

UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF ILLINOIS  
PEORIA DIVISION

ALBERTA LEE GERK,	)	
	)	
Plaintiff	)	
	)	
v.	)	Case No.: 15-1145
	)	
CL MEDICAL SARL; CL MEDICAL, INC.)	)	
AND UROPLASTY, INC.	)	
	)	
Defendants.	)	

**ORDER AND OPINION**

This matter is now before the Court on Defendant CL Medical, Inc.’s Partial Motion to Dismiss [11] and Plaintiff’s Response [17] thereto. For the reasons set forth below, the Motion [11] is Granted in Part and Denied in Part.

**Background**

The following facts are taken from Alberta Gerk’s Complaint. On May 22, 2012, Plaintiff underwent a medical procedure for stress urinary incontinence where an I-STOP transvaginal mesh sling device was implanted. The I-STOP device was designed and manufactured by CL Medical SARL (“SARL”), a French company, and sold and distributed by CL Medical, Inc. (“CL Medical”), a Delaware corporation with its principal place of business in California. Vincent Gorla and his wife are owners of SARL and supermajority owners of CL Medical.

The FDA approved the 510(k) expedited application for the device as “substantially equivalent” to previously approved devices and cleared the I-STOP device for market in the United States in August of 2005. SARL began selling I-STOP devices to CL Medical some time

in 2007. The I-STOP was marketed as more safe and effective than competing pelvic mesh products. In 2009, the FDA was notified of complications from the I-STOP device. As a result of her I-STOP implant, Plaintiff has suffered severe and permanent injuries despite subsequent surgeries.

Gerk's Complaint alleges nine causes of action against Defendants: (1) Strict Liability: Failure to Warn; (2) Strict Liability: Design Defect; (3) Negligence; (4) Breach of Implied Warranties; (5) Breach of Express Warranty; (6) Fraud; (7) Fraud by Concealment; (8) Negligent Misrepresentation; and (9) Negligent Infliction of Emotional Distress. Plaintiff also requests punitive damages. Defendant CL Medical, Inc. moved for dismissal of Claims 3 through 9, as well as the punitive damages claim.

### **Discussion**

Courts have traditionally held that a complaint should not be dismissed unless it appears from the pleadings that the plaintiff could prove no set of facts in support of her claim which would entitle her to relief. *See Conley v. Gibson*, 355 U.S. 41 (1957); *Gould v. Artisoft, Inc.*, 1 F.3d 544, 548 (7<sup>th</sup> Cir. 1993). Rather, a complaint should be construed broadly and liberally in conformity with the mandate in the Federal Rules of Civil Procedure 8(e). More recently, the Supreme Court has phrased this standard as requiring a showing sufficient "to raise a right to relief beyond a speculative level." *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1965 (2007).

The claim for relief must be "plausible on its face." *Id.*; *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1953 (2009). For purposes of a motion to dismiss, the complaint is construed in the light most favorable to the plaintiff; its well-pleaded factual allegations are taken as true, and all reasonably-drawn inferences are drawn in favor of the plaintiff. *See Albright v. Oliver*, 510 U.S. 266, 268 (1994); *Hishon v. King & Spalding*, 467 U.S. 69 (1984); *Lanigan v. Village of East*

*Hazel Crest*, 110 F.3d 467 (7<sup>th</sup> Cir. 1997); *M.C.M. Partners, Inc. V. Andrews-Bartlett & Assoc., Inc.*, 62 F.3d 967, 969 (7<sup>th</sup> Cir. 1995); *Early v. Bankers Life & Cas. Co.*, 959 F.2d 75 (7<sup>th</sup> Cir. 1992). When a Complaint alleges fraud or mistake, it must state the allegations with particularity. Fed. R. Civ. P. 9(b). A Complaint will meet the heightened pleading standard of Rule 9(b) when it “show[s], in detail, the nature of the charge, so that vague and unsubstantiated accusations of fraud do not lead to costly discovery and public obloquy.” *U.S. ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854-55 (7<sup>th</sup> Cir. 2009).

