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:	**Hon. Rebecca R. Pallmeyer**
Inman v. Mead Johnson & Company, LLC, et al.	
Case No. 22 C 3737	

MEMORANDUM OPINION AND ORDER

On May 12, 2020, Plaintiff Alexis Inman delivered her son Daniel at 29 weeks gestation. Weighing less than two pounds at birth, Daniel was classified as "very premature" and kept in the neonatal intensive care unit ("NICU"). Daniel was initially fed his mother's breast milk, but later, his doctors switched him to Enfamil Premature Formula ("Enfamil Premature" or "EPF"), a formula product manufactured with cow's milk by Defendant Mead Johnson & Company, LLC ("Mead Johnson" or "Mead"). Days later, Daniel developed necrotizing enterocolitis ("NEC"), a devastating and often fatal condition marked by inflamed and necrotic intestinal tissue. Daniel died shortly thereafter. Inman brings this products liability lawsuit against Mead Johnson, alleging that Enfamil Premature caused Daniel to develop NEC, that Mead failed to warn against this risk, and that feasible alternative formulations of Enfamil Premature existed and would have reduced the risk of NEC.

This case is one of hundreds of similar lawsuits that have been consolidated in a multidistrict litigation ("MDL") before this court. By agreement of the parties, this case was selected as the fourth in an initial wave of "bellwether" trials, designed to provide helpful guidance for many other cases in this MDL. Mead Johnson & Company has moved for summary judgment [56]. As explained below, this motion is denied. Mead Johnson Nutrition Company ("MJNC") has

also moved for summary judgment [54] on the basis that it had no involvement in the manufacture or sale of Enfamil Premature. That motion is granted.

BACKGROUND

I. Factual Background

The facts laid out below are taken from the parties' respective Local Rule 56.1 filings, as well as the record evidence submitted by both parties.[1] As it must at summary judgment, the court takes disputed facts in the light most favorable to the non-moving party. *See In re Greenpoint Tactical Income Fund LLC*, 168 F.4th 1002, 1007 (7th Cir. 2026).

A. Daniel's Delivery and Feeds

This case arises out of the tragic death of a preterm infant. On May 12, 2020, Plaintiff Alexis Inman gave birth to twin boys, Daniel and Deyvon, at Vidant Medical Center in Greenville, North Carolina. (DSOF [57-1] ¶ 20.) The twins' delivery followed what both parties characterize as a "high-risk pregnancy." (*Id*. ¶ 19 (undisputed in relevant part).) Inman's pregnancy was "complicated by several factors," including monochorionic-diamniotic gestation, severe selective fetal growth restriction, and twin-to-twin transfusion syndrome. (*Id.*) As Dr. Chandani DeZure,[2]

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[1] Two Mead Johnson entities are Defendants in this case: Mead Johnson & Company, LLC ("MJC"), and Mead Johnson Nutrition Company ("MJNC"). Both MJC and MJNC filed a joint Local Rule 56.1 Statement of Material Facts cited here as "DSOF [57-1] ¶ ___." Inman's Response to this Local Rule 56.1 Statement is cited here as "Pl.'s Resp. to DSOF [77] ¶ ___." Inman has also submitted an Additional Statement of Facts regarding Defendants' joint motion for summary judgment, which was amended on February 25, 2026, cited here as "PSOF [117] ¶ ___." Defendants' Response to Inman's Additional Statement of Facts is cited here as "Defs.' Resp. to PSOF [96] ¶ ___." MJNC filed a separate Local Rule 56.1 Statement of Material Facts in support of its motion for summary judgment, cited here as "MJNC SOF [54-2] ¶ ___." Inman's Response to this Local Rule 56.1 Statement is cited here as "Pl.'s Resp. to MJNC SOF [71] ¶ ___." Inman has also submitted an Additional Statement of Facts regarding MJNC's motion for summary judgment, cited here as "PSOF on MJNC MSJ [70] ¶ ___."

[2] Dr. DeZure is a board-certified attending physician at Stanford University's Lucile Packard Children's Hospital. She practices regularly in the neonatal intensive care unit ("NICU"), where she supervises medical students, residents, and fellows. She has cared for tens of thousands of premature infants over her career, including 50–100 infants with NEC. The court heard Dr. DeZure's testimony at a *Daubert* hearing and denied Mead Johnson's motion to exclude her testimony. *See* DeZure Daubert Order [113], No. 22 C 3737, 2026 WL 446330 (N.D. Ill. Feb. 17, 2026).

Plaintiff's specific causation witness, explained, this means that Daniel and Deyvon shared a single placenta, causing Deyvon to develop at the expense of Daniel. (DeZure Hearing Tr. [111] at 40:4–10.) Accordingly, Deyvon weighed 1278g at birth, while Daniel weighed just 670g. (DSOF [57-1] ¶ 22.) In addition, Ms. Inman suffered from maternal Rh alloimmunization (*id.* ¶ 19), meaning that the infant's "blood types and blood proteins" did not "mix" with his mother's, causing the fetus's immune system to attack those cells. (DeZure Hearing Tr. [111] at 40:15–19.) This led to Daniel's becoming anemic, even prior to his birth. He received six blood transfusions *in utero*, and nine after his birth. (DSOF [57-1] ¶ 23.) Combined, these factors rendered Daniel a very vulnerable infant. He was cared for by a medical team at Vidant consisting of Dr. Kelly Bear, a neonatologist; Dr. Brian Livingston, a pediatric hospitalist; and Jennifer Fowler, a nutrition expert. (DSOF [57-1] ¶ 66; Pl.'s Resp. to DSOF [77] ¶ 66; *see also* Bear Dep. [78-24] at 8:21; Livingston Dep. [78-50] at 7:20–22.)

After delivery, Inman chose to breastfeed both twins, as she had done with her prior children. This initially proved difficult. Ms. Inman already had one nursing infant at home, so producing enough to feed three infants was challenging. (DSOF [57-1] ¶ 25; Pl. Dep. [78-51] at 90:13–21.) Thus, for the first three days after their birth, both Daniel and Deyvon received donor human milk. (DSOF [57-1] ¶ 32.) A few days later, when Inman's milk supply increased, doctors began feeding her own milk to both twins. (*Id.* ¶ 34.) Beginning on May 19, doctors began fortifying Inman's breastmilk with a cow's-milk-based fortifier to increase its nutritional density.[3] (*Id.* ¶¶ 36–37.)

When Daniel was about two weeks old, his care team began to suspect that he had galactosemia—a genetic disorder that prevents the body from metabolizing certain sugars

[3] Fortifier is a product used to supplement human milk with additional nutrients. "[H]uman 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. To solve this problem, fortifier is added to human milk to supplement it with necessary nutrients." *Brown v. Abbott Lab'ys*, No. 22 C 2001, 2025 WL 2987083, at *2 (N.D. Ill. Oct. 23, 2025).

present in both human and cow's milk. (*Id.* ¶¶ 39, 40.) On May 25, doctors temporarily started Daniel on a course of Pregestimil and Nutramigen, two hypoallergenic formulas made from cow's milk, while they investigated his potential galactosemia. (DSOF [57-1] ¶ 41.) By June 3, Daniel's galactosemia test had come back negative, so the care team returned him to fortified mother's own milk. (*Id.* ¶ 44.) He continued to receive this feeding course through June 5.

On June 6, however, things changed. Daniel's care team switched him from fortified mother's milk to a mix of donor milk and Enfamil Premature Formula ("Enfamil Premature" or "EPF"), a product manufactured by Defendant Mead Johnson. (*Id.* ¶ 48.) Unlike fortifier, Enfamil Premature is intended to be a complete solution that can independently feed a premature infant without any human milk. It is manufactured using cow's milk, and is part of a class of products known as cow's-milk-based formulas ("CMBFs"). Daniel received a mix of donor milk and Enfamil through June 11, when—for reasons that are not at all clear from the record—Vidant staff took the additional step of removing donor milk from his feeds entirely. (*Id.* ¶ 50.) From June 11 through his death on June 23, Daniel was fed exclusively Enfamil Premature Formula.

Both parties agree this course of action took place (*id.* ¶ 48; Pl.'s Resp. to DSOF [77] ¶ 48), but they disagree as to the reason. Mead Johnson claims that formula was added to Daniel's regimen because his slow growth necessitated supplementation with formula to increase his protein and calorie intake. (DSOF [57-1] ¶ 53; Pl.'s Resp. to DSOF [77] ¶ 53.) Inman counters that the switch to formula was the result of mechanical application of a hospital feeding policy referred to by the parties as the "Roadmap"—a protocol that, according to Plaintiff, was adopted by Vidant largely as the result of (or heavily influenced by) Mead Johnson's marketing activity. (Pl.'s Resp. to DSOF [77] ¶ 66.) The Roadmap does state clearly that "maternal breast milk is the preferred option and mothers should be highly encouraged to pump." (Roadmap [63-4] at 2.) In the event that mother's milk is not available, the Roadmap dictates that donor milk would be used for all babies weighing less than 1800g and born at 32 weeks gestational age or less "for the first 30 days of life," with a transition from donor milk to formula starting at around 27 days of

life. (*Id.*) Mead Johnson acknowledges that the Roadmap influenced Daniel's feedings (DSOF [57-1] ¶¶ 27, 37, 50, 67), but maintains that Daniel's "feeding decisions were [not] solely dictated by the feeding roadmap, because the ultimate decision and choice was individualized, tailored, and decided by [the neonatologist] Dr. Bear." (Defs.' Resp. to PSOF [96] ¶ 20.)

