UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

SHAWNA LYNN JAMES,

Civil No. 20-654 (JRT/TNL)

Plaintiff,

v.

COLOPLAST CORP. and COLOPLAST MANUFACTURING US, LLC,

MEMORANDUM OPINION AND ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGEMENT

Defendants.

Aaron M. Levine, **AARON LEVINE & ASSOCIATES**, 1310 L Street Northwest, Suite 800, Washington, DC 20005; Jeffrey L. Haberman, **SCHLESINGER LAW OFFICES, P.A.**, 1212 Southeast Third Avenue, Fort Lauderdale, FL 33316; and Noah C. Lauricella, and Stuart L. Goldenberg, **GOLDENBERGLAW**, **PLLC**, 800 LaSalle Avenue, Suite 2150, Minneapolis, MN 55402 for plaintiff.

Aaron Parks, TaCara D. Harris, Todd Patrick Davis, & Val Leppert, **KING & SPALDING**, 1180 Peachtree Street, Suite 1700, Atlanta, GA 30309; Cheryl A. Sabnis, **VEDDER PRICE P.C.**,1 Post Street, Suite 2400, San Francisco, CA 94104; and Kacie Phillips, Kadee Jo Anderson, and Timothy P. Griffin, **STINSON LLP**, 50 South Sixth Street, Suite 2600, Minneapolis, MN 55402 for defendants.

Plaintiff Shawna Lynn James, a resident of Oklahoma, filed this action against Defendants Coloplast Corp. and Coloplast Manufacturing US, LLC (collectively, "Coloplast") for injuries allegedly caused by an Altis Single Incision Sling System ("Altis")—a synthetic mid-urethral sling made of a polypropylene polymer that is designed and sold by Coloplast to surgically treat stress urinary incontinence ("SUI"), as well as other medical issues, within the pelvic floors of women—used during James's pelvic floor reconstructive

surgery. James brings claims for negligence, defective design, failure to warn, breach of express and implied warranties, unjust enrichment, fraud, negligent misrepresentation, violations of both Minnesota and Oklahoma fraud and deceptive trade practices laws, violation of Minnesota's False Statements in Advertising Act, and violation of Minnesota's Prevention of Consumer Fraud Act. Coloplast moved to exclude testimony from James's experts in this case and for summary judgment on all of James's claims.

The Court will grant Coloplast's Motion to Exclude the specific causation opinion rendered by Dr. William Gold because he did not conduct a differential diagnosis—thereby ruling out James's extensive medical history as the cause of her alleged injuries—leaving his causation opinion unreliable. The Court will also grant Coloplast's Motion for Summary judgment as to James's (1) negligence and defective design claims because James has not established that the Altis caused her injuries and, alternatively, because there is no evidence that the Altis was unreasonably dangerous; (2) failure to warn claim because the record establishes that the warnings in Altis's Instructions for Use ("IFU") are adequate as a matter of law; (3) Minnesota state law claims because the parties agree that Oklahoma law applies to this case; (4) fraud claims because she has abandoned them; (5) breach of express warranties, negligent misrepresentation, and violation of Oklahoma's consumer protection laws because James did not rely upon a statement or representation that Coloplast made; (5) breach of implied warranty claim because James has not established that the Uniform Commercial Code provides an implied warranty in

this case; and (6) unjust enrichment claim because she had an adequate remedy at law. Because the Court will dismiss all of James's claims, the Court will deny as moot Coloplast's remaining motions to exclude the testimony of James's experts.

BACKGROUND

I. FACTS

In May 2018, James saw a medical professional after experiencing nocturia, urinary frequency and urgency, pain with urination, and urinary dribbling. (1st Decl. of Timothy Griffin ("Griffin Gold Decl.") Supp. Mot. Exclude William Gold, M.D.'s Expert Test., Ex. 10, Oct. 15, 2021, Docket No. 70.) James was referred to Dr. Henry Ramirez, a pelvic surgeon, who diagnosed James with mixed urinary incontinence. (*Id*., Ex. 11.) As part of her treatment, Dr. Ramirez performed an implantation procedure and implanted James with the Altis. (*Id*., Ex. 12.)

