Filing # 244520509 E-Filed 03/24/2026 07:07:17 PM

IN THE CIRCUIT COURT OF THE 17TH JUDICIAL CIRCUIT
IN AND FOR BROWARD COUNTY, FLORIDA

CASE NO. **CACE23020810** DIVISION: **26** JUDGE: **Phillips, Carol-Lisa (26)**

TIANA ENNIX

Plaintiff(s) / Petitioner(s)

v.

ABBOTT LABORATORIES, et al

Defendant(s) / Respondent(s)

_____/

FINAL ORDER ON DEFENDANT ABBOTT LABORATORIES' MOTION FOR SUMMARY JUDGMENT

THIS CAUSE came before the Court on March 2, 2026 upon Defendant Abbott Laboratories' Motion for Summary Judgment (the "Motion"). The Court having reviewed the Motion, Plaintiff Tiana Ennix's Response in Opposition and Defendant's Reply, the record, applicable case law and having heard argument of counsel, and being duly advised in the premises, hereby finds as follows:

Factual Background

On July 7, 2019, Plaintiff gave birth to her daughter Iyiana Joy McLeod at an estimated 28 weeks 2 days gestational age, and weighed 2 pounds 11 ounces. *See* Plaintiff's Response and Statement of Additional Facts at ¶6. Iyiana was initially fed a combination of her mother's breast milk, donor breast milk, and eventually a human milk fortifier, during which time she was "tolerating full feeds" and "gaining weight." *Id.* at ¶120. On July 31, 2019, Iyiana, then at an estimated 31 weeks 5 days gestational age, began being transitioned from donor breast milk to formula—specifically Defendant's Similac Special Care cow's milk-based infant formula. *Id.* at ¶¶19 and 122. After a few days, Iyiana was being fed exclusively Defendant's formula. *Id.* at ¶20. Less than one week after the formula was initiated, the NICU staff noted "probable" NEC based on the "acute onset of emesis, lethargy, and tachycardia" as well as "bloody stools" and ceased Iyiana's preterm formula feeds. *Id.* at ¶122. The

NICU staff alerted Plaintiff of "NEC concerns" and Iyiana's "status [became] critical." *Id.* at ¶123. On August 6, 2019, Iyiana was taken to surgery where 20 centimeters of her necrotic bowel were removed. *Id.* at ¶23. Afterwards, Plaintiff was "advised… of the very poor prognosis", and that Iyiana's "condition kept declining." *Id.* at ¶124. Shortly thereafter, Iyiana "became bradycardic" and was pronounced dead at 7:03 p.m. on August 6, 2019. *Id.* at ¶125.

Legal Standard

Florida Rule of Civil Procedure 1.510(a), provides, in pertinent part: that "[a] party may move for summary judgment, identifying each claim or defense--or the part of each claim or defense--on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." "The summary judgment standard provided for in this rule shall be construed and applied in accordance with the federal summary judgment standard." *Id.*

Analysis

Defendant moves for summary judgment on count-II strict liability for design defect, count-III strict liability for failure to warn, count-IV negligence, count-V intentional misrepresentation, count-VI negligent misrepresentation, and count-VII constructive fraud. Defendant argues Plaintiff's failure to warn claim fails because an inadequate warning cannot be the proximate cause of Iyiana's injuries. Next, Defendant argues Plaintiff's design defect claim fails because its preterm formula is an important product whose utility far outweighs any risks, and thus, Plaintiff cannot overcome the risk utility test. Defendant further argues that even if the consumer-expectations test applies, the expectations of the product is that of the medical professionals, and not the consumer. Third, Defendant argues that Plaintiff's negligence claim fails because it relies on the same failure to warn and design defect theories that are themselves deficient. Finally, Defendant contends that Plaintiff's misrepresentation and constructive fraud claims also fail, as they are merely repackaged failure to warn claims. Defendant further contends that Plaintiff cannot identify any false statement made by Defendant or show that she or her doctors relied on any such statement. The Court will address these arguments in turn below.

• Count III- Strict Liability Failure to Warn

Defendant argues Plaintiff cannot overcome the causation element for her failure to warn claim. Specifically, Defendant maintains that Plaintiff was warned of the risks associated with feeding formula to pre-term infants, and ignoring the warning defeats her claim. Furthermore, the treating physicians' testimony that they were aware formula feeding increases the risk of NEC in preterm infants and would have used the formula regardless defeats the causation element.