It remains unclear, however, why Daniel's doctors switched him from a combination of Enfamil Premature and human milk to exclusively Enfamil Premature. According to Dr. Bear, the Roadmap calls for, at very most, a combination of fifty percent Enfamil formula and fifty percent mother's own milk, so the complete removal of Inman's breastmilk from Daniel's feeding regimen is perplexing. (Bear Dep. [78-24] at 134:13–135:6.) In fact, nobody involved—neither Plaintiff, nor Defendant, nor Dr. Bear—appears to know why mother's milk was removed from Daniel's feeding regimen. (*See* DSOF [57-1] ¶ 52.) Dr. Bear's testimony suggests that mother's milk was removed from Daniel's feeds due to "insufficient" milk production (*id.*; *see also id.* ¶ 14 (claiming that Vidant used formula "when human breast milk is not available")), as she testifies that Daniel would have been fed "as much" mother's milk "as was available" under the Roadmap. (Bear Dep. [78-24] at 134:13–24.) But Ms. Inman claims that she was producing more than enough to feed both twins. In fact, Inman recalls that roughly two weeks after Daniel's birth, a nurse at the hospital (whose identity Inman does not specify) told her that "they didn't have any more room" for her breastmilk in the hospital and "that they would let [Ms. Inman] know when more breast milk was needed." (Pl. Dep. [78-51] at 116:13–23.) This suggests that the switch to donor milk, and later to formula, was caused in part by Vidant's failure to request additional milk from Ms. Inman. (*See id.* at 117:19–23.)

In any event, by June 18, after being fed exclusively formula for approximately one week, Daniel's condition began to deteriorate. (DeZure Rep. [57-21] at 8–9.) He was documented to have "'poor' tolerance of feeds," with "multiple desaturation episodes," a "large emesis" (or vomiting), an "increase in respiratory support," and "clay stools." (*Id.* at 8.) After doctors suspected he had developed sepsis, they took an X-ray; the images showed signs consistent with

necrotizing enterocolitis ("NEC"). NEC is a devastating disease characterized by the inflammation of the abdominal wall; in severe cases, this inflammation can lead to cell death, resulting in a hole in the intestine. Gut bacteria can enter the bloodstream through such an opening, causing sepsis and death. Daniel's NEC diagnosis was later confirmed by exploratory laparotomy. He never recovered. He died on June 23, 2020, from "shock due to NEC." (*Id.* at 9.)

B. Necrotizing Enterocolitis and Infant Formula

As noted, Daniel is just one of hundreds of other premature infants who have become very ill or perished after ingesting a cow's-milk-based formula product. Hundreds of products liability lawsuits are pending in this court and in state courts throughout the country against manufacturers of these products—Mead Johnson and a competitor, Abbott Laboratories ("Abbott"). Plaintiffs in these cases pursue a common theory: that cow's-milk-based formula causes NEC in premature infants. Specifically, these plaintiffs, including Ms. Inman here, assert that the cow's-milk-based formula produced by Mead or Abbott contains complex carbohydrates, proteins, and fats that are difficult for a premature infant's gut to break down. These "[m]alabsorbed macronutrients" then accumulate in the gut, and act as a "food source" for the dangerous bacteria that lead to NEC.[4] (PSOF [117] ¶ 3.)

To establish this causal link, Inman has offered the opinions of several expert witnesses, including Dr. Logan Spector, who opines as to general causation, and Dr. DeZure, who explores specific causation in Daniel's case.[5] In a prior MDL-wide provisional order, the court rejected Defendants' collective *Daubert* challenge to Dr. Spector's testimony. *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). Mead Johnson has also raised a case-specific *Daubert* challenge

[4] Inman does acknowledge that the exact causal mechanism is "incompletely understood." (PSOF [117] ¶ 3.)

[5] 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. [53-6] at 3.)

moving to exclude Dr. Spector's testimony for lack of "fit" to the facts of this bellwether [53]; the court rejects that challenge in a separate order. Likewise, in a prior opinion in this case, the court rejected Defendants' *Daubert* challenge to Dr. DeZure's testimony [113]. The court assumes familiarity with those opinions, but briefly summarizes the experts' methodologies and conclusions here.

Dr. Spector conducted a systematic literature review of the relationship between CMBF and NEC in premature, low-birth weight infants. 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 human milk diet. (Spector Rep. [53-6] at 11–21.) For example, the meta-analysis of all cohort studies showed that premature infants who ingest a predominantly CMBF diet have a 226% higher risk of NEC compared to premature infants who ingest a predominantly human milk diet. (*Id.* at 19.) The meta-analysis for all randomized clinical trials showed that premature infants who ingest a CMBF 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 causality from an association)[6], ultimately concluding that feeding preterm infants CMBF causes NEC. (*Id.* at 22–26.)

Dr. DeZure was tasked with examining Daniel's medical records to determine whether his feedings of Enfamil Premature caused him to develop NEC. (DeZure Hearing Tr. [111] at 30:5–15.) Dr. DeZure conducted a differential etiology to "evaluate[] and rule[] out several potential causes and contributing factors of Daniel's NEC." (DeZure Rep. [52-5] at 13.) Ultimately, she concluded to a reasonable degree of medical certainty that "the transition to full volume [Enfamil

[6] The court described the Bradford Hill criteria in some detail in a prior order in this MDL. *See* General Causation Order, No. 22 C 00071, 2025 WL 1283927, at *5 (N.D. Ill. May 2, 2025).

Premature] formula and the increase in caloric density was a substantial factor in causing Daniel's NEC and subsequent death." (*Id.* at 15.)

C. Mead Johnson's Marketing

While Mead Johnson denies that its products cause NEC (Defs.' Resp. to PSOF [96] ¶ 29), Inman contends that Mead Johnson has long been aware of the association between Enfamil Premature and NEC, and deliberately downplayed that risk in communications with medical professionals and in marketing materials. According to Inman, in the mid-2010s, Mead Johnson grew concerned about the increasing reliance in NICUs on human donor milk to feed preterm infants. Mead Johnson commissioned a "68-page independent consultant report"; the consultant concluded that human milk from donors would fully replace infant formula by 2021. (PSOF [117] ¶ 6.) Inman characterizes this as a grave threat to Mead Johnson's business: because a parent is more likely to continue using the infant formula provided in the hospital, Mead Johnson allegedly viewed its premature infant formula portfolio as a way to ensure brand loyalty and see continued sales of its products. Mead Johnson feared reliance on human donor milk would reduce or eliminate this valuable marketing tool, according to Plaintiff. (*Id.*)

Inman asserts that Mead Johnson responded to this concern by adopting an "own the NICU" strategy to protect its market share. (*Id.* ¶ 8.) She identifies a number of examples of this strategy at play; for example, she claims that Mead Johnson "manipulat[ed] science to manufacture a false equivalency between donor milk and bovine formula" by sponsoring a study that downplayed NEC risk. (*Id.* ¶¶ 10–11.)

Likewise, she claims, Dr. Christina Valentine, an in-house physician for Mead Johnson, held seminars where she "taught clinicians that preterm infants must be taken off donor milk 'sooner' because of the risks associated with donor milk including being 'special needs,' while claiming that formula did not carry a higher risk of NEC than donor milk." (*Id.* ¶ 12.) Mead Johnson also recruited "key opinion leaders" who were paid to promote the company's Enfamil

products. (*Id.* ¶ 8.) One of these key opinion leaders was Jennifer Fowler—the nutritionist at Vidant who played a role in Daniel's feeding decisions. (*Id.* ¶ 13.)

According to Inman, Mead Johnson's marketing campaign had an impact on Daniel's care as a result of Fowler's involvement. Recall that all parties acknowledge that Daniel's switch to Enfamil Premature Formula was precipitated, at least in part, by adherence to the "Roadmap" for infant feedings at Vidant Medical Center. (*E.g.*, PSOF [117] ¶ 20; DSOF [57-1] ¶¶ 14, 27; *see also* Roadmap [63-4].) Fowler wrote the Roadmap, and later sought Mead Johnson's input on studies that she drafted exploring the Roadmap's application at Vidant. (*E.g.*, PSOF [117] ¶¶ 19, 20 (undisputed in relevant part); Defs.' Resp. to PSOF [96] ¶ 19.) Because of this relationship between Mead Johnson and Fowler, and because the Roadmap influenced the decision to switch Daniel to formula, Inman argues that Mead indirectly influenced Daniel's feeding regimen. Notably, in their depositions Dr. Bear and Ms. Fowler downplayed NEC risks associated with formula. (Bear Dep. [78-48] at 17:18–18:6 (referring to NEC risk as "slight" and "not significant"); Fowler Dep. [63-5] at 86:8–10 (denying that Enfamil increases the risk of NEC).) Inman claims these statements demonstrate that Daniel's doctors underestimated the risk of NEC, a fact that she attributes to Mead Johnson's marketing and the feeding Roadmap. (Pl.'s Opp'n [74] at 14.)

Mead Johnson denies all of this. Mead Johnson acknowledges that many of the facts described above are accurate, but accuses Inman of mischaracterizing the record and making much ado about very little. (Reply [98] at 10, 12 (minimizing Inman's accusations).) The company insists that its products do not cause NEC, and, while it acknowledges the benefits of human milk, Mead Johnson contends that Enfamil Premature is beneficial to infants—like Daniel—who are not adequately developing. (*Id.* at 13 ("Daniel's care team was fully informed that there was a difference in NEC risk . . . [and] nevertheless made the decision to feed Daniel formula because he needed it to grow.").)

D. Reformulation Studies

Inman also claims that Mead Johnson considered, but inexplicably declined, to adopt a safer design of Enfamil Premature Formula. Beginning in 2015, several scientists and executives at Mead Johnson became aware of studies suggesting that infant formula that uses lactose as the main source of carbohydrates, rather than corn syrup solids and maltodextrin, resulted in a lower incidence of NEC in piglets. (*See* PSOF [117] ¶ 28; Pl.'s Ex. KKK [117-4].) Dr. Rosaline Waworuntu, a Senior Scientist on Mead Johnson's Global Discovery team, suggested a reformulation of Enfamil Premature based on these findings in a 2015 project proposal, where she described the "[t]ype of innovation" as "mak[ing] lactose the main carbohydrate source [in EPF] to promote growth and protect against NEC". (Pl.'s Ex. NNN [117-7] at 14; Waworuntu Dep. [78-41] at 194:14–195:5.) She gave her proposal a perfect score for ease of innovation because "the component parts already existed" and noted that if Mead Johnson were to adopt this proposal, there would be no need to "make anything or discover anything." (Waworuntu Dep. [78-41] at 192:20–193:1.) In emails dating back to 2015, Dr. Colin Rudolph, Mead Johnson's Chief Medical Officer and Vice President of Global Medical Affairs, discussed the piglet studies and wrote, "Wouldn't it be amusing if the primary factor differentiating [human milk] feeding from formula feeding per NEC morbidity turns out to be lactose?" (PSOF ¶ 28; Pl.'s Ex. O [78-15] at 4.) A 2018 study funded by Mead Johnson and authored by Mead Johnson scientists, Drs. Brian Berg and Waworuntu, found that formula with lactose could protect piglets from developing NEC better than formula with corn syrup solids; emails exchanged by Mead Johnson executives discussed the study optimistically. (Pl.'s Ex. UU [78-45] at 2 (Dr. Rudolph: "Lactose is good . . ."; Susan Sholtis[7]: "another reason to shift away from corn syrup solids.").) In November 2018, Dr. Tim Cooper, Mead Johnson's Associate Director of Clinical Innovation wrote in an email to other

[7] Susan Sholtis was Mead Johnson's "[G]lobal [M]edical [M]arketing [L]ead" at the time. (PSOF [117] ¶ 10.)

