IN THE UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISON

CHRISTINE JOHNSON, DENNIS JOHNSON, Plaintiffs, v. EISAI, INC., ARENA PHARMACEUTICALS, INC., Defendants,	)	CASE NO. 4:21-CV-00876-CEH MAGISTRATE JUDGE CARMEN E. HENDERSON **MEMORANDUM OPINION AND ORDER**

I. Introduction

This is before the Court on Defendant Eisai, Inc.'s ("Eisai") motion for partial dismissal (ECF No. 11) and Defendant Arena Pharmaceuticals, Inc.'s ("Arena") motion for partial dismissal. (ECF No. 13). For the reasons discussed below, both motions are DENIED in part and GRANTED in part. Specifically, the Court dismisses part of Count I (Design Defect) and Count IV (Breach of Implied Warranty of Merchantability). Part of Count I (Failure to Warn), Count II (Failure to Conform to Representations), Count III (Breach of Express Warranty), Count V (Fraudulent Misrepresentation), and Count VI (Loss of Consortium) remain. Additionally, the Court GRANTS Defendants' Motion to Strike Plaintiffs' Demand for Punitive Damages.

II. Background

Christine and Dennis Johnson (collectively "Plaintiffs") brought this personal injury action against Eisai on April 27, 2021. (ECF No. 1). Plaintiffs sought relief after Mrs. Johnson was

diagnosed with colon cancer as a result of her use of the prescription medication Belviq. (ECF No. 1 at 2–3). Eisai and Arena (collectively "Defendants") manufactured Belviq and marketed it as a weight-loss medication. (ECF No. 1 at 2–3). Dr. Denise Bobouynik, Mrs. Johnson's primary care physician, prescribed Mrs. Johnson Belviq around August 2016. (ECF No. 1 at 4). Mrs. Johnson used Belviq through October 2016 and was diagnosed with colon cancer on October 24, 2016. (ECF No. 1 at 4).

Plaintiffs allege not only that there were safety issues—i.e., an increased risk of cancer—associated with Belviq, but also that, contrary to Defendants' representations, Belviq was not effective as a weight-loss adjunct. Plaintiffs further contend that Defendants knowingly represented that Belviq was safe and effective as a weight-loss medication despite the known information about Belviq's carcinogenic effects. (ECF No. 1 at 19–20). Plaintiffs base their allegations on Defendants' clinical trials on mice and rats, scientific publications, and the subsequent withdrawal of Belviq in 2020. (ECF No. 1 at 11–12, 18). The clinical trials allegedly resulted in an abnormal increase in tumors in the rats and mice. (ECF No. 1 at 11–12). As a result of these trials, the Food and Drug Administration ("FDA") initially rejected Belviq. (ECF No. 1 at 14). Plaintiffs state that the FDA only later approved Belviq after Defendants reclassified the data in its favor. (ECF No. 1 at 14–17). On January 14, 2020, the FDA issued a safety communication regarding trial results showing a possible increased risk of cancer with Belviq. (ECF No. 1 at 18). On February 13, 2020, the FDA announced that Eisai submitted a request to voluntarily withdraw Belviq from the market. (ECF No. 1 at 18). The FDA reported that analysis of data "indicated an imbalance of cancer inpatients taking Belviq that increased with treatment duration." (ECF No. 1 at 18). The FDA stated that "the risks of Belviq outweigh its benefits and recommended that patients stop taking Belviq and dispose of any unused pills." (ECF No. 1 at 18).

As noted, Plaintiffs brought this claim on April 27, 2021. (ECF No. 1). Plaintiffs allege: 1) violation of the Ohio Products Liability Act (Defective Design and Failure to Warn); 2) violation of the Ohio Products Liability Act (Failure to Conform to Representations); 3) Breach of Express Warranty; 4) Breach of Implied Warranty of Merchantability; 5) Fraudulent Misrepresentation; and 6) Loss of Consortium. (ECF No. 1). On June 25, 2021, Eisai moved for partial dismissal. (ECF No. 11). That same day, Arena also filed for partial dismissal, "fully join[ing] and adopt[ing] the law and argument set forth in the Memorandum of Defendant EISAI." (ECF No. 13 at 1). Plaintiffs opposed both motions for partial dismissal. (ECF Nos. 24, 25). Eisai replied. (ECF No. 26). Arena also replied, again joining and adopting the law and argument set forth in Eisai's reply. (ECF No. 27 at 1–2).

