UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

KEVIN FERRY, AS ADMINISTRATOR OF THE ESTATE OF TYLEA HUNDLEY,
Plaintiff,

v.

MEAD JOHNSON & CO., LLC, MEAD JOHNSON NUTRITION CO., and ABBOTT LABS., INC.,
Defendants.

No. 3:20-cv-99 (SRU)

RULING AND ORDER

This case is about the death of a baby—Tylea Hundley—who was born prematurely and died 48 days after her birth from an intestinal disease. Kevin Ferry—the administrator of Tylea's estate—sues the producers of three infant formulas that doctors at Yale New Haven Hospital fed Tylea before she died. Specifically, Ferry alleges that Mead Johnson & Company, LLC and/or Mead Johnson Nutrition Company ("Mead Johnson") and Abbott Laboratories, Inc. ("Abbott") (collectively, the "Defendants") violated the Connecticut Product Liability Act (the "CPLA") on several different theories: (1) failure to warn and/or instruct; (2) strict liability for design defect; (3) misrepresentation; and (4) breach of warranty. Ferry argues that the Defendants' infant formulas contained cow milk, which the Defendants knew was unsafe. The Defendants have made motions to dismiss Ferry's complaint. They argue that Ferry's allegations are barred in part by Connecticut state law, preempted in part by federal law, and entirely fail to rise to the level of plausibility. For the following reasons, the Defendants' motions to dismiss, doc. nos. 51 and 52, are **granted in part and denied in part**. In addition, in a subsequent order, I will certify relevant and partially controlling questions of law to the Connecticut Supreme Court. The

portions of the Defendants' motions to dismiss that relate to that certification order are **denied without prejudice** to refiling once the Connecticut Supreme Court answers the certified questions.

I. Standard of Review

A motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6) is designed "merely to assess the legal feasibility of the complaint, not to assay the weight of evidence which might be offered in support thereof." *Ryder Energy Distrib. Corp. v. Merrill Lynch Commodities, Inc.*, 748 F.2d 774, 779 (2d Cir. 1984) (quoting *Geisler v. Petrocelli*, 616 F.2d 636, 639 (2d Cir. 1980)). When deciding a motion to dismiss pursuant to Rule 12(b)(6), the court must accept the material facts alleged in the complaint as true, draw all reasonable inferences in favor of the plaintiffs, and decide whether it is plausible that plaintiffs have a valid claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555–56 (2007); *Leeds v. Meltz*, 85 F.3d 51, 53 (2d Cir. 1996).

Under *Twombly*, "[f]actual allegations must be enough to raise a right to relief above the speculative level" and assert a cause of action with enough heft to show entitlement to relief and "enough facts to state a claim to relief that is plausible on its face." 550 U.S. at 555, 570; *see also Iqbal*, 556 U.S. at 679 ("While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations."). The plausibility standard set forth in *Twombly* and *Iqbal* obligates the plaintiff to "provide the grounds of his entitlement to relief" through more than "labels and conclusions, and a formulaic recitation of the elements of a cause of action." *Twombly*, 550 U.S. at 555 (cleaned up). Plausibility at the pleading stage is nonetheless distinct from probability, and "a well-pleaded complaint may proceed even if it strikes a savvy

judge that actual proof of [the claims] is improbable, and . . . recovery is very remote and unlikely." *Id.* at 556 (cleaned up).

In deciding a motion to dismiss pursuant to Rule 12(b)(6), a district court must be mindful not to violate the "conversion rule." "If, on a motion under Rule 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion." Fed. R. Civ. P. 12(d). The major harm of considering extrinsic materials on a Rule 12(b)(6) motion is "the lack of notice that the material may be considered." *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (citing *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 48 (2d Cir. 1991)). Thus, when the plaintiff "has actual notice of all the information in the movant's papers and has relied upon these documents in framing the complaint[,] the necessity of translating a Rule 12(b)(6) motion into one under Rule 56 is largely dissipated." *See id.* (cleaned up).

In the Second Circuit, a court may consider extrinsic materials on a Rule 12(b)(6) motion without converting it to a Rule 56 motion if the materials are either (1) integral to the complaint, or (2) facts appropriate for judicial notice. *See Glob. Network Commc'ns, Inc. v. City of New York*, 458 F.3d 150, 156 (2d Cir. 2006); *see also Chernosky v. Amica Mut. Ins. Co.*, 2018 WL 529956, at *1 n.1 (D. Conn. Jan. 24, 2018) ("The Court may consider documents attached to, integral to, or incorporated by reference in the complaint.") (citing Fed. R. Civ. P. 10(c); *Chambers*, 282 F.3d at 153). For materials to be "integral" to a complaint, the plaintiff must have relied on those materials in drafting the complaint; it is not enough that the plaintiff had mere notice or possession of them. *See Glob. Network Commc'ns*, 458 F.3d at 156 (citing *Chambers*, 282 F.3d at 152–53). Courts may take judicial notice of facts "not subject to

reasonable dispute" either because they are generally known or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). A court "does not ordinarily look beyond the complaint and attached documents in deciding a motion to dismiss brought" pursuant to Rule 12(b)(6). *Halebian v. Berv*, 644 F.3d 122, 130 (2d Cir. 2011).

II. Background

A. Factual Background

Tylea was born at Yale New Haven Hospital ("YNHH") on November 26, 2016. *See* Am. Compl., Doc. No. 50, at ¶ 1. Tylea was born after a 26-week, 6-day pregnancy (normal pregnancies last about 40 weeks) and weighed 355 grams (just over three-quarters of a pound). *See id.* at ¶ 7. On January 11, 2017, Tylea had bloody stool, and subsequent imaging confirmed that she was suffering from necrotizing enterocolitis ("NEC"), which is an intestinal infection. *See id.* at ¶¶ 53–54. On January 12, 2017, after a failed emergency bedside surgery, Tylea died from the effects of NEC. *See id.* at ¶¶ 3, 55–56. Tylea lived a total of 48 days, and she spent her entire life in the neonatal intensive care unit (the "NICU") at YNHH.

Mead Johnson produces (1) Enfamil Human Milk Fortifier ("Enfamil") and (2) EnfaCare Powder ("EnfaCare"). *Id.* at ¶ 5. Abbott produces Similac Special Care ("Similac"). *See id.* at ¶ 6. Enfamil, EnfaCare, and Similac all contain cow milk. *See id.* at ¶¶ 39–41; Enfamil Packaging, Ex. A to Am. Compl., Doc. No. 50-1, at 2 (Enfamil's packaging repeatedly states that it is "milk-based powder," and its ingredients list includes "milk protein isolate"); EnfaCare Packaging, Ex. A to Am. Compl., Doc. No. 50-1, at 3 (EnfaCare's ingredients list includes "nonfat milk"); Similac Packaging, Ex. C to Am. Compl., Doc. No. 50-3, at 3 (Similac Special

Care 20's ingredients list includes "Nonfat Milk" and says, in bold, that the product "[c]ontains milk and soy ingredients").

After Tylea was born, she "was provided total parenteral nutrition by vein . . . and was transitioned to donor human milk beginning six days after birth." Am. Compl., Doc. No. 50, at ¶ 9. Tylea "did well on human breast milk." *Id.* at ¶ 10.[1] From December 25, 2016 through either January 8 or January 9, 2017, doctors at YNHH fed Tylea Enfamil, apparently always with human breast milk. *See id.* at ¶¶ 11–18. From December 29, 2016 through January 7, 2017 (except for January 5 and 6), doctors at YNHH fed Tylea EnfaCare, apparently always with human breast milk. *See id.* at ¶¶ 23–26. From January 5 to January 11, 2017, doctors at YNHH fed Tylea Similac, sometimes with human breast milk and other times alone. *See id.* at ¶¶ 31–34.

According to Ferry, Enfamil's packaging and warning label "contained only the following packaging information guidelines, instructions and warnings":

- WARNING: Your baby's health depends on carefully following the instructions below. Use only as directed by a medical professional. Improper hygiene, preparation, dilution, use or storage may result in severe harm. Although this powder is formulated for premature infants, nutritional powders are not sterile and should not be fed to premature infants or infants who might have immune problems unless directed and supervised by your baby's doctor.

- CAUTION: Regarding use in extremely low-birth-weight infants (ELBW-1 kg or less): Hypercalcemia has been reported in some of these infants on full enteral feeds of human milk supplemented with human milk fortifiers.

Am. Compl., Doc. No. 50, at ¶ 19. However, Enfamil's packaging—attached to the complaint as an exhibit—displays other cautionary language. For instance, the packaging says, in three different places: "CAUTION: Nutritionally Incomplete: To be used only under the supervision

[1] The amended complaint initially alleged that Tylea "did well on human breast milk and fortified human breast milk." *See* Am. Compl., Doc. No. 50, at ¶ 10. However, I have since granted Ferry's motion to amend his complaint, doc. no. 74, in which Ferry asks to strike the reference to "fortified human breast milk" in that paragraph. *See* Min. Entry, Doc. No. 80; Hr'g Tr., Doc. No. 82, at 49:24–51:7.

of a physician." Enfamil Packaging, Ex. A to Am. Compl., Doc. No. 50-1, at 2. It also says: "For premature and low-birth-weight infants fed breast milk." *Id.* It also says: "Enfamil® Human Milk Fortifier is designed for premature infants as a nutritional supplement to be added to human milk." *Id.*

According to Ferry, EnfaCare contained "only" a warning highly similar to the language following "Warning" on Enfamil's packaging. *See* Am. Compl., Doc. No. 50, at ¶ 27. That is also not correct. The Enfamil packaging—attached to the complaint as an exhibit—also said: "Experts agree on the many benefits of breast milk. If you choose to use infant formula, ask your baby's doctor about . . . EnfaCare." *See* EnfaCare Packaging, Ex. A to Am. Compl., Doc. No. 50-1, at 3.

There are several different kinds of Similac. Ferry does not specify which kind of Similac the YNHH doctors fed Tylea. Instead, Ferry provides the highly similar packaging for Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 – High Protein, and Similac Special Care 30. *See* Am. Compl., Doc. No. 50, at ¶ 35; Similac Packaging, Ex. C to Am. Compl., Doc. No. 50-3. Ferry alleges that Similac "contained only the following packaging information guidelines, instructions and warnings":

- Very low-birth-weight infants are particularly susceptible to gastrointestinal complications; therefore, feeding should be initiated cautiously
- Tolerance to enteral feedings should be confirmed by initially offering small volumes of formula followed by cautious progression to higher caloric feedings
- Spitting up, abdominal distention, abnormal stools or stool patterns, excessive gastric residuals, or other signs of intestinal dysfunction have been associated with enteral feeding before the intestinal tract is ready to accommodate the regimen. At the first sign of these problems, enteral feeding should be slowed or discontinued
- Not intended for feeding low-birth-weight infants after they reach a weight of 3600 g (approximately 8 lb) or as directed by a physician[.]