Mead Johnson executives that he thought "increasing the lactose in our product line and minimizing [carbohydrate] polymers is a good thing to do." (Pl.'s Ex. CCC [78-53] at 5.)

Despite much discussion regarding the benefits of a possible reformulation, it appears Mead Johnson made no effort to pursue this path beyond the initial animal research phase. When asked about this reformulation during his deposition, Dr. Cooper testified that Mead Johnson considered "increasing its use of lactose in its preterm infant formula products," but this consideration stalled because a reformulation would require a reeducation campaign for neonatologists who were taught that premature infants are lactose intolerant and because such a reformulation would need a clinical study on human infants before going to market. (Cooper Dep. [78-57] at 302:9–305:14, 316:18–317:13; PSOF [117] ¶ 6; *see* Pl.'s Ex. CCC [78-53] at 5.) It is not clear, from the record, why Mead Johnson never evaluated the feasibility of this allegedly necessary reeducation campaign, or why the company declined to pursue a clinical trial on the reformulation. Plaintiff suggests that Mead Johnson declined to pursue this project further because it would "not present a big enough boost to Mead's bottom line." (PSOF [117] 28 (citing Sholtis email from July 3, 2018 [117-3]: "We may want to do it sooner if there is an opportunity to open up the formulation. Issue being: I am not sure this would stand on its own as a project because it will be difficult to say we are going to sell THAT MUCH MORE!").)

II. Procedural Background

Following Daniel's death, Ms. Inman filed this lawsuit against Mead Johnson in the Southern District of Indiana. This case, along with hundreds of others, has been consolidated by the Judicial Panel on Multidistrict Litigation and transferred to this court. The parties selected this case as part of an initial wave of four "bellwether" trials. Such trials can "provide significant information regarding the entire pool of cases that are part of the MDL," giving the parties helpful guidance as the cases progress.[8] *In re Testosterone Replacement Therapy Prods. Liab. Litig.*

[8] Bellwether trials also "allow coordinating counsel to hone their presentation for subsequent trials and can lead to the development of 'trial packages' for use by local counsel

Coordinated Pretrial Proc., No. 14 C 1748, 2017 WL 2574057, at *1 (N.D. Ill. May 22, 2017) (Kennelly, J.). The court has already granted summary judgment on three prior bellwether cases, each of which involved Abbott's preterm product "Similac Special Care." *See Mar v. Abbott Lab'ys, Inc.*, No. 22 C 00232, 2025 WL 1282749 (N.D. Ill. May 2, 2025*); Diggs v. Abbott Lab'ys, Inc.*, No. 22 C 05356, 2025 WL 2377686 (N.D. Ill. Aug. 14, 2025); *Brown v. Abbott Lab'ys, Inc.*, No. 22 C 2001, 2025 WL 2987083 (N.D. Ill. Oct. 23, 2025). For various reasons, in those cases the court concluded that plaintiffs failed to identify evidence sufficient to support a jury inference of liability on the part of formula manufacturers. *E.g.*, *Mar*, 2025 WL 1282749, at *6 ("Plaintiff has presented no evidence as to feasibility."); *Brown*, 2025 WL 2987083, at *14 (noting that plaintiffs provided "nothing from which the court can draw a favorable inference to allow this case to proceed to trial").

Defendants now move for summary judgment [54, 56] in this fourth bellwether, the first involving Mead Johnson's Enfamil Premature product. Plaintiff has responded [72, 74], and both Mead Johnson Defendants filed reply briefs [95, 98]. The court heard oral argument on the pending motions on February 26, 2026. (*See* Oral Arg. Tr. [119].) The motions are now fully briefed.

LEGAL STANDARD

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.'" *Johnson v. Edwards*, 164 F.4th 1074, 1079 (7th Cir. 2026) (quoting 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.'" *Brown v. Osmundson*, 38 F.4th 545, 549 (7th Cir. 2022) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S.

upon the dissolution of MDLs." *See* Eldon E. Fallon, Jeremy T. Grabill & Robert Pitard Wynne, *Bellwether Trials in Multidistrict Litigation*, 82 TULANE L. REV. 2323, 2338 (2008). They also "can precipitate and inform settlement negotiations by indicating future trends, that is, by providing guidance on how similar claims may fare before subsequent juries." *Id.*

242, 249 (1986)). In considering a motion for summary judgment, the court construes "the facts in the light most favorable" to the non-moving party and draws "all reasonable inferences in its favor." *Waukegan Potawatomi Casino, LLC v. City of Waukegan*, 128 F.4th 871, 873 (7th Cir. 2025). It does not "weigh evidence or make credibility determinations." *Johnson*, 164 F.4th at 1079.

Once a motion for summary judgment has been properly supported, the opposing party must produce affirmative evidence showing there is more than "'some metaphysical doubt as to the material facts.'" *Tech. Sec. Integration, Inc. v. EPI Techs., Inc.*, 126 F.4th 557, 560 (7th Cir. 2025) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986)). An opposing party must produce affirmative evidence raising a genuine issue for trial; they may not rest upon allegations in the pleadings. *Anderson*, 477 U.S. at 256–57. Speculation "cannot create a genuine issue of fact" and "is insufficient to defeat a summary judgment motion." *Flowers v. Kia Motors Fin.*, 105 F.4th 939, 946 (7th Cir. 2024) (citing *Circle City Broad. I, LLC v. AT&T Servs., Inc.*, 99 F.4th 378, 384 (7th Cir. 2024)).

ANALYSIS

I. Products Liability

Ms. Inman's lawsuit is a products liability claim brought under the law of North Carolina, where Daniel was born.[9] Because this case arises under the court's diversity jurisdiction, the court applies substantive state law to the facts of this case. *Giovannelli v. Walmart Inc.*, 164 F.4th 1052, 1054 (7th Cir. 2026) (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938)).

Inman brings two claims under the North Carolina Products Liability Act, N.C. GEN. STAT. § 99B-1, *et seq.* First, she contends that Mead Johnson's failure to provide an adequate warning of the NEC risks associated with Enfamil Premature was the proximate cause of Daniel's illness and death. Second, she asserts that Mead Johnson utilized a defective formulation of Enfamil

[9] While this lawsuit was originally filed in Indiana (where Mead Johnson is headquartered), this case is governed by North Carolina law. (Order [25] at 4.)

Premature that increased the risk of its products. The court considers each claim in turn, keeping in mind that it must proceed with "care and caution" while interpreting a state statute. *Smith v. RecordQuest, LLC*, 989 F.3d 513, 517 (7th Cir. 2021); *see also Giovannelli*, 164 F.4th at 1054 ("When applying state law, a state supreme court's rule would control, and a state appellate court's decision can provide controlling guidance as well." (cleaned up)).

A. Failure to Warn

To recover on a failure-to-warn claim in North Carolina, a plaintiff must show that "the manufacturer or seller acted unreasonably in failing to provide [an appropriate] warning or instruction" and that "the failure to provide adequate warning or instruction was a proximate cause" of an injury. N.C. GEN. STAT. § 99B-5. The plaintiff must also prove one of the following:

> (1) At the time the product left the control of the manufacturer or seller, the product, without an adequate warning or instruction, created an unreasonably dangerous condition that the manufacturer or seller knew, or in the exercise of ordinary care should have known, posed a substantial risk of harm to a reasonably foreseeable claimant.
>
> (2) After the product left the control of the manufacturer or seller, the manufacturer or seller became aware of or in the exercise of ordinary care should have known that the product posed a substantial risk of harm to a reasonably foreseeable user or consumer and failed to take reasonable steps to give adequate warning or instruction or to take other reasonable action under the circumstances.

Id. § 99B-5(a). Invoking this statute, Inman argues that Mead Johnson should have provided a warning that alerted doctors and patients of NEC risk associated with Enfamil Premature Formula. (Am. Compl. [20] ¶¶ 54–65.) She advances two theories of causation: first, that Mead Johnson's failure to warn Daniel's healthcare providers led them to make misguided decisions that caused Daniel's NEC; and second, that Mead Johnson had a duty to warn Ms. Inman directly of the risks associated with its products, but failed to do so. As explained below, there are jury questions here that foreclose an entry of summary judgment.

1. Failure to Warn Daniel's Healthcare Providers

The first theory of proximate cause advanced by Inman is that Mead Johnson negligently failed to warn Daniel's healthcare providers, including Dr. Bear, Dr. Livingston, and Ms. Fowler,

that its products cause necrotizing enterocolitis. In moving for summary judgment, Mead Johnson argues that a warning would have made no difference because Daniel's doctors were already aware of the NEC risks associated with formula, and nevertheless chose to give it to him due to his slow growth. (Mem. [57] at 18–20 (arguing that "the risks of inadequate growth outweighed any risk of NEC").) Inman disagrees. While she acknowledges that Daniel's doctors were technically aware of NEC risk, she claims that they underestimated it due to Mead Johnson's marketing materials. (Pl.'s Opp'n [74] at 13.) She argues that this aggressive marketing campaign gave rise to a duty on the part of Mead Johnson to issue a "direct and unambiguous warning" about Enfamil Premature's NEC risks. (*Id*. at 21.)

