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: ***Brown v. Abbott Laboratories, Inc.*** **Case No. 22 C 2001**	**Hon. Rebecca R. Pallmeyer**

MEMORANDUM OPINION AND ORDER

Plaintiffs' infant child, D.B., was born on July 7, 2021, at just 24 weeks gestational age. His mother was unable to produce breast milk, so for more than two months, D.B. was fed fortified human donor milk. Then on September 11, 2021, his doctors began to transition him to Similac Special Care 24 ("SSC-24"), a cow's-milk-based formula designed for preterm infants and manufactured by Abbott Laboratories, Inc. ("Abbott"). A few days later, D.B. died from necrotizing enterocolitis ("NEC"), a devastating disease affecting preterm infants. In this lawsuit—one of hundreds of similar actions consolidated before this court by the Judicial Panel on Multidistrict Litigation ("JPML")—D.B.'s parents allege that the formula's design was unreasonably dangerous and caused D.B. to develop NEC.

D.B.'s case is one of an initial wave of four bellwether cases, the first two of which ended in summary judgment for Abbott. Abbott seeks summary judgment in this third bellwether as well, arguing that the evidence does not support Plaintiffs' state law products liability claims. As explained below, the court agrees with Abbott. Abbott has presented substantial and uncontested evidence as to utility of SSC-24 formula and the infeasibility of Plaintiffs' suggested alternative.

The motion for summary judgment [57] is granted. Abbott's separate *Daubert* motions [60] to exclude the testimony of Dr. Spector and Dr. Flanigan are stricken without prejudice as moot.

BACKGROUND

I. Factual Background

This case, like the others in this MDL, involves allegations that preterm infant formula manufactured by Abbott causes necrotizing enterocolitis, also known as "NEC." NEC is a life-threatening disease characterized by inflammation of the tissue lining a premature infant's intestinal wall. In severe cases, the disease can lead to necrosis (tissue death), creating a hole in the intestine. Once the intestinal wall is perforated, bacteria can enter, which can cause sepsis—the infection of the bloodstream. While any infant can develop NEC, the overwhelming majority of cases occur in infants born prematurely, with NEC risk increasing the earlier that a child is born. The risk of NEC is especially high among very-low birth weight (VLBW) and extremely-low birth weight (ELBW) infants. There are two subcategories of NEC relevant here: classic NEC, and fulminant NEC. As Plaintiffs' expert Dr. Jennifer Sucre explains,[1] classic NEC occurs "shortly after birth" and is "often associated with the introduction of enteral feeding."[2] (Sucre Rep. [60-24] at 13.) Fulminant NEC, on the other hand, is characterized by rapid onset and fulminant prognosis, with "death typically occurring 48–72 hours after diagnosis." (*Id.*)

The facts of this case are largely similar to the other cases in this MDL.[3] Infant D.B. was born on July 7, 2021, at just 24 weeks gestational age and weighing only 1.5 pounds. (PSOF ¶ 5.) Despite multiple efforts, his mother, Rebekah Etienne, was unable to produce breastmilk; she

---

[1] Dr. Sucre is Associate Professor of Neonatology at the Vanderbilt University School of Medicine. (Sucre Rep. [60-24] at 5.)

[2] According to Dr. Sucre, enteral feeding "is dietary intake that is absorbed through the GI tract" (as opposed to nutrition delivered intravenously). (Sucre Rep. [60-24] at 13 n.d.)

[3] The court assumes the parties' general familiarity with the factual background of the MDL. The facts included in this section are taken from the parties' respective Local Rule 56.1 submissions and the cited expert reports. (*See* Abbott Local Rule 56.1(A)(2) Statement of Material Facts [59] (hereinafter "DSOF"); Plaintiffs' Local Rule 56.1(b)(3) Statement of Additional Material Facts [68] (hereinafter "PSOF").) In examining this motion, the court draws all reasonable inferences in favor of Plaintiffs, the non-moving party. *Hess v. Bd. of Trs. of S. Ill. Univ.*, 839 F.3d 668, 673 (7th Cir. 2016).

subsequently consented to feeding D.B. with fortified donor milk. (DSOF ¶¶ 32–33.) Beginning on July 9, his doctors began to feed him with donor human milk, a feeding regimen that was "slowly advanced" and "fortified" with Prolacta, a human-milk based fortifier. (PSOF ¶ 5.) Throughout the time he was fed fortified donor milk, D.B.'s medical records show that he was "responding well" and "tolerating feeds" for the most part, but experiencing occasional feeding intolerance and digestive issues. (*See id.* ¶ 6; Def. Resp. to PSOF [84] ¶ 6.) He continued to receive this regimen until September 11, 2021, when his doctors began to transition him to Abbott's SSC-24 formula. (PSOF ¶ 7.)

A few days later, on September 15, 2025, D.B.'s condition began to deteriorate. These events are described in the report of Dr. Elizabeth Flanigan, an expert neonatologist retained by Plaintiffs.[4] According to this report, doctors observed "increased apnea events, abdominal distention, and increased gastric residuals" from D.B. (Flanigan Rep. [68-7] at 3.) A radiograph taken later that evening revealed findings consistent with NEC. (*Id.* at 16–17.) On September 16, doctors conducted an exploratory laparotomy, which confirmed the NEC diagnosis. (*Id.* at 3–4.) His prognosis was described as "grave"—he was placed on ventilation, but his condition continued to worsen throughout the day. (*Id.* at 8–9.) Later that evening, as his heart rate began to drop, his parents requested resuscitation with epinephrine, but this failed. (*Id.* at 9.) At 10:35 pm on September 16, 2021, five days after he first ingested formula, D.B. died in his mother's arms. (*Id.* at 3, 10.) His death certificate lists "necrotizing enterocolitis" as the cause of death. (PSOF ¶ 9.)

Plaintiffs believe that D.B.'s consumption of Abbott's Similac Special Care 24 ("SSC-24") formula caused him to develop NEC. Across all feedings, D.B. received 281.4 ounces of human milk, fortified with Prolacta, and 29.1 ounces of SSC-24. (Flanigan Rep. [68-7] at 14.) This

[4] Dr. Flanigan is an attending neonatologist and Chief of Clinical Operations for the Department of Pediatrics at Brigham and Women's Hospital in Boston, Massachusetts. She is board-certified in pediatrics and neonatal-perinatal medicine. (Flanigan Rep. [68-7] at 2.)

corresponds to a total diet that consisted of around 10% SSC-24. As noted, SSC-24 is an infant formula manufactured by Abbott Laboratories, and is part of a category of products known as bovine-based nutritional products ("BBNPs") or cow's-milk-based formula ("CMBFs"). SSC-24, like other CMBFs, is manufactured using proteins derived from cow's milk. (Opp. [69] at 4; PSOF ¶ 2.) Abbott markets SSC-24 to VLBW infants, and distributes it to NICUs nationwide. (PSOF ¶ 1.)

CMBFs like SSC-24 are not the only option for feeding preterm infants. The breast milk of one's own mother is the preferred option, but human milk alone is not sufficient to meet the nutritional needs of premature infants, who require certain nutrients that, if born full-term, they would have received from the umbilical cord.[5] To solve this problem, fortifier is added to human milk to supplement it with necessary nutrients. Prolacta Biosciences ("Prolacta") manufactures the fortifier that was given to D.B. while he was receiving donor human milk. (*See* Flanigan Rep. [68-7] at 3.) Prolacta also manufacturers a "ready to feed" ("RTF") formula product made from human milk that provides a substitute for donor milk whenever it is unavailable. Prolacta fortifier, which D.B. received, has been sold since approximately 2006; there is no indication that he received Prolacta's RTF formula product, which was introduced in September 2014. *See Mar v. Abbott Lab'ys*, No. 22 C 00071, 2025 WL 1282749, at *5 (N.D. Ill. May 2, 2025).[6]

Plaintiffs note that, beginning in 2009, Abbott and Prolacta engaged in a joint venture with the goal of creating a "total feeding solution" for VLBW infants. (PSOF ¶ 27.) According to internal

[5] As Abbott expert Dr. Camilia R. Martin explains, donor human milk does not contain all of the nutrients needed for a preterm infant's development. (Martin Rep. [59-18] at 10.) There are a number of proteins and nutrients that an infant usually receives from the placenta but are absent from human milk. The purpose of fortifier is to bridge this gap and "fortify" donor milk with these additional nutrients. (*See id.*)

[6] *See also* September 2014 Prolacta Press Release, https://www.prolacta.com/en/news/prolact-rtf-100-human-milk-based-premature-infant-formula-for-nicus/ (last accessed October 23, 2025).

company documents,[7] the plan was for Abbott to promote the use of Prolacta fortifier in infants with a birth weight of less than 1250g (2 lbs, 10 oz). (PSOF, Ex. 15 [68-16], at 2–4.) These especially fragile infants would be fed donor human milk fortified with Prolacta for at least some time during their stay in the NICU. (*Id.*) In 2013 and 2014, before the introduction of Prolacta RTF formula, Abbott explored an acquisition of Prolacta; this acquisition was never consummated. (PSOF ¶¶ 32–38; Def. Resp. to PSOF [84] ¶ 32–38.)