Am. Compl., Doc. No. 50, at ¶ 35;[2] *see also* Similac Packaging, Ex. C to Am. Compl., Doc. No. 50-3, at 2–8.

Ferry alleges that the Defendants, despite knowing for years that their products increased the risk of NEC and death, did not warn of—and did not provide instructions or guidance about how to avoid—those possible outcomes. *See* Am. Compl., Doc. No. 50, at ¶¶ 22, 30, 38, 42–52, 57–66. Ferry also alleges that Mead Johnson did not cite any medical literature or research regarding Enfamil's and EnfaCare's risks on those products' labels or in their package inserts. *See id.* at ¶¶ 21, 29. Even though Abbott cited medical literature on Similac's package insert, Ferry alleges that that literature did not properly warn of the potential threat of NEC and death. *See id.* at ¶¶ 36–37.

Ferry alleges that recent scientific understanding emphasizes "the dangers of . . . cow-based product[s] in causing N.E.C. and death in premature infants, yet the defendants[] did nothing to change [their] product, packaging, guidelines, instructions and warnings." *Id.* at ¶¶ 71–72. Ferry cites six scientific articles that, in his view, establish that premature infants must be exclusively fed a diet of human milk to avoid NEC. *See id.* at ¶¶ 73–84.[3] Ferry explains that, even though "[t]he studies show the [Defendants'] products should not be sold for use in extremely premature infants," the Defendants continued to market and sell them. *Id.* at ¶¶ 87–88. And, even though it was foreseeable that their products would be used on Tylea, the Defendants failed to warn or provide instructions about how their products should be used. *See*

[2] That language is printed on all Similac versions except Similac Special Care 30, which has similar cautionary language.

[3] Ferry cites one study from 2017. *See* Am. Compl., Doc. No. 50, at ¶ 83–84. Because Tylea died on January 12, 2017, that study would be relevant only if it were available before then. It is not clear when that study was published, but it appears to be January 18. *See* Shulhan Article, Ex. 2 to Abbott's Mot. to Dismiss, Doc. No. 51-3, at 2 (see sideways text on side of page). However, because the Defendants do not raise that issue, I consider the study for purposes of this ruling.

id. at ¶¶ 89–92. Ferry alleges that, despite this solidifying scientific consensus, the Defendants did not take steps to re-evaluate and then alter their products. *See id.* at ¶¶ 93–102. Ferry explains that—although she "saw the product containers"—Tylea's mother was never told that cow milk-based formula could be harmful to Tylea nor that it could lead to NEC or death. *See id.* at ¶¶ 103–07, 110.

Ferry thus alleges that the Defendants are liable under the CPLA in "one or more of the following ways":

(1) Failure to Warn and/or Instruct;
(2) Strictly Liable for Defective Product
(3) Negligence[4]
(4) Misrepresentation
(5) Breach of Warranty
(6) Reckless Disregard – Punitive Damages under Conn. Gen. Stat. § 52-240b.[5]

See id. at ¶¶ 113–18. Ferry requests money damages and punitive damages under Conn. Gen. Stat. § 52-240b based on recklessness. *See id.* at 53 (demands).

B. Procedural Background

In April 2019, Ferry sued YNHH and Tylea's treating physicians in state court. *See* Abbott's Mem. of Law in Supp. Mot. to Dismiss ("Abbott's Mem. of Law"), Doc. No. 51-1, at 12; Compl., Ex. 1 to Abbott's Mot. to Dismiss ("YNHH Case Compl."), Doc. No. 51-2. (I will

[4] In his amended complaint, Ferry appears to assert a CPLA claim based, in part, on a broad theory of negligence relating to numerous disparate topics. *See* Am. Compl., Doc. No. 50, at ¶ 113(C)(a)–(o). It is thus difficult for me to evaluate Ferry's negligence theory based solely upon his complaint. Upon first blush, Ferry's opposition does not help clarify his negligence theory because he does not discuss it. However, near the end of his opposition, Ferry writes that his brief has "previously addressed" his negligence theory. *See* Pl.'s Opp'n, Doc. No. 62-1, at 43 n.3. The topics "previously addressed" in Ferry's opposition were Ferry's failure to warn and strict liability design defect claims. *See id.* at 10–34 (failure to warn and learned intermediary doctrine), 34–41 (design defect and preemption). Thus, it seems clear that Ferry's "negligence" theory consists of a negligent failure to warn theory. *See Leonard v. Gen. Motors, LLC*, 2020 WL 7024906, at *15 (D. Conn. Nov. 30, 2020) (discussing CPLA claim based on negligent failure to warn theory). I address Ferry's negligent failure to warn theory in this ruling.

[5] "Reckless disregard" is not a cognizable cause of action under the CPLA. Instead, "[i]n Connecticut, a plaintiff in a product liability action may recover punitive damages if she proves that the compensable harm suffered was a result of the defendant's reckless disregard for the safety of the product's user." *Izzarelli v. R.J. Reynolds Tobacco Co.*, 767 F. Supp. 2d 324, 325 (D. Conn. 2010) (citing Conn. Gen. Stat. § 52-240b).

refer to the state case against Tylea's physicians as the "YNHH case.") That complaint alleged that YNHH and Tylea's doctors were negligent and that they failed to inform Tylea's parents of the risks associated with feeding cow milk-based formulas to premature infants. *See id.* In the YNHH case, Ferry repeatedly alleges that Tylea's treating physicians knew that feeding Tylea cow milk-based formula might increase the risk that Tylea would develop NEC, or even die. YNHH Case Compl., Doc. No. 51-2, at ¶¶ 11, 13, 22–23. The YNHH case is currently in discovery. *See Superior Court Case Look-up*, STATE OF CONN. JUD. BRANCH, http://civilinquiry.jud.ct.gov/GetDocket.aspx (last visited Jan. 25, 2021) (enter docket number KNL-CV19-6040390-S).

On December 20, 2019, Ferry filed this case in state court. *See* Compl., Ex. 1 to Notice of Removal, Doc. No. 1-1. On January 21, 2020, the Defendants removed the case to this court. *See* Notice of Removal, Doc. No. 1. On March 19, 2020, the Defendants made motions to dismiss the complaint. *See* Mot. to Dismiss, Doc. No. 38 (Abbott); Mot. to Dismiss, Doc. No. 39 (Mead Johnson). On March 23, 2020, the parties submitted a Rule 26(f) report. *See* 26(f) Report, Doc. No. 40. On April 6, 2020, I held a Rule 16 pretrial conference. *See* Min. Entry, Doc. No. 45. At that conference, I indicated that I would allow Ferry to file an amended complaint. *See* Mem. of Conf., Doc. No. 46. Thus, I denied the two then-pending motions to dismiss without prejudice. *See* Order, Doc. No. 47.

On April 22, 2020, Ferry filed his amended complaint. *See* Am. Compl., Doc. No. 50. On May 13, the Defendants made the instant motions to dismiss. *See* Abbott's Mot. to Dismiss, Doc. No. 51; Mead Johnson's Mot. to Dismiss, Doc. No. 52.[6] On July 10, Ferry filed an

[6] Mead Johnson's motion to dismiss is just four pages and does not advance any unique legal arguments. *See* Mead Johnson's Mot. to Dismiss, Doc. No. 52, at 4 ("For brevity['s] sake, Mead Johnson will not duplicate the legal arguments advanced by Abbott Laboratories. Rather, the Mead Johnson Defendants adopt the legal arguments set forth in Abbott Laboratories' Memorandum of Law . . . as its own, as if fully set forth herein.").

opposition. *See* Pl.'s Opp'n, Doc. No. 62-1. On August 7, the Defendants filed replies in further support of their motions to dismiss. *See* Abbott's Reply, Doc. No. 69; Mead Johnson's Reply, Doc. No. 70.[7] Abbott also filed a motion to strike certain statements contained in Ferry's opposition. *See* Abbott's Mot. to Strike, Doc. No. 71. On August 19, 2020, Ferry filed an objection to Abbott's motion to strike. *See* Ferry's Obj. to Mot. to Strike, Doc. No. 72. Also on August 19, 2020, Ferry filed motions to amend his opposition and to amend his complaint. *See* Mot. to Am. Opp'n, Doc. No. 73;[8] Mot. to Am. Compl., Doc. No. 74.

On August 26, 2020, I held a hearing on the Defendants' motions to dismiss. *See* Min. Entry, Doc. No. 80. There, I took the Defendants' motions to dismiss under advisement, but I granted (1) the Defendants' motion to strike, doc. no. 71, and (2) Ferry's motion to amend his complaint, doc. no. 74. *See id.*; *see also* Hr'g Tr., Doc. No. 82, at 49:24–52:17.

III. Discussion

A. The CPLA Framework

The CPLA, Conn. Gen. Stat. § 52-572m, *et seq.*, is the "exclusive remedy" for—and the only cause of action available to—plaintiffs in Connecticut for product liability claims. *See Greco v. Broan-NuTone LLC*, 2020 WL 1044002, at *9 (D. Conn. Mar. 4, 2020); *Lynn v. Haybuster Mfg., Inc.*, 226 Conn. 282, 292 (1993); *see also* Conn. Gen. Stat. § 52-572n(a). Even though the CPLA provides for only a single cause of action, a plaintiff may "assert various

[7] Again, Mead Johnson joined Abbott's reply and submitted a "short, separate reply to highlight a few important points." Mead Johnson's Reply, Doc. No. 70, at 1.

[8] In particular, Ferry sought to add two exhibits to his opposition, doc. no. 62-1. Those exhibits are (1) the amended complaint in the YNHH case and (2) the defendants' answer to the amended complaint in the YNHH case. *See* Ex. H to Mot. to Am. Opp'n, Doc. No. 73-1 (YNHH amended complaint); Ex. I to Mot. to Am. Opp'n, Doc. No. 73-2. Ferry attaches those exhibits to show that the defendants in the YNHH case deny Ferry's allegations that the YNHH doctors knew that feeding Tylea cow milk-based formula could lead to NEC and death. *See* Mot. to Am. Opp'n, Doc. No. 73, at 1. Ferry also seeks to add a case citation to his brief: *Svege v. Mercedes-Benz Credit Corp.*, 329 F. Supp. 285 (D. Conn. 2004). *See id.* at 2.

Ferry's motion to amend his opposition was docketed as an exhibit and not a motion. To the extent it is a motion, I grant that motion and consider its contents as part of Ferry's opposition.

common law theories of liability thereunder." *Phila. Indem. Ins. Co. v. Lennox Indus., Inc.*, 2019 WL 1258918, at *2 (D. Conn. Mar. 18, 2019) (cleaned up). The available theories of liability include: (1) strict liability in tort, (2) negligence, (3) breach of warranty, express or implied, (4) breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent, and (5) misrepresentation or nondisclosure, whether negligent or innocent. *See* Conn. Gen. Stat. § 52-572m(b). Because the CPLA does not "alter the substance of a plaintiff's rights . . . any sub-claim brought under the CPLA . . . must sufficiently allege all elements that would be required at common law." *Phila. Indem.*, 2019 WL 1258918, at *2 (citing *LaMontagne v. E.I. Du Pont De Nemours & Co., Inc.*, 41 F.3d 846, 855 (2d Cir. 1994)).