As an initial matter, contrary to Mead Johnson's assertions (*e.g.*, Mem. [57] at 15, 19), the court's reasoning in the prior *Mar* and *Diggs* bellwethers does not control the outcome here. Plaintiff Inman has offered more substantial evidence of causation. In *Mar* and *Diggs*, there was no evidence that any alternative product, such as donor milk, was available at the hospital. A warning in such cases would have made no difference in the infant's feedings, as formula was the only available option. *See, e.g.*, *Mar*, 2025 WL 1282749, at *9 ("Well, what else would we feed this baby?"). Here, in contrast, Inman has presented evidence that alternatives to Enfamil Premature—including her own breast milk—were available; the presence of alternative options makes it possible that an adequate warning would have spurred either Ms. Inman or a member of the medical team to pursue those options. *Mar* and *Diggs* are distinguishable on this basis.

When a failure-to-warn case is premised on the action of healthcare providers, establishing causation under North Carolina law "requires evidence that [the plaintiff] or her treating physician relied" on the warning. *See Carlson v. Bos. Sci. Corp*., 856 F.3d 320, 324 (4th Cir. 2017) (citing *Holley v. Burroughs Wellcome Co*. ("*Holley I*"), 74 N.C. App. 736, 330 S.E.2d 228, 233 (N.C. Ct. App. 1985)); *Asby v. Medtronic, Inc.*, 673 F. Supp. 3d 787, 794–95 (E.D.N.C. 2023) (dismissing failure-to-warn claim where plaintiff failed to allege that healthcare providers "read or heard any of the defendants' warnings" regarding a defective medical product). While

causation is typically a question of fact for the jury, summary judgment is warranted whenever the evidence offered in support of the plaintiff's causation theory is purely conjectural and speculative. *Sparks v. Oxy-Health, LLC*, 134 F. Supp. 3d 961, 988–89 (E.D.N.C. 2015). To survive summary judgment, therefore, Inman "must bring forth 'fact-specific and not merely speculative evidence'" establishing that the lack of a warning was a "cause of her injury." *Ross v. F.D.I.C.*, 625 F.3d 808, 817 (4th Cir. 2010) (quoting *Driggers v. Sofamor, S.N.C.*, 44 F. Supp. 2d 760, 765 (M.D.N.C. 1998)).

Mead Johnson argues that Inman has not done so, and that her claims fail as a matter of law because Dr. Bear, Daniel's treating neonatologist, disavowed any reliance on warnings. Specifically, Mead Johnson points to portions of Dr. Bear's deposition in which she testified that Enfamil Premature labeling never influenced her feeding decisions (Bear Dep. [78-24] at 103:22–25); that she had never even read a label on an Enfamil Premature product label (*id.* at 102:24–103:1); and that she would not have changed Daniel's treatment plan even if Enfamil Premature had included a warning about the NEC risks of formula (*id.* at 137:4–138:7). Mead Johnson repeatedly cites to these snippets of her deposition, each of which was elicited by leading questions from Mead's own attorneys, as categorically barring this case from going to the jury. (Mem. [57] at 15, 17, 18, 19; Reply [98] at 7–8.)

Mead Johnson's view of the evidence may be persuasive to a jury, but it is not the only plausible interpretation, and the court sees a material dispute of fact here. For example, both Dr. Bear and Dr. Livingston testified that they would have read and considered a warning in a letter if one had been sent by Mead Johnson. (*E.g.*, Livingston Dep. [78-50] at 111:17–112:5, Bear Dep. [78-24] at 21:1–22:1.) Dr. Bear also testified that she viewed NEC risk from formula as "slight" and "not significant," a view that Plaintiff attributes to Mead Johnson disinformation. (Bear Dep. [78-48] at 17:18–18:6.) And there is evidence that Ms. Fowler, the hospital nutritionist who played a role in Daniel's care, was paid to promote Mead Johnson products. A reasonable jury can ascertain from this evidence that Mead Johnson acted negligently in misleading or concealing

from Daniel's providers information about the relative risks of formula and breast milk. A reasonable jury could conclude, further, that an adequate and timely warning to providers would have been read by the providers and led to a different course of treatment for Daniel.[10]

Further, Mead Johnson is mistaken about the legal significance of Dr. Bear's testimony. Relying on *Lightfoot v. Georgia-Pac. Wood Prods., LLC*, 441 F. Supp. 3d 159 (E.D.N.C. 2020), and *Carlson v. Bos. Sci. Corp.*, No. 3:15CV211-RLV, 2015 WL 5732107 (W.D.N.C. Sept. 30, 2015), Mead Johnson appears to believe that a plaintiff can never proceed to trial where the treating physician (here, Dr. Bear) states they did not read or rely on any manufacturer warnings. The court declines to endorse this broad approach. For one, it is hardly surprising that physicians would deny reliance on warnings when prompted by defense counsel. By their very nature, failure-to-warn claims in the healthcare context are asserted by patients who had some kind of adverse, negative complication from a medical procedure. Depending on the context, acknowledging that reliance on an inadequate manufacturer warning led to an adverse outcome for the patient might well expose the physician to malpractice liability, and would certainly be embarrassing for the doctor. That is especially the case here, where Ms. Inman, or Mead Johnson itself, might assert that the hospital was negligent in failing to procure additional milk from Ms. Inman.

In light of this, at least some courts have suggested that plaintiffs can proceed to trial on a warnings claim, notwithstanding a physician's denial of reliance on warnings, if they offer "objective evidence" that a reasonable physician would have behaved differently in light of an adequate warning, *see Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 212 n.15 (5th Cir. 2008)

[10] Mead Johnson repeatedly objects that Inman's evidence of causation is speculative, correctly citing to cases that hold that speculation is insufficient to survive summary judgment. (Mem. [57] at 15, 22 (citations omitted).) But determining proximate causation necessarily involves speculation to some extent. The rule against speculation at summary judgment is to prevent cases from going to trial based on conjectural guesses as to liability. It does not prevent the jury from drawing reasonable inferences based on what Daniel's doctors would have done if they had been given a different warning. *See Cloutier v. GoJet Airlines, LLC*, 996 F.3d 426, 442 (7th Cir. 2021).

(Texas law), or evidence that suggests the doctor's credibility is suspect, *see Fussman v. Novartis Pharms. Corp.*, No. 106CV149, 2010 WL 4104707, at *4 (M.D.N.C. Oct. 18, 2010). It remains to be seen what warning Inman believes should have been provided to Daniel's doctors, but from this record, a reasonable jury could conclude that *some* warning would have prevented (or at least mitigated) his NEC. Mead Johnson's attempt to solicit self-serving, ambiguous testimony from a physician, and then assert it as a "gotcha" moment that categorically bars the case from jury consideration, is simply not persuasive. *See Fussman*, 2010 WL 4104707, at *4; *cf. Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 645 (4th Cir. 1981) (Virginia law) (recognizing a "judicial inclination" to "forbid intervening acts or omissions of a physician from insulating a drug manufacturer from liability").

Evers v. Hologic, Inc., No. 22-CV-11895-ADB, 2024 WL 4309413 (D. Mass. Sept. 26, 2024), decided under North Carolina law, is relevant here. *Evers* concerned a medical device known as "BioZorb" used to assist in radiation treatment of persons with breast cancer. *Id.* at *2. When one patient had complications from the BioZorb device implanted in her chest, she sued the manufacturer in products liability. In its motion for summary judgment, the defendant manufacturer argued, among other things, that the treating doctor made clear that no warning would have affected her decision to use the product. *Id.* at *13. The court nevertheless declined to enter summary judgment, observing that the credibility of the doctor's testimony could be questioned—for example, the doctor no longer used the device, suggesting she may have ceased using the device in response to some warning—and credibility is an issue for the jury. *Id.* ("Although [the doctor] testified that such a warning would not have affected her decision to use BioZorb, the Court nonetheless agrees with [the plaintiff] that [the doctor's] subsequent decision not to use the device as a consequence of that risk undermines her testimony.").

Similar factors are present in this case. Dr. Bear did testify that she did not rely on warnings, but there is other evidence, including Dr. Bear's testimony that she would have read a warning letter from Mead Johnson, that might support a jury finding that her testimony is not

dispositive. *See, e.g.*, *Fussman*, 2010 WL 4104707, at *4 (denying summary judgment in a case where evidence showed prescribing doctor would have changed treatment plan in response to warning letter from drug manufacturer). While it is true that a motion for summary judgment cannot typically be "defeated by simply arguing that a jury might not believe a witness's testimony," *Beatty v. Olin Corp.*, 693 F.3d 750, 754 (7th Cir. 2012), in light of all the factors here, the court finds that a material dispute of fact exists as to warnings causation in this case.

Summary judgment on Plaintiff's failure-to-warn is inappropriate here for an independent reason as well: Mead Johnson's marketing campaign. A reasonable jury could find that campaign—and the company's subsequent failure to correct its own record by warning doctors of its inaccuracies—was the proximate cause of Daniel's harm. Inman claims the evidence shows that Mead "deliberately created" an "informational vacuum" that concealed the risks of its Enfamil Premature product. She states that

> Mead Johnson's argument that a warning would have been futile ignores the informational vacuum it deliberately created. Mead Johnson executed a systematic misinformation campaign designed to neutralize independent medical judgment and replace it with a curated, pro-formula narrative that obscured the true, catastrophic risk of necrotizing enterocolitis (NEC). A clear, legally adequate warning would have pierced through this fog of misinformation and armed both the medical team and Daniel's mother with the accurate information needed to make a different, life-saving choice. Because a jury could readily conclude that an adequate warning would have altered the tragic outcome, summary judgment must be denied.

