IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF GEORGIA SAVANNAH DIVISION

BETTY C. FIELDS,

Plaintiff,

CIVIL ACTION NO.: 4:21-cv-00020

v.

ETHICON, INC., and JOHNSON & JOHNSON,

Defendants.

ORDER

Presently before the Court is Defendants Ethicon, Inc., and Johnson & Johnson's (collectively "Defendants") Motion for Partial Summary Judgment. (Doc. 99). This case originated in the United States District Court for the Southern District of West Virginia as part of multi-district ligation ("MDL") No. 2327. (See doc. 1 ("Short Form Complaint").) Plaintiff Betty Fields is one of thousands who alleged injury after being implanted with pelvic mesh products designed, manufactured, and sold by Defendants. (See generally docs. 1, 238 ("First Amended Master Long Form Complaint").) The case was transferred to this Court on January 26, 2021. (See docs. 86, 87.) After the parties completed discovery, Defendants filed the at-issue Motion for Partial Summary Judgment on Plaintiff's failure to warn claims (Counts I and III) and on Plaintiff's claim for "strict liability—defective product" (Count IV). (Doc. 99.) Defendants argue, inter alia, that Plaintiff cannot carry her burden on these claims because she has failed to demonstrate that Defendants' failure to warn caused her injuries, and because "defective product" is not a cognizable products liability claim under Georgia law. (Doc. 99.) The Motion has been

fully briefed. (See id.; docs. 102, 106.) For the reasons stated below, the Court **GRANTS in part** and **DENIES in part** Defendants' Motion. (Doc. 99.)

BACKGROUND

I. Factual Background

On December 14, 2006, Plaintiff Betty Fields went to her ob/gyn, Dr. Alan Smith. (Doc. 99-1, p. 1; doc. 102-1, p. 1; see doc. 99-3, p. 11.) At the time of Plaintiff's visit, Dr. Smith had been practicing as an ob/gyn and performing pelvic surgeries for ten years. (Doc. 99-1, p. 2; doc. 102-1, p. 3.) During this visit, Plaintiff reported problems with urine leakage and bowel elimination. (Doc. 99-1, p. 1; doc. 102-1, p. 1; see doc. 99-3, p. 11.) Dr. Smith thereafter evaluated Plaintiff and found, upon a vaginal exam, that she had "a mild rectocele," and, upon a rectal exam, a "more significant" rectocele. (Doc. 99-3, p. 11.) As a result, Dr. Smith believed her to have "symptomatic pelvic prolapse." (Id. at p. 12.) Dr. Smith decided to perform a rectocele repair using mesh to treat Plaintiff's pelvic organ prolapse. (Doc. 99-1, p. 2; doc. 102-1, p. 3.) Dr. Smith performed this implantation surgery using Ethicon's Gynemesh PS ("Gynemesh"), which is a type of mesh implant, on February 6, 2007. (Doc. 99-1, p. 2; doc. 102-1, p. 2; see doc. 99-3, p. 14.)

At his deposition, Dr. Smith testified that he was aware of the common risks that any pelvic floor surgery poses, regardless of whether the procedure uses mesh or not. (Doc. 99-1, p. 2; doc. 102-1, p. 3; see doc. 99-3, pp. 8-9.)¹ However, he additionally testified that it was his

Plaintiff, in her response to Defendant's Statement of Material Facts, claims, at various points, that a particular fact is disputed, without pointing to any evidence or record cites to rebut the factual allegation and by simply stating that Defendants' "attempt to paraphrase or characterize select portions of . . . Dr. Smith's testimony is improper." (See doc 102-1, pp. 2–3.) However, "[a] party asserting that a fact . . . is genuinely disputed must support the assertion by . . . citing to particular parts of materials in the record . . . or . . . showing that the materials cited do not establish the . . . presence of a genuine dispute" Fed. R. Civ. P. 56(c). As Plaintiff has failed to support her contentions of disputed facts with any supporting record citations, the Court may deem the given factual allegation undisputed for purposes of this Motion. See Fed. R. Civ. P. 56(e) ("If a party fails to properly support an assertion of fact . . . as required by Rule 56(c), the court may . . . consider the fact undisputed for purposes of the motion").

