**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| IN RE: COVIDIEN HERNIA MESH PRODUCTS LIABILITY LITIGATION NO. II, | MDL No. 22-md-03029-PBS |
| LARRY PATTERSON and TAMMY PATTERSON, Plaintiffs, v. COVIDIEN, INC., et al., Defendants. | Civil Action No. 22-cv-10153-PBS |

**MEMORANDUM AND ORDER**

June 2, 2026

Saris, J.

**INTRODUCTION**

This multidistrict litigation involves hernia mesh products manufactured by Defendants Covidien LP and Sofradim Production SAS (together, "Covidien"). In the first bellwether case, Plaintiff Larry Patterson ("Plaintiff") alleges that he was implanted with a Symbotex Composite Mesh ("Symbotex") during a 2017 hernia repair operation, that the Symbotex adhered to his bowel, and that these adhesions caused a bowel obstruction and hernia recurrence necessitating another operation in 2020. Plaintiff brings claims against Covidien under Alabama law, including under the Alabama

Extended Manufacturer's Liability Doctrine ("AEMLD"), "a judicially created accommodation of Alabama law to the doctrine of strict liability for damage or injuries caused by allegedly defective products," Keck v. Dryvit Sys., Inc., 830 So. 2d 1, 5 (Ala. 2002), as well as for negligence, negligent and fraudulent concealment and misrepresentation, and breach of warranty.[1]

Plaintiff's main theory of liability centers on Symbotex's porcine (i.e., from pigs) collagen barrier, which is meant to prevent the mesh from attaching to other organs and tissues in the abdomen during the initial stages of healing following a hernia repair. Plaintiff claims that this barrier could significantly, if not entirely, degrade within seven days of implantation, leaving the bowel exposed to Symbotex's inflammatory polyester material. In Plaintiff's view, this exposure triggers the formation of adhesions that may eventually cause various complications, such as a bowel obstruction and hernia recurrence. Plaintiff alleges that Symbotex is defectively designed for this reason and that Covidien failed to accurately warn about this dangerous feature of the product.

[1] The Court accepts the parties' reasonable agreement that Alabama law governs Plaintiff's claims because his hernia repair surgery and injuries occurred in the state. See Martins v. Vt. Mut. Ins. Co., 92 F.4th 325, 328 (1st Cir. 2024) (explaining that "'a federal court sitting in diversity is free, if it chooses, to forgo independent analysis and accept the parties' agreement' as to which state's law controls" (quoting Borden v. Paul Revere Life Ins. Co., 935 F.2d 370, 375 (1st Cir. 1991))).

Covidien has moved for summary judgment on Plaintiff's claims. After a hearing, rulings on certain motions pursuant to Federal Rule of Evidence 702, and a review of the record, the Court **DENIES IN PART** Covidien's motion for summary judgment (Dkt. 51) and otherwise **RESERVES** ruling on the motion.

## BACKGROUND

When evaluating a summary judgment motion, courts "construe the relevant facts in the light most favorable to the non-moving party." Deaton v. Town of Barrington, 100 F.4th 348, 353 (1st Cir. 2024). The following facts are undisputed except where otherwise noted.

### I. Symbotex

Symbotex is a surgical mesh manufactured and sold by Covidien. It is one of many surgical meshes on the market, which differ in material, construction, pore size, and other characteristics. Symbotex is made from a non-absorbable monofilament polyester textile. The mesh is implanted during a hernia repair to provide long-term reinforcement of the tissue, with the aim of preventing recurrence. The side of the mesh facing away from the reinforced tissue has an absorbable coating consisting of porcine collagen and glycerol. The purpose of this coating is to minimize tissue attachment to the mesh if the mesh comes into direct contact with other organs and tissues in the abdomen while the patient's peritoneum -- a cellular barrier -- regrows or "reperitonealizes."

Symbotex is a Class II medical device cleared by the FDA under the § 510(k) premarket notification process in August 2013. Under the § 510(k) process, the FDA may "'clear' a device that is substantially equivalent in safety and effectiveness to an existing [legally marketed] device and thereby allow the device to be used for the same intended purposes." Zhou v. Desktop Metal, Inc., 120 F.4th 278, 284 (1st Cir. 2024) (quoting Fire & Police Pension Ass'n of Colo. v. Abiomed, Inc., 778 F.3d 228, 232 (1st Cir. 2015)).[2] In its § 501(k) notification, Covidien listed as predicate devices various "Parietex"-brand meshes it also manufactures, including the Parietex Composite Mesh ("PCO") and the Parietex Optimized Composite Mesh ("PCOx"). Like Symbotex, both PCO and PCOx are polyester meshes with a porcine collagen

[2] "At least ninety days before introducing a new device to the market, a manufacturer seeking § 510(k) clearance must submit a premarket notification to the FDA." United States v. Facteau, 89 F.4th 1, 14 (1st Cir. 2023). This submission must disclose proposed labeling and marketing materials for the new device and provide data demonstrating substantial equivalence with the pre-existing device. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 345 (2001); Facteau, 89 F.4th at 14. "If the FDA concludes on the basis of the § 510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis." Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996). Unlike potentially more dangerous Class III devices subject to a more fulsome premarket approval process, "devices that enter the market through § 510(k) have 'never been formally reviewed . . . for safety or efficacy.'" Riegel v. Medtronic, Inc., 552 U.S. 312, 323 (2008) (quoting Lohr, 518 U.S. at 493).

barrier. The FDA determined that Symbotex was substantially equivalent to these predicate devices.

Symbotex's instructions for use ("IFU") state that the product "is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary abdominal wall and incisional hernia surgeries." Dkt. 54-16 at 2. According to the IFU, Symbotex's "absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera," and the "collagen film is essentially degraded in less than 1 month." Id. The IFU lists the "possible complications associated with" Symbotex as "seroma, hematoma, recurrence, adhesions, fistula formation, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product." Id. The IFU warns that "[p]otential events associated with state of the art mesh with similar indication may include: organ injury (including bowel and visceral injury), trocar-site herniation, bowel obstruction and urinary retention." Id.

Other Covidien marketing materials tout Symbotex's collagen barrier as well. Symbotex's Value Analysis Committee Product Information Kit ("vac pac"), for example, discusses animal studies purportedly showing that "[t]he anti-adhesion collagen barrier remained intact after 7 days" and "[s]mall bowel adhesion was never observed in all groups receiving the composite mesh." Dkt. 90-6 at MDT-MA-00921872. The vac pac also summarizes four clinical studies

examining Parietex meshes that were published between 2005 and 2010 to support the efficacy and safety of Symbotex.