III. Standard of Review

When considering a motion to dismiss, the Court "construe[s] the complaint in the light most favorable to the plaintiff, accept[s] all well-pleaded factual allegations as true, and examine[s] whether the complaint contains 'sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Hill v. Snyder*, 878 F.3d 193, 203 (6th Cir. 2017) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Neither legal conclusions couched as factual allegations nor recitations of the elements of a cause of action are sufficient to state a claim. *Fritz v. Charter Twp. of Comstock*, 592 F.3d 718, 722 (6th Cir. 2010)). The Court "cannot dismiss a complaint for failure to state a claim 'unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *Woodard v. O'Brien*, 415 F. Supp. 3d 794, 796 (S.D. Ohio 2019).

IV. Analysis

Defendants argue that the Court should dismiss Plaintiffs' Ohio Products Liability Act (Counts I and II), Breach of Express Warranty (Count III), Breach of Implied Warranty of Merchantability (Count IV), and Fraudulent Misrepresentation (Count V) claims.[1] Defendants also ask the Court to strike Plaintiffs' demand for punitive damages. The Court will consider each argument in turn.

A. Ohio Products Liability Act – Design Defect

Defendants argue that the Court should dismiss Plaintiff's Ohio Products Liability Act ("OPLA") based on design defect because the claim is preempted by federal law and Plaintiffs failed to allege sufficient facts to establish the elements of the claim. Plaintiffs agree to withdraw this cause of action. Accordingly, Plaintiff's design defect claim is dismissed.

B. Ohio Products Liability Act – Failure to Warn

Plaintiffs allege that Defendants violated the OPLA because they failed to adequately warn Mrs. Johnson or Dr. Bobouynik that Belviq had not been sufficiently or adequately tested for safety risks, including cancer. Defendants argue that this claim, as it relates to Mrs. Johnson, should be dismissed because Defendants only had a duty to warn Dr. Bobouynik.[2] In making this argument, Defendants rely on the "learned intermediary" doctrine. Plaintiff responds that the "learned intermediary" doctrine only applies where the manufacturer of the drugs has provided adequate warnings to the physician, which did not occur here. The Court agrees.

Whether or not a drug manufacturer has a duty to warn the user of the drug depends on the drug manufacturer's relationship to the user. *Tracy v. Merrell Dow. Pharms., Inc.*, 569 N.E.2d

[1] Notably, Defendants did not argue that the Court should dismiss part of Plaintiffs' failure to warn claim or Plaintiffs' loss of consortium claim. Both claims, therefore, remain

[2] Notably, Defendants do not seek dismissal of Plaintiffs' failure to warn claim as it relates to communications to Dr. Bobouynik. (ECF No. 11-1 at 11 n.3).

875, 878 (Ohio 1991). The learned intermediary doctrine provides that "[w]here a prescription drug has been prescribed for a patient by the patient's physician, the manufacturer has been held to discharge its duty to warn *if the manufacturer adequately warns the physician*." *Id.* (emphasis added) (citations omitted); *see also* Ohio Rev. Code Ann. § 2307.76(C) ("An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question . . . ."). However, "[t]he learned intermediary doctrine does not relieve the manufacturer of liability to the ultimate user for an inadequate or misleading warning; it only provides that the warning reaches the ultimate user through the learned intermediary." *Tracy*, 569 N.E.2d at 878 (citations omitted). Therefore, "a manufacturer's duty can only be discharged upon providing a learned intermediary with an adequate warning." *Boyd v. Lincoln Elec. Co.*, 902 N.E.2d 1023, 1035 (Ohio Ct. App. 2008).

Defendant's sole argument is that "Defendants' alleged communications with Plaintiff do not bear on whether they provided an adequate warning to her prescribing physicians." (ECF No. 11-1 at 11). However, as stated above, this is not true. If Defendants failed to adequately warn Dr. Bobouynik, then their duty to Mrs. Johnson was not discharged. The communications between Defendants and Mrs. Johnson then become relevant to determine whether Defendants adequately warned Mrs. Johnson of the potential risks. The communications between Defendants and Mrs. Johnson only become irrelevant if Defendants' warnings to Dr. Bobouynik were adequate. Accepting Plaintiffs' allegations as true, the Court cannot make such a determination. Plaintiff specifically alleged "Communications made by Defendants to [Mrs. Johnson] and her prescribing healthcare provider, Dr. Denise Bobouynik, were inadequate because Defendants failed to warn and/or adequately warn them that Belviq had not been sufficiently and/or adequately tested for

safety risks, including cancer." (ECF No. 1 at 26). This is sufficient for Plaintiffs' claim to survive a motion to dismiss. Accordingly, the Court denies Defendant's motion to dismiss Plaintiff's OPLA claim based on failure to warn as it relates to Mrs. Johnson.