All product liability claims brought in Connecticut "are governed by the same elements." *Bifolck v. Philip Morris*, 324 Conn. 402, 433–34 (2016). That is, a plaintiff must prove:

> (1) the defendant was engaged in the business of selling the product; (2) the product was in a defective condition unreasonably dangerous to the consumer or user; (3) the defect caused the injury for which compensation was sought; (4) the defect existed at the time of the sale; and (5) the product was expected to and did reach the consumer without substantial change in condition.

Id. at 434 (quoting *Izzarelli v. R.J. Reynolds Tobacco Co.*, 321 Conn. 172, 184–85 (2016)). In this case, Ferry alleges the following theories of product liability: (1) failure to warn, (2) strict liability for design defect, (3) breach of warranty, both express and implied, and (4) misrepresentation. I will address each in turn.

B. Failure to Warn

1. The Law

Courts evaluating a failure to warn claim engage in a three-step analysis. *See Karavitis v. Makita U.S.A., Inc.*, 243 F. Supp. 3d 235, 252–53 (D. Conn. 2017). First, a plaintiff must satisfy the five elements governing all product liability claims, as described above. *See id.* at 252.

Second, the plaintiff must show that product instructions or warnings "were required, and if so, whether they were adequate." *Id.* In that determination, the following factors are relevant: "(1) [t]he likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions." *Id.* at 252–53 (citing Conn. Gen. Stat. § 52-572q(b)). Third, a plaintiff must establish that "if adequate warnings or instructions had been provided, the claimant would not have suffered the harm." *Id.* at 253 (quoting Conn. Gen. Stat. § 52-572q(c)).

"Under the CPLA, a product seller is liable for a plaintiff's injuries when a product lacks adequate warnings directed to the person best positioned to keep the plaintiff from being hurt, and if the plaintiff would not have been injured if the warnings had been provided." *Klorczyk v. Sears, Roebuck & Co.*, 2019 WL 1433645, at *13 (D. Conn. Mar. 29, 2019) (citing Conn. Gen. Stat. § 52-572q). "Warnings must specifically identify for the user the danger inherent in the product's use." *Id.* at *14 (quoting *Giglio v. Conn. Light & Power Co.*, 180 Conn. 230, 237 (1980)); *see also Fraser v. Wyeth, Inc.*, 992 F. Supp. 2d 68, 81 (D. Conn. 2014) ("An overly broad or confusing warning will not suffice to discharge a prescription drug manufacturer's duty to adequately warn a prescribing physician, nor is the mere mention or equivocal reference to a particular injury sufficient.") (cleaned up).

The threshold question regarding Ferry's failure to warn claim is whether the warnings on the Defendants' products must have been adequate to warn medical professionals or, rather, consumers (*i.e.*, parents of premature infants). The answer depends on whether the learned intermediary doctrine applies. "The learned intermediary doctrine provides that adequate

warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly." *Vitanza v. Upjohn Co.*, 257 Conn. 365, 376 (2001) (cleaned up). "The learned intermediary doctrine applies particularly to the medical field, and generally involves unavoidably unsafe products." *Id.* at 390. The doctrine "developed in the area of prescription drugs." *Hall v. Ashland Oil Co.*, 625 F. Supp. 1515, 1518 (D. Conn. 1986) (citing *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969)). However, the Connecticut Supreme Court has extended the doctrine to other kinds of medical products, such as prescription medical devices. *See Hurley v. Heart Physicians, P.C.*, 278 Conn. 305, 317 (2006) (pacemaker). "The doctrine is based on the principle that prescribing physicians act as 'learned intermediaries' between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment." *Vitanza*, 257 Conn. at 376 (cleaned up).

2. Certification of Learned Intermediary Doctrine Issue

The parties disagree regarding whether the learned intermediary doctrine applies to Ferry's failure to warn claim. Ferry argues that it does not apply and so the Defendants had a duty to adequately warn Tylea's parents about the risks and benefits of the infant formulas. In contrast, the Defendants argue that the learned intermediary doctrine applies and so the Defendants had a duty to adequately warn Tylea's doctors about the risks and benefits of the infant formulas. Because of the issue's importance, the possibly broad effect of any potential answer, and the fact that resolving it will involve weighing policy considerations—and because Connecticut law does not shed light on the issue—I will certify this issue to the Connecticut Supreme Court. *See* Conn. Gen. Stat. § 51-199b(d); *see also Munn v. Hotchkiss School*, 795 F.3d 324, 334 (2d Cir. 2015).

To that end, I will enter a certification order 60 days from now that will set forth the basis for certification. In the 60 days between now and the date I enter that certification order, the parties are directed to engage in limited discovery regarding facts that will be important in resolving whether the learned intermediary doctrine applies to Ferry's failure to warn claim. Those facts might relate to, but are not limited to, the following issues:

- What are the exact products at issue in this case?
- How are those products made available for use, both in general and specifically in this case? That is, are those products provided directly to hospitals? Are they available for purchase on store shelves?
- How are the products at issue in this case marketed?
- What role, if any, did Tylea's parents play in her care?

3. Adequacy of Warnings

The parties also disagree about whether the warnings provided on the products were adequate. I will defer addressing that issue until the Connecticut Supreme Court decides whether to grant certification and, if so, whether the learned intermediary doctrine applies. Then, I will know to whom the warnings must have been directed, and I will be able to evaluate the parties' arguments regarding the adequacy of those warnings.

C. Defective Design: Ingredient of Cow Milk

1. The Infant Formula Act ("IFA") Framework

Infant formula is a food. 21 U.S.C. § 321(z). Adulterated food may not be introduced into interstate commerce. 21 U.S.C. § 331(a). The IFA, 21 U.S.C. § 350a, and its implementing regulations, 21 C.F.R. §§ 106–07, outline the requirements that infant formulas must meet and the procedures that manufacturers must follow before introducing infant formula into interstate commerce. The IFA lays out (1) the minimum (and sometimes maximum) nutrient requirements

in infant formula,[9] (2) the quality factors and manufacturing practices that manufacturers must follow,[10] and (3) registration and notification requirements for manufacturers.[11] "The only substances that may be used in an infant formula are substances that are safe and suitable for use in infant formula." 21 C.F.R. § 106.40(a).

A "new infant formula" is either a formula manufactured by a party "which has not previously manufactured an infant formula" or a previously manufactured formula "in which there is a major change, in processing or formulation." 21 U.S.C. § 350a(c)(2). A "major change" includes a "significant revision, addition, or substitution of a macronutrient (i.e., protein, fat, or carbohydrate), with which the manufacturer has not had previous experience." 21 C.F.R. § 106.3. Before introducing into interstate commerce any "new infant formula," a manufacturer must (1) register with the FDA, and (2) submit a notice[12] to the FDA at least 90 days before marketing such formula. 21 U.S.C. § 350a(c)(1); 21 C.F.R. § 106.120. "The manufacturer shall not market the new infant formula before the date that is 90 days after" the date on which the manufacturer submits the required notice. 21 C.F.R. § 106.120(e).

The FDA has slightly different review requirements for "exempt" infant formulas, which are infant formulas meant for especially low-birth-weight babies, such as the three formulas at issue in this case. *See* 21 U.S.C. § 350a(h); 21 C.F.R. § 107.50. Manufacturers of exempt formulas must "on or before the 90th day before the first processing of the infant formula for commercial or charitable distribution" submit the formula's (1) label, (2) "complete quantitative formulation," and (3) "a detailed description of the medical conditions for which the infant

[9] 21 U.S.C. § 350a(i); 21 C.F.R. § 107.100(a).
[10] 21 U.S.C. § 350a(b); 21 C.F.R. §§ 106.5–06.96.
[11] 21 U.S.C. § 350a(c), (d); 21 C.F.R. §§ 106.110–06.160.
[12] That notice includes the formula's quantitative formulation, a description of any reformulation or change in processing, and assurances that the manufacturer conducted the required testing and processing. *See* 21 U.S.C. § 350a(d).

formula is represented." 21 C.F.R. § 107.50(b)(3); *see also* 21 C.F.R. § 107.50(c)(4). Whenever a manufacturer of an exempt formula makes "any change in ingredients . . . that may result in an adverse impact on levels of nutrients or availability of nutrients," the manufacturer must submit to the FDA "before the first processing of the infant formula" the exempt formula's (1) label, (2) quantitative formulation, and (3) descriptions of the reformulation and the rationale behind it. 21 C.F.R. § 107.50(b)(4).

The FDA—in a Guidance from 2006—describes its infant formula review process as follows:

> FDA does not approve infant formulas before they can be marketed. However, all formulas marketed in the United States must meet federal nutrient requirements and infant formula manufacturers must notify the FDA prior to marketing a new formula. If an infant formula manufacturer does not provide the elements and assurances required in the notification for a new or reformulated infant formula, the formula is defined as adulterated . . . and FDA has the authority to take compliance action if the new infant formula is marketed.

Guidance for Industry: Frequently Asked Questions about FDA's Regulation of Infant Formula, U.S. FOOD AND DRUG ADMIN. (Mar. 2006), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-frequently-asked-questions-about-fdas-regulation-infant-formula.

2. The Law on Preemption

Under the Supremacy Clause, the laws and treaties of the United States are the "supreme Law of the Land." U.S. Const. Art. VI. "[I]t has long been settled that state laws that conflict with federal law are 'without effect.'" *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 479–80 (2013) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). When considering whether federal law preempts state law, courts should begin their analysis "with the assumption that the historic police powers of the States are not to be superseded by the Federal Act unless that was

the clear and manifest purpose of Congress." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008) (cleaned up). Preemption can be either express or implied.

"Express preemption arises when a federal statute expressly directs that state law be ousted." *Air Transp. Ass'n of Am., Inc. v. Cuomo*, 520 F.3d 218, 220 (2d Cir. 2008) (cleaned up). "Implied preemption arises when, in the absence of explicit statutory language, Congress intended the Federal Government to occupy a field exclusively, or when state law actually conflicts with federal law." *Id.* (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)) (cleaned up).

In this case, only one type of implied preemption is at issue: impossibility preemption. "Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law." *Fidelity Fed. Sav. and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982). Such a conflict arises when it is "impossible for a private party to comply with both state and federal requirements." *Bartlett*, 570 U.S. at 480 (quoting *English*, 496 U.S. at 79). "Impossibility pre-emption is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

In recent years, the Supreme Court and some lower courts have held that certain plaintiffs' state law product liability claims against brand-name and generic drug manufacturers were impliedly preempted based on impossibility. For instance, in *Bartlett*, the Supreme Court held that a plaintiff's state-law product liability claim, which asked a drug manufacturer to unilaterally change the composition of a generic drug—sulindac—or the warnings on sulindac's label, was preempted under federal law because "it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label." *Bartlett*, 570 U.S. at 480. Sulindac was a generic drug, and federal law

clearly prohibits a generic drug manufacturer from unilaterally changing that drug's label. *Id.* at 486 (citing, *inter alia*, 21 U.S.C. § 355(j)(2)(A)(v)); *see also PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) ("It was not lawful under federal law for the Manufacturers to do what state law required of them" because if they "had independently changed their labels to satisfy their state-law duty, they would have violated federal law").

