UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TODD TAUPIER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3:19-cv-10184-KAR
	)	
DAVOL, INC.	)	
	)	
Defendant.	)	

MEMORANDUM AND ORDER REGARDING DEFENDANT'S MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT
(Dkt. No. 26)

ROBERTSON, U.S.M.J.

I. INTRODUCTION

This product liability case is before the court on Defendant Davol, Inc.'s ("Defendant") motion to dismiss Plaintiff Todd Taupier's ("Plaintiff") First Amended Complaint for failure to state a claim upon which relief may be granted (Dkt. No. 26). *See* Fed. R. Civ. P. 12(b)(6). Plaintiff has opposed the motion (Dkt. No. 28). The parties have consented to this court's jurisdiction (Dkt. No. 10). *See* 28 U.S.C. § 636(c); Fed. R. Civ. P. 73. For the reasons that follow, the motion is ALLOWED in part and DENIED in part.

II. FACTUAL BACKGROUND[1]

On or about October 21, 1999, Plaintiff underwent surgery to repair a left inguinal hernia at the Massachusetts General Hospital in Boston, Massachusetts (Dkt. No. 23 ¶ 4).[2] A Reconix

[1] The facts are drawn from the first amended complaint, Dkt. No. 23, unless otherwise stated.

[2] A hernia is defined as a "[p]rotrusion of a part or structure through the tissues normally containing it." STEDMAN'S MED. DICTIONARY 879 (28th ed. 2006). A left inguinal hernia would be on the left side of the pelvis and would involve either "the deep epigastric artery and

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polytetrafluoroethylene ("ePTFE") mesh patch, which was manufactured by Defendant, was inserted during the procedure (Dkt. No. 23 ¶¶ 4, 18).

An April 3, 2017 CT scan of Plaintiff's abdomen revealed an abscess (Dkt. No. 23 ¶¶ 6, 7). On or about May 8, 2017, Plaintiff presented at the Holyoke Medical Center Emergency Department complaining of sharp pain and cramping on the left side of his left pelvis and in his left lower quadrant (Dkt. No. 23 ¶ 5). A CT scan of Plaintiff's abdomen and pelvis on that date revealed inflammation that was consistent with a recurrent abscess that was "considerably worse" than it appeared on the April CT scan (Dkt. No. 23 ¶ 6, 7). The abscess was located on the left anterior wall of Plaintiff's abdomen in the area where the Reconix ePTFE mesh patch had been implanted (Dkt. No. 23 ¶ 6). Plaintiff was diagnosed with perforated sigmoid diverticulitis[3] with an abscess and "probable infection" of the mesh patch, which was identified in the left inguinal canal (Dkt. No. 23 ¶ 8). Because John Mazzucco, M.D., determined that the mesh patch required immediate removal, Plaintiff was admitted to the hospital and underwent surgery on May 10, 2017 (Dkt. No. 23 ¶¶ 9, 10). Dr. Mazzucco removed the infected mesh patch and drained the inguinal abscess (Dkt. No. 23 ¶ 10). On May 15, 2017, Dr. Mazzucco performed a laparoscopic sigmoid resection with mobilization of the splenic flexure (Dkt. No. 23 ¶ 11).[4] Plaintiff was discharged from the hospital on May 19, 2017 (Dkt. No. 23 ¶ 14).

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the edge of the rectus muscle," or "the internal inguinal ring [which] passes into the inguinal canal." *Id.* at 880.

[3] Perforated sigmoid diverticulitis is "inflammation in the lower part of the colon." *Sheldon v. Colvin*, No. 13-C-1219, 2014 WL 5682526, at *1 (E.D. Wis. Nov. 4, 2014).

[4] A sigmoid resection is a "partial removal of the sigmoid colon." *Achtermann v. West*, No. 96-679, 1998 WL 864554, at *2 (Vet. App. Sept. 11, 1998) (citing STEDMAN'S MED. DICTIONARY 24, 366, 1529 (26th ed. 1995)).

Plaintiff alleges that the Reconix ePTFE mesh patch "migrated and/or deteriorated over time" and perforated his large intestine thereby directly causing his injuries (Dkt. No. 23 ¶ 19). In addition, according to the complaint, the ePTFE mesh "had a propensity to allow bacteria to enter and hide from [his body's] defenses" that were designed to eliminate the bacteria (Dkt. No. 23 ¶ 20). Specifically, Plaintiff alleges that "[t]he bacteria . . . secrete[d] an encasing slime which protect[ed] them from destruction by the . . . body's defenses including white blood cells" (Dkt. No. 23 ¶ 20). According to the complaint, the ePTFE mesh also had a "propensity" to shrink by 30% to 50% (Dkt. No. 23 ¶ 21). In addition, Defendant's ePTFE mesh allegedly was "known to depolymerize and stress crack" after implantation and to "flake and crack" and degrade inside the body (Dkt. No. 23 ¶¶ 22, 23). Plaintiff alleges that, at the time the Reconix ePTFE mesh patch was implanted, he "was not informed of and had no knowledge of the known complications and risks" associated with it (Dkt. No. 23 ¶ 25).

Plaintiff filed his First Amended Complaint on October 25, 2019 (Dkt. No. 23). He brings claims for breach of warranty (Count I), negligence (Count II), and "strict liability" for Defendant's failure to warn (Count III). He alleges that, in addition to producing "prolonged pain and suffering and permanent scarring," Defendant's "dangerous and defective" mesh patch caused him to incur medical expenses and lose wages and restricted his ability to enjoy life and engage in his usual activities (Dkt. No. 23 ¶¶ 16, 17, 18).