understanding at the time of his recommendation that mesh repairs generally have a lower failure rate than traditional repairs—which he understood to have a failure rate of around 25 to 30 percent. (Doc. 99-1, p. 3; see doc. 99-3, pp. 12–13.) He was additionally aware of certain risks that mesh implants, like Gynemesh, pose, including acute or chronic pain, infection, bleeding, wound complications, inflammation, and a need for surgeries to treat a potential adverse event. (Doc. 99-1, p. 4; see also doc. 99-3, p. 22.) While Dr. Smith testified that other types of mesh were available for him to use, (doc. 99-3, p. 25), at the time of the surgery, he believed implanting Gynemesh was the best option for treating Plaintiff's condition. (Id. at p. 5.) However, Dr. Smith also identified additional information that he was unaware of and that he would have liked to have known before performing the implantation, including risks arising from the porousness of the mesh, and mesh contraction, erosion, and potential degradation in the body. (Doc. 102-1, pp. 3–5; see also doc. 99-3, pp. 25, 29, 30, 35, 36.) Neither party disputes that Dr. Smith's treatment of Plaintiff met the requisite standard of care.

The surgery ultimately led to complications. Specifically, Plaintiff suffered from erosion, chronic infections, chronic pain, chronic bleeding, and pudendal neuralgia. (Doc. 99-1, p. 5; 102-1, p. 6.) Plaintiff has additionally undergone two mesh excision surgeries to remove portions of the Gynemesh. (Doc. 99-1, p. 5; doc. 102-1, p. 6.)

II. Procedural History

Plaintiff initially filed this lawsuit for the injuries she suffered as a result of the Gynemesh implantation on October 19, 2012, by submitting her Short Form Complaint in the MDL in the Southern District of West Virginia. (See doc. 1.) She amended her Short Form Complaint on August 6, 2014. (Doc. 18.) In the Amended Short Form Complaint, Plaintiff includes all the claims brought in the Master Complaint: Negligence (Count I); Strict liability – Manufacturing

Defect (Count II); Strict Liability – Failure to Warn (Count III); Strict Liability – Defective Product (Count IV); Strict Liability – Design Defect (Count V); Fraud (Count VI); Fraudulent Concealment (Count VII); Constructive Fraud (Count VIII); Negligent Misrepresentation (Count IX); Negligent Infliction of Emotional Distress (Count X); Breach of Express Warranty (Count XI); Breach of Implied Warranty (Count XII); Violation of Consumer Protection Laws (Count XIII); Unjust Enrichment (Count XV); and Punitive Damages (Count XVII). (See doc. 18, pp. 4–5.)

During the course of discovery in the MDL, Dr. Smith was identified as a non-retained expert witness by both parties. (Docs. 107-2, 107-3.) He was subsequently deposed on March 27, 2019. (See generally doc. 99-3.) On May 9, 2019, while this case was still a part of the MDL, Defendants filed a Motion for Partial Summary Judgment on Plaintiff's failure to warn and strict liability–defective product claims. (Doc. 67.) The case was officially transferred to this Court on January 26, 2021, (docs. 86, 87), and Defendants' Motion for Partial Summary Judgment was part of the designated record, (doc. 67).

Once the case was transferred, the Court, on March 22, 2021, directed the Parties to provide a status update and concurrently dismissed Defendants' then-pending Motion for Summary Judgment based on the fact that it had been pending since May 2019 and was originally filed in a different court. (Doc. 97.) The Court thereafter ordered Defendants to refile the Motion. (Id.) The Court specifically noted that it would "not accept any motion or response that incorporates by reference any factual allegation or argument contained in an earlier filing[,]" and that "[e]ach motion and response should be a stand-alone filing that independently contains all the factual allegations and arguments that the filing party wishes the Court to consider." (Id. at p. 2.)

