UNITED STATES DISTRICT COURT FOR THE DISTRICT OF PUERTO RICO

KIZZY MORALES VELAZQUEZ, *et al.*, **Plaintiffs,** **v.** ABBOTT LABORATORIES, **Defendant.**	**Civil No.** 11-1131 (FAB)

OPINION AND ORDER

BESOSA, District Judge.

Plaintiffs Kizzy Morales-Vazquez[1] ("Morales") and Fernando Guzman-Merly ("Guzman") bring this diversity action on their own behalf and on behalf of their minor child F.J.G.M. against Abbott Laboratories, Inc. ("Abbott" or "defendant") for strict product liability and negligence. (Docket No. 1.)

Pending before the Court is the magistrate judge's Report and Recommendation (Docket No. 56), recommending that defendant Abbott's motion for summary judgment (Docket Nos. 44, 45 and 46.), be **GRANTED.**

I. Background

A. Procedural History

On February 4, 2011, plaintiffs Morales and Guzman (collectively, "plaintiffs"), on their own and as parents of their

[1] Plaintiff Morales' surname is listed as "Velazquez" in the caption of the case, but both plaintiffs and defendant refer to her as "Kizzy Morales Vazquez" in their briefs. Therefore, the Court will use "Vazquez" as her second last name.

minor child, F.J.G.M., filed a complaint against Abbott for negligence and strict product liability. (Docket No. 1.) Plaintiffs allege that they fed their infant Similac Go & Grow formula, which Abbott manufactured, promoted, and advertised. Id. at ¶¶ 9 & 12. They also contend that after F.J.G.M. ingested the milk, which was allegedly recalled by Abbott for possible contamination, their child began to have diarrhea, fever, and pain. Id. at ¶¶ 13 & 17. The child was allegedly admitted to Ryder Hospital and was eventually discharged with a diagnosis of acute gastroenteritis. Id. at ¶ 14.

On May 3, 2011, Abbott filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that plaintiffs failed to state a claim of negligence and strict liability under Puerto Rico law. (Docket No. 7.) On June 17, 2011, plaintiffs filed a response in opposition to the motion to dismiss, (Docket No. 11), and Abbott filed a reply to plaintiffs' response on June 21, 2011, (Docket No. 14).

Pursuant to a referral order issued by the Court, on September 30, 2011, Magistrate Judge Camille Velez-Rive filed a report and recommendation ("R&R") regarding Abbott's motion to dismiss. (Docket Nos. 19 & 23.) The magistrate judge recommended that Abbott's motion to dismiss be denied. (Docket No. 23 at p. 10.) Both plaintiffs and defendant Abbott failed to file any objections. On March 26, 2012, the Court adopted the findings of the R&R in a Memorandum and Order. (Docket No. 28.)

On June 29, 2012, Abbott filed a motion for summary judgment, a statement of uncontested facts, and a memorandum in support of its motion for summary judgment. (Docket Nos. 44, 45, & 46.) Abbott argues (1) that plaintiffs fail to provide any expert testimony, which they allege is mandatory in this case; (2) that plaintiffs have not provided evidence from which a reasonable jury could find defect or causation; and (3) that plaintiffs have not provided any evidence that Abbott was negligent. (Docket No. 46.) On July 16, 2012, plaintiffs filed an opposition to Abbott's motion for summary judgment, (Docket No. 48), to which Abbott filed a reply on July 23, 2012, (Docket No. 51). On August 6, 2012, plaintiffs filed a sur-reply to Abbott's reply. (Docket No. 55.)

On September 26, 2012, the magistrate judge filed a R&R recommending that Abbott's motion for summary judgment be granted. (Docket No. 56.) The magistrate judge found (1) that the plaintiffs failed to introduce any expert testimony for its strict liability claim; and (2) that Abbott's recall notice for the powder milk formula, as well as the United States Food and Drug Administration's ("FDA") notices about Abbott's recall are inadmissible under Federal Rules of Evidence 403 and 407. Id. at pp. 13-23. Neither the plaintiffs nor the defendant filed objections to the magistrate judge's R&R. The Court addresses each of defendant Abbott's arguments and the magistrate judge's findings in turn.

B. Factual Background

1. F.J.G.M's Hospitalizations and Abbott's Recall of its Similac Powder Milk

The relevant facts of the case are summarized here after applying Local Rule 56, which imposes requirements for the presentation of proof at summary judgment.[2]

Plaintiffs' child, F.J.G.M., was born in July 2009 and has suffered from health problems since birth. (Docket No. 46-3 at p. 16.) Initially, his pediatrician, Dr. Juan Vargas-Raposo ("Dr. Vargas"), recommended that his parents feed him a specific

[2] The First Circuit Court of Appeals has "repeatedly . . . emphasized the importance of local rules similar to Local Rule 56 [of the District of Puerto Rico]." Hernandez v. Philip Morris USA, Inc., 486 F.3d 1, 7 (1st Cir. 2007). Rules such as Local Rule 56 "are designed to function as a means of 'focusing a district court's attention on what is—and what is not—genuinely controverted.'" Id. (quoting Calvi v. Knox County, 470 F.3d 422, 427 (1st Cir. 2006)). Local Rule 56 sets out the requirements for both the movant and the party opposing summary judgment; it "relieve[s] the district court of any responsibility to ferret through the record to discern whether any material fact is genuinely in dispute." CMI Capital Market Inv. v. Gonzalez-Toro, 520 F.3d 58, 62 (1st Cir. 2008); Loc. Rule 56.