However, not all state law product liability claims against drug manufacturers are preempted. In *Wyeth*, the plaintiff pursued a state law tort claim based on a brand-name drug's inadequate warnings on its labels. 555 U.S. at 558. The Court held that the plaintiff's claim was not preempted because strengthening the label would not necessarily have been a change that required FDA pre-approval. Indeed, there existed an "FDA regulation that permits a manufacturer to make certain changes [such as strengthening a warning] to its label before receiving the agency's approval." *Id.* at 568. Even though the FDA would ultimately need to approve the labeling change, the Court explained that there was no "clear evidence that the FDA would not have approved a change to" the label, and so the Court refused to find impossibility preemption. *Id.* at 571.

From these cases, a modern impossibility preemption test emerges. To determine whether impossibility preemption exists in a particular case, a court should: (1) "identify the defendant's duties under state law"; (2) "ascertain whether federal law expressly prohibits the defendant from complying with state law"; (3) if not, "determine whether the defendant has presented clear evidence that the FDA would have prohibited the defendant from taking the necessary steps under state law." *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 294 (6th Cir. 2015) (quoting *Levine* throughout) (cleaned up).

3. The Parties' Arguments

a. Preemption

The Defendants argue that impossibility preemption bars Ferry's design defect claim regarding the presence of cow milk in the Defendants' formulas. *See* Abbott's Mem. of Law, Doc. No. 51-1, at 18 (quoting *Bartlett*, 570 U.S. at 480). More particularly, the Defendants claim that their formulas "went through FDA's special review process for exempt formulas." *Id.* at 19. Thus, the Defendants submitted—and the FDA reviewed—the ingredients, labeling, and product descriptions for those formulas. *See id.* (quoting 21 C.F.R. § 107.50(b)(3)). That FDA review necessarily included a determination whether cow milk—an ingredient in the formulas—was "safe and suitable for use in infant formula." *See id.* (quoting 21 C.F.R. § 106.40(a)).[13] By allowing the Defendants to market their products, the FDA concluded that the formulas were "permitted for sale . . . as [] formula[s] specifically designed for an infant with 'low birth weight.'" *Id.* (quoting 21 C.F.R. § 107.50(a)).

The Defendants argue that they cannot "unilaterally remove" cow milk from their products because "such a change requires FDA review." *Id.* at 20. The Defendants conclude: "Any unilateral change by [the Defendants] would violate the [IFA] and its regulations, so by insisting on that change in the name of state law, Plaintiff would make it impossible for [the Defendants] to comply with federal law." *Id.* Finally, the Defendants note that, although they could comply with both federal and state law by ceasing to sell their infant formulas, that "stop-selling" outcome has been rejected as a valid alternative to impossibility preemption. *See id.* (citing *Bartlett*, 570 U.S. at 488).

Ferry disagrees. As a general matter, Ferry notes that courts are not quick to find impossibility preemption. *See* Pl.'s Opp'n, Doc. No. 62-1, at 37. More specifically, Ferry

[13] The Defendants also note that cow milk is "safe and suitable for use in infant formula," as evidenced by the fact that "many infant formulas for sale today include cow milk." Abbott's Mem. of Law, Doc. No. 51-1, at 9.

argues it is not impossible for the Defendants to comply with both state and federal requirements in this case. *See id.* at 34–41. Ferry points out that the cases on which the Defendants rely are inapposite because they regard manufacturers of prescription and generic *drugs*, which are subject to a much more stringent regulatory regime under relevant federal law than are baby foods under the IFA. *See id.* Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, drug manufacturers must gain pre-approval for their drugs' composition before bringing them to market, so any unilateral change in a drug's composition (even if mandated by state law) would violate federal law. In contrast, infant formulas are "not governed by the same provisions," the relevant provisions of the IFA do "not contain the same prohibitions against product alteration," and, thus, the infant formulas do "not trigger impossibility preemption." *Id.* at 35.

Ferry claims that the Defendants "fail to point to any portions of the [IFA] that would prohibit the Defendant[s] from altering the product or the formulation." *Id.* Indeed, Ferry points out, "the FDA does not *approve* infant formulas before they can be marketed. Rather, the [IFA] simply mandates that all formulas marketed in the United States must meet certain nutrient requirements." *Id.* at 36. Thus, "infant formula manufacturers must merely notify the FDA prior to marketing a new formula." *Id.* If a manufacturer wishes to market an infant formula with a major change, it must simply "provide FDA with a notification about" the major change and assure the FDA that its formula will meet all the necessary requirements of federal law. *Id.* at 36–37.[14]

[14] Ferry also argues that—rather than preempting it—the IFA *supports* his state-law tort claim. More specifically, Ferry cites a recent FDA guidance regarding exempt infant formula production. *See Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports*, Ex. F to Pl.'s Opp'n, Doc. No. 62-7, at 4. The informal guidance "provides [the FDA's] current thinking about the significance of the regulations in part 106 [which apply to non-exempt infant formulas] . . . for exempt infant formulas." *Id.* at 5. The guidance explains that, logically, exempt infant formulas, which are for premature babies, should be subject to production requirements at least as stringent as those mandated

b. On the merits – if not preempted

The Defendants construe Ferry's complaint as alleging that formulas containing cow milk are defective. *See* Abbott's Mem. of Law, Doc. No. 51-1, at 16 (citing Am. Compl., Doc. No. 50, at ¶ 113(B)(b)). The Defendants point out that the studies Ferry cites in his complaint do not say that; instead, they "report on the apparent protective effects of human breast milk." *See id.* The Defendants concede that "breast milk is the best source of nutrition for all infants when it is safe and available." *Id.* (citing Amy B. Hair, et al., *Beyond Necrotizing Enterocolitis Prevention: Improving Outcomes with an Exclusive Human Milk-Based Diet*, BREASTFEEDING MEDICINE (2016), Ex. 5 to Abbott's Mot. to Dismiss, Doc. No. 51-6, at 2 ("It has been long established that breast milk is the best source of nutrition for all infants when it is safe and available.")); *see also* Am. Compl., Doc. No. 50, at ¶¶ 81–82. However, human breast milk is *not* always safe and available, and "the amended complaint never attempts to allege how the design was unreasonable given the need for alternative sources of nutrition." Abbott's Mem. of Law, Doc. No. 51-1, at 17 (cleaned up). The Defendants also note that some studies that Ferry cites indicate that babies born extremely prematurely—such as Tylea—are statistically at a high risk for developing NEC; in fact, "prematurity is a predominant risk factor." *Id.* (citing Jocelyn Shulhan, et al., *Current Knowledge of Necrotizing Enterocolitis in Preterm Infants and the Impact of Different Types of Enteral Nutrition Products*, ADVANCES IN NUTRITION (January 2017), Ex. 2 to Abbott's Mot. to Dismiss, Doc. No. 51-3, at 3 ("Prematurity is a predominant risk factor for NEC.") (the "Shulhan Article")); *see also* Am. Compl., Doc. No. 50, at ¶¶ 83–84.

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for non-exempt infant formulas. *Id.* Thus, the FDA "recommend[s] that manufacturers of exempt infant formulas follow . . . subparts A, B, C, D, and F of 21 CFR part 106." *Id.* at 6. Ferry points out that subpart F "requires the manufacturers to fully investigate all adverse events and complaints and notify the FDA." Pl.'s Opp'n, Doc. No. 62-1, at 40 (citing 21 C.F.R. § 106.100). Ferry accuses the Defendants of failing to do that: They "began to learn" that their products caused NEC and death, but they did not take immediate action to alter their products accordingly. *Id.*

The Defendants argue, too, that even if Ferry had plausibly alleged a design defect based on cow milk, Ferry has not plausibly alleged causation. That is, Ferry has not plausibly alleged that "a single week of being fed Similac Special Care, given all of the challenges facing the infant, was responsible for her [NEC] and death." Abbott's Mem. of Law, Doc. No. 51-1, at 17. Mead Johnson argues the same with respect to Enfamil and EnfaCare, although the time that Tylea was fed those formulas was longer than one week. *See* Am. Compl., Doc. No. 50, at ¶¶ 11–18, 24–26.

Although Ferry does not mount much of an argument against the Defendants' position—his opposition simply contains paragraphs-long block quotations from other opinions—he apparently argues that he has pleaded facts sufficient to make out a prima facie design defect case under both the "consumer expectation" and "modified consumer expectation" tests. *See* Pl.'s Opp'n, Doc. No. 62-1, at 43–45.

4. Discussion

At this motion to dismiss stage, it is a close question whether federal law preempts Ferry's claim for design defect based on the presence of cow milk in the Defendants' exempt infant formulas. I am aware of no court that has held that the IFA impliedly preempts state-law product liability claims regarding infant formula, and it seems that no court has even addressed that precise issue.[15]

The first step in the impossibility preemption test is determining what duties state tort law imposes on the Defendants. *See Bartlett*, 570 U.S. at 480. Under Connecticut law, "[a] design

[15] At the hearing on the Defendants' motions to dismiss in this matter, the Defendants admitted that they, too, were aware of no case in which a court had held that the IFA preempted a state law product liability claim. *See* Hr'g Tr., Doc. No. 82, at 39:3–40:24. I agree with Ferry that the case the Defendants cite as most analogous—*Marentette v. Abbott Labs., Inc.*, 886 F.3d 112 (2d Cir. 2018)—is of limited import here because it regards a different statute: the Organic Foods Production Act, 7 U.S.C. §§ 6501, *et seq.*

defect . . . exists when the product is otherwise properly manufactured, but is nonetheless unreasonably dangerous because its attributes can cause unexpected injury." *Moss v. Wyeth, Inc.*, 872 F. Supp. 2d 162, 166 (D. Conn. 2012). A plaintiff may show that a product "was in a defective condition unreasonably dangerous to the consumer or user" using one of two tests. *Bifolck*, 324 Conn. at 434. "A product is defectively designed if: (1) it failed to perform as safely as an ordinary consumer would expect when used in a reasonably foreseeable manner" or "(2) in the case of complex products, the risk of danger inherent in the design of the product outweighs its utility." *Moss*, 872 F. Supp. 2d at 166. Test (1) is called either the "ordinary consumer expectations" test or the "consumer expectations test." *Bifolck*, 324 Conn. at 432. Test (2) is called either the "modified consumer expectations" test or the "risk-utility" test. *Id.* The Connecticut Supreme Court has clarified that the second test—the "risk-utility" test—is "our primary test" and will "govern most cases." *Id.* at 416, 434 (citing *Izzarelli*, 321 Conn. at 194).

