IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

CHRISTINA SUTTMAN-VILLARS,
An individual,

Plaintiff,

vs. Civ. No. 20-778 KG/JFR

ARGON MEDICAL DEVICES, INC.,
REX MEDICAL, INC., d/b/a
REX MEDICAL, L.P. and REX
MEDICAL, L.P.,

Defendants.

MEMORANDUM OPINION AND ORDER

This is a products liability lawsuit involving an implantable and removable medical device called the Option Elite Inferior Vena Cava Filter (Filter). Defendants Rex Medical, Inc., d/b/a Rex Medical, L.P. and Rex Medical, L.P. (collectively, Rex) maintain that Rex designed and/or manufactured the Filter while Defendant Argon Medical Devices, Inc. (Argon) distributed the Filter. *See* (Doc. 4) at 1.

Plaintiff alleges that in February 2017 her physician, Willie Nunez, M.D., implanted the Filter in her inferior vena cava (IVC) to prevent recurrent blood clots from developing into pulmonary embolisms. Plaintiff, however, alleges that the Filter became embedded in the IVC and could not be removed. In becoming embedded, the Filter perforated the wall of Plaintiff's IVC. According to Plaintiff, the Filter can likely be removed by open surgery. Plaintiff, therefore, sued Rex and Argon asserting that the Filter was defectively designed and manufactured as well as asserting related claims for failure to warn, breach of implied and express warranties, and negligent misrepresentation.

On November 6, 2020, Rex filed a Fed. R. Civ. P. 12(b)(6) Motion to Dismiss in which Rex moves to dismiss all of Plaintiff's claims against it.[1] (Doc. 4). Shortly thereafter, Argon filed its Motion to Dismiss pursuant to Fed. R. Civ. P. 8(a)(2), 9(b), and 12(b)(6) to dismiss all of Plaintiff's claims against it. (Doc. 9). Plaintiff opposes the Motions to Dismiss, in part, and asks, in the alternative, for leave to amend her Complaint (Doc. 1) to address any deficiencies in the Complaint. The Motions to Dismiss are now fully and timely briefed.[2] *See* (Docs. 7, 13, 16, 17, 18, 20, and 22).

Having considered the Motions to Dismiss, the briefing, the Complaint, the controlling law, and for the following reasons, the Court (1) dismisses Plaintiff's manufacturing defect claims without prejudice because Plaintiff has voluntarily withdrawn those claims; (2) denies Defendants' motions to dismiss Plaintiff's remaining claims under Rules 12(b)(6) and 9(b); and (3) allows Plaintiff to file an amended complaint to cure Rule 8 deficiencies in her Complaint.

*I. Summary of the Complaint*

Plaintiff alleges that "Argon was the agent, servant, partner, predecessor in interest, and joint venturer of the Rex Defendants…." (Doc. 1) at ¶ 9. Plaintiff further contends that Argon and Rex are alter egos. *Id.* at ¶ 44.

Plaintiff alleges that Defendants "design, research, develop, manufacture, test, market, advertise, promote, distribute, and/or sell products such as IVC filters that are marketed and sold as a temporary/retrievable device to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava." *Id.* at ¶ 18. "One such product is the … Filter." *Id.* In

[1] Rex also filed its Motion to Dismiss pursuant to Fed. R. Civ. P. 12(f) (motion to strike) but does not argue a motion to strike. The Court assumes that Rex inadvertently referred to Rule 12(f).

[2] The Court notes jurisdiction under 28 U.S.C. § 1332 (diversity jurisdiction).

December 2013, "Defendants obtained FDA[3] clearance to market" the Filter "under Section 510(k) of the Medical Device Amendment." *Id.* at ¶ 20.

According to Plaintiff, "Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of said device." *Id.* at ¶ 21. Here, Plaintiff maintains that the "[F]ilter was substantially equivalent to the Option IVC filter." *Id.*

Plaintiff contends that after the Filter was implanted, she underwent two unsuccessful "complex percutaneous" attempts to retrieve the Filter. *Id.* at ¶ 28-29. Plaintiff later learned that the Filter was tilted and embedded in her IVC, and had perforated the wall of the IVC. *Id.* at ¶ 31. Plaintiff alleges that she

> is at risk for future progressive perforations and potential fractures of the [Filter], which could further injure adjacent organs and blood vessels. Plaintiff faces numerous health risks, including the risk of death. Plaintiff will require ongoing medical care and monitoring for the rest of her life. It is unlikely that the filter can be retrieved by any means other than an open surgical procedure.

*Id.* at ¶ 33.

Plaintiff brings seven Counts against Defendants, collectively. Count I is a negligence claim based on both design defect and failure to warn.[4] Count II is a strict products liability claim based on a failure to warn. Count III is a strict products liability claim based on a design defect. Count V is a claim for breach of the implied warranty of merchantability. Count VI is a

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[3] The "FDA" is the Food and Drug Administration. *See* (Doc. 1) at ¶ 19.