II. Expert Testimony

Plaintiffs' contention that SSC-24 formula caused D.B.'s NEC relies primarily on the testimony of expert witnesses. Plaintiffs offer the testimony of Dr. Logan Spector and Dr. Jennifer Sucre, who opine as to general causation, and Dr. Elizabeth Flanigan, who discusses the specific facts of D.B.'s case. In an earlier ruling, the court addressed *Daubert* challenges to these experts; their opinions and methodologies are only briefly summarized here. *See In re Abbott Lab'ys, et al, Preterm Infant Nutrition Prods. Liab. Litig.* (Omnibus Order), No. 22 C 00071, 2025 WL 1283927 (N.D. Ill. May 2, 2025).

Dr. Spector conducted a systemic literature review of the relationship between CMBF and NEC in premature, low-birth weight infants.[8] He conducted multiple meta-analyses of randomized clinical trials, cohort studies, and case control studies, all of which showed that an infant who ingests a predominantly CMBF diet has a statistically-significant higher risk of NEC than an infant who ingests a predominantly HM diet. (Spector Rep. [60-1] at 10–15.) For example, the meta-analysis of all cohort studies showed that premature infants who ingest a predominantly CMBF diet have a 326% higher risk of NEC compared to premature infants who ingest a predominantly HM diet. (*Id.* at 13, 18, 21.) RCTs, however, are the "least biased and objective [research]

[7] These documents include emails, memoranda, PowerPoint slide decks, and calendar invitations. (*See* PSOF ¶¶ 27–38.)

[8] Dr. Spector is Professor and Director of the Division of Epidemiology and Clinical Research in the Department of Pediatrics at the University of Minnesota Medical School. (Spector Rep. [60-1] at 3.)

method," followed by cohort studies, and then case control studies. (*Id.* at 10–11.) The meta-analysis for all RCTs showed that premature infants who ingest a BBNP diet have a 67% higher risk of NEC than premature infants who ingest a diet of only human milk. (*Id.* at 16.) Dr. Spector then applied the Bradford Hill criteria (a set of criteria used to assess the causality of an association), ultimately concluding that feeding preterm infants CMBF causes NEC as compared to feeding HM. (*Id.* at 22–23.)

Dr. Sucre performed a qualitative assessment to evaluate the weight of the evidence for the following hypothesis: "does exposure to CMBF cause and/or substantially contribute to the development of NEC?" (Sucre Rep. [60-24] at 9.) She identified relevant publications, assessed their quality, and then "graded" them. (*Id.* at 10.) She relied on Dr. Spector's report to determine that there is epidemiological evidence showing a causal relationship between CMBF and NEC, and that Prolacta fortifier is a safer alternative to CMBF. (*Id.* at 15–17.) She also reviewed animal models, which, although they contain limitations, commonly used CMBF alongside other factors to induce NEC. (*Id.* at 19–24.) Dr. Sucre then discussed the biochemistry of NEC, the digestive process, and the impact of the development of the digestive tract, ultimately tracing "the biologic pathway from ingestion of CMBF to NEC." (*Id.* at 25–38.) Dr. Sucre concludes that the weight of the scientific evidence supports her hypothesis that CMBF is casually associated with, and/or substantially contributes to, the development of NEC. (*Id.* at 40.)

Dr. Flanigan conducted a differential diagnosis, which involved reviewing D.B.'s medical records, confirming his NEC diagnosis, identifying his risk factors for NEC, and subsequently ruling out alternative causes of D.B.'s NEC. (*See generally* Flanigan Rep. [68-7].) D.B.'s risk factors included premature birth, low birth weight, chorioamnionitis, and antibiotic use, among others. She proceeded to rule out these causes of NEC, ultimately concluding that "the Similac Special Care formula was the most important contributing factor to [D.B.]'s development of severe, fulminant [NEC]," and that human-milk-based products are "a safer alternative to [CMBF]." (*Id.* at 23.)

Abbott has also produced extensive expert testimony, including the report of Dr. Camilia R. Martin, who rebuts the general causation opinions of Dr. Spector and Dr. Sucre, as well as the report of Dr. Amanda Starc, a health economist, who testified (as more fully described below) concerning the feasibility of producing a human-milk alternative to SSC-24.[9] (*See generally* Martin Rep. [59-18] and Starc Rep. [59-41].)

III. Procedural Background

The Complaint in this case was originally filed in November 2021 in the Middle District of Louisiana.[10] (*See* Compl. [1].). On April 19, 2022, the case was transferred to this court by order of the JPML [23] and later selected by agreement of the parties as the third of an initial round of "bellwether" trials. Bellwether trials serve a valuable purpose in multidistrict litigation: they can "provid[e] significant information regarding the entire pool of cases that are part of the MDL." *Mar*, 2025 WL 1282749, at *1 (quoting *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)). The court nevertheless assesses cases chosen for bellwether treatment using the same standard applicable in any civil litigation: Summary judgment is appropriately granted "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)); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). 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).

A party moving for summary judgment bears the burden of establishing that the summary judgment standard is met, and if the moving party does so, the opposing party must present

[9] Dr. Martin is Division Chief of Neonatology at Weill Cornell Medicine. (Martin Rep. [59-18] at 2.) Dr. Starc is Associate Professor of Strategy at the Kellogg School of Management at Northwestern University. (Starc Rep. [59-41] at 5.)

[10] The case number in the Middle District of Louisiana is 3:21-00687.

evidence sufficient for a jury to find in their favor on all matters on which they bear the burden of proof. *Celotex*, 477 U.S. at 323. But a "party opposing summary judgment does not have to rebut factual propositions on which the movant bears the burden of proof and that the movant has not properly supported in the first instance." *Johnson v. Hix Wrecker Serv., Inc.*, 651 F.3d 658, 662 (7th Cir. 2011). Thus, when the moving party bears the burden of proof on an issue, summary judgment is warranted only when the issue is so one-sided that it must prevail as a matter of law. *Hotel 71 Mezz Lender LLC v. Nat'l Ret. Fund*, 778 F.3d 593, 601 (7th Cir. 2015).

DISCUSSION

Because the court's jurisdiction over this action is based on diversity under 28 U.S.C. § 1332, the court applies Louisiana substantive tort law, and federal procedural law.[11] *See Musser v. Gentiva Health Servs.*, 356 F.3d 751, 754 (7th Cir. 2004); *Chang v. Baxter Healthcare Corp.*, 599 F.3d 728, 732 (7th Cir. 2010) ("When a diversity case is transferred by the multidistrict litigation panel, the law applied is that of the jurisdiction from which the case was transferred . . . ."). This court is bound by the Seventh Circuit's interpretation of the relevant federal procedural rules, including the Federal Rules of Evidence. *See In re Abbott Lab'ys, et al, Preterm Infant Nutrition Products Liab. Litig.*, No. 22-c-71, 2022 WL 3716277, at *3 (N.D. Ill. Aug. 29, 2022) (discussing the application of the "transferee circuit's interpretation of federal law"); *see also Nat'l Collegiate Athletic Ass'n Student-Athlete Concussion Inj. Litig.*, 314 F.R.D. 580, 589 n.7 (N.D. Ill. 2016).