(Pl.'s Opp'n [74] at 7–8.) Rhetoric aside, there is indeed evidence that Mead Johnson's representatives downplayed Enfamil Premature's risks relative to mother's milk. As noted earlier, in one instance, a Mead employee told providers that breast milk would lead to "special needs" among preemies. Mead Johnson has not suggested there is evidence to support this warning, and a fact finder could infer that Mead Johnson was negligent in making statements that generated misconceptions about the safety of formula vis-à-vis mother's milk. *See Holley v. Burroughs Wellcome Co.* (*"Holley II"*), 318 N.C. 352, 360, 348 S.E.2d 772, 777 (N.C. 1986) (finding that "overpromotion" on the part of a manufacturer supports an inference of negligence),

aff'g Holley I, 74 N.C. App. at 736.[11]

Mead Johnson counters that there was "no . . . option" other than Enfamil Premature in light of Daniel's slow growth. Again, Mead Johnson may prevail on this basis, but the argument does not support taking this case away from the jury. Even if, with the benefit of more information, Dr. Bear, Dr. Livingston, and others would have given Daniel cow's-milk-based formula, it does not necessarily follow that *no* aspects of Daniel's treatment would have changed in a manner that could have prevented his death. Unlike many medical procedures, feeding an infant with formula versus mother's milk is not a one-off, binary decision. To the contrary, infant feeding in the NICU is a complex endeavor that involves multiple decisions, as Daniel's own medical records demonstrate. His physicians did not simply choose whether or not to feed him formula—they chose the specific type and amount of formula, whether to fortify mother's milk as an alternative to formula, whether to supplement Daniel's human milk feedings with formula, and whether to use mother's own milk versus donor milk. A reasonable jury could find that tweaks to any of these variables might have changed the outcome for Daniel. Summary judgment is not warranted.

2. Failure to Warn Ms. Inman Directly

Ms. Inman also advances a theory that Mead Johnson had a duty to warn her directly of the risks associated with Enfamil Premature formula, but failed to do so. The evidence in support of this theory is less robust. Before explaining its reasoning, the court pauses to address Mead Johnson's invocation of the learned intermediary doctrine. That doctrine protects drug

[11] The court recognizes that *Holley II* is not on all fours with this case. For example, the plaintiff in *Holley II* produced expert testimony from a pharmacologist who testified as to "the reliance of physicians" on manufacturer marketing materials. 318 N.C. at 354. Inman has not produced similar expert testimony. This court nevertheless finds *Holley II* persuasive here for the proposition that manufacturer overpromotion can be evidence of causation in a failure-to-warn case. Notably, while *Holley II* was decided more than 40 years ago, modern North Carolina courts continue to cite it, *see Fussman*, 2010 WL 4104707, at *2, and Mead Johnson does not challenge its authority. Nor has Mead Johnson otherwise argued that manufacturers' promotional materials cannot be evidence in support of an inference of proximate cause in a failure-to-warn case.

manufacturers from liability whenever the prescribing physician is a "learned intermediary" between the manufacturer and patient. In North Carolina, the doctrine is established by statute, which states that

> no manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product.

N.C. GEN. STAT. § 99B-5(c). The policy rationale for such a rule is obvious: medical decisions are complex, and certain drugs and procedures are risky. Patients are best served when their own physicians provide personalized assessments of the risks and benefits associated with a drug or device. A generalized, one-size-fits-all warning from the drug manufacturer is far less useful, given the complexity of healthcare decisions, and could well dissuade patients from consenting to drugs or procedures that are in fact in their own best interest. For this reason, similar versions of the learned intermediary doctrine have been adopted by other jurisdictions around the country. *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (A.L.I. 1998).

Mead Johnson argues with some force that this doctrine applies here and provides it with a defense from any liability for failing to warn Ms. Inman directly. (Mem. [57] at 23.) The argument has appeal, in that preterm infant formula is administered in hospital settings, for babies under physician's care. In support of its argument, Mead Johnson cites FDA regulations governing formula; Mead Johnson observes that Enfamil Premature is "typically prescribed by a physician and must be requested from a pharmacist," and argues that the product is effectively a "prescription drug" that goes by a different name.[12] (*Id.* at 24.) But as explained in North

[12] Both parties agree that infant formula is regulated under 21 C.F.R. § 107.50(c), a subsection that applies to "infant formulas not generally available at the retail level." This regulation references infant formulas that are "prescribed by a physician," suggesting that there are formulas out there that are only available by prescription. But § 107.50(c) does *not* state that Enfamil Premature is one of those prescription-only formulas; the simple fact that EPF is regulated by § 107.50(c) as a formula "generally not found on retail shelves" does not necessarily mean a prescription is required to administer it. Defendants appear to recognize the limited persuasive

Carolina's Model Jury Instructions, a "prescription drug" is a "[1] drug that [2] can be bought only when prescribed by a person authorized by law." N.C. MODEL JURY INSTRUCTIONS § 744.13 n.2. Even assuming that infant formula qualifies as a "drug," Mead Johnson has identified no federal or state law requiring that a doctor issue a prescription prior to administering Enfamil Premature Formula.[13]

By its terms, § 99B-5 appears to apply only to "prescription drugs," not to preterm infant formula. The fact that the product is primarily administered by healthcare providers in the NICU does not necessarily transform it into a prescription drug. *See Hunte v. Abbott Lab'ys, Inc*., 569 F. Supp. 3d 115, 122 (D. Conn. 2021) (expressing skepticism that "the medical use of a non-prescription product can bring that product within the LID's scope," but certifying the question to the Connecticut Supreme Court).[14] The legislature's decision to "specifically enumerate[]" only prescription drugs in the statutory text suggests that "no broader . . . learned intermediary defense exists in North Carolina." *Walls v. Ford Motor Co.*, No. 1:20-CV-98, 2022 WL 582611, at *6 (M.D.N.C. Feb. 25, 2022). For similar reasons, at least three state courts have refused to apply other jurisdictions' versions of the learned intermediary doctrine in cases involving preterm infant formula because a prescription is not required to administer it. *Gill v. Abbott Lab'ys, Inc*., No. 2322-CC01251, 2024 WL 5396574 (Mo. Cir. June 28, 2024) ("[P]re-term infant formula is not a

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value of this regulation: citing to § 107.50(c), they characterize EPF as a "product dispensed to patients by doctors," but not as a prescription-only formula. (Mem. [57] at 24 (internal citations omitted).)

[13] The court observes that federal law is generally not favorable to Defendants' characterization of Enfamil Premature as a prescription drug: the Food, Drug, and Cosmetic Act explicitly categorizes "infant formula" as a "*food*" in 21 U.S.C. § 321(z), and not as a "drug" or "device," both of which are defined separately by the Act. *See* 21 U.S.C. §§ 321(g) (defining drugs); *id.* § 321(h) (defining devices).

[14] The Connecticut Supreme Court did not decide the issue, as the case was voluntarily dismissed. *Collins v. Mead Johnson & Co., LLC*, No. 24 C 7140, 2025 WL 1836119, at *7 n.10 (N.D. Ill. July 3, 2025). For reasons explained in the text, this court shares the *Hunte* district court's skepticism but would not certify the issue—and notes, in any event, that North Carolina does not permit federal court certification of questions of state law. *See Town of Nags Head v. Toloczko*, 728 F.3d 391, 398 (4th Cir. 2013).

recognized prescription medication or medical device."); *Simmons v. Abbott Lab'ys*, No. 21L00000144, slip op. at 20 (Ill. Cir. Sept. 8, 2021) ("There is no caselaw cited by Defendants, nor found by this Court, extending the learned intermediary doctrine to nonprescription drugs or devices, or food products."); *Whitfield v. St. Louis Children's Hosp.*, No. 2222-CC06214, at 3 (Mo. Cir. Sept. 18, 2024) (declining to "extend the scope of the learned intermediary doctrine" to include formulas that are "rendered in the hospital").[15] Mead Johnson ignores Inman's invocation of these cases, and makes no attempt to distinguish them. (*See generally* Reply [98] at 18.)

Instead, Mead Johnson asks the court to expand the scope of the learned intermediary doctrine to encompass "cases where a defendant manufactures a product which is dispensed to patients by doctors, rather than directly." (Mem. [57] at 23 (citation and internal quotation marks omitted).) The court is not inclined to do so. It is true, as Defendant points out, that some courts interpreting North Carolina law have broadened § 99B-5 past "prescription drugs" to encompass other medical products.[16] (*E.g.*, Reply [98] at 18.) But these cases differ from this one in that each concerns a medical *device* that is implanted by a physician and is regulated separately by the FDA. The Restatement of Torts and many jurisdictions explicitly apply the learned intermediary doctrine to both prescription drugs *and devices*, so the broad interpretation adopted by these cases simply conforms interpretation of § 99B-5 with the rule in other jurisdictions. *E.g.*, RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 (A.L.I. 1998). Mead Johnson's interpretation requires the court to expand the statute one step further, to also encompass food products

[15] The *Simmons* and *Whitfield* opinions are unpublished, but are available on the public docket in this case. (*See* [130-1] and [130-2].)

[16] *See Evers*, 2024 WL 4309413 (breast implants); *Teague v. Johnson & Johnson, Inc.*, 578 F. Supp. 3d 743 (E.D.N.C. 2022) (urinary incontinence implant device); *Carlson v. Bos. Sci. Corp.*, No. 3:15CV211-RLV, 2015 WL 5732107 (W.D.N.C. Sept. 30, 2015), *aff'd on other grounds*, 856 F.3d 320 (4th Cir. 2017) (transvaginal mesh); *Smith v. Ethicon, Inc.*, No. 1:20CV212, 2020 WL 3256926 (M.D.N.C. June 16, 2020) (pelvic mesh device).

administered in hospitals, a step no court appears to have taken.[17] *See State v. Daw*, 386 N.C. 468, 476, 904 S.E.2d 765, 772 (N.C. 2024) ("[W]hen the words have a definite and precise meaning, [courts cannot] go elsewhere in search of conjecture in order to restrict or extend the meaning."); *see also Walls*, 2022 WL 582611, at *6 ("[N]o broader . . . learned intermediary defense exists in North Carolina.").