Under the "risk-utility" test, a product was in a defective condition unreasonably dangerous to the consumer or user if:

> (1) A reasonable alternative design was available that would have avoided or reduced the risk of harm and the absence of that alternative design renders the product unreasonably dangerous . . . ; or
>
> (2) The product is a manifestly unreasonably design in that the risk of harm so clearly exceeds the product's utility that a reasonable consumer, informed of those risks and utility, would not purchase the product.

Id. at 434–35. Under the "consumer expectations" test, "a product is in a defective condition unreasonably dangerous to the consumer or user only if it is 'dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.'" *Id.* at 436 (quoting Restatement (Second) of Torts, § 402A, cmt. (i)).

Ferry alleges that the Defendants' infant formulas are "unavoidably unsafe" products. Connecticut courts have held that prescription drugs are "unavoidably unsafe" products because they "may cause untoward side effects despite the fact that they have been carefully and properly manufactured." *Vitanza*, 257 Conn. at 375 (quoting *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90 (2d Cir. 1980)). Ferry alleges that the Defendants' products cause "untoward" side effects—NEC and death—about which the Defendants do not warn. *See* Am. Compl., Doc. No. 50, at ¶¶ 22, 30, 38–47 (alleging that the infant formulas contain cow milk and so are "dangerous to premature infants" because they "significantly increase[] the risk that the baby will develop N.E.C." and thus "significantly increase[] the risk that the baby will die"). Thus, for purposes of these motions to dismiss, I view the three exempt infant formulas at issue as "unavoidably unsafe products."

In Connecticut, "[a] manufacturer of an unavoidably unsafe product can avoid strict liability if the product is properly prepared, and accompanied by proper directions and warning." *Batoh v. McNeil-PPC, Inc.*, 167 F. Supp. 3d 296, 321 (D. Conn. 2016) (quoting *Vitanza*, 257 Conn. at 375) (cleaned up). As in the case of brand-name drug manufacturers, then, a manufacturer of an exempt infant formula can avoid liability "by choosing a safer design for the [product] or by strengthening the [product]'s warning label." *Id.* (quoting *Yates*, 808 F.3d at 297) (cleaned up).[16] As relevant to the design defect claim, Ferry argues that the Defendants should have altered the design of their exempt infant formulas—by omitting cow milk—when they became aware that cow milk could cause NEC and death.[17]

[16] The Defendants do not argue that Ferry's failure to warn claim is preempted by federal law. *See* Hr'g Tr., Doc. No. 82, at 40:2–17.

[17] Ferry does not argue that the Defendants should have chosen a different product design in the first place, decades ago, and so I do not address that issue. *Cf. Yates*, 808 F.3d at 297–300 (treating pre-FDA approval and post-FDA approval preemption arguments differently); *Guidry v. Janssen Pharm., Inc.*, 206 F. Supp. 3d 1187, 1206–09 (E.D. La. 2016) (same).

At the second step in the impossibility preemption analysis, I must determine whether federal law expressly prohibits the Defendants from complying with state law. It seems possible that federal law does prohibit the Defendants from simply choosing a safer design for their exempt infant formulas by removing cow milk and substituting a different ingredient. However, I cannot yet draw that conclusion as a matter of law.

As previously mentioned, no court (to my or the parties' knowledge) has yet addressed the issue whether the IFA and its implementing regulations prevent a manufacturer of an infant formula from unilaterally changing the design of its formulas. The most relevant precedent regards impossibility preemption of state law product liability claims against generic and brand-name drug manufacturers. But the regulatory scheme applicable to drug manufacturers is not the same as the regulatory scheme applicable to manufacturers of infant formulas, which are food. Thus, I do not have the benefit of prior courts' discussions regarding this issue of apparent first impression. Further, although the parties' briefs outline the IFA's regulatory regime and discuss the preemption issue, those discussions are not overly extensive. *See* Abbott's Mem. of Law, Doc. No. 51-1, at 8–10, 18–20; Pl.'s Opp'n, Doc. No. 62-1, at 34–38. As a result, I am left with several questions regarding the relevant regulatory regime that prevent me from granting the Defendants' motions to dismiss on this ground.

The first issue regards whether re-notification would be necessary under the IFA if the Defendants were to replace cow milk with some other nutrient. That depends on whether replacing cow milk with a different ingredient would constitute a "major change" to the Defendants' infant formulas at issue.[18] Although the Defendants are possibly correct when they

[18] The Defendants argue that "any reformulation" of a previously manufactured infant formula also necessitates a new submission because "any reformulation" is a "major change." *See, e.g.*, Abbott's Mem. of Law, Doc. No. 51-1, at 9; Abbott's Reply, Doc. No. 69, at 13. For that proposition, Abbott cites 21 U.S.C. § 350a(d)(1)(B), which reads: "A person shall, with respect to any infant formula subject to subsection (c), make a

assert that replacing cow milk with another nutrient would "obviously" be a major change to its formulas,[19] I do not yet have the facts necessary to make that determination. A "major change" is defined as:

> any new formulation, or any change in ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or bioavailability of nutrients, or any change that causes an infant formula to differ fundamentally in processing or in composition from any previous formulation produced by the manufacturer.

21 C.F.R. § 106.3. A "major change" includes a "significant revision, addition, or substitution of a macronutrient (i.e., protein, fat, or carbohydrate), with which the manufacturer has not had previous experience." *Id.*

At the motion to dismiss stage, I do not yet know whether the Defendants' replacing cow milk with another nutrient would be a "major change." The answer might depend, in part, on how many infant formulas on the market contain cow milk or, instead, a substitute nutrient. The Defendants report in their briefs that "many infant formulas for sale today include cow milk" and that "some other exempt formulas . . . also contain cow milk." *See* Abbott's Mem. of Law, Doc. No. 51-1, at 9–10. But for those propositions the Defendants cite the portion of Ferry's complaint that alleges that the three products at issue in *this case* contain cow milk[20] and a

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submission to the Secretary which shall include . . . a description of any reformulation of the formula or change in processing of the infant formula." Thus, by its terms, section 350a(d)(1)(B) applies only to "any infant formula subject to subsection (c)." 21 U.S.C. § 350a(d)(1)(B). As described above, Section 350a(c)(2) defines "new infant formula" to include "(A) an infant formula manufactured by a person which has not previously manufactured an infant formula, and (B) an infant formula manufactured by a person which has previously manufactured infant formula and in which there is a major change, in processing or formulation, from a current or any previous formulation produced by such manufacturer." 21 U.S.C. § 350a(c)(2). "Major change" is defined in 21 C.F.R. § 106.3. Nowhere in that section is "major change" defined to include "any reformulation." *See* 21 C.F.R. § 106.3. Thus, I disagree with the Defendants that "[m]ajor changes include 'any reformulation.'" Abbott's Mem. of Law, Doc. No. 51-1, at 9.

[19] *See* Abbott's Mem. of Law, Doc. No. 51-1, at 20 ("Removing cow milk would be a 'major change' to the formula."); Abbott's Reply, Doc. No. 69, at 13 ("Replacing cow milk—of which there is more in Similac Special Care than any other ingredient save water—would obviously be a major change and reformulation.").

[20] *See* Am. Compl., Doc. No. 50, at ¶¶ 39–41.

section of the C.F.R. that simply defines infant formula.[21] Thus, the Defendants assume facts that are not before me. Without knowing more about the infant formula market in general, I cannot yet conclude as a matter of law that substituting a different ingredient for cow milk would be a "change of ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or bioavailability of nutrients." 21 C.F.R. § 106.3.[22]

Further, without knowing more about the Defendants' particular manufacturing practices and histories, I cannot know whether substituting cow milk for another nutrient would constitute a "fundamental[]" difference in composition from "any previous formulation produced by" the Defendants. 21 C.F.R. § 106.3. In addition, I cannot know whether the substitution to a different macronutrient would result in the Defendants' producing a formula based on a macronutrient "with which the manufacturer has not had previous experience." *Id.* In sum, because I am constrained in what I can consider at the motion to dismiss stage, I cannot yet determine as a matter of law that substituting cow milk for another nutrient would constitute a "major change" in the Defendants' infant formulas.

Even if I could so determine, I still would not grant the Defendants' motions to dismiss Ferry's design defect claim on preemption grounds because of uncertainty regarding the FDA's notification process for previously registered infant formulas that have undergone a "major change." As described above, in the case of previously approved drugs, the FDA must *pre-*

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[21] 21 C.F.R. § 106.3 ("Infant formula means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.").

[22] The same reasoning applies regarding exempt infant formulas. A manufacturer of an exempt formula must submit certain information to the FDA "before the first processing of" an exempt infant formula whenever the manufacturer makes "any change in ingredients . . . that may result in an adverse impact on levels of nutrients or availability of nutrients." 21 C.F.R. § 107.50(b)(4). Because I do not yet know whether substituting cow milk for another nutrient "may result in an adverse impact on levels of nutrients or availability of nutrients," I cannot say that Ferry's design defect claim is preempted as a matter of law.

approve all major changes "prior to distribution of the product." *See* 21 C.F.R. § 314.70(b); *Bartlett*, 570 U.S. at 477 ("Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to . . . the drug product . . . ."). In contrast, in the case of previously registered infant formulas, the FDA does *not* "pre-approve" major changes, but it does require *registration* and *notification* 90 days before the manufacturer may introduce the product into interstate commerce and begin marketing the product. *See* 21 U.S.C. § 350a(c)(1), (d); 21 C.F.R. §§ 106.110, 106.120.

