# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF ILLINOIS

MARILYN CARLEN,	)
Plaintiff,	)
vs.	) Case No. 3:19-cv-1304-GCS
COLOPLAST CORPORATION,	)
Defendant.	)

## MEMORANDUM & ORDER

#### SISON, Magistrate Judge:

Plaintiff Marilyn Carlen alleges that she was injured by surgical mesh that was developed, manufactured, marketed, distributed, and sold by Defendant Coloplast Corporation. Carlen brings claims for strict product liability, negligence, breach of express and implied warranties, common law fraud, constructive fraud, and negligent misrepresentation. By motion dated March 16, 2020, Coloplast seeks dismissal of Carlen's amended complaint. (Doc. 38). Carlen responded in opposition on May 4, 2020. (Doc. 43). Coloplast filed a reply on May 18, 2020. (Doc. 48). The matter is fully briefed and ripe for ruling. For the reasons delineated below, Coloplast's motion is granted in part and denied in part.

#### FACTUAL ALLEGATIONS

Carlen alleges that Coloplast develops, designs, manufactures, labels, packages, distributes, markets, supplies, advertises, sells, and otherwise engages in activities related to the sale and distribution of pelvic mesh products. These products, which

include Coloplast's mesh, hammock, and sling products and something called the Aris Transobturator Tape System ("Aris System"), are medical devices used for treating pelvic issues in females, primarily pelvic organ prolapse and stress urinary incontinence. Surgical mesh, including transvaginal mesh, is used to repair weakened or damaged tissue.

Carlen alleges that most transvaginal meshes are comprised of non-absorbable synthetic polypropylene, but Coloplast's products are comprised of a synthetic, petroleum-based mesh. The Food and Drug Administration ("FDA") cleared the first mesh product, including the Aris System, for use in the treatment of stress urinary incontinence in 1996. In May 2005, Mentor announced the launch of its new ArisTM Trans-Obturator Tape. In launch reports, Mentor called its tape "the newest technical achievement and advanced generation of trans-obturator slings for the treatment of stress urinary incontinence in women." (Doc. 34, p. 4). Coloplast purchased Mentor's surgical, urological, clinical, and consumer healthcare business segments on June 2, 2006.

On February 2, 2007, Carlen had the Aris System surgically implanted to treat stress urinary incontinence. She alleges that both she and her treating physician were exposed to an advertising and marketing campaign by Coloplast and that they received Coloplast's message that its pelvic mesh products were safe and effective. At some point after her surgery, Carlen began experiencing severe debilitating pain, dyspareunia, and mesh erosion. On November 29, 2017, she underwent a second surgery to remove the pelvic mesh products. She alleges that it was "not until recently" that she learned that the products were defective and were the cause of her pain, suffering, and complications.

(Doc. 34, p. 13). Carlen also claims that Coloplast fraudulently concealed, through affirmative misrepresentations and omissions, the risks associated with their products, preventing Carlen and her physicians from knowing or learning through due reasonable diligence that she was exposed to the risks as a direct and proximate result of Coloplast's actions.

Carlen advances eight claims against Coloplast.¹ She alleges Coloplast violated the product liability act by defectively manufacturing and designing its mesh products (Count I – strict liability) and by failing to warn Carlen and her healthcare providers about the safest and most effective methods of use of its products (Count II - negligence). She further alleges that Coloplast was negligent in its sale and distribution of the pelvic mesh products (Count III). Carlen also claims the products were subject to an express warranty (Count IV) and an implied warranty (Count V) and that Coloplast breached the warranties. Finally, she brings claims for common law fraud (Count VII), constructive fraud (Count VII), and negligent misrepresentation (Count VIII).²

#### MOTION TO DISMISS STANDARD

To survive a motion to dismiss brought pursuant to Rule 12(b)(6), a complaint must include enough factual content to give the opposing party notice of what the claim is and the grounds upon which it rests. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 698 (2009). To satisfy the notice-pleading

<sup>&</sup>lt;sup>1</sup> Carlen includes a ninth claim for punitive damages. Punitive damages need not be pleaded in a separate count as they do not raise a standalone claim for relief.

