UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

BRIAN CORRIGAN and SHERI BEMENT, **Plaintiffs,** **v.** **COVIDIEN LP, COVIDIEN SALES LLC, COVIDIEN HOLDING INC. and MEDTRONIC, INC.,** **Defendants.**	**Case No. 22-cv-10220**

MEMORANDUM AND ORDER

CASPER, J. **November 21, 2022**

I. Introduction

Plaintiffs Brian Corrigan and Sheri Bement ("Plaintiffs") have filed this product liability suit against Defendants Covidien LP, Covidien Sales LLC, Covidien Holding Inc. and Medtronic, Inc. (collectively, "Defendants") alleging breach of warranty for defective manufacture, design and failure to warn (Counts I–II), negligence (Count III), negligent misrepresentation (Count IV), loss of consortium (Count V), and unfair and deceptive trade practices in violation of Mass. Gen. L. c. 93A (Count VI). D. 4. Defendants have moved to dismiss Plaintiffs' complaint for failure to state a claim for which relief should be granted, Fed. R. Civ. P. 12(b)(6). D. 9. For the reasons discussed below, the Court ALLOWS the motion in part and DENIES it in part.

II. Standard of Review

On a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6), the Court must determine if the facts alleged "plausibly narrate a claim

for relief." Schatz v. Republican State Leadership Comm., 669 F.3d 50, 55 (1st Cir. 2012) (internal citation omitted). Reading the complaint "as a whole," the Court must conduct a two-step, context-specific inquiry. García-Catalán v. United States, 734 F.3d 100, 103 (1st Cir. 2013). First, the Court must perform a close reading of the claim to distinguish the factual allegations from the conclusory legal allegations contained therein. Id. Factual allegations must be accepted as true, while conclusory legal conclusions are not entitled credit. Id. Second, the Court must determine whether the factual allegations present a "reasonable inference that the defendant is liable for the conduct alleged." Haley v. City of Boston, 657 F.3d 39, 46 (1st Cir. 2011). In sum, the complaint must provide sufficient factual allegations for the Court to find the claim "plausible on its face." García-Catalán, 734 F.3d at 103.

III. Factual Background

The following factual allegations are from the amended complaint, D. 4, and are accepted as true for the purposes of resolving the motion to dismiss. Defendants are involved in the design, testing, manufacture, distribution, sales, marketing, regulatory management and services for the "the specific surgical stapler at issue in this suit . . . the Covidien Medtronic EEA31, which is part of the EEA (End-to-End Anastomosis) staples with DST (Directional Stapling Technology Series line" ("EEA31 stapler"). Id. ¶¶ 4–7, 19. Surgical staplers have become common medical devices used in general surgery as well as thoracic surgery, bariatric surgery and colo-rectal surgery and have a primary function of delivering staples to cut through and seal tissue. Id. ¶¶ 12–15.

On February 14, 2019, Plaintiff Brian Corrigan ("Corrigan"), underwent a laparoscopic sigmoidectomy with end-to-end anastomosis, laparoscopic mobilization of splenic flexure and percutaneous liver biopsy. Id. ¶¶ 2, 95. During the procedure, the surgeon created a circular stapled anastomosis using the EEA31 stapler. Id. ¶¶ 19, 95. Approximately three days after

Corrigan's procedure, he had an anastomotic leak, which allegedly indicated that the surgical stapler used during the procedure failed to completely seal the tissue. Id. ¶¶ 96–97. This resulted in bowel contents leaking into Corrigan's lower abdomen, contaminating his internal sterile spaces. Id. ¶ 97. Doctors then had to create "an everted loop ileostomy," which required Corrigan to wear an ostomy pouch to hold his bowel contents while the damaged tissue healed. Id. On June 6, 2019, four months after Corrigan's initial procedure, the injured bowel tissue healed and the ostomy pouch was removed. Id. ¶ 101. Over a year later, on September 21, 2020, Corrigan had further complications and underwent laparoscopic surgery for an incisional hernia repair, resulting in a nine-day hospital stay. Id. ¶ 102.