In order to establish a failure to warn claim, Plaintiff must "prove that the warning label was inadequate, that the inadequacy of the warning proximately caused his injury, and that he suffered an injury." *Hoffmann-La Roche, Inc. v. Mason*, 27 So. 3d 75, 77 (Fla. 1st DCA 2009). In the instant matter, Defendant's summary judgment focuses on the causation element. In order to establish causation, Plaintiff must show that Defendant's alleged failure to warn was more likely than not a substantial cause of Iyiana's injury. *See Van Deese v. McKinnonville Hunting Club, Inc.*, 874 So. 2d 1282, 1287 (Fla. 1st DCA 2004) (quoting *Stahl v. Metro. Dade County*, 438 So. 2d 14, 17 (Fla. 3d DCA 1983)) ("'to constitute proximate cause there must be such a natural, direct, and continuous sequence between the negligence [sic] act [or omission] and the [plaintiff's] injury that it can reasonably be said that *but for* the [negligent] act [or omission] the injury would not have occurred.'"). Additionally, Defendant maintains that because Plaintiff relied on her doctors to make decisions about how to feed her daughter the learned intermediary doctrine applies. Therefore, Plaintiff must show that Defendant failed to adequately warn the doctors about the NEC risks linked to its formula, which she cannot do.

Florida adheres to the learned intermediary doctrine, which holds that a drug manufacturer's duty to warn is directed to the prescribing physician rather than the patient. *Hoffmann-La Roche, Inc.*, 27 So. 3d at 77. The physician acts as a "learned intermediary" between the manufacturer and the patient, as the physician is in the best position to evaluate the risks and benefits of a drug for a particular patient. *Id.* (citing *Buckner v. Allergan Pharm., Inc.*, 400 So. 2d 820, 822 (Fla. 5th DCA 1981)). If the manufacturer provides an adequate warning to the physician, it is generally presumed that the physician

will use this information to make an informed decision in the patient's best interest. *Id*. Traditionally, the doctrine is limited to prescription products because they require a physician's involvement in their use, and the physician is expected to exercise independent judgment in advising the patient. *Id*. Thus, based on this reasoning, the Court concludes that the learned intermediary doctrine may apply depending on the manner in which the product was obtained and used. In the instant matter, although Plaintiff, as Iyiana's mother, had the ultimate say in how to feed her daughter, she relied on the advice of her doctors on how to feed her, which included Defendant's formula. *See* Defendant's Statement of Material Facts at ¶26. (Plaintiff "relied on Iyiana's physicians to" make decisions about "how to feed her".). Therefore, since Plaintiff relied on her doctor's medical expertise on how to feed her daughter, Plaintiff's doctors acted as a learned intermediary between Defendant and Plaintiff, and the learned intermediary doctrine applies.

Next, when applying the learned intermediary doctrine the Court must look to whether Plaintiff's doctors were adequately warned of the risks of NEC associated with Defendant's formula. Pursuant to the record evidence, all of Iyiana's treating physicians testified that they were aware of the significant risks associated with formula feeding in preterm infants, including the risk of NEC. For example, Dr. Mitchell Stern one of Iyiana's neonatologists testified that he knew about the "association of formula use and NEC" and still wouldn't have "changed how [she] was fed if warned of an "increased risk of NEC." *See* Defendant's SOF ¶¶39-41. Another one of Iyiana's neonatologists, Dr. Laura Aviles-Medina testified that she knew the research showing "human milk is associated with a significant reduction" in NEC compared to formula, and yet would not have "changed anything" if warned of a "higher risk of NEC." *Id*. at ¶¶31-33; 36. The last neonatologist, Dr. Marc Bedrin also testified that he knew human milk provides "significant reduction in the incidence of NEC compared to formula" and could not "think of anything [he] would have changed" with his "feeding decisions." *Id*. at ¶¶42-43; 46.

Ultimately, based on the uncontroverted record evidence that Plaintiff's doctors testified that they knew of the risks associated with Defendant's formula causing NEC, and despite having a different

warning, would have still have fed her the formula, there cannot be an inadequacy in the warning to establish proximate causation. *See Hoffmann-La Roche, Inc.*, 27 So. 3d at. 77. (The First District Court of Appeal found that the physician's independent understanding of the risks and decision to prescribe the drug despite those risks precluded a finding of proximate causation, even if the warning label was arguably inadequate, stating: "Thus, any inadequacies in Accutane's warning label could not have been the proximate cause of Appellee's injury because Dr. Fisher *understood* that there was a possibility that use of the drug could lead to Appellee developing IBD and he made an *informed decision* to prescribe the drug for Appellee *despite this risk*.") (emphasis added). As a result, and for the reasons stated, Defendant's Motion is **granted** as to count-III strict liability failure to warn.