III. LEGAL STANDARD

"A Rule 12(b)(6) motion to dismiss challenges a party's complaint for failing to state a claim." *Ngomba v. Olee*, CIVIL ACTION NO. 18-11352-MPK, 2020 WL 107969, at *2 (D. Mass. Jan. 9, 2020). In ruling on the motion, a court must "treat all well-pleaded facts in the complaint as true and draw all reasonable inferences in favor of the plaintiff." *In re Fin.*

Oversight & Mgmt. Bd. for P.R., 919 F.3d 121, 127 (1st Cir. 2019) (citing *Ocasio-Hernández v. Fortuño-Burset*, 640 F.3d 1, 7 (1st Cir. 2011)). "In order to survive a motion to dismiss under Rule 12(b)(6), the plaintiff must provide 'enough facts to state a claim to relief that is plausible on its face.'" *Ngomba*, 2020 WL 107969, at *2 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). "A determination of plausibility is 'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Grajales v. P.R. Ports Auth.*, 682 F.3d 40, 44 (1st Cir. 2012) (quoting *Iqbal*, 556 U.S. at 679). "[L]abels and [legal] conclusions, and a formulaic recitation of the elements of a cause of action" are insufficient to "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. "Simply put, the court should assume that well-pleaded facts are genuine and then determine whether such facts state a plausible claim for relief." *Ngomba*, 2020 WL 107969, at *2 (citing *Iqbal*, 556 U.S. at 679).

IV. ANALYSIS

In addition to raising specific legal challenges, Defendant generally disputes Plaintiff's claims on the ground that they are conclusory allegations, which fail to meet the minimum degree of specificity required by *Twombly, Iqbal,* Fed. R. Civ. P. 8(a)(2) (a complaint for relief must state "a short and plain statement of the claim showing that the pleader is entitled to relief"), and Fed. R. Civ. P. 12(b)(6) (Dkt. No. 27 at 7-8).

A. Count I: Breach of Warranty

"In Massachusetts, there is no strict liability cause of action for a defective product." *Phillips v. Medtronic, Inc.*, 754 F. Supp. 2d 211, 216 (D. Mass. 2010) (citing *Commonwealth v.*

Johnson Insulation, 682 N.E.2d 1323, 1326 (Mass. 1997)).[5] "Such a claim must be brought as a claim for breach of the implied warranties of merchantability and/or fitness for a particular purpose under Mass. Gen. Laws ch. 106, §§ 2–314 and 2–315, or of an express warranty under § 2–313." *Id.* Plaintiff claims that Defendant's Reconix ePTFE mesh patch breached the express warranty and the implied warranties of merchantability and fitness for its intended use (Dkt. No. 23 ¶¶ 30, 31, 32).

1. The First Amended Complaint Fails to State a Claim for Breach of the Express Warranty

Plaintiff alleges that Defendant "expressly warranted, through its mesh patch, and by the statements and conduct of its employees and agents, that the mesh patch was fit for use, and not otherwise adulterated or injurious to health" (Dkt. No. 23 ¶ 30). Defendant argues that the express warranty claim should be dismissed because Plaintiff fails to allege the express warranty's terms and his reliance upon them (Dkt. No. 27 at 10-11).

Under Massachusetts law, "'an express warranty claim is and generally has been understood to be an action of contract.'" *Sprague v. Upjohn Co.*, Civ. A. No. 91-40035-NMG, 1995 WL 376934, at *2 (D. Mass. May 10, 1994) (quoting *Anthony's Pier Four Inc. v. Crandall Dry Dock Eng'rs, Inc.*, 489 N.E.2d 172, 175 (Mass. 1986)). According to the Massachusetts version of the Uniform Commercial Code, Mass. Gen. Laws ch. 106 § 2-313(1):

> (a) any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
>
> (c) any sample or model which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the sample or model.

[5] There is no dispute concerning the application of Massachusetts law.

Mass. Gen. Laws ch. 106, § 2-313(1). "The theory of such a claim is that the defendants are liable to the plaintiff for failure to provide a design that meets a standard of performance allegedly promised by the defendants." *Anthony's Pier Four, Inc.* 489 N.E.2d at 175. "Because the standard of performance is set by defendant's express promises to the plaintiff, 'the plaintiff must demonstrate that the defendant promised a specific result' and that defendant failed to deliver on his promise and, therefore, breached the express warranty." *Jackson v. Johnson & Johnson & Janssen Pharms., Inc.*, 330 F. Supp. 3d 616, 627 (D. Mass. 2018) (quoting *Anthony's Pier Four, Inc.*, 489 N.E.2d at 175). "Furthermore, in an express warranty claim, plaintiff must show reliance on such warranty." *Sprague*, 1995 WL 376934, at *3 (citing *Roth v. Ray-Stel's Hair Stylists, Inc.*, 470 N.E.2d 137, 138 (Mass. App. Ct. 1984) (rescript)).

Notwithstanding Plaintiff's claim that he was not informed of the "known complications and risks" associated with the Reconix ePTFE mesh patch, his complaint fails to identify "any affirmation of fact or promise" made by Defendant or to allege that the patch failed to conform to a description, sample or model. Mass. Gen. Laws ch. 106, § 2-313(1). *See Chapman ex rel. Estate of Chapman v. Bernard's, Inc.*, 167 F. Supp. 2d 406, 414 (D. Mass. 2001) (allowing summary judgment based on plaintiff's failure to produce any evidence of the express warranty for the allegedly defective product). In addition, the complaint lacks an allegation concerning Plaintiff's reliance on an express warranty. *See Provanzano v. MTD Prods. Co.*, 215 F. Supp. 3d 134, 137 (D. Mass. 2016); *Roth*, 470 N.E.2d at 175. Because the First Amended Complaint fails to establish the requisites for a viable breach of express warranty claim, so much of Count I as alleges a claim for breach of the express warranty is dismissed. *See Jackson*, 330 F. Supp. 3d at 627 (allowing summary judgment because the plaintiff failed to demonstrate the specific result the defendants promised and failed to establish that he relied on any representation made by the

defendants); *Sprague,* 1995 WL 376934, at *3 (dismissing a complaint that failed to establish either the existence of an express warranty or reliance thereon).