C. Ohio Products Liability Act – Failure to Conform to Representations

Defendants next argue that the Court should dismiss Plaintiffs' failure to conform claim "because they have not alleged facts sufficient to establish that [Defendants'] made any representations that could form the basis for their claim." (ECF No. 11-1 at 11–12). Plaintiffs allege that Defendants represented, through labeling and their representatives, that Belivq was safe and effective. Plaintiffs state that they relied on those representations and suffered injuries as a result. Defendant argues that these allegations are "broad all-encompassing" statements that "cannot support a valid failure to conform claim." (ECF No. 11-1 at 13) (citations omitted). The Court disagrees.

In Ohio, a "product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer." Ohio Rev. Code § 2307.77. "Representation" is defined as "an express representation of a material fact concerning the character, quality, or safety of a product." *Id.* § 2307.71(A)(14). To be successful on a failure to conform to representation claim under the OPLA, a plaintiff must prove: "(1) the manufacturer made [a] representation as to a material fact concerning the character or quality of the product; (2) the product did not conform to that representation; (3) [the plaintiff] justifiably relied on that representation; and (4) the plaintiff's reliance on the representation was the direct and proximate cause of the plaintiffs' injuries." *Saraney v. TAP Pharm. Prods., Inc.*, No. 1:04 CV 02026, 2007 WL 148845, at *8 (N.D. Ohio Jan. 16, 2007).

Plaintiffs have pled facts which, if accepted as true, sufficiently allege a claim for failure to conform with representation under Ohio Rev. Code § 2307.77. First, Plaintiffs allege that Defendants represented to both Dr. Bubonic and Mrs. Johnson, through labeling, patient information sheets, and Defendants' representatives, that Belviq was effective and safe to use—material facts regarding the character, quality, and safety of the product. Second, Plaintiffs allege that Belviq was neither effective nor safe to use. Third, Plaintiffs allege that Mrs. Johnson and Dr. Bobouynik justifiably relied on that representation—proscribing and ingesting the medication for the purpose of weight loss. Finally, Plaintiffs state that Mrs. Johnson's reliance on that representation—and thus, taking Belviq—was the direct cause of her colon cancer.

Defendants argue to the contrary that "courts have held that general allegations that a prescription medicine failed to conform to representations it was safe and effective are insufficient to state a claim under the OPLA." (ECF No. 11-1 at 12). However, the cases that Defendants rely on to support their argument are distinguishable. Defendants most significantly rely on *Harris v. Eli Lilly & Co.*, where the court dismissed a failure to conform claim where the complaint alleged that the defendants failed to conform to representations about safety and efficiency because plaintiff's "broad all-encompassing" statements could not support the claim. No. 4:12CV2481, 2012 WL 6732725, at *4 (N.D. Ohio Dec. 28, 2012). This, of course, is not all that the court said. The court additionally stated that the Complaint failed to "identify when these representations were made by Defendants, when the decedent learned of the representations, who relayed the information to her, and how they induced her to rely on them." *Id.* The court really took issue with the plaintiff's "boilerplate language" that failed to even reference the OPLA—not allowing the defendants to properly defend the claim. *Id.*

Similarly, in *Tolliver v. Bristol-Myers Squibb Co*., the court reasoned that the Plaintiffs' Complaint only stated that "Defendants are liable to the Plaintiffs for breaching express and implied products representations that they made regarding [the drug]. These product representations include fitness of merchantability and/or fitness for a particular use." No. 1:12 CV 00754, 2012 WL 3074538, at *5 (N.D. Ohio July 30, 2012). The court explicitly noted that the Complaint contained "no factual allegations to support these conclusory legal statements" and failed to provide any "factual allegations connecting the supposed conformance with [plaintiff's] injuries." *Id.* In *Saraney v. TAP Pharm. Prods., Inc*., the court granted summary judgment against plaintiffs because the "bare allegation, contained in their complaint, that [defendant] generally warranted . . . 'good, safe and merchantable quality' is insufficient to prove the express representation necessary to meet the standards." No. 1:04 CV 02026, 2007 WL 148845, at *8 (N.D. Ohio Jan. 16, 2007). The court stated that the plaintiff's claim could not survive summary judgment because plaintiffs provided no evidence of an express representation. *Id.*

In contrast to each of these cases, Plaintiffs have done much more than simply state that Defendants represented that the drug was "safe and effective" for use. Plaintiffs' Complaint identifies three mediums through which representations were made—labeling, patient information sheets, and Defendant's representatives. Plaintiffs state that Defendant made the representations to Dr. Bobouynik who then relayed the information to Mrs. Johnson in August 2016. (ECF No. 1 at 29). Plaintiffs' also claim that representations were made directly to Mrs. Johnson in August 2016. (ECF No. 1 at 30). Both Dr. Bobouynik and Mrs. Johnson allegedly relied on Defendants' representations that Belviq was safe and effective when deciding to proscribe and inject the drug. (ECF No. 1 at 30). Plaintiffs allege that Belviq did not conform to these representations, as it was neither safe nor effective. (ECF No. 1 at 31–32). Plaintiffs directly tie the injection of Belviq to

Mrs. Johnson's injuries. (ECF No. 1 at 32). This distinguishes Plaintiffs' Complaint from those involved in the cases Defendants cite. Plaintiff's have sufficiently alleged a failure to conform claim.