[4] Plaintiff also includes in Count I a negligence claim based on a manufacturing defect and brings a strict products liability claim based on a manufacturing defect in Count IV. Plaintiff, however, "will withdraw her manufacturing defect allegations at this time but reserves the right to seek leave to amend and reassert the claims once appropriate discovery has occurred." (Doc. 7) at 7. The Court, therefore, will dismiss the manufacturing defect claims without prejudice.

breach of express warranty claim. And, finally, Count VII is a negligent misrepresentation claim. Plaintiff seeks punitive damages among other damages.

*II. Discussion*

As an initial matter, Rex requests that the Court take judicial notice of three FDA documents: (1) an "FDA website publication on Pre-market Notification/510(k) clearance process;" (2) the FDA's "Guidance for Cardiovascular Intravascular Filter 510(k) Submissions;" and (3) the "FDA Guidelines on Investigational Device Exemptions, including 21 CFR 812.25." [5] (Doc. 4) at 3-4 (footnotes omitted). Rex notes that these FDA documents "state and describe the strict regulatory framework with which companies, such as Rex, must comply in bringing their medical device products to the market." (Doc. 4) at 3. Plaintiff opposes the request to take judicial notice of those FDA documents.

It is well-established that courts may "take judicial notice of official government publications." *High Desert Relief, Inc. v. United States*, 917 F.3d 1170, 1175 n.1 (10th Cir. 2019) (quoting Fed. R. Evid. 201(b)(2) ("permitting courts to take notice of a 'fact that is not subject to reasonable dispute because it ... can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned'")); *see also Spier,* 121 F. Supp. 3d at 811 n. 2 (taking judicial notice of "publicly-available" FDA documents). Accordingly, the Court will take judicial notice of the FDA documents. The Court, of course, can consider regulations and court descriptions of the FDA regulatory process for marketing medical devices without having

[5] The Court notes that "while ordinarily, a motion to dismiss must be converted to a motion for summary judgment when the court considers matters outside the complaint …, matters that are judicially noticeable do not have that effect…." *Nowell v. Medtronic Inc.*, 372 F. Supp. 3d 1166, 1208 (D.N.M. 2019); *see also Spier v. Coloplast Corp.,* 121 F. Supp. 3d 809, 811 n. 2 (E.D. Tenn. 2015) (stating that court can take into account "matters of public record" when considering Rule 12(b)(6) motion to dismiss) (citation omitted).

to take judicial notice of those legal sources. Moreover, the fact the Court takes judicial notice of the FDA documents does not necessarily mean that the Court needs to resort to those documents to decide the Motions to Dismiss.

*A. Rule 8(a)(2) and Rule 12(b)(6) Legal Standards*

Federal Rule of Civil Procedure 8(a)(2) requires that a plaintiff's complaint contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). That means the complaint must "give the defendant fair notice of what the ... claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quotation omitted). Hence, a complaint must "make clear exactly *who* is alleged to have done *what* to *whom*, to provide each individual with fair notice." *Robbins v. Oklahoma*, 519 F.3d 1242, 1250 (10th Cir. 2008) (emphasis original).

Aside from providing fair notice of a claim, the complaint must state a claim upon which relief can be granted or else face dismissal under Rule 12(b)(6). Rule 12(b)(6) requires that a complaint set forth the grounds of a plaintiff's entitlement to relief through more than labels, conclusions and a formulaic recitation of the elements of a cause of action. *See Bell Atlantic Corp.*, 550 U.S. at 555. While a complaint does not need to include detailed factual allegations, "factual allegations must be enough to raise a right to relief above the speculative level...." *Id.* In other words, dismissal of a complaint under Rule 12(b)(6) is proper only where it is obvious that the plaintiff failed to set forth "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570.

> A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'"

*Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citations omitted). In making a plausibility determination, courts must accept all well-pleaded allegations as true and must view them in the light most favorable to the plaintiff. *See Zinermon v. Burch*, 494 U.S. 113, 118 (1990); *Swanson v. Bixler*, 750 F.2d 810, 813 (10th Cir. 1984).

Finally, "a defendant may raise an affirmative defense by a motion to dismiss for the failure to state a claim. If the defense appears plainly on the face of the complaint itself, the motion may be disposed of under this rule." *Miller v. Shell Oil Co.*, 345 F.2d 891, 893 (10th Cir. 1965).

*B. Argon's Rule 8(a)(2) Motion to Dismiss*

The Court begins its discussion by addressing Argon's Rule 8(a)(2) motion to dismiss first. *See, e.g., Carroll v. Lamour*, 2021 WL 1207359, at *2 (E.D. Mich.) (observing that "[t]o survive a motion to dismiss under Rule 12(b)(6), a plaintiff must first comply with Rule 8(a)(2)"); *Tartt v. Magna Health Sys.*, 2016 WL 6585281, at *4 (N.D. Ill.), *aff'd,* 2017 WL 4772538 (7th Cir.) (noting that "[t]o avoid dismissal for failure to state a claim upon which relief can be granted under Rule 12 (b)(6), a complaint must first comply with Rule 8(a)"). Argon argues that the Complaint violates Rule 8(a)(2)'s requirement that a complaint give a defendant fair notice of a claim and the grounds for the claim by not "distinguishing the particular allegations pled against each Defendant." (Doc. 9) at 9. Argon also notes the overly broad definition of Rex Defendants. *See* (Doc. 1) at ¶ 7.

