UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ABBOTT LABORATORIES, ET AL., PRETERM INFANT NUTRITION PRODUCTS LIABILITY LITIGATION	**MDL NO. 3026** **Master Docket No. 22 C 00071**
This Document Relates to: ***Mar v. Abbott Laboratories*** **Case No. 22 C 00232**	**Hon. Rebecca R. Pallmeyer**

MEMORANDUM OPINION AND ORDER

Plaintiff Ericka Mar's infant daughter, RaiLee, was 12 weeks premature at her birth in January 2014. RaiLee never left the hospital; she died several days after birth, very soon after ingesting infant formula manufactured by Abbott Laboratories ("Abbott") for preterm infants. Ms. Mar contends Abbott's cow's-milk-based formula caused RaiLee to develop necrotizing enterocolitis ("NEC")—a devastating disease affecting preterm infants. In this lawsuit, she seeks to hold Abbott liable for her tragic loss and alleges design defect and failure to warn claims under West Virginia law.

Ms. Mar's action is one of hundreds of similar actions brought against Abbott and its competitor, Mead Johnson, consolidated before this court as MDL No. 3026. By agreement of the parties, her action was chosen as the first of four "bellwether" cases to proceed to trial before this court, with the hope of "provid[ing] significant information regarding the entire pool of cases that are part of the MDL." *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proc.*, No. 14 C 1748, 2017 WL 2574057, at *1 (N.D. Ill. May 22, 2017). As explained here, however, the record does not support the state law claims Ms. Mar has filed in this case. Plaintiff has not been able to present evidence of a feasible alternative design to Abbott's cow's-milk formula, nor has she been able to demonstrate that Abbott's alleged failure to warn was the cause-in-fact of RaiLee's NEC. For these reasons, the court grants Abbott's motion [48] for summary judgment.

BACKGROUND

I. Factual Background

The court relies on the parties' respective Local Rule 56.1 submissions[1] in providing the background to Plaintiff's claims against Abbott. The court also assumes familiarity with its prior rulings in this case and the multi-district litigation ("MDL") proceeding, particularly its order denying Abbott's motion to exclude experts Dr. Spector and Dr. Sucre also issued today in the main docket. *See* General Causation Order [646] in No. 22 C 71.)

A. RaiLee's Birth and Initial Treatment

Plaintiff's daughter RaiLee was born on January 1, 2014, via emergency C-section in Summersville Regional Medical Center in Summersville, West Virginia. (DSOF ¶ 34-35.) She was 12 weeks early and weighed approximately three pounds—"very preterm" and "very low birthweight." (*Id*.) After being placed on oxygen in the delivery room, RaiLee was airlifted from Summersville Regional Medical Center to the NICU at Charleston Area Medical Center ("CAMC") in Charleston, West Virginia. (*Id*.) While the parties dispute the severity of her health complications immediately following her birth, it is undisputed that RaiLee experienced hypothermia, hyperoxia, and anemia, and presented symptoms of a heart defect called patent ductus arteriosus and sepsis in the days following her birth. (*See id*. ¶ 36; Resp. to DSOF ¶ 36.)

B. RaiLee's Feeding and NEC

For the first four days of her life, RaiLee was fed her mother's milk intravenously. Then on January 5, she began enteral feeding. (*Id*. ¶ 38.) "Enteral feeding" refers to a method of feeding preterm infants that feeds milk through a tube to their stomach. (*Id*. ¶ 39.) Beginning on January 5, RaiLee was provided 72 enteral feedings (across nine days) of 100% milk produced by her mother. (*Id*.) On January 13, however, Plaintiff stopped pumping as she was not producing

[1] (*See* Abbott Local Rule 56.1(a)(2) Statement of Undisputed Material Facts [50] (hereinafter "DSOF"); Pl.'s Resp. to DSOF [52] (hereinafter "Resp. to DSOF").)

adequate amounts of milk, despite her efforts, and the amount she was producing was tainted with blood. (*Id*. at 40.)

At this point, there was no donor milk available to supplement Plaintiff's production, nor was human-milk fortifier (Prolacta)[2] available at the hospital. (*Id*. ¶ 46.) Plaintiff states in her deposition that a friend, Christina Stanley, who had also recently given birth, was overproducing milk and offered to donate some to feed RaiLee. (Mar Dep. Tr. [52-30] at 39:10–41:13.) But a nurse in the NICU (whom Plaintiff does not identify) informed Plaintiff and her friend that "we [CAMC staff] don't do that." (*Id*.)[3] Instead, RaiLee's treating physician, Dr. Stefan Maxwell, changed her diet to a "mixed-feeding" of 50% mother's own milk and 50% Similac Special Care 24 ("SSC24")—a cow's-milk-based formula produced by Abbott. (DSOF ¶ 41.) SSC24 was packaged with a warning that read "USE AS DIRECTED BY A DOCTOR." (*Id*. ¶ 42.) It is undisputed that Dr. Maxwell's administration of formula to RaiLee was in accordance with CAMC's feeding instructions[4] at the time. (*Id*. ¶ 47.)

RaiLee was given three mixed feedings between January 13 and January 14. (*Id*. ¶ 41.) On January 14, just hours after her first ingestion of formula, RaiLee was diagnosed with surgical NEC; she passed away the following day. (*Id*. ¶¶ 49–50.)

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[2] Despite its importance to this case, the parties provided little information about Prolacta and how it is manufactured. As the court has explained in its General Causation Order, Prolacta refers to human-milk-derived infant feeding products manufactured by Prolacta Biosciences. (*See* General Causation Order at 7 n. 12.) The court discusses Prolacta in more depth *infra* pp. 8–9.