Pursuant to the Court's Order, Defendants filed their renewed Motion for Partial Summary Judgment on May 6, 2021, again moving for summary judgment on Plaintiff's failure to warn and

strict liability—defective product claims. (Doc. 99.) In their Motion, Defendants first assert that Plaintiff has conceded all claims except for: Negligence (Count I), Failure to Warn (Count III), "Defective Product" (Count IV), and Design Defect (Count V). (Id. at pp. 1–2.) As to these remaining claims, Defendants only move for summary judgment on Counts I and III for failure to warn and Count IV for "defective product." (See generally id.) Defendants rely heavily on Dr. Smith's March 27, 2019, deposition in support of their Motion on the failure to warn claim, arguing that Plaintiff cannot show that Dr. Smith was unaware of the risks Gynemesh posed and that Plaintiff also cannot show that Dr. Smith would not have taken the same course of action if he had had the information Plaintiff claims Defendants should have provided him. (See id. at pp. 7–13.) Plaintiff filed a Response to Defendants' Motion, to which she attached a declaration from Dr. Smith executed on May 20, 2021. (Docs. 102, 102-3.)² Defendants thereafter filed a Reply. (Doc. 106.)

STANDARD OF REVIEW

Summary judgment "shall" be granted 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 fact is "material" if it "might affect the outcome of the suit under the governing law." FindWhat Inv'r Grp. v. FindWhat.com, 658 F.3d 1282, 1307 (11th Cir. 2011) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). A dispute is "genuine" if the "evidence is such that a reasonable jury could return a verdict for the nonmoving party." Id.

The moving party bears the burden of establishing that there is no genuine dispute as to any material fact and that it is entitled to judgment as a matter of law. See Williamson Oil Co. v.

² Defendants moved to strike this declaration as untimely, (doc. 105), which they reference in their briefing, (see doc. 106, pp. 1–2, 6.) Defendants' briefing seems to assume that this declaration would ultimately be excluded. (<u>Id.</u>) The Magistrate Judge, however, denied Defendants' Motion to Strike the declaration. (Doc. 133.) Accordingly, the Court will consider its contents in ruling on this Motion.

Philip Morris USA, 346 F.3d 1287, 1298 (11th Cir. 2003). Specifically, the moving party must identify the portions of the record which establish that there are no "genuine dispute[s] as to any material fact and the movant is entitled to judgment as a matter of law." Moton v. Cowart, 631 F.3d 1337, 1341 (11th Cir. 2011). When the nonmoving party would have the burden of proof at trial, the moving party may discharge his burden by showing that the record lacks evidence to support the nonmoving party's case or that the nonmoving party would be unable to prove his case at trial. See id. (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322–23 (1986)). If the moving party discharges this burden, the burden shifts to the nonmovant to go beyond the pleadings and present affirmative evidence to show that a genuine issue of fact does exist. Anderson, 477 U.S. at 257.

In determining whether a summary judgment motion should be granted, a court must view the record and all reasonable inferences that can be drawn from the record in a light most favorable to the nonmoving party. Peek-A-Boo Lounge of Bradenton, Inc. v. Manatee Cnty., 630 F.3d 1346, 1353 (11th Cir. 2011) (citing Rodriguez v. Sec'y for Dep't of Corr., 508 F.3d 611, 616 (11th Cir. 2007)). However, "facts must be viewed in the light most favorable to the non-moving party only if there is a 'genuine' dispute as to those facts." Scott v. Harris, 550 U.S. 372, 380 (2007). "[T]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Id. (citation and emphasis omitted).

DISCUSSION

I. Plaintiff's Concession of Certain Claims

At the beginning of their Motion for Summary Judgment, Defendants request that the Court dismiss ten of Plaintiff's claims, which they say she has conceded and "has stated that she will not pursue." (Doc. 99, pp. 1–2.) In support, Defendants cite only to the Amended Short Form

Complaint. (<u>Id.</u> at p. 2 (citing doc. 18).) That document, however, does not support Defendants' contention; in that document, Plaintiff affirmatively indicated—by checking boxes on the form—that she in fact *did* (at least at that time) intend to pursue all ten of the at-issue claims. (Doc. 18.) Notably, however, Plaintiff did not address Defendants' assertion that she has elected not to pursue these claims, much less does she present any argument in support of these claims. (<u>See generally</u> doc. 102).