An additional factor counsels against Mead Johnson's proposed reading: Section 99B-5 is a state statute, and the Seventh Circuit has instructed that "[f]ederal courts must exercise caution before recognizing novel legal theories brought under uncharted state laws." *Ostrowski v. Lake Cnty.*, 33 F.4th 960, 965 (7th Cir. 2022). Applying the learned intermediary doctrine to the facts of this case would require the court to adopt an interpretation of a state statute that appears unsupported by state law authority. Principles of federalism and federal-state comity weigh against traveling down this path.[18] *See Fontenot v. Taser Int'l, Inc.*, 736 F.3d 318, 330–31 (4th Cir. 2013) (recognizing that when "there are no analogous North Carolina cases supporting the availability of [a] defense under the novel circumstances presented," the federal courts often "decline[] to expand state common law principles to encompass novel circumstances when the

[17] Mead Johnson has submitted, as supplemental authority, an unpublished case from a Florida trial court that applies Florida's learned intermediary doctrine to infant formula. (Supp. Auth. [123-1].) That case is not persuasive; it is not binding even within Florida, and Florida law does not supply the rule of decision here. Likewise, Florida's learned intermediary doctrine is a common law doctrine, and North Carolina's doctrine is based in statute. Even if this court were to find the policy rationale within the Florida decision persuasive, this court is not at liberty to "create or extend the North Carolina common law." *Time Warner Entm't-Advance/Newhouse P'ship v. Carteret-Craven Elec. Membership Corp.*, 506 F.3d 304, 314–15 (4th Cir. 2007); *see also Warren v. Cielo Ventures, Inc.*, 926 S.E.2d 716, 719 (N.C. 2026) ("It is not for the courts to second-guess legislative policy decisions").

[18] The court observes that the North Carolina Supreme Court has repeatedly discouraged courts from adopting creative, atextual interpretations of state statutes. *See, e.g.*, *Warren*, 926 S.E.2d at 719 (recognizing, in a different context, that courts interpreting state law may not "insert unwritten terms into a statutory scheme"); *Belmont Ass'n, Inc. v. Farwig*, 381 N.C. 306, 313, 873 S.E.2d 486, 490 (N.C. 2022) (reversing lower court for failing to give a state statute its "plain and definite meaning" and adopting alternative interpretation "based on sources outside the text").

courts of that state have not done so first."). In short, unless Mead Johnson can (in any future submission) identify federal or state law authority for its contention that Enfamil Premature may be understood as a prescription drug, the learned intermediary defense is not available here.

A decision that the learned intermediary doctrine does not protect Mead Johnson is not the end of the inquiry, however. To prevail on a theory of liability premised on failing to warn the end consumer, Ms. Inman would have to convince the jury that Mead Johnson negligently failed to warn her, and that said lack of a warning was the proximate cause of Daniel's NEC. The court believes this would be a heavy lift. Even assuming that Defendant was negligent, the evidence that any warning would have changed things for Daniel appears slim. The sole evidence identified by Plaintiff is an affidavit in which Ms. Inman states that a "clearly visible warning" would have "caught [her] attention" and led her to communicate her preference for human milk to Daniel's doctors. (Pl. Aff. [78-52] ¶¶ 7–8.) In her deposition testimony, however, Plaintiff acknowledges that she never saw a label for Enfamil Premature while in the NICU, she did not read any of the coupons or Mead Johnson material she was provided, and she was not even aware that Daniel was being fed Enfamil Premature by his doctors.[19] (Mem. [57] at 21–22 (quoting DSOF [57-1] ¶¶ 42, 62–64, 66).) It is also not clear that Inman's expressing a preference for human milk would have made a difference in Daniel's care; according to her deposition testimony, Ms. Inman *did* tell her doctors that she wanted her breast milk fed to Daniel (DSOF [57-1] ¶ 25), but Daniel's doctors proceeded to switch him to formula regardless, evidently without ever telling Inman or asking her for more breastmilk. (*See* Pl. Dep. [78-51] at 121:2–8.) Mead Johnson was of course not involved in that failure of communication.

[19] Mead Johnson asks the court to disregard Inman's affidavit as a sham affidavit. (Reply [98] at 8–10.) The inconsistency is not so blatant as to justify invocation of the sham affidavit rule, as the affidavit can be read as clarifying her "ambiguous or confusing deposition testimony." *James v. Hale*, 959 F.3d 307, 317 (7th Cir. 2020); *see also Castro v. DeVry Univ., Inc.*, 786 F.3d 559, 571 (7th Cir. 2015) (cautioning that the sham-affidavit rule "must be applied with great care").

These circumstances suggest the difficulties Ms. Inman faces; they do not require summary judgment in Mead Johnson's favor on this theory.

3. Common Knowledge

Mead Johnson raises one additional argument in support of summary judgment: it invokes an affirmative defense under North Carolina law that insulates a manufacturer from liability for "failing to warn about an open and obvious risk or a risk that is a matter of common knowledge." N.C. GEN. STAT. § 99B-5(b). It claims that the risk of NEC was common knowledge among Daniel's physicians, and thus, it had no duty to warn them of NEC risks.

The court disagrees. Mead Johnson can, of course, move for summary judgment on an affirmative defense, but the burden is heightened: to succeed, it "must affirmatively put forward evidence that is so one sided that it must prevail as a matter of law." *Brown*, 2025 WL 2987083, at *12 (cleaned up). It has not done so. At least one member of Daniel's care team, Ms. Fowler, testified that she was not aware of NEC risk (*e.g.*, Fowler Dep. [63-5] at 86:10), and while Dr. Bear was aware of such risks, she believed the difference in risk between formula and human milk was "slight." (*E.g.*, Bear Dep. [78-24] at 17:18–22 (referring to the increase as "slight").) If the jury does not agree with this assessment of the risk from formula, the jury could also conclude that Mead Johnson concealed information not otherwise obvious from practitioners.

That said, the court recognizes that in using the word "slight" regarding the risk of NEC as a result of formula use, Dr. Bear may well have demonstrated an accurate understanding. Dr. Spector opines that formula increases the risk of NEC by approximately 60%. *Diggs*, 2025 WL 2377686, at *2. Such an increase is significant, but NEC is a rare disease to begin with, and even a 60% increase in a small risk may fairly be characterized as "slight." For example, if the overall risk of NEC is 5%, a 60% increase would bring the risk to 8%—a 3% difference that may still be viewed as "slight." Regardless, again, Mead Johnson bears the burden on this defense, and Ms. Fowler and Dr. Bear's testimony is sufficient to defeat the company's request for summary judgment.

* * * * *

To sum up: Plaintiff's failure-to-warn claim survives this motion. Disputes of fact preclude summary judgment on the claim that Mead Johnson failed to give adequate warnings to healthcare providers. Plaintiff is also free to present evidence in support of her direct-to-consumer warnings theory, and the court anticipates using special verdict forms in which, if the verdict is in favor of Plaintiff, the jury will be asked to identify the relevant causation theor[ies] for purpose of Rule 50 and/or appellate review. *See* FED. R. CIV. P. 49(a).

B. Defective Design

Inman also claims that Enfamil Premature was defectively designed. Pursuant to North Carolina's product liability statute, a product is defective if (1) "a safer practical, feasible, and otherwise reasonable alternative design or formulation" existed which "would have prevented or substantially reduced the risk of harm" complained of, without "substantially impairing the usefulness, practicality, or desirability of the product," and (2) that the defendant acted unreasonably in failing to adopt the alternative design. N.C. GEN. STAT. § 99B-6(a); *DeWitt v. Eveready Battery Co.*, 144 N.C. App. 143, 155, 550 S.E.2d 511, 519 (N.C. Ct. App. 2001), *aff'd,* 355 N.C. 672, 565 S.E.2d 140 (N.C. 2002). North Carolina applies a negligence standard, not a strict-liability standard, in products liability actions. N.C. GEN. STAT. § 99B-1; *Wilson Bros. v. Mobil Oil*, 63 N.C. App. 334, 341, 305 S.E.2d 40, 45 (N.C. Ct. App. 1983) ("In this State, a plaintiff's claim in a products liability case must be determined by the principles of negligence or breach of warranty.") Finders of fact are instructed to consider several factors to determine whether a manufacturer acted unreasonably in failing to adopt an alternative design, including, relevant here, "the nature and magnitude of the risks of harm," "the utility of the product," and the "technical, economic, and practical feasibility of using an alternative design or formulation at the time of manufacture." N.C. GEN. STAT. § 99B-6(b).

Ms. Inman invokes § 99B-6 to argue that (1) Mead Johnson acted unreasonably in designing Enfamil Premature as a cow's-milk-based product, (2) this defective design proximately

caused Daniel's NEC, and (3) safer, feasible alternative designs existed that would have prevented or substantially reduced the risk of NEC without impairing the product's usefulness. Mead Johnson moves for summary judgment on the design defect claim on two bases: first, that Ms. Inman cannot show an existing, feasible alternative design, and second, that Ms. Inman's defective design claim must fail is an impermissible "categorical challenge." (Mem. [57] at 26–27.) The court disagrees on both fronts. As explained below, Ms. Inman has presented evidence of a possible reformulation of Enfamil Premature that would have reduced the risk of NEC. Triable questions of fact remain regarding the safety, feasibility, and reasonableness of the possible reformulation as an alternative design, precluding summary judgment.

1. Existing, Feasible Alternative Design

An inherent part of proving that formula, like any product, is defective requires showing that an alternative, safer design was possible and feasible. Under North Carolina law, an alternative design is an explicit requirement: to establish a claim for defective design, a plaintiff must make a showing (1) that the proposed alternative design or formulation was a safer, practical, feasible, and otherwise reasonable design or formulation; (2) that the alternative design or formulation could then have been reasonably adopted; (3) that the alternative design or formulation would have prevented or substantially reduced the risk of harm complained of; and (4) that the alternative design or formulation would not have substantially impaired the usefulness, practicality, or desirability of the product. *Sparks*, 134 F. Supp. 3d at 987; *see DeWitt*, 144 N.C. App. at 159. One way for a plaintiff to meet this test is by offering evidence of an alternative design adopted by a competitor or the defendant itself. *Sparks,* 134 F. Supp. 3d at 988 (finding that plaintiff's evidence of an alternative design adopted by a competitor was sufficient to show that alternative design was feasible); *see also Thrope v. Davol, Inc.*, No. C.A. 008-463ML, 2011 WL 470613, at *29 (D.R.I. Feb. 4, 2011) (applying N.C. GEN. STAT. § 99B-6 and finding a feasible alternative design based on evidence that a manufacturer's prior product on the market did not contain an allegedly dangerous product component). A plaintiff can also furnish evidence of an

alternative prototype that a manufacturer was aware of, but negligently failed to adopt, to survive summary judgment. *In re Bos. Sci. Corp., Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2326, 2015 WL 1509380, at *6 (S.D.W. Va. Apr. 1, 2015) (applying North Carolina law). Evidence of even just one feasible alternative design is enough, but plaintiffs bear the burden of demonstrating that their proposed alternative design is feasible.