As to their claims, Plaintiffs, Corrigan and his wife, Sheri Bement, allege that Defendants knew that surgical staplers had a history of malfunction. Id. ¶¶ 20–35. Plaintiffs note that Defendants knew or should have known that by 2001 surgical stapler malfunctions caused 112 deaths, 2,180 injuries and 22,804 adverse events. Id. ¶ 20. Plaintiffs further allege that Defendants created a dangerous knowledge-gap for surgeons using staplers by misusing the Food and Drug Administration's ("FDA") Alternative Summary Reporting Program ("ASR Program"). Id. ¶¶ 44–51. The FDA created this program to "cut down on redundant paperwork," allowing certain medical device manufacturers to submit quarterly reports privately for certain "well-known" and "well-characterized" incidences of device malfunction, instead of publicly reporting each incident to the Manufacturer and User Facility Device Experience Database ("MAUDE Database"). Id. ¶¶ 23, 45. Plaintiffs allege that Defendants were misusing the ASR Program, over-reporting surgical stapler malfunction privately through the ASR Program, and under-reporting to the MAUDE Database to increase the merchantability of surgical staplers and increase their profit. Id. ¶¶ 48–51. This led to a dangerous information gap because surgeons use the publicly available MAUDE

Database to inform their opinion of medical devices. Id. ¶¶ 36–43. As alleged by Plaintiffs, in the eight years leading up to Corrigan's 2019 surgery, Defendants submitted adverse event reports regarding the EEA31 stapler specifically to the ASR Program and far fewer to the MAUDE Database that was available to surgeons. Id. ¶¶ 46-47.

"[D]ue to [the] misuse" of the ASR Program, the FDA stopped offering it to medical device manufacturers in 2019. Id. ¶ 24. In March 2019, the FDA issued a letter to healthcare providers highlighting issues with surgical staplers. Id. ¶ 62. Shortly thereafter, in April 2019, the FDA also announced its intention to reclassify surgical staplers from Class I medical devices to Class II medical devices, requiring manufacturers to give "premarket notification and allow[ing] the FDA to establish mandatory special controls to help mitigate known risks of the device." Id. ¶¶ 63–72. This change became effective on October 8, 2021. Id. ¶ 72.

Further, Plaintiffs also cite recalls by Defendants for two other surgical staplers that they claim are substantially similar to the EEA31 stapler used in Corrigan's surgery. Id. ¶¶ 73-74. Defendants manufacture a line of circular staples called the EEA Hemorrhoid and Prolapse Stapler that like the EEA31 stapler has DST technology and "places a circular, double-staggered row of titanium DST staples and removes a circular tissue specimen," but is primarily used for the control of rectal prolapse and hemorrhoid disease. Id. ¶ 73. In April 2018, Defendants recalled both the 3.5 mm and 4.8 mm staple varieties of this stapler (HEM3335 and HEM3348) due to a "potential for improper welding of the yellow staple guide to the instrument." Id. ¶ 74. Plaintiffs claim that these staplers were "substantially similar" to the EEA31 stapler as illustrated by the fact that they served as "predicate devices" for the EEA31 stapler in Defendants' premarket notification process to the FDA. Id. ¶¶ 75-76. The EEA31 stapler was listed as a predicate devise for another device, the EEA circular stapler with Tri-Staple Technology (TRIEEA28MT, TRIEEA28XT,

TRIEEA31MT, TRIEEA31XT). Id. ¶¶ 77. In April 2018, Defendants recalled this series of stapler for the "potential for a device to have an incorrect tissue gap." Id. ¶¶ 78. As to these other staplers, Plaintiffs allege that "it is more likely than not that the design processes, manufacturing processes, and quality control measures associated with these staplers are also shared" with the EEA31 stapler at issue here.

IV. Procedural History

Plaintiffs instituted this action on February 10, 2022, D. 1, and amended their complaint on March 15, 2022. D. 4. Defendants now move to dismiss Plaintiffs' amended complaint pursuant to Fed. R. Civ. P. 12(b)(6). D. 9. The Court heard the parties on the pending motion and took the matter under advisement. D. 19.