Accordingly, as Plaintiff apparently has no objection to dismissal of these claims, the Court finds that she does not intend to pursue them and accepts Defendants' position that those claims should be dismissed. In doing so, however, the Court clarifies that it is *dismissing* those claims and not granting summary judgment. This is because "the issue of whether a claim should not proceed because it has been abandoned is not a matter on the merits of the claim but rather a matter 'in abatement.'" Cessna v. Ethicon, Inc., No. 7:20-CV-37 (WLS), 2020 WL 2121392, at *3 (M.D. Ga. Apr. 2, 2020) (quoting Bryant v. Rich, 530 F.3d 1368, 1374–76 (11th Cir. 2008)). Defendants have provided no merits-based argument for the dismissal of the at-issue claims, but simply state that Plaintiff "has stated that she will not pursue" them. (Doc. 99, p. 1.) Accordingly, Plaintiff's claims for Strict Liability–Manufacturing Defect (Count II); Fraud (Count VI); Fraudulent Concealment (Count VII); Constructive Fraud (Count VIII); Negligent Misrepresentation (Count IX); Negligent Infliction of Emotional Distress (Count X); Breach of Express Warranty (Count XI); Breach of Implied Warranty (Count XII); Violation of Consumer Protection Laws (Count XIII); and Unjust Enrichment (Count XV), are all dismissed without prejudice.

II. Failure to Warn Claims (Counts I and III)

Defendants argue that they are entitled to summary judgment on Plaintiff's failure to warn claims, contained in Counts I and III, because Plaintiff cannot prove that Defendants' failure to

warn caused her injuries. (Doc. 99, pp. 5–13.) To prevail on a failure to warn claim under Georgia law,³ a plaintiff must prove that (1) the defendant had a duty to warn; (2) the defendant breached that duty; and (3) the breach was the proximate cause of the plaintiff's injuries. See Dietz v. Smithkline Beecham Corp., 598 F.3d 812, 815 (11th Cir. 2010). Defendants do not seek summary judgment as to the adequacy of the warnings, (doc. 99, p. 6), and thus, for purposes of ruling on these counts, the Court assumes the warnings were inadequate. See Hubbard v. Bayer Healthcare Pharms. Inc., 983 F.3d 1223, 1232 (11th Cir. 2020). However, even "[i]f the warning is inadequate, or merely presumed to be," a plaintiff still "must demonstrate that the deficient warning proximately caused the alleged injury." Dietz, 598 F.3d at 816. To show that the warning proximately caused the injury, "the plaintiff must prove a causal link between the inadequate warning and the prescription decision." Hubbard, 983 F.3d at 1232.

In determining whether a causal link exists where, as here, the warning was given not to the user of the product but to a prescribing physician, Georgia courts employ the "learned intermediary doctrine." Under this doctrine, a medical device manufacturer⁴ "does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer." In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig., 711 F. Supp. 2d 1348, 1365 (M.D. Ga. 2010); see also McCombs, 587 S.E.2d at 595 (explaining the doctrine in identical

³ The parties agree that all relevant events took place in Georgia and thus, in this diversity action, Georgia law applies. (Doc. 99, p. 3; doc. 102, p. 4, n.1); see <u>Dowis v. Mud Slingers, Inc.</u>, 621 S.E.2d 413, 414 (Ga. 2005) (explaining Georgia's *lex loci delicti* rule, which holds that "a tort action is governed by the substantive law of the state where the tort was committed").

⁴ Although the learned intermediary doctrine has its roots in prescription drugs, Georgia courts have repeatedly deemed it applicable to prescription medical devices. <u>Ellis v. C.R. Bard, Inc.</u>, 311 F.3d 1272, 1279 (11th Cir. 2002); <u>see McCombs v. Synthes</u>, 553 S.E.2d 17, 20 (Ga. Ct. App. 2001) ("It is well settled that the 'learned intermediary' rule . . . is applicable to medical devices implanted in patients under the supervision of a physician.").