A party moving for summary judgment must submit factual assertions in "a separate, short, and concise statement of material facts, set forth in numbered paragraphs." Loc. Rule 56(b). A party opposing a motion for summary judgment must "admit, deny, or qualify the facts supporting the motion for summary judgment by reference to each numbered paragraph of the moving party's statement of facts." Loc. Rule 56(c). The moving party may reply and admit, deny, or qualify the opponent's newly-stated facts, again in a separate statement and by reference to each numbered paragraph. Loc. Rule 56(d). Facts which are properly supported "shall be deemed admitted unless properly controverted." Loc. Rule 56(e); P.R. Am. Ins. Co. v. Rivera-Vazquez, 603 F.3d 125, 130 (1st Cir. 2010). Due to the importance of this function to the summary judgment process, "litigants ignore [these rules] at their peril." Hernandez, 486 F.3d at 7.

milk formula called Enfamil A.R., which is only given to patients who exhibit vomiting and reflux. (Docket No. 46-3 at pp. 39-40.) In July 2010, when F.J.G.M. was about one-year old, his parents switched him to the Similac Go & Grow formula, which is manufactured by Abbott, because Enfamil is only used for the first year of a child's life. (Docket Nos. 46-1 & 48-8 at p. 33; Docket No. 46-3 at p. 39.)

On March 13, 2010, several months before he switched to the Similac formula, F.J.G.M. visited Dr. Vargas with a cough. He was diagnosed with an upper respiratory infection. (Docket No. 46-3 at pp. 20-21.) On July 29, 2010, about one month after F.J.G.M. began consuming the Similac formula, F.J.G.M. was taken to Ryder Memorial Hospital because he had nasal discharge and a fever. (Docket No. 46-3 at p. 45; Docket No. 46-5 at p. 8.) His throat and tonsils were inflamed, and he was prescribed several medications, including an antibiotic called Cephalexin. Id.

On August 10, 2010, F.J.G.M. visited the emergency room again, where he was diagnosed with an upper respiratory infection. (Docket No. 46-3 at pp. 46-47; Docket No. 46-5 at p. 9.) An x-ray taken the following day showed a viral respiratory infection and gastric distention–bloating of the stomach–from excessive swallowing of air. (Docket No. 46-3 at pp. 47-49; Docket No. 46-5 at p. 10.) About two weeks later, on August 31, 2010, F.J.G.M. visited Ryder Hospital again because of a cough. (Docket

No. 46-3 at p. 49; Docket No. 46-5 at p. 11.) He was diagnosed with another upper respiratory infection. Id.

On September 15, 2010, Abbott detected warehouse beetles in its powdered milk while performing quality testing on an unreleased batch of Similac powdered milk at its Sturgis, Michigan facility. (Docket Nos. 46-8 & 18-10 at ¶¶ 6-8.) The Sturgis facility reported this finding to Abbott's headquarters, and it stopped all production and shipment of its powder products the following day. Id. at ¶ 15. Despite extensive quality testings, Abbott had not previously detected warehouse beetles in its Similac powder milk product.[3] Id. at ¶¶ 11-14.

After the detection of warehouse beetles, Abbott tested 30,486 additional containers from twenty-two batches of its powdered milk. Id. at ¶ 16. To test the milk, Abbott liquified it and passed it through a sock filter with pores that were 200-micron (0.2 millimeters or 0.0079 inches) in size. Id. In the 30,486 containers tested, Abbott detected a total of forty-nine beetles, larvae, or parts; a rate of 0.16% of the milk tested was deemed contaminated. Id. Even though the tests showed that a very small percentage of the milk contained warehouse beetles or parts, on

[3] Abbott employed a prominent third-party pest-control company to service its Sturgis facility on a regular basis and Abbott followed the company's advice for pest-control. (Docket Nos. 46-8 & 48-10 at ¶¶ 11-15 & 18-20.) An internal compliance audit performed from July 27 to August 3, 2010 and an inspection by the FDA in March 2010 found no significant problems with the Sturgis facility. Id. at ¶¶ 21-22.

September 22, 2010, Abbott issued a voluntary recall of Similac powder products that were manufactured since September 2007 in the Sturgis facility because the shelf life of the powdered milk is up to three years. Id. at ¶¶ 6, 9-10 & 16.

Two days before the recall occurred, on September 20, 2010, plaintiffs took F.J.G.M. to the hospital again. (Docket Nos. 46-1 & 48-8 at pp. 26 & 37; Docket No. 46-3 at p. 50; Docket No. 46-5 at p. 12.) He had another upper respiratory infection. (Docket No. 46-3 at p. 52; Docket No. 46-5 at p. 12.) Plaintiff Morales also reported that the minor had diarrhea that would not stop, but the hospital emergency room record reflected that the "No" box was checked off next to "nausea, vomiting, diarrhea."[4] (Docket Nos. 46-1 & 48-8 at pp. 27 & 30; Docket No. 46-5 at p. 12.) At that time, F.J.G.M. was taking Amoxil, an oral antibiotic used to treat the upper respiratory and tonsil

[4] Plaintiffs also state a number of other facts in their memorandum of law in opposition to Abbott's motion for summary judgement, (Docket No. 48), and in their opposition to Abbott's statement of uncontested facts, (Docket No. 48-1), and cite only to their complaint, (Docket No. 1), for support. The Court will not consider these bare assertions of fact in rendering its decision on defendant's motion for summary judgment. It is fundamental that plaintiffs may not rest on this type of allegations, uncorroborated by evidence, to overcome a properly supported motion for summary judgment. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986) (stating that the non-moving party "may not rest upon the mere allegations or denials of [the] pleading, but must set forth specific facts" to show the existence of a genuine issue of material fact); Serrano-Cruz v. DFI Puerto Rico, 109 F.3d 23, 27 (1st Cir. 1997) (finding that "to oppose [a] summary judgment motion, plaintiff cannot rely on assertions in [her] pleadings and must come forward with evidence that a jury could consider") (internal citation omitted).

infection. (Docket No. 46-3 at p. 52; Docket No. 46-5 at p. 12.) Dr. Vargas also indicated that the infant was "asymptomatic," meaning that he had no fever and that he was sent home with a regular diet. (Docket No. 46-3 at p. 52; Docket No. 46-5 at p. 12.) There was no order to stop taking the Amoxil and there were no other medications prescribed on this date. Id.