Additionally, Defendants argue that Plaintiffs failed to "identify any specific language in the Belviq label or product information sheet that constitutes the representations that purportedly support their claim." (ECF No. 26 at 3). However, the Complaint does not need to provide the exact representations Plaintiffs relied on. It simply must "set forth facts from which the Court may plausibly infer that a representation was made and that the [product] did not conform to that representation." *Darwish v. Ethicon*, No. 1:20 CV 1606, 2020 WL 7129582, at *9 (N.D Ohio Dec. 4, 2020) (alteration in original) (citations omitted). This "is all that is required by Ohio Rev. Code § 2307.00 at the pleading stage." *Id.* Plaintiffs have alleged that the product label, product information sheet, and Defendants' representative all represented that Belviq was safe and effective to use and that its efficiency outweighed its risks.[3] Plaintiffs state that Mrs. Johnson justifiably relied on these representations causing her injuries. This is enough to survive a motion to dismiss. *See Barreca v. AngioDynamics, Inc.*, No. 4:15CV1111, 2015 WL 5085260, at *4 (N.D. Ohio Aug. 27, 2015) (concluding that an allegation that "representations to Plaintiff that the product was safe and fit for the particular purpose to which Plaintiff . . . would use the product" was sufficient to survive a motion to dismiss). Accordingly, the Court denies Defendants' motion to dismiss Plaintiffs' OPLA failure to conform to representations claim.

D. Breach of Express Warranty

[3] Although Defendants attach the Belviq label and attempt to argue that there is nothing in the label or patient information sheet that could be construed as an express warranty, the Court notes that Defendant says nothing about representations made by Defendants' representatives. Thus, even if the Court were to agree that there were no express warranties made in the exhibits Defendants provided, the claim would survive.

Next, Defendants argue that the Court should dismiss Plaintiffs' breach of express warranty claim because: 1) Plaintiffs did not provide Defendants with pre-suit notice of the alleged breach; and 2) Plaintiffs failed to state a claim.

i. Pre-Suit Notice

Defendant first argues that Plaintiffs failed to provide Defendants with pre-suit notice of the breach of warranty. Plaintiffs do not contest that they did not provide Defendants' notice prior to filing suit but instead respond that pre-suit notice was not required in this case. Generally, as part of a breach of warranty claim, Ohio Rev. Code § 1302.65(C)(1) requires the buyer to "notify the seller of breach" "within a reasonable time after [she] discovers or should have discovered any breach." If the buyer fails to give such notice, she is "barred from any remedy." *Id*. However, the Supreme Court of Ohio concluded this statute did not provide an absolute rule and "was not meant to exclude the possibility that notice may be inferred." *Chemtrol Adhesives. v. Am. Mfrs. Mut. Ins. Co.*, 537 N.E.2d 624, 638 (Ohio 1989) (citations omitted). The court specifically held that "in a proper case the filing of a civil complaint could serve as notice of breach." *Id.*

What exactly qualifies as "a proper case" is not clear. "In an attempt to determine when a complaint can serve as notice, federal courts have looked primarily to two factors: whether the defendant had any prior knowledge of the defects prior to filing the complaint, and the length of delay between the alleged breach and the filing of the complaint." *Albright v. Sherwin-Williams Co.*, No. 1:17 CV 2513, 2019 WL 5307068, at *3 (N.D. Ohio Jan. 29, 2019) (citations omitted). Courts also consider the fact that the purposes of the notice requirement are to provide an opportunity for settlement and to minimize the possibility of prejudice to the seller by allowing an opportunity to cure the defect, investigate the claim, or minimize the damages. *Standard All. Indus., Inc. v. Black Clawson Co.*, 587 F.2d 813, 826 (6th Cir. 1978).