[3] As explained in later depositions, CAMC policies prohibit informal donations of unpasteurized milk to prevent the transmission of any diseases from the donor to the child. (Maxwell Dep. Tr. [52-2] at 71:7–72:5; Sheridan Dep. Tr. [596-39 in No. 22 C 71] 58:11–19 (explaining reason for policy).)

[4] Abbott attaches to its motion a worksheet that Dr. Maxwell filled out and signed recording how much (in ml/kg/day) RaiLee was fed during her ten days of life. (*See* Abbott's Ex. 45, Feeding Schedule [50-45] at 2.) For each entry, the sheet includes a "recommended" feeding order for "Neonates with Weight 1001-1500 Grams." (*See id*.) Dr. Maxwell's entries show that he ordered feedings roughly consistent with the recommended schedule, and both parties agree this was proper.

II. Procedural History

Plaintiff filed her complaint [1] against Abbott in the Northern District of Illinois on January 14, 2022. (*See* Compl. at 1.) Her complaint alleged three counts: a strict liability design defect claim asserting that Abbott's formula was unreasonably dangerous for its intended use (Count I), a broad negligence claim that Abbott failed to use reasonable care in designing, manufacturing, and marketing its cow's-milk-based products (Count II), and a strict liability failure-to-warn claim that Abbott failed its duty to the public to provide adequate warnings of the dangers and risks of its formula (Count III). (*See generally id*. ¶¶ 42–74.) On April 8, 2022, her case was joined with hundreds of similar claims against Abbott and Mead Johnson before this court as MDL No. 3026. (Transfer Order [15].) On October 25, 2023, the parties selected Mar's action as one of four bellwether trials to proceed in mid-to-late 2025. (Order [416] in No. 22 C 71.) The trial is now scheduled to begin on May 12, 2025. (*See* Stip. [561] in No. 22 C 71.)

In the months leading up to her trial, Plaintiff Mar has developed significant expert testimony to support her claims. In addition to the MDL-wide general causation experts Dr. Jennifer Sucre and Dr. Logan Spector—whose reports the court discusses at length in its General Causation Order—Plaintiff has also supplied the testimony of three case-specific experts. Dr. Chandani Dezure, a practicing pediatrician and professor of pediatrics at Stanford University, performed a differential analysis of RaiLee's medical records to conclude that Abbott's SSC24 formula was a substantial factor and but-for cause of RaiLee's NEC. (*See generally* Dezure Rep. [52-32].) Dr. Darren Scheer, an epidemiologist and pharmaceutical marketing consultant, opines that Abbott's labeling and marketing of its cow's-milk-based products failed to communicate the increased risk of NEC that Abbott was aware of. (*See generally* Scheer Rep. [45-1].) Dr. Jakki J. Mohr, a professor emerita of marketing at the University of Montana, explains how Abbott targeted their marketing and promotion of preterm infant formulas to NICUs despite knowledge of an association between formula and NEC. (*See generally* Mohr Rep. [44-2].)

Abbott moved [49] for summary judgment on Plaintiff's individual claims on January 24, 2025. The matter is now fully briefed (*see* Abbott Mem. [49]; Pl.'s Opp'n [51]; Abbott Reply [53]) and the court heard oral argument on the motion at a hearing held on March 31, 2025.

LEGAL STANDARDS

"Summary judgment is appropriate if there is no genuine dispute as to any material fact, and the moving party is entitled to judgment as a matter of law." *Dunderdale v. United Airlines, Inc.*, 807 F.3d 849, 853 (7th Cir. 2015) (citing FED. R. CIV. P. 56(a)). A genuine issue of material fact exists only if "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). The court's jurisdiction over this action is based on diversity under 28 U.S.C. § 1332, and the parties agree that West Virginia law controls Plaintiff's substantive design defect and failure-to-warn claims. (*See* Abbott Mem. [49] at. 3; Pl.'s Opp'n [51] at 1.)

DISCUSSION

Abbott raises three distinct grounds for summary judgment in its motion. The first is its broadest; asserting that Plaintiff has failed to establish through her general (Dr. Sucre and Dr. Spector) and specific (Dr. Dezure) causation experts that Abbott's formula caused RaiLee to suffer from NEC. (Abbott Mem. at 6–13.) Some aspects of this argument are reiterations of what Abbott has argued in support of excluding Plaintiff's experts, which the court rejects for reasons explained in its companion ruling.[5] But the crux of Abbott's argument—that none of Plaintiff's experts can opine that a 5% formula diet causes NEC (*id*. at 11)—raises a central issue in this MDL that the parties have hotly contested: what is the right way to measure a preterm infant's exposure to formula? Abbott urges that an infant's exposure must be measured from the moment

[5] For example, Abbott argues here that Plaintiff has failed to prove causation because none of her experts testify to a threshold dose at which ingestion of cow's milk formula causes NEC. (*See* Abbott Mem. at 12–13.) This court has rejected the argument that Plaintiff's general causation experts *must* testify to threshold dose in its prior order. (*See* General Causation Order at 20–23.)

of birth to the moment they develop NEC—because RaiLee was given 72 feedings of 100% mother's milk before three feedings of 50% human milk immediately prior to developing NEC, Abbott's interpretation would result in a determination that she received a 95% human milk diet (a level of exposure that no expert has opined is toxic). Plaintiff counters that an infant's diet must be measured beginning at their first exposure to formula—because the three mixed feedings RaiLee received immediately prior to developing NEC were all 50% formula, the relevant question under Plaintiff's interpretation is whether a 50% formula diet, not 5%, can and did cause NEC in this case. (Pl.'s Opp'n at 8.) As the parties recognize, answering this question could have resounding effects across all the claims in the MDL, but the court need not answer it here. Defendants have identified reasons specific to Plaintiff's state law claims that require this court to grant summary judgment in its favor. Abbott's second ground for summary judgment is that Plaintiff's design defect claims must fail because Plaintiff has not provided evidence of a feasible alternative design to cow's-milk formula, as required under West Virginia law (Abbott Mem. at 14–16);[6] its third ground is that Plaintiff's failure-to-warn claims must fail because Abbott owed no duty to Plaintiff directly, and Plaintiff cannot establish that RaiLee's treatment at CAMC would have been any different, had Abbott given a proper warning (*id*. at 21–30). The court discusses these arguments in turn.

