant argues adding one of the most ubiquitous substances on Planet Earth creates a whole new product. Between these two arguments, there would be little that would constitute an alternative design, and the policy behind design defect claims would be eviscerated.

Design defect claims create "incentives for manufacturers to achieve optimal levels of safety in designing . . . products." Restatement (Third) of Torts: Products Liability, § 2, cmt. a. Semantic disputes, such as whether a proposed alternative constitutes an alternate product or design simply miss the point. In the context of design defect law, to say a proposed alternative creates an alternate product rather than an alternate design, is to say the proposed alternative cannot fulfill the function of the initial product. To make this determination requires evidence which is simply

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products are made from grain, yeast and water." Docket No. 56, 5. The measure of the similarity of two products is inexorably related to the purposes for which they are used. Because liquid infant formula and powdered infant formula are both designed to nourish babies, and beer and bread are used for entirely separate purposes, the Defendant's comparison is untenable.

unavailable in a motion to dismiss. Though many "product related accident costs can be eliminated only by excessively sacrificing product features," in order for risk-utility analysis to serve its underlying policy purpose, "the various trade-offs" between a manufacturers actual product and a proposed alternative "need to be considered," rather than presumed. Id.

Finally, in its reply brief, Defendant argues Plaintiff, in relation to all of its proposed alternatives, fails to "allege how any of these suggestions would change the composition of Abbott's PIF or its properties" and so fails to allege "all the elements of its purported claim." Docket No. 56, 5. In support of its argument, Defendant cites the Iowa Supreme Court's decision in Wright. Id. (citing 652 N.W.2d at 168-69). After thoroughly reviewing Wright, this Court could find nothing indicating a Plaintiff must specifically allege how an alternative design would change the composition of a product. As discussed above, the idea of a change of composition is subsumed in and part of the vary definition of what constitutes an alternative design. The Defendant appears to be manufacturing elements.

In summation, though Plaintiff's suggested storage, maintenance, and testing alternatives do not constitute alternative designs, biocidal treatment and the distribution of solely liquid infant formula do constitute proposed alternative designs sufficient to survive Defendant's motion to dismiss.

2. Failure to Allege Alternative Designs Constitute a Reasonable Alternative

Defendant cites the Iowa Supreme Court's decision in Parish v. Jumpking, Inc., for the proposition that "a plaintiff must not only allege '***the existence*** of a reasonable alternative design,' but . . . also . . . that the 'design would, at a reasonable cost, have reduced the foreseeability of harm posed by the product.'" Docket No. 47-1, 10 (quoting 719 N.W.2d 540, 543 (Iowa 2006).

Though a plaintiff must allege facts consistent with the elements of a cause of action, Parish was a summary judgment case and simply did not require a plaintiff to allege anything. The quote Defendant relies on from Parish was contemplating what a plaintiff would have to show in order to ultimately "succeed" and did not address the question of whether a proper claim for relief was made. Id. The Defendant does not cite and this Court is unaware of a case

that truly holds a plaintiff must specifically allege a proposed alternative design can be achieved at a reasonable cost.

Again, the general rule for a design defect claim in the state of Iowa requires a plaintiff to show that "the foreseeable risks of harm posed by" a defendant's "product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design" rendered a defendant's "product not reasonably safe." Restatement (Third) Torts: Products Liability, § 2(b) (1997); Wright, 652 N.W.2d at 169. That a proposed alternative can be achieved at a reasonable cost is implicit in an allegation that something constitutes a reasonable alternative design; that is, if an alternative design is too costly to be realistically implemented in a free market economy, it will ultimately be proven to be unreasonable. In this case, Plaintiff sufficiently alleges there were "[r]easonable alternative safer . . . designs," including biocidal treatment and liquid infant formula. Docket No. 46 at 10 and 13. Plaintiff also alleges Defendant's failure to implement these alternative designs prior to J.M.K.'s illness made Similac PIF not reasonably

safe. Id. at 14. If the Defendant's line of reasoning were adopted, a plaintiff would have to allege all the various aspects of what makes an alternative design reasonable;[7] this would impose an unnecessary burden and is, by definition, contrary to the requirements of notice pleading.

3. Conclusion

Plaintiff has alleged sufficient facts for a design defect claim. Liquid infant formula and the addition of biocide to powdered infant formula are plausibly reasonable alternative designs to powdered infant formula. **Defendant's motion to dismiss is denied as to these two alternative designs**.