The Court agrees with Argon that the Complaint, with its references to collective "Defendants" and broad definition of Rex Defendants, "is a quintessential 'kitchen-sink' or 'shotgun' complaint which 'brings every conceivable claim against every conceivable defendant.'" *Granado v. LNU*, 2016 WL 9819528, at *4 (D.N.M.) (citation omitted). "Such

complaints are 'pernicious' because they 'unfairly burden defendants and courts' by shifting onto them 'the burden of identifying plaintiff's genuine claims and determining which of those claims might have legal support.'" *Id.* (citation omitted). Consequently, '"kitchen-sink' or 'shotgun' complaints violate Rule 8 of the Federal Rules of Civil Procedure, which requires a pleading to include 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" *Id.* (quoting Fed. R. Civ. P. 8(a)(2)).

Plaintiff, however, justifies her use of the collective "Defendants" because she "specifically alleged that [Rex and Argon] were operating and acting in some form of joint enterprise." (Doc. 18) at 5. Plaintiff cites only a 2011 press release that indicates "Argon entered into an exclusive license and distribution agreement with Rex for the global rights to market and distribute the Option Filter," the apparent predecessor of the Filter. (Doc. 18) 4-5 and n. 1. Nonetheless, Plaintiff concedes that, without discovery, she "has no way of knowing what involvement or responsibility Rex and Argon each, individually, had in the development, design, testing, manufacture, production, distribution, marketing, promotion, sale, monitoring, and/or obtained FDA clearance for the … Filter." *Id.* at 5. Even so, Plaintiff asserts that "for each count in Plaintiff's Complaint, the conduct at issue involved ***both*** Argon and Rex." *Id.*

As the District Court of Kansas observed in *Moore v. The Climate Corp.*, the "plaintiffs' need for discovery does not relieve them of their obligation to assert a sufficient factual basis to support their claims against *each* defendant at the outset of the case." *Moore v. The Climate Corp.*, 2016 WL 4527991, at *4 (D. Kan.) (emphasis added). The court further stated that the "[p]laintiffs' purported lack of knowledge also does not excuse their failure to plead specific facts that they currently possess or could ascertain with some investigation." *Id.*

Plaintiff, in this case, has not convinced the Court that "some investigation," in addition to the 2011 press release, would not have revealed more information about the roles Argon and Rex each "had in the development, design, testing, manufacture, production, distribution, marketing, promotion, sale, monitoring, and/or obtained FDA clearance for the … Filter," or about the nature of Defendants' alleged joint venture and/or alter ego relationship. (Doc. 18) at 5. As the Complaint stands, it fails to give Argon fair notice of the claims which truly apply to it. Argon, therefore, has the unfair "burden of identifying [P]laintiff's genuine claims and determining which of those claims might have legal support." *Granado*, 2016 WL 9819528, at *4 (citation omitted). As such, the Complaint violates Rule 8(a)(2).

Although the Complaint does not comply with Rule 8(a)(2), the Court will still determine whether Plaintiff has alleged plausible claims under Rules 12(b)(6) and 9(b). Then, if appropriate, the Court will consider Plaintiff's request to amend the Complaint to cure any pleading deficiencies. *See Moore*, 2016 WL 4527991, at *5 (declining to dismiss Complaint "[d]espite the shortcomings presented by plaintiffs' general allegations" and addressing individual claims to determine whether plaintiffs alleged plausible claims before "granting plaintiffs leave to amend to cure the deficiencies in the current pleading"); *Granado*, 2016 WL 9819528 at *4 (permitting plaintiff to file amended complaint "which includes *all* of his claims against each defendant").

*C. Defendants' Rule 12(b)(6) Motions to Dismiss*

*1. Breach of Express Warranty Claim (Count VI)*[6]

Plaintiff alleges in Count VI that Defendants breached express warranties under the New Mexico Uniform Commercial Code (UCC), NMSA 1978, § 55-2-313 (2020).[7] Defendants contend that the breach of express warranty claim fails as a matter of law due to lack of direct contractual privity between Defendants and Plaintiff, a subsequent or ultimate purchaser of the Filter.[8] Argon also contends that the Complaint "does not specify the precise terms of any such alleged express warranty." (Doc. 9) at 14.

*a. Privity*

Defendants correctly observe that "[o]rdinarily, the obligations arising out of a contract are due only to those with whom it was made; a contract cannot be enforced by a person who is not a party to it or in privity with it...." *Tarin's, Inc. v. Tinley*, 2000-NMCA-048, ¶ 12, 129 N.M. 185 (citation omitted). However, the New Mexico Supreme Court has observed that "[t]he New Mexico Legislature has effectively eliminated the need for analysis of privity in the context of express or implied warranties under the UCC." *Badilla v. Wal-Mart Stores E. Inc.*, 2015-NMSC-029, ¶ 18 n. 2, 357 P.3d 936. The New Mexico Supreme Court further noted that "[t]he Legislature has indicated its intent not to rely on privity to determine the persons entitled to bring an action asserting those warranties." *Id.*

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[6] The Court addresses Plaintiff's claims in the order Rex does in its Motion to Dismiss.

[7] Section 55-2-313 is taken directly from the Uniform Commercial Code, § 2-313. *See* UCC Text § 2-313 (Dec. 2020 update).