Plaintiffs bring two claims under Louisiana state law: a products liability claim, and a loss of consortium claim.[12] The court considers these claims in turn.

---

[11] Because Louisiana is a civil law jurisdiction, courts interpreting Louisiana law are bound by the statute's language, but not necessarily by state court precedent. *See Boyett v. Redland Ins. Co.*, 741 F.3d 604, 607 (5th Cir. 2014) ("Unlike in common law systems, stare decisis is foreign to the Civil Law . . . we are guided by decisions rendered by the Louisiana appellate courts . . . but we are not strictly bound by them." (cleaned up)).

[12] Plaintiffs have voluntarily dismissed their failure-to-warn claim. (Opp. [69] at 10.)

I. Products Liability Claim

The court turns first to the products liability claim, which is the central dispute in this case. In Louisiana, products liability claims are governed by the Louisiana Products Liability Act (LPLA), which provides the "exclusive remedy" for products liability actions in the state, displacing all other theories of tort liability. *See Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 182 (5th Cir. 2012). Under the LPLA, a product manufacturer is liable for damage proximately caused by products that are "unreasonably dangerous." LA. STAT. ANN. § 9:2800.54(A). A plaintiff can meet the burden of showing that a product is unreasonably dangerous under any one of four theories:

> (1) The product is unreasonably dangerous in construction or composition as provided in R.S. § 9:2800.55;
> (2) The product is unreasonably dangerous in design as provided in R.S. § 9:2800.56;
> (3) The product is unreasonably dangerous because an adequate warning about the product has not been provided as provided in R.S. § 9:2800.57; or
> (4) The product is unreasonably dangerous because it does not conform to an express warranty of the manufacturer about the product as provided in R.S. § 9:2800.58.

Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 261 (5th Cir. 2002) (quoting LA. STAT. ANN. § 9:2800.54(B)). As noted, Plaintiffs have withdrawn a failure-to-warn claim and have no claim for breach of warranty or problems in the product's manufacture. Instead, Plaintiffs here contend Abbott's product is dangerous in its design. Such a claim requires a prima facie showing of two elements:

> (1) There existed an alternative design for the product that was capable of preventing the claimant's damage; and
>
> (2) The likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product. An adequate warning about a product shall be considered in evaluating the likelihood of damage when the manufacturer has used reasonable care to provide the adequate warning to users and handlers of the product.

LA. STAT. ANN. § 9:2800.56. The burden is on plaintiff to establish these elements. Another provision of the LPLA provides the product's manufacturer with several affirmative defenses. *See id*. § 9:2800.59. One of them shields a manufacturer from liability if it can show that "[t]he alternative design identified by the claimant under R.S. § 9:2800.56(1) was not feasible, in light of then-existing reasonably available scientific and technological knowledge or then-existing economic practicality." *Id*. § 9:2800.59(A)(3). The manufacturer bears the burden of proof on all affirmative defenses. *See* 1 Louisiana Tort Law § 15.10.

Plaintiffs' claim is relatively straightforward: that Abbott's cow's-milk-based SSC-24 formula causes NEC, and that a design based on human milk (such as Prolacta) would have been a safer alternative. In response, Abbott counters that (1) SSC-24 did not cause D.B.'s NEC, and (2) Plaintiffs' proposed design changes to SSC-24 are not economically or functionally practical. (Def. Mem. [69] at 8–10.) The court concludes that summary judgment is warranted on the latter ground; the court notes concerns about Plaintiffs' causation theory below, but declines to address that issue definitively today.

A. Causation

Under the LPLA, a plaintiff must demonstrate that her injuries were proximately caused by a characteristic of the product at issue. LA. STAT. ANN. § 9:2800.54(A). In Louisiana, proximate cause has been defined as "any cause which, in natural and continuous sequence, unbroken by any efficient, intervening cause, produces the result complained of and without which the result would not have occurred." *Scott v. Ariens Co.*, No. 23-2169, 2025 WL 786035, at *4 (E.D. La. March 12, 2025) (quoting *Pickett v. RTS Helicopter*, 128 F.3d 925, 929 (5th Cir. 1997)). As described here, Abbott challenges the expert testimony Plaintiffs have offered to establish causation.

1. Rule 702

Under FED. R. EVID. 702, an expert must be qualified by specialized knowledge or skill, their testimony must be relevant and assist the trier of fact, and their methods must "demonstrate

sufficient reliability" in both the underlying data and its application to the facts of the case. *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 834 (7th Cir. 2015) (citing FED. R. EVID. 702). "[T]he district court must make 'a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid.'" *Kirk v. Clark Equip. Co.*, 991 F.3d 865, 873 (7th Cir. 2021) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592–93 (1993)). The court may consider the following factors:

> (1) [W]hether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community.

Id. (citation omitted). "[T]his list is neither exhaustive nor mandatory." *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 780 (7th Cir. 2017) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("*Daubert* makes clear that the factors it mentions do not constitute a 'definitive checklist or test.'")). The "test is a flexible one," and "[n]o one factor is dispositive." *Kirk*, 991 F.3d at 873 (citation omitted). Further, "the correct inquiry focuses not on 'the ultimate correctness of the expert's conclusions,' but rather on 'the soundness and care with which the expert arrived at her opinion.'" *Id.* (citation omitted). Finally, an opinion connected to existing data only because the expert said as much is inadmissible. *C.W. ex rel. Wood*, 807 F.3d at 832. "A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Id.* at 832.

2. Dr. Spector and Dr. Flanigan

This court has already addressed Dr. Spector's report and has concluded that it rests on a reliable methodology. *See* Omnibus Order, 2025 WL 1283927, at *2–*7. Abbott argued earlier that his opinion was unhelpful in this MDL because "he could not opine about the 'threshold' dose at which CMBF becomes dangerous, nor did he consider studies comparing a 100% human-milk diet to a 90% human-milk diet," or a diet that is 10% formula fed. *Id.* at *10. This court rejected

that argument, noting that the law in the Seventh Circuit does not require a specific threshold dose in a general causation opinion. *Id.* at *11–*12. Further, as the court observed, Dr. Spector "explained that although a precise triggering exposure may not be ascertainable, the epidemiological literature does establish that a dose-response relationship likely exists between CMBF and NEC (more formula increases likelihood of NEC)." *Id.* at *11 (citing Spector Rep. [60-1] at 24).

As to "fit," Abbott now emphasizes that Dr. Spector's opinion appears to be limited to infants whose diets consisted of more than 50% formula. Thus, rather than arguing that Dr. Spector cannot ascertain a threshold dose, Abbott contends that he cannot determine that a diet *like D.B.'s* has a statistically significant association with NEC. Dr. Spector notes in his opinion that because the majority of studies used mixed feedings (that is, infants who received some amounts of human milk and some amounts of CMBF), he "attempted to identify comparisons based on 'predominant' and 'exclusive' composition of the diet where possible." (Spector Rep. [60-1] at 9, n.4.) His study "endeavored to compare the relative risk of developing NEC between children exposed to: (1) predominantly (i.e. over 50% HM) and those who received [CMBF] (e.g. formula or fortifier); and (2) [CMBF] (e.g., fortifier) and those who received predominantly higher [CMBF] (e.g., formula)." (*Id.* at 10.) Assuming diet is measured across all feedings, D.B. falls into the category of infants fed "human milk" as Dr. Spector himself defines that group.