One day before the recall, on September 21, 2010, the infant had another chest x-ray taken. (Docket Nos. 46-1 & 48-8 at p. 29-30; Docket No. 46-3 at p. 54-55; Docket No. 46-5 at p. 13.) The x-ray suggested that F.J.G.M. had a viral type of pneumonia or an upper respiratory infection. (Docket No. 46-3 at pp. 55-56; Docket No. 46-5 at p. 13.) On September 22, 2010, the date of the Similac formula recall, plaintiffs took the infant to see Dr. Vargas. (Docket Nos. 46-1 & 48-8 at pp. 31-32; Docket No. 46-3 at p. 56; Docket No. 46-5 at p. 14.) Dr. Vargas indicated that he saw the results from the x-ray taken the day before. (Docket No. 46-3 at p. 56; Docket No. 46-5 at p. 14.) Dr. Vargas said that F.J.G.M. was suffering from diarrhea and was vomiting. (Docket Nos. 46-1 & 48-8 at pp. 31-32; Docket No. 46-3 at pp. 56 & 60; Docket No. 46-5 at p. 14.) He told the plaintiffs to stop giving Amoxil to the infant because it might cause diarrhea.[5]

[5] Plaintiff also stated that on this date, Dr. Vargas told her to "stop the milk" but there is no indication of this in the hospital records or in Dr. Vargas' testimony about this visit. (Docket Nos. 46-1 & 48-8 at p. 38; Docket No. 46-3 at pp. 57–58; Docket No. 46-5 at p. 14.)

(Docket No. 46-3 at pp. 57–58; Docket No. 46-5 at p. 14.) Instead of Amoxil, he prescribed a stronger antibiotic called Rocephin to F.J.G.M. Id. Dr. Vargas also admitted F.J.G.M. to the hospital on that date. (Docket No. 46-3 at p. 59; Docket No. 46-5 at p. 15.) F.J.G.M. was diagnosed with acute gastroenteritis with a secondary diagnosis of otitis–an ear infection– and moderate dehydration. (Docket No. 46-3 at pp. 61–62; Docket No. 46-5 at p. 17.)

At some point during this hospitalization, the plaintiffs learned about Abbott's recall from a television news show. (Docket Nos. 46-1 & 48-8 at pp. 41-42; Docket No. 46-7 at pp. 17-18.) The recall indicated that "there is a possibility that the infants who consume formula containing the beetles or their larvae could experience gastrointestinal discomfort and refusal to eat as a result of small insect parts irritating the GI tract." (Docket Nos. 8-5 & 48-6 at p. 2.) Plaintiff Morales went to Abbott's website to determine whether the can of Similac that she fed F.J.G.M. was part of the recall; she discovered that the formula was in fact a part of the recall. (Docket Nos. 46-1 & 48-8 at pp. 41-42; Docket No. 46-7 at p. 18.)

Plaintiff Morales testified that she had six more containers of Similac milk at her house.[6] (Docket Nos. 46-1 & 48-8 at p. 42.) While the infant was still hospitalized, plaintiff Morales sent her father to the supermarket to exchange all of the

[6] Plaintiff Morales failed to indicate, however, if F.J.G.M. consumed any milk from these containers.

Similac cans for another brand of formula. (Docket Nos. 46-1 & 48-8 at pp. 46-47.) Plaintiff Guzman said that he did not examine the remaining cans of Similac formula in detail before they were returned to the supermarket. (Docket No. 46-7 at pp. 21–22.) Both plaintiffs also stated that they had not seen insects in the Similac formula that they fed to their infant. (Docket Nos. 46-1 & 48-8 at p. 50; Docket No. 46-7 at pp. 20–21.) Plaintiff Morales also testified that she called Abbott on the same day the infant was released from the hospital and was offered a refund check in the amount of $54.95. (Docket Nos. 46-1 & 48-8 at p. 45.) She does not remember, however, the name of the representative who she spoke to during the call, and she did not take any notes when she called. (Docket Nos. 46-1 & 48-8 at p. 42.)

On September 25, 2010, F.J.G.M. was discharged from the hospital. (Docket Nos. 46-1 & 48-8 at p. 40; Docket No. 46-3 at pp. 59-60; Docket No. 46-5 at pp. 15 & 17.) After the recall, plaintiffs stopped giving F.J.G.M. the Similac formula and switched to a different formula. (Docket Nos. 46-1 & 46-8 at p. 50.)

On October 26, 2010, the FDA issued an official press release,[7] which announced that Abbott had worked with state and FDA officials to correct the situation at the Sturgis facility

[7] The FDA also issued press releases regarding the Abbott recall of the Similac powdered milk formula on September 23, and September 27, 2010. (Docket Nos. 8-1, 8-2, 48-3, & 48-4.)

and to prevent its reoccurrence. (Docket Nos. 8-3, 8-4, 48-4, & 48-5.)

On November 27, 2010, over two months after plaintiffs stopped giving F.J.G.M. the Similac formula, plaintiffs took F.J.G.M. to the emergency room with an ear infection in both ears, a throat infection, a cold, and a fever. (Docket Nos. 46-1 & 48-8 at p. 53; Docket No. 46-3 at pp. 74–75; Docket No. 46-5 at p. 19.) He was not hospitalized on that date. Id. On November 30, 2010, however, the infant was admitted to the hospital. Id. He had symptoms similar to those that had led to his September 2010 hospitalization: diarrhea, vomiting, and dehydration. (Docket Nos. 46-1 & 48-8 at pp. 56 & 58; Docket No. 46-3 at p. 77; Docket No. 46-5 at p. 22.) He was diagnosed with acute gastroenteritis, moderate dehydration, otitis, and tonsilitis. (Docket No. 46-3 at p. 76; Docket No. 46-5 at p. 20.) Another x-ray of F.J.G.M.'s lungs suggested that he might have a viral type of pneumonia. (Docket No. 46-3 at pp. 76-77; Docket No. 46-5 at p. 21.) F.J.G.M. stayed in the hospital until December 4, 2010. (Docket Nos. 46-1 & 48-8 at pp. 53 & 59; Docket No. 46-3 at p. 76; Docket No. 46-5 at pp. 20 & 22.)