Applying these principles, in *Painter v. Woodstream Corp.*, this Court concluded that a combination of press releases from the Federal Trade Commission warning that the product in question was defective and scientific studies showing that the technology used was defective was sufficient to support the conclusion that the defendant had constructive knowledge of defect to survive a motion to dismiss. No. 1:18 CV 2872, 2019 WL 12346962, at *5–6 (N.D. Ohio July 15, 2019). Similarly, in *Galoski v. Stanley Black & Decker, Inc.*, this Court determined that the case fell into the category of "proper circumstance[s]," allowing the filing of the suit to satisfy the notice requirement. No. 1:14 CV 553, 2015 WL 5093443, at *6 (N.D. Ohio Aug. 28, 2015). There, the plaintiff was a private consumer that "submitted some evidence, that if developed or verified during full discovery could support a finding that [defendant] had actual or constructive knowledge of the alleged defect prior to filing of the suit." *Id.* The Court also noted that, due to the nature of the product, even if the plaintiff gave pre-litigation notice, the defendant could not have cured the defect or replaced the product. *Id.* Therefore, the Court concluded that requiring notice and a prior opportunity to cure the defect would have been "wholly futile." *Id.*

Plaintiffs argue that they fall into this category of cases because they alleged: (1) that the FDA issued a safety communication and a drug withdrawal announcement regarding the increased risks of cancer associated with Belviq, and (2) Defendants' own clinical studies as well as outside medical literature and publications demonstrated that Belviq was ineffective and unsafe. The Court agrees. Plaintiffs have alleged sufficient facts, which if accepted as true, demonstrate that Defendant had knowledge of the alleged defect prior to filing this lawsuit. On January 14, 2020, the FDA issued a safety communication discussing a possible increased risk of cancer with Belviq. On February 13, 2020, Eisai submitted a request to voluntarily withdraw Belviq from the market. The FDA reported that there appeared to be an imbalance of cancer in patients taking Belviq that

increased with treatment duration and that the risks of Belviq outweighed its benefits. Defendants, therefore, had knowledge of Belviq's defect.

The Court recognizes that more than four years passed between Mrs. Johnson's cancer diagnosis and the filing of this complaint. Defendants argue that this delay renders Plaintiffs' "lawsuit as notice" inadequate as a matter of law. However, there is a "well-established rule" in Ohio that "determination of a reasonable time and the adequacy of notice to the seller are ordinarily questions of fact." *Agf, Inc. v. Great Lakes Treating Co.*, 555 N.E.2d 634, 637 (Ohio 1990). Nonetheless, the Court acknowledges that Courts have granted summary judgment for the defendant in cases where notice was given years after the alleged breach. *See Chemtrol*, 537 N.E.2d at 636 (stating that a two-year delay in notice would be insufficient as a matter of law); *Lincoln Elec. Co. v. Technitrol, Inc.*, 718 F. Supp. 2d. 876, 883–84 (N.D. Ohio 2010) (concluding a 15-month delay in notice was unreasonable as a matter of law). These cases, however, involve motions for summary judgment and dealt with situations where the plaintiffs did not provide evidence that their delays were reasonable. *See, e.g.*, *Lincoln Elec. Co.*, 718 F. Supp. 2d at 884 ("Plaintiff has the burden of proof on this issue but has offered no evidence that its 15–month delay in notifying defendant of the alleged breach was reasonable."). The courts also emphasized that the plaintiffs had knowledge of the breach right away and the defendants did not. *See, e.g.*, *id.* That is not the situation here, where Plaintiff is not yet required to provide evidence and Defendants allegedly knew of the defect before even Plaintiff did. At this time, the Court cannot conclude that Plaintiffs' delay was unreasonable as a matter of law.

Moreover, the Court notes that, like in *Galoski*, any pre-litigation notice here would have been "wholly futile" because it would not have provided Defendant an opportunity to cure the defect. Belviq's defect is that it causes cancer. Once Mrs. Johnson developed cancer, there was

nothing a replacement drug could have done. Thus, earlier notice would not have made a difference. The Court, therefore, concludes that Plaintiff has pled sufficient facts to suggest a possibility that Defendants had actual or constructive notice of the alleged defect years before this action, making the filing of this case adequate notice. *See Galoski*, 2015 WL 5093443, at *7 (concluding that the plaintiff's claim survived a motion to dismiss where plaintiff was a private consumer and "there [was] a possibility that Defendant is alleged to have been aware of the defect long before the lawsuit was ever filed"). At this stage of the litigation, this is sufficient.

ii. Failure to State a Claim

Defendant also argues that the Court should dismiss Plaintiffs' breach of express warranty claim because the complaint failed to sufficiently allege a claim. To state a claim for a breach of warranty, the plaintiff must allege: "(1) the existence of a warranty; (2) the product failed to perform as warranted; (3) the plaintiff provided the defendant with reasonable notice of the defect; and (4) the plaintiff suffered an injury as a result of the defect." *McKinney v. Bayer Corp.*, 744 F. Supp. 2d 733, 753 (N.D. Ohio 2010) (citing *St. Clair v. Kroger Co.*, 581 F. Supp. 2d 896, 902 (N.D. Ohio 2008)). Ohio law provides that express warranties by the seller are created by "[a]ny 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." Ohio Rev. Code § 1302.26(A)(1). "It is not necessary to the creation of an express warranty that the seller use formal words such as 'warrant' or 'guarantee' or that he have a specific intention to make a warranty . . . ." *Id.* § 1302.26(B).