terms). In applying the learned intermediary doctrine, the determining factor is whether the learned intermediary had sufficient knowledge to protect the user of the product. See Stuckey v. N. Propane Gas Co., 874 F.2d 1563, 1568 (11th Cir. 1989). Accordingly, "in cases where a learned intermediary has actual knowledge of the substance of the alleged warning [that plaintiff claims should have been given] and would have taken the same course of action even with the information the plaintiff contends should have been provided . . . the causal link is broken." Hubbard, 983 F.3d at 1232. Thus, to prevail on the element of causation in learned intermediary cases, "a plaintiff must also prove: (1) that the prescribing physician was not aware of the alleged risk at issue, and (2) but for the inadequate warning, the physician would not have used or prescribed the product." Watkins v. Eli Lilly & Co., No. 1:08-CV-1665, 2010 WL 11493785, at *8 (N.D. Ga. Mar. 31, 2010).

There is no dispute here that Dr. Smith constituted a learned intermediary. As Plaintiff's treating physician, he was in the best position to warn his patients of any risks the medical devices he implanted would pose. See McCombs, 587 S.E.2d at 595. Thus, for Plaintiff to succeed on her claim, she must show that Dr. Smith was not aware of some or all of the risks that Gynemesh posed and, but for the inadequate warning on those risks, Dr. Smith would not have prescribed Gynemesh to Plaintiff. See Watkins, 2010 WL 11493785, at *8. In other words, determining whether Plaintiff's failure to warn claims may proceed depends on whether Dr. Smith would have prescribed Gynemesh if he had the information he now has regarding its risks. The Court finds that a genuine dispute of material fact exists as to whether he would have.

In their Motion, Defendants point to Dr. Smith's deposition testimony and argue that he was aware of the "relevant" risks that a mesh implant posed and thus Plaintiff cannot show the defective warning proximately caused her injuries. (Doc. 99, pp. 7–11.) Defendant's argument

misses the mark. To be sure, the record reveals ample evidence that Dr. Smith was aware that the use of mesh implants in general posed potential risks for some of the complications that Plaintiff later suffered. (See, e.g., doc. 99-3, p. 22 ("Q. Prior to her surgery in 2007, were you aware of the risk of acute or chronic pain as a risk of implanting mesh? A. Yes."); id. ("Q. Prior to 2007, were you aware of the risk of bleeding that could be associated with implanting mesh? A. Yes."); id. ("O. Prior to 2007, were you aware of the risk that your patients might have to undergo one or more surgeries to treat an adverse event in a patient who was implanted with a mesh product? A. Yes."); id. ("Q. Prior to 2007, were you aware of the risk of infection or urinary problems associated with implanting mesh? A. Yes.").) According to Defendants, the Court's inquiry should end here, because this testimony shows that Dr. Smith knew that using mesh could potentially cause injuries from which Plaintiff later suffered. (Doc. 99, p. 9.) However, while Dr. Smith was apparently aware of *some* risks associated with using mesh generally, this does not mean he was aware of the extent and potential severity of the risks that Gynemesh in particular posed, particularly to a patient with certain characteristics or conditions similar to Plaintiff's.⁵ Indeed, Plaintiff contends that had Dr. Smith known of the increased likelihood—and potentially heightened severity—of certain adverse post-operative issues linked to Gynemesh specifically, he more likely than not would not have used the Gynemesh in her procedure.

In her Response to Defendants' Motion, Plaintiff attaches Dr. Smith's sworn declaration. (Doc. 102-3.) In the declaration, Dr. Smith identifies various risks and additional information specific to Gynemesh of which he was unaware prior to her surgery, and he states that, had he

⁵ Dr. Smith had other mesh products available that he could have recommended and used in Plaintiff's surgery. (Doc. 99-3, p. 25 ("Q. So you had other options, other meshes you could have turned to or recommended to her that you use other than the Gynemesh . . . is that correct? A. Yes.").) Defendant's position here relies on Dr. Smith's knowledge of general risks of using mesh, but ignores the possibility that, had he been aware of the higher rates of adverse events *in Gynemesh specifically*, he could have opted to use another mesh product.