• Count II- Strict Liability Design Defect

Defendant argues Plaintiff's design defect claim fails under the risk-utility test. Defendant argues the risk-utility test applies opposed to the consumer-expectations test because the Similac Special Care formula that was fed to Iyiana is sold to hospitals for medical professionals to administer, and therefore considered a "complex medical product". Under this test, Defendant argues Plaintiff offers no evidence of its abilities to eliminate or minimize the danger without impairing the product or making it too expensive, nor does Plaintiff provide an alternative design. Last, Defendant argues even if this Court were to apply the consumer-expectations test, the relevant expectations apply to those of the healthcare providers, not Plaintiff, and her doctors' expectations were that the formula was safe.

In opposition, Plaintiff contends that the consumer-expectations test governs because Defendant's formula is not a complex medical product warranting application of the risk-utility test. Plaintiff argues the fact that the formula was administered in the hospital does not automatically render it "complex". Plaintiff further argues because Defendant's formula is not classified as a medical or prescription product, her own expectations control and the record evidence demonstrates that she did not anticipate the risk of NEC.

"Under Florida law, a strict products liability action based upon design defect requires the plaintiff to prove that (1) a product (2) produced by a manufacturer (3) was defective or created an

unreasonably dangerous condition (4) that proximately caused (5) injury." *R.J. Reynolds Tobacco Co. v. Nelson*, 353 So. 3d 87, 89 (Fla. 1st DCA 2022) (citing *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1257 (11th Cir. 2002)). Florida recognizes two primary tests to determine whether a product is defective in design: the consumer-expectations test and the risk-utility test. *See Aubin v. Union Carbide Corp.*, 177 So. 3d 489, 504 (Fla. 2015). The consumer-expectations test is set forth in the Second Restatement of Torts, whereas, the alternative risk-utility test is set forth in the Third Restatement of Torts. *Id.* at 505. In *Force v. Ford Motor Co.*, 879 So. 2d 103 (Fla. 5th DCA 2004), the Fifth District Court of Appeal addressed how some products may be too complex for the consumer-expectations test, and ultimately, the use of the risk-utility test is more appropriate under those circumstances. *See Id.* at 110. ("We conclude that there may indeed be products that are too complex for a logical application of the consumer-expectation standard."). Furthermore, trial courts have discretion to determine whether a product is "complex" and to select the appropriate test based on the specific facts of the case. *See Id.* ("We leave the definition of those products to be sorted out by trial courts."). For instance, in cases involving complex products or where consumer-expectations are not easily ascertainable, courts may lean toward the risk-utility test. *See* e.g., *Cavanaugh v. Stryker Corp.*, 308 So. 3d 149 (Fla. 4th DCA 2020) ("The Fourth District Court of Appeal held that the consumer-expectation test could not be logically applied to a complex medical device that is available to an ordinary consumer only as an incident to a medical procedure."). Conversely, for products with well-understood functions and safety expectations, the consumer-expectations test may be more suitable. *See* e.g., *Aubin*, 177 So. 3d 489. (The Supreme Court of Florida determined asbestos was not a complex product and applied the consumer-expectations test.).

After review, the Court finds that Defendant's Similac Special Care formula is not a complex product where the risk-utility test applies. Formula is a well-understood product, in which the safety expectations of a consumer can be logically applied. *See Id.* Therefore, the Court will apply the consumer-expectations test. Under "[t]he 'consumer expectations' test… a product is unreasonably dangerous in design because it failed to perform as safely as an ordinary consumer would expect when

used as intended or in a reasonably foreseeable manner." *Id.* at 503. Although the consumer-expectations test focuses on the expectations of the ordinary consumer and whether the product's performance deviates from those expectations, the facts of this case warrant focusing on the expectations of the medical professional, not the ordinary consumer. *See* *Cavanaugh*, 308 So. 3d at 156. ("Even assuming that some version of the consumer expectations test should apply to complex medical products which are provided to a consumer through a *learned intermediary*… the *relevant expectations are those of the health care professional*."). (emphasis added).

As explained above, Plaintiff relied on the advice of her doctors on how to feed Iyiana. Furthermore, Plaintiff's doctors testified that despite their awareness of the risks of NEC associated with formula feeding in preterm infants, their expectations about the safety of the product remained unchanged, and they still would have fed her the formula. *See* Dr. Aviles-Medina Deposition (129:23-130:3) ("We have used this type of formula years before this case. And up to today we still use this formula."). Therefore, because Plaintiff's physicians testified that they expected Defendant's formula to be safe and had no expectation that it would fail to perform as intended, a design defect cannot be established. As a result, and for the reasons stated, Defendant's Motion is **granted** at to count-II strict liability design defect.