V. Discussion

A. Breach of Warranty Claims (Counts I –II)

"Under Massachusetts law, product defect claims can be brought either as negligence actions or breach of warranty actions." Laspesa v. Arrow Int'l, Inc., No. 07-cv-12370-NG, 2009 WL 5217030, at *3 (D. Mass. Dec. 23, 2009) (citation omitted). Although the "inquiry [in a breach of warranty action] focuses on product characteristics rather than on the defendant's conduct [as in negligent design], . . . the nature of the decision [in both actions] is essentially the same." Cigna Ins. Co. v. Oy Saunatec, Ltd., 241 F.3d 1, 15 (1st Cir. 2001) (citation and internal quotation marks omitted). "Manufacturers warrant that their products will be fit for the ordinary purposes for which such goods are used, and, as in negligent design claims, ordinary purposes include both intended and foreseeable uses of a product." Id. (citation and internal quotation marks omitted). Plaintiffs bring claims under both theories of liability.

To sustain a claim under a breach of warranty action, Plaintiffs must show "'(1) the defendant[s] produced or sold a defective product and (2) the product caused the plaintiff's injury.'" Burnham v. Wyeth Labs. Inc., 348 F. Supp. 3d 109, 111–12 (D. Mass. 2018) (quoting Fertik v. William Stevenson, M.D., 186 F. Supp. 3d at 101–02 (D. Mass. 2016)). "A seller breaches its warranty obligation when a product that is defective and unreasonably dangerous . . . for the [o]rdinary purposes for which it is fit causes injury." Evans v. Lorillard Tobacco Co., 465 Mass. 411, 422 (2013) (citation and internal quotation marks omitted). "A product may be defective and unreasonably dangerous because of a manufacturing defect, a design defect, or a warning defect, that is, a failure reasonably to warn of the product's foreseeable risks of harm." Id. at 422. Plaintiffs allege that the EEA31 stapler had all three defects.

To state a manufacturing defect claim, Plaintiffs must allege that there is a "'deviation from the design [that] rendered the product unreasonably dangerous and therefore unfit for its ordinary purposes.'" Burnham, 348 F. Supp. 3d at 112 (quoting Back v. Wickes Corp., 375 Mass. 633, 641 (1978)). Plaintiffs allege that the EEA31 stapler was defective as a result of "an improper or incorrect manufacturing process," D. 4 ¶ 111, but they do not allege what that process was or how the device "deviated" from the intended design in a way that rendered it unreasonably dangerous and unfit for its ordinary purpose. See Bergman v. Johnson & Johnson, No. 20-2693, 2021 WL 3604305, at *3 (D. Minn. Aug. 13, 2021) (dismissing design and manufacture claim where, among other things, plaintiffs had not alleged "how the products they received deviated from a correctly-manufactured version," but failure to warn claim proceeded). In an attempt to support this claim, Plaintiffs allege that Defendants had to initiate recalls for two lines of Covidien circular staplers, the EEA Hemorrhoid and Prolapse Stapler and the EEA Circular Stapler with Tri-Staple Technology. D. 4 ¶¶ 73–80. Plaintiffs assert that both were "substantially similar" to the EEA31

stapler, citing Defendants' premarketing submissions to the FDA, where Defendants allegedly claimed that EEA31 stapler was "substantially equivalent" to both of the recalled staplers. Id. ¶¶ 75, 77. Plaintiffs, therefore, allege that it is "likely" that the manufacturing process "associated with these staplers are also shared." Id. at D. ¶ 76, 79.

Even accepting these allegations are true, as the Court must at this juncture, Plaintiffs still fail to identify in the present complaint any "particular flaw or deviation" in the manufacturing process for the EEA31 stapler that was used in Corrigan's surgery. See Engren v. Johnson & Johnson, Inc., No. 21-10333-RGS, 2021 WL 4255296, at *2 (D. Mass. Sept 17, 2021) (stating that "[w]ithout identifying a particular flaw or deviation, [plaintiff's] conclusory statement that the product was improperly manufactured does not state a plausible claim for relief") (citation omitted). Recalls for different products do not suffice to allege that the stapler at issue also had a manufacturing defect. See Goldin v. Smith & Nephew Inc., No. 12 Civ. 9217(JPO), 2013 WL 1759575, at *3 (S.D.N.Y. Apr. 24, 2013) (stating that even when plaintiffs alleged that the product at issue was recalled it was not enough to state a manufacturing defect claim because it does not show how the product was "defective as compared to other products manufactured pursuant to the same design") (citation omitted); see also Bertini v. Smith & Nephew, Inc., No. 13 Civ. 0079(BMC), 2013 WL 6332684, at *3 (E.D.N.Y. July 15, 2013) (stating that "merely alleging that the device was recalled due to this performance issue does not suffice to plausibly show that the device itself was defective"). That is, particularly true where, even as alleged, the two lines of other Covidien staplers were allegedly recalled for different reasons: as to the HEM3335/HEM3348 for a "potential for improper welding of the yellow staple guide to the instrument" that the FDA described as a "'nonconforming material/component' in its manufacturing process," D. 4 ¶ 74; as to the