Plaintiff's claims largely rest on evidence that Symbotex's porcine collagen barrier degrades more rapidly than the period of up to one month indicated on the IFU. In 2004, Covidien changed the composition of the barrier on PCO, a predicate device to Symbotex, from bovine (cow) to porcine (pig). Covidien conducted a rat study the prior year, "Study #12778," to test "the capability of the porcine collagen meshes to decrease the risk of visceral adhesion & erosion, in comparison to bovine collagen mesh." Dkt. 90-8 at MDT-MA-00464028. Study #12778 showed that "[a]t 7 days of implantation, the film resorption of [the] groups [implanted with porcine collagen mesh] is completed whereas it is starting for [the] group [implanted with bovine collagen mesh]." Id. at MDT-MA-00464034. The same study found "no difference in the cellular inflammatory reaction between the . . . groups" and no statistically significant difference in the occurrence of adhesions. Id. In November 2018, Covidien received a report of a patient who had his Symbotex explanted only three days post-surgery due to complications from the procedure. As part of its assessment of the report, Covidien identified that there was no "coating on about 80% of the mesh." Dkt. 90-22 at MDT-MA-08498467.

According to Covidien's chief scientist, Study #12778 demonstrated that "the barrier is not functioning . . . [a]fter

about a week," although he noted his belief that this was "over the critical time window for tissue attachment formation." Dkt. 90-21 at 7. The chief scientist also conceded that if "some bare parts of the mesh [are] exposed to the bowel during this critical time window," there is a "risk of more tissue attachment formation." Id. at 8. Covidien's senior director of clinical research indicated that adhesions could start within a few weeks of implantation "[i]f the coating is not doing its job." Dkt. 87-5 at 3.

In response, Covidien stresses clinical data that, in its view, demonstrates Symbotex's safety. For instance, Köckerling (2018) analyzed registry data one year post-surgery for patients who underwent elective hernia repairs. The study found a lower rate of hernia recurrence among the ninety-three patients who were implanted with Symbotex than among those who were implanted with any other mesh analyzed. Gillion (2019) followed one hundred patients who were implanted with Symbotex for two years post-surgery and observed only one recurrence. At the end of the two-year period, 87.1% of patients reported no pain or discomfort.

## II. Plaintiff's Surgery and Injuries

In March 2016, Plaintiff received a CT scan for abdominal pain and constipation, which revealed an umbilical hernia. On July 26, 2017, Plaintiff went to the emergency department with a bulged out hernia and moderate abdominal pain. The next day, Dr. Lucian

Newman III performed a laparoscopic repair of Plaintiff's hernia with a Symbotex mesh. During the operation, Dr. Newman used a bridging technique in which he brought the edges of the tissue closer together and then implanted the mesh to cover the remaining gap. Plaintiff had a history of diabetes and, at the time of his hernia repair, had a body mass index of around 30.

Dr. Newman's practice was to discuss the risks of the hernia repair surgery, including the possibility of bowel adhesions and recurrence, with his patients before conducting the surgery. Plaintiff signed a consent form indicating that Dr. Newman had informed him of the risks of the surgery.

Dr. Newman has performed at least one hundred hernia repairs using Symbotex. He is aware of the risks of the surgery, including obstructions. Dr. Newman has not read an IFU for any product in many years and has no memory of ever reviewing Symbotex's IFU. At his deposition, Dr. Newman stood by his decision to use Symbotex for Plaintiff's hernia repair surgery and testified that he did not believe Plaintiff's outcome would have differed with another mesh. In a supplemental declaration, however, Dr. Newman explained that his decision to use Symbotex for Plaintiff's surgery rested on his "belief that the absorbable collagen barrier would last long enough" -- up to thirty days -- "to protect the mesh from forming adhesions to the internal organs." Dkt. 95-12 ¶ 6. He added that he "relied upon the sales representatives from Covidien to

advise [him] about the unique characteristics of its products"; that "[n]o one from Covidien . . . ever informed [him] that the collagen barrier could be resorbed within seven days"; and that he would have used another mesh for Plaintiff's surgery "[h]ad [he] known . . . that the collagen barrier could be resorbed within seven days or anything substantially less than thirty days." Id. ¶ 9.

On July 1, 2020, Plaintiff sought emergency care for sharp, burning abdominal pain and nausea. He was diagnosed with a small bowel obstruction and an incarcerated hernia at the level of his umbilical hernia repair. Dr. Newman performed another surgery the next day to repair the recurrent hernia and bowel obstruction. In his operative report, Dr. Newman wrote that he found a "minimal/small hernia with bowel stuck and obstructed at level of old repair" and that he removed a "3[-]inch segment of bowel . . . at point of obstruction stuck tightly to old mesh." Dkt. 54-20 at 3.

## LEGAL STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A genuine dispute is one which 'a reasonable jury could resolve . . . in the favor of the non-moving party,' and a material issue is one with the 'potential to affect the outcome . . . under

the applicable law.'" Kinzer v. Whole Foods Mkt., Inc., 99 F.4th 105, 108 (1st Cir. 2024) (alterations in original) (quoting Cherkaoui v. City of Quincy, 877 F.3d 14, 23-24 (1st Cir. 2017)). In determining whether to grant summary judgment, a court must construe "the facts in the light most favorable to the non-moving party" and "draw[] all reasonable inferences" in his favor. Id. (quoting Harley-Davidson Credit Corp. v. Galvin, 807 F.3d 407, 408 (1st Cir. 2015)).

The party seeking summary judgment "must [first] adumbrate 'an absence of evidence to support the nonmoving party's case.'" Pleasantdale Condos., LLC v. Wakefield, 37 F.4th 728, 733 (1st Cir. 2022) (alteration in original) (quoting Brennan v. Hendrigan, 888 F.2d 189, 191 (1st Cir. 1989)). Once the movant does so, "[t]he burden then shifts to the nonmovant to establish the existence of a genuine issue of material fact." Id. To satisfy this burden, the nonmovant "must present definite, competent evidence" showing that a trialworthy issue exists. Id. (quoting Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991)). "[C]onclusory allegations, improbable inferences, and unsupported speculation" do not suffice. Kinzer, 99 F.4th at 108 (quoting Ellis v. Fid. Mgmt. Tr. Co., 883 F.3d 1, 7 (1st Cir. 2018)).