The Defendants argue that the FDA's pre-approval process for drugs is identical in all important respects to the FDA's registration and notification procedure for infant formulas.[23] Although that position may ultimately be correct, I am hesitant to conclude—without more factual development and further briefing—that the "pre-approval" process for drugs that have undergone a major change and the "notification" process for infant formulas that have undergone a major change are, essentially, identical. The IFA and its implementing regulations at issue in this case conspicuously omit the word "approve." Indeed, the Defendants concede that the FDA need not "approve" new infant formulas. *See* Abbott's Mem. of Law, Doc. No. 51-1, at 19 (referring to the IFA's pre-market process as the "FDA's special review process"). When

[23] The Defendants' basic argument is that they cannot unilaterally replace cow milk in their formulas because doing so would be a major change that would require the Defendants to go through the IFA's 90-day notification process before marketing that infant formula. *See* 21 U.S.C. § 350a(c)(1)(B); Abbott's Mem. of Law, Doc. No. 51-1, at 20. If state law required that the Defendants' infant formulas could not contain cow milk, the Defendants would have to stop selling infant formula with cow milk or be in violation of state law. But, according to federal law, the Defendants argue, they could not independently and immediately substitute a different nutrient for cow milk because doing so would run afoul of the IFA's 90-day pre-marketing notification window applicable to "new infant formulas." Thus, the Defendants would not be able to "independently do under federal law what state law requires of" them. *Batoh*, 167 F. Supp. 3d at 322 (quoting *Mensing*, 564 U.S. at 620) (cleaned up). The Defendants argue that "preemption cannot be avoided if the only way a manufacturer can comply with both federal and state law is to exit the market." *Yates*, 808 F.3d at 296; *see also Bartlett*, 570 U.S. at 488–89 (rejecting stop-selling rationale). "When a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Batoh*, 167 F. Supp. 3d at 322 (quoting *Mensing*, 564 U.S. at 623–24) (cleaned up).

drafting the IFA, Congress knew how to require FDA pre-approval of a substance having undergone a major change; instead, Congress installed a notification procedure. That statutory mismatch gives me pause. *Cf. Erlenbaugh v. United States*, 409 U.S. 239, 243–44 (1972) (discussing the statutory canon of *in pari materia*, which instructs that "a legislative body generally uses a particular word with a consistent meaning in a given context"). Similarly, in my view, the cases on which the Defendants rely regard regimes in which a government body or agent actively *approves* a drug or food. *See, e.g.*, *Marentette v. Abbott Labs., Inc.*, 886 F.3d 112, 115–16 (2d Cir. 2018) (noting that under the Organic Foods Production Act, an "accredited certifying agent" must "approve[]" an applicant's "organic plan" and then "perform[] an on-site inspection"); *Yates*, 808 F.3d at 298–300 (discussing brand-name drug that went through FDA's new drug approval process); *Bartlett*, 570 U.S. at 476–77 (describing, in detail, the FDA's new drug approval process and characterizing it as "both onerous and lengthy"). In contrast, the notification procedure outlined in the IFA seems much more passive. In any event, I need not now reach that question because I have already held that, at the current stage of litigation, I cannot conclude as a matter of law that replacing cow milk with another ingredient would be a "major change" within the meaning of the IFA.

Finally, because Ferry's design defect claim is not preempted, I must assess the claim on the merits. "[T]o recover under the doctrine of strict liability in tort the plaintiff must prove that: (1) the defendant was engaged in the business of selling the product; (2) the product was in a defective condition unreasonably dangerous to the consumer or user; (3) the defect caused the injury for which compensation was sought; (4) the defect existed at the time of the sale; and (5) the product was expected to and did reach the consumer without substantial change in condition." *Kuzmech v. Werner Ladder Co.*, 2012 WL 6093898, at *11 (D. Conn. Dec. 7, 2012)

(quoting *Giglio*, 180 Conn. at 234). "In a products liability action, the plaintiff must plead and prove that the product was defective and that the defect was the proximate cause of the plaintiff's injuries." *Id.* (quoting *Haesche v. Kissner*, 229 Conn. 213, 218 (1994)). Only elements (2) and (3) are at issue.[24] As I have already described, Ferry may prove element (2) using either the "risk-utility" test or the "consumer expectations" test.

Taking Ferry's allegations as true, as I must, I have little trouble concluding that he has plausibly alleged a design defect claim based on the presence of cow milk in the Defendants' formulas. Ferry alleges that cow milk is dangerous and that the Defendants concealed the extent of its threat from unwitting consumers. *See, e.g.*, Am. Compl., Doc. No. 50, at ¶¶ 22, 30 (alleging that the Defendants knew that their products "increase[] the risk of N.E.C. and death," and still did not warn of those outcomes). Although he does not say so explicitly, the substance of Ferry's allegations is that the Defendants could reasonably re-design their infant formulas by substituting some other nutrient for cow milk.

To the extent that the Defendants argue that the scientific literature that Ferry references in his complaint contradicts his allegations, I disagree. *See* Abbott's Mem. of Law, Doc. No. 51-1, at 16 (arguing that the studies, rather than substantiating a link between cow milk in infant formula and NEC and death, "report on the apparent protective effects of human breast milk"). In my view, the scientific literature referenced in Ferry's complaint does, in places, suggest that cow milk-based formulas may cause NEC and death. *See, e.g.*, Shulhan Article, Ex. 2 to Abbott's Mot. to Dismiss, Doc. No. 51-3, at 6 ("Several studies . . . have indicated that bovine

[24] With respect to element (1), the Defendants were in the business of selling the infant formulas at issue. *See* Am. Compl., Doc. No. 50, at ¶¶ 5–6. With respect to element (4), Ferry's theory of the case is that there is a defect in the nutritional composition of the infant formulas at issue, and so the defects by definition existed at the time of sale. With respect to element (5), there is no allegation that the infant formulas at issue were manipulated before being fed to Tylea.

milk-based products may increase the risk of NEC."); Am. Compl., Doc. No. 50, at ¶ 83 (discussing the Shulhan Article). Thus, Ferry has adequately alleged that the Defendants' infant formulas were unreasonably dangerous to the consumer or user.

With respect to causation, the Defendants apparently argue that Ferry has failed to allege that the Defendants' products were the proximate cause of Tylea's death. The Defendants highlight the fact that Tylea was born extremely prematurely and that such babies are statistically at a high risk for developing NEC; in fact, "[p]rematurity is a predominant risk factor." Abbott's Mem. of Law, Doc. No. 51-1, at 17 (citing Shulhan Article, Ex. 2 to Abbott's Mot. to Dismiss, Doc. No. 51-3, at 3).

Although Ferry may have a difficult time proving that the Defendants' exempt infant formulas caused Tylea's NEC, Ferry has adequately alleged causation at this point. First, Ferry need not allege that the Defendants' infant formulas were the *only* cause of Tylea's developing NEC and dying. *See* Conn. Judicial Branch Civil Jury Instr. § 3.1–2 (Proximate Cause – Multiple Causes); *Fleming v. Garnett*, 231 Conn. 77, 86 (1994). Second, Ferry alleges a temporal connection between Tylea's health and her ingestion of the Defendants' formulas: Tylea was progressing well in the NICU, then started taking the Defendants' products, and quickly got worse. *See* Am. Compl., Doc. No. 50, at ¶¶ 10–18; 23–26; 31–34. Third, Ferry alleges that the Defendants' cow milk-based infant formulas significantly increased the risk of—and, in fact, caused—Tylea to develop NEC. *See, e.g.*, Am. Compl., Doc. No. 50, at ¶¶ 51–52 (alleging that the Defendants' "cow-based formula[s] did cause the baby . . . to develop N.E.C."), 95–102 (describing the Defendants' products as "leading to" and "causing" NEC). Ferry also alleges that several scientific studies confirm that cow milk-based formulas increase the risk of premature infants' developing NEC. *See, e.g.*, Am. Compl., Doc. No. 50 at ¶¶ 77 (citing study

claiming that "it is well established that the risk [of NEC] is increased by the administration of infant formula and decreased by the administration of breast milk"); 83 (citing study claiming that "bovine milk-based formula . . . significantly increases the risk of NEC"). In sum, Ferry has plausibly alleged causation for a design defect claim.

D. Warranty and Misrepresentation

1. The Law

a. Express Warranty

To recover for breach of an express warranty a plaintiff must show (1) that a warranty existed, (2) a breach of that warranty, and (3) damages proximately caused by the breach. *See, e.g.*, *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 114 (D. Conn. 2014). A seller of a product can create an express warranty in the following ways:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description. (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

Conn. Gen. Stat. § 42a-2-313(1). To survive a motion to dismiss a claim for breach of express warranty, a plaintiff must have adequately alleged both the representation that the defendant allegedly made and breached and to whom it was conveyed and how. *See, e.g.*, *Phila. Indem.*, 2019 WL 1258918, at *9; *Simoneau v. Stryker Corp.*, 2014 WL 1289426, at *14 (D. Conn. Mar. 31, 2014) ("[A] breach of express warranty claim without any reference to the underlying representation lacks plausibility.").

Normally, "whether a particular statement from a manufacturer [i]s an 'affirmation or promise'" is a question of fact. *K.E. v. GlaxoSmithKline LLC*, 2017 WL 440242, at *21 (D.

Conn. Feb. 1, 2017) (cleaned up). However, in Connecticut, "a drug manufacturer's representation in advertising or a warning label that a product is safe or effective, or an advertisement or warning label that does not adequately highlight a particular known or knowable risk does not create an express warranty in the absence of a guarantee that the particular product is free from all harmful side effects." *Fraser v. Wyeth, Inc.*, 857 F. Supp. 2d 244, 257–58 (D. Conn. 2012) (citing, *inter alia*, *Basko*, 416 F.2d at 428).

b. Implied Warranty

Just as in the case of a breach of express warranty claim, to establish a claim for breach of implied warranty, a plaintiff must show (1) that a warranty existed, (2) a breach of that warranty, and (3) damages proximately caused by the breach. *See Phila. Indem.*, 2019 WL 1258918, at *8 (citing *McConologue*, 8 F. Supp. 3d at 114). There are two kinds of implied warranties at issue in this case. The first is the implied warranty of merchantability. In Connecticut, "[a] warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Conn. Gen. Stat. § 42a-2-314(1). Merchantable goods must be "fit for the ordinary purposes for which such goods are used" and "conform to the promises or affirmations of fact made on the container or label if any." *Id.* § 42a-2-314(2). Put simply, "[u]nder Connecticut law, a product must be fit for the ordinary purpose for which such goods are used." *GlaxoSmithKline LLC*, 2017 WL 440242, at *22 (cleaned up).

> [T]o state a claim for breach of the implied warranty of merchantability, a party must plead that: 1) a merchant sold the goods; 2) the goods were defective and not merchantable at the time of sale; 3) injury occurred to the buyer or his property; 4) the injury was caused by the merchant's defective product; and 5) notice was given to the seller of the claimed breach.

Gallinari v. Kloth, 148 F. Supp. 3d 202, 215 (D. Conn. 2015) (quoting *State v. McGriff,* 1991 WL 257221, at *2 (Conn. Super. Ct. Nov. 27, 1991)).

The second kind of implied warranty relevant here is the implied warranty of fitness for a particular purpose. "Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." Conn. Gen. Stat. § 42a-2-315. "To establish a cause of action for breach of the implied warranty of fitness for a particular purpose, a party must establish (1) that the seller had reason to know of the intended purpose and (2) that the buyer actually relied on the seller." *Gallinari*, 148 F. Supp. 3d at 215 (D. Conn. 2015) (quoting *Miller v. Ne. Utilities*, 1993 WL 137577, at *4 (Conn. Super. Ct. Apr. 20, 1993)).

c. Misrepresentation

Ferry's complaint alleges that the Defendants engaged in both intentional and negligent misrepresentation. *See* Pl.'s Opp'n, Doc. No. 62-1, at 48. Because intentional misrepresentation claims sound in fraud, a heightened pleading standard applies. *See ARMOUR Capital Mgmt. LP v. SS&C Techs., Inc.*, 2018 WL 1368908, at *6 (D. Conn. Mar. 16, 2018). "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). That means that the plaintiff must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *ARMOUR Capital*, 2018 WL 1368908, at *6 (quoting *United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017)) (cleaned up).