TRIEEA28MT/TRIEEA28XT/TRIEEA31MT/TRIEEA31XT for an incorrect tissue gap caused by a "process design" defect. Id. ¶ 78. That is, even between the two classes of different staplers that Plaintiffs claim are substantially similar to the EEA31 stapler, Plaintiffs have not identified what the particular defect was in this device at issue where the issues in the other staplers were different from each other and allegedly caused by different issues. Accordingly, Plaintiffs have failed to plausibly allege that Defendants defectively manufactured the EEA31 stapler.

Plaintiffs' design defect claim also fails. "In determining warranty liability for defective design, 'the relevant inquiry focuses on the product's features, not the seller's conduct.'" Taupier v. Davol, Inc., 490 F. Supp. 3d 430, 439 (D. Mass. 2020) (quoting Haglund v. Philip Morris, Inc., 446 Mass. 741, 747 (2006)). "Although the manufacturer is not expected to design against bizarre, unforeseeable accidents, the manufacturer will be liable if its conscious design choices fail to anticipate the reasonably foreseeable risks of ordinary use." Haglund, 446 Mass. at 747–48 (citation and internal quotation marks omitted). To bring a plausible implied warranty claim based on defective design, Plaintiffs must allege that "(1) the defendant[s] manufactured or sold the product that eventually injured the plaintiff; (2) the product had a defect or otherwise unreasonably dangerous condition such that it was unsuited for the ordinary use for which it was sold; (3) the plaintiff used the product as intended by the defendant or in a manner that was at least foreseeable to the defendant; and (4) the defect or unreasonably dangerous condition was a legal cause of the plaintiff's injury." Taupier, 490 F. Supp. 3d at 439–40 (internal citations omitted). A requisite part of said claim is "the existence of a safer alternative design." Coonan v. Ethicon, Inc., No. 4:21-10310-TSH, 2021 WL 5111867, at *3 (D. Mass. Nov. 3, 2021) (citing Evans, 465 Mass. at 437–40, 443). When evaluating a product's design, courts weigh "'the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility

of a safter alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design.'" Varney v. R.J. Reynolds Tobacco Co., 118 F. Supp. 2d 63, 69–70 (D. Mass. 2000) (quoting Back, 375 Mass. at 642).

As suggested by the discussion above, Plaintiffs fail to point to a specific design defect in the EEA31 stapler. Plaintiffs assert that the EEA31 stapler was defectively designed because it failed to completely seal his tissue, which resulted in bowel contents leaking into his lower abdomen. D. 4 ¶¶ 94–103. But as to what the *design* defect was, Plaintiffs does not identify one, but cites to the "most common device-related malfunctions included failure of the stapler to fire the staple, failure to form staples, difficulty opening/closing the stapler, stapler misfiring, and stapler breakage," a 2020 study that identified "an issue with fixed-style surgical staplers like the [EEA31 stapler], " and the recalls of other classes of Defendants' staplers, only one of which was apparently attributed to a design defect. Id. ¶¶ 67, 73–80, 82.