D. Inadequate Warnings

Iowa has also adopted the Restatement (Third) of Torts

[7] Defendant, citing the Restatement (Third), strongly implies a plaintiff must plead "whether a nationwide substitution of products is practicable, would result in comparable production costs, and would provide consumers with products with similar longevity, portability and esthetics." Docket No. 56, 6 (citing Restatement (Third) of Torts: Products Liability, § 2, cmt. f. (continued)
The proposition for which Defendant cites this comment is questionable. The Restatement (Third) refers to the above considerations as mere "factors" of which a "plaintiff is not required to introduce proof . . . ." Furthermore, the entire section contemplates the various considerations that may go into a determination of whether or not a proposed alternative is ultimately preferred and does not contemplate what a plaintiff must plead to survive a motion to dismiss. Id.

for inadequate warning causes of action. Wright, 652 N.W. 2d at 168. The Restatement provides:

> A product . . . is defective because of inadequate instructions 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 . . . and the omission of the instructions or warnings renders the product not reasonably safe.

Restatement (Third) Torts § 2 (1997).

Defendant's motion to dismiss this cause of action can be boiled down to two general arguments: (1) Plaintiff fails to allege Defendant's warning was inadequate in such a manner that it rendered their product not reasonably safe; and (2) even if Plaintiff did so allege, their allegations are implausible. Docket No. 47-1, 12-13.

1. Whether Plaintiff Properly Pled Defendant's Warning Label Was Inadequate in Such a Manner as to Render Its Product Not Reasonably Safe

Evaluation of a complaint is a "context-specific task . . . ." Iqbal, 129 S. Ct. at 1950. A "complaint should be read as a whole, not parsed piece by piece . . . ." Braden v. Wal-Mart Stores, Inc., 588 F.3d 585, 594 (8th Cir. 2009). Plaintiff's specific allegations as to the inadequate warning on Defendant's PIF are grounded in their general allegations. As previously noted, Plaintiff alleges "[t]he only known cause

of neonatal *Enterobacter sakazakii* meningitis is . . . PIF . . . [t]he Center for Disease Control has associated PIF with every documented case of neonatal *Enterobacter sakazakii* except one." Defendant's product was the cause of J.M.K.'s illness, and Similac PIF's label states it is suitable for 0-12 month infants. Id. at 5 and 7. From the above, general allegations, Plaintiff concludes Similac PIF's warning label was "inadequate," and, due to this inadequacy, the product was not "reasonably safe," particularly in the case of "full term neonates with normal immune systems for their age, such as J.M.K." Id. at 15. Plaintiff also specifically suggests four types of warnings, which, if employed, would have "reduced or avoided" the "foreseeable risks of harm posed by [Defendant's] PIF." Id. Thus, Plaintiff has gone above and beyond what is required under notice pleading. The Defendant's assertion that Plaintiff failed to allege its warning was inadequate in such a manner as to render its product not reasonably safe has no merit and simply ignores the plain language of Plaintiff's complaint.[8]

[8] In their reply, Defendant argues Plaintiff's allegation that Defendant's warning is inadequate is a mere legal conclusion. Docket No. 65, 7. This is inaccurate. Plaintiff's allegation that Similac PIF's warning is inadequate, because it is based in pure factual allegations,

2. Whether Plaintiff's Allegations are Implausible

Defendant first argues that, because Plaintiff admits Similac PIF's label states it is not sterile, and a sterile product is a product "'free from bacteria or other microorganisms,'" Plaintiff's allegation that the warning label is inadequate is implausible. Docket No. 47-1, 14 (quoting THE AMERICAN HERITAGE DICTIONARY 1195 (2d ed. 1985). Defendant next argues that, because PIF has been given to infants for the last century, Plaintiff's allegation that Similac PIF is not reasonably safe is "patently implausible." Docket No. 47-1, 15.

"Warnings alert users . . . to the existence and nature of product risks." Restatement (Third) of Torts: Products Liability, § 2, cmt. I. They allow users to make informed decisions as to whether they want to assume the risks associated with a product, as well as inform users how to avoid certain risks associated with misuse of the product. Id. If a warning is unclear, and the harm it warns against real, the warning cannot be adequate. Though Defendant warns

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is at once a legal and a factual conclusion. Defendant would have this Court look at each phrase of Plaintiff's Complaint in a vacuum. See Iqbal, 556 U.S. 662, 1950 ("legal conclusions can provide the framework of a complaint," when "supported by factual allegations").

its product is not sterile, they do not warn it, even if properly prepared, may still contain potentially life-threatening bacteria. As previously touched upon, this Court is not persuaded the general public equates a warning that a product is not sterile with the presence of potentially life threatening bacteria; and, even if clever consumers would initially understand Similac PIF's warning in this manner, the label's insistence that it is suitable for 0-12 month old infants, would no doubt override their concerns. Docket No. 46, 15. Overall, this Court is persuaded Plaintiff's allegations that Defendant's warning is inadequate, is more than plausible - at this early stage and accepting Plaintiff's allegations as true, it appears likely. Whether Similac PIF is actually harmful or whether that harm is significant enough to require a more precise warning label is something which should ultimately be determined further on in the proceedings.