## DISCUSSION

Covidien asserts numerous independent grounds for summary judgment, which the Court addresses in turn.[3]

### I. Evidence of Specific Causation

Covidien first argues that it is entitled to summary judgment on all of Plaintiff's claims because Plaintiff lacks admissible expert evidence of specific causation, i.e., that any defect with respect to Symbotex caused his injuries. See Milward v. Acuity Specialty Prods. Grp., 639 F.3d 11, 13 (1st Cir. 2011) ("'Specific causation' exists when exposure to an agent caused a particular plaintiff's disease." (quoting Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 28 cmt. c(4) (A.L.I. 2010))). This argument is premised on Covidien's motion under Federal Rule of Evidence 702 to exclude the specific causation

[3] In its summary judgment briefing, Covidien refers to the causes of action and count numbers in Plaintiff's original complaint. The original complaint, however, was superseded by the master complaint in the multidistrict litigation and Plaintiff's short form complaint. See In re Covidien Hernia Mesh Prods. Liab. Litig. No. II, No. 22-md-03029 (Feb. 2, 2023), Dkt. 86 at 2 ("For each action in this [multidistrict litigation], the Master Complaint together with the Short Form Complaint shall be deemed the operative complaint."). The Court therefore refers to the causes of action and count numbers in the master and short form complaints.

Additionally, after Covidien moved for summary judgment, Plaintiff voluntarily dismissed his claims alleging a manufacturing defect under the AEMLD (Count III) and breach of express warranty (Count IX). The Court thus does not address Covidien's arguments about these claims.

opinions offered by Dr. Stephen Ferzoco, one of Plaintiff's expert witnesses. The Court has since denied Covidien's motion with respect to Dr. Ferzoco's specific causation opinions. See In re Covidien Hernia Mesh Prods. Liab. Litig. No. II, __ F. Supp. 3d __, __ (D. Mass. 2026) [2026 WL 1129617, at *12]. This argument for summary judgment therefore fails.

## II. Product Liability Claims

Plaintiff brings product liability claims under two theories: the AEMLD (Counts I and II) and negligence (Count IV). Under Alabama law, "a negligence claim is not subsumed by an AEMLD claim," DISA Indus., Inc. v. Bell, 272 So. 3d 142, 144 n.1 (Ala. 2018), as the two causes of action "have different eFINlements that must be proven," McMahon v. Yamaha Motor Corp., U.S.A., 95 So. 3d 769, 772 (Ala. 2012). Nonetheless, "there is . . a measure of commonality between those claims." Id.

In this case, Covidien advances its arguments for summary judgment on Plaintiff's product liability claims under the framework of the AEMLD and contends that those same grounds apply to the negligence claim. Plaintiffs do not argue in response that the AEMLD and negligence claims differ in any respect that is material to the arguments Covidien advances. Solely for purposes of this motion, then, the Court follows the parties' lead in

framing its analysis under the AEMLD and treats the AEMLD and negligence claims as coextensive.[4]

The AEMLD imposes liability on a defendant that "manufactures, designs, or sells an unreasonably dangerous product that reaches the consumer substantially unaltered and, because of its unreasonably dangerous condition, injures the consumer when put to its intended use." DISA Indus., 272 So. 3d at 149 (quoting Beam v. Tramco, Inc., 655 So. 2d 979, 981 (Ala. 1995)). A "defective product is one that is unreasonably dangerous, i.e., one that is not fit for its intended purpose or that does not meet the reasonable expectations of the ordinary consumer." Id. (quoting Beam, 655 So. 2d at 981). At this stage, there is no dispute that Covidien designed and sells Symbotex, that Dr. Newman implanted a Symbotex during Plaintiff's hernia repair surgery in accordance with its intended use, or that Plaintiff's Symbotex was substantially unaltered when it reached Plaintiff.

As relevant here, an AEMLD claim may rest on either a design defect, see Gen. Motors Corp. v. Jernigan, 883 So. 2d 646, 662 (Ala. 2003), or a failure to warn, see Turner v. Westhampton Ct.,

[4] Covidien contends that Plaintiff has waived his negligence claim by not addressing that claim in his opposition to its summary judgment motion. The Court disagrees. Plaintiff opposes the grounds on which Covidien seeks summary judgment on the AEMLD claims, which Covidien asserts also apply to the negligence claim. Covidien does not advance any basis for summary judgment that is specific to the negligence claim.

L.L.C., 903 So. 2d 82, 90 (Ala. 2004). Plaintiff presses both theories in this case.

**A. Design Defect**

Covidien moves for summary judgment on Plaintiff's design defect claims (Counts I and IV) on two grounds. First, Covidien argues that design defect claims concerning prescription medical devices like Symbotex are not cognizable under the AEMLD pursuant to the "unavoidably unsafe product" doctrine. Second, Covidien contends that Plaintiff has not offered sufficient evidence of a safer alternative design to Symbotex.

The "unavoidably unsafe product" doctrine derives from comment k to § 402A of the Restatement (Second) of Torts, which the Alabama Supreme Court has adopted for AEMLD claims. See Blackburn v. Shire U.S., Inc., 380 So. 3d 354, 362 (Ala. 2022); Purvis v. PPG Indus., Inc., 502 So. 2d 714, 718 (Ala. 1987); Stone v. Smith, Kline & French Lab'ys, 447 So. 2d 1301, 1303 (Ala. 1984). Comment k provides as follows:

> 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. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. 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 for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k (A.L.I. 1965).

Under this doctrine, "an unavoidably unsafe product, when properly prepared and accompanied by proper directions and warnings, is not 'defective' or 'unreasonably dangerous.'" Blackburn, 380 So. 3d at 362 (quoting Purvis, 502 So. 2d at 718). Put differently, "in the case of an 'unavoidably unsafe' yet properly prepared [product], the adequacy of the accompanying warning determines whether the [product], as marketed, is defective, or unreasonably dangerous." Stone, 447 So. 2d at 1304 (footnote omitted) (quoting Reyes v. Wyeth Lab'ys, 498 F.2d 1264, 1274 (5th Cir. 1974)); see Smith v. AngioDynamics, Inc., 731 F. Supp. 3d 1262, 1267 (M.D. Ala. 2024) (explaining that, when triggered, comment k "allow[s] only failure-to-warn claims in personal injury cases").

Comment k is most commonly applied to AEMLD claims involving prescription drugs, see, e.g., Tatum v. Schering Corp., 795 F.2d 925, 926 (11th Cir. 1986); Barnhill v. Teva Pharms. USA, Inc., 819

F. Supp. 2d 1254, 1260 (S.D. Ala. 2011); Stone, 447 So. 2d at 1303-04, but the Alabama Supreme Court has made clear that its application is not limited to such products, see Purvis, 502 So. 2d at 718 (applying the doctrine to a dry cleaning solvent). As relevant here, courts applying Alabama law have employed this doctrine in the context of prescription medical devices. See Smith, 731 F. Supp. 3d at 1268; Grubbs v. Medtronic, Inc., No. 18-cv-01468, 2019 WL 3288263, at *4 (N.D. Ala. July 22, 2019); Emody v. Medtronic, Inc., 238 F. Supp. 2d 1291, 1296 (N.D. Ala. 2003); Gunter v. Bos. Sci. Corp., No. N20C-11-032, 2021 WL 1921891, at *4 (Del. Super. Ct. May 12, 2021).