2. Findings from Abbott's Expert Witness

Abbott submitted an expert report by Dr. Paul E. Hyman, ("Dr. Hyman"), Professor of Pediatrics at Louisiana State University and Chief of Pediatric Gastroenterology at Children's Hospital of New Orleans. (Docket No. 46-2 at p. 1.) Dr. Hyman is

also a fellow in Digestive Diseases at the National Institutes of Health and a fellow in Pediatric Gastroenterology at the University of California, Los Angeles. Id. He has chaired and co-chaired two working teams that developed the official criteria for diagnosing childhood functional bowel disorder, and has received an award for outstanding achievements from both the American Gastroenterological Association and the International Foundation for Functional Gastrointestinal Disorders. Id. at pp. 1-2. In addition, Dr. Hyman has published over 100 peer-reviewed articles, edited three books, and given lectures all over the world. Id. at p. 2.

Dr. Hyman's medical opinion is that "the ingestion of Trogoderma variabile beetles, [which are the beetles that were found at the Abbott Sturgis facility,] larvae, or parts has no capability of causing any injury or disorder in human infants." (Docket No. 46-2 at p. 2.) While it is "undesirable" and "disturbing to some" to have insects in infant formula, he stated that "there is no health risk from ingestion of warehouse beetles." Id. Additionally, he indicated that his research of medical literature "revealed no reports of warehouse beetle ingestion associated with illness or disease of any sort." Id. He did find one case report from the 1960s in an agricultural newsletter–not a medical journal–that suggested there may be a connection between two different types of beetle (but there was no discussion about the warehouse beetle at issue) and two episodes of illness in infants. Id. In those two episodes, however, no causal connection

was shown. Id. at pp. 2-3. Furthermore, since the 1960s article, he has found no studies demonstrating a link between warehouse beetle consumption and illness. Id. at p. 3.

Dr. Hyman also specified four reasons why he does not believe that F.J.G.M.'s symptoms were caused by the warehouse beetles that were found in Abbott's Sturgis facility: (1) "there is no physiological process by which consuming *Trogoderma variabile* beetles could cause gastrointestinal illness;" (2) in addition to gastrointestinal symptoms, F.J.G.M. also had respiratory symptoms, tonsilitis, and ear infections, and none of these symptoms can be caused by insect parts in the digestive system even if one assumes that the insect parts could cause gastrointestinal problems; (3) in November 2010, the infant experienced similar symptoms, months after the recall and after the plaintiffs switched F.J.G.M. to a different formula, which cannot be caused by the *Trogoderma variabile*; and (4) plaintiffs never saw anything "abnormal in F.J.G.M's formula." (Docket No. 46-2 at p. 9.) Dr. Hyman stated that "the possibility that F.J.G.M.'s [September 2010] illness was caused by consumption of warehouse beetles is zero." Id. Instead, he stated that a viral respiratory illness was most likely the underlying cause of F.J.G.M's illness. Id.

3. Observations by Dr. Vargas, F.J.G.M.'s Treating Physician

Aside from the testimony of F.J.G.M.'s parents, plaintiffs only introduce the deposition testimony of Dr. Vargas,

F.J.G.M.'s pediatrician. (See Docket Nos. 46-3 & 48-9.) Although Dr. Vargas' license is up-to-date and he has to "report 200 credit hours [of training]" every year to receive approval for his license, id. at p. 95, he is not board-certified by any medical organization and has no specialization in pediatric gastroenterology, id. at p. 10. Aside from the 200 credit hours each year, he has had no additional medical training since he concluded his residency in the early 1970s. Id.

Dr. Vargas admitted that he has never read or heard of a child suffering gastroenteritis due to eating insects, including warehouse beetles. (Docket Nos. 46-3 & 48-9 at p. 66.) He also conceded that the acids or enzymes in the stomach would digest or dissolve any insect parts before they could cause any damage to the gastrointestinal system. (Docket Nos. 46-3 & 48-9 at pp. 67-68). He also indicated that when he treated F.J.G.M., he did not contemplate that F.J.G.M.'s illness was caused by insect consumption. Id. at p. 81. He stated that the infant's blood test and white cell counts suggested that his vomiting and diarrhea could have been bacteria-related. (Docket Nos. 46-3 & 48-9 at pp. 60 & 90-94.) Dr. Vargas admitted, however, that he could not completely rule out that F.J.G.M.'s condition was caused by a virus because the infant was taking antibiotics, which can cause "changes" to the blood and "the picture gets fuzzy." Id. at 96-97.

Although Dr. Vargas did not believe that F.J.G.M.'s condition was caused by a viral infection, he identified several

other possible causes of the infant's gastroenteritis, which include an intolerance to the lactose in the milk; a secondary infection, such as the ear infection that F.J.G.M. had at the time; the infant's ingestion of Amoxil, an antibiotic that can provoke diarrhea; rotavirus, which is a regular virus that attacks the gastrointestinal area; and some other food or beverage that the infant ingested. (Docket Nos. 46-3 & 48-9 at pp. 62–64 & 80.) Furthermore, when questioned about whether it was more likely than not that the recalled Abbott formula caused the infant's hospitalization in September 2010, he answered, "I do not believe so." (Docket Nos. 46-3 & 48–9 at pp. 85–87.) He said that "many things" are feasible and that "[i]t's possible" that the F.J.G.M's illness was somehow related to the recall, "but [he] do[es] not have the elements to say so." Id. at p. 87.