After James's Altis procedure, James did not immediately present further issues or complications. (*Id*., Ex. 13.) However, James told Dr. Ramirez in February 2019 that she was experiencing pelvic and lower back pain, as well as vaginal discharge and bleeding. (*Id*.) Dr. Ramirez referred James to urogynecologist Dr. Lieschen Quiroz, who diagnosed James with a small sling exposure in her vagina. (*Id*., Ex. 3.)

On October 17, 2019, Dr. Quiroz performed a complete removal of the Altis implant. (*Id*., Ex. 15.) Following surgery, James continued to complain of pelvic and vaginal pain, inability to have sex, urinary pain and frequency, vaginal discharge, urinary urgency, vaginal itching and burning, nocturia, and urinary leakage. (*Id*., Ex. 16.)

Prior to implantation of the Altis, James's extensive medical history included (1) two vaginal deliveries, (2) hyperthyroidism, (3) tubal ligation, (4) vaginal atrophy caused by decreased estrogen, (5) a pelvic fracture, (6) ovarian cysts, (7) prior pelvic and abdominal surgeries, including a hysterectomy, (8) osteoarthritis, (9) chronic neck, back, hip, and knee pain, (10) cervical, thoracic, and lumbar spondylosis and cervicalgia, and (11) sacroiliac joint dysfunction. (*Id.*, Exs. 1–2, 4–8.)

On March 20, 2020, James initiated this action against Coloplast, alleging that the Altis surgical mesh implant that Dr. Ramirez selected to treat her SUI was defective and caused her injuries. (Compl. ¶¶ 28–33, Mar. 3, 2020, Docket No. 1.) Specifically, James alleges that the Altis caused post-surgery complications that necessitated its removal because it is biologically incompatible with human tissue and the polypropylene used to create the Altis results in a severe foreign body reaction and chronic inflammatory response due to degradation of the polypropylene polymer. (*Id*. ¶¶ 11, 32.)

James retained numerous experts to substantiate her claims including: (1) urogynecologist Neeraj Kohli, M.D., M.B.A. ("Dr. Kohli") and Bruce Rosenzweig, M.D. ("Dr. Rosenzweig") to offer general causation opinions; (2) retired gynecologist William Gold, M.D. ("Dr. Gold") to offer a case specific causation opinion; (3) Jimmy Mays Ph.D. ("Dr. Mays") to opine that the polypropylene used in the Altis degrades within the human body; (4) Peggy Pence, Ph.D. ("Dr. Pence") as a regulatory expert; and (5) Susan K. Theut, M.D.,

M.P.H. ("Dr. Theut") as a psychiatry expert. (1st Decl. of Timothy Griffin Supp. Defs.' Mot. Exclude Susan K. Theut, M.D.'s Expert Test., Ex. 2, Oct. 15, 2021, Docket No. 58–1.)

Defendants now move to exclude James's expert witnesses' opinions and for summary judgment on all of James's claims.[1]

DISCUSSION

I. STANDARD OF REVIEW

A. Motions to Exclude Expert Testimony

Federal Rule of Evidence 702 governs the admissibility of expert testimony. *McMahon v. Robert Bosch Tool Corp.*, 5 F.4th 900, 903 (8th Cir. 2021). An expert's opinion testimony is admissible if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

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[1] (Mot. Summ. J., Oct. 15, 2021, Docket No. 50; Defs.' Mot. Exclude Susan K. Theut, M.D.'s Expert Test., Oct. 15, 2021, Docket No. 55; Defs.' Mot. Exclude Bruce Rosenzweig, M.D.'s Expert Test., Oct. 15, 2021, Docket No. 61; Defs.' Mot. Exclude William Gold, M.D.'s Expert Test., Oct. 15, 2021, Docket No. 67; Defs.' Mot. Exclude Neeraj Kohl, M.D. MBA's Expert Test., Oct. 15, 2021, Docket No. 73; Defs.' Mot. Exclude Peggy Pence, Ph.D.'s Expert Test., Oct. 15, 2021, Docket No. 79; Defs.' Mot. Exclude Jimmy Mays, Ph.D.'s Expert Test., Oct. 15, 2021, Docket No. 85.)