<sup>&</sup>lt;sup>2</sup> Count VIII is mislabeled as a second Count VII in the amended complaint. The Court will refer to Plaintiff's negligent misrepresentation claim as Count VIII.

standard of Rule 8, a complaint must provide a "short and plain statement of the claim showing that the pleader is entitled to relief" in a manner that provides the defendant with "fair notice" of the claim and its basis. *Erickson v. Pardus*, 551 U.S. 89, 93 (2007)(citing *Twombly*, 550 U.S. at 555 and quoting FED. R. CIV. PROC. 8(a)(2)). In ruling on a motion to dismiss for failure to state a claim, a court must "examine whether the allegations in the complaint state a 'plausible' claim for relief." *Arnett v. Webster*, 658 F.3d 742, 751 (7th Cir. 2011)(citing *Iqbal*, 556 U.S. at 677-678). A complaint "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face," rather than providing allegations that do not rise above the speculative level. *Arnett*, 658 F.3d at 751-752 (internal quotations and citation omitted).

#### **ANALYSIS**

## 1. Breach of Warranty Claims

Carlen brings two breach of warranty claims: breach of an express warranty (Count IV) and breach of an implied warranty (Count V). Coloplast argues that both are barred by the applicable statute of limitations. Under Illinois law, the statute of limitations for a claim of breach of an implied or an express warranty is four years. *See* 810 ILCS § 5/2-725.<sup>3</sup> The statute requires that any "action for breach of any contract for sale must be commenced within 4 years after the cause of action has accrued." 810 ILCS § 5/2-725(1). Section 2-725(2) explains when a cause of action accrues:

A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty

A federal court sitting in diversity applies the substantive law of the state in which it sits. *See Erie R. Co. v. Tompkins*, 304 U.S. 64, 78-79 (1938).

occurs when tender of delivery is made, except that where a warranty *explicitly extends* to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered.

810 ILCS § 5/2-725(2) (emphasis added).

Carlen filed suit on November 27, 2019, but her amended complaint alleges that the pelvic mesh products were implanted, and thus delivered, on February 2, 2007. She argues, without citing to any law in support thereof, that there is "no question" that the warranty of the mesh products explicitly extended to future performance and that her claim did not accrue until the date the mesh was removed on November 29, 2017.

The Illinois Supreme Court defines "explicit" within the meaning of § 2-725(2) as not "implied merely, or conveyed by implication; distinctly stated; plain in language; clear; not ambiguous; express; unequivocal." *Moorman Mfg. Co. v. National Tank Co.*, 435 N.E.2d 443, 454 (Ill. 1982)(citing *Binkley Co. v. Teledyne Mid-America Corp.*, 333 F. Supp. 1183, 1186 (E.D. Mo. 1971), *aff'd* 460 F.2d 276 (8th Cir. 1972)). *See also Singer v. Sunbeam Products, Inc.*, No. 15-C-1783, 2016 WL 1697777, at \*2 (N.D. Ill. Apr. 28, 2016)(citing *Cosman v. Ford Motor Co.*, 674 N.E.2d 61, 65 (Ill. App. Ct. 1996)(stating that "[w]e require that the extension of a warranty to 'future performance' be explicit.")). Carlen points to no explicit extension to future performance for the mesh products. Instead, her argument rests on the implication that a permanent medical device's warranty must extend to future performance or else the warranty is meaningless. Under Illinois law, that implication is insufficient. As such, Carlen's breach of warranty claims are barred by the applicable statute of limitations.

## 2. Applicability of the Illinois Statute of Repose

Coloplast asks the Court to find that all of Carlen's claims are barred by the statute of repose. Under the Illinois statute of repose, "no product liability action based on any theory or doctrine shall be commenced except within the applicable limitations period and, in any event, within 12 years from the date of first sale, lease or delivery of possession by a seller or 10 years from the date of first sale, lease or delivery of possession to its initial user, consumer, or other non-seller, whichever period expires earlier." 735 ILCS § 5/13-213(b). Carlen suggests, however, that her claims are saved by the discovery rule in 735 ILCS § 5/13-213(d). Section 13-213(d) adds that "notwithstanding the provisions of subsection (b) . . . if the injury complained of occurs within any of the periods provided by subsection (b) . . . , the plaintiff may bring an action within 2 years after the date on which the claimant knew, or through the use of reasonable diligence should have known, of the existence of the personal injury, . . . but in no event shall such an action be brought more than 8 years after the date on which such personal injury, death or property damage occurred." 735 ILCS § 5/13-213(d).