Ms. Inman asserts that Mead Johnson could have reformulated Enfamil Premature by making lactose the main carbohydrate source to reduce the risk of NEC, an alternative she claims Mead Johnson was aware of, but inexplicably failed to adopt. (Pl.'s Opp'n [74] at 31.) She also presents four "alternative designs" to meet her burden under the statute: fortified donor milk from Human Milk Banking Association of North America ("HMBANA"), Prolacta formula, MedoLac formula, and Ni-Q formula, each discussed below. (*Id.* at 29.)

a. Lactose Reformulation

The court starts by examining the possible reformulation of Enfamil Premature to make lactose the main carbohydrate source in the formula. Plaintiff has presented evidence that such a formulation reduced the incidence of NEC in premature piglets, that Mead Johnson researchers were aware of these studies and considered reformulating EPF based on this research, and that a reformulation would be relatively feasible. (PSOF [117] ¶ 28.) As far back as 2015, Mead Johnson scientists exchanged emails about these piglet studies, noting that they warranted possible reconsideration of the EPF recipe. (Pl.'s Ex. KKK [117-4] at 5 (Dr. Rudolph writing: "[I]f we had some comparative data, it may indicate the selection of [carbohydrates] is important, and the [carbohydrate] blend in preterm formula should be reconsidered. Certainly the preterm infant appears to tolerate lactose well in human milk and there is no reason to assume that the lactose in preterm formula would be handled differently").) In 2018, Mead went so far as to commission its own study, and its researchers found, again, that a lactose-based formula lowered the incidence of NEC in piglets, and as before, Mead scientists and executives spoke positively about the results. (Pl.'s Ex. UU [78-45] at 2.)

While Mead Johnson admits that Plaintiff accurately quotes these documents, it disputes that this evidence demonstrates that a reformulation would, in fact, be a feasible alternative design. According to Mead Johnson's expert Dr. Erika Claud—a board-certified neonatologist and tenured professor at the University of Chicago, whose research focuses on NEC—these piglet studies cannot be extrapolated to human infants because the "enzymatic profile of piglets is the exact opposite of that seen in preterm infants," specifically in terms of the levels of enzymes that digest maltose and lactose. (Claud Report [57-13] at 24.) Still, evidence to the contrary exists in the record. In her deposition testimony, Dr. Waworuntu, a senior scientist with Mead Johnson, agreed that piglets were "generally recognized as the best [] animal model for pediatric nutrition research," and indeed stated, in her words, that the piglet model was "the closest, closest physiology with infant." (Waworuntu Dep. [117-5] at 95:23–96:6.) And, as explained above, Mead Johnson scientists and executives took the piglet studies seriously and even went so far as to suggest that a reformulation may be wise in light of these studies. If the piglet studies are truly inapplicable, it is not clear to the court why Mead Johnson employees would have taken them so seriously, or why Mead Johnson's scientists would have used piglets in their own studies on infant feeding products.

It may well be that the metabolic make-up in piglets is distinct enough from human infants that there is no evidentiary basis for extrapolation to human infants. But such a dispute of material fact cannot be resolved at this stage. Indeed, Dr. Rudolph, summarized the existence of such a dispute in his deposition testimony:

> Different people would dispute which model is the best model for NEC. [The piglet] model is one of several models for NEC, in my view. And there are some particular aspects of pig gut development that might make it not the best for every variable that you're looking at . . . But it's a reasonable model for certain aspects of mechanisms of NEC, although there's differences in the immune development and the development of the digestive enzymes, again, between the pig and the human. So there's limitations to the model as there's limitations to any model.

(Rudolph Dep. [78-39] at 107:7–108:12.) It is not the role of the court to resolve this scientific debate at summary judgment. Instead, the court's role here is only to determine whether there is

a genuine issue of triable fact for a jury. *Anderson*, 477 U.S. at 249 ("[A]t the summary judgment stage, the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.") Because there is conflicting evidence regarding the safety and feasibility of a possible reformulation of Enfamil Premature that would reduce the risk of NEC, such a genuine dispute exists, and the court must defer this determination to the jury.

b. Human-Milk-Based Alternatives

The possibility of a reformulation is sufficient basis for the denial of summary judgment; the court nevertheless briefly notes concerns with regard to Ms. Inman's other proposed alternative designs. Ms. Inman, like prior plaintiffs in this MDL, has proffered alternative designs that are derived from human milk. But as the court discussed in *Brown* and *Mar*, there is basis for considerable skepticism that these proposed alternatives could feasibly meet the demand for cow's-milk-based formula, and Inman has produced little evidence to address this concern.

First, Ms. Inman suggests fortified donor milk from HMBANA as a feasible alternative design. This proposed alternative design bears only brief discussion. Ms. Inman appears to be suggesting that *human milk itself* is a feasible alternative design to Mead Johnson's cow's-milk-based formula. The court rejected this idea squarely in *Mar* when it found that Dr. DeZure could not have been speaking to alternative product designs when she included "mother's own milk" and "donor milk" in her list of "safer alternatives," because these are "two substances that no one is suggesting Abbott could manufacture." 2025 WL 1282749, at *6. Feeding donor milk to an infant is an alternative *care* protocol; but as a matter of law and common sense, donor milk is not a feasible *manufacturing* alternative.

Next, Ms. Inman offers human-milk-based formula, commercially sold by Prolacta, MedoLac, and Ni-Q, as other feasible alternative designs. She contends that "as early as 2010, the technology existed to make a sterile, commercially available human milk-based formula," and Mead Johnson recognized such a product was "feasible" for commercial distribution. (PSOF [117]

¶¶ 23, 24.) Mead Johnson admits that it considered proposals whereby it would become the exclusive agent for a human milk fortifier and a human-milk-based preterm formula, but disputes that these proposals were ultimately considered feasible by the company. The court similarly questions Inman's characterization of the evidence on this issue. The record does not suggest that Mead Johnson was considering reformulating Enfamil Premature from a cow's-milk-based product to a human-milk-based product or that the supply of donor milk would make it possible for Mead Johnson to do so. Instead, it appears that conversations about a partnership with Neolac—another company that, at the time, was exploring an exclusive distributorship proposal with Mead whereby Neolac would source raw material for and develop human-milk-based nutrition products—were aimed at expanding Mead's footprint in the infant feeding space to include human-milk-based products. For example, in his deposition testimony, Robert Cleveland, Mead Johnson's Global Marketing Director for Premature Products, discussed "add[ing] a human milk-based product to [MJC's] NICU portfolio." (Cleveland Dep. [78-9] at 149–151; Pl.'s Ex. DD [78-30] at 2.)

Ms. Inman repeatedly quotes various witnesses' statements out of context, that, when considered more carefully, undermine her claims. For example, she cites the deposition testimony of John Alvey, Mead Johnson's Product Development Engineer, to suggest that human-milk-based formula was feasible at scale. (PSOF [117] ¶ 24 (quoting Alvey Dep. [78-46] at 86:10–25).) But Mr. Alvey did not so testify. Rather, he testified that Mead Johnson explored manufacturing a human milk *fortifier* made from human milk. (*Id.* at 85:6–86:25 (question relating to "Project Bamboo"); Pl.'s Ex. BB [78-28] at 16 (noting that "Project Bamboo" was an effort to explore a possible "[h]uman milk fortifier").) Inman blurs the distinction between human milk fortifier and human-milk-based formula—as the court has repeatedly explained, fortifier and formula are different products, and "it is a basic matter of tort principles that an 'alternative design must not be an altogether essentially different product.'" *Mar*, 2025 WL 1282749, at *6 (quoting *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 549 (S.D.W. Va. 2011)). As the court explained in *Brown*:

> [T]he 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." Because they have entirely different purposes, no reasonable jury could conclude that Prolacta fortifier is an alternative design to Abbott's formula.

Brown, 2025 WL 2987083, at *10 (citation and internal quotation marks omitted).

And even if Alvey's testimony did relate to the production of human-milk-based formula (it does not), Alvey testified that the product was assessed to be feasible only at "lab scale,"—sufficiently available for research purposes but not for widespread commercial use. Similarly, Ms. Inman claims Robert Cleveland testified that human-milk-based formula is available at scale, but closer examination of Cleveland's deposition testimony reveals that Cleveland, too, stated only that these products were available at "a niche scale," revealing very little about human-milk-based formula's economic feasibility. (PSOF [117] ¶ 25; Cleveland Dep. [117-6] at 271:18–24.) This testimony undercuts Ms. Inman's claims of feasibility.

As the parties are aware, the court has considered the issue of feasibility in its opinion in an earlier case. Dr. Amanda Starc, a healthcare economist offered by Abbott in *Brown,* analyzed the supply of human milk and human milk products in relation to the nutritional demand of premature infants in the United States. After performing a careful mathematical analysis, Dr. Starc determined 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.' "[20] *Brown*, 2025 WL 2987083, at *12–13.

[20] Ms. Inman suggests there is a basis to challenge that conclusion. She has presented the statement of HMBANA, an advocacy group with the mission of "advanc[ing] nonprofit milk banking through advocacy, evidence-based standards, and member accreditation," regarding the availability of donor human milk. HMBANA Mission & Vision, https://www.hmbana.org/about-us/mission.html (last visited May 8, 2026). HMBANA suggests there is a surplus of donor milk, rather than a shortage. (PSOF [117] ¶ 22 ("If preterm formula were unavailable, HMBANA's current capacity, combined with mom's own milk, is sufficient to meet needs." (quoting Pl.'s Ex. CC [78-29] at 1).) As the court understands HMBANA's position,

Meeting this demand by way of a human-milk-based formula would require Mead Johnson to increase the supply of human milk from donors, a task that comes with many systemic challenges, outlined in detail in Dr. Starc's report: recruiting donors is difficult considering the regulatory landscape around human milk donation, donors are only able to supply milk for the short time they are lactating, and compensating donors raises ethical concerns about the possibility that women who are in greatest financial need might donate their milk to the detriment of their own infant. *See id.* Moreover, Mead, like Abbott, would have little standing as a for-profit pharmaceutical company to encourage women to donate, a commitment that is most often fueled by a woman's altruism.