2. The First Amended Complaint States a Claim for Breach of the Implied Warranty of Merchantability Based on a Design Defect

According to the First Amended Complaint, Defendant's Reconix ePTFE mesh patch was "defective" and was not fit for its intended use and purpose (Dkt. No. 23 ¶¶ 31, 32). Relying on comment k of the Restatement (Second) of Torts § 402A, Defendant counters that Plaintiff's implied warranty claim should be dismissed because Massachusetts exempts manufacturers of unavoidably unsafe products from liability (Dkt. No. 27 at 9-10). Viewing the First Amended Complaint under the plaintiff-favorable standard that is applicable at this stage of the litigation and predicting that the Massachusetts Supreme Judicial Court ("SJC") would not apply comment k to bar the claim, Count I sufficiently alleges a claim for breach of the implied warranty based on a defective design.

"Massachusetts does not recognize strict products liability in tort." *Smith v. Robertshaw Controls Co.*, 410 F.3d 29, 32 n.4 (1st Cir. 2005). Instead, it "recognizes liability for breach of an implied warranty of merchantability under the Uniform Commercial Code as the 'functional equivalent of strict liability in other jurisdictions.'" *Anunciacao v. Mitsubishi Heavy Indus., Ltd.*, CIVIL ACTION NO. 08-11353-MLW, 2009 WL 10694162, at *2 (D. Mass. Oct. 14, 2009), *rec. dec. adopted,* C.A. No. 08-11353-MLW, 2009 WL 10694160 (D. Mass. Dec. 11, 2009) (quoting *Haglund v. Philip Morris Inc.*, 847 N.E.2d 315, 321-22 (Mass. 2006)). "[A]s a matter of social policy, the warranty of merchantability imposes a 'special responsibility' on the seller toward '*any* member of the consuming public who may be injured' by its product." *Haglund*, 847 N.E.2d at 321 (quoting *Correia v. Firestone Tire & Rubber Co.*, 446 N.E.2d 1033, 1040 (Mass. 1983)).

"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." *Id.* at 322 (alteration in original) (citation omitted). *See Plastic Surgery Assocs., S.C. v. Cynosure, Inc.*, 407 F. Supp. 3d 59, 80 (D. Mass. 2019) ("Under Massachusetts law, a seller impliedly warrants that a product is 'fit for the ordinary purposes for which such goods are used.'") (quoting Mass. Gen. Laws ch. 106, § 2-314(2)(c)). "'Ordinary purposes' refers to a product's intended and foreseeable uses." *Haglund,* 847 N.E.2d at 322 (quoting *Back v. Wickes Corp.*, 378 N.E.2d 964, 969 (Mass. 1978)). "'Fitness' is a question of degree that primarily, although not exclusively, concerns reasonable consumer expectations." *Id.* "Both 'ordinary purposes' and 'fitness' are concepts that demand close attention to the actual environment in which the product is used." *Id.* "The plaintiff may base a claim for breach of an implied warranty on a manufacturing, design or warning defect that makes the product unreasonably dangerous." *Provanzano,* 215 F. Supp. 3d at 138 (citing *Evans v. Lorillard Tobacco Co.*, 990 N.E.2d 997, 1010 (Mass. 2013)).

Here, Plaintiff alleges that Defendant's use of ePTFE in the Reconix mesh patch constituted a design defect (Dkt. No. 23 ¶ 18).[6] In determining warranty liability for defective design, "the relevant inquiry focuses on the product's features, not the seller's conduct." *Haglund,* 847 N.E.2d at 322. Although the manufacturer is not obliged "to design against bizarre unforeseeable accidents," it "must anticipate the environment in which the product will be used, and it must design against the reasonably foreseeable risks attending the product's use in that

[6] "In order to establish a manufacturing defect, a plaintiff must demonstrate that there is a 'deviation from the design [that] rendered the product unreasonably dangerous and therefore unfit for its ordinary purposes.'" *Burnham v. Wyeth Labs. Inc.*, 348 F. Supp. 3d 109, 112 (D. Mass. 2018) (alteration in original) (quoting *Back,* 378 N.E.2d at 970). The First Amended Complaint is devoid of allegations that the Reconix mesh patch was manufactured in a manner that differed from its intended design.

setting." *Back*, 378 N.E.2d at 969. Thus, a plaintiff bringing an implied warranty of merchantability claim based on a defective design must plead facts sufficient to allege that:

> (1) the defendant 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.

DaSilva v. Toyota Motor Corp., Civil Action No. 20-cv-10984-ADB, 2020 WL 3977405, at *5 (D. Mass. July 14, 2020) (citing *Fireman's Fund Ins. Co. v. Bradford-White Corp.*, Civil Action No. 12-10509-NMG, 2014 WL 1515266, at *7 (D. Mass. Apr. 15, 2014)). *See Town of Westport v. Monsanto Co.*, Civil Action No. 14-12041, 2017 WL 1347671, at *4 (D. Mass. Apr. 7, 2017), *aff'd*, 877 F.3d 58 (1st Cir. 2017) ("To demonstrate that a product is defective under a design defect theory, it must be shown that the product was 'made according to an unreasonably dangerous design and does not meet a consumer's reasonable expectation as to its safety.'") (quoting *Everett v. Bucky Warren, Inc.*, 376 Mass. 280, 290 (1978) (internal quotations omitted)). There is no dispute that Defendant manufactured the Reconix ePTFE mesh patch for implantation to repair an inguinal hernia, or that Defendant foresaw that it would be used for that purpose.