Finally, simply because a product is or was a staple of every day life does not mean an allegation that it is not reasonably safe due to an inadequate warning is "patently implausible." Docket No. 47-1, 15. This Court's judicial experience and common sense dictate otherwise. For instance, Defendant's reasoning could equally apply to other formerly

heralded products, such as asbestos, DDT, or tobacco; each of these products had inherent risks that only became common knowledge well after their wide scale acceptance and deployment. Of course, this is not to say Similac PIF will ever be proven to be as dangerous as those products, but well pled allegations that Similac PIF is not reasonably safe due to an inadequate warning certainly cannot be deemed implausible at this juncture.

3. Conclusion

Plaintiff has properly alleged Defendant's warning label is inadequate in such a manner as to make their PIF not reasonably safe, and there is nothing inherently implausible about Plaintiff's allegations. **Thus, Defendant's motion to dismiss Plaintiff's inadequate warning cause of action is denied**.

E. Warranty Claims

Plaintiff asserts three warranty causes of action: (1) breach of express warranties, (2) breach of the implied warranty of fitness for a particular purpose, and (3) breach of the implied warranty of merchantability. Docket No. 46, 16-20. Prior to determining whether Plaintiff has properly alleged a cause of action for its three warranty claims, this

Court must decide a threshold issue, i.e., whether there was a sale of goods, which is necessary for a warranty, express or implied, to be created.

1. Whether There was a Sale of Goods

Iowa breach of warranty claims are based in the Iowa Uniform Commercial Code, Chapter 554, Article 2 - Sales (hereinafter "IUCC"). All three of the warranty claims Plaintiff asserts expressly require a "seller," and, therefore, implicitly require a sale of goods. Iowa Code §§ 554.2313, 554.2314, 554.2315; see also Levien Leasing Co. v. Dickey Co., 380 N.W.2d 748, 751 n. 1 (Iowa App. 1985) ("Article 2 of the Iowa Uniform Commercial Code only applies to the sale of goods."). Far from arbitrary, this requirement separates commercial transactions for economic gain from benevolent donations. Sound policy dictates that donations be encouraged, and unsound business practices be discouraged. Warranty law imposes duties on individuals and companies motivated by economic gain in relation to their implicit and explicit representations which induce buyers to purchase their goods.

As previously noted, Plaintiff alleges Defendant "supplied gift bags to the hospital containing Similac PIF in

exchange for consideration[9] from the hospital." Docket No. 46, 2. The question is whether Plaintiff's allegation of goods "in exchange for consideration" constitutes a sale under the IUCC.[10]

Though at times unclear, Defendant's contention seems to hinge on the popular notion that a sale is the exchange of goods for currency. Plaintiff's Complaint does not specify whether the hospital's consideration given for Defendant's PIF was actual currency. Regardless, after reviewing relevant case law and relevant sections of the IUCC, this Court is convinced Plaintiff has sufficiently alleged Defendant sold the goods to the hospital as contemplated under the IUCC.

A sale of goods under the IUCC does not require the exchange of goods for currency but includes other types of

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[9] "Something (such as an act, a forbearance, or a return promise) bargained for and received by a promisor from a promisee." Black's Law Dictionary (9th ed. 2009), consideration.

[10] In its reply brief, the Defendant claims that Plaintiff's allegation is a "legal conclusion." While the difference between legal conclusions and facts are often difficult to distinguish, and an allegation that consideration was given may constitute a conclusion in a contract case, in these circumstances, the allegation is more factual than legal in nature. The Plaintiff is clearly saying that the Defendant received something in exchange for the product it usually sells for money, even if that something was nothing more than enhanced good will among the hospital's customers.

consideration. § 554.2102 provides the scope of Article 2 covers "transactions[11] in goods," which is broad enough to incorporate non-cash consideration. Furthermore, § 554.2304 provides a "price can be made payable in money or otherwise." Though this "otherwise" is not explained, this Court thinks it is obvious it is intended to include various, non-currency consideration. Finally, in Johnson County v. Guernsey Ass'n of Johnson, the Iowa Supreme court ruled the IUCC definition of a sale was "[p]ractically the same definition" as found in a former Section of the Iowa Code[12] dealing with the marketing of dairy products. 232 N.W.2d 84, 86 (Iowa 1975). In that Section, a sale was defined as "any commercial transfer for consideration, exchange, barter, gift, or offer for sale and distribution in any manner or by any means." Clearly, under this definition, Plaintiff's allegation constitutes a sale as contemplated by the IUCC.