The parties dispute whether comment k applies categorically to all prescription medical devices, as Covidien argues, or whether a case-by-case analysis is required to determine if the specific medical device at issue is unavoidably unsafe, as Plaintiff posits. While the Alabama Supreme Court has used language suggesting that comment k may apply categorically to all prescription drugs, see, e.g., Stone, 447 So. 2d at 1303 ("Comment k provides for drugs and vaccines an exception to the strict liability defined in [§] 402A."), it has not addressed whether a categorical rule governs medical devices. Some courts applying Alabama law have employed comment k in the context of medical devices in a seemingly categorical manner, see, e.g., Grubbs, 2019 WL 3288263, at *4; Gunter, 2021 WL 1921891, at *4, while one has held that "the

applicability of [c]omment k to a medical device must be determined on a case-by-case basis," Smith, 731 F. Supp. 3d at 1268. Covidien relies heavily on Emody, which seemed to express agreement with the manufacturer's categorical argument that "prescription medical devices are unavoidably unsafe products" but then explained that the specific device at issue was "a prescription-only medical device that has an unavoidably unsafe characteristic." 238 F. Supp. 2d at 1296.

The majority of jurisdictions employ a case-by-case analysis to determine whether comment k applies to a specific medical device, see In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig., 888 F.3d 753, 772 (5th Cir. 2018); Transue v. Aesthetech Corp., 341 F.3d 911, 916 n.2 (9th Cir. 2003), including at least one jurisdiction that employs a categorical rule with respect to prescription drugs, see Burningham v. Wright Med. Tech., Inc., 448 P.3d 1283, 1287, 1290 (Utah 2019). Most courts also apply comment k to prescription drugs in a case-by-case manner. See Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 836 (Neb. 2000).

This Court's task as "a federal court sitting in diversity jurisdiction" is to "'"endeavor to predict how [Alabama's] highest court would" rule on the' state-law issue[] presented." Abdisalam v. Strategic Delivery Sols., LLC, 171 F.4th 30, 36 (1st Cir. 2026) (quoting Blakesley v. Marcus, 158 F.4th 90, 95 (1st Cir. 2025)). Given that the majority of jurisdictions apply comment

k to medical devices in a case-by-case manner, the Court predicts that the Alabama Supreme Court would follow this approach. See Vt. Mut. Ins. Co. v. Zamsky, 732 F.3d 37, 44 (1st Cir. 2013) (resting a prediction on how a state supreme court would rule in part on "the weight of authority elsewhere"). Categorically barring design defect claims under the AEMLD for medical devices would improperly "extend the reach of state law." Abdisalam, 171 F.4th at 36 (quoting Doe v. Trs. of Bos. Coll., 942 F.3d 527, 535 (1st Cir. 2019)). Moreover, the Court concludes that, as in most jurisdictions that have adopted a case-by-case approach to comment k, the Alabama Supreme Court would hold that the analysis presents a factual question for the jury to resolve unless the evidence supports only one reasonable determination on the issue. See, e.g., In re DePuy, 888 F.3d at 772 n.22; Huskey v. Ethicon, Inc., 848 F.3d 151, 158 (4th Cir. 2017); Burningham, 448 P.3d at 1290; Tansy v. Dacomed Corp., 890 P.2d 881, 886 (Okla. 1994); Castrignano v. E.R. Squibb & Sons, Inc., 546 A.2d 775, 782 (R.I. 1988); Ortho Pharm. Corp. v. Heath, 722 P.2d 410, 416 (Colo. 1986), overruled on other grounds by, Armentrout v. FMC Corp, 842 P.2d 175 (Colo. 1992). But see Johnson v. Am. Cyanamid Co., 718 P.2d 1318, 1323 (Kan. 1986) ("The trial judge should have heard the evidence on th[e comment k] issue outside the presence of the jury and made the determination thereon.").

Plaintiff argues that even if the jury finds that Symbotex falls within the ambit of comment k as "unavoidably unsafe," comment k does not bar a design defect claim if the seller does not adequately warn about the product's risks (which he asserts is the case here). In Plaintiff's view, the existence of adequate warnings is a condition for comment k to apply and bar a design defect claim for an "unavoidably unsafe" product. While some jurisdictions have adopted this view of the doctrine, see, e.g., Burningham, 448 P.3d at 1292; Taylor v. Intuitive Surgical, Inc., 389 P.3d 517, 528 (Wash. 2017); Tansy, 890 P.2d at 886, the Alabama Supreme Court has not. Rather, under Alabama law, "in the case of an 'unavoidably unsafe' yet properly prepared [product], the adequacy of the accompanying warning determines whether the [product], as marketed, is defective, or unreasonably dangerous." Stone, 447 So. 2d at 1304 (footnote omitted) (quoting Reyes, 498 F.2d at 1274). In other words, comment k, when triggered, "allow[s] only failure-to-warn claims in personal injury cases." Smith, 731 F. Supp. 3d at 1267; see McDaniel v. Mylan, Inc., No. 19-cv-00209, 2019 WL 11638407, at *5 (N.D. Ala. Dec. 16, 2019) (explaining that, under comment k, "no AEMLD design defect claim for prescription drugs exists apart from a challenge to the adequacy of the warning" (quoting Barcal v. EMD Serono, Inc., No. 14-cv-01709, 2016 WL 1086028, at *3 (N.D. Ala. Mar. 21, 2016))).

The next step of the analysis is evaluating Covidien's contention that Plaintiff has failed to set forth sufficient evidence of a safer alternative design. To demonstrate that a product is defective under the AEMLD based on a design defect, a plaintiff must show "that a safer, practical, alternative design was available to the manufacturer at the time it manufactured the allegedly defective product." Hosford v. BRK Brands, Inc., 223 So. 3d 199, 203 (Ala. 2016) (quoting McMahon, 95 So. 3d at 772). "The existence of a safer, practical, alternative design may, in turn, be established by showing (1) that the injuries inflicted by the product would have been less severe or eliminated by the use of the alternative design and (2) that the utility of the alternative design outweighed the utility of the design actually used." Id. The existence of a safer alternative design for Symbotex and the utility and risk of any alternative design bear not only on this requirement for a design defect claim but also on whether Symbotex is an "unavoidably unsafe" product. See, e.g., Burningham, 448 P.3d at 1292 (explaining that the comment k inquiry asks whether "(1) when the product was made, it could not be made safe for its intended use even applying the best available testing and research, and (2) the benefits of the product justified its risk"); Freeman, 618 N.W.2d at 837 (describing "the trend toward the use of a risk-utility test" to determine whether comment k applies, under which

"the existence of a reasonable alternative design is generally the central factor").