[6] Abbott raises other reasons that Plaintiff's design defect claims must fail as a matter of law, including arguments that Plaintiff's claim impermissibly challenges the entire category of cow's-milk-formula as defective (Abbott Mem. at 17–19) and that the testimony of medical professionals that formula is within the standard of care undermines any theory that it is unsafe for its intended use (*id*. at 19–21.) The court focuses on Abbott's feasible alternative argument, however, because it finds the most support in West Virginia case law and is sufficient to dispose of Plaintiff's design defect claims in this case.

I. Design Defect Claims

Plaintiff brings both a strict liability design defect claim and a negligent design claim,[7] both of which are available under West Virginia tort law. (*See* Pl.'s Resp to DSOF ¶ 2.) Her strict liability claim requires proof that Abbott's formula was "not reasonably safe for its intended use," determined by "what a reasonably prudent manufacturer's standard should have been at the time the product was made." *See Morningstar v. Black & Decker Mfg. Co*., 253 S.E.2d 666, 683, 162 W. Va. 857 (1979). Her negligent design claim requires proof that Abbott "fail[ed] to use the amount of care in designing the product that a reasonably careful designer would use in similar circumstances to avoid exposing others to a foreseeable risk of harm." *Ford Motor Co. v. Tyler*, 896 S.E.2d 444, 452, 249 W. Va. 471 (Ct. App. 2023) (alterations omitted) (quoting W. Va. Pattern Jury Instructions ("W. Va. P.J.I.") § 424), *overruled in part on other grounds by Shears v. Ethicon, Inc*., 902 S.E.2d 775, 250 W. Va. 226 (2024). The Supreme Court of Appeals of West Virginia (the state's highest court) has recently clarified that to meet *either* of these burdens, a plaintiff in a design defect claim must prove "an alternative, feasible design existing at the time the subject product was made would have substantially reduced the risk of the specific injury suffered by the plaintiff." *Shears v. Ethicon, Inc*., 902 S.E.2d 775, 785, 250 W. Va. 226 (2024); *see also Ford*, 896 S.E.2d at 452, 249 W. Va. 471 (applying alternative, feasible design requirement in negligence case).[8] Where a Plaintiff cannot provide evidence of a safer, alternative design in a

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[7] As noted above, Count II of Plaintiff's complaint raises a negligent design *and* a negligent failure-to-warn claim. (*See generally* Compl. ¶¶ 54–62.) There is no standalone negligence claim. (*See* Resp. to DSOF ¶ ("Count I is for strict-liability design defect. Count II is for negligent design defect and failure to warn. Count III is for strict-liability failure to warn.").) Because Abbott's argument for summary judgment on each strict liability claim applies in equal force to their negligence counterparts, the court discusses Plaintiff's negligent design claim in this section and her negligent failure-to-warn claims in the next.

[8] In *Shears*, the Supreme Court of Appeals of West Virginia considered only a strict liability design defect case and did not touch explicitly on design defect claims in negligence. The rule that a plaintiff bringing a design defect claim *in negligence* must prove that an alternative, feasible design existed comes from the Intermediary Court of Appeals' decision in *Ford.* In that pre-*Shears* case, the court held that negligent design plaintiffs must prove (in line with the Third

design defect action, judgment is appropriate as a matter of law. *Nease v. Ford Motor Co*., 848 F.3d 219, 222 (4th Cir. 2017) (applying West Virginia law) (directing judgment as a matter of law for defendant where expert testimony establishing safer alternative design was improperly admitted at trial, holding that "without any other expert testimony to establish [availability of alternative design], [plaintiffs] cannot prove their case under West Virginia law).

Abbott urges that Plaintiff has failed to present the evidence of an alternative, feasible design for its cow's milk formula that West Virginia law requires. (Abbott Mem. at 14–16.) Plaintiff responds in two ways: first, she proposes that Prolacta, a human milk-based product, was a safer, alternative design that Abbott could have manufactured instead of its cow's milk formula. (Pl.'s Opp'n at 10.) Second, that Abbott could have "ma[de] its preterm formula safer . . . by altering its components . . . or by providing an adequate warning." (*Id*.) Neither of these arguments, however, find support in the record sufficient to survive summary judgment.

A. Prolacta

Plaintiff's primary case for an alternative, feasible design for cow's-milk formula is the human-milk derived product Prolacta.[9] "Prolacta" refers to a class of human-derived feeding

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Restatement of Torts) that an alternative, feasible design would have *reduced or avoided* the plaintiff's injuries. *See Ford*, 896 S.E.2d at 452, 249 W. Va. 471. The *Shears* court rejected the "reduced or avoided" language of the Third Restatement in favor of a "substantially reduced" standard, and overruled *Ford* only insofar as it adopted the Third Restatement's language. *See Shears*, 902 S.E.2d at 785, 250 W.Va. 226 ("To the extent that the West Virginia Intermediate Court of Appeals recently adopted the Restatement's standard for design defect claims in [*Ford*] it is overruled.") After *Shears*, the court understands *Ford* to hold that a plaintiff pursuing a negligent design claim (like Plaintiff here) must prove that there was an alternative, feasible design that would have substantially reduced the harm in question. Plaintiff, for her part, does not dispute that West Virginia law requires that she supply an alternative, feasible design for both her strict liability and negligent design defect claims.