II. STANDARDS

A. STANDARD UNDER 28 U.S.C. § 636(b)(1)

A district court may refer, *inter alia*, "motions for summary judgment" to a magistrate judge for a report and recommendation. Loc. Rule 72(a)(9); see 28 U.S.C. § 636(b)(1)(B); Fed.R.Civ.P. 72(b). Any party adversely affected by the report and recommendation may file written objections within fourteen days of being served with the magistrate judge's report. See 28 U.S.C. § 636(b)(1)(C); Loc. Rule 72(d). A party that files a timely objection is entitled to a *de novo* determination of "those portions of the report or specified proposed findings or recommendations to

which specific objection is made." Sylva v. Culebra Dive Shop, 389 F.Supp.2d 189, 191 (D.P.R. 2005) (citing United States v. Raddatz, 447 U.S. 667, 673 (1980)). Failure to comply with this rule precludes further review. See Davet v. Maccarone, 973 F.2d 22, 30-31 (1st Cir. 1992) ("Failure to raise objections to the Report and Recommendation waives the party's right to review in the district court . . . ."). In conducting its review, a court is free to "accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge." 28 U.S.C. § 636(b)(1)(C); Jasty v. Wright Med. Tech., Inc., 528 F.3d 28, 33-34 (1st Cir. 2008). Furthermore, a court may accept those parts of the report and recommendation to which the parties do not object. See Hernandez-Mejias v. Gen. Elec., 428 F.Supp.2d 4, 6 (D.P.R. 2005) (citing Lacedra v. Donald W. Wyatt Det. Facility, 334 F.Supp.2d 114, 126 (D.R.I. 2004)).

B. Summary Judgment Standard

The Court may grant a motion for summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). A fact is "material" if it has the potential to "affect the outcome of the suit under the governing law." Id. A dispute is "genuine" when it "could be resolved in favor of either party." Calero-Cerezo v. U.S. Dep't. of Justice, 355 F.3d 6, 19 (1st Cir. 2004).

The party moving for summary judgment has the initial burden of "demonstrat[ing] the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The party must identify "portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any'" which support its motion. Id. (citing Fed.R.Civ.P. 56(c)). Once a properly supported motion has been presented, the burden shifts to the non-moving party "to demonstrate that a trier of fact reasonably could find in [its] favor." Santiago-Ramos v. Centennial P.R. Wireless Corp., 217 F.3d 46, 52 (1st Cir. 2000) (internal citation omitted); see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986) (discussing how the burden shifts to the nonmoving party, who "must do more than simply show that there is some metaphysical doubt as to the material facts").

It is well-settled that "[t]he mere existence of a scintilla of evidence" is insufficient to defeat a properly supported motion for summary judgment. Anderson, 477 U.S. at 252. It is therefore necessary that "a party opposing summary judgment must 'present definite, competent evidence to rebut the motion.'" Maldonado-Denis v. Castillo-Rodriguez, 23 F.3d 576, 581 (1st Cir. 1994) (internal citation omitted). Otherwise, summary judgment is appropriate if the non-moving party's case rests merely upon "conclusory allegations, improbable references, and unsupported

speculation." Forestier Fradera v. Municipality of Mayagüez, 440 F.3d 17, 21 (1st Cir. 2006).

III. Legal Analysis

A federal court sitting in a diversity case must apply the substantive law of the forum where the action is filed. See Rodriguez v. Señor Frog's de la Isla, Inc., 642 F.3d 28, 36 (1st Cir. 2011) (internal citations omitted). In their complaint, plaintiffs fail to identify the Puerto Rico Civil Code provisions on which they base their claims. (Docket No. 1.) In Puerto Rico, strict liability and negligence claims are governed by Article 1802 of the Puerto Rico Civil Code ("Article 1802"). P.R. Laws. Ann. Tit. 31 § 5141; see also Isla Nena Air Servs., Inc. v. Cessna Aircraft Co., 449 F.3d 85, 88 (1st. Cir. 2006) (Even though the Puerto Rico Civil Code does not explicitly incorporate "the doctrine of strict liability, it is well-settled that Puerto Rico courts have adopted that doctrine under Article 1802.") (internal citations omitted). Defendant Abbott claims that it is entitled to summary judgment on both plaintiffs' strict liability and negligence claims. (Docket No. 46.) The Court first addresses defendant Abbott's arguments regarding strict liability and then turns to Abbott's arguments regarding negligence.

A. Strict Liability

With regard to products liability, Puerto Rico has adopted the doctrine of strict liability "under principles flowing from Article 1802." Isla Nena Air Servs., 449 F.3d at 88 (internal

citation omitted). Puerto Rico courts rely upon the principles in section 402A of the Restatement (Second) of Torts in adopting the strict liability doctrine. Id.; see also Cruz-Vargas v. R.J. Reynolds Tobacco Co., 348 F.3d 271, 276 (1st Cir. 2003); Perez-Trujillo v. Volvo Car Corp (Sweden), 137 F.3d 50, 55 (1st Cir. 1998); Malave-Felix v. Volvo Car Corp., 946 F.2d 967 (1st Cir. 1991) (citing Montero Saldaña v. Am. Motors Corp., 107 D.P.R. 452 (1978)). Under Puerto Rico law, a plaintiff must prove four elements to prevail in a strict liability action: (1) the product had a manufacturing defect; (2) the defect made the product unsafe[8]; (3) plaintiff used the product in a reasonably foreseeable way; and (4) the defect proximately caused injury to the plaintiff. Perez-Trujillo, 137 F.3d at 55 (internal citations and quotation marks omitted).

Defendant Abbott argues that plaintiffs fail to provide any expert testimony regarding the first element, that the product was defective, or the fourth element, proximate causation. (Docket No. 46 at p. 14.) Plaintiffs respond that the evidence on the docket–Abbott's admission regarding the recall and the depositions of plaintiffs and their infant's treating physician–are sufficient to establish that the infant's acute gastroenteritis was caused by contamination of the Similac formula. (Docket No. 48 at p. 7.)