In opposing Covidien's summary judgment motion, Plaintiff points to the safer alternative design opinions offered by Dr. Ferzoco, one of his expert witnesses. Dr. Ferzoco's expert report opines that there are two safer alternative designs: (1) a lighter-weight, bare polypropylene mesh placed in the retro rectus space and (2) Ventralight ST. The Court has, however, excluded these safer alternative design opinions under Rule 702. See In re Covidien, __ F. Supp. 3d at __ [2026 WL 1129617, at *13].

Following that ruling, Plaintiff submitted an affidavit from Dr. Ferzoco stating that he is also of the opinion that "a version of Symbotex mesh that uses the earlier bovine collagen-based film" would be a safer alternative design. Dkt. 186-25 ¶ 6. While Dr. Ferzoco's expert report discusses Covidien's switch from bovine collagen to porcine collagen for certain hernia meshes, it does not expressly opine that a version of Symbotex with the bovine collagen barrier is a safer alternative design. Covidien subsequently filed a motion to strike Dr. Ferzoco's affidavit and exclude his opinion regarding the bovine collagen barrier, which remains pending. Because that motion may be dispositive of Plaintiff's design defect claims, the Court reserves ruling on Covidien's summary judgment motion with respect to those claims.

**B. Failure to Warn**

Covidien also requests summary judgment on Plaintiff's failure-to-warn claims (Count II and IV). To succeed on a failure-to-warn claim under the AEMLD, a plaintiff must demonstrate that "(1) the defendant had a duty to warn the plaintiff regarding the danger when the product is used in its intended or customary manner, (2) the warning the defendant[] provided breached that duty because it was inadequate, and (3) the breach proximately caused the plaintiff's injuries." Reed v. Tracker Marine, LLC, 574 F. Supp. 3d 1065, 1091-92 (N.D. Ala. 2021) (quoting Jackson v. E & R Mfg. Co., No. 06-cv-412, 2007 WL 2806831, at *6 (M.D. Ala. Sep. 25, 2007)). Covidien contends that no reasonable jury could find it liable for failure to warn because Symbotex's IFU expressly warned of the specific injuries Plaintiff suffered. Covidien also argues that Plaintiff has not offered sufficient evidence of proximate causation, as Dr. Newman both chose to use Symbotex for Plaintiff's hernia repair despite independently knowing of the risks of the injuries Plaintiff suffered and did not read Symbotex's IFU or any other warnings.

Under Alabama law, a "manufacturer is under a duty to warn users of the dangerous propensities of a product . . . when such products are dangerous when put to their intended use." Gurley ex rel. Gurley v. Am. Honda Motor Co., 505 So. 2d 358, 361 (Ala. 1987). "Where a warning is necessary, the warning need only be one

that is reasonable under the circumstances and it need not be the best possible warning." Id. Moreover, a manufacturer has "no duty to warn of every potential danger or to explain the scientific rationale for each warning, but only a duty to warn of those dangers which the owner or user would not be aware of under the particular circumstances of his use of the product in question." Id. The adequacy of any warnings given is a question of fact for the jury. See Toole v. McClintock, 999 F.2d 1430, 1433 (11th Cir. 1993); Hicks v. Com. Union Ins. Co., 652 So. 2d 211, 217 (Ala. 1994) (per curiam); State Farm Fire & Cas. Co. v. J.B. Plastics, Inc., 505 So. 2d 1223, 1227 (Ala. 1987).

In cases involving prescription medical products, the manufacturer's "duty to warn is filtered through the 'learned-intermediary doctrine.'" Blackburn, 380 So. 3d at 358; see Morguson v. 3M Co., 857 So. 2d 796, 801-02 (Ala. 2003) (applying this doctrine to an AEMLD claim involving a medical device). Under this doctrine, the "manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries [i.e., physicians] who prescribe the drug" or device. Blackburn, 380 So. 3d at 360 (quoting Wyeth, Inc. v. Weeks, 159 So. 3d 649, 673 (Ala. 2014)). The manufacturer need not "warn the patient directly." Id. (quoting Wyeth, 159 So. 3d at 673). But "if the warning to the learned intermediary is inadequate or misrepresents the risk, the

manufacturer remains liable for the injuries sustained by the patient." Id. (quoting Wyeth, 159 So. 3d at 673). Thus, to succeed on a failure-to-warn claim in this context, the "patient must show that the manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury." Id. (emphasis omitted) (quoting Wyeth, 159 So. 3d at 673).

Plaintiff has offered sufficient evidence for a reasonable jury to conclude that Covidien failed to adequately warn about Symbotex's dangers. Symbotex's IFU states that "the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera" and that the "collagen film is essentially degraded in less than 1 month." Dkt. 54-16 at 2. Covidien trained its sales representatives that Symbotex's collagen barrier "completely resorb[s]" in "30 [d]ays." Dkt. 95-16 at 5. And Symbotex's vac pac discusses animal studies purportedly showing that "[t]he anti-adhesion collagen barrier remained intact after 7 days." Dkt. 90-6 at MDT-MA-00921872. Plaintiff asserts that these warnings and marketing representations are inadequate, and even outright false, because Symbotex's barrier actually resorbs within seven days before reperitonealization is complete and, thus, fails to prevent the formation of adhesions (which, in turn, may cause a bowel obstruction and/or hernia recurrence). Although Covidien disputes

the merits of Plaintiff's theory, Covidien does not argue that no reasonable jury could find that the collagen barrier degrades prematurely and in significantly less than one month. If the jury so concludes, it could also supportably find that Symbotex's IFU and Covidien's marketing statements affirmatively misrepresent both the ability of the collagen barrier to prevent adhesions and the resulting risk of adhesion formation and related complications. See Blackburn, 380 So. 3d at 360 ("[I]f the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient." (quoting Wyeth, 159 So. 3d at 673)).

Covidien counters that it did adequately warn about the specific injuries Plaintiff suffered, as the IFU states that the "possible complications associated with" Symbotex and other meshes include "recurrence, adhesions," and "bowel obstruction." Dkt. 54-16 at 2. Covidien thus argues that Plaintiff is merely quibbling with the specific language of its warning rather than asserting a triable claim that it failed to adequately warn about certain risks. Yet for the reasons just discussed, the record supports a reasonable conclusion that Covidien's warnings and marketing statements affirmatively misrepresented Symbotex's characteristics and resulting risks. Moreover, the Alabama Supreme Court has rejected the notion that a manufacturer necessarily satisfies its duty to warn by listing the known side effects or

complications of a medical product. See Blackburn 380 So. 3d at 362; see also id. at 365 (holding that "a failure-to-warn claim may include allegations of inadequate instructions about how to mitigate warned-of risks"). Rather, such a warning may be inadequate if it fails to "inform[] a physician about the degree of danger associated with a particular side effect." Id. at 362. In this case, a jury could reasonably find that the generic warnings about adhesions, bowel obstructions, and recurrences were inadequate because they did not apprise physicians about the heightened risk of complications based on the premature resorption of the collagen barrier.