[8] The relationship between Defendants and Plaintiff constitutes vertical privity. "Vertical privity is defined as 'the chain of distribution of the product from the manufacturer through the wholesaler, retailer, and the ultimate buyer.'" *Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1326 n. 5 (M.D. Ga. 2011) (quoting 18 *Williston on Contracts* § 52:41).

In considering the New Mexico Supreme Court's statements about how privity is not needed in the context of express warranties, this Court has concluded that "it is likely that New Mexico courts would interpret broadly the scope of warranty protections afforded to subsequent purchasers." *Bellman v. NXP Semiconductors USA, Inc.*, 248 F. Supp. 3d 1081, 1151 (D.N.M. 2017). "Indeed, the Supreme Court of New Mexico has observed that 'the law today has moved drastically away from the strict limitations of privity of contract.'" *Id.* at 1152 (citation omitted).

In addition to the above New Mexico caselaw, as one treatise writer on the UCC states, "With respect to vertical privity, Official Comment 2 to § 2-313 seems to be an open invitation by the drafters to remove it as a defense where the plaintiff's claim is based upon an express warranty." Matt Crockett, 1 *The Law of Prod. Warranties* § 10:11 (Feb. 2021 update). Official Comment 2 provides:

> Although [Section 2-313] is limited in its scope and direct purpose to warranties made by the seller to the buyer as part of a contract for sale, the warranty sections of this Article are not designed in any way to disturb those lines of case law growth which have recognized that warranties need not be confined either to sales contracts or to the direct parties to such a contract.

*Id.* (same as Official Comment 2 to NMSA 1978, § 55-2-313). In analyzing Official Comment 2, the treatise writer further states,

> With this Official Comment as ammunition, it makes policy sense to ignore vertical privity as a defense where a manufacturer makes an express warranty (normally in writing) that is intended to follow the product into the hands of the ultimate purchaser, though several links removed in the chain of distribution. If affirmations of fact or promises are made regarding the goods, to whom are they beamed if not the retail purchaser?

1 *The Law of Prod. Warranties* § 10:11. Additionally, the treatise writer notes that "the great weight of authority follows" *Randy Knitwear, Inc. v. American Cyanamid Co.*, a pre-UCC case which is still good law under Official Comment 2. *Id.*; *see Randy Knitwear, Inc.*, 181 N.E.2d 399 (N.Y. 1962). In that case, "the court overturned its former rule imposing vertical privity as a

bar to express warranty actions against a remote manufacturer." 1 *The Law of Prod. Warranties* § 10:11.

Considering the above New Mexico case law, Official Comment 2, and the treatise commentary, it appears that, in New Mexico, privity is not essential to bring a breach of express warranty claim under Section 55-2-313 of the New Mexico UCC. Defendants' lack of privity argument, therefore, fails.

*b. Terms of the Express Warranty*

In New Mexico, a seller can create an express warranty in one of three ways, two of which are relevant here. First, the seller creates an express warranty by making an "affirmation of fact or promise … to the buyer which relates to the goods and becomes part of the basis of the bargain…." NMSA 1978, § 55-2-313(1)(a). Second, the seller creates an express warranty by making a "description of the goods … part of the basis of the bargain…." NMSA 1978, § 55-2-313(1)(b). In other words, "[a] breach of warranty presents an objective claim that the goods do not conform to a promise, affirmation, or description …." *Badilla*, 2015-NMSC-029 at ¶ 23.

Moreover, in New Mexico,

> [i]t 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, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.

NMSA 1978, § 55-2-313(1)(2). Indeed, in New Mexico, an express warranty need not "be specifically bargained for or even included as part of a written contract." *Salazar v. D.W.B.H., Inc.*, 2008-NMSC-054, ¶ 8, 144 N.M. 828. In addition, New Mexico does not require that a buyer rely on the express warranty, "but it does require evidence that the representation entered into the buyer's decision to purchase the defendant's product…." *Porcell v. Lincoln Wood Prod., Inc.*, 713 F. Supp. 2d 1305, 1319 (D.N.M. 2010). Such a representation can include

advertisements. *Id.* at 1318 (noting that "[s]tatements in sales literature unquestionably can create express warranties"); *see also Deaton, Inc. v. Aeroglide Corp.*, 1982-NMSC-147, ¶ 11, 99 N.M. 253 (finding that representations in seller's literature amounts to express warranty under Section 55-2-313).

Argon argues that Plaintiff's allegation that Defendants "expressly represented and warranted" that the Filter was "safe" does not constitute a term of an express warranty under New Mexico law. *See* (Doc. 1) at ¶ 99. Plaintiff, however, also alleges that, at all relevant times, the "[F]ilter was widely advertised and promoted by … defendants as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava." *Id.* at ¶ 34. Plaintiff further alleges that, "through her attending physicians," she relied on Defendants' "representations in determining which IVC filter to use for implantation…." *Id.* at ¶ 100.