As to the product's defect or unreasonably dangerous condition, taking the allegations in the First Amended Complaint in the light most favorable to Plaintiff and resolving reasonable inferences in his favor, the allegations are sufficient to state a claim for breach of the implied warranty based on a defective design, albeit barely. The First Amended Complaint alleges that the ePTFE mesh was unreasonably dangerous or defective for implantation to repair an inguinal hernia because it had a propensity to permit bacteria to enter the body, to shrink up to 50% in size, to depolymerize and stress crack after implantation, and to flake, crack, and eventually

degrade (Dkt. No. 23 ¶¶ 20-23). It is reasonable to infer that these alleged defects in the ePTFE mesh patch's design caused Plaintiff's injuries by perforating his large intestine and producing an infection (Dkt. No. 23 ¶¶ 6, 8, 10, 19-23).

Relying on the SJC's statement that "liability under the implied warranty of merchantability in Massachusetts is 'congruent in nearly all respects with the principles expressed in Restatement (Second) of Torts § 402A,'" *Vassallo v. Baxter Healthcare Corp.*, 696 N.E.2d 909, 923 (Mass. 1998) (quoting *Johnson Insulation*, 682 N.E.2d at 1326), Defendant argues that Plaintiff's implied warranty claims are categorically barred because the Reconix ePTFE mesh patch "falls squarely within the reach of" comment k to section 402A of the Restatement (Second) of Torts and that "Massachusetts court decisions have consistently held to the letter of comment k" (Dkt. No. 27 at 9-10, 15-17). However, Defendant fails to cite Massachusetts authority that applies comment k to bar a breach of warranty claim based on the defective design of an implanted medical device. The weight of authority from other jurisdictions does not support Defendant's contention that Plaintiff's claim is precluded by comment k.

Restatement Section 402A generally provides for strict liability for anyone who "sells any product in a defective condition unreasonably dangerous to the ultimate user or consumer . . . ." RESTATEMENT (SECOND) OF TORTS § 402A(1) (AM. LAW INST. 1965). Comment k, which addresses unavoidably unsafe products, states:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. . . . The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. . . . The seller of such products, again with the qualification that they are properly prepared and

> marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability

RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (AM. LAW INST. 1965).

In Massachusetts, comment k has been applied to shield manufacturers of prescription drugs from claims of breach of the implied warranty of merchantability based on design defects. *See Burnham*, 348 F. Supp. 3d at 112 (dismissing complaint alleging defective design of prescription medication based on comment k); *see also Lareau v. Page*, 840 F. Supp. 920, 923, 933 (D. Mass 1993) (relying on comment k to enter summary judgment for the pharmaceutical company that manufactured the contrast dye that was injected into plaintiff's brain during neurosurgery); *Sprague*, 1995 WL 376934, at *2 (dismissing a claim of negligent design of a prescription sleeping medication as a matter of law and finding that a court may review the way in which a drug "was marketed to [a] user [and may] evaluate any alleged harm derived therefrom," but finding the question of "whether it was unreasonable to market the drug at all" to be "improper"); *Payton v. Abbott Labs*, 437 N.E.2d 171, 189 (Mass. 1982) ("Public policy favors the development and marketing of new and more efficacious *drugs*. The Restatement (Second) of Torts recognizes this policy by rejecting strict liability in favor of negligence for drug related injuries. Restatement (Second) of Torts § 402A, comment k (1965).") (emphasis added)).

However, neither the SJC, the Massachusetts Appeals Court, nor the First Circuit has addressed the question of whether Massachusetts applies comment k to bar breach of warranty claims for defectively designed implanted medical devices.[7] In diversity cases concerning

[7] The plaintiff in *Vassallo* claimed that she was injured by silicone breast implants that were designed and manufactured by the defendant's predecessor company. *See Vassallo*, 696 N.E.2d at 912. Because the manufacturer in *Vassallo* was found liable for negligent design, negligent product warnings, a violation of the consumer protection statute, Mass. Gen. Laws ch. 93A, as well as for a breach of the implied warranty of merchantability and because the SJC could affirm the jury's verdict in favor of the plaintiff on the negligence and Chapter 93A theories, the court

Massachusetts law, the federal courts are bound to take the law of the state's highest court, the SJC, if that court has stated its position on the issue. *See EMC Corp. v. Arturi,* 655 F.3d 75, 78 (1st Cir. 2011). If the SJC has not definitively spoken on a question, as here, the court "'make[s] an informed prophecy' about what rule the state courts would likely follow." *Phoung Luc v. Wyndham Mgmt. Corp.,* 496 F.3d 85, 88 (1st Cir. 2007) (quoting *N. Am. Specialty Ins. Co. v. Lapalme,* 258 F.3d 35, 37-38 (1st Cir. 2001)). *See Eustace v. Springfield Pub. Schs.*, Civil Action No. 17-30158-MGM, 2020 WL 2798260, at *6 (D. Mass. May 29, 2020) ("'when a federal court is confronted with an unresolved question of state law, [its] job is to "ascertain the rule the state court would most likely follow under the circumstances."'") (alterations in original) (quoting *CVS Pharmacy, Inc. v. Lavin*, 951 F.3d 50, 58 (1st Cir. 2020)). Courts "consider the decisions of other state and federal courts and the general weight of the authority" when determining the result the SJC likely would reach. *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 655 (1st Cir. 1981).

Jurisdictions are split on whether medical devices enjoy blanket immunity for being unavoidably unsafe under comment k with the majority of courts rejecting a categorical bar and, instead, favoring a product-by-product analysis. *See In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.,* 888 F.3d 753, 772 (5th Cir. 2018); *Burningham v. Wright Med. Grp., Inc.*, Case No. 2:17-CV-92, 2018 WL 922362, at *4 (D. Utah Feb. 15, 2018), *certified question answered sub nom. Burningham v. Wright Med. Tech., Inc.*, 448 P.3d 1283 (Utah 2019); *Moss v. Wyeth Inc.*, 872 F. Supp. 2d 162, 167 (D. Conn. 2012).