known of these risks, he, "more likely than not, would not have implanted Gynemesh" in Plaintiff. (Id. at p. 3.) First, he notes that he was not aware that Gynemesh had been shown to be "more suitable for women with more severe disease, specifically women with grade 4 prolapse or worse," which, he notes, Plaintiff did not have. (Id.) He next states that he was unaware of evidence known by Defendants—that smaller pore sizes in the mesh, specifically pores less that one millimeter in diameter, could be a "major cause" of "bridging fibrosis, mesh shrinkage, increased inflammatory response, suboptimal tissue growth, or rigid scar plate formation." (Id. at p. 3–4.) He states that only after reviewing Defendants' documents did he learn that many of the Gynemesh pores were below this one millimeter diameter range. (Id. at p. 4.) He additionally described a number of reports—written prior to Plaintiff's surgery—from clinical studies that had been performed using Gynemesh. (<u>Id.</u> at pp. 4–5.) Dr. Smith stated that he was unaware of these reports prior to Plaintiff's surgery and that they reflected high rates of patients suffering adverse events post-operation, including "painful mesh shrinkage," and that some of the results of the studies did not meet Defendants' own "criteria of success." (Id.) As to all of this information of which he claims he was unaware prior to Plaintiff's surgery, he states unequivocally that, "had [he] been informed . . . [he], more likely than not, would not have implanted Gynemesh . . . in [Plaintiff]." (Id. at 5.) Defendants have not argued that Dr. Smith was actually aware of these specific risks (i.e., those related to the small pore size or the possibility that Gynemesh was not well-suited for Plaintiff) or the extent of the risks that he identifies in the declaration. Accordingly, because Dr. Smith's declaration indicates that he was unaware of certain potential complications and concerns associated specifically with Gynemesh, that he was unaware of the extent of the risk of complications resulting from Gynemesh (as opposed to mesh in general and/or prolapse surgery in general), and also because he has testified that he, more likely than not, would not have used

Gynemesh on Plaintiff had he been aware of the extent of those risks, Plaintiff has enough evidence to survive summary judgment on the issue of causation. See Milton v. C.R. Bard, Inc., No. 5:14-CV-00351-TES, 2021 WL 2483143, at *5 (M.D. Ga. June 17, 2021) (finding the implanting physician's testimony "that had she known the [implant] had a 'much higher' complication rate than other filters, she would not have implanted it" was sufficient to survive a summary judgment challenge on the issue of proximate causation).

In their Motion, Defendants rely heavily on the Eleventh Circuit Court of Appeals' decision in Hubbard, 983 F.3d 1223. (See doc. 99, pp. 5–7.) However, Hubbard, as well as the other cases cited by Defendants in their Motion, are clearly distinguishable from the present case. In all the cited cases, the courts ruled in favor of the manufacturers only when presented with clear testimony from the prescribing physicians that an adequate warning would not have altered their treatment. See, e.g., Dietz, 598 F.3d at 816 (finding plaintiff could not prevail on causation where learned intermediary provided "explicit, uncontroverted testimony that . . . he still would have prescribed [the drug in question]") (emphasis added); Hubbard, 983 F.3d at 1234 (finding plaintiff could not prove causation where doctor gave "unequivocal testimony that knowledge of the information . . . would not have altered his . . . decision to prescribe [the drug in question]") (emphasis added); Porter v. Eli Lilly & Co., 291 Fed. App'x 963, 964 (11th Cir. 2008) (finding plaintiff could not prove causation where the doctor "unequivocally testified that even if he had read the warning that [plaintiff] asserts should have been given, he still would have prescribed [the drug in question]") (emphasis added); Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351, 1363 (N.D. Ga. 1999) ("Each of the plaintiffs' treating physicians testified that he was aware of the risks associated with spinal implant surgery . . . and that he would have taken the same course of action in spite of the information Plaintiffs contend should have been provided."). The record here does

not reflect the same level of unequivocal evidence that Dr. Smith would not have altered his prescription of Gynemesh.