Defendant implies the definition of sale at § 554.2106 of the IUCC defeats Plaintiff's warranty claims, but this Court fails to comprehend how. Docket No. 47-1, 15. § 554.2106

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[11] Black's Law Dictionary defines a "business transaction" as an "action that affects the actor's financial or economic interest." (9th ed. 2009).

[12] Former Iowa Code § 192A.1(9)

provides a "'sale' consists in the passing of title from the seller to the buyer . . . ." § 554.2401 provides "title passes to the buyer at the time and place at which the seller completes the seller's performance with reference to the physical delivery of the goods." Clearly, assuming Defendant received some type of consideration for providing its product to the hospital, as alleged by Plaintiff and as is likely considering the Defendant and the hospital are businesses, rather than charities, title passed to the hospital upon Defendant's delivery of the PIF and a sale was consummated.

Even assuming a sale of goods under the IUCC involves the exchange of goods for currency, Plaintiff's allegation of an exchange of goods for consideration is sufficient. Absent the cooperation of the hospital or Defendant, Plaintiff has no means to verify the nature of the consideration given by the hospital. When considering a motion to dismiss for failure to state a claim, a court must take into account a plaintiff's "limited access to crucial information." U.S.A. v. Dico, 2011 WL 677448 (S.D. Iowa 2011). When a fact is in the control of defendant(s) but can be reasonably inferred from a plaintiff's allegations, specific allegations are not necessary. See Braden v. Wal-Mart Stores, Inc., 588 F.3d 585, 598 (8th Cir.

2009) ("If plaintiffs cannot state a claim without pleading facts which tend systematically to be in the sole possession of defendants, the remedial scheme . . . will fail, and . . . crucial rights . . . will suffer."). Therefore, even assuming a sale requires an exchange of currency, which it does not, it is reasonable to infer the hospital paid cash for the Similac PIF, and Plaintiff's allegation is sufficient.

Defendant also argues that, because Plaintiff alleges J.M.K.'s parents received an unsolicited gift bag, there was no sale. Docket No. 47-1, 15. Defendant's argument confuses the issue. The question is not whether there was a sale between the hospital and J.M.K.'s parents but whether there was a sale between Defendant and the hospital. § 554.2318 of the IUCC unambiguously provides that a "seller's warranty whether express or implied extends to any person who may reasonably be expected to use, consume or be affected by the goods and who is injured by breach of the warranty." Thus, assuming Defendant sold the PIF to the hospital, as alleged by Plaintiff, any and all warranties associated with that sale extended to J.M.K.'s parents, who were reasonably expected to use the product.

Defendant further argues Plaintiff, in order to state a warranty claim under Iowa law, must allege title passed from buyer to seller but failed to do so. Docket No. 47-1, 17. As with many of its arguments, Defendant fails to cite a single case stating that such an allegation is necessary and instead relies on inapplicable case law. Id. (citing Top of Iowa Coop. v. Sime Farms, Inc., 608 N.W.2d 454, 464 (Iowa 2000) (citations omitted). Plaintiff's allegation that Defendant gave the hospital its Similac PIF in exchange for consideration, as explained above, is another manner of saying that title passed from Defendant to the hospital. Defendant would have Plaintiff allege the same thing under every conceivable variation in the English language, something clearly not contemplated under notice pleading.

Finally, in its reply, Defendant argues Similac PIF was exchanged for services, or, specifically, "the distribution of the infant formula gift bags,"[13] and, since the "provision of

[13] Defendant specifically notes, "[i]f anything, the Complaint suggests that the 'consideration' was exchanged for Abbott's ***services*** in distributing infant formula gift bags." If taken literally, this argument would make little sense. First, Plaintiff alleges the goods were exchanged for consideration, not that consideration was exchanged for services. Second, Defendant did not distribute the gift bags, the hospital did. Given these facts, this Court has decided to cast Defendant's argument in its best light.