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did not address the defendant's liability for breach of the implied warranty of merchantability based on a design defect. *See Vassallo,* 696 N.E.2d at 912, 921-22.

> Some courts have found that comment k categorically bars design defect claims for certain medical products. *See, e.g.*, *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) (leading case adopting categorical approach). In these states, comment k is an absolute bar to claims of design defect for particular classes of products. [8] Other courts have adopted a case-by-case approach. *See, e.g.*, *Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 308 (Idaho 1987) (leading extant case adopting case-by-case approach). Thus, in these states, whether comment k bars a claim of design defect depends on the particular product at hand.[9]

Jenkins v. Boston Sci. Corp., Civil Action No. 2:13-cv-09968, 2016 WL 1448867, at *5 (S.D. W. Va. Apr. 12, 2016).

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[8] *See Breen v. Synthes-Stratec, Inc.*, 947 A.2d 383, 388 n.5 (Conn. App. 2008) (citing cases that have extended the reach of comment k to include prescription medical devices).

[9] *Burningham* notes that the following cases view comment k as an affirmative defense:

> *Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989) ("We agree with th[e] courts that view comment k as an affirmative defense." (citing *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1301 (D. Minn. 1988))); *Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1338 (9th Cir. 1985) (upholding a case-by-case application of comment k); *Hawkinson v. A.H. Robins Co.*, 595 F. Supp. 1290, 1308 (D. Colo. 1984) (providing that comment k is an affirmative defense); *Moss* . . . , 872 F. Supp. 2d [at] 174 . . . (concluding comment k should provide an affirmative defense); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1149 (D. Or. 1989) (applying comment k similarly, but to prescription drugs); *Larsen v. Pacesetter Sys., Inc.*, . . . 837 P.2d 1273, 1285–86 ([Haw.] 1992) (holding that a pacemaker did not fall under comment k because it was "demonstrably capable of being made safe for its intended use"); *Toner*,. . . 732 P.2d [at] 308 . . . (concluding that comment k is an affirmative defense to a claim based on strict liability).

Burningham, 448 P.3d at 1291 n.13. *See also Arruda v. C.R. Bard, Inc.*, No. 6:19-cv-1523(TJMATB), 2020 WL 4569436, at *6 (N.D.N.Y. Aug. 6, 2020) (denying medical device manufacturer's request to categorically apply comment k to medical devices and to find that all prescription implanted medical devices were unavoidably unsafe because New York state courts had not "'extend[ed] the "unavoidably unsafe" products exception to all medical devices'") (citation omitted); *Tansy v. Dacomed Corp.*, 890 P.2d 881, 885 (Okla. 1994) (noting that comment k could be raised as an affirmative defense where a medical device was incapable of being made safe but its societal benefit warranted its production).

Courts in other jurisdictions in the First Circuit have applied comment k on a case-by-case basis. *See Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 505 (2013) (Sotomayor, J., dissenting) ("Drug manufacturers in New Hampshire have an affirmative defense under comment *k* to § 402A of the Second Restatement, which exempts '[u]navoidably unsafe products' from strict liability if the product is properly manufactured and labeled. . . . New Hampshire takes a case-by-case approach to comment *k* under which a defendant seeking to invoke the defense must first show that the product is highly useful and that the danger imposed by the product could not have been avoided through a feasible alternative design.") (first alteration in original) (citations omitted); *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8, 13 & n.3 (1st Cir. 1995) (because Maine applied the "danger/utility test" to design defect claims, "the evidence of an alternative safe method of surgery defeat[ed] [defendant's] claim that its product is unavoidably unsafe and therefore exempt from strict liability under comment k of section 402A of the Restatement (Second) of Torts, which requires a showing that the utility or benefit of the product outweighs its risk of danger."); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988) (rejecting preclusion of strict liability for prescription drugs based on comment k and adopting the "case-by-case approach to determine whether a prescription drug is exempt from strict liability for defective design.").

There are three reasons to conclude that the SJC likely would follow the jurisdictions that employ a product-by-product analysis to determine whether a medical device is unavoidably unsafe and excepted from strict product liability by comment k. First, the SJC has stated that, as a matter of social policy, "holding sellers liable for the quality and safety of their products," supports the breach of warranty theory of liability. *Johnson Insulation,* 682 N.E.2d at 1330. *See Guzman v. MRM/Elgin*, 567 N.E.2d 929, 932 (Mass. 1991) (the goal of strict liability is to place

responsibility for defective products on those who manufacture and market them). Relying on comment k to exempt manufacturers of implanted medical devices from design defect liability irrespective of the risks and benefits of those products would frustrate the SJC's articulated policy by removing the incentive for manufacturers to employ the highest quality and safety standards when designing devices that are intended to be implanted in the human body.

Next, comment k uses "drugs, vaccines, and the like" as examples of unavoidably unsafe products and specifically identifies the rabies vaccine. RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k (AM. LAW INST. 1965). Although Massachusetts cases have exempted drugs from breach of warranty liability under comment k, *see, e.g., Burnham,* 348 F. Supp. 3d at 112, courts in other jurisdictions that have applied comment k to bar strict liability claims for design defects in prescription drugs have distinguished drugs from medical devices based, in part, on the FDA's "more rigorous oversight" of drugs. *Burningham*, 448 P.3d at 1290. Therefore, even courts that exempt manufacturers of prescription drugs from strict liability based on comment k have applied a case-by-case analysis to medical devices. *See, e.g., Robbins v. Boston Sci., Corp.,* Civil Action No. 2:12-cv-01413, 2015 WL 5842753, at *4 (S.D. W.Va. Oct. 6, 2015); *Burningham,* 448 P.3d at 1287, 1290.