The district court has a gate-keeping obligation to make certain that all testimony admitted under Rule 702 satisfies these prerequisites and that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). The proponent of the expert testimony has the burden of establishing by a preponderance of the evidence that the expert is qualified, that the methodology used is scientifically valid, and that "the reasoning or methodology in question is applied properly to the facts in issue." *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757–58 (8th Cir. 2006). "Expert testimony is inadmissible if it is speculative, unsupported by sufficient facts, or contrary to the facts of the case." *Id.* at 757.

"Courts should resolve doubts regarding the usefulness of an expert's testimony in favor of admissibility." *Id.* at 758. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Robinson v. GEICO Gen. Ins. Co.*, 447 F.3d 1096, 1100 (8th Cir. 2006) (quoting *Daubert*, 509 U.S. at 595). "Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929–30 (8th Cir. 2001) (quoting *Hose v. Chi. Nw. Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1995)).

B. Summary Judgment[2]

Summary judgment is appropriate when there are no genuine issues of material fact, and the moving party can demonstrate that it 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, and a dispute is genuine if the evidence is such that it could lead a reasonable jury to return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A court considering a motion for summary judgment must view the facts in the light most favorable to the nonmoving party and give that party the benefit of all reasonable inferences to be drawn from those facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The nonmoving party may not rest on mere allegations or denials but must show, through the presentation of admissible evidence, that specific facts exist creating a genuine issue for trial. *Anderson*, 477 U.S. at 256. "The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient;

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[2] James fails to respond to a litany of Coloplast's arguments and Coloplast's motion for summary judgment is therefore unopposed on many issues. For example, James did not address or otherwise engage with Coloplast's arguments that her design defect claim fails because there is not reliable evidence to establish specific causation and because the Altis is not unreasonably dangerous as a matter of law. James also did not respond to Coloplast's argument regarding her claims for breach of express and implied warranties, fraud, negligent misrepresentation, unjust enrichment, and state law claims for violations of consumer protections laws.

While James herself does not raise any issues of material fact in failing to respond to Coloplast's arguments, Coloplast is not immediately entitled to having its motion granted on these issues. Instead, "[e]ven if a motion for summary judgment on a particular claim stands unopposed, the district court must still determine that the moving party is entitled to judgment as a matter of law on that claim." *Interstate Power Co. v. Kansas City Power & Light Co.*, 992 F.2d 804, 807 (8th Cir. 1993).

there must be evidence on which the jury could reasonably find for the plaintiff." *Id.* at 252.

II. ANALYSIS

Coloplast argues that it is entitled to summary judgment on numerous claims because Dr. Gold, James's case specific causation expert, is not qualified to offer expert testimony and his opinions are based on an unreliable methodology. Accordingly, the Court first addresses Coloplast's motion to exclude Dr. Gold's specific causation opinion.

A. Motion to Exclude Dr. Gold's Testimony

Coloplast moves to exclude Dr. Gold's specific causation opinion because he failed to rule out James's previous medical history as causes of James's alleged injuries and his opinion is therefore based on an unreliable methodology and inadmissible.

The entirety of Dr. Gold's specific causation opinion states:

> [James's] symptoms complex, a recurrence of urinary incontinence, and the vaginal mesh exposure which required another surgical procedure was caused by the defects in design, testing, and marketing of the Coloplast Altis single incision mid-urethral sling she had implanted in August 2018. [James'] symptoms of recurrence of urinary incontinence, abdominal pain, vaginal discharge, vaginal bleeding, dyspareunia, vaginal wall separation, and mesh exposure were the result of her body's intrinsic foreign body reaction and chronic inflammation in the pelvis due to the polypropylene device that was implanted.