The Court is also unpersuaded by Covidien's contention that any inadequacy in its warnings did not proximately cause Plaintiff's injuries as a matter of law. See id. at 360 (requiring that a plaintiff prove "that the failure to warn was the actual and proximate cause of [his] injury" (emphasis omitted) (quoting Wyeth, 159 So. 3d at 673)). To make the required showing of causation, Plaintiff must establish that giving an adequate warning "would have altered the prescribing physician's conduct in a way that would have prevented [his] injury." Blackburn v. Shire US Inc., 18 F.4th 1310, 1318 (11th Cir. 2021) (applying Alabama law). As such, Plaintiff "must demonstrate that, had [Covidien] given an adequate warning, it would have been read and heeded by the prescribing physician[]." Barnhill, 819 F. Supp. 2d at 1261

(second alteration in original) (quoting Brasher v. Sandoz Pharms. Corp., No. cv-98-TMP-2648, 2001 WL 36403362, at *13 (N.D. Ala. Sep. 21, 2001)); see Deere & Co. v. Grose, 586 So. 2d 196, 198 (Ala. 1991) (explaining that a failure-to-warn claim requires "evidence that an adequate warning would have been read and heeded and would have prevented the accident"). And under Alabama law, "a plaintiff who does not read an allegedly inadequate warning cannot" establish proximate causation for a failure-to-warn claim, "unless the nature of the alleged inadequacy is such that it prevents him from reading it." Clarke Indus., Inc. v. Home Indem. Co., 591 So. 2d 458, 461 (Ala. 1991) (quoting E.R. Squibb & Sons, Inc. v. Cox, 477 So. 2d 963, 971 (Ala. 1985) (per curiam)); see Jones v. Coty Inc., 362 F. Supp. 3d 1182, 1214-15 (S.D. Ala. 2018); Chase v. Kawasaki Motors Corp., U.S.A., 140 F. Supp. 2d 1280, 1287-88 (M.D. Ala. 2001); Kelly v. M. Trigg Enters., Inc., 605 So. 2d 1185, 1192 (Ala. 1992) (per curiam).

While Dr. Newman did not testify that he read the warnings in the IFU, the Court concludes that a reasonable jury could find that the inadequate warnings by Covidien's sales representatives proximately caused Plaintiff's injuries. As Covidien stresses, Dr. Newman testified during his deposition both that he has no recollection of ever reading Symbotex's IFU and that he stood by his decision to use a Symbotex mesh for Plaintiff's hernia repair surgery. But Plaintiff submitted a supplemental declaration from

Dr. Newman in which he explained his belief that Symbotex's barrier lasted up to thirty days.[5] The record also reflects that William Flowers, a Covidien sales representative, targeted Dr. Newman as a potential Symbotex customer starting in 2015, had contact with Dr. Newman on multiple occasions over the following year, and secured a large order of Symbotex meshes from Dr. Newman's hospital in 2016. Given that Covidien's sales representatives were trained that Symbotex's collagen barrier lasts up to thirty days and that Covidien's marketing materials for Symbotex emphasize the collagen barrier and the product's ability to prevent adhesions, a reasonable jury could infer that Dr. Newman was exposed to Covidien's representations about the duration of the collagen barrier via Flowers or marketing materials provided by him.

Moreover, Dr. Newman's supplemental declaration stated that his decision to use Symbotex for Plaintiff's surgery rested on his "belief that the absorbable collagen barrier would last long enough to protect the mesh from forming adhesions to the internal organs"; that he "relied upon the sales representatives from Covidien to advise [him] about the unique characteristics of its products"; that "[n]o one from Covidien . . . ever informed [him] that the collagen barrier could be resorbed within seven days"; and that he

[5] Covidien moved to strike Dr. Newman's supplemental declaration, which the Court denied. See In re Covidien Hernia Mesh Prods. Liab. Litig. No. II, No. 22-md-03029, 2026 WL 538604, at *2 (D. Mass. Feb. 26, 2026).

would have used another mesh for Plaintiff's surgery "[h]ad [he] known . . . that the collagen barrier could be resorbed within seven days or anything substantially less than thirty days." Dkt. 95-12 ¶¶ 6, 9. From this evidence, a jury could reasonably conclude that Dr. Newman would not have used a Symbotex mesh for Plaintiff's surgery had he received adequate warnings from Covidien's sales representatives about the premature resorption of the collagen barrier and the degree of the risks of adhesions and resulting complications.

Covidien contends that any inadequacy in its warnings did not cause Plaintiff's injuries because Dr. Newman had independent knowledge of the risks of the injuries Plaintiff suffered. It is true that a plaintiff cannot prove proximate causation when the physician was independently aware of the risks about which the manufacturer failed to adequately warn and nonetheless decided to prescribe or use the product. See Bodie v. Purdue Pharma Co., 236 F. App'x 511, 521 (11th Cir. 2007); Woods v. Wyeth, Inc., No. 13-cv-543, 2016 WL 1719550, at *9 (N.D. Ala. Apr. 29, 2016). But although Dr. Newman testified that he was generally aware of the risks of the injuries Plaintiff suffered, he stated in his supplemental declaration that he believed that Symbotex's collagen barrier lasted up to thirty days, which was necessary to protect the mesh from forming adhesions, and that he did not learn that the barrier could resorb within seven days from any source

independent of Covidien. This testimony provides a reasonable basis for a jury to find that Dr. Newman did not know about the magnitude of the risks of adhesions and resulting complications that Plaintiff alleges Symbotex poses.

Accordingly, the Court denies Covidien's motion for summary judgment with respect to Plaintiff's failure-to-warn claims.