Even at the pleading stage, this is insufficient. see Varney, 118 F. Supp. 2d at 70 (dismissing the warranty claim for design defect failing to "allege that there were specific defects in the design of defendants' [product]"); DeLellis v. Johnson & Johnson, No. 20-11665-MLW, 2021 WL 3206772, at *7 (D. Mass. July 26, 2021) (stating that "Massachusetts law does not allow for the categorical imposition of liability on an entire class of products") (citation omitted). Plaintiffs must point to "some unique feature of design" of the EEA31 stapler that makes it "more dangerous than other[ ]" staplers. Varney, 118 F. Supp. 2d at 70; see Gonzalez v. Johnson & Johnson Co., No. 20-cv-12057-RGS, 2022 WL 2658975, at *3 (D. Mass. July 8, 2022) (dismissing plaintiff's design defect claim where plaintiff "fail[ed] to identify any defective aspect of the [product] or its causal relation to his injuries – he recited only that [the product] was used in his

surgery, that he developed a subsequent infection, and that others have sued these same defendants alleging the [product] is defective").

Plaintiffs also fail to allege sufficient facts to suggest the existence of a feasible alternative design. See Ducat v. Ethicon, 534 F. Supp. 3d 152, 158–59 (D. Mass. 2021) (recognizing that Massachusetts law requires a reasonable alternative design as an element of a design defect claim at the pleading stage and dismissing claim where such had not been pleaded); see also DeLellis, 2021 WL 3206772, at *7 & n.12 (following Ducat, rather than the earlier Taupier, 490 F. Supp. 3d at 446, because of "its reliance on more recent caselaw on this issue"). "Simply asserting that a feasible alternative design exists—without pleading any supportive facts—is not sufficient to plead a defective design claim or to put Defendant[s] on notice as to what that design might be." Coonan, 2021 WL 5111867, at *3 (citation and internal quotation marks omitted). Plaintiffs only assert here that the "foreseeable risks of harm posed by the products at issue could have been reduced or avoided by the adoption of a reasonable alternative design." D. 4 ¶ 113. Plaintiffs, therefore, fail to sufficiently plead a design defect claim on this ground as well.[1]

The outcome, however, is different as to Plaintiffs' failure to warn claim. Plaintiffs plausibly allege that Defendants failed to provide Corrigan with "proper warnings on instructions" so that he could avoid the danger associated with the EEA31 stapler. Id. ¶ 122. Massachusetts courts consider claims for negligent failure to warn and failure to warn under breach of warranty under the same standard. Hoffman v. Houghton Chem. Corp., 434 Mass. 624, 637 (2001). "[A] manufacturer of a product, which the manufacturer knows or should know is dangerous by nature or is in a dangerous condition, is under a duty to give warning of those dangers to persons who it

[1] Given the Court's conclusion regarding dismissal of the manufacturing and design defect claims on the aforementioned grounds, the Court does not reach Defendants' further arguments challenging these claims. D. 10 at 13.

is foreseeable will come in contact with, and consequently be endangered by, that product." Plourde v. Sorin Group United States, 517 F. Supp. 3d 76, 88 (D. Mass. 2021) (quoting MacDonald v. Ortho Pharm. Corp., 394 Mass. 131, 135 (1985)) (internal quotation marks omitted). "It is not required that the product be negligently designed or manufactured; the failure to warn [consumers] of hazards associated with foreseeable uses of a product is itself negligence." Taupier, 490 F. Supp. 3d at 446–447 (citation and internal quotation marks omitted).

Defendants raise the learned intermediary doctrine, which Massachusetts courts apply to manufacturers of medical devices. Plourde, 517 F. Supp. 3d at 88–89 (collecting cases). Under this learned intermediary doctrine, "'it is widely accepted that the manufacturer's duty to warn runs to the physician rather than the patient.'" Id. (quoting Garside v. Osco Drug, Inc., 976 F.2d 77, 80 (1st Cir. 1992)). "The immunity conferred by the doctrine is, however, limited: when the manufacturer breaches the duty to warn the doctor, it is directly liable to the patient." Taupier, 490 F. Supp. 3d at 447 (citation and internal quotation marks omitted). "Courts use a burden-shifting framework '[t]o determine whether a plaintiff can make a prima facie case of negligence despite imposition of the learned intermediary rule.'" Engren, 2021 WL 4255296, at *3 (quoting Langlois v. Am. Med. Sys., Inc., 462 F. Supp. 3d 1, 3 (D. Mass. 2020)). Under this framework, "'the plaintiff carries the initial burden of producing sufficient evidence that the defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known.'" Engren, 2021 WL 4255296, at *3 (quoting Garside, 976 F.2d at 81).