[9] Before turning to the merits of this argument, the court notes the irregular course Plaintiff has taken in pursuing this theory in her submissions. When queried through Abbott's formal interrogatories about which products she believed were safer alternative designs, Plaintiff responded that "Plaintiff has not yet determined what evidence she intends to use at trial in this matter." (*See* Pl.'s Interrog. Resps. [50-51] at 11.) Plaintiff never amended this response. Rather, she first stated her theory to pursue Prolacta as an alternative, feasible design in her response to Abbott's Rule 56.1 Statement. (*See* Resp. to DSOF ¶ 62.) Notably, Plaintiff did *not* file a Local

products produced by Prolacta Biosciences; this includes both a human-milk-derived fortifier and a "ready-to-feed" human-milk-derived formula.[10] *See* Prolacta Products, https://www.prolacta.com/en/products/ (last accessed May 2, 2025). While the record includes little information about how Prolacta is manufactured, it appears from internal Abbott documents cited by both parties that Prolacta products require donations of human milk, which Prolacta then processes into ready-to-feed preterm products. (*See* Pl.'s Ex. U, Email Chain [52-22] at 4–5.) The parties represent that Prolacta fortifier has been on the market since approximately 2006, while its infant formula product entered the market in September 2014 (Abbott Mem. at 7 (citing September 2014 Prolacta Press Release, https://www.prolacta.com/en/news/prolact-rtf-100-human-milk-based-premature-infant-formula-for-nicus/ (last accessed May 1, 2025)). There is no evidence in the record, however, as to the scale at which Prolacta was manufactured during the relevant period of Plaintiff's claims.

Plaintiff's argument that Prolacta was a safer alternative to SSC24 relies solely on the testimony of her causation experts. Plaintiff's general causation expert, Dr. Spector, conducted a meta-analysis of studies comparing NEC rates between infants fed cow's-milk products (fortifier and formula) and those fed Prolacta products and concluded that NEC was 89% more likely to occur in infants fed cow's-milk-based products. (Spector Rep. [616-23] in No. 22 C 71, at 17.)

Rule 56.1 Statement of Additional Facts providing evidence in support of this theory, which would have given Abbott the opportunity to respond in a Local Rule 56.1(c)(2) Statement. As a result of these choices, the record is significantly lacking as to basic facts about Prolacta's history, manufacturing practice, and market presence. The court has attempted to remedy this, to an extent, by requesting the parties identify evidence in the record that provides information about Prolacta. (*See* Order [82].)

[10] The distinction between fortifier and formula products is poorly explained in the parties' briefs. As explained by Abbott's MDL-wide expert Dr. Camilia Martin, fortifier products "add energy, protein, and nutrients" to human milk because "to meet the massive nutritional demands of premature infants who would otherwise be receiving nutrition from the placenta." (*See* Martin Rep. [616-25] at 9–10.) But "[w]hen human milk is unavailable, specialty preterm infant formula is the best option for nourishing premature infants." (*Id*. at 10.) In other words, fortifier *supplements* key nutritional benefits to supplement an available supply of human milk, while formula *substitutes* for human milk where there is an absence of supply.

Relying on this finding, Plaintiff's other general causation expert, Dr. Sucre, concludes in her report that "Prolacta (or other human-milk-based fortified nutrition) are safter alternatives to [cow's-milk-based formula] and serve the same function of providing nutrition to premature infants as [formula] without substantially increasing the risk of NEC." (Sucre Rep. [616-35] in No. 22 C 71, at 16.) Plaintiff's specific causation expert, Dr. Chandani Dezure, agrees with Dr. Sucre, concluding that "safer alternatives to cow's-milk-based formulas are mother's own milk, donor milk, and human milk-based formulas, like Prolacta." (Dezure Rep. at 7.) This testimony is the extent of Plaintiff's evidence that Prolacta was an alternative, feasible design of Abbott's SSC24, but it is not enough for a reasonable jury to find in Plaintiff's favor for several reasons.

First, Dr. Sucre and Dr. Dezure's conclusions that Prolacta is a "safer alternative" must be understood in the context of their expertise and opinions. Neither is an expert on formula manufacturing, nor do they provide testimony as to how SSC24 or Prolacta are produced or distributed. As such, while their medical and clinical expertise allows Dr. Sucre and Dr. Dezure to opine that Prolacta is a safer feeding alternative to cow's milk formula, evidence of a better *treating* option is not the same as evidence of alternative, feasible *product design*. *Hornbeck v. Danek Med., Inc.*, No. CIV. A. 6:96-2559, 1999 WL 1117107 (W.D. La. Aug. 5, 1999), *aff'd*, 226 F.3d 641 (5th Cir. 2000) ("[W]hile [expert's] report may propose alternative surgical procedures that a physician may choose when treating a patient, a different procedure is not an alternative product design.") (citing *Theriot v. Danek Medical, Inc.*, 168 F.3d 253, 255 (5th Cir.1999)). It does not appear that either expert intended to testify as to alternative (much less feasible) product designs in this case. When asked in her deposition whether she was "proposing an alternative design for preterm infant formula as an expert in this case," Dr. Sucre answered with an unambiguous "[n]o, I'm not." (Sucre Dep. Tr. at 38:12–18.) That Dr. Dezure was not speaking to alternative product designs in her report should be obvious from the fact that she included "mother's own milk" and "donor milk" in her list of "safer alternatives," (Dezure Rep. at 7), two substances that no one is suggesting Abbott could manufacture.