services . . . is not subject to the" IUCC, there can be no warranty claims. Docket No. 56, 8. First, Defendant asks this Court to assume something Plaintiff does not allege, which would be inappropriate in a motion to dismiss. This Court has no reason to and refuses to presume a certain type of consideration was given. In a motion to dismiss, a court may not draw inferences in the moving parties favor. Braden, 588 F.3d at 595. Second, Defendant's argument distorts the purpose of the IUCC. "'Goods' means all things . . . which are movable . . . ." Iowa Code § 554.2105(1). Similac PIF is movable and constitutes a good. The price paid for goods, as previously noted, "can be made payable in money or otherwise," including services. Iowa Code § 554.2304. If, as alleged, Defendant exchanged goods for a price, they are subject to the duties imposed under the IUCC. If the hospital's consideration given in fact consisted of distributing Similac PIF, the hospital is a seller of services and could not be held liable under IUCC warranty claims. In short, a single transaction may constitute both a sale of goods and a sale of services; in which case, one party is subject to the warranty provisions of the IUCC and one party is not. How a seller of goods is paid has nothing to do with the policy underlying

warranty causes of action; again, warranty law imposes duties on individuals and companies motivated by economic gain in relation to their implicit and explicit representations which induce buyer to purchase their goods.

In conclusion, Plaintiff properly alleged there was a sale of goods between Defendant and the hospital and any warranties created by such an alleged sale passed on to J.M.K. However, various warranties identified in the IUCC are not automatically created once there is a sale of goods; each requires an additional set of circumstances to apply. The remainder of this Section will determine whether Plaintiff properly alleges sufficient facts to show an express warranty, an implied warranty of fitness for a particular purpose and an implied warranty of merchantability were actually created; and, if so, if Plaintiff properly alleges they were breached.

2. Express Warranties

§ 554.2313 of the Iowa Code provides three means whereby a seller creates an express warranty; two are relevant here:

> a. Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

> b. Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

Defendant primarily contends Plaintiff relies on "***post injury*** advertisements" as the "basis of an express warranty." Docket No. 47-1, 18. Though Plaintiff does provide examples of post injury advertisements, Defendant's contention ignores other aspects of Plaintiff's Complaint. As previously noted, Plaintiff specifically alleges the product used by J.M.K. was accompanied by "a label that expressly warranted that its product was beneficial and safe for infants, including neonates." Docket No. 46, 16. Plaintiff also alleges that "[f]rom 2006 [prior to J.M.K.'s injuries] to the present, [Defendant] has expressly stated that its infant formula is microbiologically safe . . . ." Id. Plaintiff also provides specific examples of express warranties made by Defendant's commercial advertisements and alleges Defendant "made similar representations and statements in 2008 at the time the PIF was distributed to J.M.K.." Id. at 17. Clearly, Plaintiff does not rely on post injury advertisements as the "basis" of its express warranty claim but only as exemplifications of it.

Defendant also contends it disavowed any warranty related to the presence of microorganisms when they included a warning on the product that it was not sterile. Docket No. 47-1, 18. § 554.2316 of the Iowa Code provides that express warranties and disclaimers should be read as consistent when possible and "negation or limitation" of an express warranty "is inoperative to the extent that such construction is unreasonable." It would be consistent to say something is at once not sterile but also microbiologically safe or intended for the use of 0-12 month infants, and so Defendant's warning that its product is not sterile does not serve as a disclaimer or limitation of their express warranties. Further, it would be unreasonable to say that, because Defendant claims their product is not sterile, they negate their warranties related to its safety for infant consumption. As previously noted, the average, reasonable consumer would not equate the statement that Defendant's PIF is not sterile with a statement that it is not suitable for neonates and not microbiologically safe for infants.

Defendant also contends its express warranties were not part of the basis of the bargain with J.M.K.'s parents, or, stated differently, J.M.K.'s parents did not rely on

Defendant's express warranties. Docket No. 47-1, 18. Again, an express warranty is created when a seller makes an affirmation of fact, promise, or description related to the goods to the buyer of the goods. Iowa Code § 554.2313. In this case, the hospital, not J.M.K.'s parents, was the alleged buyer. Further, and as previously noted, once a warranty is created, it "extends to any person who may reasonably be expected to use, consume or be affected by the goods and who is injured by breach of the warranty." Iowa Code § 554.2318. There is no requirement that a defendant reissue its warranty to those reasonably expected to use their product, and there is no requirement that those reasonably expected to use their product use it in reliance on the initial warranty; all that is required is a warranty be made to the initial buyer and be part of the basis of the initial bargain. As previously noted, express warranty causes of action under the IUCC and other commercial codes seek to hold sellers responsible for their representations made in search of profit and which actually induce buyers to purchase their products. The conduct warranty law seeks to influence the conduct leading up to a sale. Thus, to require a seller to reissue its warranty to a third party, or to require an injured third party to have

relied on those representations, as opposed to the purchaser, would confuse and undermine the underlying purpose of an express warranty claim for no discernible competing policy purpose. A warranty is created at the point of sale and generally endures thereafter.