Finally, comment k has been viewed as "in essence, nothing more than another name for the risk-utility test," which the SJC has accepted. *Huskey v. Ethicon, Inc.*, CIVIL ACTION NO. 2:12-cv-05201, 2015 WL 4944339, at *4 (S.D. W. Va. Aug. 19, 2015), *aff'd*, 848 F.3d 151 (4th Cir. 2017). *See Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1340 (M.D. Fla. 2015) ("the . . . risk-utility analysis appears to embody the intent of comment k in the Second Restatement."); *Grinage v. Mylan Pharms., Inc.*, 840 F. Supp. 2d 862, 869 n.5 (D. Md. 2011) ("the determination of whether a product is unavoidably unsafe [under comment k] requires a weighing of relevant

risk/utility factors.") (citing *Doe v. Miles Lab., Inc. Cutter Lab. Div.*, 927 F.2d 187, 191 (4th Cir. 1991)). "Thus in states that have adopted a form of the risk-utility test, comment k is a 'redundant,' 'useless relic' reflective of an era from decades past, when courts relied exclusively on the consumer-expectations test in product liability cases." *Huskey*, 2015 WL 4944339, at *4 (quoting *Mullins v. Ethicon, Inc.*, Civil Action No. 2:12-cv-02952, 2015 WL 4635573, at *4-9 (S.D. W. Va. Aug. 4, 2015)). Because the SJC has adopted a risk-utility balancing test in product liability cases, it likely would not apply comment k to categorically bar liability for a design defect. *See Evans*, 990 N.E.2d at 1013 ("In short, in determining whether a product's design is unreasonably dangerous, we have been applying a risk-utility balancing standard, where consumer expectations are a factor but not necessarily the determinative factor, since well before the Third Restatement articulated this liability standard."); *Haglund*, 847 N.E.2d at 323 ("To determine the adequacy of a product's design, the jury must weigh multiple factors, including 'the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer 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.'") (quoting *Back*, 378 N.E.2d at 970).

Defendant's contention that comment k absolutely bars Plaintiff's claim for breach of the implied warranty of merchantability based on a design defect in the implanted medical device is not supported. Because Plaintiff has stated a cognizable claim for breach of the implied warranty based on a design defect, Defendant's motion to dismiss so much of Count I as alleges liability under that theory is denied.

3. The First Amended Complaint Fails to State a Claim for Breach of the Implied Warranty of Fitness for a Particular Purpose

The First Amended Complaint fails to allege facts to support a claim for breach of the implied warranty of fitness for a particular purpose. "The warranty of fitness for a particular purpose is similar to the warranty of merchantability but applies only 'where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods.'" *Pub. Serv. Mut. Ins. v. Empire Comfort Sys., Inc.*, 573 F. Supp. 2d 372, 381 (D. Mass. 2008) (quoting Mass. Gen. Laws ch. 106, § 2–315). "'A "particular purpose" differs from an "ordinary purpose" in that it "envisages a specific use by the buyer which is peculiar to the nature of his business."'" *Id.* (citation omitted). Because Plaintiff fails to allege that he used the Reconix ePTFE mesh patch for a purpose that differed from the purpose for which it was ordinarily used, the complaint falls short of stating a viable claim.

In summary, the motion to dismiss is allowed as to so much of Count I as alleges breach of the express warranty and breach of the implied warranty of fitness for a particular purpose and denied as to so much of Count I as alleges breach of the implied warranty of merchantability based on defective design.

B. Count II: Negligence

In the First Amended Complaint, Plaintiff's negligence claim is subdivided into two parts. He alleges that Defendant was negligent in (1) designing the Reconix mesh product and (2) failing to adequately warn "of the dangers known to it or which in the use of reasonable care [it] should have known and which a user of its mesh products ordinarily would not discover" (Dkt. No. 23 ¶¶ 37, 38).

1. The First Amended Complaint States a Claim for Negligent Design

Defendant argues that Plaintiff fails to allege "how the product was unreasonably dangerous or defective with any specificity" (Dkt. No. 27 at 15). Defendant further contends that Plaintiff's allegations are "devoid of any factual allegations that raise a right to relief above the speculative level and support causation" (Dkt. No. 27 at 15).

"In a negligence action, the conduct of the defendant takes center stage, and liability will be imposed where the defendant 'has failed to use reasonable care to eliminate foreseeable dangers which subject a user to an unreasonable risk of injury.'" *Haglund,* 847 N.E.2d at 322 n.9 (quoting *Colter v. Barber-Greene Co.*, 525 N.E.2d 1305, 1313 (Mass. 1988)). "Proof of design negligence requires satisfaction of the following elements: (1) the manufacturer's failure to exercise a reasonable degree of care under the circumstances; (2) proximate causation; and (3) injury and/or loss." *Geshke v. Crocs, Inc.*, 889 F. Supp. 2d 253, 261 (D. Mass. 2012), *aff'd*, 740 F.3d 74 (1st Cir. 2014) (footnote omitted) (citing *Ulwick v. DeChristopher*, 582 N.E.2d 954, 958 (Mass. 1991); *Beaver v. Costin*, 227 N.E.2d 344, 345-46 (Mass. 1967); *Scott v. Thompson*, 363 N.E.2d 295, 296 (Mass. App. Ct. 1977)). As to the first element, "[a] designer has a duty 'to design the [product] with reasonable care.'" *Uloth v. City Tank Corp.*, 384 N.E.2d 1188, 1191 (Mass. 1978) (quoting *doCanto v. Ametek, Inc.*, 328 N.E.2d 873, 877 (Mass. 1975); RESTATEMENT (SECOND) OF TORTS § 398 (AM. LAW INST. 1965)). To establish breach of duty, the plaintiff must prove that the defendant "1) failed to exercise reasonable care to eliminate avoidable dangers to the user and 2) there is an alternative design available which would allow the product to perform the same function in a safer fashion." *Provanzano*, 215 F. Supp. 3d at 139 (citing *Uloth*, 384 N.E.2d at 1191); *Evans*, 990 N.E.2d at 1024 ("In claims alleging negligence in the design of a product, . . . the plaintiff must show an available design

modification which would reduce the risk without undue cost or interference with the performance of the product . . . .").