In determining whether § 13-213(d)'s discovery rule saves Carlen's claims, the Court must first look to § 13-213(b) to determine the period of repose. *See Garza v. Navistar Intern. Transp. Corp.*, 666 N.E.2d 1198, 1203 (Ill. 1996). The shorter of the ten- or twelve-year period is the one that "serve[s] to extinguish a claim." *Id.* Here, Carlen's pelvic mesh was implanted on February 2, 2007, the latest date it could be said to be sold or delivered to its initial user. As a result, the latest date the repose period ended was ten years later on February 2, 2017.

In order for Carlen "to take advantage of subsection (d)'s two-year extension, she must have sustained her injuries" within the period of repose. *Garza*, 666 N.E.2d at 1203 (citing *Taylor v. Redmond Corp.*, 719 F. Supp. 738, 743 (N.D. Ill. 1989) *aff'd* 909 F.2d 225 (7th Cir. 1990)). The Illinois Supreme Court allows filing of a suit outside the repose period under § 13-213(d) only for injuries suffered during the period. *See Davis v. Toshiba Machine Co., America*, 710 N.E.2d 399, 401-402 (Ill. 1999). That is to say, if a consumer purchased a product and was injured by it years later, the discovery rule could save the claim and allow filing suit within 2 years of the date of injury so long as the injury occurred before the § 13-213(b) repose period expired.

To assess whether Carlen's claim is barred, the Court must determine when her injury occurred. Courts interpret the date of injury as the "date of exposure, ingestion, or implantation surgery." *Stark v. Johnson & Johnson*, No. 18-cv-06609, 2020 WL 1914767, at \*5 n.9 (citing *Zimmerman v. Abbott Labs, Inc.*, 545 N.E.2d 547 (Ill. 1989)). For Carlen, that date was February 2, 2007. Section 13-213(d) clearly states that "in no event shall such an action be brought more than 8 years after the date on which such personal injury . . . occurred," or February 2, 2015, so § 13-213(d) does not appear to save Carlen's claim even if, as she claims, she did not discover her injury until November 2017.

The amended complaint does not allege a specific date in 2017 when Carlen discovered her injury, but the mesh was not removed until November 29, 2017, almost ten months after the § 13-213(b) repose period expired on February 2, 2017. Carlen's argument, however, is that her suit is timely because it was filed within two years of her second surgery on November 27, 2017, pointing to that date as the date she knew or

should have known of her injury. Because her second surgery occurred after the expiration of the § 13-213(b) repose period, this line of argument is unpersuasive, and the Court finds that Carlen's suit is barred, at least in part, by the Illinois statute of repose.

Carlen's strict liability claims (Counts I and II) fall squarely within the reach of the statute of repose and are barred. Coloplast argues, however, that all of Carlen's claims fall within the reach of the repose period based on *Jablonski v. Ford Motor Co.*, 955 N.E.2d 1138 (Ill. 2011). *Jablonski* arose out of a rear-end automobile accident that caused a wrench in the trunk of the plaintiffs' car to puncture the gas tank, setting the car on fire. One of the car's occupants was killed and the other was severely burned and permanently disfigured. Plaintiffs brought nine claims against Ford Motor Company, including strict liability and negligence claims, alleging that, at the time the car was manufactured and thereafter, Ford had a legal duty to ensure the vehicle was not unreasonably dangerous and defective. Plaintiffs also alleged negligence and strict liability claims related to the failure to warn consumers of the risk of trunk contents puncturing the fuel tank.

In clarifying the duty analysis required for negligent product design cases, the Illinois Supreme Court noted that "[n]umerous commentators have concurred that the balancing test developed for strict liability claims, which examines whether a product is unreasonably dangerous, is essentially identical to the test applied in determining whether a defendant's conduct in designing a product is unreasonable and that any distinction is mere semantics." *Jablonski*, 955 N.E.2d at 1155 (citing references omitted). The Court, however, did not address any implications that similarity might have on the statute of limitations or the statute of repose.