(Griffin Gold Decl., Ex. 21 ("Gold Report") at 53, Oct. 15, 2021, Docket No. 70-10.)[3]

[3] For clarity, references to Dr. Gold's expert report use the CM/ECF pagination listed at the top of the filing because Dr. Gold's report lacks other usable pagination.

Coloplast contends that this short, two-sentence opinion is unreliable because it does not identify any scientifically accepted methodology and should be excluded under *Daubert*. Rather than directly engage with Coloplast's criticism of Dr. Gold's specific causation opinion, James argues "that Dr. Gold's causation opinion is short because [Coloplast]'s lawyer's questions were short,"[4] that it is not indicative of an insufficient methodology because "it was based on peer review and publications," and "Dr. Gold was given the totality of the medical records in this case." (Pl.'s Mem. Opp. Mot. Exclude Dr. William Gold's Expert Test. at 7, Dec. 14, 2021, Docket No. 118.)[5]

Although a differential diagnosis is not the only form of scientifically accepted methodology, "a medical opinion about causation, based upon a proper differential diagnosis, is sufficiently reliable to satisfy *Daubert*." *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000). The Eighth Circuit describes a differential diagnosis as a process wherein a physician "begins by 'ruling in' all scientifically plausible causes of

[4] The Court is perplexed by James's assertion that Dr. Gold's specific causation opinion is a result of questions asked by Coloplast's lawyers because experts formulate their opinions and draft expert reports by themselves, not in response to questions from opposing counsel. Irrespective of questions or issues posed by an opposing party, the burden of establishing that an expert's methodology is scientifically valid rests with the proponent of this evidence, *Marmo*, 457 F.3d at 757–58, therefore even if the report was only drafted in response to Coloplast's questions, James cannot hold Coloplast responsible for the contents of Dr. Gold's report.

[5] Because every page in James's opposing brief is erroneously paginated as page six, the Court considers the first page of her filing as "page one" with each subsequent page being label in numerical order. This practice is also applicable to James's brief opposing summary judgment wherein each page is erroneously paginated as page nine. (Pl.'s Mem. Opp. Summ. J, Dec. 14, 2021, Docket No. 106.)

plaintiff's injury" and then "'rules out' the least plausible causes of injury until the most likely cause remains. The final result of a differential diagnosis is the expert's conclusion that a defendant's product caused (or did not cause) the plaintiff's injury." *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262–66 (4th Cir. 1999)). Therefore, when "a properly qualified medical expert performs a reliable differential diagnosis through which, to a reasonable degree of medical certainty, all other possible causes of the victims' condition can be eliminated, leaving only the [defendant's product] as the cause, a causation opinion based on that differential diagnosis should be admitted." *Turner*, 229 F.3d at 1209.

While Dr. Gold states that his opinion is based on his "review of the plaintiff's medical record excerpts, published medical literature, reports from experts pertaining to these topics, Coloplast materials available online, and FDA materials," (Gold Report at 53), his opinion is significantly flawed in failing to address James's previous surgeries, injuries, and complaints of symptoms she claims the Altis caused. Without delineating **any** connections between his causation opinion and the records he purports to have reviewed, the Court is forced to assume, improperly, that Dr. Gold "ruled in" all scientifically plausible causes and that Dr. Gold "ruled out" James's previous medical history as the least plausible. *Medalen v. Tiger Drylac U.S.A., Inc.*, 269 F. Supp. 2d 1118, 1128 (D. Minn. 2003) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data

only by the ipse dixit of the expert." (quoting *General Electric Co. v. Joiner*, 522 U.S. 136 146 (1997))). The Court cannot make these assumptions; experts must explain their process.