The previously recited facts that support the First Amended Complaint's claim of breach of the implied warranty based on a design defect, when taken as true, are sufficient to "raise a reasonable expectation that discovery [may] reveal evidence of" Defendant's negligent design and causation (Dkt. No. 23 ¶¶ 8, 10, 19-23). *Twombly,* 550 U.S. at 556. The complaint's allegations that specifically identify the defective properties of the ePTFE mesh are sufficient to state a viable claim that Defendant was negligent in using that material in a patch that would be implanted in the human body (Dkt. No. 23 ¶¶ 20-23). Those allegations and the descriptions of Plaintiff's specific injuries in the area in and around where the device was implanted are sufficient to support an inference at the pleading stage that the ePTFE mesh patch was the proximate cause of Plaintiff's infection and perforated large intestine (Dkt. No. 23 ¶¶ 6, 8, 10, 19-23). *Compare Exum v. Stryker Corp.,* Civil No. 1:13-CV-10247-PBS, 2013 WL 3786469, at *2 (D. Mass. July 17, 2013) (dismissing negligence claim against the manufacturer of a hip prosthetic where the plaintiff failed "to identify any facts that plausibly demonstrate such a device was designed or manufactured defectively, or that such a defect caused [p]laintiff's injury or death.").[10]

[10] In addition to *Vassallo,* which was discussed earlier, other Massachusetts decisions suggest that the determination of liability for a design defect is fundamentally the same under a breach of implied warranty theory as under a negligence theory. *See, e.g., Simmons v. Monarch Mach. Tool Co.*, 596 N.E.2d 318, 320 n.3 (Mass. 1992), *abrogated on other grounds by Vassallo*, 696 N.E.2d at 909 ("Because we find no error on the negligence count, resolution of this case does not require us to discuss Monarch's various claims of error pertaining to the breach of warranty count."); *Back*, 378 N.E.2d at 970 ("In deciding [the design defect] issue [in a breach of warranty case], the jury must weigh competing factors much as they would in determining the fault of the defendant in a negligence case. The inquiry focuses on product characteristics rather than on the defendant's conduct, but the nature of the decision is essentially the same."). *See Vassallo,* 696 N.E.2d at 912 (affirming judgment against manufacturer of breast implants on negligence

Relying on *Johnson v. Brown & Williamson Tobacco Corp.*, 122 F. Supp. 2d 194 (D. Mass. 2000), a tobacco product liability case, Defendant claims that Plaintiff must "show the existence of a safer alternative design that can be implemented without undue cost" (Dkt. No. 27 at 14). Although proof of a safer alternative design may ultimately be required, *see Evans*, 990 N.E.2d at 1024; *Back*, 378 N.E.2d at 970, it does not appear that Massachusetts law would require a plaintiff to plead the existence of an alternative design. In *Osorio v. One World Techs., Inc.*, 659 F.3d 81 (1st Cir. 2011), the First Circuit observed that the plaintiff in *Smith v. Ariens*, 377 N.E.2d 954 (Mass. 1978), who was injured in a snowmobile accident, prevailed at trial on a negligent design claim without suggesting any safer alternative design. *Osorio*, 659 F.3d at 86-87 (quoting *Marchant v. Dayton Tire & Rubber Co.*, 836 F.2d 695, 700 (1st Cir. 1988)). The First Circuit concluded that the *Smith* case "suggests that Massachusetts product liability law may tolerate a finding of design defect even in the absence of evidence supporting the existence of a feasible alternative design." *Id.* at 87 (citing *Smith*, 377 N.E.2d at 957). Where the First Circuit has said that a plaintiff may not be required to prove the existence of a safer alternative design to prevail on a negligent design claim, the absence of an allegation of such an alternative in the First Amended Complaint is not a basis for dismissal.

Accordingly, Plaintiff has sufficiently pled a viable claim for negligent design.[11]

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theory); see also *Toner*, 732 P.2d at 311 ("[C]omment [k] does not shield sellers of products from negligence claims.").

[11] To support its argument that Plaintiff fails to plead sufficient facts to state a negligence claim, Defendant compares the allegations in the First Amended Complaint with the much more detailed allegations in the complaint in another implanted mesh case, *Terrell v. Davol, Inc.*, Civil Action No. 13-5074, 2014 WL 3746532, at *8-10 (E.D. Pa. July 30, 2014) (Dkt. No. 27 at 11-14). As is set forth herein, some of the plaintiff's claims fail to pass the Rule 12(b)(6) threshold based on the lack of such detailed allegations. In the court's view, however, the remainder of the complaint is sufficient to satisfy the Fed. R. Civ. P. 8(a)(2) and 12(b)(6) standards that are

