UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

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LINDA P. WARD,

Plaintiff,

-v- 5:17-CV-607

ARGON MEDICAL DEVICES, INC. and
RED MEDICAL, L.P.,

Defendants.

- -

KEVIN O'NEIL,

Plaintiff,

-v- 3:17-CV-640

ARGON MEDICAL DEVICES, INC. and
RED MEDICAL, L.P.,

Defendants.

- -

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DAVID N. HURD
United States District Judge

MEMORANDUM-DECISION and ORDER

I. INTRODUCTION

Plaintiff Linda P. Ward ("Ward") and plaintiff Kevin O'Neil ("O'Neil") (collectively "plaintiffs") filed these two separate diversity actions seeking compensatory and punitive damages for injuries they each sustained from medical devices designed, manufactured, and distributed by defendants Argon Medical Devices, Inc. ("Argon") and Rex Medical, L.P. ("Rex") (collectively "defendants").

In case number 5:17-CV-607, plaintiff Ward brought suit against defendants in New York State Supreme Court, Oswego County. In case number 3:17-CV-640, plaintiff O'Neil brought suit against defendants in New York State Supreme Court, Broome County. Defendants removed both actions to federal court based on diversity jurisdiction and the suits have been identified here as related cases. Aside from dates specific to each plaintiff and what appears to be only a slight variation in the model of the devices, the two verified complaints are nearly identical. Each assert the same claims based on allegedly similar, defective medical devices. Though the cases are not consolidated, for purposes of convenience and consistency, both motions to dismiss will be addressed in one decision.

Ward and O'Neil each assert the following eight causes of action: (1) negligence, (2) strict products liability based on design defect, (3) strict products liability based on failure to warn, (4) breach of express warranty, (5) breach of implied warranty of merchantability, (6) breach of implied warranty of fitness, (7) fraudulent misrepresentation, and (8) negligent

misrepresentation. Plaintiffs seek compensatory damages for past, present, and future pain and suffering, medical costs and expenses, and lost wages, as well as punitive damages.

Defendants moved in both cases to dismiss the complaints for failure to state a claim pursuant to Federal Rule of Civil Procedure ("Rule __") 12(b)(6) and also to strike certain allegations pursuant to Rule 12(f). The motions were fully briefed and consolidated oral argument was heard on both cases on October 20, 2017, in Utica, New York. Decision was reserved

II. BACKGROUND

The following facts are drawn from each complaint and accepted as true for purposes of the motions to dismiss.

At issue in these cases is a medical device known as an inferior vena cava ("IVC") filter. The IVC is a large vein that carries de-oxygenated blood from the lower half of the body into the atrium of the heart. In certain individuals, blood clots or thrombi travel from the blood vessels in the leg and pelvis, through the IVC and into the lungs, causing a pulmonary embolism ("PE"). Thrombi can also develop in the deep leg veins and are referred to as a deep vein thrombosis ("DVT"). Both PE and DVT are dangerous; a PE in particular can often result in death.

Individuals who are at risk of developing blood clots are often treated with anticoagulant medication. For individuals who are at a high risk for PE/DVT or for whom anticoagulants are contraindicated, doctors may recommend implantation of an IVC filter to reduce the risk of a thrombotic event. An IVC filter is a medical device that is designed to prevent blood clots from traveling from the lower extremities to the heart and lungs. It is

surgically implanted into the IVC and works by trapping and filtering clots that form in the lower portions of the body.

Defendant Rex designed and manufactured the two filters at issue here: the OptionELITE Filter Inferior Vena Cava ("OptionELITE) and the "Option Filter Inferior Vena Cava" ("Option").[1] Defendant Argon distributed the devices. Conspicuously absent from the complaints is any discussion of the difference between the OptionELITE and Option filters. Judicial notice is taken of the fact that the OptionELITE filter was put on the market in 2014 and the Option in 2011. Based on the identical descriptions in the com plaints, and the additional allegations and information which has been pled, it is only reasonable to assume that the OptionELITE is a more recent version of the Option.

The first IVC filters developed 50 years ago were permanent with no retrieval option. Concerns over long-term complications of permanent IVC filters led to the development of temporary, retrievable IVC filters. Beginning in 2003, medical device manufacturers began marketing optional or retrievable IVC filters. Retrievable IVC filters are designed to be removed from a patient when the risk of a PE/DVT has passed.