Here, James has, among other relevant medical events, had a pelvic fracture, ovarian cysts, and prior pelvic surgeries. Under Oklahoma law, plaintiffs are required to establish that an alleged defect caused their injuries and courts have stated more explicitly that "specific causation [focuses on] whether that substance caused a particular individual's injury." *Christian v. Gray*, 65 P.3d 591, 602 (Okla. 2003). Without addressing readily plausible scientific causes of James's alleged injuries, Dr. Gold unreliably concludes that the Altis caused James's injuries. *See Kudabeck v. Kroger Co.*, 338 F.3d 856, 862 (8th Cir. 2003) ("[W]here a defendant points to a plausible alternative cause and the doctor offers *no* explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable." (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999)) (emphasis in original)); *see also Kruszka v. Novartis Pharm. Corp.*, 19 F. Supp. 3d 875, 890 (D. Minn. 2014) (finding testimony unreliable when there was "no evidence that [the expert] performed a differential diagnosis regarding the cause of [the plaintiff's] condition").

Accordingly, "there is simply too great an analytical gap between the data and the opinion proffered," *Joiner*, 522 U.S. at 146, and James has not established by a preponderance of the evidence on the record before the Court that Dr. Gold's causation

opinion is reliable. The Court will, therefore, grant Coloplast's Motion to Exclude Dr. Gold's in part and exclude his specific causation opinion. Because the Court will grant Coloplast's request for summary judgment as explained *infra* Part II. B, the Court will deny the remainder of Coloplast's motion to exclude Dr. Gold's testimony and Coloplast's remaining motions to excludes James's experts as moot.

B. Summary Judgment

1. Waived claims

At the hearing on Coloplast's motion, James's counsel conceded that only Oklahoma law applies to James's claims and further asserted that James will not continue to pursue her fraud claim. (Hearing Tr. at 25:20–25, 27:1–5 (on file with the Court).) Accordingly, the Court will grant summary judgment on James's Minnesota state law claims and her claim for fraud. *See Taylor v. R&M Mfg. Co.,* 165 F.Supp.2d 950, 951 n.2 (D. Minn. 2001) (granting summary judgment on claims plaintiff expressly waived).

2. Negligence and design defect claims

Coloplast argues that James's negligence and design defect claims must be dismissed because James has failed to show that the Altis caused her injuries and, alternatively, because the Altis is not unreasonably dangerous as a matter of law. James

has not addressed Coloplast's argument,[6] and the Court therefore only analyzes whether Coloplast is entitled to summary judgement as a matter of law.

Under Oklahoma law, a plaintiff must establish three elements to maintain a products liability claim: an alleged defect must have (1) caused the injury in question, (2) existed at the time it left the manufacturer's control, and (3) made the product unreasonably dangerous. *Kirkland v. Gen. Motors Corp.,* 521 P.2d 1353, 1363 (Okla. 1974).

Because James's case requires expert testimony as to the cause of her injuries, *see Christian,* 65 P.3d at 601–02, and the Court has already determined that James's specific causation expert's opinion must be excluded, Coloplast in entitled to summary judgment as a matter of law. *See Bell v. CMH Mfg., Inc.*, No. 05-0355, 2006 WL 5103095, at *4 (W.D. Okla. Feb. 16, 2006) (granting summary judgment when "the only evidence arguably showing causation has been excluded").

Alternatively, Coloplast is entitled to summary judgment because James has not offered evidence that the Altis is unreasonably dangerous. Under Oklahoma law, a product is unreasonably dangerous if it poses a danger "beyond that which would be

[6] A portion of James's briefing attempts to proffer that James has evidence of a safer alternative Altis design and may be construed as an attempt to respond to Coloplast's arguments. However, James proffers this evidence in support of a manufacturing defect claim—a claim that is not part of James's Complaint and was later abandoned by James's counsel at the hearing on Coloplast's motion, (Hearing Tr. at 25:20–25)—and incorrectly references a different plaintiff (a "Mrs. Franklin"), a different Coloplast Product (the "Aris"), and cites to irrelevant New York law. (Pl.'s Mem. Opp. Summ. J at 6–9.)

contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Woods v. Fruehauf Trailer Corp.,* 765 P.2d 770, 774 (Okla. 1988) (quotation omitted). The consumer expectations test is evaluated from the perspective of the typical user. *See Gaines-Tabb v. ICI Explosives, USA, Inc.,* 160 F.3d 613 (10th Cir. 1998) (finding that a fertilizer formulation was not unreasonably dangerous even though an alternate formula would have been equally effective and would have reduced the risk of explosion because the ordinary user was a farmer who would not be expected to use it as an explosive).