Plaintiffs meet this burden. Plaintiffs allege that Defendants misused the FDA's ASR Program specifically as to the EEA31 stapler, which allowed manufacturers of certain device types to submit quarterly reports of certain "well-known" events instead of filing individual device failure reports to the publicly available MAUDE Database. D. 4 ¶¶ 23, 46-47. Plaintiffs assert

that the ASR program still required manufacturers to report device related events to the MAUDE database in certain instances, such as requiring a report within five days for events "related to deaths and when action is necessary to prevent substantial harm to public health." Id. Plaintiffs allege that Defendants reported adverse events through the ASR Program that should have been submitted to the MAUDE database, hiding malfunctions and injuries associated with the EEA31 stapler from the view of surgeons who would use them. Id. ¶¶ 46–51. Defendants' misuse of the ASR Program led to a knowledge gap where surgeons were unaware that the surgical stapler malfunction rate was so high. Id. at ¶¶ 48, 51. As alleged, in the seven years preceding Corrigan's procedure, surgeons "were deprived of over half of [Defendants'] data on adverse events associated with its staplers, totaling over 56,000 reports that were never publicly submitted." Id. ¶ 43. It was in this "era of clandestine reporting" that Corrigan's 2019 surgery took place, and Plaintiffs allege that Corrigan's surgeon would not have had access to EEA31 staplers' malfunction rate. Id. ¶ 44, 46-47. Plaintiffs, therefore, allege that Defendants intentionally failed to provide proper warnings to Corrigan's surgeon regarding the EEA31 stapler's propensity to cause adverse events. Id. ¶ 104.

Although Plaintiffs' design and manufacturing defect claims fail, Count I, their breach of warranty for failure to warn claim, Count II, survives.

B. Negligence (Count III)

Plaintiffs' negligent failure to warn claim survives with its claim for failure to warn under breach of warranty. See Hoffman, 434 Mass. at 637 (stating that Massachusetts courts analyze claims for negligent failure to warn and failure to warn under breach of warranty under the same standard). Plaintiffs, however, fail to allege that Defendants negligently designed and negligently marketed the EEA31 stapler. Id. ¶¶ 124–29.

"In claims alleging negligence in the design of a product, as with claims of a design defect in breach of the implied warranty of merchantability, the plaintiff must show 'an available design modification which would reduce the risk without undue cost or interference with the performance of the [product].'" Ducat, 534 F. Supp. 3d at 156 (quoting Evans, 465 Mass. at 443–44). Since Plaintiffs do not plausibly allege the existence of a feasible alternative design for the EEA31 as to their design defect claim, their negligent design claim also fails.

Plaintiffs also allege that Defendants negligently marketed the EEA31 stapler. To the extent Plaintiffs seek to bring this claim independently of a viable claim for design defect, "no court, applying Massachusetts law, has ever explicitly held that a negligent marketing claim can be maintained independent of a design defect claim," Town of Westport v. Monsanto Co., 877 F.3d 58, 68 (1st Cir. 2017), in the circumstances alleged here.[2]

Plaintiffs' claims that Defendants negligently designed and negligently marketed the EEA31 stapler therefore, fail. Count III survives, however, under Plaintiffs' negligent failure to warn claim.

C. Negligent Misrepresentation (Count IV)

To establish a negligent misrepresentation claim under Massachusetts law, Plaintiffs must show that Defendants "(1) in the course of [its] business, or in a transaction in which [it] had a pecuniary interest, (2) supplied false information for the guidance of others (3) in their business transactions, (4) causing and resulting in pecuniary loss to those others (5) by their justifiable reliance on the information, and that [it] (6) failed to exercise reasonable care or competence in

[2] "Commonwealth courts have only opined that absent a design defect, a manufacturer *might* still be liable if it intentionally targeted children," which is not at issue here. Town of Westport, 877 F.3d at 68.