To be sure, Defendants have pointed to portions of Dr. Smith's deposition testimony where he affirmatively stated that he believed his conduct met the standard of care, that he would have still prescribed Gynemesh had certain risks been disclosed, and that "when [he] implanted the Gynemesh...[he] believed that it was a safe and effective product." (Doc. 99, pp. 11–13 (quoting doc. 99-3, p. 28).) Nevertheless, reading this testimony in conjunction with the full deposition transcript and his subsequently filed declaration, the Court finds this does not equate to the type of unequivocal testimony required for summary judgment. Indeed, the testimony clearly concerns what Dr. Smith knew and believed *at the time of the surgery*, which is when he claims he was not yet aware of the full extent of Gynemesh-specific risks. Furthermore, the fact that Dr. Smith's testimony may appear contradictory as to the extent of his awareness of Gynemesh's risks and how this knowledge would have affected his treatment only highlights the existence of a triable issue of fact best suited for a jury.

To this point, the Court has located numerous cases, in districts applying the learned intermediary doctrine, that reflect the notion that even where evidence exists that the prescribing physician would not have altered their course of action, if this evidence is not unequivocally established, it remains a question of fact that should be reserved for the jury to decide. See, e.g., In re Abilify (Aripiprazole) Prod. Liab. Litig., No. 3:16-MD-2734, 2021 WL 1041017, at *3-4 (N.D. Fla. Feb. 10, 2021) (denying summary judgment because prescribing physician's inconsistent testimony on whether he would have done anything differently presented a triable issue of fact); Giles v. Wyeth, Inc., 500 F. Supp. 2d 1063, 1069 (S.D. Ill. 2007) (finding prescribing doctor's testimony that it would have been "very difficult . . . to . . . prescribe the drugs" had he

known of the potential risks precluded summary judgment); Kaiser v. Johnson & Johnson, 334 F. Supp. 3d 923, 931–32 (N.D. Ind. 2018) (finding prescribing doctor's inconsistent testimony on whether he would have modified his behavior with a full warning of the risks presented questions of credibility which were within the jury's discretion to evaluate); see also Sands v. Kawasaki Motors Corp., No. 6:08-cv-009, 2009 WL 3152859, *5 (S.D. Ga. Sept. 30, 2009) (denying summary judgment because a dispute of material fact remained where expert testified both that the warning was adequate but also that it did not include all of the risks that would have been "useful" to know).

While there may be some contradictory testimony as to the extent of the deficient warnings' effect on Dr. Smith's decision to prescribe Gynemesh in his original deposition testimony, his subsequent declaration provides unequivocal testimony that a full warning would have impacted his decision. Dr. Smith clearly and repeatedly states in his declaration that had he been aware of various risks, or the extent of risks, that were not presented to him, he, "more likely than not, would not have implanted Gynemesh." (See. doc. 102-3, pp. 3, 4.) Despite Defendants' best efforts to identify portions of Dr. Smith's deposition that show he was aware of the risks, reviewing the entire record in the light most favorable to Plaintiff, the record demonstrates that he was not aware of all risks and the extent of those risks, and that knowledge of this information likely would have altered his decision to use the implant. As a result, there is a triable issue of fact on causation. Accordingly, the Court declines to grant summary judgment on Counts I and III for failure to warn.

III. "Defective Product" Claim (Count IV)

Defendants next argue that Count IV is due to be dismissed because "defective product" is not a cognizable claim under Georgia law. (See doc. 99, pp. 14–15.) The Court agrees.

Georgia law recognizes "three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defect." <u>Banks v. ICI Americas, Inc.</u>, 450 S.E.2d 671, 672 (Ga. 1994). Plaintiff pled strict liability claims for manufacturing defect (Count II), design defect (Count V), and marketing/packages defect (Count III). (Doc. 18, pp. 4–5.) Count IV, however, simply pleads "defective product." (<u>Id.</u> at p. 4.) Defendants contend that this cannot serve as a stand-alone claim because Plaintiff's claims should be limited to the three recognized categories under Georgia law. (Doc. 99, p. 14.) Plaintiff, conversely, argues that Count IV should be read in conjunction with Count V to collectively merge to a single claim for "strict liability – design defect." (Doc. 102, pp. 12–14.)