The court once again faces the question of how to measure D.B.'s diet.[13] While D.B. was fed human milk for the first nine weeks of his life, he received mixed and formula-only feedings only in the last four days of his life. Consequently, the ratio of CMBF to human milk or HMBF changes depending on when one begins measuring D.B.'s diet. Dr. Spector himself has not

[13] The court previously ordered Dr. Makuch, Abbott's expert who is expected to testify in this case, to supplement his report to explain why measuring an infant's feeding ratio over their lifetime is appropriate (Order [685] in Master Docket, 22 C 71), and he has done so. (Makuch Supp. Rep. [693] in Master Docket, 22 C 71.)

clearly defined his method for determining whether an infant was "predominantly" fed human milk or CMBF. From the court's review of the studies he considered, it appears that they generally began measuring feedings from close to birth or the first enteral feed, and ended measuring feedings at the earlier of a list of set events, like the passage of a certain amount of time, discharge from the hospital, hospital transfer, death, or the onset of NEC. Plaintiffs have argued for a focus on the feeding ratio beginning when an infant first received CMBF; but the methods of measurement described in the studies appear more consistent with Abbott's description than with the one for proposed by Plaintiffs' attorneys: that is, the studies Dr. Spector considered measured diet over the course of all feeds, rather than from the first feed of CMBF.

Dr. Spector admitted he did no specific analysis of a diet like D.B.'s and would present no opinion on it at trial. (Spector Dep. [60-3] at 358:2-9.) Dr. Spector did not expressly limit his opinion to infants that are predominantly fed CMBF,[14] but if his opinion were to be offered in this case, the court might well share Abbott's concern "that there is simply too great an analytical gap between the data and the opinion proffered." *C.W. ex rel. Wood*, 807 F.3d at 832. Plaintiff suggests the real question is whether D.B.'s ingestion of SSC-24 formula for the first time, just days before his death, is what triggered NEC. But Dr. Spector did not answer that question; his opinion appears to be predicated on the assumption that the infant is receiving predominantly

---

[14] Specifically, he testified to the following:

> Q. And what is your ultimate opinion in this case?
> A. My ultimate opinion is that bovine-based nutrition products, that the rate of NEC is increased among infants – premature infants who consume bovine-based nutrition products.
> Q. And is that limited to particular ratios of formula versus human milk, for example, just as Mr. Saxon went through some of those subcategories?
> . . .
> A. As I've repeatedly stated today, qualitatively I can say that more leads to more risk, but I cannot give solid points of, you know, quantitative amounts because the literature did not support that kind of analysis.

(Spector Dep. [616-3] in Master Docket, 22 C 71, at 361:15-362:10.)

formula over the course of *all* feedings, not just those immediately prior to death. *Cf. Owens v. Auxilium Pharms., Inc.*, 895 F.3d 971, 973 (7th Cir. 2018) (affirming exclusion of a causation expert who gave an "opinion about a hypothetical high-risk patient using" the medication at issue at certain doses, when the plaintiff took lower doses). His opinion may not be helpful to a jury in this case, where the infant received just 10% CMBF.

Dr. Spector's opinion may nevertheless be admissible as to D.B.—but there remain serious concerns about Plaintiffs' evidence on causation generally. Plaintiff has the burden of presenting evidence from which a reasonable jury could conclude, more likely than not, that Abbott's formula could and did cause D.B.'s NEC. None of Plaintiffs' experts have offered an opinion on whether a diet of just 10% CMBF (as defined by Defendants and the cited studies) can cause NEC.

On the issue of specific causation, the fact finder is left only with Dr. Flanigan's differential diagnosis. Differential diagnosis is an acceptable methodology—the Seventh Circuit has held that it can satisfy the *Daubert* standard if the opinion is "based on scientifically valid decisions as to which potential causes should be 'ruled in' and 'ruled out,'" with timing alone being insufficient to show causation. *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007) (citing *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005)). But Dr. Flanigan's testimony raises concerns as well; Dr. Flanigan has ruled out various alternative causes of NEC but provides no clear explanation for that determination beyond timing. *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 826 (7th Cir. 2010) (affirming exclusion of expert where he ruled out causes based "solely on his past experience and the temporal proximity"). For example, she acknowledges that one NEC risk factor is antibiotic use but rules it out as relevant in D.B.'s case by simply stating that despite his early course of antibiotics, he "was otherwise remote from antibiotic use." (Flanigan Rep. [68-7] at 12, 20.) She acknowledges that infection is a risk factor, as well, and that D.B.'s urine culture on September 15, 2021 showed the presence of *Klebsiella pneumoniae*, but states without citation that it was due to "possible contamination" in an "uncircumcised male

infant." (*Id.* at 12, 15.) Her ultimate conclusion is that "the temporality of initiation" of SSC-24 "strongly supports a temporal relationship and allows to a reasonable degree of medical certainty that the provision of [CMBF was] a substantial causative factor in [D.B.'s] development of NEC." (*Id.* at 23.) She states—with no citation besides studies showing that formula-fed infants are more likely to develop NEC—that formula feeding "is generally accepted as the most significant modifiable risk factor for NEC." (*Id.* at 12.) That formula feeding is the most significant modifiable risk does not on its own establish that formula feeding was the reason that D.B. became ill. Her opinion thus appears to rest largely on temporality and her experience to rule out the other risk factors of NEC from which D.B. suffered, a potentially questionable methodology at best.

The court notes its concerns about this testimony but, for now, assumes it is sufficient to reach the jury on the question of causation. As explained below, Abbott has shown it is entitled to summary judgment for other reasons.

B. Alternative Designs

As set forth above, the LPLA requires that products-liability plaintiffs present evidence that "*[t]here existed* an alternative design for the product that was capable of preventing the claimant's damage." LA. STAT. ANN. § 9:2800.56(1) (emphasis added). Abbott argues that Plaintiffs have not met that burden. In assessing this argument, the court notes, first, that Louisiana law sets a low bar on this issue: That an alternative "existed"

> does not mean that the alternative design must have been manufactured and in actual use when the manufacturer distributed his product. Nor does it mean that the alternative design must have been feasible, i.e., could have been employed even if it was not, at that time. But "existed" does mean that the alternative design must at least have been conceived at the time the product left its manufacturer's control.[15]

[15] While this quote is itself taken from a law review article, courts applying Louisiana law continue to cite the article as an "authoritative interpretation" of various provisions of the LPLA. *Hunt v. McNeil Consumer Healthcare*, 297 F.R.D. 268, 273 (E.D. La. 2014); *Wilson v. Hobart Corp.*, No. 95-2279, 1996 WL 117502, at *1–*2 (E.D. La. Mar. 15, 1996); *Lavespere v. Niagara Mach. & Tool Works, Inc.*, 910 F.2d 167, 179 n. 50 (5th Cir. 1990), *abrogated on other grounds*, *Little v. Liquid Air Corp.*, 37 F.3d 1069 (5th Cir. 1994); *Scott*, 2025 WL 786035, at *4; *Summers v. FCA US LLC*, No. CV 23-1777, 2024 WL 3925169, at *7–*8 (E.D. La. Aug. 23, 2024).

Moyer v. Siemens Vai Servs., LLC, No. 11-3185, 2013 WL 3293668, at *9 (E.D. La. June 28, 2013) (quoting John Kennedy, *A Primer on the Louisiana Products Liability Act*, 49 LA. L. REV. 565, 596 (1989)). True, the "alternative design must be reasonably specific and not based on mere speculation." *Perrilloux v. Kubota Corp.*, No. 21-1532, 2024 WL 4346422, at *2 (E.D. La. Sept. 30, 2024) (citation omitted). But Louisiana courts nevertheless have interpreted the "existence" requirement generously in favor of products liability plaintiffs. *Dixon v. Home Depot, U.S.A.*, No. 13-2776, 2015 WL 2254861, at *6 (W.D. La. 2015) (finding, under the LPLA, an "alternative design 'existed' if it was 'at least conceived at the time the product left the manufacturer's control'" (citation omitted)); *Perrilloux*, 2024 WL 4346422, at *3 (similarly finding that plaintiff's alternative design burden is low); *Moyer*, 2013 WL 3293668, at *9 (same).