Second, it is a basic matter of tort principles that an "alternative design must not be an altogether essentially different product." *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 549 (S.D.W. Va. 2011) (applying West Virginia tort law) (quoting *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 900 (E.D. Va. 2010)); *but see Kimball ex rel. Kimball v. RJ Reynolds Tobacco Co.*, No. C03-664JLR, 2006 WL 1148506, at *3 (W.D. Wash. Apr. 26, 2006) (holding that whether proposed alternative design is an essentially different product is question for jury). Plaintiff does not clarify whether it is Prolacta fortifier or Prolacta formula that she is claiming was an alternative design for SSC24—she refers only to "Prolacta" in general terms.[11] Insofar as she is claiming that Prolacta *fortifier* was an alternative design, there is little dispute that fortifier is a different *class* of product from formula like SSC24. Fortifiers and formula serve two different clinical purposes—fortifier adds nutrients to an available supply of mother's milk *without* adding volume. (*See* Dezure Dep. Tr. [52-31] at 386:3–387:2.) The primary purpose of formula, in contrast, in Plaintiff's words, is "as a stand-alone food source—not as supplementation." (Resp. to DSOF ¶ 56.)[12] But proposing Prolacta *formula* as an alternative, feasible design raises other issues—namely, the formula product was not "existing at the time the subject product was made" as required by West Virginia law. *Shears*, 902 S.E.2d at 785, 250 W. Va. 226.

Finally, even if the court were to grant that Prolacta were a safer, alternative design for pre-term formula and that whether it constituted an "essentially different product" was a question

[11] Indeed, Dr. Sucre and Dr. Dezure, in referring to Prolacta as a "safer alternative," appear to be referring to different Prolacta products. Dr. Sucre's report only discusses Prolacta as a human-milk based fortifier, not formula. (*See* Sucre Rep. at 16.) Dr. Dezure, on the other hand, discusses Prolacta as an example of a "human milk-based formula[]." (Dezure Rep. at 7.)

[12] Furthermore, West Virginia law requires proof that an alternative, feasible design "would have substantially reduced the risk of the specific injury suffered by the plaintiff." *Shears*, 902 S.E.2d at 785, 250 W. Va. 226. In this case, RaiLee lacked a supply of human milk, not merely nutrients. *See supra*. It thus appears Prolacta fortifier would not have been a viable substitute for 50% of her diet that would have "substantially reduced" the risk of injury.

for the jury, Plaintiff has presented *no evidence* as to feasibility.[13] A key aspect to proving the availability of an alternative, feasible design is evidence that the alternative would be "be both economically and technologically feasible." *MCI Sales & Serv., Inc. v. Hinton*, 272 S.W.3d 17, 31 (Tex. App. 2008) (cited favorably in *Shears*, 902 S.E.2d at 784, 250 W. Va. 226). Under West Virginia law, "the expert witness is ordinarily the critical witness" to explain to the jury "complex technical problems relating to product failure, safety devices, *design alternatives*, the adequacy of warnings and labels, as they relate to *economic costs*." *Morningstar*, 253 S.E.2d at 682, 162 W. Va. 857 (emphasis added). Both *Shears* and *Morningstar*, moreover, confirm that proof of an "alternative, *feasible*" design is a required for plaintiff to make out a "prima facie case" for design defect; it is the plaintiff's burden to prove feasibility. *Shears*, 902 S.E.2d at 783, 250 W. Va. 226 ("*Morningstar* effectively required proof of an alternative, feasible design to establish a prima facie case for a design defect."). But Plaintiff Mar has submitted no documents explaining how Prolacta is manufactured, no testimony from a Prolacta witness or representative, and no expert testimony[14] opining on the feasibility of producing Prolacta given donor milk supply, intellectual property protections, and production costs. On this record, the court is left guessing at the

[13] Given that Plaintiff did not even address the question of feasibility in her brief in opposition and the general absence of basic information regarding Prolacta in the parties' submissions, the court gave Plaintiff a further opportunity to identify evidence in the *existing record* to support her claim regarding Prolacta. (*See* Order [82].) In responding [92], Plaintiff did not cite to documents in the record, but rather to previously unmentioned documents attached to a declaration [93] (filed separately and after the court's explicit deadline). The court declines to consider evidence or arguments that were not raised in Plaintiff's interrogatory responses, Local Rule 56.1 response, or opposition brief.

[14] The absence of expert testimony is particularly notable given that Plaintiff, in responding to Abbott's assertion in its Rule 56.1 Statement that "Plaintiff did not identify an alternative design when specifically asked to do so in discovery," explained her inability to identify an alternative design by arguing that "[r]equiring Ms. Mar, a layperson, to opine on the potential alternative design is patently speculative and as such precluded by FRE 602 . . . . Ms. Mar does not qualify under FRE 702 to render such testimony." (Resp. to DSOF ¶ 62.) Putting aside the fact that Abbott's interrogatories asked for Plaintiff's evidence and theories, not her "opinions," Plaintiff's argument recognizes that expert testimony is clearly required to establish the non-obvious conclusion that Abbott could have feasibly produced Prolacta in place of its formulas.

complexity of manufacturing Prolacta formula, and whether it has ever been produced at a large scale. Apart from a speculative claim that Abbott was considering "acquiring" Prolacta in 2013,[15] Plaintiff has made no showing that Abbott had the intention or capacity to replace SSC24 with Prolacta formula. Plaintiff states offhand that "Prolacta Bioscience's [the manufacturer of Prolacta] presence in the market for nearly two decades confirms that manufacturing formula from human milk is a feasible alternative to using cow's milk," (Pl.'s Mem. at 11) but without any testimony (much less expert testimony) as to the scale at which Prolacta was being produced and sold at or before RaiLee's birth, the jury would have no way to determine the economic and practical costs of Abbott manufacturing human-milk formula at the scale of SSC25.