• Count IV- Negligence

Defendant argues Plaintiff's negligence claim fails for the same reasons her failure to warn and design defect claims fail: there is no evidence to support her claim. Conversely, Plaintiff argues her negligence claim is broader than her failure to warn and design defect claims. Plaintiff argues her negligence count stands alone alleging Defendant failed to use reasonable care to "test… manufacture… and inspect formula". *See* Plaintiff's Second Amended Complaint at ¶104. Plaintiff further argues that Defendant failed to perform "the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products." *Id.* at ¶108. Last, Plaintiff argues Defendant failed to satisfy "their duties to the consuming public in general" and because of its failures Iyiana was fed its formula "which caused her to develop

NEC." *Id.* at ¶¶109-110.

Normally, "[t]o state a claim for negligence, the plaintiff must allege: (1) a duty recognized by law; (2) breach of the duty; (3) proximate causation; and (4) damages." *Saunders v. Baseball Factory*, 361 So. 3d 365, 369 (Fla. 4th DCA 2023) (citing *Clay Elec. Coop., Inc. v. Johnson*, 873 So. 2d 1182, 1185 (Fla. 2003)). Further, taking into consideration that this is a negligence claim relating to a product "plaintiff must establish that the product was defective or unreasonably dangerous.'" *Grieco v. Daiho Sangyo, Inc.*, 344 So. 3d 11, 17-18 (Fla. 4th DCA 2022) (quoting *Small v. Amgen, Inc.*, 134 F. Supp. 3d 1358, 1366 (M.D. Fla. 2015)). Moreover, "*proof of a defect* determines a breach of duty under a negligence theory." *Id.* at 18. (citing *O'Bryan v. Ford Motor Co.*, 18 F. Supp. 3d 1361, 1366 (S.D. Fla. 2014). As discussed in detail above, Defendant's formula does not contain a defect. Therefore, without proof of a defect, Plaintiff cannot establish a breach of duty under her negligence claim. As a result, and for the reasons stated, Defendant's Motion is **granted** as to count-IV negligence.

- Count V- Intentional Misrepresentation, Count VI- Negligent Misrepresentation and Count VII- Constructive Fraud

Defendant argues that Plaintiff's claims for intentional misrepresentation, negligent misrepresentation, and constructive fraud are merely repackaged failure-to-warn claims and, because the underlying claim fails, these claims fail as well. Defendant further contends that each of these claims requires a false statement, which Plaintiff has not identified. Accordingly, summary judgment is warranted.

After review, the Court first addresses Defendant's arguments regarding the misrepresentations claims. Defendant argues Plaintiff's claims for intentional misrepresentation, and negligent misrepresentation are merely repackaged failure to warn claims. In response, Plaintiff argues Defendant failed to inform Plaintiff and the hospital of the risk of NEC with its formula. Plaintiff also argues that Defendant intentionally and negligently made false statements that its formula was safe. *See* Plaintiff's SAC at ¶¶112 and 122; *see also*, Plaintiff's SOF at ¶127. Accordingly, fraudulent and negligent misrepresentation involve *affirmative misstatements*, while failure to warn involves

omissions or inadequate disclosures. *See Dziegielewski v. Scalero*, 352 So. 3d 931, 934 (Fla. 5th DCA 2022) (The elements of fraudulent misrepresentation and negligent misrepresentation both include the Defendant *making* a false statement.); *compare*, *Van Deese*, 874 So. 2d at 1287. (Failure to warn involves a negligent act or omission of a *required statement*.). (emphasis added). In the instant matter, Plaintiff has made a distinction between these causes of action by alleging Defendant *made* intentional and negligent false statements that its pre-term formula is safe by omitting from its label, packaging, or public communications the material fact that its formula substantially increases the risk of NEC. Therefore, this Court finds that Plaintiff's intentional misrepresentation and negligent misrepresentation claims are not repackaged failure to warn claims.

Next, Defendant argues that Plaintiff's misrepresentation claims fail because she does not identify any false statement it made about the formula or demonstrate reliance on such a statement. "There are four elements of… fraudulent misrepresentation [intentional misrepresentation]: '(1) a *false statement concerning a material fact*; (2) the representor's knowledge that the representation is false; (3) an intention that the representation induced another to act on it; and (4) consequent injury by the party acting in *reliance* on the representation.'" *Dziegielewski*, 352 So. 3d at 934. (quoting *Butler v. Yusem*, 44 So. 3d 102, 105 (Fla. 2010)). (emphasis added). "The elements of a negligent misrepresentation claim are *somewhat* different… (1) the defendant made a *misrepresentation of material fact* that he believed to be true but which was in fact false; (2) the defendant was negligent in making the statement because he should have known the representation was false; (3) the defendant intended to induce the plaintiff to rely on the misrepresentation; and (4) injury resulted to the plaintiff acting in justifiable *reliance* upon the misrepresentation." *Id*. (emphasis added).