### **(3) Negligence**

Under Illinois Law, a negligence claim contains four elements: (1) existence of a duty; (2) breach of that duty; (3) injury; and (4) proximate causation of the injury flowing from the breach. *Gouge v. Central Illinois Pub.Serv.*, 144 Ill.2d 535, 163 Ill.Dec. 842, 582 N.E.2d 108, 111 (1991). Here, Plaintiff has sufficiently pleaded these elements to survive a motion to dismiss. The Complaint adequately alleges that CL Medical owed a duty to Plaintiff and others to use reasonable care in the marketing, advertising, promotion and sale of the I-STOP device, and that CL Medical breached that duty by failing to adequately label the device, failing to warn patients and physicians about risks or defects, and failing to adequately monitor and report defects related to the device. The Complaint also sufficiently alleges that Plaintiff suffered injuries, and that those injuries were a result of CL Medical’s breach. The Seventh Circuit has acknowledged that there are no special pleading requirements for negligence claims. *See McCauley v. City of Chicago*, 671 F.3d 611, 624 (7<sup>th</sup> Cir. 2011) (“Apart from jurisdiction and damages, it is sufficient for the complaint to say only that on a stated date at a stated place, defendant ‘negligently drove a motor vehicle against the plaintiff.’”).

#### **(4) Breach of Implied Warranties**

Next, the Complaint alleges that Defendants breached both the implied warranty of fitness for a particular purpose and the implied warranty of merchantability. Illinois has adopted the Uniform Commercial Code governing sales of goods. Article 2, Section 315 states:

*Implied Warranty: Fitness for Particular Purpose.* Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose.  
810 Ill. Comp. Stat. 5/2-315.

To state a claim for breach of implied warranty of fitness for a particular purpose, plaintiff “must allege that (1) the seller had reason to know of the particular purpose for which the buyer required the goods; (2) the buyer relied on the seller's skill and judgment to select suitable goods; and (3) the seller knew of the buyer's reliance on its skill and judgment.” *In re McDonald's French Fries Litig.*, 503 F. Supp. 2d 953, 957 (N.D. Ill. 2007) quoting *Industrial Hard Chrome Ltd. v. Hetran, Inc.*, 64 F.Supp.2d 741, 746 (N.D.Ill.1999). “A ‘particular purpose’ differs from the ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question.” 810 Ill. Comp. Stat. Ann. 5/2-315.

In contrast to Section 315’s implied warranty of fitness for a particular purpose, the implied warranty of merchantability requires goods to be “merchantable.” 810 Ill. Comp. Stat. Ann. 5/2-314 (“Goods to be merchantable must be at least such as . . . (c) are fit for the ordinary purposes for which such goods are used . . . (e) are adequately contained, packaged, and labeled as the agreement may require; and (f) conform to the promises or affirmations of fact made on the container label if any.”) *Id.*

Here, Plaintiff's Complaint alleges that Defendants "impliedly warranted that the I-STOP was merchantable and fit and safe for ordinary use" and "impliedly warranted that the I-STOP device was fit for the particular purpose of correcting urinary incontinence." However, the Complaint fails to plausibly claim that the I-STOP device was sold for a particular purpose distinct from the device's ordinary use or purpose—to treat urinary stress incontinence. Because the Implied Warranty for a Particular Purpose Claim fails to identify what non-ordinary purpose the I-STOP device was used for, Plaintiff's claim is dismissed with leave to amend.

#### **(5) Breach of Express Warranty**

Plaintiff's Complaint next alleges that Defendant breached an express warranty. In Illinois, an express warranty by the seller is created when "any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." 810 Ill. Comp. Stat. 5/2-313. Additionally, "it is not necessary to the creation of an express warranty that the seller use formal words such as 'warrant' or 'guarantee' or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." *Id.*

Here, the Complaint specifically alleges affirmations of fact made by CL Medical, including claims made on Defendant's website and in marketing and promotional materials relating to the quality and efficacy of the I-STOP device. The Complaint also alleges that Plaintiff and her physician relied on Defendant CL Medical's affirmations, that such affirmations were false, and that Plaintiff would not have consented to the procedure if she was aware of the

risks associated with the I-STOP device. Plaintiff's breach of express warranty claim is therefore sufficient to survive a motion to dismiss.

#### **(6) Fraud**

Defendant CL Medical also moves to dismiss Plaintiff's claim of fraud. The Federal Rules of Civil Procedure call for a heightened pleading standard for claims alleging fraud or mistake, requiring the plaintiff to "state with particularity the circumstances constituting fraud or mistake." However, the "conditions of a person's mind may be alleged generally." Fed.R.Civ.P. 9(b). A Complaint alleges fraud with particularity when it states "the who, what, when, where, and how: the first paragraph of any newspaper story." *U.S. ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853 (7th Cir. 2009) citing *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir.1990).