Despite Coloplast's argument to the contrary, the Court finds that the discussion in *Jablonski* does not suggest that the Illinois Supreme Court views claims for negligent product design as strict liability claims for purposes of applying the statute of repose. In fact, lower Illinois courts have refused to apply the statute of repose to product liability actions sounding in negligence. *See, e.g., Dintelman v. Alliance Mach. Co.*, 453 N.E.2d 128, 129-30 (Ill. App. Ct. 1983)(holding that the statute of repose does not apply to product liability actions based upon a theory of negligence because the causes of action involve different elements). Furthermore, Coloplast itself correctly acknowledges that the Illinois Supreme Court invalidated the Civil Justice Reform Amendments of 1995, which included a broadening of the application of the statute of repose beyond actions based on the doctrine of strict liability. *See Best v. Taylor Machine Works*, 689 N.E.2d 1057, 1106 (Ill. 1997).<sup>4</sup> As such, while Carlen's strict liability claims are barred by the statute of the repose, the Court refuses to extend that bar to her negligence or fraud claims.

In Best, the Illinois Supreme Court invalidated various provisions of the Civil Justice Reform Amendments of 1995, Pub. Act 89-7, eff. March 9, 1995. The specific provisions invalided by the Court did not include the statute of repose, but the Court invalidated all of Pub. Act 89-7 on the grounds that the unconstitutional provisions could not be severed from the remainder of the act. See Best, 689 N.E.2d at 1064. As noted by Coloplast in its brief, Pub. Act 89-7 attempted to broaden the application of the statute of repose to actions beyond those based on the doctrine of strict liability in tort. (Doc. 39, p. 4 n.5). See, e.g., 735 ILCS § 5/13-213(b)(noting that statute of repose applies to a "product liability action based on any theory or doctrine", as amended by Pub. Act 89-7, § 15). See also 735 ILCS § 5/13-213(a)(3)(defining "product liability action" to include "any action based on any theory or doctrine brought against the seller of a product on account of personal injury, . . . . ", as amended by Pub. Act 89-7, § 15). The prior version of the statute applied the statute of repose to a "product liability action based on the doctrine of strict liability in tort" and defined "product liability action" to mean "any action based on the doctrine of strict liability in tort brought against the seller of a product on account of personal injury, . . . ." Dintelman, 453 N.E.2d at 130-131. Based on Best and Coloplast's acknowledgement that there are no post-Best cases applying the statute of repose to actions beyond strict liability, it appears that the prior version arguably remains in force under Illinois law as the current version, Pub. Act 89-7, § 15 (eff. March 9, 1995), is the last time the statute was amended.

#### 3. Failure to Warn Claim

In her failure to warn claim, Carlen alleges that Coloplast was aware, at the time the products left its control and while they were being marketed, that its pelvic mesh products had a high rate of failure and that they caused a high rate of infections, abscesses, vaginal erosions and extrusions, and a high rate of chronic pain. She also claims that Coloplast was aware of the necessity to remove the pelvic mesh products from patients' bodies and of the difficulty of doing so. Carlen further alleges that Coloplast failed to provide post-sale warnings or engage in post-sale marketing efforts to physicians regarding the risk of complications and the necessity to remove the pelvic mesh products.

To the extent that Carlen seeks recovery on a strict liability theory, her claim in Count II is barred by the statute of repose and will be dismissed. Carlen refers to strict liability in her amended complaint (See Doc. 34, ¶ 71), but she also includes language that sounds in negligence and, to some degree intentional tort (See Doc. 34, ¶ 69)("Coloplast intentionally, recklessly, and maliciously misrepresented the safety, risks and benefits of the Coloplast Pelvic Mesh Products . . . ."). In her response to Coloplast's motion, Carlen also describes Count II as raising negligence and strict liability claims. This lack of clarity raises concerns under Rule 12(b)(6) because it is difficult to expect Coloplast to answer Carlen's complaint when it is unclear what the nature of a claim is, but Coloplast does not raise that issue in its motion to dismiss.

Coloplast instead seeks dismissal on another ground, arguing that Carlen's claim fails due to the learned intermediary doctrine. To prove a claim for failure to warn, a

"plaintiff must demonstrate that the manufacturer did not disclose an unreasonably dangerous condition or instruct on the proper use of the product to which the average consumer would not be aware." *Salrerno v. Innovative Surveillance Tech., Inc.,* 932 N.E.2d 101, 109 (Ill. App. Ct. 2010). A duty to warn arises when a "manufacturer has greater knowledge of a product's dangerous propensities than a consumer has." *Hansen v. Baxter Healthcare Corp.,* 723 N.E.2d 302, 311 (Ill. App. Ct. 1999)(citing *Kokoyachuk v. Aeroquip Corp.,* 526 N.E.2d 607 (Ill. App. Ct. 1988)).