obtaining or communicating the information." DeWolfe v. Hingham Ctr., Ltd., 464 Mass. 795, 799–800 (2013) (citation omitted). "For pleading purposes, 'misrepresentation is considered a species of fraud.'" Engren, 2021 WL 4255296, at *5 (quoting Alt. Sys. Concepts, Inc. v. Synopsys, Inc., 374 F.3d 23, 29 (1st Cir. 2004)). "Although plaintiffs claiming misrepresentation usually are expected, pursuant to Fed. R. Civ. P. 9(b), 'to specify the who, where, and when of the allegedly false . . . representation,'" "courts are split on whether to apply [this] heightened pleading standard to claims of negligent misrepresentation." Id. (quoting Cabi v. Boston Children's Hospital, 161 F. Supp. 3d 136, 164 (D. Mass. 2016)). The First Circuit "'reads Rule 9(b) expansively to cover associated claims where the core allegations effectively charge fraud.'" Id. (quoting N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale, 567 F. 3d 8, 15 (1st Cir. 2009)). "Thus, Rule 9(b) applies to claims of negligent misrepresentation where the core allegation is fraud, and likely does not apply where the core allegation is negligence." Id. (citation and internal quotation marks omitted).

Here, Plaintiffs' core allegation is fraud. Plaintiffs allege that Defendants misused the FDA's ASR Program, choosing to over-report adverse events through the private ASR Program and to under-report to the publicly available MAUDE database "for one clear motive: profit." D. 4 ¶ 48–51. Plaintiffs, therefore, must allege the "who, where, and when of the allegedly false . . . representation.'" Engren, 2021 WL 4255296, at *5 (citation and internal quotation marks omitted).

Plaintiffs have sufficiently met the heightened pleading standard. Plaintiffs allege that the ASR Program only permitted Defendants to submit reports of certain "well-known" events and that they were to submit the rest of the adverse events to the publicly available database, MAUDE. D. 4 ¶ 23. Plaintiffs provide data asserting that from January 1, 2011 through December 31, 2018, Defendants submitted EEA31 stapler adverse event reports through the ASR Program so that

surgeons only had access to "diluted public reports." Id. ¶¶ 46–47. Defendants' alleged misuse of the ASR Program did not allow surgeons to be fully informed of the risks that the devices presented, leading to severe patient injury. Id.

Plaintiffs' negligent misrepresentation claim, Count IV, therefore, survives.

D. Chapter 93A Claim (Count VI)

Chapter 93A prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. L. c. 93A, § 2(a). To assert a Chapter 93A claim, Plaintiffs must allege "(1) a deceptive act or practice on the part of the defendant; (2) an injury or loss suffered by the plaintiff, and (3) a causal connection between the [D]efendants' deceptive act or practice and the [P]laintiffs' injury." Wagner v. Fed. Home Loan Mortg. Corp., 494 F. Supp. 3d 80, 87 (D. Mass. 2020) (citation and internal quotation marks omitted).

Defendants argue that Plaintiffs' Chapter 93A claim fails because they failed to allege that any deceptive conduct occurred in Massachusetts. D. 10 at 17–19. Under Chapter 93A, "[n]o action shall be brought or maintained under this section unless the actions and transactions constituting the alleged unfair method of competition or the unfair or deceptive act or practice occurred primarily and substantially within the commonwealth." Mass. Gen. L. c. 93A, § 11. A Chapter 93A claim, however, may proceed if "the center of gravity of the circumstances that give rise to the claim is primarily and substantially within the Commonwealth." Sonoran Scanners, Inc. v. PerkinElmer, Inc., 585 F.3d 535, 546 (1st Cir. 2009) (quoting Kuwaiti Danish Computer Corp. v. Digital Equip. Co., 438 Mass. 459, 473 (2003)) (internal quotation marks omitted). "Determining whether the conduct at issue occurred primarily and substantially within Massachusetts is 'fact-intensive,' . . . but is nevertheless 'a question of law.'" Controlled

Kinematics, Inc. v. Novanta Corp., No 17-cv-11029-ADB, 2017 WL 5892200, at *4 (D. Mass. Nov. 29, 2017) (quoting Blue Cross & Blue Shield v. AstraZeneca Pharms., LP, 582 F.3d 156, 194 (1st Cir. 2009)) (citation omitted). "Some courts have determined that due to the fact-finding process necessarily involved in evaluating the [primarily-and-substantially] issue, this particular ground for challenging a [Chapter] 93A claim . . . cannot be resolved on Rule 12 motions." Id. (allowing 93A claim to survive the motion to dismiss where claim was "based on the actions of Defendant's senior employees in Massachusetts and communications sent from Massachusetts, and thus, Plaintiff has provided enough factual detail to survive a motion to dismiss") (citation and internal quotation marks omitted).