Here, the ordinary consumers of the Altis are the implanting surgeons. *McClain v. Brainerd Chem. Co.*, Inc., 436 P.3d 752, 757 (Okla. Civ. App. 2019) ("The Oklahoma Supreme Court has defined the 'ordinary consumer' as 'one who would be foreseeably expected to purchase the product involved.'") (citing *Woods v. Fruehauf Trailer Corp.*, 765 P.2d 770, 774 (Okla. 1988)); *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1018 (10th Cir. 2001) (noting the consumer in a product liability action regarding injuries suffered due to the interaction of an anti-convulsant drug and a drug containing acetaminophen was the prescribing physician).

James has not provided any expert testimony describing what the expectations of an implanting surgeon—or any other consumer—would be or presented evidence indicating that the Altis failed to meet those standards. Instead, the record contains evidence from Coloplast's expert asserting that practicing surgeons would be aware of

the general risks associated with SUI surgeries and implantations like the Altis. (1st Decl. of Timothy Griffin Supp. Mot. Summ. J. ("Griffin Summ. J. Decl."), Ex. 8, Oct. 15, 2021, Docket No. 53.) The record also indicates that the Altis IFU contained extensive warnings about potential adverse events associated with the Altis and provided relevant clinical data. (*Id*., Ex. 5.)

Because James has not established that the Altis caused her injuries or that it was unreasonably dangerous, the Court will grant Coloplast's motion as to James's negligence and design defect claims.

3. Failure to Warn

Coloplast contends that it is entitled to summary judgment on James's failure to warn claim because the Altis warnings are adequate as a matter of law and, alternatively, James has not established that any alleged failure to warn was a substantial factor in her alleged injuries.

Applying Oklahoma law, the Tenth Circuit and the Oklahoma Court of Appeals have acknowledged five considerations as relevant in determining whether a warning is adequate as a matter of law:

> 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result

> from failure to follow it and, . . . 5. the means to convey the warning must be adequate.

Thom v. Bristol–Myers Squibb Co., 353 F.3d 848, 853 (10th Cir. 2003); *Ross v. Jacobs*, 684 P.2d 1211, 1214 (Okla. Civ. App. 1984).

Courts can decide the adequacy of a warning as a matter of law where the warning "under all the circumstances . . . reasonably discloses to the medical profession all risks inherent in the use of the drug which the manufacturer knew or should have known to exist." *Ross*, 684 P.2d at 1214 (quoting *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 836–37 (Ohio 1981).)

Here, the Altis IFU warnings are adequate as a matter of law because they warn against all of the symptoms—such as bladder and vaginal pain, dyspareunia, vaginal bleeding, and urinary frequency—that James attributes to the Altis. (Griffin Summ. J. Decl., Ex. 5.) Accordingly, Coloplast is entitled to summary judgment on James's claims. *See Harrington v. Biomet, Inc.*, No. 07-25, 2008 WL 2329132, at *6 (W.D. Okla. June 3, 2008) (granting summary judgment and finding defendant's warning accompanying prosthetic hip implant adequate as a matter of law because it warned of the precise adverse event plaintiff alleged). Even if the warnings were not adequate, James has failed to establish that Coloplast's alleged failure to warn her implanting surgeon was the cause of her injuries. Oklahoma has adopted the learned intermediary doctrine, under which manufacturers are shielded from liability "if the manufacturer adequately warns" the medical professional that prescribes the drug or implants the medical device. *Edwards v.*

Basel Pharms., 933 P.2d 298, 300 (Okla. 1997). To establish that an inadequate warning caused a plaintiff's injuries in the learned intermediary context, a plaintiff must show that, "had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided." *Eck*, 256 F.3d at 1018 (quotation omitted). Therefore, James must show that Coloplast's alleged failure to warn her implanting surgeon was "a substantial contributing factor in bringing about the harm in question." *Id.* at 1017. James has neither argued nor provided evidence indicating that her implanting surgeon would have changed his mind had Coloplast made an unspecified greater warning of the dangers of the Altis.