Plaintiffs' presentation on this score is troubling even under this generous standard. Plaintiffs have identified "Prolacta" as a potential alternative design, (Opp. [69] at 8), but have not been clear about whether this is a reference to Prolacta *formula* or Prolacta *fortifier*.[16] The distinction is important, as the products serve distinct purposes. Fortifier is added to human donor milk to supplement it with additional nutrients and proteins that premature infants require (and usually receive from the placenta), but are absent from breast milk. (Martin Rep. [59-18] at 10.) Formula, on the other hand, serves as a complete replacement for human milk, and, like CMBF, is used when donor milk is unavailable. *See Mar*, 2025 WL 1282749, at *5 & n.10 (discussing the distinction). Plaintiffs' briefing does not engage with the difference between the two products, and their presentation at oral argument was similarly unilluminating.[17] As explained below, the court

[16] Plaintiffs' failure to specificy which Prolacta product they are referring to is puzzling, as this court noted the same problem in the *Mar* opinion. "Plaintiff does not clarify whether it is Prolacta fortifier or Prolacta formula that she is claiming was an alternative design to SSC24—she refers only to 'Prolacta' in general terms. 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." *Mar*, 2025 WL 1282749, at *6.

[17] On this point, at oral argument, counsel for Plaintiffs stated only the following: "Defendants, however, we understand are arguing that there's a fortifier or formula issue. We –

concludes that summary judgment is warranted under either alternative, albeit for different reasons.

1. Prolacta Fortifier

First, as to fortifier—to put it simply, fortifier is not an alternative design to formula because the two are entirely separate products. As the court explained in *Mar*, "it is a basic matter of tort principles than an 'alternative design must not be an altogether essentially different product.'" *Id.* at *6 (quoting *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 549 (S.D. W. Va. 2011)). Because fortifier and formula serve distinct purposes, "there is little dispute that fortifier is a different *class* of product from formula." *Id.* Thus, to the extent that Plaintiffs argue that fortifier is an alternative to SSC-24, this claim fails at the threshold because Plaintiffs cannot show that fortifier is an "alternative design," which the LPLA requires as part of a plaintiff's prima facie case. *See* LA. STAT. ANN. § 9:2800.56 (requiring that "[t]here exist[] an alternative design").

As many courts have recognized, drawing the line between different products and different designs is difficult. This is especially true in cases involving healthcare products, as small differences between two products might constitute different treatment options most appropriately entrusted to the care and expertise of a doctor. For example, in *Theriot v. Danek Med., Inc.*, 168 F.3d 254 (5th Cir. 1999) (per curiam), the Fifth Circuit considered an LPLA claim by a plaintiff who alleged that the pedicle screws used in his spinal surgery were defective. *See id.* at 255. As an alternative design, the plaintiff identified alternative surgical procedures that did not use pedicle screws, such as "external neck braces or internal systems that use hooks or wires." *Id.* But, as the Fifth Circuit pointed out, removing the pedicle screws rendered the surgery an entirely different procedure. Even if these methods made the surgery safer, the claim in fact took "issue with the

---

that's not applicable to our case. This isn't a 2014 case. This is a 2021 case." (Oral Arg. Tr. [95] at 40:23–41:2.) The court understands this to be an assertion that Plaintiffs are referring to formula, which Prolacta developed at some point between 2014 and 2021. Yet the single paragraph in Plaintiffs' brief about human-milk-based products cites records that appear to relate to fortifier. (*See* Opp. [69] at 8.)

choice of treatment made by [the plaintiff's] physician, not with a specific fault of the pedicle screw." *Id*; *see also Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 722–23 (E.D. Pa. 2014) (finding that acetaminophen and ibuprofen are "entirely different product[s]").

True, these cases are fact dependent, and in many cases, the issue must be submitted to the jury. *See Mar*, 2025 WL 1282749, at *6 (recognizing that this may be a jury question); *Kimball v. RJ Reynolds Tobacco Co.*, No. C03-664JLR, 2006 WL 1148506, *3 (W.D. Wash. Apr. 26, 2006) (same); *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 900 (E.D. Va. 2010) (same). In cases where the two products have identical purposes, but differ on the basis of quality, durability, effectiveness, or a similar characteristic, jury consideration is the appropriate mechanism for answering this difficult question. In *In re DuPuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 767 (5th Cir. 2018), for example, the Fifth Circuit declined to find, as a matter of law, that a "metal on plastic" hip replacement was a different product from a more durable "metal on metal" device. Because the metal-on-metal construction was distinguished by virtue of its more durable construction, the court held that the true dispute was whether the alternative design had *utility*, not whether it existed at all. *See id.* ("Where the distinction is one of degree only, the risk-utility framework provides the proper mode of analysis.").

In this case, however, the court has no difficulty concluding that fortifier and formula are different products. Formula serves an important role in the NICU—it provides sustenance to the massive nutritional needs of preterm infants in the absence of human milk from either a donor or mother. Abbott's choice to manufacture fortifier could not meet the needs of these infants. As Abbott points out, comparing the two is analogous to "alleging a design defect in champagne by arguing that the manufacturer should have made sparkling cider instead." (Mem. [58] at 28 (quoting *City of Philadelphia v. Lead Indus. Assocs.*, No. 90-7064, 992 U.S. Dist. LEXIS 5849, at

*9 (E.D. Pa. Apr. 23, 1992).) Because they have entirely different purposes, no reasonable jury could conclude that Prolacta fortifier is an alternative design to Abbott's formula.[18]

Because the existence of an alternative design is part of Plaintiffs' prima facie case under the LPLA, Plaintiffs bear the burden of presenting evidence that fortifier is an alternative to Abbott's formula product. *See Celotex*, 477 U.S. at 322–24. Plaintiffs have made no apparent effort to meet this burden. Their briefs make no mention of the distinction between formula and fortifier, do not engage with Abbott's contentions that fortifier is a "different product," and make no attempt to distinguish this court's discussion of the issue in the *Mar* opinion, which granted summary judgment to Abbott. *See Mar*, 2025 WL 1282749, at *6 ("[T]here is little dispute that fortifier is a different *class* of product from formula like SSC24."). Instead, the only evidence Plaintiffs refer to that touches on Prolacta are documents that, as Plaintiffs see things, suggest that Abbott internally viewed manufacturing fortifier as feasible. (*See* Opp. [69] at 8–10; PSOF [68] ¶¶ 27–38.) However, the feasibility of Abbott's potential manufacture of Prolacta—or a Prolacta fortifier-like product—would be relevant to this case only if Plaintiffs could make a threshold showing that fortifier is a genuine alternative to infant formula. They have not done so here.

2. Prolacta Formula

That leaves the question of whether Prolacta *formula* was an alternative to Abbott's formula product. Abbott's initial argument on this score is that cow's-milk-based formula and human-milk-based formula are also "different products" or "different treatments." (Mem. [58] at 27–28.) This argument has merit with respect to fortifier. There may also be a sense in which

[18] In *Burks v. Abbott Lab'ys, et al.*, No. 08-3414, 2010 WL 1576779 (D. Minn. April 20, 2010), the District of Minnesota reached a similar conclusion. In that case, which applied Louisiana law, the plaintiffs alleged that Abbott's powered formula product was defective; they put forward liquid formula as an alternative design. The court did not rule definitively on whether it qualified as an alternative design under the LPLA, but suggested it did not, noting that "it appears that liquid infant formula is a different product entirely than powdered infant formula, with unique qualities and advantages or disadvantages." *Id.* at *4.

cow's-milk-based formula is not a true alternative and is appropriately used only where human milk and human-milk-based formula is unavailable.[19] Still, the parties appear to agree that cow's milk-based formula and human milk-based formula are used in the NICU for similar (if not identical) purposes. In the court's view, this issue is, then, a jury question; a reasonable jury could find that Prolacta formula is an "alternative design" to SSC-24 within the meaning of the LPLA.

Abbott next contends that Plaintiffs cannot establish the existence of an alternative design under the LPLA because they have no evidence that human-milk-based formula is a feasible alternative to CMBF. (Mem. [58] at 28–29.) Here, Abbott relies heavily on this court's ruling in *Mar v. Abbott Lab'ys*, No. 22 C 00071, 2025 WL 1282749 (N.D. Ill. May 2, 2025), where this court found that, under West Virginia law, Prolacta formula was not a feasible alternative design to SSC-24.[20] West Virginia law squarely required Plaintiff Mar to present evidence not only that an alternative existed at all, but that Prolacta was a "feasible" alternative that was "existing at the time the subject product was made." But Mar offered "*no evidence* as to feasibility," and Prolacta formula did not exist at the time of the infant's death, so summary judgment was warranted.[21] *See id.* at *6.