Defendants argue that since Plaintiffs' only connection to Massachusetts is that the principal place of business of the Defendant entities are in the Commonwealth, the claim should be dismissed. D. 4 ¶¶ 4–6; D. 10 at 17–19. Plaintiffs, however, allege that the core of Defendants' deceptive trade practices originated in or were conducted in Massachusetts. D. 13 at 18–19. Specifically, Plaintiffs allege that since Defendants Covidien LP, Covidien Holding Inc. and Covidien Sales LLC all have a principal place of business in Massachusetts, misuse of the ASR Program occurred in their regular course of business in Massachusetts. Id.; D. 4 ¶¶ 4–6. Failure to disclose the panoply of adverse information about the EEA31 stapler in the publicly available MAUDE Database and instead doing so through the ASR Program is at the center of the Defendants' allegedly deceptive acts. Cf. Controlled Kinematics, Inc., 2017 WL 5892200, at *5 (distinguishing cases in which the complaint "failed to allege *any* facts supporting the proposition that the defendant's deceptive conduct was at all linked to Massachusetts").

Defendants also argue that Plaintiffs' Chapter 93A claim should be dismissed because their claims for breach of implied warranty and negligence failed. D. 10 at 19. Defendants' arguments

fail for two reasons. First, the Court did not grant Defendants' motion to dismiss Plaintiffs' claim as to breach of implied warranty as to the failure to warn claim survives and it did not dismiss the negligent misrepresentation claim. Second, the Supreme Judicial Court stated that implied warranty claims and Chapter 93A claims should "should survive or fail under the same analysis," and therefore, Plaintiffs' Chapter 93A claim, Count VI, survives at least as to with its implied warranty claim for failure to warn, Iannacchino v. Ford Motor Co., 451 Mass. 623, 634–35 (2008), but not necessarily as to the negligent claims since although "negligence alone will not give rise to liability under Chapter 93A," it "may, however, be based on negligence where there are also unfair or deceptive acts." Weinberg v. Grand Circle Travel, LLC, 891 F. Supp. 2d 228, 250 (D. Mass. 2012) (citing Darviris v. Petros, 442 Mass. 274, 278 (2004)); see Glickman v. Brown, 21 Mass. App. Ct. 229, 234–35 (1985) (stating that "[a]lthough a negligent act, standing by itself, does not amount to a violation of [Chapter 93A], a deceptive act which is the result of a defendant's negligence is actionable without more").

E. Loss of Consortium (Count V)

"As a general rule, a claim for loss of consortium requires proof of a tortious act that caused the claimant's spouse personal injury." Sena v. Commonwealth, 417 Mass. 250, 264 (1994) (citations omitted). "Although [Massachusetts courts] have determined that a claim for loss of consortium is independent of the spouse's cause of action, . . . the implicit prerequisite [is] that the injured spouse have a viable claim." Id. (citing Feltch v. General Rental Co., 383 Mass. 603, 607–08 (1981)). Plaintiffs' loss of consortium claim, Count V, therefore, survives as to the underlying claims that survive here.

VI. Conclusion

For the foregoing reasons, the Court ALLOWS in part and DENIES in part Defendants' motion to dismiss, D. 9. Specifically, the Court allows the motion as to Count I (breach of warranty for defective manufacture and design) and as much of Count III (negligence) that alleges negligent design and manufacture and denies the motion as to Counts II (breach of warranty claim only as to failure to warn), III (negligence claim only as to the negligent failure to warn), IV (negligent misrepresentation), V (loss of consortium claim, but only to the extent that the other underlying claims survive) and VI (c. 93A claim).

So Ordered.

/s/ Denise J. Casper
United States District Judge