Defendants argue that Plaintiffs failed to state a claim. Defendants' argument focuses on Plaintiffs' alleged failure to identify specific representations to support the existence of a warranty. Their arguments substantially mirror their argument regarding Plaintiffs' failure to conform claim. Defendants argue that asserting that a product is "safe and effective" is not sufficiently clear to

create an express warranty. Plaintiffs respond that Ohio law only requires a plaintiff to assert that the seller made the affirmation of fact. The Court concludes that Plaintiffs sufficiently pled their breach of express warranty claim.

Importantly, Plaintiffs' have done more than simply state that Defendants represented that Belviq was "safe and effective" when it was not. Plaintiffs' Complaint alleges that Defendants, through labeling, Belviq's patient information sheets, and Defendants' sales representatives, warranted to Mrs. Johnson and Dr. Bobouynik that Belviq was safe and effective to use as an adjunct for chronic weight management and that Belviq's effectiveness outweighed any potential dangers and/or risks. (ECF No. 1 at 34–36). As a result, Dr. Bobouynik recommended Belviq as a safe and effective drug to use and prescribed it to Mrs. Johnson. (ECF No. 1 at 35). Mrs. Johnson took Belviq from August 2016 through October 2016. (ECF No. 1 at 36). Plaintiffs allege that Belviq did not conform to these warranties because it neither was effective as a weight loss adjunct nor safe. (ECF No. 1 at 38). Plaintiffs assert that Mrs. Johnson's "injuries and damages were directly caused by Defendants' breach of the aforementioned express warranties." (ECF No. 1 at 38). This provides sufficient factual allegations to plead a breach of express warranty.

Defendants' reliance on *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791 (N.D. Ohio 2004), to argue otherwise is misplaced. There, the Court considered a motion for summary judgment and stated "asserting that a product is 'safe and effective' is not sufficiently clear to create an express warranty.'" *Id.* The Court stated that even if it was, plaintiffs did not come forth with evidence that Defendant breached the warranty, as required at summary judgment. *Id.* This does not support Defendants' argument that Plaintiffs have not alleged a claim. First, Plaintiffs have done more than assert that Defendants represented that the product was "safe and effective." They alleged that Defendants represented that Belviq was effective as a weight loss adjunct, was

safe for use in that way, and its effectiveness outweighed its risk. Second, although there is a lack of case law in Ohio on whether stating that the defendant represented that a product is "safe and effective" is sufficient to state a claim, it is clear that "where representations concerning the safety of a product are made by a manufacturer and are proved to be false, an action for express warranty could be maintained." *Drayton v. Jiffee Chem. Corp.*, 591 F.2d 352, 358 (6th Cir. 1978). Similarly, other jurisdictions with similar statutes have found that "[a]ffirmations of fact regarding the safety of a product are actionable on a claim for breach of express warranty." *Williamson v. Stryker Corp.*, No. 12 Civ. 7083(CM), 2013 WL 3833081, at *9 (S.D.N.Y July 23, 2013) (citations omitted).

Applying these principles, the Court concludes that Plaintiff has sufficiently alleged a breach of express warranty sufficient to survive a motion to dismiss. Plaintiffs alleged that Defendants made representations through labeling, patient information sheet, and Defendants' representatives' statements that Belviq was safe and effective. Plaintiffs also alleged that Defendants represented that Belviq's benefits outweighed its risks. Assuming what Plaintiffs have alleged is true, Plaintiffs have sufficiently stated a claim of breach of an express warranty. Accordingly, Defendant's motion to dismiss Plaintiffs' breach of express warranty claim is denied.[4]

E. Breach of Implied Warranty of Merchantability

Defendants argue that the Court should dismiss Plaintiffs' breach of implied warranty claim because Plaintiffs' failed to allege sufficient facts to establish a design defect, a necessary

[4] Arena argues that it did not distribute or sell Belviq in the United States and, therefore, "there can be no basis as a matter of law for" any breach of warranty claims against it. However, Arena provided no law or further development of this argument. "[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived." *United States v. Layne*, 192 F.3d 556, 566–57 (6th Cir.1999) (quoting *McPherson v. Kelsey*, 125 F.3d 989, 995–96 (6th Cir.1997)). The Court, therefore, does not address this argument.

element of their claim. Arena additionally argues that Plaintiffs cannot demonstrate privity of contract with Arena.[5] Plaintiffs agree to withdraw this cause of action. Accordingly, Plaintiff's breach of implied warranty of merchantability claim is dismissed.