When alleging fraud, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). Although Rule 9(b) thus indicates that a plaintiff may allege scienter "generally," the Second Circuit has made clear that plaintiffs in fraud cases must "allege facts that give rise to a strong inference of fraudulent intent." *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994). That strong inference "may be established either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Id.*

To make out a claim for intentional misrepresentation, a plaintiff must establish "(1) that a false representation was made as a statement of fact; (2) that it was untrue and known to be untrue by the party making it; (3) that it was made to induce the other party to act on it; and (4) that the latter did so act on it to his injury." *456 Corp. v. Utd. Nat'l Foods, Inc.*, 2011 WL 87292, at *3 (D. Conn. Jan. 11, 2011) (quoting *Updike, Kelly, & Spellacy, P.C. v. Beckett*, 269 Conn. 613, 643 (2004)). To make out a claim for negligent misrepresentation, a plaintiff must establish (1) that the defendant made a misrepresentation of fact (2) that the defendant knew or should have known was false, (3) that the plaintiff reasonably relied on the misrepresentation and thus (4) suffered pecuniary harm. *See McNeil v. Yale Univ.*, 436 F. Supp. 3d 489, 536 (D. Conn. 2020) (citing *Nazami v. Patrons Mut. Ins. Co.*, 280 Conn. 619, 626 (2006)). Courts disagree about whether the heightened pleading standard of Rule 9(b) applies to negligent misrepresentation claims. *See ARMOUR Capital*, 2018 WL 1368908, at *6 (describing the disagreement). However, courts agree that when "negligent misrepresentation is couched in fraud-like terms of known falsity," the heightened fraud pleading standard applies. *See Karazin*

v. Wright Med. Tech., Inc., 2018 WL 4398250, at *7 (D. Conn. Sept. 14, 2018); *ARMOUR Capital Mgmt. LP v. SS&C Techs., Inc.*, 2020 WL 64297, at *2 (D. Conn. Jan. 5, 2020).

2. Parties' Arguments

a. Warranties

Ferry argues that he has made out prima facie cases for breaches of both express and implied warranties because the complaint alleges that "the Defendants specifically sold, promoted, and marketed their products as safe and beneficial for premature infants," and that "the hospitals, physicians and parents were falsely led to believe these products were beneficial for premature infants." Pl.'s Opp'n, Doc. No. 62-1, at 46; *see also* Am. Compl., Doc. No. 50, at ¶¶ 65–72. Ferry, citing an out-of-jurisdiction case, argues that the Defendants represented their infant formulas as safe, and so he need not point to any specific warranty to satisfy the heightened fraud pleading standard. *See id.* at 48 (citing *Baudin v. AstraZeneca Pharm., LP*, 413 F. Supp. 3d 498, 511–12 (D. La. 2019) (construing Louisiana law)).[25] Ferry also argues that it is a question of fact for the jury whether there was a breach of an implied warranty of fitness for a particular purpose. *See id.* at 48 (citing *Crotty v. Shartenberg's-New Haven, Inc.*, 147 Conn. 460, 467–68 (1960)).

The Defendants point out that Ferry's breach of warranty allegation is extremely thin—just one sentence: "The defendant expressly or impliedly breached its warranty that its product was safe to be fed to premature infants, when, in fact, it was extremely dangerous." Abbott's

[25] Ferry also includes a full-page block quotation from another case in this district in which a court found that the Defendants had made an express warranty. *See* Pl.'s Opp'n, Doc. No. 62-1, at 47–48 (quoting *Liberty Mut. Ins. Co. v. Howmet Casting & Servs., Inc.*, 2016 WL 5661999, at *2–3 (D. Conn. Sept. 29, 2016)). However, Ferry provides no analysis and does not indicate why the reasoning in that case should apply here. In my view, that case is inapposite because, there, the Defendants did make an express warranty by "represent[ing] that they took the responsibility to provide their customers blades that were safe and free of malfunction defects." *Howmet Casting*, 2016 WL 5661999, at *3. In this case, as I explain, Ferry has not alleged that the Defendants made an express warranty.

Mem. of Law, Doc. No. 51-1, at 20 (citing Am. Compl., Doc. No. 50, at ¶ 113(E)). The Defendants explain that that threadbare recitation does not satisfy the elements of a breach of warranty claim under Connecticut law. Specifically, the Defendants claim that Ferry does not identify any particular warranty or representation that the Defendants made and then breached. *See id.* at 21 (citing *Phila. Indem.*, 2019 WL 1258918, at *9). Indeed, the Defendants note that the paragraphs in the amended complaint that Ferry cites in his support—paragraphs 65 through 72—do not "cite or quote any statement made by Abbott," and no such statement is made on Similac's product label or packaging insert. Abbott's Reply, Doc. No. 69, at 14. (The same goes for Mead Johnson's products.)

In any event, Abbott notes that Similac's packaging is highly caveated and cautious. For instance, in numerous places, the Similac package insert directs a user to consult with her physician before use. Second, it specifically warns against the possibility of a gastrointestinal side effect. *See* Similac Packaging, Doc. No. 50-3, at 2, 4, 6, 8. The scientific studies cited in Similac's package insert also contain statements to the effect that human breast milk has advantages over formula for premature infants. *See* Abbott's Mem. of Law, Doc. No. 51-1, at 21. Although Mead Johnson's products—Enfamil and EnfaCare—have less explicit warnings on their product labels (and do not cite any scientific studies), they still contain substantial warnings and cautions.

The Defendants claim that they also did not breach any implied warranty, either (1) of merchantability or (2) of fitness for a particular purpose. With respect to (1), the Defendants note that to prove a breach, the Plaintiff must show that the goods did not "pass without objection in the trade under the contract description," or that they are not "fit for the ordinary purposes for which such goods are used." Abbott's Mem. of Law, Doc. No. 51-1, at 21 (citing

Conn. Gen. Stat. § 42a-2-314(2)). The Defendants note that "if the product conforms to the quality of other brands on the market, it will normally be merchantable." *Id.* at 22 (quoting *Std. Structural Steel v. Bethlehem Steel*, 597 F. Supp. 164, 188 (D. Conn. 1984)). And, the Defendants argue, Ferry does not allege that most infant formulas do not have cow milk. *See id.* With respect to (2), to prove a breach, the plaintiff must show that the buyer was relying on the seller's skill or judgment to select or furnish suitable goods. *See* Conn. Gen. Stat. § 42a-2-315. The Defendants note that Ferry "does not allege that anyone relied on *Abbott's* skill and judgment"; rather, as Ferry's complaint in the YNHH case acknowledges, Tylea's parents "relied on the doctors' skill and judgment, not Abbott's." Abbott's Mem. of Law, Doc. No. 51-1, at 22. Further, in a claim of this type, the buyer must have given notice to the seller regarding the claimed breach. *See Gallinari*, 148 F. Supp. 3d at 215. Because no notice was given here, the claim also fails.

b. Misrepresentation

Ferry alleges that each Defendant "misrepresented that its cow-based product was safe and beneficial for premature infants when it knew or should have known that its product was unreasonably dangerous and causing N.E.C. and death in premature infants." Am. Compl., Doc. No. 50, at ¶¶ 113(D); 65–72. The Defendants argue that those allegations, and the similar allegations regarding the Defendants' reckless misconduct,[26] sound in fraud and so are subject to the heightened pleading standard of Fed. R. Civ. P. 9(b). The Defendants argue that Ferry cannot meet that standard.

3. The Hearing and the Subsequent Motion to Amend

[26] *E.g.*, Am. Compl., Doc. No. 50, at ¶ 113(F)(a) ("[T]he defendant was reckless in that it continued to market and sell its cow-based product to premature infants when it knew its product was causing death and N.E.C. in these babies.").

Although I did not rule on Ferry's misrepresentation and warranty claims at the motion hearing in this matter, I did "express some skepticism" about them. *See* Hr'g Tr., Doc. No. 82, at 42:12–13. Particularly, with respect to Ferry's misrepresentation claim, I noted that Ferry's complaint did not allege any specific statements that were false when made and so did not "come close to satisfying [Rule] 9(b)." *Id.* at 46:1. At the hearing, Ferry orally requested an opportunity to amend his complaint to "do research" so that he could allege more particular misrepresentation and warrant claims. *Id.* at 47:1–3. I did not rule on Ferry's oral motion to amend his complaint.

However, on September 4 (about one week after the hearing), Ferry filed a fourth motion to amend/correct his complaint. *See* Fourth Mot. to Amend, Doc. No. 81. In that motion, Ferry includes 18 attachments, all of which are printouts from the Defendants' websites. *See* Exs. A–R to Fourth Mot. to Amend, Doc. Nos. 81-1 through 81-18. Some of those exhibits purport to show that certain of the Defendants' infant formulas are available for purchase through the Defendants' websites. *See, e.g.*, Exs. A–D to Fourth Mot. to Amend, Doc. Nos. 81-1 through 81-4. Others purport to show that the Defendants' websites "contain premature infant formula advertisements which contain specific language which the Plaintiff could plead to further his claims of warranty and misrepresentation." Fourth Mot. to Amend, Doc. No. 81, at 2. Ferry's motion identifies the statements from each exhibit that he believes can support a misrepresentation or breach of warranty claim. *See id.* at 2–4. Ferry asks for "Leave to Amend the Warranty and Misrepresentation claims with specific details mentioned above, and where appropriate add the corporate advertising and claims of safety to the other claims already existing within the Complaint." *Id.* at 4. It is thus clear that Ferry requests to amend his complaint by

adding those 18 exhibits and including allegations relating to the statements that he identifies in his motion to amend.

On September 25, Abbott filed an opposition. *See* Abbott's Opp'n, Doc. No. 83. Abbott points out that in Ferry's fourth motion to amend, "there is not a single mention of Similac Special Care," which is the only Abbott product at issue in this case. *Id.* at 2. The closest that Ferry comes is "mentioning *other* Similac formulas that were *never* administered to" Tylea. *Id.* "[E]ven for those products," Abbott continues, "there is no allegation that the infant's parents ever saw or considered the materials attached to the motion," which are "just website printouts that Plaintiff's counsel found in the week after the hearing, over three and a half years after the January 2017 events of this case." *Id.* at 2, 4.

Also on September 25, Mead Johnson filed an opposition. *See* Mead Johnson's Opp'n, Doc. No. 84. Like Abbott, Mead Johnson points out that Ferry "has not alleged now, or ever, that Plaintiff's mother or father reviewed or relied on any of the materials appended to his Motion." *Id.* at 2. Also like Abbott, Mead Johnson notes that several of Ferry's exhibits regard products not at issue in this case. *See id.* However, Mead Johnson concedes that Exhibits B and M–O regard Enfamil. *See id.* Finally, Mead Johnson argues that Ferry's motion is procedurally defective because he does not attach the proposed amendment or new pleading, in violation of Local Rule 7(f). *See id.* at 4; *see also* D. Conn. L. Civ. R. 7(f).

On September 30, Ferry submitted a reply. *See* Ferry's Reply, Doc. No. 85. To that reply, Ferry attached one more exhibit, which is another website printout that purportedly shows Similac Special Care 24 available for sale through Abbott's website. *See* Ex. S to Ferry's Reply, Doc. No. 85-1. Ferry writes:

> These products are marketed and sold directly to the public and, as the exhibits show, the Defendants warrant and represent their premature infant formulas as safe.