Defendants obtained Food and Drug Administration ("FDA") clearance in June 2009 to market their device for use as a retrievable or permanent IVC filter; safe for both temporary and permanent placement. Under the provision which defendants obtained clearance, they bypassed the requirement to have the filter independently evaluated by the FDA. Instead, Argon conducted its own clinical trial with 100 male subjects. The average implementation period of the trial subjects was 67 days. After the median 67 day period, removal or intervention was achieved without medical complication in 88% of subjects. The remaining

[1]

12% experienced complications including migration of the filter, embolization, symptomatic thrombosis, and other effects requiring complex revision or removal. Of all surgical attempts at removal, 92% were successful, but 8% were unable to have the filter removed from their body due to migration or complication of placement.

In 2010, the FDA issued a warning against leaving IVC filters implanted in patients for extended periods due to their potential to cause adverse health complications, including: irretrievability of the filters, device fractures, devices embedding into the walls of the IVC and organs, and tilting of the filters, causing them to fail and actually cause thrombotic events, rather than prevent them. FDA warnings advised that retrievable IVC filters are for short-term use and implanting doctors are to remove the devices once the risk for thrombotic events subsides.

According to plaintiffs, following approximately 900 adverse event reports, the FDA issued alerts in 2010 and 2015 advising of the risks of long-term implantation and urging doctors to remove IVC filters within one to two months once the danger has passed. Despite these alerts and known complications, defendants continued to market the OptionELITE and Option filters safe for both temporary and long-term use. Further, federal law requires defendants to disclose information relating to the following complications: fracture or migration of the device, perforation of the heart, lungs, or other vital organs, the wall of the IVC and tissue, cardiac or pericardial tamponade, chest pain, shortness of breath, severe recurrent PE/DVT, occlusion or clogging of the filter, subsequent revision surgeries, and difficulty or impossibility of removal.

Despite these requirements, defendants issued no redactions or warnings recommending removal in accordance with the FDA alerts. Federal law also prohibits

manufacturers and distributers such as defendants from minimizing these risks and making misleading claims that their filters are safer than other filters on the market or that IVC filters in general are a safer long-term alternative to anticoagulant therapies.

Moreover, in 2013, an incident was reported to the FDA wherein the defendants' filter became so deeply embedded in a patient's IVC that it was deemed irretrievable after an unsuccessful attempt. Another published incident report documented the death of a patient after one of defendants' filters failed to properly function and actually caused multiple thrombotic events leading to the patient's death. The FDA published at least six additional reports in which patients experienced various malfunctions of the OptionELITE or Option, including device fracture, perforation of the IVC, and death.

On May 5, 2015, plaintiff Ward underwent a surgical procedure wherein an OptionELITE filter was implanted in her IVC for treatment of blood clots from a prior knee surgery. She was never considered for revision or removal of the device by any medical professional. The OptionELITE is still implanted in her body today, nearly three years later, and she experiences pain and discomfort she believes is attributable to the device. She has been advised by medical professionals that removal or revision of the device would be excessively dangerous, and thus must remain indefinitely, despite the pain and discomfort she experiences, and the possibly life threatening side effects.

Similarly, on December 13, 2011, plaintiff O'Neil underwent a surgical procedure wherein an Option filter was implanted in his IVC for treatment of blood clots from a prior knee surgery. He was never considered for revision or removal of the device by any medical professional. The Option is still implanted in his body today, over six years later, and he suffers from stomach pain he believes is attributable to a migrated device. He was informed

that after such an extended period of time, retrieval of the device would be difficult, if not impossible.

In addition to the continued marketing of the OptionELITE and Option as safe for both temporary and long-term placement at the time of plaintiffs' surgical procedures, instructional literature available to the medical community at that time also indicated the OptionELITE and Option were safe for long-term use.

III. LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). Although a complaint need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2)), more than mere conclusions are required. Indeed, "[w]hile legal conclusions can provide the complaint's framework, they must be supported by factual allegations." Ashcroft v. Iqbal, 556 U.S. 662, 664 (2009).

When considering a motion to dismiss, the complaint is to be construed liberally, and all reasonable inferences must be drawn in the plaintiffs' favor. Zinermon v. Burch, 494 U.S. 113, 118, 110 S. Ct. 975, 979 (1990); In re NYSE Specialists Secs. Litig., 503 F.3d 89, 91 (2d Cir. 2007). Dismissal is appropriate only where plaintiff has failed to provide some basis for the allegations that support the elements of his claims. See Twombly, 550 U.S. at 570 (requiring only enough facts to state a claim to relief that is plausible on its face). The issue on a motion to dismiss is "not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." Todd v. Exxon Corp., 275 F.3d 191, 198 (2d Cir. 2001) (internal quotations omitted).