The absence of any evidence of feasibility from Plaintiff is particularly jarring in contrast to uncontroverted evidence submitted by Abbott demonstrating significant shortfalls in the supply of donor human milk, necessarily making the production of human-milk-derived formula difficult at scale. Specifically, Abbott's expert Dr. Amanda Starc[16] opines that "the supply of donor human milk is relatively inelastic, meaning it is unlikely to rise substantially in response to changes in price, demand, or other factors" and further notes dramatic shortfalls in the availability of donor

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[15] (*See* Resp. to DSOF ¶ 25.) As evidence for this claim, Plaintiff cites to an email chain between various Abbott executives discussing Prolacta's business model in mid-2013 (which, at that point, was only selling fortifier). (*See* Pl.'s Ex. U, Email Chain at 7.) Far from showing an intention to acquire Prolacta or develop human-derived infant products, however, the email chain shows a lack of knowledge on the part of Abbott as to whether Prolacta could meet demand/scale of infant nutrition products, the importance of Prolacta's model relying on milk donations, and intellectual property concerns. (*See id*. at 2–3.) The email chain further shows that Abbott only considered Prolacta as a fortifier product, not a formula substituting for human milk. (*Id*. at 7.) In Plaintiff's most recent submissions (responding to the court's request for citations to the existing record), she submits *new* evidence that Abbott's plans to acquire Prolacta were more concrete in the spring and summer of 2013. (*See* Pl.'s Supp. [92] ¶¶ 13–14.) But even these new, untimely additions to the record do not suggest that Abbott (even after acquiring Prolacta) could produce Prolacta formula at a scale and cost to meet the needs of hospitals like CAMC.

[16] The court notes that Plaintiffs in the MDL have a pending motion to exclude Dr. Starc's opinion under Federal Rule of Evidence 702. (*See* Pls. Omnibus *Daubert* Mot. [612] in No. 22 C 71.) The court's ruling on that motion is forthcoming; for now, the court has not excluded that testimony.

milk and human milk products in the relevant time period. (Starc Rep. [611-10] in No. 22 C 71 at ¶¶ 83–87, 100.) Moreover, in Prolacta Bioscience's press release announcing the availability of human-milk-derived formula in September 2014 (cited by Abbott), the company touts that "Prolacta operates the first and only pharmaceutical-grade manufacturing facility for the processing of human breast milk." (September 2014 Prolacta Press Release, https://www.prolacta.com/en/news/prolact-rtf-100-human-milk-based-premature-infant-formula-for-nicus/ (last accessed May 1, 2025).) Plaintiff has offered no countervailing evidence that Abbott could obtain sufficient donor milk supply or feasibly manufacture human-milk products to meet the feeding needs of NICU's in hospitals like CAMC in January 2014.

B. Altering Component or Warning

Plaintiff's alternative theory, that Abbott could have made its product safer by "altering its components" (Pl.'s Mem. at 10) also falters for lack of evidence. As noted above, Dr. Sucre's testimony is that every macronutrient in cow's milk-based formula, not just one component or ingredient, contributes to the development of NEC. (Sucre Rep. at 37–38.) Plaintiff has supplied no testimony as to the possibility or feasibility of altering or replacing each or all of these components.

As for Plaintiff's suggestion that "an alternative, feasible design could simply be the same product with a significantly more robust warning" (Pl.'s Opp'n at 12), this merely collapses Plaintiff's design defect argument into a failure-to-warn claim. Indeed, the case cited by Plaintiff to suggest the existence of a such an "inadequate-warning-defective-design" claim explains that such a claim is properly termed a "failure to warn" claim that is *distinct* from a challenge to the design of the product. *See Wilkinson v. Duff*, 575 S.E.2d 335, 340, 212 W. Va. 725 (2002) ("A failure to warn cause of action covers situations when a product may be safe as designed and manufactured, but which becomes defective because of the failure to warn of dangers which may be present when the product is used in a particular manner.") (quotation omitted). The court discusses Plaintiff's claims against Abbott's labeling and warnings in the next section; for now,

Plaintiff has failed to produce a workable theory of an alternative, feasible design of SSC24 sufficient to pursue a design defect claim at trial.

II. Failure to Warn

Plaintiff brings a strict liability failure-to-warn claim and a negligent failure-to-warn claim. For both claims, Plaintiff asserts that Abbott failed to properly inform Plaintiff and RaiLee's physicians of the extent of SSC24's causation of NEC. (*See* Pl.'s Opp'n at 3.) Under West Virginia law, failure-to-warn claims in strict liability and negligence share two elements critical to Abbott's motion. First, Plaintiff must show that "it was reasonably foreseeable to the manufacturer that the product would be unreasonably dangerous if distributed without a warning" giving rise to a duty to warn. *Church v. Wesson*, 385 S.E.2d 393, 396, 182 W. Va. 37 (1989). Second, Plaintiff must prove that the failure-to-warn was the cause in fact of RaiLee's injury (her suffering from NEC), or provide "evidence that a[n] [adequate] warning would have made a difference." *Meade v. Parsley*, No. 2:09-CV-00388, 2010 WL 4909435, at *8 (S.D.W. Va. Nov. 24, 2010) (quoting *Tracy v. Cottrell*, 524 S.E.2d 879, 890 n. 9, 206 W. Va. 363 (1999)). Abbott's motion charges that Plaintiff has failed to establish either that Abbott owed a duty to warn (Abbott Mem. at 21–27) or that any additional warning would have made a difference given the lack of donor milk available at CAMC (*id*. at 27–30).