Defendant is not alone in misunderstanding the nature of warranties under the IUCC. Plaintiff's complaint also operates under the assumption that the warranty needed to be made to J.M.K.'s parents and that J.M.K.'s parents were the ones who needed to rely on the warranty as part of the basis of the bargain. Docket No. 46, 16-38. This is, of course, problematic for the Plaintiff. Regardless, this Court is persuaded Plaintiff has sufficiently pled an express warranty claim. "A complaint states a plausible claim for relief if its 'factual content . . . allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" Braden, 588 F.3d at 594 (quoting Iqbal, 129 S. Ct. at 1949). Further, in a motion to dismiss, a court is required to draw "reasonable inferences in favor of the nonmoving party." Braden, 588 F.3d at 598. In this case, Plaintiff alleges Defendant made a variety of express warranties at the time of its transaction with the hospital

and included an express warranty on the container of the product; and, it is reasonable to infer that, just as J.M.K.'s parents would not have fed their baby a product unless assured it was healthy and safe, the hospital, a sophisticated organization, would not have accepted the PIF and given it to their customers had they not also been so assured. Further, requiring Plaintiff to allege Defendant's express warranties served as part of the basis of the bargain with the hospital, would require Plaintiff to allege something they could not possibly know: the state of mind of hospital personnel. As previously noted, a court must take into account a plaintiff's "limited access to crucial information." Id. at 598. Overall, the inference that the hospital entered into its transaction with Defendant based on Defendant's affirmations of fact, promises, and descriptions related to its products' safety and ability to nourish infants is more than reasonable, it is obvious. To dismiss Plaintiff's claim for a failure to allege something which they could not know for sure, but is obvious, would fly in the face of Rule 8(e)'s command that courts construe pleadings "so as to do justice." Fed. R. Civ. P. 8(e).

Therefore, Defendant's motion to dismiss Plaintiff's express warranty claim is denied.

3. Implied Warranty of Fitness for a Particular Purpose

The implied warranty of fitness for a particular purpose only applies . . .

> [w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods . . . .

Iowa Code § 554.2315.

"A 'particular purpose' differs from the ordinary purpose for which . . . goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business. Iowa Code § 554.2315, cmt. 2. In this case, Plaintiff admits the goods were used for their "ordinary" or customary purpose, i.e., feeding babies; and, therefore, Plaintiff has no claim based in the implied warranty of fitness for a particular purpose.

Plaintiff's inclusion of this claim in their Second Amended Complaint appears to be an oversight; in fact, Plaintiff earlier conceded "that this claim should be dismissed." Docket 38, 18 fn. 10. **Therefore, Defendant's**

motion to dismiss Plaintiff's implied warranty of fitness for a particular purpose claim is granted.

4. Implied Warranty of Merchantability

A warranty that products are merchantable "is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Iowa Code § 554.2314(1). Defendant is clearly a merchant of PIF.

Iowa Code § 554.2314(2) outlines several standards that goods must meet to be merchantable; three of those standards apply here: (1) the goods must "pass without objection in the trade under the contract description;" (2) the goods must be "fit for the ordinary purposes for which such goods are used;" and (3) the goods must "conform to the promises or affirmations of fact made on the container or label."

Defendant's sole argument for dismissal is that "Plaintiff's breach of implied warranty of merchantability claim . . . fails because [P]laintiff has not alleged a product defect." Docket No. 47-1, 20. As previously discussed in detail, Plaintiff has sufficiently alleged a product defect, i.e., Defendant's product contained *E. sakazakii* meningitis. **Therefore, Defendant's motion to**

dismiss Plaintiff's implied warranty of merchantability is denied.

F. Fraud

Rule 9(b) of the Federal Rules of Civil Procedure provides that, "[i]n alleging fraud . . . a party must state with particularity the circumstances constituting fraud." The elements of fraud in the State of Iowa are:

> (1) defendant made a representation to plaintiff, (2) the representation was false, (3) the representation was material, (4) the defendant knew the representation was false, (5) the defendant intended to deceive the plaintiff, (6) the plaintiff acted in reliance on the truth of the representation and was justified in relying on the representation, (7) the representation was a proximate cause of plaintiff's damages, and (8) the amount of damages.