IV. DISCUSSION

In New York, a plaintiff injured by an allegedly defective product may seek recovery against the manufacturer on the basis of any one or more of four theories of liability, including negligence, strict liability, breach of implied warranty, and strict products liability. Parillo v. Stryker Corp., No. 15-CV-155, 2015 WL 12748006, at *2 (N.D.N.Y. Sept. 29, 2015) (Sannes, J.). "Although the available defenses and applicable limitations principles of the various liability theories differ, there can be a high degree of overlap between the substantive aspects of the causes of action." Id. (internal quotations omitted).

Defendants argue plaintiffs have not sufficiently pled a product defect nor an injury and therefore the negligence, strict liability, and breach of warranty claims fail. They contend the strict liability claims also fail as a matter of law under Comment K of Section 402A of the Restatement (Second) of Torts. They further claim the failure to warn claims are insufficiently pled, the breach of express warranty claims fail, and the fraud based claims must be dismissed for failure to state fraud with particularity. Defendants also argue plaintiffs' fraud-on-the FDA allegations must be stricken along with their requests for punitive damages.

1. Negligence

To state a negligence claim, plaintiffs must allege: (1) defendants owed them a legally cognizable duty; (2) a breach of that duty; (3) a causal relationship between defendants' conduct and the resulting injury; and (4) loss or damage resulting from the breach. Parillo, 2015 WL 12748006, at *2 (citing McCarthy v. Olin Corp., 119 F.3d 148, 156 (2d Cir. 1997)).

Plaintiffs allege defendants designed, set specification for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the OptionELITE and

Option filters; that defendants owed them a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of the devices, including the duty to take all reasonable steps necessary to manufacture and sell a product that was not defective and unreasonably dangerous to consumers, and a duty to warn health care providers and users of the risks of implantation of the devices. They contend defendants breached that duty because defendants knew or should have known that the devices were unsafe when used as designed and manufactured—that is, for long-term use—and that defendants failed to exercise due diligence and care and were otherwise negligent in the design, manufacture, and marketing of the devices, including the failure to adequately test the devices and provide adequate warnings to health care providers and consumers, particularly with respect to the duration and long-term use of the devices—that is, that the devices should be removed within two months of implantation or as soon as the risk of a thrombotic event has diminished.

As of today, the OptionELITE filter has been implanted in plaintiff Ward's body for nearly three years. She has been medically deemed a non-candidate for removal of the device because of the risky nature of retrieval attempts. As of today, the Option filter has been implanted in plaintiff O'Neil's body for over six years. He has been advised that after such an extended implantation period, retrieval of the device would be difficult, if not impossible.

Plaintiffs contend the devices were the proximate cause of their injuries which include irretrievability, the possible risk of migration of the devices to other parts of the IVC, heart, or other organs, PE/DVT, and fracture of the devices, in addition to economic damages, mental anguish, and psychological trauma. Both plaintiffs suffer pain and discomfort they believe is

attributable to the devices. Because plaintiffs may not possess technical information at this stage of the case, they are not required to identify exactly what the defect was or how the devices failed. They have alleged sufficient facts to state plausible negligence claims based on the circumstances of the long-term implantation and resulting irretrievability of the devices. Plaintiffs received medical advice that because the devices had been implanted in their bodies so long, removal was not possible.

Taking the well pleaded facts as true, the allegation of a defect and injury is more than mere speculation as defendants argue, and plaintiffs have stated plausible negligence claims.

2. Design Defect

Under New York law, there are three separate claims for strict products liability:

> (1) a manufacturing defect, which results when a mistake in manufacturing renders a product that is ordinarily safe dangerous so that it causes harm; (2) a warning defect, which occurs when the inadequacy or failure to warn of a reasonably foreseeable risk accompanying a product causes harm; and (3) a design defect, which results when the product as designed is unreasonably dangerous for its intended use.

McCarthy, 119 F.3d at 154-55.

To plausibly assert a strict liability claim for a design defect, plaintiffs "must allege that the product was unreasonably dangerous for its intended use." McCarthy, 119 F.3d at 155. They must show: "(1) the product, as designed, posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury. Maxwell v. Howmedica Osteonics Corp., 713 F. Supp. 2d 84, 90 (N.D.N.Y. 2010) (Suddaby, J.).