F. Fraudulent Misrepresentation

Next, Defendants argue that Plaintiffs' fraudulent misrepresentation claim fails to satisfy Fed. R. Civ. Pro. 9(b) because it does not state with particularity the circumstances constituting fraud. Fed. R. Civ. Pro. 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." The Sixth Circuit "reads this rule liberally" but requires that plaintiff to, at a minimum, "allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Coffey v. Foamex L.P.*, 2 F.3d 157, 161–62 (6th Cir. 1993). "The threshold test is whether the complaint places the defendant on 'sufficient notice of the misrepresentations,' allowing the defendants to 'answer, addressing in an informed way plaintiffs [sic] claim of fraud.'" *Id.* at 162. (alterations in original) (citations omitted).

Defendants argue that Plaintiffs did not meet their burden because they failed to "identify any specific representations on the Belviq label or product information sheet that they contend were fraudulent," "identify any sales representatives who made any statements, much less false ones," or explain which Defendant "supposedly is responsible for any alleged false statement."

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[5] Arena's privity of contract argument was made in reference only to Plaintiffs' breach of implied warranty of merchantability claim. (ECF No. 13-1 at 2). As such, the Court does not address this argument as to the breach of express warranty claim. However, because Arena stated "there can be no basis as a matter of law for Plaintiffs' claims premised on any alleged warranty by Arena," the Court notes that, even if there were no privity of contract, "[i]t is undisputed that privity is not required with respect to [a plaintiff's] breach of express warranty claim." *McKinney v. Bayer Corp.*, 744 F. Supp. 733, n.10 (N.D. Ohio Sept. 30, 2010)).

(ECF No. 11-1 at 77) (ECF No. 26 at 7). The Court disagrees. The Complaint alleges the following. In 2016, Defendants "falsely and fraudulently" represented to Mrs. Johnson through a patient information sheet "that Belviq had been adequately and sufficiently tested and was found to be safe and effective." (ECF No. 1 at 44). Defendants also falsely represented to Mrs. Johnson and Dr. Belviq, through the patient information sheet, Belviq's label, and Defendants' sales representatives, that Belviq's effectiveness outweighed its dangers and risks. (ECF No. 1 at 45–47). Prior to 2016, Defendants knew or should have known that Belviq was not effective and not safe to use given its increased risk of cancer (as demonstrated by Defendants' clinical studies on mice and rats). (ECF No. 1 at 44–45). Defendants should have known that Belviq's effectiveness, if any, did not outweigh the dangers and risks associated with it. (ECF No. 1 at 45). These fraudulent representations were given "with the intent of defrauding and deceiving consumers" and healthcare providers, including Mrs. Johnson and Dr. Bobouynik. (ECF No. 1 at 45–46). The representations were also done with the intent of inducing consumers into using Belviq. (ECF No. 1 at 46). As a result of these representations, in August 2016, Dr. Bobouynik was induced to prescribe Belviq to Mrs. Johnson and Mrs. Johnson was induced to use Belviq. (ECF No. 1 at 47–48). Mrs. Johnson developed colon cancer as well as other serious and dangerous side effects because of these misrepresentations. (ECF No. 1 at 50).

This is sufficient to meet the heightened pleading standards. The Complaint informs the Defendant of the time, place, and content of the alleged misrepresentation, the fraudulent scheme, the fraudulent intent of the defendants; and the injury resulting from the fraud—putting them on sufficient notice of the claim. The Court recognizes that Plaintiffs did not identify a specific sales representative that made the false statements. However, when the defendant is a corporation, "the plaintiff does not need to identify 'the corporation's individual employee who made the alleged

fraudulent misrepresentation' as long as the plaintiff identifies the 'particular corporate defendant as well as the time, place, and content of the alleged misrepresentation.'" *Bell v. Kokosing Indus.*, No. 19-53-DLB-CJS, 2020 WL 4210701, at *17 (E.D. Ky. July 22, 2020) (citing *Newberry v. Serv. Experts Heating & Air Conditioning, LLC*, 806 F. App'x 348, 362 (6th Cir. 2020)). Although Plaintiffs did not identify which specific defendant made the fraudulent misrepresentation, where the defendants are both allegedly responsible for manufacturing and promoting a product and allegedly misrepresenting, it is sufficient to plead that both defendants made the misrepresentation. *Gordon v. B. Braun Med. Inc.*, No. 1:19-cv-121, 2020 WL 1491378, at *11 (S.D. Ohio Mar. 27, 2020). To hold otherwise and require the plaintiffs to separately allege their claims against each defendant would be redundant. *Id.* Finally, in regard to Defendants' argument that Plaintiffs failed to identify any specific representations, the Court concludes Plaintiffs satisfied the particularity requirement. Plaintiffs simply must allege the time, place, and content of the misrepresentations. Regarding the statements, Plaintiffs alleged that 1) in August 2016, 2) through labels, information sheets, and representatives, 3) Defendant falsely stated that Belviq was safe and effective to use, Belviq's efficacy outweighed its risk. This, along with Plaintiffs' other allegations, adequately put Defendant on notice of the alleged misrepresentation. Defendant did not argue that Plaintiffs failed to allege any other aspect of their fraudulent misrepresentation claim. Accordingly, the Court denies Defendants' motion to dismiss Plaintiffs' fraudulent misrepresentation claim.