---

[19] Abbott argues that cow's-milk-based formula places an important and unique role in the NICU, given that it is cheaper and more widely available than Prolacta formula or donor milk. (Mem. [58] at 27–29.) This argument has merit; as explained below, production of a human-milk-based formula like Prolacta is challenging because it also relies on donor milk, a scarce resource. Because the existence of an alternative design is, as the court has established, a very low bar, *see Dixon*, 2015 WL 2254861, at *6; *Perrilloux*, 2024 WL 4346422, at *3; *Moyer*, 2013 WL 3293668, at *9, Abbott's arguments on this point are better suited for the risk-utility balancing inquiry.

[20] The record is sparse on detail relating to Prolacta formula. As the court has explained, it appears that Prolacta formula was introduced to the market in 2014, but it is unclear even now how widely it is available or whether it was available to D.B. *Cf. Mar*, 2025 WL 1282749 at *6 ("On this record, the court is left guessing at the complexity of manufacturing Prolacta formula, and whether it has ever been produced at a large scale.")

[21] As the court then explained: "Plaintiff Mar has submitted no documents explaining how Prolacta is manufactured, no testimony from a Prolacta witness or representative, and no expert testimony opining on the feasibility of producing Prolacta given donor milk supply, intellectual property protections, and production costs." *Mar*, 2025 WL 1282749 at *6.

This case differs in certain ways. First, Louisiana law does not require any evidence on feasibility as part of the plaintiff's prima facie defective-design case. The statute instead only requires the plaintiff to put forward evidence that "[t]here existed an alternative design for the product"—not necessarily that the design be a feasible one. LA. STAT. ANN. § 9:2800.56(1). Many courts in Louisiana have so stated. *See, e.g.*, *Sisk v. Sears, Roebuck & Co.*, 959 F. Supp. 337, 339 (E.D. La. 1996) ("Thus, feasibility is not an issue except as an affirmative defense once the plaintiff has established the elements set out by § 2800.56, including that the alternative design was in existence."); *Moyer*, 2013 WL 3293668, at *15 ("Lack of feasibility is an affirmative defense for the manufacturer, and does not become relevant unless and until the plaintiff establishes the three elements of her alternative design claim.").[22] Further, the facts are also different—unlike in *Mar*, Prolacta formula was available on the market at the time that D.B. died in 2021.[23]

In the LPLA, feasibility is part of the analysis, but is addressed in a separate provision, § 9:2800.59(3), which recognizes that the *in*feasibility of an alternative is an affirmative defense on which the manufacturer bears the burden of proof.[24] *See Sisk*, 959 F. Supp. at 339. A party

---

[22] *See* John Kennedy, *A Primer on the Louisiana Products Liability Act*, 49 LA. L. REV. 565, 596 (1989) ("Nor does [the LPLA] mean that the alternative design must have been feasible, i.e. could have been employed even if it was not, at that time.").

[23] Like West Virginia, Louisiana requires that an alternative design be existing at the time that the subject product was made. *See* LA. STAT. ANN. § 9:2800.56. Plaintiffs have offered no more information about Prolacta *formula* than was before the court in *Mar*, but it appears undisputed that Prolacta was in existence by 2021. *See infra* at 4 n. 6.

[24] Abbott acknowledges that Louisiana law treats feasibility as an affirmative defense, but nonetheless insists that, under the LPLA, feasibility evidence ought to be considered within the plaintiff's prima facie risk-utility showing. (Reply [83] at 11.) In its view, because the statute instructs courts to consider "the burden on the manufacturer," LA. STAT. ANN. § 9:2800.56(2), as part of the prima facie case, the LPLA "in substance" places the burden on plaintiff to show feasibility. (*Id.* at 6.) The court disagrees. As many Louisiana courts have held, the LPLA does not—in substance or otherwise—place the burden of proving feasibility on the plaintiff. LA. STAT. ANN. § 9:2800.59(3); *see, e.g.*, *Sisk*, 959 F. Supp. at 339; *Moyer*, 2013 WL 3293668, at *15. Abbott's reading would render the affirmative defense redundant, which is a disfavored outcome. *See United States v. Berkos*, 543 F.3d 392, 396 (7th Cir. 2008). While there is certainly "overlap between the plaintiff's proof of a prima facie case and the manufacturer's proof of an affirmative defense," the LPLA keeps both inquiries separate and distinct. 1 Louisiana Tort Law § 15.10.

can move for summary judgment on an affirmative defense, but in such cases, the bar is higher. Instead of showing that the plaintiff has no evidence in support of their position, *see Anderson*, 477 U.S. at 252, the defendant must affirmatively put forward evidence that is so "one sided that [it] must prevail as a matter of law." *Reserve Supply Corp v. Owens-Corning Fiberglas Corp.*, 971 F.2d 37, 42 (7th Cir. 1992) (cleaned up); *Johnson,* 651 F.3d at 662 (same); *El v. Southeastern Penn. Transp. Auth.*, 479 F.3d 232, 237 (3d Cir. 2007) (party moving for summary judgment on an affirmative defense "must show that it has produced enough evidence to support the findings of fact necessary to win"). Abbott is entitled to summary judgment on its affirmative defense only if it meets this substantial burden.

The court concludes that in this case Abbott has done so, by presenting substantial and unrebutted evidence that Prolacta formula is not in fact a feasible alternative to SSC-24. Abbott has presented the expert opinion of Dr. Starc, a healthcare economist, who analyzes "whether the supply of human milk and human milk products has been sufficient to meet the nutritional demand of premature infants" in the United States. (Starc Rep. [59-41] at 8.) As Dr. Starc explains in detail, in order to replace SSC-24 with a human-milk formula, Abbott would need vast amounts of milk from human donors. As explained in her report, the supply is simply not available. Dr. Starc notes that from 2010 to 2022, the "shortfall of human milk and human milk products exceeded 215 million mL per year," meaning that 62,000 infants would have been unfed "in the absence of cow's milk-based preterm infant formula." (*Id*. at 9.) Assuming that Abbott could, like Prolacta, produce a human-milk-based formula, Abbott would still have to find a way to increase the available supply of human milk from donors.

As Dr. Starc further explained, doing so would be extremely difficult. Many systemic issues constrain the supply of donor milk. Because only women who lactate can serve as donors, a mother can donate milk only for a short period of time, meaning that milk banks must constantly recruit new donors. Recruiting donors itself is difficult because many women do not qualify; existing regulations disqualify donations from lactating women who are vegan, smoke, have

tattoos or piercings, or have certain communicable diseases. (*Id.* at 59.) Those women who do qualify might well be unwilling to undergo the intense tests and screenings necessary to become a donor, might be anxious about their ability to provide adequate milk for their own infant, or might be unable to meet a milk bank's volume requirement.[25] (*Id.* at 56–57.) And that says nothing of the intense time commitment required to pump, store, and transmit the milk to the milk bank—Dr. Starc estimates that pumping alone could take up to two hours a day. (*Id.* at 60 & n.200.)

Perhaps Abbott could find ways to address or mitigate these problems. Even so, Dr. Starc's analysis suggests it would be impossible for Abbott to expand the supply of donor milk to the scale necessary to phase out cow's-milk-based formula. Milk banks typically rely on the altruism of their donors to encourage them to donate. (*Id.* at 56.) Abbott, a for-profit pharmaceutical company, would have little standing to encourage altruism on the part of milk donors. And any proposal to pay women for milk donations would face obvious ethical obstacles: Milk donation could jeopardize the nutrition of the donor's own infant. (*See id.* at 56–57.) Because the mothers most likely to be motivated by the prospect of payment are also likely to be of limited means, the negative consequences for their own infants could be magnified. According to Dr. Starc, while some companies (including Prolacta) do provide payments to their donors, the amount is very low—these token payments seem designed more to compensate mothers for their time than to incentivize donations.[26] (*See id.* at 56 (describing Prolacta's approach); *id.* at 60–61 (explaining the modest financial gain to donors).)