Holiday v. Rain and Hail L.L.C., 690 N.W.2d 59, 64 (Iowa 2004)(quoting Gibson v. ITT Hartford Ins. Co., 621 N.W. 2d 388, 400 (Iowa 2001).

In Wright v. Brooke Group Limited, the Iowa Supreme Court explained fraud in the context of product liability cases. The Court ruled,

> a manufacturer who makes statements for the purpose of influencing the purchasing decisions of consumers has a duty to disclose sufficient information so as to prevent statements made from being misleading, as well as a duty to reveal subsequently acquired information that

> prevents a prior statement, true when made, from being misleading.

652 N.W.2d 159, 176 (Iowa 2002).

Thus, under the decision in Wright, fraud, in the product liability context, lies not just in a false representation meant to induce customers to purchase a product that a manufacturer knows to be false, but also in a misleading representation for which a manufacturer has or develops the requisite knowledge to correct. In addition, the representation must be material; it must have actually and justifiably induced the customer to purchase the product; and the product must have ultimately been the direct cause of Plaintiff's damages.

Defendant first argues "Plaintiff does not (and cannot) allege that [Defendant] made any misrepresentation of fact to JMK or her parents." Docket No. 47-1, 21. In support of its argument, Defendant notes the sole representation allegedly made to J.M.K.'s parents was that contained on the label of the powdered infant formula, indicating it was suitable "for use by infants from 0-12 months and that **it is not sterile**." Id. First, Defendant's representation that its PIF is suitable for 0-12 month infants is, when read in the context of Plaintiff's other allegations relating to the dangers of *E.*

sakazakii in PIF, sufficient to raise a reasonable inference that Defendant made a false or misleading, material representation to the Plaintiff. Second, Plaintiff also alleges the post injury advertisements were similar to those made at the time J.M.K.'s parents fed the Defendant's PIF to J.M.K.. Docket No. 46, 21. That J.M.K.'s parents, like the parents of other newborns, were careful to become familiar with the products they fed their newborn, is a reasonable inference. Finally, as previously discussed, a warning that something is not sterile does not equate with a warning that it may contain potentially life threatening bacteria, especially in the context of baby food.

Defendant also argues Plaintiff fails to allege facts indicating Defendant had knowledge of its false or misleading claims. Docket No. 47-1, 21. Again, Defendant ignores the plain letter of Plaintiff's Complaint. As previously noted, Plaintiff specifically alleges "[D]efendant failed to disclose . . . matters known to it that it knew to be necessary to prevent its statements of fact made to consumers from being misleading." Docket No. 46, 22. Plaintiff also alleges, "[o]n information and belief, between March 29, 2002, and September 19, 2006, environmental sampling from [Defendant's]

PIF facility . . . tested positive for *Enterobacteriaceae* . . . ." Id. at 6. Plaintiff also alleges, again, "[o]n information and belief, between March 29, 2002, and September 19, 2006, finished product sampling from [Defendant's] PIF finished product prior to consumer distribution tested positive." Id. Plaintiff, also alleges, "on information and belief," Defendant "has testing procedures in place (although inadequate) to test for the presence of *Enterobacter sakazakii* and discards batches of PIF found to contain the bacteria." Id. at 7. All of these allegations make it perfectly clear that Defendant was not only aware that its PIF was prone to the alleged contamination with *E. sakazakii* but that such alleged contamination was potentially harmful. Finally, Plaintiff alleges, "prior to October 2004," Defendant "knew that its PIF [was] not reasonably safe and that it should not be fed to . . . neonates . . . ." Id. at 6.

Defendant also argues Plaintiff failed to allege J.M.K.'s parents relied on its false representations. Again, this argument simply ignores what Plaintiff actually alleges. Plaintiff alleges the PIF was given to J.M.K. in "justifiable reliance upon statements of fact made by [Defendant] to consumers of its product." Id. at 21. This allegation is

highly plausible. Most newborn parents are acutely aware of the products, especially the food products, they give their newborns. It is unlikely J.M.K.'s parents were unaware of Defendant's representations in relation to its PIF, or that J.M.K.'s parents would have fed their newborn Defendant's PIF without first being assured that it was safe and healthy.

Finally, Defendant argues Plaintiff failed to meet the particularity requirements under Federal Rules of Civil Procedure 9(b). In order to meet the particularity requirements a . . .

> complaint must allege 'such matters as the time, place and contents of false representations, as well as the identity of the person making the misrepresentation' . . . In other words, the complaint must plead the 'who, what, where, when, and how' of the alleged fraud.