> The marketing over decades causes mothers like Tylea Hundley[’s mother] to believe “Enfamil” and “Similac,” which she saw being fed to her child, are safe.

Ferry’s Reply, Doc. No. 85, at 2.

A party may amend its pleading “once as a matter of course within . . . 21 days after serving it, or . . . if the pleading is one to which a responsive pleading is required, 21 days after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier.” Fed. R. Civ. P. 15(a). “In all other cases, a party may amend its pleading only with the opposing party’s written consent or the court’s leave.” Fed. R. Civ. P. 15(a)(2). “The court should freely give leave when justice so requires.” *Id.*; *see also Friedl v. City of New York*, 210 F.3d 79, 87 (2d Cir. 2000) (“In general, district courts should not deny leave unless there is a substantial reason to do so, such as excessive delay, prejudice to the opposing party, or futility.”).

In this case, Ferry can no longer amend his already-thrice-amended complaint as a matter of course, and the Defendants did not give him written consent to do so. Thus, he requests my leave. I **grant** Ferry’s motion for leave to amend his complaint, doc. no. 84. As a result, I consider the “specific details” and “corporate advertising and claims of safety” that Ferry mentions in his fourth motion to amend and the 19 website printouts attached as exhibits to that motion and to Ferry’s reply. As I explain, though, none of those statements or exhibits helps Ferry plead plausible misrepresentation and warranty claims.

4. Discussion

Ferry has not adequately alleged any misrepresentation or breach of warranty claims. Ferry’s complaint identifies hardly any misrepresentations or express warranties. In fact, Ferry

has identified just two statements that are potentially relevant misrepresentations.[27] *See* Fourth Mot. to Amend, Doc. No. 81, at 3; Ex. N to Fourth Mot. to Amend, Doc. No. 81-14, at 3 (noting that Enfamil "has the nutrition needed by these special babies while still allowing them to receive their mother's milk"); Ex. O to Fourth Mot. to Amend, Doc. No. 81-15, at 4 (advertising that Enfamil is "[w]ell tolerated"). Both of those statements regard Enfamil; they derive from printouts from Mead Johnson's website that were apparently printed in late August 2020. The remainder of Ferry's complaint does not identify any misrepresentations or express warranties.[28]

Further, Ferry's complaint is extremely vague regarding to whom any alleged misrepresentations or alleged warranties were made. Specifically, Ferry's complaint does not clarify whether any alleged misrepresentations and warranties were made to (1) Tylea's parents or (2) the YNHH medical professionals.[29] In either case, Ferry's misrepresentation and express warranty claims both fail.

a. Misrepresentation

Ferry has not stated a claim for intentional misrepresentation for several independent reasons. First, to state a claim for intentional misrepresentation, Ferry must plausibly allege,

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[27] Of the 19 website printout exhibits that Ferry submitted as attachments to his fourth motion to amend his complaint, not a single one regards EnfaCare. Further, only one regards Similac; in that exhibit, Ferry singles out just one (irrelevant) statement and does not identify why it is false. *See* Ex. S to Ferry's Reply, Doc. No. 85-1; Ferry's Reply, Doc. No. 85, at 2 n.1. The only two potentially relevant statements regard Enfamil, as described above.

[28] Although Ferry attaches product packaging and labeling to his complaint, Ferry does not identify with particularity any misstatement or express warranty on that packaging or labeling. Even if Ferry did, his misrepresentation and warranty claims would fail for the reasons I articulate.

In opposition to the Defendants' motions to dismiss Ferry's misrepresentation and warranty claims, Ferry pointed to paragraphs 65 through 72 of his amended complaint. *See* Pl.'s Opp'n, Doc. No. 62-1, at 46; Am. Compl., Doc. No. 50, at ¶¶ 65–72 The Defendants are correct that those paragraphs do not identify any particular representations that the Defendants made—or to whom they made such representations.

[29] Ferry's misrepresentation claim reads: "The defendant misrepresented that its cow-based product was safe and beneficial for premature infants when it knew or should have known that its product was unreasonably dangerous and causing N.E.C. and death in premature infants." Am. Compl., Doc. No. 50, at ¶ 113(D). Notably, that allegation does not identify to whom any alleged misrepresentation was made. Similarly, Ferry's warranty claim reads: "The defendant expressly or impliedly breached its warranty that its product was safe to be fed to premature infants, when, in fact, it was extremely dangerous." *See id.* at ¶ 113(E). Again, that allegation does not identify the parties to the alleged warranty. The rest of Ferry's complaint does not clarify those ambiguities.

inter alia, that a false statement "was made to induce the other party to act on it" and that "the latter did so act on it to his injury." *Updike, Kelly, & Spellacy*, 269 Conn. at 643 (cleaned up). Ferry has not plausibly alleged either of those things. Indeed, Ferry does not allege that Tylea's parents (or any of Tylea's doctors) ever looked at Mead Johnson's website.[30] Second, because intentional misrepresentation sounds in fraud, Ferry must allege a strong inference of scienter either "(a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Shields*, 25 F.3d at 1128. Ferry has done neither. The complaint does not suggest any motive or strong circumstantial evidence of recklessness. If Ferry attempts to rely on Mead Johnson's desire to earn profits,[31] courts are clear that such a motive is too generalized to give rise to a strong inference of scienter. *See, e.g.*, *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 268 (2d Cir. 1996) (explaining that generalized motives—those that "could be imputed to any publicly-owned, for-profit endeavor"—are not "sufficiently concrete for purposes of inferring scienter"); *Kuriakose v. Fed. Home Loan Mortg. Corp.*, 897 F. Supp. 2d 168, 184 (S.D.N.Y. 2012) (explaining that a generalized motive is one that is "ubiquitous in business").

Ferry has also not stated a claim for negligent misrepresentation. In my view, Ferry's negligent misrepresentation claim sounds in fraud,[32] and so it fails for the same reasons that

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[30] Even if I took into consideration the product labels and packaging attached to Ferry's complaint, that would make no difference. That is because Ferry never alleges that Tylea's parents or YNHH's doctors relied on the representations made on the products' labels. To be sure, Ferry alleges that Tylea's mother "saw the product containers and was aware that formula was being fed to her daughter." Am. Compl., Doc. No. 50, at ¶ 103. But that allegation is a far cry from reading and *relying* on representations on the labels of the product containers at issue. Indeed, Ferry does not allege that Tylea's parents were actively involved in her care during her very short and tragic life.

[31] *See, e.g.*, Pl.'s Opp'n, Doc. No. 62-1, at 48 ("The Plaintiff has alleged a long-standing policy of Mead and Abbott to continue to market their premature baby formula for profit, despite knowing it is causing N.E.C. and death.").

[32] Although inconsistently, Ferry repeatedly alleges that the Defendants engaged in fraud-type behavior. *See, e.g.*, Am. Compl., Doc. No. 50, at ¶¶ 22 ("Despite knowing that its product increases the risk of N.E.C. and death, Mead did not warn of N.E.C. or death, nor did it provide any instruction or guidance on how to avoid N.E.C.

Ferry's intentional misrepresentation claim fails. Even if the claim did not sound in fraud, it fails because Ferry has not alleged that Tylea's parents (or the YNHH doctors) relied on any of the Defendants' misrepresentations. *See Nazami*, 280 Conn. at 626 (noting that to prove a negligent misrepresentation claim a plaintiff must establish, *inter alia*, "that the plaintiff reasonably relied on the misrepresentation"). Thus, I dismiss Ferry's misrepresentation claims.

b. Warranty Claims

Ferry has failed to plausibly allege any claim for breach of warranty. Ferry has not alleged a breach of express warranty. As discussed above, Ferry identifies only two statements that could even inferentially be the basis of any warranty. *See* Ex. N to Fourth Mot. to Amend, Doc. No. 81-14, at 3; Ex. O to Fourth Mot. to Amend, Doc. No. 81-15, at 4. However, Ferry does not allege any facts regarding the relationship between those statements and the purchase or use of Enfamil in this case. Courts routinely dismiss claims for breach of express warranty in similar circumstances. *See, e.g.*, *Phila. Indem.*, 2019 WL 1258918, at *9 (citing cases). Finally, to the extent that Ferry attempts to rely on the Defendants' statements on their products' labels, he does not identify any statement that is the basis for an express warranty or the circumstances surrounding the formation of the express warranty.

Ferry also has not alleged a breach of any implied warranty. To establish a claim for breach of the implied warranty of merchantability, a plaintiff must show, *inter alia*, that notice was given to the seller of the claimed breach. *See Gallinari*, 148 F. Supp. 3d at 215. Ferry does not allege that anyone notified the Defendants of any claimed breach. In any event, Ferry has not made out a claim for breach of the implied warranty of merchantability for a separate reason: Ferry does not plausibly allege that the presence of cow milk in infant formula makes the

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or death."); 30 (same); 38 (same for Abbott); 95–96 (accusing the Defendants of "knowing [their] product[s] w[ere] leading to N.E.C. and death"); 99–102 (same); 108–09 (same); 111–12 (same); 113(F)(a) (same).

Defendants' formulas un-merchantable. That is because if a product "conforms to the quality of other brands on the market, it will normally be merchantable." *Zito v. Utd. Techs. Corp.*, 2016 WL 2946157, at *8 (D. Conn. Mar. 11, 2016) (cleaned up). Ferry does not allege that the presence of cow milk in exempt infant formulas is a market outlier.

Ferry also has not plausibly alleged a claim for breach of the implied warranty of fitness for a particular purpose. To make out such a claim, Ferry must show, *inter alia*, that the buyer actually relied on the seller's skill or judgment. *See* Conn. Gen. Stat. § 42a-2-315; *Gallinari*, 148 F. Supp. 3d at 215. As described above, Ferry does not clarify whether the "buyers" in this situation were Tylea's parents or the YNHH doctors. In either case, Ferry's claim fails because Ferry does not allege that either relied on the Defendants' skill or judgment. Indeed, as described above, the closest Ferry comes is his assertion that Tylea's mother "saw the product containers and was aware that formula was being fed to her daughter." Am. Compl., Doc. No. 50, at ¶ 103. But, again, that allegation is a far cry from alleging that Tylea's mother relied on the Defendants' skill or judgment. Thus, I dismiss all of Ferry's claims based on breach of implied warranties.

IV. Conclusion

For the foregoing reasons, I **grant in part and deny in part** the Defendants' motions to dismiss, doc. nos. 51 and 52. Those portions of the Defendants' motions to dismiss that are the subject of my future certification order are **denied without prejudice** to refiling once the Connecticut Supreme Court answers the certified questions. Ferry's fourth motion to amend his complaint, doc. no. 81, is **granted**.

So ordered.

Dated at Bridgeport, Connecticut, this 25th day of January 2021.

/s/ STEFAN R. UNDERHILL
Stefan R. Underhill
United States District Judge