Accordingly, because the Altis IFU warnings include the precise injuries alleged by James and, alternatively, because James has not argued that a different waring would have altered her implanting surgeon's decision to use the Altis, the Court will grant Coloplast's Motion for Summary Judgment on James's failure to warn claim.

4. Negligent Misrepresentation, Breach of Express Warranties, and Violation of Oklahoma's Consumer Protection Act

Coloplast contends James has not sufficiently established a dispute of material fact as to whether she relied upon a statement or representation made by Coloplast and that James's negligent misrepresentation, breach of express warranties, and violation of Oklahoma's Consumer Protect Act claims fail.

Under Oklahoma law, a plaintiff is required to show that either her or her implanting surgeon relied on a statement or representation made by the manufacturer

to establish a claim for negligent misrepresentation and breach of express warranties. *Recker v. C.R. Bard, Inc.*, 491 F. Supp. 3d 1029, 1035 (W.D. Okla. 2020) (requiring plaintiffs show an "affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain" to prevail on a claim of breach of express warranties); *Southcrest, L.L.C. v. Bovis Lend Lease, Inc.*, No. 10-0362, 2011 WL 3881495, at *6 (N.D. Okla. Sept. 2, 2011) (stating that a plaintiff must show reasonable reliance by the plaintiff in a claim for negligent misrepresentation). Similarly, under Oklahoma's Consumer Protection Act, Okla. Stat. § 761.1(A), plaintiffs must show that they were damaged by the defendant's unlawful statement or representation. *Patterson v. Beall*, 19 P.3d 839, 846 (Okla. 2000).

James has not offered any testimony from her implanting surgeon and has therefore not argued or established that he relied on any statement. Moreover, James herself admitted that she relied on **her doctor's** advice when deciding to use the Altis and did not review any of Coloplast's materials related to the Altis. (Griffin Summ. J. Decl., Ex. 10 at 2.)

Accordingly, the record before the Court establishes that James solely relied on her implanting surgeon's advice, and the Court will grant Coloplast's motion as to her claims for negligent misrepresentation, breach of express warranties, and violation of Oklahoma's Consumer Protect Act.

5. Breach of Implied Warranties

Coloplast also moves for summary judgment on James's claim for breach of implied warranties. "In a products liability action, breach of implied warranty is no longer an appropriate remedy except as provided in the Uniform Commercial Code," *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1310, 1322 (N.D. Okla. 2000), and Oklahoma law does not recognize implied warranty claims for products liability actions outside the context of the Uniform Commercial Code, as that theory of liability has "merged into the theory and doctrine of manufacturers' products liability." *Miller v. C.R. Bard, Inc.*, No. 19-1200, 2021 WL 1063800, at *6 (W.D. Okla. Mar. 19, 2021) (citing *Kirkland*, 521 P.2d at 1355).

James has not submitted an argument supporting any implied warranty under the Uniform Commercial Code or argued that Coloplast breached any such warranty. The Court will therefore grant Coloplast's motion as to James's claim for breach of implied warranty. *See Miller,* 2021 WL 1063800, at *6 (W.D. Okla. Mar. 19, 2021) (granting summary judgment and dismissing breach of implied warranty claim because "[p]laintiffs raise no arguments or evidence implicating the Uniform Commercial Code").