[8] This criteria is "the single significant departure" from the Restatement of Torts, which requires a plaintiff to prove that "the defective product was unreasonably dangerous." Perez-Trujillo, 137 F.3d at 55 (internal citations and quotation marks omitted).

The magistrate judge found that plaintiffs failed to establish causation, and, therefore, did not meet their burden to survive summary judgment. (Docket No. 56 at pp. 15-16.) The Court agrees with the magistrate judge because the plaintiffs have failed to demonstrate a genuine dispute about (1) whether a defect existed in the product, and (2) whether a defect in the milk formula caused F.J.G.M.'s injury.

1. Defect

Defendant Abbott argues that there is no evidence from which a reasonable jury could find a defect in the milk formula. (Docket No. 46 at p. 18.) Abbott argues that plaintiffs only use the recalls and the FDA notices to support their contention that the milk formula contained a defect. Id. This evidence, Abbott contends, is inadmissible under the Federal Rules of Evidence. Id. Even if this evidence is admissible, however, Abbott argues that it contains little probative value. Id. at pp. 18-19. Finally, Abbott argues that aside from the recall notices, there is no other admissible evidence showing a defect in the milk formula. Id. at p. 18. Plaintiffs respond that the notices serve as Abbott's admission that the formula was defective. (Docket No. 48 at p. 11.)

The magistrate judge agreed with Abbott in her R&R regarding Abbott's motion for summary judgment. She found that Abbott's recall notice and the FDA notices regarding the recall are inadmissible under Federal Rules of Evidence 407 and 403. The

Court concurs with the magistrate judge; it finds that defendant Abbott has shown that there is no genuine dispute of material fact regarding the element of defect and that plaintiffs have failed to show that a jury could reasonably find for them on this matter.

a. Federal Rule of Evidence 407

Federal Rule of Evidence 407[9] ("Rule 407") prohibits plaintiffs from introducing evidence that a defendant, after an injury, took steps that would have made the injury or harm less likely to occur. The rule only applies to evidence of a defendant's remedial measures when offered to prove the defendant's fault; this includes, but is not limited to, when the evidence is offered to prove a product defect. Id. Rule 407 allows this type of evidence, however, for other purposes, such as to show that a defendant had ownership or control of a product, or that precautionary measures were feasible, if controverted. Id. Recall

[9] Rule 407 provides, in relevant part:

> "When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, *evidence of the subsequent measures is not admissible to prove* negligence, culpable conduct, *a defect in a product*, a defect in a product's design, or a need for a warning or instruction. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment." Fed.R.Evid. 407 (emphasis added).

notices and warning decals that are issued after an accident or injury are considered to be subsequent remedial measures under Rule 407. See Carballo-Rodriguez v. Clark Equipment, Co., Inc., 147 F.Supp.2d 66, 77 (D.P.R. 2001); see also Cameron v. Otto Brock Orthopedic Indus., Inc., 43 F.3d 14, 17 (1st Cir. 1994); Raymond v. Raymond Corp., 938 F.2d 1518, 1523 (1st Cir. 1991); Benitez-Allende v. Alcan Aluminio do Brasil, S.A., 857 F.26, 33 (1st Cir. 1988).

Abbott's recall notice occurred on September 22, 2010, announcing "a proactive, voluntary recall of certain Similac-brand, powder infant formulas." (Docket No. 48-6.) In addition, Abbott stated that "[t]he FDA has determined that while the formula containing [the] beetles poses no immediate health risk, there is a possibility that infants who consume formula containing the beetles or their larvae, could experience symptoms of gastrointestinal discomfort and refusal to eat as a result of small insect parts irritating the GI tract." Id. The FDA notices, which were issued on September 23, September 27, and October 26, 2010, respectively, also state that while there are "no long-term health problems, there is a possibility that infants who consume formula containing the beetles or their larvae could experience gastrointestinal discomfort and refusal to eat as a result of small insect parts irritating the GI tract." (Docket Nos. 48-2, 48-3, & 48-5.)

These statements, the plaintiffs argue, are sufficient to show that a defect occurred. The recall notices that

plaintiffs seek to use as evidence of a defect fall within the purview of Rule 407: they were issued after the accident or injury, and they indicated that consumers should return the product to Abbott. Therefore, the notices are inadmissible to show that the Similac formula contained warehouse beetles. Plaintiffs fail to argue that the notices are admissible for other purposes permitted by Rule 407. Nor do plaintiffs argue that defendant Abbott has controverted any of the Rule 407 admissible purposes. That result serves the "twofold purpose of Rule 407" as stated in the Advisory Committee Notes. Raymond, 938 F.2d at 1523. First, it prevents unfair prejudice to a defendant because "jurors would too readily equate subsequent design modifications with admissions of a prior defective design." Id. Second, it "further[s] the social policy of encouraging manufacturers to create safer products" by "continuing to update and improve upon the safety features of their products after initial manufacture." Id.

b. Federal Rule of Evidence 403

Even if the notices are admissible and are relevant,[10] they must comport with the requirement of Federal Rule of Evidence 403 ("Rule 403") that their probative value outweigh

[10] Evidence is relevant when "(a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed.R.Evid. 401. The recall notices from Abbott and the FDA are relevant because they have a tendency to make more probable the existence of a defect in the Similac formula that F.J.G.M. consumed.

the danger of "unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." See also United States v. Varoudakis, 233 F.3d 113, 122 (1st Cir. 2000). The First Circuit Court of Appeals has held that Rule 403 protects "against *unfair* prejudice, not against all prejudice" (emphasis added). United States v. Whitney, 524 F.3d 134, 141 (1st Cir. 2008); see also United States v. Amaya-Manzanares, 377 F.3d 39, 45 (1st Cir. 2004) (discussing how all relevant evidence that the government introduces is prejudicial in some way to a defendant). "'Unfair prejudice'" within its context means an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." Fed.R.Evid. 403, Advisory Committee Notes. Pursuant to Rule 403, a trial court has "considerable latitude in determining whether to admit or exclude evidence." Santos v. Sunrise Medical, 351 F.3d 587, 592 (1st Cir. 2003) (internal citations omitted). When a trial court finds the balancing close, "Rule 403 tilts the balance in favor of admission." Whitney, 524 F.3d at 141 (internal citations omitted).