Plaintiffs allege the devices were defective and not reasonably safe due to their improper, inadequate, and defective design, and the defective devices caused their injuries. Further, they assert that safer, reasonable alternative designs existed and could have been utilized. Again, while plaintiffs do not allege a specific design defect or an alternative, safer design, that is not required at this early stage. Parillo, 2015 WL 12748006, at *5. Plaintiffs may not possess this sort of technical information without discovery and expert consultation.

Plaintiffs have alleged sufficient facts from which to infer the existence of a design defect and raise their right to relief above the speculative level. Therefore, they have stated plausible claims for strict product liability based on a design defect.

3. Failure to Warn

To assert a failure to warn under strict liability, plaintiffs must establish: "(1) the manufacturer had a duty to warn, i.e., it knew or should have known of latent dangers resulting from intended or reasonably foreseeable unintended uses of the product; (2) plaintiffs used the products in a reasonably foreseeable manner; and (3) the manufacturer's failure to provide a warning was the cause of the plaintiffs' harm." Monell v. Scooter Store, Ltd., 895 F. Supp. 2d 398, 413 (N.D.N.Y. 2012) (D'Agostino, J.). A failure to warn claim should be dismissed if a plaintiff does not plead facts indicating how the provided warnings were inadequate. Parillo, 2015 WL 12748006, at *6.

Plaintiffs allege defendants knew or should have known of the dangers resulting from one of its intended uses—long-term placement of the devices—and had a duty to warn of the risks associated with that intended use. Ward and O'Neil assert they used the devices in an intended manner, that is, their medical providers implanted the devices for the treatment of blood clots. Finally, they allege that defendants' failure to provide adequate warnings to their

medical providers indicating that the devices created a risk of serious and dangerous side effects, including but not limited to, the migration of the filter to other parts of the IVC, heart or other organs, PE/DVT, and fracture of the filter, was the cause of their harm. They contend the warnings provided did not accurately reflect the risk, incidence, symptoms, scope, or severity of such risk and injuries. Moreover, they claim that defendants downplayed the serious and dangerous side effects of the devices to encourage sales and use, putting profits above users' safety.

Taking all of the allegations in the complains as true and drawing all reasonable inferences in plaintiffs' favor, they have stated plausible failure to warn claims.

4. Breach of Express Warranty

To plausibly assert a breach of express warranty claim, plaintiffs must plead: (1) a material statement amounting to a warranty; (2) the buyer's reliance on the warranty as a basis for the contract with seller; (3) the breach of the warranty; and (4) injury to the buyer caused by the breach. Avola v. Louisiana–Pacific Corp., 991 F. Supp. 2d 381, 391 (E.D.N.Y. 2013) (citing CBS Inc. v. Ziff–Davis Publ'g Co., 75 N.Y.2d 496, 502-04 (1990)).

Plaintiffs allege defendants expressed in their literature, advertisements, and promotions and through representations by their marketing team and sales agents that the devices were safe, effective, and fit for implantation, both temporary and long-term. Ward and O'Neil allege that through their healthcare providers, they relied on these express warranties regarding the safety and efficacy of the devices and defendants breached these warranties because the devices were not safe, effective, fit, nor proper for the use which they were designed, manufactured, and marketed—that is, long-term use. Finally, plaintiffs assert they were injured by those breaches.

Though plaintiffs have not identified specific statements by defendants at this time, they have alleged facts sufficient to make their express warranty claims plausible at this early stage.

5. Breach of Implied Warranty of Merchantability and Breach of Implied Warranty of Fitness

The only argument defendants make to dismiss these claims are that plaintiffs have not sufficiently pled a defect nor an injury. For the reasons already explained, plaintiffs have plausibly alleged both a defect and injuries and therefore the breach of implied warranty of merchantability and breach of implied warranty of fitness claims may proceed.

6. Fraud Based Claims: Fraudulent Misrepresentation or Concealment and Negligent Misrepresentation

First, regarding defendants' motion to strike alleged fraud-on-the-FDA assertions pursuant to Rule 12(f), "[m]otions to strike are generally disfavored and infrequently granted." Wermann v. Excel Dentistry, P.C., No. 13 Civ. 7028, 2014 WL 846723, at *5 (S.D.N.Y. Feb. 25, 2014). On a motion to strike, the movant must show: "(1) no evidence in support of the allegations would be admissible; (2) the allegations have no bearing on the relevant issues; and (3) permitting the allegations to stand would result in prejudice to the movant." Lynch v. Southampton Animal Shelter Found. Inc., 278 F.R.D. 55, 63 (E.D.N.Y. 2011) (internal quotations omitted). Defendants have failed to meet that showing and the request will be denied.