2. The First Amended Complaint Fails to State a Claim for Negligent Failure to Warn

On the other hand, Plaintiff fails to plead sufficient facts to support his claim that Defendant breached its duty to warn of the risks associated with an implanted Reconix ePTFE mesh patch. "'In Massachusetts, a manufacturer can be found liable to a user of the product if the user is injured due to the failure of the manufacturer to exercise reasonable care in warning potential users of hazards associated with the use of the product.'" *Langlois v. Am. Med. Sys., Inc.*, CIVIL ACTION NO. 4:20-40021-TSH, 2020 WL 2616305, at *2 (D. Mass. May 22, 2020) (footnote omitted) (quoting *Laaperi v. Sears, Roebuck & Co.*, 787 F.2d 726, 729 (1st Cir. 1986) (footnote 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, and if that negligence proximately results in a plaintiffs [sic] injuries, the plaintiff may recover.'" *Jackson*, 330 F. Supp. 3d at 627 (quoting *Laaperi*, 787 F.2d at 729). "[U]nder Massachusetts law [the manufacturer] may rely on the 'learned intermediary' doctrine, which 'provides that "a . . . manufacturer's duty to warn of dangers associated with its product runs only to the physician; it is the physician's duty to warn the ultimate consumer."'" *Calisi v. Abbott Labs.*, Civil Action No. 11-10671-DJC, 2013 WL 5441355, at *3 (D. Mass. Sept. 27, 2013) (quoting *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 820 (Mass. 2002)). *See Knowlton v. Deseret Med., Inc.*, 930 F.2d 116, 120 n.12 (1st Cir. 1991); *Langlois*, 2020 WL 2616305, at *2 ("The learned intermediary rule . . . carves out a middleman exception in context of medical products.") (citing *Tersigni v. Wyeth-Ayerst Pharms., Inc.*, Civil Action No. 11-10466-RGS, 2013 WL 6531118, at *5 (D. Mass. Dec. 13, 2013)). "The justification for the doctrine is that

articulated in *Iqbal* and *Twombly*. For the reasons discussed herein, the First Amended Complaint in the instant case meets those criteria as to some claims, albeit barely.

'the prescribing physician, as the "learned intermediary" standing between the manufacturer and the consumer/patient, is generally in the best position to evaluate the potential risks and benefits of [the use of the product] and to advise the patient accordingly.'" *Tersigni,* 2013 WL 6531118, at *5 (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." *Id.* (citing *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 69 (Mass. 1985)).

"To determine whether a plaintiff can make a prima facie case of negligence despite imposition of the learned intermediary rule, courts uses a burden-shifting framework." *Langlois*, 2020 WL 2616305, at *2 (citing *Liu v. Boehringer Ingelheim Pharm., Inc.*, 230 F. Supp. 3d 3, 8 (D. Mass. 2017)). Under this framework,

> (1) 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; (2) assuming the plaintiff raises a triable issue on this question, a rebuttable presumption arises that the physician would have heeded an adequate warning; (3) defendant must then come forward with sufficient evidence to rebut that presumption; and (4) once the presumption is rebutted, plaintiff must produce sufficient evidence to create a triable issue on the question of causation.

Garside, 976 F.2d at 81 (citations omitted).

While recognizing that Plaintiff has not conducted discovery, he fails to offer any description of the warnings and instructions that Defendant provided or should have provided to his physician. His assertions that he "was not informed of and had no knowledge of the known complications and risks associated with the ePTFE mesh patch" and that the warnings and instructions were incorrect, inadequate, and incomplete are conclusory and insufficient to state a claim for negligent failure to warn even under the relatively lenient standard afforded to the

pleadings at this stage of the litigation (Dkt. No. 23 ¶¶ 25, 42). Consequently, so much of Count II as alleges negligent failure to warn is dismissed.

In summary, Defendant's motion to dismiss is denied as to so much of Count II as alleges negligent design and is allowed as to so much of Count II as alleges negligent failure to warn.

C. Count III: Strict Liability for Failure to Warn

Plaintiff's strict liability claim alleges that "the mesh product placed in [him] was unreasonably dangerous and defective and not reasonably safe for its intended or reasonably foreseeable purposes because it did not have correct, adequate and complete warnings and instructions issued in language that was direct, unequivocal and sufficiently forceful to adequately explain and warn of the hazards of the product or the way to use the product safely" (Dkt. No. 23 ¶ 42). Plaintiff further alleges that the inadequate warning was a "substantial factor" in causing his injuries (Dkt. No. 23 ¶ 43). Those claims lack the specificity necessary to survive the motion to dismiss.

As discussed earlier, "Massachusetts law on products liability derives from the law on implied warranties, as codified in the Uniform Commercial Code, Mass. G[en.] L[aws] c[h]. 106, §§ 2–314—2–318." *Mavilia v. Stoeger Indus.*, 574 F. Supp. 107, 109 (D. Mass. 1983). "There is no separate doctrine of strict products liability . . . " in Massachusetts. *Id.*

To the extent Plaintiff alleges that Defendant breached the implied warranty of merchantability for failing to warn of the foreseeable risks of implanting the Reconix ePTFE mesh patch, that claim overlaps as to all elements with the negligent failure to warn claim.

> The Supreme Judicial Court has effectively collapsed the two standards for negligence and breach of warranty where the plaintiffs' allegations are based upon a failure to warn, determining that "negligent failure to warn and failure to warn under breach of warranty are to be judged by the same standard: the reasonableness of the defendant's actions in the circumstances."

Calisi, 2013 WL 5441355, at *14 (quoting *Hoffman v. Houghton Chem. Corp.*, 751 N.E.2d 848, 859 (Mass. 2001)). *See Sprague*, 1995 WL 376934, at *3. Because the conclusory allegations in the First Amended Complaint are insufficient to allege a claim for negligent failure to warn and are dismissed, the claim for breach of the implied warranty based on defective warnings fails as well. *See Calisi*, 2013 WL 5441355, at *4; *Sprague*, 1995 WL 376934, at *3.

V. CONCLUSION

For the above-stated reasons, Defendant's Motion to Dismiss Plaintiff's Amended Complaint (Dkt. No. 26) is denied as to so much of Count I as alleges breach of the implied warranty of merchantability based on a design defect and as to so much of Count II as alleges negligent design. The motion is allowed as to all other claims.

It is so ordered.

Date: September 23, 2020

/s/ Katherine A. Robertson____
KATHERINE A. ROBERTSON
United States Magistrate Judge