Defendant Abbott contends that the recall notices are "not remotely probative of defectiveness." (Docket No. 46 at pp. 18-19.) Plaintiff makes no arguments in response to this contention. They merely state, in a cursory manner, that Abbott admits in its notices that the formula was contaminated and thus, defective. (Docket No. 48 at p. 11.) The Court agrees with defendant Abbott.

First, the First Circuit Court of Appeals has stated that "[a]t best, subsequent remedial measures are considered marginally probative of prior negligence." Keller v. United States, 38 F.3d 16, 32 (1st Cir. 1994) (internal citation omitted). Second, defendant Abbott has provided other evidence to suggest that the probative value of the recall notices is low. Matthew Painter, the Senior Program Manager for Third Party Manufacturing in the Abbott Nutrition Supply Chain of Abbott Laboratories, provided an uncontested declaration that after Abbott discovered beetles in its machinery, it tested an additional 30,486 containers from over twenty batches of Similac powder manufactured in the Sturgis plant. In total, only forty-nine beetles, larvae, or parts were found in these containers, which means that only 0.16% of the sample was found to be contaminated. Plaintiffs also stated that they never saw any insects in the formula that they fed to F.J.G.M. Furthermore, defendant's expert witness, Dr. Hyman, indicated that he thoroughly reviewed the two sources that the FDA relied upon in issuing its statement that the warehouse beetles "could" cause minor illness, and he concluded that the FDA was not realistically assessing the actual medical risk of ingesting the beetles; rather, his research indicates that the FDA was acting with the "utmost of caution." (Docket No. 46-2 at p. 4.)

The danger of unfair prejudice is high in this case because of the possibility that the recall notices would confuse or mislead the jury. A recall notice by a manufacturer

"does not admit a defect in a particular product, but refers to the possibility of a defect in a class of products." See e.g., Bailey v. Monaco Coach Corp., 350 F.Supp.2d 1036, 1045 (N.D. Ga. 2004) (internal citation omitted). As the Court indicated earlier, however, jurors would too readily equate a recall notice with an admission that the product was defective, and make the leap that because warehouse beetles were found in the facility that produced the milk formula, then the particular can of formula ingested by F.J.G.M. also contained warehouse beetles. Raymond, 938 F.2d at 1523; see also Carballo-Rodriguez, 147 F.Supp.2d at 77 (citing Bogosian v. Mercedes-Benz of N. Am., Inc., 104 F.3d 472, 481 (1st Cir. 1997)).

Because the high danger of unfair prejudice outweighs the marginal probative value of the recall notices issued by defendant Abbott and the FDA, the Court finds that there is no evidence from which a reasonable jury could find a defect in the milk formula. Therefore, the Court **ADOPTS IN FULL** the magistrate judge's findings on the element of a product defect.

2. Causation

Even if the plaintiffs established that a jury could reasonably find for them with regard to whether there was a defect in the milk formula, they have failed to demonstrate that a jury could reasonably find that the milk formula caused F.J.G.M.'s injuries. As the magistrate judge found, plaintiffs have failed to introduce any expert testimony or any circumstantial evidence to

support their claims that the milk formula caused the infant's illness.[11] The Court **ADOPTS IN FULL** the magistrate judge's findings on the element of causation.

In Puerto Rico, strict liability claims "need not adduce expert testimony to overcome a motion for summary judgment." Perez-Trujillo, 137 F.3d at 55. "Strict liability claimants may resort to an array of circumstantial evidence," including direct observations regarding the malfunction of a product, or other circumstantial evidence, such as similar accidents involving the same product, elimination of other possible causes of the accident, and proof tending to establish that the accident does not occur absent a manufacturing defect. Id. at n. 10. The necessity of expert opinion evidence, however, is whether the question is one of common knowledge such that lay people could "reach the conclusion as intelligently as the witness." Collazo-Santiago v. Toyota Motor Corp., 937 F.Supp. 134, 140 (D.P.R. 1996) (internal citation and quotation marks omitted). If the question cannot be answered by common experience, then expert testimony is required. Id. For example, in Collazo, the plaintiff established that a car airbag caused her injury because she "will personally testify that she felt the airbag hit her face and abrade it." Id. In this case,

[11] Plaintiffs also argue that the recall notices issued by Abbott and the FDA are sufficient to prove causation. Because the Court found that these notices are inadmissible under Rule 407 and Rule 403 as to the element of product defect, they are inadmissible under these rules as to the element of causation as well.

the facts are scientifically driven and plaintiffs cannot show that the milk formula caused F.J.G.M.'s injury simply via common experience. Cf. Martinez-Serrano v. Quality Health Servs. of Puerto Rico, Inc., 568 F.3d 278, 286 (1st Cir. 2009) (discussing how plaintiffs generally have to provide expert testimony in medical malpractice cases because "they tend to be scientifically driven and more nuanced than most tort cases" but in a "narrow band" of tort cases, some plaintiffs may not have to produce expert testimony).