Ward and O'Neil contend they are not asserting fraud-on-the-FDA claims. To the extent that any fraud claims are premised on any interaction between the defendants and the FDA, they would be preempted. See generally Buckman Co. v. Pl.s' Legal Comm., 531 U.S.

341 (2001). To the extent these claims seek to reach any other statements or conduct by the defendants, they are not preempted.

Turning to Counts VII and VIII, Rule 9(b) mandates a heightened pleading standard for fraud-based claims, and provides that plaintiffs must state with particularity the circumstances constituting the fraud or mistake. To satisfy the requirements of Rule 9(b), the complaint must: (1) detail the events giving rise to the fraud, such as the statement/omission that is alleged to be fraudulent, the identity of the speaker, the location of the fraud, and the reason the statement is fraudulent; and (2) allege facts that give rise to a strong inference of fraudulent intent. Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC, 797 F.3d 160, 171 (2d Cir. 2015).

To assert a fraudulent concealment claim, plaintiffs must allege: (1) defendants made a material, false representation; (2) defendants intended to defraud plaintiffs thereby; (3) plaintiffs reasonably relied upon that representation; and (4) plaintiffs suffered damage as a result of that reliance. Woods v. Maytag Co., 807 F. Supp. 2d 112,121 (E.D.N.Y. 2011) (citing Wall v. CSX Transp., Inc., 471 F.3d 410, 415-16 (2d Cir. 2006)). Plaintiffs must also allege that defendants had a duty to disclose the material information allegedly withheld. Id.

Ward and O'Neil allege that defendants, in selling the devices, misrepresented and omitted material information regarding the devices by failing to disclose the known risks of the OptionELITE and Option filters. Moreover, by failing to disclose the known dangers, defendants engaged in unfair and deceptive consumer-oriented acts which intentionally, willfully, knowingly, and fraudulently misrepresented to the medical community and consumers, including plaintiffs and their healthcare providers, that the devices had been adequately tested in clinical trials and found to be safe and effective, when that was not the

case. Further, defendants knew or believed at the time they made these fraudulent representations that the statements regarding the dangers and risks associated with the devices were false, and that the statements were made with the intent of defrauding and deceiving the medical community, plaintiffs, and the public, and made to induce the medical community and the public to recommend, dispense, and use the devices.

The fraudulent concealment claims have been adequately pleaded based on the statements and conduct allegedly attributed to defendants.

Finally, to prevail on a claim of negligent misrepresentation, plaintiffs must show: "(1) carelessness in imparting words; (2) upon which others were expected to rely; (3) and upon which they did act or failed to act; (4) to their damage." Dallas Aerospace, Inc. v. CIS Air Corp., 352 F.3d 775, 788-89 (2d Cir. 2003). Additionally, "the declarant must express the words directly, with knowledge or notice that they will be acted upon, to one to whom the declarant is bound by some relation or duty of care." Id.

Plaintiffs allege defendants exuded carelessness in their representations regarding the devices, which they knew or should have known plaintiffs and their medical providers would rely on, and which they did in fact rely on when deciding to implant the devices. Ward and O'Neil allege that the devices were released and distributed despite defendants' knowledge, by way of their own 67 day clinical study, FDA alerts, and other incident reports, that the foreseeable risks exceeded the devices' benefits in a majority of the patients in which they were intended to be implanted. Further, that defendants are alleged to have known, through multiple studies, that the medical community at large had not concluded that such devices were effective, necessary, or safe for long-term implantation, and rather that the

OptionELITE and Option filters contained a high incidence of malfunction, migration, tilt, and other serious side effects.

Based on these allegations, plaintiffs' negligent misrepresentation claims will remain.

To the extent defendants raise any other arguments in support of dismissal, they have been considered and are found to be without merit. Finally, it is not necessary to strike plaintiffs' request for punitive damages at this early stage. There are factual allegations that would demonstrate actual malice if proven. Thus, the punitive damages claims will remain.

V. CONCLUSION

Accordingly, defendants' motions to dismiss and to strike certain allegations will be denied in their entirety.

Therefore, it is

ORDERED that

1. Defendants' motion to dismiss and strike in 5:17-CV-607 is DENIED and defendants are directed to file an answer on or before April 9, 2018; and

2. Defendants' motion to dismiss and strike in 3:17-CV-640 is DENIED and defendants are directed to file an answer on or before April 9, 2018.

IT IS SO ORDERED.

United States District Judge

Dated: March 22, 2018
Utica, New York