Pursuant to these elements, both causes of action share two key requirements: a false statement by Defendant and Plaintiff's reliance on that statement. Defendant maintains that Plaintiff has failed to identify any false statement made about its formula, and this Court agrees. Although Plaintiff contends that Defendant misrepresented the formula's safety, she has not presented record evidence demonstrating that any statements in the labeling, marketing, or related materials were actually false.

For example, Plaintiff's marketing expert, Jennifer Pomeranz, identifies statements that Defendant's made about its formula, such as, "[c]loser than ever to breast milk" and "our closest formula to breast milk", but fails to identify how these statements are in fact *false*. Mrs. Pomeranz further attempts to argue that it created a marketing environment that *suggests* "infant formula is not only safe and appropriate for infants, but better than breastmilk", but in actuality Defendant did not make such statements. Without identifying a false statement or misstatement Defendant made about its formula, Plaintiff fails to establish an essential element of both intentional misrepresentation and negligent misrepresentation.

Moreover, even if the Court were to find that Defendant made false statements regarding its formula, Plaintiff has not produced record evidence showing that her physicians relied on any such statements. As explained above, Plaintiff relied on the advice of her doctors on how to feed Iyiana. Furthermore, Plaintiff's doctors all testified that Defendant had no say in their decisions on how to feed Iyiana, and instead relied on their training and expertise. *See* Defendant's SOF ¶¶35, 45, and 47-48. Ultimately, Plaintiff fails to put forth record evidence of Defendant's false statement about its formula, and her doctor's reliance on the false statement. As a result, and for the reasons stated, Defendant's Motion is **granted** as to count-V intentional misrepresentation and count-VI negligent misrepresentation.

Last, a constructive fraud claim *may* involve a false statement or omission, but it is more primarily concerned with the breach of a fiduciary or confidential relationship to take advantage of another party. *See Levy v. Levy*, 862 So. 2d 48, 53 (Fla. 3d DCA 2003) (citing *Beers v. Beers*, 724 So. 2d 109 (Fla. 5th DCA 1998)) ("Constructive fraud occurs when a duty under a confidential or fiduciary relationship has been abused or where an unconscionable advantage has been taken. Constructive fraud may be based on a misrepresentation or concealment, or the fraud may consist of taking an improper advantage of the fiduciary relationship at the expense of the confiding party."). Here, Plaintiff's arguments for constructive fraud remain similar to those of its intentional misrepresentation and negligent misrepresentation claims: that Defendant breached its duty to the public by making false

statements about the safety of its formula. *See* Plaintiff's SAC at ¶¶ 130-132, and 135. Again, the Court does not find that this cause of action is a repackaged failure-to-warn claim. However, because Plaintiff's constructive fraud claim is premised on alleged false statements by Defendant and the Court has already found that Plaintiff has not produced record evidence identifying any such false statement, this claim likewise fails. As a result, and for the reasons stated, Defendant's Motion is **granted** as to count-VII constructive fraud.

Thus, after careful consideration and for the reasons stated both above and on the record, the Court finds that no genuine disputes of material fact remain and Defendant is entitled to judgment as a matter of law.

Accordingly, it is hereby:

ORDERED and ADJUDGED:

1. Defendant Abbott Laboratories' Motion for Summary Judgment filed on September 9, 2025 is hereby **GRANTED**.
2. It is further ordered that Defendant Abbott Laboratories separate *Daubert* motions to exclude the testimony of Dr. Sevini Hallaian and Jennifer Pomeranz are stricken without prejudice as **moot**.
3. Final Judgment is hereby entered in favor of Defendant Abbott Laboratories. The Plaintiff Tiana Ennix shall take nothing by this action, and the Defendant Abbott Laboratories shall go hence without day.
4. Jurisdiction over this matter is retained to address appropriate motions such as an award for attorney's fees and costs, and any other matters the Court deems appropriate.

DONE AND ORDERED in Chambers at Broward County, Florida on 24th day of March, 2026.

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Hon. Carol-Lisa Phillips
CIRCUIT COURT JUDGE
Electronically Signed by Carol-Lisa Phillips

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