G. Punitive Damages

Finally, Defendants argue that the Court should strike Plaintiffs' demand for punitive damages because punitive damages are unavailable in cases involving FDA-approved medicines unless the plaintiff can show the manufacturer committed fraud-on-the-FDA. Defendants assert that Plaintiff cannot show fraud-on-the-FDA because such claims are preempted by federal law.

Plaintiffs acknowledge the merit of Defendants' argument, but state that punitive damages are available if the FDA itself has made a finding of fraud. Plaintiff states that "courts have permitted requests for punitive damages to survive the motion to dismiss stage when the plaintiff has pled facts to support a finding that the product did not conform to the terms of the FDA approval." (ECF No. 24 at 20).

As both parties acknowledge, Ohio law precludes punitive damages against a manufacturer if the drug that caused the plaintiff's harm was "manufactured and labeled in relevant and material respects in accordance with the terms of an approval" of the FDA. Ohio Rev. Code § 2307.80(C)(1)(a). An exception to this rule allows punitive damages if the plaintiff can establish "that the manufacturer fraudulently and in violation of applicable regulations of the [FDA] withheld from the [FDA] information known to be material and relevant to the harm that the [plaintiff] allegedly suffered." *Id.* § 2307.80(C)(2). However, the Supreme Court has rendered this exception moot as it concluded that such "fraud-on-the-FDA" claims are impliedly preempted by federal law. *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 348 (2001). As a result, "a punitive-damages claim for an FDA-approved drug is allowed under Ohio law *only if* the FDA has made a finding of either fraud or misrepresentation." *Monroe v. Novartis Pharms. Corp.*, 29 F. Supp. 3d 1115, 1130 (S.D. Ohio 2014) (citations omitted).

Nonetheless, Plaintiffs argue that the court should allow its punitive damages demand to survive this motion because the Complaint alleged that Defendants failed to represent "several subsequent known dangers and risks of Belviq" to the FDA. (ECF No. 24 at 21). Plaintiffs rely on *Gordon v. B. Braun Med., Inc.*, which states "[a]lthough a plaintiff must show that the FDA has made a determination of fraud to avoid application of OPLA's exception to punitive damages under § 2307.80(C)(1)(a), courts have permitted requests for punitive damages to survive the

motion to dismiss stage when the plaintiff has pled facts to support a finding that the product did not conform to the terms of the FDA approval." No. 1:19-cv-121, 2020 WL 1491378, at *12 (S.D. Ohio Mar. 27, 2020). Even if the Court were to agree with this statement, Plaintiffs have not alleged that the product did not conform to the terms of the FDA approval. Plaintiffs merely state that Defendant knew of several dangers and risk that they failed to represent to the FDA. Moreover, this statement does not exemplify the required standard. For punitive damages to be available to a plaintiff, the plaintiff must show that the FDA itself found fraud-on-the-FDA. Plaintiffs have not provided a finding of such fraud. Therefore, applying the Sixth Circuit's binding precedent, Plaintiffs' claims are preempted. *See In re Aredia & Zometa Prods. Liab. Litig.*, 352 F. App'x 994, 995 (6th Cir. 2009) ("Plaintiffs' claims undisputedly require proof of fraud committed against the FDA. Plaintiffs have no federal finding to that effect. Under this circuit's binding precedent, therefore, Plaintiffs' claims are preempted."). Accordingly, the Court grants Defendants' motion to strike Plaintiffs' punitive damages demand.

V. Conclusion

For the foregoing reasons, the Court DENIES in part and GRANTS in part Defendants' motions to dismiss. Plaintiffs' claims for design defect and breach of implied warranty of merchantability are dismissed. All other counts remain. The Court GRANTS Defendants' motion to strike Plaintiffs' punitive damages claim. Per the Court's Case Management Conference Order (ECF No. 42), Plaintiffs have until March 31, 2022 to amend their Complaint.

IT IS SO ORDERED.

Dated: March 9, 2022

s/ *Carmen E. Henderson*
CARMEN E. HENDERSON
U.S. MAGISTRATE JUDGE