Accepting Plaintiff's well-pleaded allegations as true and viewing them in the light most favorable to Plaintiff, the Court can reasonably infer from those allegations that Defendants' advertising and promotion of the Filter constituted an affirmation, promise, or even a description of the Filter that it was "a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava." *Id.* at ¶ 34. The Court can also reasonably infer that such advertising and promotion entered into Plaintiff's decision, through her physicians, to purchase the Filter for implantation. Thus, Plaintiff has alleged facts that show an express warranty existed and that the express warranty became part of the basis of the bargain.

For all of the foregoing reasons, Plaintiff has pled a plausible breach of express warranty claim in Count VI. Accordingly, Count VI is not subject to dismissal under Rule 12(b)(6).

*2. Design Defect and Breach of Implied Warranty of Merchantability Claims (Counts I, III, and V)*

*a. Design Defect (Counts I and III)*

Plaintiff brings common law claims in Count I (negligence) and Count III (strict products liability) based on the alleged design defect of the Filter. Defendants argue that Plaintiff has not sufficiently plead a design or product defect claim under New Mexico common law. In New Mexico, a product is defective if "an unreasonable risk of injury result[s] from a condition of the product or from a manner of its use...." *McDonald v. Zimmer Inc.*, 2020-NMCA-020, ¶ 26, 461 P.3d 930 (quoting UJI 13-1406 NMRA 1998 (2021 ed.)). "An unreasonable risk of injury is 'a risk which a reasonably prudent person having full knowledge of the risk would find unacceptable. This means that a product does not present an unreasonable risk of injury simply because it is possible to be harmed by it.'" *Id.* (quoting UJI 13-1407 NMRA 1998 (2021 ed.)).

"In determining whether a product design poses an unreasonable risk of injury, the fact-finder conducts a risk-benefit analysis...." *Id.* That risk-benefit analysis may include "risk-benefit considerations" like "the ability to eliminate the risk without seriously impairing the usefulness of the product or making it unduly expensive.'" *Bustos v. Hyundai Motor Co.*, 2010-NMCA-090, ¶ 53, 149 N.M. 1 (quoting Committee Comment for UJI 13-1407). That particular risk-benefit consideration contemplates that a fact-finder take into account any "reasonable alternative design." *Id.* at ¶ 54. The ultimate question is whether the medical device, configured as it is, "posed an unreasonable risk of [injury], taking into account the relative risks and benefits of its design." *McDonald*, 2020-NMCA-020, at ¶ 28.

While Defendants purportedly had FDA clearance to market the Filter as a medical device to filter blood clots, Plaintiff alleges the Filter, nonetheless, was designed in such a way that there was a risk of tilting, embedding, perforating or damaging the IVC wall, fracturing, and

migrating. *See* (Doc. 1) at ¶ 52(a)-(d). Plaintiff also alleges that the Filter's design "increased the potential for recurrent thrombosis and clot formation." *Id.* at ¶ 52(f). Plaintiff explains in the Complaint that the above risks occur because the design produces a Filter with "unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body…." *Id.* at ¶ 52(e). Plaintiff maintains in the Complaint that Defendants "knew that safer alternative designs were available, which would have prevented or significantly reduced the risk of the injury presented by [the Filter]." *Id.* at ¶ 72. Plaintiff concludes that the Filter "failed to perform as safely as persons who ordinarily use the product would have expected at the time of use; and … [i]ts risks of harm exceeded its claimed benefits." *Id.* at ¶ 71. To bolster the idea that the Filter had a design defect as opposed to a single badly manufactured Filter, Plaintiff alleges that the "[u]nreasonably and carelessly designed" Filter "presented a risk of harm to Plaintiff and others similarly situated in that it was prone to fail." *Id.* at ¶ 53(c).

Accepting Plaintiff's well-pleaded allegations as true and viewing them in the light most favorable to Plaintiff, the Court can reasonably infer from those allegations that the risks of implanting the Filter, as currently designed, outweigh its benefit to such an extent that "a reasonably prudent person having full knowledge of the risk would find [that risk] unacceptable." *McDonald*, 2020-NMCA-020 at ¶ 26. Consequently, Plaintiff has alleged sufficient facts to show that the condition or design of the Filter causes an unreasonable risk of injury and that the Filter's design is defective. Plaintiff, therefore, has pled plausible design defect claims in Counts I and III.

*b. Breach of Implied Warranty of Merchantability (Count V)*

Plaintiff alleges in Count V that Defendants breached the implied warranty for merchantability under the New Mexico UCC, NMSA 1978, § 55-2-314 (2020). Defendants

argue that Plaintiff's breach of the implied warranty of merchantability claim fails as a matter of law because Plaintiff fails to plead a product or design defect claim under New Mexico law and her allegations are vague and conclusory.