The Illinois Supreme Court has explained the duty of a manufacturer of a prescription medical device:

Generally, the manufacturer of a prescription medical device has a duty to warn prescribing physicians or other health professionals who may prescribe the device of the product's known dangerous propensities. Likewise, physicians, using their medical judgment, have a duty to convey the warnings to their patients. The duty to warn the healthcare professional, rather than the ultimate consumer or patient, is an expression of the "learned intermediary" doctrine. A corollary of that doctrine is the principle that a prescription medical device manufacturer need not provide a warning of risks already known to the medical community.

Hansen v. Baxter Healthcare Corp., 764 N.E.2d 35, 42 (Ill. 2002) (citations omitted). In terms of Carlen's allegations, she claims that Coloplast failed to warn both Carlen and her healthcare providers, and, absent the deficiencies mentioned above, Carlen could state a claim under Count II.

## 4. Failure to Plead Reliance in Negligence Claim

Coloplast argues that Carlen failed to plead reliance by her healthcare providers, as required for a negligent failure to warn claim (Count II). In *Norabuena v. Medtronic, Inc.*, an Illinois Appellate Court upheld a trial court order dismissing a failure to warn claim

that lacked "specific factual allegations in the complaint asserting that [the plaintiff's] surgeon encountered or relied on any of the asserted promotional marketing." 86 N.E.3d 1198, 1209 (Ill. App. Ct. 2017). Carlen does not challenge the application of *Norabuena* to this action. Instead, she argues that her complaint mentions her physicians and healthcare providers, so her claims do not have the pleading deficiencies addressed in *Norabuena*.

A careful review of the amended complaint shows that Carlen alleges various marketing statements and efforts by Coloplast. She also alleges that Coloplast failed to warn patients and physicians of the risks associated with its pelvic mesh products. Coloplast allegedly marketed to the medical community, at large, and Carlen claims that she and her physicians were exposed to Coloplast's marketing and advertising. She also claims that both she and her physicians "either through direct promotional contact . . . , through word-of-mouth with other health care providers, and/or through promotional materials, received the information . . . that the Pelvic Mesh Products were safe and effective for use . . . ." (Doc. 34, ¶45).

Carlen, however, does not plead any sort of reliance on the marketing materials by her or her healthcare providers in the allegations applicable to Count II, so her failure to warn claim lacks the necessary allegations to state a claim as a result of that omission. Due to the pleading errors in Count II, the Court dismisses it with prejudice as to any strict liability failure to warn claim but without prejudice with leave to amend as to any non-strict liability claim.

## 5. Negligent Misrepresentation

The elements of a negligent misrepresentation claim are: "(1) a false statement of

material fact, (2) carelessness or negligence in ascertaining the truth of the statement by the party making it, (3) an intention to induce the other party to act, (4) action by the other party in reliance on the truth of the statement, and (5) damages to the other party resulting from such reliance, (6) when the party making the statement is under a duty to communicate accurate information." *Fox Associates, Inc. v. Robert Half Intern., Inc.,* 777 N.E.2d 603, 606 (Ill. App. Ct. 2002).

In Count VIII, Carlen alleges that Coloplast had a duty to represent truthfully that its mesh products had not been tested adequately or found to be safe or effective for treatment of incontinence or pelvic organ prolapse. She alleges further that statements to the contrary were false and either negligently made or made without the exercise of ordinary care. She claims Coloplast breached its duty by representing that the products had no serious side effects and that her injuries were a direct and proximate result of the misrepresentations. She also claims that she reasonably and justifiably relied on Coloplast's misrepresentations.

Coloplast seeks dismissal of this claim because Carlen fails to plead that she acted in reliance on the truth of the statements about the mesh products' safety. This claim, as pleaded, presents a close call, but the Court finds that it satisfies the notice-pleading requirements of Rule 8. Throughout her amended complaint and in Count VIII, which Carlen's final claim for relief incorporates by reference, Carlen pleads that Coloplast negligently or carelessly provided false safety information about its medical devices to Carlen and her doctors. And, while it could be fleshed out in greater detail, Carlen claims that she relied on the false information about safety in choosing to move forward with a

surgery with the Aris System. That is sufficient to satisfy Rule 8.