Drobnak v. Andersen Corp., 561 F.3d 778, 783 (8th Cir. 2009). (quoting Schaller Tel. Co. v. Golden Sky Sys., Inc., 298 F.3d 736, 746 (8th Cir. 2002); and United States ex rel. Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 556 (8th Cir. 2006)).

In relation to the "who" component of the particularity requirement, Defendant contends "Plaintiff makes no effort to identify the source of the alleged representation, and refers only generally to [Defendant]." This Court does not understand Defendant's argument. Defendant is the "who" alleged, and Plaintiff is required to plead no more. The

specific individual who ultimately made each decision, assuming decisions were not made in committee, need not be pled. It would make no sense and would be overly burdensome to require a plaintiff, when alleging corporate fraud in relation to a product liability claim, to state that "Bob from advertising, on behalf of Corporation X, decided to include representation Y in advertisement Z," or "Bill from packaging, on behalf of Corporation X, decided to include representation Y on package Z."

In relation to the "what" component of the particularity requirement, Defendant argues "Plaintiff has not identified the contents of the allegedly false statement[s] . . . ." Again, Defendant's assessment of Plaintiff's complaint is inaccurate. Plaintiff specifically alleges the Similac PIF label stated it was safe for infants aged "0-12 months." Docket No. 46, 21. This, by itself, meets the particularity requirement. The Plaintiff also provides seven different examples of representations Defendant has made since the injury to J.M.K. and states that "similar representations and statements" were made prior to J.M.K. being fed Defendant's PIF. When a fraud claim hinges upon false representations in advertising, this Court is of the opinion, and is unaware of

any binding precedent to the contrary, that examples of advertisements made soon after an injury are sufficient to meet the particularity requirement. To require otherwise would be unreasonable. Though representations in advertisements clearly influence consumer decisions, people are not apt to memorize or save examples of them until after they become aware those representations were false or misleading and they were injured in relation thereto. In the unlikely event Defendant only made the representations Plaintiff alleges after J.M.K.'s injuries were sustained, summary judgment will be available.

Defendant also argues Plaintiff "fails to allege when and where the allegedly false" representations were made. Docket No. 30-1, 21. Again, Defendant ignores Plaintiff's Complaint. Plaintiff clearly alleges that "at St. Luke's Regional Medical Center of Sioux City, County of Woodbury, State of Iowa . . . on April 17, 2008, J.M.K.'s mother was given an unsolicited gift bag containing Similac PIF," and the label on the Similac PIF "contained a statement that the product was suitable for infants '0-12 months' of age." Docket No. 46, 2-3. It simply cannot get any more particular than that. Furthermore, for the same reasons pleading representations in advertisements

made after an injury meets the what particularity requirement, this Court is of the opinion that Plaintiff's precise allegations as to the time and places of post injury advertisements, and its allegation that Defendant "made similar representations and statements in 2008 at the time the PIF was distributed to J.M.K.," are sufficient to meet the particularity requirements of when and where in a product's liability fraud claim based on false or misleading advertisements.

Defendant also argues Plaintiff "makes no effort to allege how" the false representations were made. Docket No. 30-1. Defendant's contention is false. Plaintiff clearly alleges the false representations were made through the internet, press releases, print ads, and on the label of the product itself. Docket No. 46, 20-22.

In conclusion, Plaintiff's allegations are sufficient to sustain its fraud claim, and Defendant's motion to dismiss is denied.

G. Punitive Damages

Defendant argues Plaintiff fails to allege facts sufficient to support punitive damages. Docket No. 47-1. As this Court noted at the last hearing, punitive damages are not

a cause of action, and as such, so long as there are surviving claims, they are not subject to a motion to dismiss. Only after a plaintiff has proven their case are punitive damages considered.

IV. SUMMARY

Defendant's motion to dismiss is denied in part and granted in part. In relation to Plaintiff's manufacturing defect, design defect, inadequate warning, breach of express warranty, breach of implied warranty of merchantability, and fraud claims, Defendant's motion to dismiss is denied. In relation to Plaintiff's implied warranty of fitness for a particular purpose claim, Defendant's motion is granted.

Though Plaintiff has alleged facts sufficient for six of its seven causes of action to survive Defendant's motion to dismiss, this Court again urges Plaintiff to consider paring down its causes of action. Based on thirty-three years on the bench, this Court has grave doubts about the wisdom and overall efficiency of presenting six causes of action at trial.

IT IS SO ORDERED this 1st day of February, 2012.

Donald E. O'Brien, Senior Judge
United States District Court
Northern District of Iowa