---

[25] According to Dr. Starc, some banks require donors to "contribute at least 100 ounces per donation." (Starc Rep. [59-41] at 58.) She estimates that most women have between 7–11 ounces left over per day after feeding their own infant. Based on this, many donors must keep and store milk for a week or longer in order to meet the volume requirement.

[26] Once again, all of the court's information on Prolacta—including this evidence on the company's business model, its product offerings, and its clinical use—comes from Abbott. Plaintiff has put forward *no* evidence relating to any of this; indeed, her brief entirely ignores Dr. Starc's conclusions and Abbott's extensive argument on this issue. Perhaps a different case, with a more developed record, would proceed to trial. But based on the sparse evidence available here, summary adjudication is appropriate.

Indeed, Miles White, Abbott's former CEO, said as much in a deposition. When asked about the feasibility of producing a human-milk product at scale, he said:

> [I]magine that you have to go out and find an enormous quantum leap in the numbers of lactating mothers, persuade them by paying them to give their milk, which could go to their own babies, to give their milk to a company to create a product that you can't scale because you can't get that many [women] without impacting their own babies and without impacting lower socioeconomic populations, that's not scaleable [sic].

(White Dep. [59-52] at 139:23–140:7.)

The supply of donor milk is not the only barrier. Insurance coverage, including Medicaid coverage, of human-milk products is spotty at best, so it is unclear who would bear the likely substantial expense of ramping up donor milk supply. (Starc Rep. [59-41] at 68.) There are also logistical concerns, as collecting milk, manufacturing product, and distributing formula could be unrealistically expensive endeavors. But most importantly: even if Abbott were able to procure donor milk, there would certainly be some intermittent shortfalls in the supply of donor milk and, thus, human-milk formula. This means that cow's-milk-based formulas, including SSC-24, will remain essential products until the production of human-milk formula is sufficient to eliminate any risk of shortfalls in all NICUs nationwide.

Abbott bears the burden to show infeasibility. Plaintiffs thus might be able to survive summary judgment on this affirmative defense by offering their own evidence of feasibility, or even by calling Abbott's feasibility arguments into question. Plaintiffs have not done so. *See Mar*, 2025 WL 1282749, at *7. They have offered no evidence as to the feasibility of recruiting new donors, the logistics of producing human-milk formula at the scale necessary, or even any testimony as to how human-milk formula is manufactured. Moreover, it is not clear even now whether Prolacta formula is a product that is widely available at all. Nor have Plaintiffs suggested any other chemical formulation or design that would mitigate the NEC risk associated with SSC-24.[27]

[27] The court notes that Abbott has moved *in limine* to bar the testimony of Plaintiffs' proposed witness, Dr. Buddington. Plaintiffs assert that Buddington would testify as a fact witness that he "told Abbott employees in 2020 about a NICU in India that supposedly eliminated NEC

Plaintiffs' only response is a cursory citation to internal documents from Abbott, which they argue show that Abbott internally viewed manufacturing Prolacta as feasible. This court disagrees with this characterization of these documents, but in any event, they are not relevant to this question as they relate to Prolacta *fortifier*, not *formula*. (*See* PSOF [68] ¶¶ 27–29; PSOF [68] Exs. 5, 10, 14, 15, 17, 18.)

The lack of evidence or argument from Plaintiffs relating to the feasibility issue is particularly disappointing, considering that it took center stage in both Abbott's brief and the court's *Mar* decision. *See Mar*, 2025 WL 1282749, at *6 ("Plaintiff has presented *no evidence* as to feasibility."). Instead, as in *Mar*, the court is "left guessing" as to Plaintiffs' responses to these arguments, leaving nothing from which the court can draw a favorable inference to allow this case to proceed to trial. *See id.*

In short, to meet the needs of the nation's NICUs, the proposed alternative to a cow's-milk-based infant formula would require a dramatic increase in the supply of human donor milk. If such an increase were possible at all, it would be prohibitively expensive, would raise serious ethical concerns, and would almost certainly require the availability of some CMBF as a backup. The court concludes that on this record, no reasonable jury would find that Prolacta formula is a feasible alternative to SSC-24.[28]

---

from their NICU by stopping the use of preterm formulas with glucose polymers." (Pl. Opp. to Mot. in Limine [97] at 6.) The proposed testimony raises obvious hearsay concerns and appears to relate to a failure-to-warn claim, which Plaintiffs have withdrawn. *Expert* testimony about a potential alternative formula design without glucose polymers might support a finding of a feasible alternative design. But Plaintiffs have not identified Buddington as an expert witness in this case, and neither side mentions this alternative in summary judgment submissions. Plaintiffs themselves assert only that "a human-milk based preterm formula was a feasible alternative for Abbott during the relevant time period." (Pl.'s Resp. [69] at 4.)

[28] The court also notes an additional concern: Dr. Flanigan and Dr. Sucre, two of Plaintiff's causation witnesses, seem to be referring exclusively to fortifier, *not* formula. When asked in a deposition, Dr. Flanigan explicitly said that her opinions were with reference to human milk fortified with Prolacta, not formula. (Flanigan Dep. [59-5] at 357:3–359:11.) And as the court explained in *Mar*, "Dr. Sucre's report only discusses Prolacta as a human-milk based fortifier, not formula." *Mar*, 2025 WL 1282749, at *6 n.11 (citing Sucre Rep. [60-24] at 16).

C. Risk-Utility Analysis

Abbott has argued that summary judgment is independently warranted for a second reason—that Plaintiffs have not met the second requirement for their prima facie case under the LPLA, which requires that they show that SSC-24's risk outweighs its utility. Again, as explained here, the court agrees.

Section 9:2800.56(2) of the LPLA requires the plaintiff to show that the "likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such design on the use of the product." LA. STAT. ANN. § 9:2800.56(2). This is known as the "risk-utility" balancing test, and it mirrors the test endorsed by the Third Restatement and subsequently adopted by many jurisdictions.[29]

Under this test, there is no exhaustive list of factors to consider. The statute lists the "likelihood . . . [of] damage," the "gravity of that damage," and the "burden on the manufacturer" as relevant, but this is not a complete list. LA. STAT. ANN. § 9:2800.56(2). The Fifth Circuit has held that the LPLA requires evidence of other factors, such as evidence "concerning the frequency of accidents like his own, the economic costs entailed by those accidents, or the extent of the reduction in frequency of those accidents that would have followed on the use of his proposed alternative design." *Krummel v. Bombardier Corp.*, 206 F.3d 548, 551 (5th Cir. 2000) (quoting *Lavespere*, 910 F.2d at 183; *see also McDaniel v. Terex USA, L.L.C.*, 466 Fed. App'x 365, 376 (5th Cir. 2012) (applying this same test). Moreover, "Louisiana law does not allow a fact finder to presume an unreasonably dangerous design solely from the fact that injury occurred." *McCarthy v. Danek Med., Inc.*, 65 F. Supp. 2d 410, 412 (E.D. La. 1999).

[29] The risk-utility test in use by many common-law jurisdictions across the country influenced the legislative drafters of the LPLA. *See* 1 Louisiana Tort Law § 15.10; Kennedy, 49 LA. L. REV. at 600.

Plaintiffs in this case have focused almost exclusively on the risk issue. They emphasize the testimony of the causation witnesses—Dr. Spector, Dr. Sucre, and Dr. Flanigan—who have opined extensively on the relationship between formula and NEC. Dr. Spector conducted a systemic literature review, noting that cohort studies showed that infants ingesting a predominantly cow's-milk-based formula diet had a 326% higher risk of NEC compared to infants ingesting predominantly human milk. (Spector Rep. [60-1] at 15.) Dr. Sucre analyzed the biochemistry of NEC, the digestive process, and the impact of the development of the digestive tract, ultimately concluding that there was a causal relationship between formula and NEC. (Sucre Rep. [60-24] at 24–37.) Dr. Flanigan conducted a differential diagnosis with respect to D.B. specifically, ruling out alternative causes of NEC and concluding that SSC-24 was the most important cause of his NEC. (Flanigan Rep. [68-7] at 24.)