Here, Plaintiff's Complaint alleges that Defendant CL Medical ("who") marketed and sold medical devices that it knew to be defective ("what") in the United States and Illinois ("where") via patient brochures and websites offering exaggerated and misleading expectations about the safety and utility of the device ("how"). "To say that fraud has been pleaded with particularity is not to say that it has been proved." *U.S. ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d at 855. Plaintiff's fraud claim is therefore sufficient to survive a motion to dismiss.

#### **(7) Fraud by Concealment; (8) Negligent Misrepresentation**

To state a claim for fraudulent misrepresentation in Illinois, a plaintiff must allege "(1) a false statement of material fact; (2) that the party making the statement knew the statement was false or believed it to be untrue; (3) the party to whom the statement was made had a right to rely on that statement and did, in fact, rely on it; (4) the statement was made for the purpose of

inducing the other party to act; and (5) that reliance by the person to whom the statement was made led to his injury.” *Cangemi v. Advocate S. Suburban Hosp.*, 364 Ill. App. 3d 446, 468, 845 N.E.2d 792, 811 (2006) citing *Stewart v. Thrasher*, 242 Ill.App.3d 10, 15–16, 182 Ill. Dec. 930, 610 N.E.2d 799, 803 (1993). Moreover, “mere concealment may amount to a misrepresentation when it is “done with an intent to deceive under circumstances creating an opportunity and a duty to speak,” and the “concealed information is such that the other party would have acted differently had he been aware of it.” *Id.* at 812.

Negligent misrepresentation consists essentially of the same elements as fraudulent misrepresentation, except that the defendant’s mental state is different. *Board of Educ. Of City of Chicago v. A, C, and S, Inc.*, 131 Ill. 2d 428, 452 (1989). Unlike fraudulent misrepresentation, negligent misrepresentation does not require that the defendant know the statement is false. *Id.* Rather, “carelessness or negligence in ascertaining its truth will suffice for a cause of action.” *Id.*

Here, the Complaint alleges that Defendants either knew the I-STOP device was faulty from the beginning, or that they subsequently learned of, and concealed, serious defects with the device. The Complaint also alleges that reports from the FDA and test results indicating that mesh implants, including the I-STOP, were causing complications, and that CL Medical was or should have been aware of this information when it advertised and sold the I-STOP device that was implanted in Plaintiff. As to the third element, the Complaint alleges that Plaintiff’s physician did in-fact rely on Defendant’s claims and representations about the I-STOP. Moreover, it is certainly reasonable to infer that doctors, including Plaintiff’s physician, have a right to rely on information by medical device manufacturers and distributors regarding the safety and efficacy of the device. As to the fourth and fifth elements, the Complaint has adequately alleged that Defendants made materially false statements or concealed information related to the safety of the I-STOP, and that Plaintiff and her physician would have acted

differently had they known otherwise. Thus, the fraudulent concealment and negligent misrepresentation claims in the Complaint were sufficiently pleaded to survive a motion to dismiss.

#### **(9) Negligent Infliction of Emotional Distress**

Defendant CL Medical also moves to dismiss Claim 9 of the Complaint, negligent infliction of emotional distress, as “duplicative of Counts 1 and 2.” However, CL Medical does not substantiate or provide factual or legal support for such argument. Because CL Medical has only provided a perfunctory and unsubstantiated argument, it is waived. *See, e.g., Colburn v. Trustees of Indiana Univ.*, 973 F.2d 581, 593 (7th Cir. 1992); *Freeman United Coal Mining Co. v. Office of Workers' Compensation Programs, Benefits Review Board*, 957 F.2d 302, 305 (7th Cir.1992) (“[W]e have no obligation to consider an issue that is merely raised, but not developed, in a party's brief.”); *United States v. Haddon*, 927 F.2d 942, 956 (7th Cir.1991) (“A skeletal ‘argument’, really nothing more than an assertion, does not preserve a claim.”).

#### **Punitive Damages**

Finally, Defendant CL Medical moves to dismiss Plaintiff’s claim for punitive damages. Punitive damages require development of a factual record not available at this stage of the litigation. Accordingly, the challenge to the claim for punitive damages is premature, and is denied without prejudice to reconsideration on summary judgement.



## CONCLUSION

For the reasons set forth above, Defendant's Partial Motion to Dismiss [11] is granted in part and denied in part. Plaintiff is granted leave to file an amended complaint re-pleading her claim for breach of implied warranties within 14 days if she has a good-faith basis for doing so.

Entered this 10 day of November, 2015.      s/Chief Judge James E. Shadid

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James E. Shadid  
Chief United States District Judge