Recall that under North Carolina law, Plaintiff bears the burden of proof on the existence and feasibility of a proposed alternative design. In the face of these systemic supply issues, Ms. Inman's only real evidence for feasibility is a few excerpts from transcripts taken out of context. She has "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." *Brown*, 2025 WL 2987083, at *14. The court will not foreclose the possibility that she might be able to produce more evidence on this issue at trial,[21] but as the record stands, Ms. Inman has produced no real evidence regarding the feasibility of these human-milk-based alternatives.

HMBANA is not suggesting that human milk is available for Defendant's use in manufacturing formula—but that, instead, formula is not necessary at all. To say that a product is not (or should not be) necessary is not the same as proposing an alternative design for the product.

[21] In her response to Mead Johnson's Statement of Facts, Ms. Inman states that "Defendants have repeatedly delayed the depositions of Prolacta witnesses (originally scheduled for July and August and cross-noticed in the MDL . . .) that would better position Plaintiff to counter Defendant's threadbare assertions." (Pl.'s Resp. to DSOF [77] ¶ 77.) Plaintiff "reserv[ed] the right to supplement this response when that testimony is finally taken." Though Plaintiff's response was filed on October 25, 2025, she has yet to file a supplemental response based on testimony from Prolacta witnesses.

2. Affirmative Defenses

North Carolina law also establishes two affirmative defenses relevant to this case. Defendants can avoid liability if they prove one of the following: (1) that a plaintiff's claim challenges "an inherent characteristic of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability," if that inherent characteristic would be "recognized by the ordinary person with the ordinary knowledge common to the community," N.C. GEN. STAT. § 99B-6(c); N.C. MODEL JURY INSTRUCTIONS § 744.16; or (2) that the proximate cause of the injury alleged was "an alteration or modification of the product," therefore shielding them from liability "unless . . . [t]he alteration or modification was in accordance with the instructions or specifications of such manufacturer." N.C. GEN. STAT. § 99B-3; N.C. MODEL JURY INSTRUCTIONS § 743.07.

Invoking the first defense, Mead Johnson argues that Ms. Inman's design defect claim is an "impermissible categorical challenge" because she cannot "meet [her] burden of demonstrating a design defect by alleging that an entire class of products is inherently dangerous." (Mem. [57] at 30 (quoting *Town of Lexington v. Pharmacia Corp.*, 133 F. Supp. 3d 258, 270 (D. Mass. 2015)).) While Mead Johnson faults Ms. Inman for failing to prove that her claim is not prohibited by § 99B-6, this improperly shifts the burden of proof: North Carolina's model jury instructions make clear that *defendants* bear the burden of proof on this defense. N.C. MODEL JURY INSTRUCTIONS § 744.16. (*See also* Answer [36] at 31 (pleading this defense among other affirmative defenses).) But the court does not read Ms. Inman's claim to be based on an inherent characteristic of Enfamil Premature Formula. She does not allege that all cow's-milk-based formula is defective, as evidenced by her suggestion that a reformulation of EPF, still using cow's milk, would have rendered EPF safer. Instead, she alleges that specific design choices were made by Mead Johnson that ultimately led to Daniel's death, and evidence in the record exists to support these arguments. (*See* PSOF [117] ¶ 28 ("Mead Johnson products have the lowest lactose ratio in

preterm products").) If Mead Johnson intends to raise this defense at trial, it will be submitted to the jury.

Mead Johnson also confusingly argues that Ms. Inman's claim is barred because the doctors caring for Daniel mixed two formulations of formula—Enfamil 24 calorie and Enfamil 27 calorie—and that this combined formulation is not a product manufactured by Mead Johnson. But as Ms. Inman points out, Mead Johnson instructs practitioners to do that very thing. While the North Carolina statute makes clear that products liability does not apply when the injury was caused by "an alteration or modification [that] occurred after the product left the control" of the manufacturer, it explicitly leaves the door open for modifications (1) made "in accordance with the instructions or specifications" of the manufacturer, or (2) done with "the express consent" of the manufacturer. N.C. GEN. STAT. § 99B-3*; see also Walls v. Ford Motor Co.*, No. 1:20-CV-98, 2022 WL 588901, at *6 (M.D.N.C. Feb. 25, 2022) ("When the change 'was in accordance with the instructions or specifications' of the manufacturer, he will not escape liability." (quoting N.C. GEN. STAT. § 99B-3(a)(1))). Given the evidence that Mead Johnson instructed providers to mix formulas, the court declines to enter summary judgment on this defense.

Summary judgment on the basis of these two affirmative defenses is denied.

II. Punitive Damages

Mead Johnson also invites the court to exclude punitive damages from this case. (Mem. [57] at 32.) North Carolina law allows for punitive damages in cases of "fraud, malice, or willful and wanton conduct," N.C. GEN. STAT. § 1D-15(a) (cleaned up), and Mead Johnson believes that Inman cannot meet that bar. The court declines, at this early stage, to exclude the possibility of punitive damages at trial. The court will address the parties' arguments at a later stage in these proceedings, where the evidentiary record and parties' arguments will be clear.

III. Mead Johnson Nutrition Company

Finally, Mead Johnson Nutrition Company filed a separate motion for summary judgment, arguing (1) that it was not involved in the manufacture, sale, or design of the product and thus

cannot be held liable under the Products Liability Act; and (2) that Ms. Inman has failed to provide any evidence that would justify piercing the corporate veil to hold MJNC liable for MJC LLC's actions. The court agrees with MJNC.

Both parties acknowledge that only a manufacturer—i.e, "a person or entity who designs, assembles, fabricates, produces, constructs, or otherwise prepares a product or component part of a product prior to its sale to a user or consumer"—or seller—i.e., "a retailer, wholesaler, or distributor"—can be held liable under North Carolina's product liability statute. N.C. GEN. STAT. § 99B-1(2). The evidence that Mead Johnson Nutrition Company is involved in the manufacture or sale of baby formula is scant. Plaintiff offers, first, SEC filings by MJNC wherein MJNC represents that "We design products such as Enfamil Premature to meet the unique needs of premature and low birth weight infants." (PSOF on MJNC MSJ [70] ¶ 5.) But Ms. Inman takes these claims out of context. The first paragraph of MJNC's SEC filing clearly states: "In this Annual Report on Form 10-K, we refer to Mead Johnson Nutrition Company and its subsidiaries as 'the Company,' 'MJN,' 'Mead Johnson,' 'we' or 'us.'" (Childers Decl. Ex. 1 [79-1] at 3.) The "we" in the language used by Ms. Inman logically refers to Mead Johnson & Company LLC, the only MJNC entity that has submitted information to the FDA regarding the design and manufacturing of EPF and the only MJNC entity that contracts with hospitals to make premature infant products available for use in the NICU. (MJNC SOF [54-2] ¶¶ 1, 7.) Indeed, MJNC's corporate representative, Andy Lannert, testified that MJNC did not have any "sales operations" and has never had any employees. (Lannert Dep. [94-1] at 20:22–23; 17:6–8.) To the extent that Ms. Inman argues ambiguity in the language of the SEC filings warrants a denial of summary judgment, such ambiguity is not sufficient to create a genuine dispute of material fact in light of the ample and undisputed evidence that MJNC had no involvement in the design, manufacture, or sale of EPF. *Carroll v. Lynch*, 698 F.3d 561, 564 (7th Cir. 2012) (cautioning that identifying "[m]ere 'metaphysical doubt as to the material facts' is not enough" to survive summary judgment (quoting *Matsushita Elec. Indus. Co.*, 475 U.S. at 586)).

Next, Ms. Inman points to patent applications filed by MJNC. This evidence suffers from two key pitfalls. First, while Ms. Inman points to several patents where MJNC is named as the patent applicant, she provides no evidence that any of these patents were used in the design of Enfamil Premature. See *Personalized Media Commc'ns, LLC v. Apple, Inc.*, No. 215CV01366JRGRSP, 2021 WL 662237, at *6 (E.D. Tex. Feb. 20, 2021) ("Simply owning a patent does not mean that it is being practiced in a particular product. It cannot be assumed any one patent is being practiced without a more thorough investigation/analysis."). And second, ownership of patent rights does not, without more, render an entity a manufacturer of a product. *Cf. Allgood v. CNA Int'l, Inc.*, 806 F. Supp. 3d 742, 749 (N.D. Ill. 2025) ("Courts applying North Carolina law have held that mere sellers, including those who add only finishing touches to a product, are not manufacturers within the meaning of § 99B-1."); *Morrison v. Sears, Roebuck & Co.*, 80 N.C. App. 224, 341 S.E.2d 40, 41 (N.C. Ct. App. 1986), *rev'd on other grounds,* 319 N.C. 298, 354 S.E.2d 495 (N.C. 1987) ("We note that the imprinting of Sears' trademark in the shoe does not make Sears the manufacturer of the shoe.").

Finally, Ms. Inman points to the CVs of various Mead Johnson employees listing "Mead Johnson Nutrition," "Mead Johnson Nutrition, a subsidiary of Reckitt," and/or "Mead Johnson Nutritionals" as their employer. But the name employees give to their employer on their resume reveals very little—if not nothing at all—about an entity's corporate structure and activities. Even if MJNC did have employees, that fact alone does not render it a "manufacturer" or "seller" of a product.

As to MJNC's argument that Ms. Inman has not presented evidence sufficient to justify piercing the corporate veil, Ms. Inman's only response is that "there is no need to attempt to pierce the corporate veil in order to show that MJNC is a proper party in this case." (Pl.'s Opp'n [72] at 1 n.1.) Because Ms. Inman does not otherwise respond to MJNC's assertion that piercing the corporate veil is inappropriate here, the court deems this argument waived. *Ennin v. CNH Indus.*

Am., LLC, 878 F.3d 590, 595 (7th Cir. 2017) ("Failure to respond to an argument generally results in waiver.").

In sum, Ms. Inman has provided no evidence of MJNC's involvement in the manufacture or sale of EPF. MJNC's motion for summary judgment is granted.

CONCLUSION

Mead Johnson & Company's motion for summary judgment [56] is denied. Mead Johnson Nutrition Company's motion for summary judgment [54] is granted.

ENTER:

Dated: May 8, 2026

REBECCA R. PALLMEYER
United States District Judge