However robust this evidence may be on the issue of *risk*, Plaintiffs have offered no evidence on *utility*. None of Plaintiffs' expert witnesses discuss the burdens associated with developing a human milk alternative or the effect that removal of SSC-24 would have on treatment options for premature infants. Other than the testimony of causation witnesses, the only evidence that Plaintiffs offer that is germane to the risk-utility test are the aforementioned Abbott internal documents. Plaintiffs argue that these documents show two things: (1) that they serve as an "acknowledgement" that "human-milk-based preterm infant products are safer than cow's-milk-based formulations," and (2) that Abbott "investigated" the "safer design" of Prolacta, but nonetheless "abandoned efforts to manufacture human-milk-based products." (Opp. [69] at 8–9.)

The court does not share Plaintiffs' view of the significance of these documents. There is no dispute that human milk is the preferred source of nutrition for tiny infants; Abbott has not argued otherwise. With respect to Abbott's consideration of Prolacta, all of the identified documents predate the 2014 introduction of Prolacta formula, and appear to relate to fortifier, which, as explained above, is not an alternative design. For example, Plaintiffs cite to one memorandum entitled "Recommendation to Acquire Prolacta Bioscience," arguing that it shows

the "feasibility of the alternative design." (Pl. Resp. to DSOF [67] ¶ 54.) But the document itself is clearly referring only to fortifier—it describes how an acquisition could "transform[] [Abbott] from the leader in infant formula to the leader in infant nutrition," implying that Abbott could improve its formula business by expanding into fortifier. (PSOF, Ex. 5 [68-5], at 1.) Likewise, in a separate memorandum, Abbott internally noted that it did not view Prolacta as a competitor, noting that "Abbott Nutrition's products compete against other brands of infant formula, not breast milk." (PSOF, Ex. 16 [68-16] at 3.) The fairest reading of this material is that it shows that Abbott viewed fortifier as a complimentary product, not a substitute. But even if these documents did refer to formula, it is not clear how they support Plaintiffs' case. At most, they show that Abbott investigated, and abandoned, efforts to make a human-milk alternative, a decision consistent with Abbott's claims of infeasibility. (*See* Reply [83] at 8.)

In contrast, Abbott has submitted substantial evidence on both risk and utility. Much of this the court has already discussed. Abbott characterizes its formula as a key part of the NICU doctor's toolkit, for use whenever mother's milk or donor milk or human milk products (perhaps even including Prolacta) are unavailable. (Mem. [58] at 11.) As explained above, Abbott (by way of Dr. Starc) contends that procuring human milk from donors is extremely expensive and difficult due to a myriad of economic, legal, ethical, and intellectual property obstacles. (*Id.* at 28–31.) Abbott also points to "serious public health concerns" that could arise if SSC-24 formula were removed from the market. (*Id.* at 28.)

In some cases, perhaps strong evidence of risk alone would be enough to tilt the scale in the plaintiff's favor—the court is not prepared to endorse Abbott's insistence that in every products liability case, the plaintiff must introduce evidence on the utility side of the scale. (*See* Mem. [59] at 29–32; Reply [83] at 9–11.) But Abbott's evidence in this record concerning the difficulty of substitution is so strong that the balancing supports summary judgment on the risk-utility scale. Formula is designed to serve as a replacement whenever donor milk or mother's milk is unavailable, so the product's utility is categorical, not marginal. (*See* Mem. [59] at 27–29.) Even

if human milk is always a safer option, SSC-24 still has utility by virtue of its widespread availability and important role as a backup nutrition source for an infant who otherwise has no feeding option. Because of this, even if Plaintiffs are correct, and formula can cause NEC, those risks cannot outweigh SSC-24's utility unless Plaintiffs put forward some evidence that shows that cow's milk formula is unnecessary—which they have not done. A lifeboat is not as safe as a cruise ship, but that fact alone does not render the lifeboat defective.

That Plaintiffs have not offered expert testimony on this issue is telling. *See Mar*, 2025 WL 1282749, at *6 (finding that plaintiff's expert opinions must be "understood in the context of their expertise and opinions"). As many cases under the LPLA have concluded, expert testimony is typically needed to allow the jury to properly determine whether a product is defective. *See Krummel*, 206 F.3d at 551–52. Because one "cannot balance items of indeterminate weight," experts must typically provide information such as "extent of the risk the alternative design would have avoided" and "evidence concerning the burden of the alternative design." *Lavespere*, 910 F.2d at 183 affirming summary judgment in favor of manufacturer of press brake where plaintiff's expert failed did not address the nature and extent of economic difficulties presented by the proposed alternative design). Plaintiffs' causation experts have addressed the risks posed by SSC-24; but Plaintiffs have offered no evidence on the design, the manufacturing process, or the costs associated with manufacturing human-milk formula, or on the feasibility of acquiring donor milk—all of which are crucially important to risk-utility balancing. *See Mar*, 2025 WL 1282749, at *6.

True, as the Fifth Circuit observed in *Lavespere*, there are some cases where expert testimony on these matters is unnecessary. In that case, the plaintiff alleged that a hydraulic press brake, a machine used to bend or cut meal parts, was defective. *Lavespere*, 910 F.2d at 170. The court noted:

> In arriving at this result, we do not mean to suggest that the plaintiff must, in every case, introduce evidence that details and quantifies the risk avoided and the burden incurred in order to prevail under the defective design theory set out in the

> LPLA. As courts in other jurisdictions that have placed on plaintiffs the burden of proof on the risk-utility issue have suggested, there may be cases in which the judge or the jury, by relying on background knowledge and "common sense," can "fill in the gaps" in the plaintiff's case, estimating the extent of the risk avoided, the costs of implementing the proposed design change, or the adverse effects of the design modification on the utility of the machine. For this to be possible, however, the product itself, or at least the design feature in question, must be relatively uncomplicated, and the implications of the change in design must be such that a layman could readily grasp them.

Id. at 184; *see also McKey v. Gen. Motors Corp.*, 691 So.2d 164, 170 n.2 (La. Ct. App. 1st Cir. 1997) (citing *Lavespere* in affirming summary judgment where plaintiff had presented no evidence on "the issue of alternative designs, the effect of alternative designs, or whether the risk avoided by such designs outweighed the burden of adopting the designs . . . ."). But this is not one of those cases. The products are complex; the evidence on risk is derived from difficult-to-understand scientific evidence; and weighing risk and utility requires assessing complicated evidence as to risk, complex industry factors, and the interplay of ethics and human biology. *See McKey*, 691 So.2d at 170 (requiring expert testimony in a case involving an automobile); *Graham v. Hamilton*, No. CIV.A. 3:11-609, 2012 WL 1252590, at *7 (W.D. La. Apr. 12, 2012) (same); *Dixon*, 2015 WL 2254861 at *7 (quoting *Graham*, 2012 WL 1252590, at *6–*7) (applying the same reasoning, in a case involving a table saw). This is not a case where jurors' "background knowledge" and "common sense" can provide the answers.

The court concludes that Plaintiffs have not met their burden as to the risk-utility element of the LPLA.

II. Loss of Consortium

Plaintiffs also bring a loss of consortium claim under Louisiana law. Under state law, loss of consortium is a derivative claim, meaning that it rises and falls with the underlying products liability action. *See Williams v. Genesis Energy, LLC*, No. 20-35-JWD-EWD, 2021 WL 1227873, at *13 (M.D. La. March 31, 2021) "A loss of consortium claim is a derivative claim and cannot be maintained if the primary claim is not viable as a matter of law."). Because the court grants

summary judgment on the LPLA claim, the court must also grant summary judgment on the loss of consortium claim.

CONCLUSION

Abbott's motion for summary judgment [57] is granted. The Clerk is directed to enter judgment in favor of Abbott and against Plaintiffs. Remaining motions are stricken without prejudice as moot.

ENTER:

Dated: October 23, 2025

REBECCA R. PALLMEYER
United States District Judge