In her R&R regarding defendant Abbott's motion to dismiss, the magistrate judge warned that plaintiffs must provide "expert medical testimony" because the issue of medical causation is not something "within common knowledge of the layman." (Docket No. 23 at pp. 9-10.) The fact that the infant was sick after consuming the Similac formula is insufficient to show that the formula caused the infant's illness. See, e.g., Carmona v. S. Am. Rests. Corp., No. 07-1314 (SEC), 2009 WL 928722, at *5 (D.P.R. March 31, 2009) (granting summary judgment in a negligence action when "nothing in the record points to [d]efendants' product as the cause of [plaintiff's illness]" even though plaintiff was clearly ill after consuming food at the restaurant). Yet, plaintiffs have failed to provide any expert testimony regarding causation. Abbott argues that plaintiffs have not tendered any expert during discovery in compliance with Federal Rule of Civil Procedure 26. (Docket No. 46 at p. 17.) Plaintiffs do not respond to this

argument in their opposition to Abbott's motion for summary judgment. (Docket No. 48.) Indeed, their only testimony aside from that of F.J.G.M.'s parents comes from Dr. Vargas, the infant's treating physician. (Docket No. 48-9.)

Even if no expert testimony is required in this case, plaintiffs fail to provide any circumstantial evidence to establish that the Similac formula caused F.J.G.M.'s illness. In fact, both the testimony of the plaintiffs and Dr. Vargas show circumstantial evidence establishing that F.J.G.M.'s sickness was not caused by the Similac formula.

First, the plaintiffs testified that they did not see any insect parts in the formula and have presented no other evidence that anyone else who consumed the Similac formula has experienced similar problems. Second, on November 30, 2010, about two months after the plaintiffs stopped giving F.J.G.M. the Similac formula, F.J.G.M. was admitted to the hospital again with symptoms similar to his September 2010 illness, including acute gastroenteritis, moderate dehydration, otitis, and tonsilitis. This suggests that F.J.G.M.'s illness was not caused by the formula, as contended by plaintiffs; rather, the infant's medical history suggests that these symptoms are recurring problems for F.J.G.M.

Finally, Dr. Vargas' testimony eliminates contamination of the Similac formula as the cause of F.J.G.M.'s illness and suggests that there are other more likely causes of the

sickness. For example, he testified that not only has he never read or heard of a child suffering gastroenteritis due to eating insects, including warehouse beetles, but that he also stopped F.J.G.M's ingestion of Amoxil because it can cause diarrhea. He also listed a number of other reasons that could have caused F.J.G.M.'s gastroenteritis, including lactose intolerance and the possibility that the infant's ear infection caused a secondary infection in the stomach and intestines. Furthermore, Abbott's expert report confirms Dr. Vargas' observations that F.J.G.M. may have had a secondary infection from his illness: Dr. Hyman stated that there is "zero" chance that F.J.G.M.'s September 2010 illness was caused by the ingestion of warehouse beetles and instead indicated that the illness was probably due to an underlying infection.

Plaintiffs have failed to establish that a jury could reasonably find for them as to whether Abbott's allegedly defective milk formula caused the F.J.G.M.'s injury. Instead, the defendant has provided sufficient evidence to show that there is no genuine dispute on the issue of causation. Therefore, the Court **ADOPTS IN FULL** the magistrate judge's findings on the element of causation.

Defendant Abbott has shown that there is no genuine issue of material fact regarding the elements of defect and causation in a strict liability action, and plaintiffs have failed to show that a jury could reasonably find in their favor. For

these reasons, the Court **GRANTS** defendant Abbott's motion for summary judgment regarding plaintiffs' products liability claim.

B. Negligence Under Article 1802

In Puerto Rico, Article 1802 of the Civil Code[12] provides for a cause of action resulting from an individual's negligent act. Isla Nena Air Servs., 449 F.3d at 88 (1st. Cir. 2006). Under Article 1802, plaintiffs must prove three elements of negligence: (1) an injury, (2) a breach of duty, and (3) proximate causation. Vasquez-Filippetti v. Banco Popular de P.R., 504 F.3d 43, 49 (1st Cir. 2007) (internal citations omitted). The second element requires plaintiffs to show the existence of a duty and its breach. Id. (quoting Rodriguez-Ortega v. Philip Morris, Inc., Civil No. 03-1529 (CCC), 2005 WL 2977795, at *5-6 (D.P.R. Nov. 7, 2005) ("Plaintiffs bear the burden of establishing the applicable standard of care and proving that [defendant] acted below that standard.") (internal citations and quotations omitted). Abbott correctly argues that plaintiffs have failed to establish the applicable standard of care and that Abbott acted below that standard. (Docket No. 46 at p. 21.) Abbott has provided evidence to show that it performed extensive quality testing on the Similac powdered milk formula at the Sturgis facility. Furthermore, Abbott provided specific evidence that it employs a third-party pest-

[12] The statute states, in relevant part, that "[a] person who by an act or omission causes damage to another through fault or negligence shall be obliged to repair the damage so done." P.R. Laws Ann. Tit. 31, § 5141.

control company to service its Sturgis plant and that a July-August 2010 internal compliance audit and a March 2010 audit by the FDA found no significant issues with the facility. There is no evidence from plaintiffs in the record establishing that these actions by Abbott breached any applicable standard of care. Thus, there is no evidence in the record from which a jury could conclude that Abbott breached any duty owed to plaintiffs. Plaintiffs fail to make any argument regarding this portion of Abbott's motion even though they acknowledge that they must show the duty owed by defendant and that defendant breached that duty. (Docket No. 48 at p. 11.) Therefore, defendant Abbott is entitled to summary judgment on plaintiffs' Article 1802 negligence claim.

For these reasons, the Court **ADOPTS IN FULL** the magistrate judge's findings on plaintiffs' negligence claim and **GRANTS** defendant Abbott's motion for summary judgment regarding plaintiffs' negligence claim.

IV. CONCLUSION

Accordingly, the Court **GRANTS** defendant Abbott's motion for summary judgment. This case is therefore **DISMISSED with prejudice.**

Judgment shall be entered accordingly.

IT IS SO ORDERED.

San Juan, Puerto Rico, October 30, 2012.

s/ FRANCISCO A. BESOSA
FRANCISCO A. BESOSA
UNITED STATES DISTRICT JUDGE