A. Duty to Warn

The court rejects Abbott's arguments that Plaintiff has failed to create a material dispute as to its duty to warn Plaintiff and her physicians of the dangers or risks of its cow's-milk-based formula products. Central to Abbott's argument that it owed no duty to warn Plaintiff about the possible dangers is its assertion that the learned intermediary doctrine existed in West Virginia at the time of RaiLee's birth and limited its duty to a duty to warn RaiLee's physicians of non-obvious risks. (*Id*. at 23.) The learned intermediary doctrine is an exception to a manufacturer's general duty to warn; under the learned intermediary doctrine, "a drug manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the

prescribing physician of the product's dangers." *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 902, 220 W. Va. 463 (2007) (quotation omitted). In 2016, the West Virginia legislature passed a statute recognizing the doctrine, W. VA. STAT. § 55-7- 30(a), but Abbott urges that the statute merely codified existing law that already recognized the learned intermediary doctrine in the medical context.

Plaintiff disagrees with this reading, and she has the better of the argument. As Plaintiff points out, the Supreme Court of Appeals of West Virginia squarely considered and rejected the learned intermediary doctrine in *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 220 W. Va. 463 (2007). As the court stated unambiguously in the first sentences of the case:

> In this action invoking the original jurisdiction of this Court in prohibition, a drug manufacturer asks this Court to adopt the learned intermediary doctrine as an exception to the general duty of manufacturers to warn consumers of the dangerous propensities of their products. After thorough consideration of the learned intermediary doctrine in light of the current state of the prescription drug industry and physician/patient relationships, we decline to adopt this doctrine.

647 S.E.2d at 900–01, 220 W. Va. 463. Abbott argues that this opinion was limited to "just declin[ing] to apply [the learned intermediary doctrine] in the context of direct-to-consumer advertising, which is not at issue here" (Abbott Reply at 10), but the court finds no such limiting language in the opinion. Indeed, the Supreme Court of Appeals could not have used broader language in explaining the duty of drug manufacturers.[17] *K*arl*,* 647 S.E.2d at 914, 220 W. Va. 463 ("[W]e now hold that, under West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers. We decline to adopt the learned intermediary exception to this general rule.") Any reasonable reading of *Karl* (not to mention the absence of *any* caselaw prior to *Karl*

[17] Indeed, because infant formula is regulated as a food by the FDA (*see* 21 U.S.C. § 321(z)) there is an open question—even where the learned intermediary doctrine applies—whether infant formulas are covered by the doctrine. *See Ferry v. Mead Johnson & Co., LLC*, 514 F. Supp. 3d 418, 433 (D. Conn. 2021) (submitting the question of whether the learned intermediary doctrine applies to Enfamil under Connecticut law to the Connecticut Supreme Court) (case was voluntarily dismissed before the certified question was answered).

discussing the learned intermediary doctrine in West Virginia) makes clear that there was no learned intermediary doctrine shielding manufacturers like Abbott from providing adequate warnings.

Putting aside the learned intermediary doctrine, however, Abbott goes on to argue that it had no duty to warn of the dangers of cow's-milk formula relative to human milk because the law does not require Abbott to warn of comparative risks. (Abbott Mem. at 21–23.) But Abbott finds no support in West Virginia case law for the proposition that a duty cannot exist where a product increases the risk of disease *relative* to a broad category of alternatives. Though it cites opinions where courts have held, in other jurisdictions, that a manufacturer does not have a duty to warn of the relative benefits of different products, the cases are easily distinguishable on their facts and do not establish that a manufacturer can never have a duty to warn that there is a safer alternative. *See Pluto v. Searle Lab'ys*, 294 Ill. App. 3d 393, 396, 690 N.E.2d 619 (1st Dist. 1997) (IUD manufacturer had no duty to warn of lower risk of STDs in other forms of birth control because IUD not intended to protect from STDs); *Slisze v. Stanley-Bostitch*, 1999 UT 20 ¶ 13, 979 P.2d 317 (nail manufacturer had no duty to warn of safer model of nail because warning would "reduce the likelihood of injury so minimally that to impose the duty would be unduly burdensome"); *Cowart v. Avondale Indus*., Inc., 2001-0894, pp. 7–9 (La. App. 4 Cir. 7/3/01), 792 So. 2d 73 (holding that manufacturer had no duty to warn of safer alternative products *in addition* to adequate warnings about the hazards of product). In this case, Plaintiff has expressed the dangers of Abbott's products, through Dr. Sucre and Dr. Spector's reports, in terms of an *increased risk* of NEC as compared to human-milk alternatives. Should a jury be persuaded that such a risk exists and was foreseeable to Abbott, the court sees no basis to reject as a matter of law Plaintiff's theory that an adequate warning would warn of this relative risk.

B. Cause in Fact

Abbott's more forceful argument is that Plaintiff has failed to present evidence that an adequate warning would have made a difference in RaiLee's treatment. As a preliminary point,

the only testimony that has been provided as to what an adequate warning would have been is testimony from Plaintiff's regulatory and labeling expert, Dr. Scheer, that Abbott's labeling of SSC24 should have included a warning that "human milk has a lower risk of NEC than formula" rather than the general "USE AS DIRECTED BY A DOCTOR" warning. (*See* DSOF ¶ 64.) Thus, Plaintiff must point to evidence in the record sufficient for a jury to find that such a warning, if provided, would have resulted in a different course of action by Plaintiff or RaiLee's physicians.

It is undisputed that there was no donor milk or Prolacta available at CAMC when RaiLee's diet was changed to a mixed feeding with SSC24. *See supra* p. 3. Plaintiff's various submissions in opposition, however, raise three distinct theories for how things would have been different with an adequate warning. The court addresses these theories and the evidentiary hurdles they face below.