**III. Fraud Claims**

Plaintiff brings three claims that sound in fraud: negligent misrepresentation (Count XII), fraud and fraudulent misrepresentation (Count XIII), and fraudulent concealment (Count XIV). In seeking summary judgment on these claims, Covidien recycles similar arguments to the ones it advances with respect to the failure-to-warn claims. Covidien asserts that (1) it made no misrepresentation or omission because it adequately warned of the injuries Plaintiff suffered, (2) Dr. Newman did not reasonably rely on any misrepresentation or omission because he did not review Symbotex's IFU, and (3) any misrepresentation or omission did not proximately cause Plaintiff's injuries because Dr. Newman did not read the IFU and independently knew of the risks of the injuries Plaintiff suffered. See Brickhouse Cap., LLC v. Coastal Cryo AL, LLC, 393 So. 3d 467, 473 (Ala. 2023) (explaining that the elements

of fraud under Alabama law include a false representation or omission, reasonable reliance, and proximate causation).[6]

The Court rejects these arguments for the reasons discussed above with respect to Plaintiff's failure-to-warn claims. Plaintiff has offered sufficient evidence to support reasonable findings that Covidien misrepresented the resorption period of Symbotex's collagen barrier, that Dr. Newman relied on misrepresentations and omissions on this topic from Covidien sales representatives or marketing materials in deciding to use Symbotex, and that Dr. Newman would not have used Symbotex for Plaintiff's surgery had he known about the barrier's allegedly premature resorption. Covidien is therefore not entitled to summary judgment on Plaintiff's fraud claims.

## IV. Breach of Implied Warranty

Covidien next seeks summary judgment on Plaintiff's claim alleging breach of the implied warranty of merchantability under the Uniform Commercial Code (Count VIII). Covidien first argues that Plaintiff did not provide Covidien with the pre-suit notice

[6] Courts applying Alabama law have employed the learned intermediary doctrine in the context of fraud claims involving prescription medical products. See, e.g., Russell v. Ethicon Inc., No. 20-cv-00752, 2020 WL 4732106, at *6-7 (N.D. Ala. Aug. 14, 2020); Aldridge v. Ethicon, Inc., No. 20-cv-0039, 2020 WL 1308335, at *4-5 (S.D. Ala. Mar. 19, 2020); Southern v. Pfizer, Inc., 471 F. Supp. 2d 1207, 1217-18 (N.D. Ala. 2006); Wyeth, 159 So. 3d at 655-56, 672-74. Plaintiff does not dispute the applicability of the learned intermediary doctrine to his fraud and misrepresentation claims in this case.

required to bring a breach of warranty claim under Alabama law. Before suing for breach of warranty, a plaintiff generally "must within a reasonable time after he discovers or should have discovered any breach notify the seller of [the] breach." Ala. Code § 7-2-607(3)(a); see Morris v. AngioDynamics, Inc., 716 F. Supp. 3d 1205, 1210 (M.D. Ala. 2024); Parker v. Bell Ford, Inc., 425 So. 2d 1101, 1102 (Ala. 1983). While Plaintiff appears to concede that pre-suit notice was required in this case, the Alabama Supreme Court has held that a third-party warranty beneficiary alleging personal injury need not provide notice before bringing suit. See Simmons v. Clemco Indus., 368 So. 2d 509, 513-15 (Ala. 1979); see also In re 3M Combat Arms Earplug Prods. Liab. Litig., 679 F. Supp. 3d 1314, 1324-25 (N.D. Fla. 2023) (applying Alabama law); Hobbs v. Gen. Motors Corp., 134 F. Supp. 2d 1277, 1283 (M.D. Ala. 2001).

In any event, assuming Plaintiff was required to give pre-suit notice to Covidien, he did so. The notice required by Alabama law must come from the plaintiff specifically; "a general awareness on [the defendant]'s part of alleged defects in its [product]" from other consumers' complaints or litigation does not suffice. Smith v. Apple, Inc., No. 08-AR-1498, 2009 WL 3958096, at *2 (N.D. Ala. Nov. 4, 2009); see Carter v. L'Oreal USA, Inc., No. 16-cv-508, 2019 WL 4786949, at *9 (S.D. Ala. Sep. 30, 2019). But the "notification which saves the [plaintiff]'s rights . . . need only

be such as informs the seller that the transaction is claimed to involve a breach, and thus opens the way for normal settlement through negotiation." Jewell v. Seaboard Indus., Inc., 667 So. 2d 653, 660 (Ala. 1995) (quoting Ala. Code § 7-2-607 cmt. 4). Whether notice was sufficient "must be tested in light of the facts of the particular case." Id. (quoting Page v. Camper City & Mobile Home Sales, 297 So. 2d 810, 812 (Ala. 1974)).

On September 28, 2021, four months before Plaintiff filed suit, his counsel notified Covidien's counsel via email that Plaintiff was being added to a tolling agreement. Plaintiff's counsel informed Covidien that Plaintiff had been implanted with a Symbotex in July 2017 and described his injuries. This email adequately put Covidien on notice that Plaintiff believed there was a defect with his Symbotex and "open[ed] the way for normal settlement through negotiation." Id. (quoting Ala. Code § 7-2-607 cmt. 4). Covidien argues that this email was insufficient because it did not specifically mention a breach of warranty claim, but it cites no authority imposing such a requirement when a plaintiff otherwise provides notice to the defendant of problems with the product at issue. Nor does Covidien argue that this notice, even if substantively adequate, did not come "within a reasonable time after [Plaintiff] discover[ed] or should have discovered any breach." Ala. Code § 7-2-607(3)(a).

Covidien also contends that it is entitled to summary judgment on the breach of implied warranty claim because the claim is subsumed by Plaintiff's AEMLD claims and because Plaintiff has not offered sufficient evidence that Symbotex is not fit for its intended purpose. The Alabama Supreme Court has made clear that a "breach-of-warranty claim . . . is 'separate and distinct from an AEMLD claim.'" Ex parte Integra LifeSciences Corp., 271 So. 3d 814, 820 (Ala. 2018) (quoting Spain v. Brown & Williamson Tobacco Corp., 872 So. 2d 101, 111 (Ala. 2003) (per curiam)). A plaintiff may maintain a claim for breach of the implied warranty of merchantability separate from an AEMLD if he offers sufficient evidence that the product is not "fit for the ordinary purposes for which [the product is] used." Ala. Code § 7-2-314(2)(c); see Garrison v. Sturm, Ruger & Co., 322 F. Supp. 3d 1217, 1234 (N.D. Ala. 2018); Spain, 872 So. 2d at 109-11. Thus, "when the evidence shows that the product is so unreasonably dangerous that it is not fit for its intended use, i.e., it is not a merchantable product, both AEMLD and warranty claims remain viable." Garrison, 322 F. Supp. 3d at 1234. But Alabama law "subsume[s] . . . breach of implied warranty claims into tort and product liability claims[] where the product is fit for its intended use and there is no evidence of 'non-merchantability' other than a general allegation that the product contains inherent dangers." Bodie, 236 F. App'x at 523; see Darnell v. Yamaha Motor Corp., USA, 476 F. Supp. 3d

1170, 1180-81 (N.D. Ala. 2020); Garrison, 322 F. Supp. 3d at 1234. Courts applying Alabama law have therefore rejected breach of warranty claims concerning a prescription drug where the drug achieved its intended function but had other effects that the plaintiff alleged made the drug unreasonably dangerous. See Bodie, 236 F. App'x at 524; Houston v. Bayer Healthcare Pharms., Inc., 16 F. Supp. 3d 1341, 1347 (N.D. Ala. 2014).