## 6. Negligence Claim

In Count III, Carlen alleges that Coloplast was negligent in the development, design, marketing, and sale of its mesh products. To state a claim for negligence under Illinois law, a plaintiff must allege that a defendant owed the plaintiff a duty of care, that the defendant breached that duty, and that the breach proximately caused plaintiff's injury. See Thompson v. Gordon, 948 N.E.2d 39, 45 (Ill. 2011)(citing Iseberg v. Gross, 879 N.E.2d 278 (2007)). Carlen alleges Coloplast had a duty to exercise reasonable care in the development, design, marketing, and sale of its mesh products, including a duty to ensure the products did not pose a significantly increased risk of bodily injury. She alleges Coloplast breached its duty by failing to warn the general public, including Carlen, of the risks associated with its products and by failing to exercise reasonable care in designing a safe product and issuing appropriate warnings. Carlen also alleges that she was injured as a result of these failures. These allegations are sufficient to state a claim for negligence under Illinois law.

#### 7. Fraud Claims

State law fraud claims raised in federal court are subject to the heightened pleading requirements of Rule 9(b). See Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Financing Servs., Inc., 536 F.3d 663, 668 (7th Cir. 2008). To plead a fraudulent concealment claim, a plaintiff must prove that the defendant "intentionally omitted or concealed a material fact that it was under a duty to disclose to the plaintiff." Wigod v. Wells Fargo Bank, N.A., 673 F.3d 547, 571 (7th Cir. 2012). A duty to disclose arises if

"'plaintiff and defendant are in a fiduciary or confidential relationship' or in a 'situation where plaintiff places trust and confidence in defendant, thereby placing defendant in a position of influence and superiority over plaintiff." *Id.* (quoting *Connick v. Suzuki Motor Co.*, 675 N.E.2d 584, 593 (1996). A special trust relationship between a plaintiff and defendant is "'extremely similar to that of a fiduciary relationship.'" *Id.* (quoting *Benson v. Stafford*, 941 N.E.2d 386, 403 (2010)). As the Seventh Circuit has noted, "state and federal courts in Illinois have rarely found a special trust relationship to exist in the absence of a more formal fiduciary one." *Id.* (citing references omitted).

While Coloplast only raises the lack of a fiduciary duty with respect to Carlen's constructive fraud claim, the issue applies equally to her common law fraud claim. In her common law fraud claim, Carlen alleges that Coloplast had sole access to material facts about the defective nature of its products, placing it in a position of superiority with respect to her common law and constructive fraud claims. That is sufficient at this stage to plead the existence of a duty to disclose.

To satisfy Rule 9(b), however, Carlen must also plead the particulars of reliance, that is the "who, what, when, where, and how" of Coloplast's alleged omission. Carlen's complaint satisfies these requirements, as it states what information was withheld (the extent of risk posed by using Coloplast's mesh products), when it should have been provided (during marketing and advertising, prior to Carlen's surgery, and throughout the time period when the mesh products were implanted in her), who was responsible for providing the information (Coloplast), and the where and the how (via a public medium). Coloplast's arguments to the contrary attempt to inject a greater degree of

specificity at the pleading stage than the federal rules require. As such, Carlen's fraud claims pass muster under Rule 9(b).

#### **CONCLUSION**

For the above-stated reasons, Defendant Coloplast Corporation's motion to dismiss (Doc. 38) is **GRANTED in part** and **DENIED in part**. Plaintiff Marilyn Carlen's strict liability claims in Count I and Count II are barred by the Illinois statute of repose and are dismissed with prejudice. Count II is dismissed without prejudice with leave to amend as to any non-strict liability failure to warn claim. Carlen's breach of warranty claims in Count IV and Count V are barred by the statute of limitations and are dismissed with prejudice. Coloplast's motion is denied as to Count III (Negligence), Count VI (Common Law Fraud), Count VII (Constructive Fraud), and Count VIII (Negligent Misrepresentation). Plaintiff is **DIRECTED** to file an amended complaint that complies with the rulings in this order on or before July 6, 2020.

IT IS SO ORDERED.

Dated: June 8, 2020.

Digitally signed by Judge Sison Date: 2020.06.08 09:59:40 -05'00'

GILBERT C. SISON United States Magistrate Judge