"To establish a claim for breach of the implied warranty of merchantability, a plaintiff must prove that the seller sold goods or products that failed to meet the statutory definition of 'merchantable.'" *Am. Mech. Sols., L.L.C. v. Northland Process Piping, Inc.*, 184 F. Supp. 3d 1030, 1059 (D.N.M. 2016). Section 55-2-314 states that, *inter alia*, goods are merchantable if they "are fit for the ordinary purposes for which such goods are used...." "A breach of the implied warranty of merchantability claim 'thus requires proof of a defect.'" *Am. Mech. Sols., L.L.C.*, 184 F. Supp. 3d at 1060 (citations omitted). Even so, "to establish a breach of the implied warranty, a buyer is not required to prove a *specific* defect in the goods." *Salazar v. D.W.B.H., Inc.*, 2008-NMSC-054, ¶ 21, 144 N.M. 828. "Rather, a buyer can use circumstantial evidence to show that the goods were not fit for the ordinary purpose for which they were intended." *Id.*

As discussed above, the Court finds that Plaintiff has plausibly alleged a defectively designed Filter. Furthermore, Plaintiff alleges that the use and purpose of the Filter was "as a surgically implanted device used to prevent pulmonary embolisms...." (Doc. 1) at ¶ 85. Plaintiff alleges that the Filter, however, "was not fit for its intended use and purpose" because its defective design made it "prone to an unreasonably high incident of tilt, embedment, fracture, perforation of vessels and organs, and/or migration...." *Id.* at ¶¶ 89(a) and 94. Plaintiff maintains that she and her physicians "reasonably relied on the superior skill and judgment of" Defendants to design and manufacture a Filter that was "safe and fit for its intended use...." *Id.* at ¶ 92.

Accepting Plaintiff's well-pleaded allegations as true and viewing them in the light most favorable to Plaintiff, the Court can reasonably infer from those allegations that the Filter was "not fit for the ordinary purposes for which" a Filter is used, i.e., to safely prevent pulmonary embolisms. Plaintiff, therefore, has alleged sufficient facts to show that the Filter was not merchantable. Thus, Plaintiff has alleged a plausible claim for breach of the implied warranty of merchantability, as brought in Count V.

*3. Failure to Warn Claims (Counts I and II)*

Plaintiff brings common law failure to warn claims in Count I (negligence) and Count II (strict products liability). Defendants argue that the Court should dismiss the failure to warn claims based on its "sophisticated user" affirmative defense. Defendants assert that they are entitled to this affirmative defense because they "provided legally adequate warnings of the Plaintiff's alleged complications to a sophisticated user—Plaintiff's implanting physician…." (Doc. 4) at 11; *see also* (Doc. 9) at 14. Argon also argues that Plaintiff fails to allege "how or why such warnings were allegedly inadequate" or to even "quote, characterize, or describe the warnings that were provided with the device." (Doc. 9) at 16.

*a. Sophisticated User Affirmative Defense*

While "[n]o New Mexico court has squarely adopted the sophisticated–user or sophisticated-purchaser doctrines," this Court has "conclude[d] that New Mexico courts likely would adopt the sophisticated-user/purchaser defenses." *Bellman*, 248 F.Supp.3d at 1143. "The sophisticated user defense insulates suppliers of dangerous or defective products from liability for failing to warn ultimate users of the product if the supplier reasonably relied on an intermediary to provide a warning." *State v. Exxon Mobil Corp.*, 406 F. Supp. 3d 420, 464 (D. Md. 2019). "The purpose of this defense is 'to put some restraints on the expanding liability of

manufacturers."' *Id.* (citation omitted). Notably, a defendant can raise the sophisticated user affirmative defense in either a negligence or strict products liability cause of action based on a failure to warn. *See* 161 *Am. Jur. Proof of Facts* 3d § 1 (Originally published in 2017) (describing sophisticated user affirmative defense in relation to failure to warn claims raised in "one or more of the products liability theories of recovery (negligence, breach of implied warranty, or strict liability)").

Defendants assert that they provided "Dr. Nunez, who was armed with his medical professional knowledge, training, and clinical experience with IVC filters," with "FDA-approved instructions for use … and warnings accompanying the filter device [which] informed Dr. Nunez, and all other sophisticated users, of the specific complications Plaintiff alleges in this case." (Doc. 4) at 12; *see also* (Doc. 9) at 15-16. Those "warnings of potential risks" are provided in the FDA materials the Court took judicial notice of. *See* (Doc. 17) at 4-5. Defendants conclude that they, therefore, "fulfilled [their] duty to Dr. Nunez" under the sophisticated user defense. (Doc. 4) at 12; (Doc. 9) at 16.

As this Court has previously determined, simply providing "manufacturer safety information does not, alone, conclusively establish the sophisticated-purchaser defense." *Bellman*, 248 F.Supp.3d at 1147. "The dispositive issue" is whether the means by which the safety information is conveyed "gives a reasonable assurance that the information will reach those whose safety depends upon their having it," the "ultimate consumer." *Id.* (citation omitted). Put another way, "the intermediary must have knowledge or sophistication equal to that of the manufacturer…." *Id.* at 1140 (citation omitted).

"Cases applying the sophisticated-purchaser doctrine use a fact-intensive, case-by-case analysis to determine the intermediary's knowledge" and sophistication. *Id.* at 1146. To

determine whether a supplier reasonably relied on an intermediary to give appropriate warnings, courts consider three factors: (1) "the 'reliability of the [intermediary] as a conduit of necessary information about the product;'" (2) "the magnitude of the risk involved;" and (3) "the burdens imposed on the supplier by requiring it to directly warn the ultimate users[.]" *Id.* at 1147 (citation omitted).