Plaintiff may proceed to trial on a claim alleging breach of the implied warranty that is not subsumed by his AEMLD claim. Plaintiff has provided sufficient evidence for a reasonable jury to conclude that Symbotex's collagen barrier degrades prematurely. And Plaintiff offers admissible expert testimony from Dr. Ferzoco that the barrier's premature resorption, along with the underlying polyester material, may cause, among other injuries, a hernia recurrence and did so in this case. If the jury credits Dr. Ferzoco's causation opinions, the jury could also reasonably find that Symbotex is not "fit for the ordinary purposes for which [it is] used," Ala. Code § 7-2-314(2)(c), i.e., that Symbotex does not adequately perform its intended function of reinforcing the tissue and preventing recurrence. Covidien responds that clinical data show that Symbotex is safe and effective and has similar or better clinical outcomes compared to other hernia meshes. Yet, as this Court indicated in rejecting Covidien's Rule 702 challenge to Dr. Ferzoco's general causation opinions, Symbotex's safety and

efficacy present a factual question for the jury to resolve. See In re Covidien, __ F. Supp. 3d at __ [2026 WL 1129617, at *9]. Because the record supports a reasonable finding that Symbotex is not fit for its ordinary purposes, the Court denies Covidien's motion for summary judgment with respect to Plaintiff's claim for breach of the implied warranty.

## V. Loss of Consortium

Covidien also argues that summary judgment is warranted in its favor on Plaintiff Tammy Patterson's loss-of-consortium claim (Count XVI) because none of Plaintiff's claims survive summary judgment. See Flying J Fish Farm v. Peoples Bank of Greensboro, 12 So. 3d 1185, 1196 (Ala. 2008) (explaining that a "loss-of-consortium claim is derivative of the claims of the injured spouse" such that the "loss-of-consortium claim must fail if [the injured spouse]'s claims fail"). As the Court denies Covidien's summary judgment motion on a number of Plaintiff's claims, the loss-of-consortium claim survives as well.

## VI. Punitive Damages

Lastly, Covidien seeks summary judgment on Plaintiff's count for punitive damages (Count XVII). Under Alabama law, punitive damages are authorized "in a tort action where it is proven by clear and convincing evidence that the defendant consciously or deliberately engaged in oppression, fraud, wantonness, or malice with regard to the plaintiff." Ala. Code § 6-11-20(a). "Clear and

convincing evidence" means "[e]vidence that, when weighed against evidence in opposition, will produce in the mind of the trier of fact a firm conviction as to each essential element of the claim and a high probability as to the correctness of the conclusion." Id. § 6-11-20(b)(4). Here, Plaintiff asserts that the record contains sufficient evidence for a reasonable jury to find by clear and convincing evidence that Covidien acted wantonly. The Court agrees.

"Wantonness" refers to "[c]onduct which is carried on with a reckless or conscious disregard of the rights or safety of others." Id. § 6-11-20(b)(3). It involves "the conscious doing of some act or the omission of some duty while knowing of the existing conditions and being conscious that, from doing or omitting to do an act, injury will likely or probably result." Tutor v. Sines, 380 So. 3d 1035, 1038 (Ala. 2023) (quoting Lands v. Ward, 349 So. 3d 219, 229 (Ala. 2021)). "The knowledge of the defendant is the sine qua non of wantonness." Mazda Motor Corp. v. Hurst, 261 So. 3d 167, 189 (Ala. 2017) (quoting McMahon, 95 So. 3d at 773). It "is not essential," however, "to prove that the defendant entertained a specific design or intent to injure the plaintiff." Imperial Aluminum-Scottsboro, LLC v. Taylor, 295 So. 3d 51, 65 (Ala. 2019) (quoting Alfa Mut. Ins. Co. v. Roush, 723 So. 2d 1250, 1256 (Ala. 1998) (per curiam)).

Plaintiff has offered sufficient evidence that Covidien wantonly failed to adequately warn about Symbotex's risks. Symbotex's IFU represented that the collagen barrier lasts up to one month, and Covidien trained its sales representatives on this fact. Although the duration of the barrier is a disputed issue, certain internal Covidien documents reflect that the barrier may degrade in a significantly shorter period of time. Moreover, multiple senior research employees at Covidien testified to understanding that exposing a bare mesh to adjacent tissue and organs creates a risk of adhesions and bowel obstructions, that it is therefore important to have an effective barrier on the mesh, and/or that Symbotex's collagen barrier rapidly degrades. From these facts, a reasonable jury could conclude by clear and convincing evidence that Covidien knowingly misrepresented the duration of the collagen barrier and the degree of risk of using Symbotex with awareness that the product could cause injuries of the sort Plaintiff suffered.[7]

**VII. Remaining Claims**

Plaintiff's remaining claims allege negligence per se (Count V), gross negligence (Count VI), and negligent and intentional

[7] The Court does not address Plaintiff's argument in favor of punitive damages based on the opinions of Madris Kinard, one of his experts, about Covidien's handling of reports regarding complications involving Symbotex. Covidien's Rule 702 motion with respect to Kinard's testimony remains under advisement.

infliction of emotional distress (Counts X and XI). Except for the argument that all of Plaintiff's claims fail for lack of admissible expert testimony on specific causation -- which the Court has already rejected, see supra Section I -- Covidien does not advance any grounds for awarding summary judgment in its favor on these four remaining claims. Covidien is therefore not entitled to summary judgment on these claims.

**ORDER**

For the foregoing reasons, Covidien's motion for summary judgment (Dkt. 51) is **DENIED** with respect to Plaintiff's claims alleging failure to warn under the AEMLD (Count II), negligence premised on a failure to warn (Count IV), negligence per se (Count V), gross negligence (Count VI), breach of the implied warranty of merchantability (Count VIII), negligent infliction of emotional distress (Count X), intentional infliction of emotional distress (Count XI), negligent misrepresentation (Count XII), fraud and fraudulent misrepresentation (Count XIII), fraudulent concealment (Count XIV), loss of consortium (Count XVI), and punitive damages (Count XVII). The Court **RESERVES** ruling on Covidien's motion with respect to Plaintiff's claims alleging a design defect under the AEMLD (Count I) and negligence premised on a design defect (Count IV).

SO ORDERED.

/s/ PATTI B. SARIS
Hon. Patti B. Saris
United States District Judge