6. Unjust Enrichment

Coloplast lastly argues that it is entitled to summary judgment on James's claim for unjust enrichment. To prevail on a claim of unjust enrichment under Oklahoma law, a plaintiff must show (1) an enrichment to the adverse party; (2) an impoverishment to the claimant; (3) a connection between the enrichment and impoverishment; (4) an absence

of justification; and (5) an absence of remedies at law. *Quarles v. Little River Energy Co.,* No. 00-913, 2008 WL 185715, at *1–2 (N.D. Okla. Jan.18, 2008). Thus, where a plaintiff has an adequate remedy at law, courts ordinarily refrain from exercising equitable jurisdiction to grant relief. *Id.* at *2; *Harvell v. Goodyear Tire and Rubber Co.,* 164 P.3d 1028, 1035 (Okla. 2006). "[The Oklahoma Supreme Court] has repeatedly held that where the plaintiff has a plain, speedy and adequate remedy at law equity will not intervene in his behalf." *Robertson v. Maney,* 166 P.2d 106, 108 (Okla. 1946).

Here, the Court is persuaded that exercising its equitable discretion is neither proper nor warranted when a plaintiff's claims and remedies for alleged injuries resulting from a defective product, like James, are controlled by robust and well-developed product liability law. *Naylor Farms, Inc. v. Anadarko OGC Co*., No. 08-668, 2011 WL 7267851, at *1 (W.D. Okla.15 June 2011) (granting summary judgment as a matter of law against an unjust enrichment claim after concluding that an adequate remedy at law precludes a claim for unjust enrichment irrespective of whether a party actually recovers based upon the adequate remedy).

Accordingly, the Court finds that Coloplast is entitled to summary judge as a matter of law and will grant its motion as to James's unjust enrichment claim.

CONCLUSION

James has failed to demonstrate that there is any material fact in dispute to preclude summary judgment. James's expert, Dr. Gold, used an insufficient and unreliable methodology to support his opinion that the Altis was the cause of James's

alleged injuries, and his specific causation opinion is therefore excludable. Moreover, James's negligence and defective design claims cannot survive without expert testimony opining that the Altis caused her injuries, and her claims alternatively fail because the record before the Court does not establish that the Altis was unreasonably dangerous. Similarly, James's claim for failure to warn cannot survive because the record establishes that the warnings in Altis IFU are adequate as a matter of law. James also waived her Minnesota state law claims and claim for fraud, and her claims for breach of express warranties, negligent misrepresentation, and violation of Oklahoma's consumer protection laws fail because James did not rely upon any of Coloplast's statements or representations. James also did not demonstrate that the Uniform Commercial Code provides an implied warranty sufficient to sustain her breach of implied warranty claim, and her claim for unjust enrichment fails because she had an adequate remedy in product liability law.

Accordingly, Coloplast is entitled to summary judgment on all of James's claims. And because Coloplast is entitled to summary judgment, Coloplast's motions to exclude Dr. Theut's, Dr. Rosenzweig's, Dr. Kohli's, Dr. Pence's, and Dr. Mays's expert testimony are moot.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that:

1. Defendants' Motion to Exclude Dr. William Gold's Expert Testimony [Docket No. 67] is **GRANTED in part and DENIED in part.**

    a. Defendants' motion is **GRANTED** as to Dr. Gold's specific causation opinion and **DENIED** as moot as to all other portions.

2. Defendants' Motion for Summary Judgment [Docket No. 50] is **GRANTED** as to all of Plaintiff's claims and this action is **DISMISSED**.

3. Defendants' Motion to Exclude Susan K. Theut, M.D.'s Expert Testimony [Docket No. 55], Motion to Exclude Bruce Rosenzweig, M.D.'s Expert Testimony [Docket No. 61], Motion to Exclude Neeraj Kohli, M.D. MBA's Expert Testimony, [Docket No. 73], Motion to Exclude Peggy Pence, Ph.D.'s Expert Testimony [No. 79] and Motion to Exclude Jimmy Mays, Ph.D.'s Expert Testimony, [Docket No. 85] are **DENIED** as moot.

LET JUDGMENT BE ENTERED ACCORDINGLY.

DATED: September 26, 2022
at Minneapolis, Minnesota.

John R. Tunheim

JOHN R. TUNHEIM
United States District Judge