First, Plaintiff claims that "[d]onor milk was available to RaiLee—her mother's friend volunteered it—but RaiLee's doctors refused because Abbott failed to warn." (Pl.'s Opp'n at 3.) There is little evidence concerning this offer in the record beyond Plaintiff's deposition testimony. Assuming it was made, however, there is no evidence to suggest that an adequate warning would have resulted in RaiLee's being fed the friend's unpasteurized milk. As described above, the rejection of the friend's milk does not appear to be based on the treating nurse's judgment on the relative risk of formula and donor milk, but instead on the hospital's official policy on rejecting informal milk donations given the unrelated risks of unpasteurized milk. *See supra* n. 2. Plaintiff has provided no evidence for a jury to conclude that CAMC staff would have (or could have) circumvented this policy with a stronger warning from Abbott.

Second, Plaintiff urges that "[h]ad Abbott warned about the real risk posed by SSC24, RaiLee's doctors would have recommended, and Ms. Mar would have made, a different choice about how to feed RaiLee that would have substantially reduced the risk of NEC." (Pl.'s Opp'n at 3 (no internal citation).) Plaintiff has no evidence to support this claim. So far as Plaintiff suggests that RaiLee's treating physicians would have made a different choice if there was a different

warning from Abbott, her claim is directly contradicted by the statements of Dr. Maxwell, RaiLee's treating physician. When asked by Plaintiff's counsel whether a stronger warning from Abbott would have changed his decision to feed RaiLee a 50% SSC24 diet, Dr. Maxwell answered:

> Well, what else would we feed this baby? I mean, we have to have some sort of formula, if we run out of mom's milk and there was no option for donor's milk. You can't send babies home on donor's milk anyway, so we have no other option.

Maxwell Dep. at 91:20-92:5. As for the claim that Plaintiff herself would have made a "different choice"[18] for feeding RaiLee had an adequate warning been provided, it is undisputed that Plaintiff did not review the packaging on SSC24 or any warnings and "relied on RaiLee's NICU team" to make the best choice for feeding RaiLee. (*See* Resp. to DSOF ¶¶ 43–44; Mar Dep. Tr. at 88:14–22.) There is simply no testimony or evidence on which a jury could find that a different warning would have resulted in different actions taken by Plaintiff or the physicians.

Third, Plaintiff suggests in various responses to Abbott's Rule 56.1 Statement that "Dr. Maxwell indicated that had he known of the extent of the risk, he would have advocated sooner for a donor milk program at CAMC or Prolacta." (*See* Resp. to DSOF ¶ 45; *see also id*. ¶¶ 17, 46.) Plaintiff's only citation, at each of these mentions, is to a small portion of Dr. Maxwell's deposition where he is asked about policy changes that he would have encouraged had he been more aware of the risks of cow's milk-based formula—but Plaintiff overstates the strength of these answers. When asked, again by Plaintiff's counsel, whether he would have taken more steps to obtain donor milk, Dr. Maxwell testified:

> It's not that easy. It would make sense, wouldn't you think? But, you know, it took us five years before we could get donor milk. I mean, it doesn't happen that easily. You have to go through the hospital, go through the board and the foundation and all of this to get funding to get donor milk. It's not something that happens over

[18] Plaintiff's briefing does not expand on what this "different choice" would have been. At the hearing held on March 31, 2025, Plaintiff's attorneys suggest that she would have transferred RaiLee to a different hospital, or otherwise not have allowed RaiLee to be fed SSC24 formula. These representations by her attorneys, however, are unsupported by any of Plaintiff's testimony in the record, nor by evidence that donor milk or Prolacta were available in any nearby hospitals.

> night . . . But we would have tried, yes, to get donor milk maybe quicker than we did. *I'm not sure we had that opportunity at the time*.

(Maxwell Dep. Tr. at 119:16–120:8 (emphasis added).) In short, assuming that a stronger warning would have prompted Dr. Maxwell himself to push for a donor milk program, he can only speculate about what the results of his efforts might have been within CAMC. And Plaintiff has entered no testimony from CAMC administrators or policymakers supporting her assertion that the warning for which she advocates would have resulted in a different world where donor milk or Prolacta were available for RaiLee.

The loss of a child is heartbreaking, and for Ms. Mar and her family, RaiLee's death is a profound tragedy. Abbott could have made more forceful warnings about the relative risks of its formula. The factual reality, however, is that at the time and location of this baby's birth, cow's-milk-based infant formula was the only option to feed her. Abbott cannot be liable for its failure to warn of a better but unavailable alternative.

III. Impact of this Ruling on the MDL

The purpose of selecting a bellwether case is to provide information helpful to the resolution of all cases in the MDL. The court has granted summary judgment in this case, but its holding has limited direct application to the other claims in the MDL—the court does not, for example, weigh in on Plaintiff's causation experts' ability to sufficiently prove a connection between formula and RaiLee's illness, nor does it adopt Abbott's framing that it is absence of human milk rather than the presence of cow's milk formula that causes NEC. Other plaintiffs pursuing similar claims in this MDL may be able to produce a more thorough record as to the basic facts and manufacturing process of Prolacta formula and procure expert testimony as to the feasibility of Prolacta as an alternative design for cow's-milk-based formula at the time of their child's birth. Similarly, as it relates to the court's opinion on Plaintiff's failure-to-warn claim, a different plaintiff may readily be able to present evidence that she or physicians would have and

could have made different decisions with different warnings from Abbott or the co-Defendant, Mead Johnson.

CONCLUSION

Abbott's motion for summary judgment [48] is granted. The Clerk is directed to enter judgment for Abbott. Dates for jury selection and trial are stricken. The parties' remaining pending motions in this case are terminated without prejudice.

ENTER:

Dated: May 2, 2025

REBECCA R. PALLMEYER
United States District Judge