In this case, Plaintiff's allegations in the Complaint do not indicate whether Dr. Nunez had knowledge or sophistication equal to that of Defendants on the use and safety of the Filter. Specifically, the Complaint does not contain any allegations regarding the extent to which Dr. Nunez was a reliable conduit of safety information about the Filter. Although Plaintiff makes allegations regarding the magnitude of the risk of implanting the Filter, Plaintiff makes no allegations regarding what burdens, if any, would be imposed on Defendants had they been required to directly warn ultimate users, like Plaintiff, about the risks of implanting the Filter. The sophisticated user affirmative defense, therefore, does not plainly appear on face of the Complaint. Accordingly, the sophisticated user affirmative defense cannot support a Rule 12(b)(6) dismissal of the failure to warn claims brought in Counts I and II.

*b. The Warnings*

In New Mexico, "[a] plaintiff asserting causes of action based on a failure to warn must prove that, (1) no warning was provided or the warning was inadequate; and (2) the inadequacy or absence of the warning caused the plaintiff's injury." *Aguirre v. Atrium Med. Corp.*, 2019 WL 2210801, at *6 (D.N.M.). In the context of a failure to warn claim involving a medical device, "a medical device manufacturer must warn the doctor, not the patient." *Id.* "A warning, to be adequate, must disclose the nature and extent of the danger." *Jones v. Minnesota Min. & Mfg. Co.*, 1983-NMCA-106, ¶ 32, 100 N.M. 268.

Argon contends that Plaintiff does not allege what the warnings provided with the Filter said. Thus, Argon concludes that Plaintiff fails to allege facts showing that Defendants failed to provide a warning or provided an inadequate warning. Plaintiff, however, alleges that Defendants failed "to properly warn of the dangers and risks of harm associated with the … Filter, specifically its incidents of tilt, embedment, fracture, migration, perforation, recurrent thrombosis and other failures…." (Doc. 1) at ¶ 53(a). Plaintiff also alleges that "[n]o health care provider, including Plaintiff's, … would have used [the F]ilter in the manner directed, had those facts been made known to the prescribing healthcare providers…." *Id.* at ¶ 62. Accepting these well-pleaded allegations as true and viewing them in the light most favorable to Plaintiff, the Court can reasonably infer from those allegations that whatever warnings Defendants provided Dr. Nunez were inadequate because they failed to disclose the nature and extent of several specifically alleged risks associated with the Filter. At this early stage of the litigation, the above allegations are sufficient to state a plausible claim that Defendants failed to adequately warn Dr. Nunez about the dangers associated with the Filter.

For the aforementioned reasons, Plaintiff has alleged plausible failure to warn claims in Counts I and II. Those claims, thus, are not subject to a Rule 12(b)(6) dismissal.

*4. Negligent Misrepresentation Claim (Count VII)*

In Count VII, Plaintiff brings a common law negligent misrepresentation claim. Defendants argue that Plaintiff fails to state a plausible negligent misrepresentation claim for three reasons. First, Defendants assert that the sophisticated user affirmative defense applies to any allegation that a failure to warn constitutes negligent misrepresentation. Second, Defendants

assert that "Plaintiff's vague pleading fails to comport with F.R.C.P. 9(b)...."[9] (Doc. 4) at 14; (Doc. 9) at 17. Third, Defendants argue that Plaintiff's conclusory allegations do not establish the elements of negligent misrepresentation.

As the Court concluded above, the sophisticated user affirmative defense does not support a Rule 12(b)(6) dismissal of the failure to warn claims, which includes any failure to warn claims brought in conjunction with the negligent misrepresentation claim. Furthermore, "the heightened pleading standards of Rule 9(b) do not apply" to a negligent misrepresentation claim. *Greene v. Bank of Am.*, 2014 WL 11497813, at *6 (D.N.M.).

"To recover under a theory of negligent misrepresentation, a plaintiff must show that: (1) the defendant made a material representation to plaintiff, (2) the plaintiff relied upon the representation, (3) the defendant knew the representation was false or made it recklessly, and (4) the defendant intended to induce reliance by the plaintiff." *Robey v. Parnell*, 2017-NMCA-038, ¶ 31, 392 P.3d 642.

Plaintiff alleges in the Complaint that Defendants made material misrepresentations regarding the safety and efficacy of the Filter, the failure rate of the Filter, and the approved uses of the Filter. (Doc. 1) at ¶ 105. More particularly, Plaintiff alleges that the representations and omissions by Defendants were material because the Filter, in fact, "is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner," and the use of the "[F]ilter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered." *Id.* at ¶ 109.

Plaintiff further alleges that the representations were contained in information Defendants distributed "to the public, the medical community, and Plaintiff's health care providers" and that

[9] Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."

information was conveyed in "reports, press releases, advertising campaigns, labeling materials, print advertisements, [and] commercial media...." *Id.* at ¶ 106. Specifically, Plaintiff alleges that "[t]hese materials included instructions for use and warning document [sic] that was included in the package of the ... [F]ilter that was implanted in Plaintiff." *Id.*

Plaintiff alleges that she and her health care providers relied on the above communications or representations when Plaintiff's health providers, in fact, implanted the Filter in Plaintiff. *Id.* at ¶ 110. According to Plaintiff,

> Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by ... Defendants, and would not have prescribed and implanted same if the true facts regarding the device had not been concealed and misrepresented by Defendants.