The Court sees no reason, and Plaintiff has provided no explanation, as to why an additional claim of "product defect" is necessary to be read in conjunction with its design defect claim.⁶ The only basis Plaintiff provides to support this standalone claim is that dismissal could potentially be used "at a later stage in the proceedings to limit Plaintiff['s] ability to pursue [her] design defect claim." (Doc. 102, p. 14.) The only case cited to support this contention is to a district court case out of South Dakota. See Sluis v. Ethicon, Inc., 529 F. Supp. 3d 1004, 1019 (D.S.D. 2021) (merging the claims because "Ethicon might try to limit their strict liability – design defect claim during later proceedings"). The Court finds the South Dakota district court's decision to merge the claims unpersuasive and instead looks to district courts in *this* circuit, indeed *in this district*, that have declined to merge such claims as duplicative. See, e.g., Jones v. Ethicon, Inc., No. 7:20-

⁶ In her Response, Plaintiff relies on "multi-factorial risk-utility balancing test" set out in <u>Banks</u> to support her contention that "Count IV states a strict liability claim for design defect under Georgia law." (Doc. 102, pp. 12–13 (citing <u>Banks</u>, 264 Ga. 732, 736 & n.6).) However, Defendants' challenge on the present Motion is not that Plaintiff cannot plead a design defect claim—indeed they have made no motion with respect to Count V—but rather that "product defect" is simply not a standalone claim, and, insofar as it can be read as a design defect claim, it is duplicative of Count V. Accordingly, because the Court agrees with Defendants that Count IV is duplicative, it sees no need to analyze Count IV in conjunction with Count V under the balancing test Plaintiff proposes.

CV-128 (HL), 2020 WL 5836555, at *5 (M.D. Ga. Sept. 30, 2020) (granting the defendant's motion for summary judgment because "Plaintiff has not . . . demonstrated that Georgia law recognizes an independent claim for 'defective product'" and concluding that "Plaintiff's 'defective product' claim arises from identical allegations in another count"); Jones v. Ethicon, Inc., No. 4:21-CV-23, 2021 WL 1199028, at *7 (S.D. Ga. Mar. 30, 2021) (dismissing a "defective product" claim in a case involving pelvic mesh because "[p]laintiff ma[de] no argument and point[ed] to no evidence to support a stand-alone 'defective product' claim"); Kuchenbecker v. Johnson & Johnson, No. 19-61712-CIV, 2019 WL 4416079, at *2-3 (S.D. Fla. Sept. 16, 2019) (dismissing similarly pled "defective product" claim as "duplicative of Plaintiffs' defective design and defective warning claims" under Florida's identical products liability framework); Messina v. Ethicon, Inc., No. 6:20-CV-1170-PGB-LRH, 2021 WL 1329072, at *2 (M.D. Fla. Mar. 31, 2021) (describing the "strict liability – defective product claim" as "duplicative" of a "design defect" claim under Florida law). The Court finds no reason to merge Counts IV and V and, accordingly, grants Defendants' Motion for Summary Judgment on Plaintiff's defective product claim (Count IV).

CONCLUSION

Based upon the forgoing, the Court GRANTS in part and DENIES in part Defendants

Ethicon, Inc., and Johnson & Johnson's Motion for Partial Summary Judgment. (Doc. 99.) As to

Defendants' Motion for Summary Judgment on Plaintiff's Failure to Warn Claims (Counts I and

III), the Court finds that a genuine issue of material fact exists as to whether Plaintiff's treating

physician would have used the Gynemesh implant if he had been warned of certain risks and the

extent of other risks and, accordingly, the Court **DENIES** Defendants' Motion with respect to

those claims. As to Plaintiff's "Defective Product" claim (Count IV), the Court finds this is not

an independently cognizable claim under Georgia law and, accordingly, GRANTS Defendants'

Motion on that Count. The Court additionally DISMISSES without prejudice the additional

conceded claims identified in Defendant's Motion (Counts II, VI, VII, VIII, IX, X, XI, XII, XIII,

XV).

SO ORDERED this 28th day of March, 2023.

R. STAN BAKER

UNITED STATES DISTRICT JUDGE

SOUTHERN DISTRICT OF GEORGIA