*Id.* at ¶ 111.

Plaintiff also alleges that Defendants made those "misrepresentations knowing that they were false or without reasonable basis." *Id.* at ¶ 107. Plaintiff alleges that Defendants knew the Filter was defective due "to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*." *Id.* at ¶ 35. Plaintiff further contends that Defendants promoted the Filter as safe but "failed to disclose to physicians, patients, or Plaintiff that [the F]ilter was subject to tilting, embedment, breakage, and migration or the appropriate degree of risk of perforation and damage to the vena cava wall." *Id.* at ¶ 36. Finally, Plaintiff alleges that Defendants promoted the "[F]ilter as safe and effective even though the clinical trials that had been performed were not adequate to support long- or short-term efficacy." *Id.* at ¶ 37.

Finally, Plaintiff alleges Defendants' intent in making the misrepresentations

> was: (1) to deceive and defraud the public and the medical community, including Plaintiff's health care providers; (2) to gain the confidence of the public and the medical community, including Plaintiff's health care providers; (3) to falsely assure them of the quality of the ... [F]ilter and its fitness for use; and (4) to induce the public and the

> medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the …[F]ilter.

*Id.* at ¶ 108.

Accepting Plaintiff's well-pleaded allegations as true and viewing them in the light most favorable to Plaintiff, the Court can reasonably infer from those allegations that (1) Defendants made material representations about the Filter's efficacy and safety to Plaintiff and her healthcare providers; (2) Plaintiff and her healthcare providers relied upon those representations; (3) Defendants knew the representations were false or made recklessly; and (4) Defendants intended to induce Plaintiff and her healthcare providers to rely on the misrepresentations. Hence, Plaintiff has alleged a plausible negligent misrepresentation claim. As such, the negligent misrepresentation claim brought in Count VII survives a Rule 12(b)(6) motion to dismiss as well as a dismissal under Rule 9(b).

*5. Punitive Damages Claim*

Finally, Defendants move to dismiss Plaintiff's punitive damages claim under Rule 12(b)(6). The Court notes that "[a] punitive damage claim is not an independent cause of action or issue separate from the balance of a plaintiff's case." *Mason v. Texaco, Inc.* 948 F.2d 1546, 1554 (10th Cir. 1991). Instead, a punitive damages claim "is part and parcel of a liability determination and does not have any independent being until a jury has decided ... that not only was a defendant's conduct negligent, but that it was gross, willful, wanton or malicious." *Id.* Consequently, "[a] request for punitive damages is not the proper subject of a Rule 12(b)(6) motion because such a request is not a separate cause of action." *In re Gold King Mine Release in San Juan Cty., Colorado, on Aug. 5, 2015*, 2019 WL 1442850, at *3 (D.N.M.). Put another way, "[a] Rule 12(b)(6) motion tests the sufficiency of a claim; it is not a proper mechanism for challenging a request for punitive damages." *Atlantis Car Care, Inc. v. Phoenix Ins. Co.*, No.

2019 WL 3892867, at *1 n. 1 (W.D. Okla.); *see also Khan v. Barela*, 2021 WL 107245, at *8 (D.N.M.), *report and recommendation adopted,* 2021 WL 371515 (D.N.M.) (noting that "only issue on a motion dismiss is whether the claim as stated would give the plaintiff a right to any relief, rather than to the particular relief demanded").

Here, Plaintiff does not bring a separate Count or cause of action to assert a claim for punitive damages. Plaintiff merely asserts that she "is entitled to an award of punitive and exemplary damages" based on Defendants' conduct. (Doc. 1) at ¶¶ 117 and 118. In that same section of the Complaint, Plaintiff lists her other damages. *Id.* at ¶ 119. Consequently, Plaintiff's request for punitive damages is not a "claim" subject to Rule 12(b)(6) scrutiny.

*C. Conclusion*

Pursuant to Plaintiff's voluntary withdrawal of the manufacturing defect claims brought in Counts I and IV, the Court will dismiss those claims without prejudice. The Court also determines that Plaintiff has violated Rule 8(a)(2) but grants Plaintiff's request for leave to file an amended complaint that cures the Rule 8(a)(2) deficiencies in the current Complaint. Otherwise, the Court determines that Plaintiff has stated plausible claims that survive a Rule 12(b)(6) motion to dismiss and a Rule 9(b) dismissal.

IT IS ORDERED that

1. Defendant Rex Medical, Inc., d/b/a Rex Medical L.P. and Rex Medical, L.P. Motion to Dismiss (Doc. 4), and the Motion of Defendant Argon Medical Devices, Inc. to Dismiss Plaintiff's Complaint Pursuant to F.R.C.P. 8, 9(b), and 12(b)(6) (Doc. 9) are granted in part;

2. the manufacturing defect claim in Count I is dismissed without prejudice;

3. Count IV is dismissed without prejudice;

4. Plaintiff has 30 days from the date of this Memorandum Opinion and Order to file an

amended complaint that cures the Rule 8(a)(2) deficiencies described in the Memorandum Opinion and Order; and

5. failure to timely file an amended complaint that complies with Rule 8(a)(2) may result in the dismissal of this action without further notice.

UNITED STATES DISTRICT JUDGE