

UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
TAMPA DIVISION

BARBARA HAMBLEN and HERBERT  
HAMBLEN,

Plaintiffs

v.

Case No. 8:17-cv-1613-T-33TGW

DAVOL, INC. and C.R. BARD, INC.,

Defendants.

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**ORDER**

This cause is before the Court pursuant to Defendants Davol, Inc. and C. Bard Inc.'s Motion to Dismiss, in Part, Plaintiffs' Amended Complaint (Doc. # 18), which was filed on October 10, 2017. Plaintiffs Barbara Hamblen and Herbert Hamblen filed a Response in Opposition to the Motion (Doc. # 23) on October 23, 2017. For the reasons that follow, the Motion is denied.

**I. Background**

On December 14, 2005, Ms. Hamblen had an incisional hernia repaired by Dr. John Manubay at the Pine Brook Medical Center in Brooksville, Florida. (Doc. # 15 at ¶ 42). Dr. Manubay used a Large Circle Bard® Composix® Kugel® Hernia Patch. (Id. at ¶ 43). The Large Circle Bard® Composix® Kugel® Hernia Patch "is designed for the repair of ventral and inguinal hernias." (Id. at ¶ 20). Defendants' Large Circle

Bard® Composix® Kugel® Hernia Patch "has two layers of polypropylene mesh, a layer of expanded polytetrafluoroethylene ('ePTFE') and a single rigid plastic polyethylene terephthalate ring." (Id. at ¶ 23).

The Patch implanted in Ms. Hamblen was unreasonably dangerous, according to Plaintiffs, because "it may malfunction after being implanted; the rigid plastic ring may break; in response to body forces the Bard CK Patch may distort, buckle, or warp; it was not properly manufactured; [it] was defectively designed; [and its] components could cause a chronic inflammatory response." (Id. at ¶ 10).

Defendants issued a product recall covering the Large Circle Bard CK Patch in January of 2007. (Id. at ¶ 64). Ms. Hamblen indicates that she "suffered years of severe abdominal pain and sought treatment from multiple doctors to identify the cause of the pain and to find relief. She was ultimately seen by Dr. Marc Polecritti who diagnosed her abdominal wall pain to be caused by her Bard CK Hernia Patch." (Id. at ¶ 67). Dr. Polecritti removed the mesh from Ms. Hamblen's abdomen in an operation that occurred on July 10, 2013. (Id. at ¶ 68). Her doctor opines that "to a reasonable degree of medical probability, that the memory recoil ring in Ms. Hamblen's Bard CK Patch was fractured and this break was a contributing cause

of the injuries suffered by Ms. Hamblen." (Id. at ¶ 70).

Plaintiffs claim that Defendants omitted information about the "risks, dangers, and disadvantages" of the product, and "marketed, advertised, promoted, sold and distributed" the product "as safe," when in fact, Defendants "knew or should have know" that the product "was not safe." (Id. at ¶ 74).

On July 3, 2017, Plaintiffs Barbara Hamblen and Herbert Hamblen filed a Complaint against Defendants Davol, Inc. and C. Bard Inc. (Doc. # 1) and filed an Amended Complaint (Doc. # 15) on September 26, 2017. The Amended Complaint contains the following six counts: negligence (count 1), strict liability - design and/or manufacturing defect (count 2), failure to warn (count 3), negligent misrepresentation (count 4), fraud - fraudulent misrepresentation and fraudulent nondisclosure (count 5), and loss of consortium (count 6).

At this juncture, Defendants move for the dismissal of counts 4 and 5 of the Amended Complaint. (Doc. # 18). Plaintiffs have filed a response in opposition to the Motion to Dismiss and the Motion is ripe for review.

## **II. Legal Standard**

On a motion to dismiss, this Court accepts as true all of the factual allegations in the complaint and construes them in the light most favorable to the plaintiff. Jackson v.

Bellsouth Telecomms., 372 F.3d 1250, 1262 (11th Cir. 2004). Further, this Court favors the plaintiff with all reasonable inferences from the allegations in the complaint. Stephens v. Dep't of Health & Human Servs., 901 F.2d 1571, 1573 (11th Cir. 1990) ("On a motion to dismiss, the facts stated in [the] complaint and all reasonable inferences therefrom are taken as true."). However, the Supreme Court explains that:

While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (internal citations omitted). Further, courts are not "bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986).

In accordance with Twombly, Federal Rule of Civil Procedure 8(a) calls "for sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 663 (2009) (quoting Twombly, 550 U.S. at 570). A plausible claim for relief must include "factual content [that] allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id.

### **III. Analysis**

With respect to fraud and misrepresentation claims, Rule 9(b), Fed. R. Civ. P., requires that "a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." The Court is mindful of the directive that "a court considering a motion to dismiss for failure to plead fraud with particularity should always be careful to harmonize the directives of rule 9(b) with the broader policy of 'notice pleading' found in Rule 8." Friedlander v. Nims, 755 F.2d 810, 813 n.3 (11th Cir. 1985), (abrogated on other grounds).

Fraud allegations must be stated with particularity to alert defendants to the "precise misconduct with which they are charged" and to protect defendants "against spurious charges of immoral and fraudulent behavior." Durham v. Bus. Mgmt. Assocs., 847 F.2d 1505, 1511 (11th Cir. 1988) (internal quotation marks omitted). Rule 9(b) is satisfied if the claim sets forth:

- (1) precisely what statements were made in what documents or oral representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or, in the case of omission, not making) same, and (3) the content of such statements and the manner in which they misled the plaintiff, and (4) what the defendants obtained as a consequence of the fraud.

Ziembra v. Cascade Int'l, Inc., 256 F.3d 1194, 1202 (11th Cir. 2001) (citing Brooks v. BCBS Fla., Inc., 116 F.3d 1364, 1371 (11th Cir. 1997)).

**A. Negligent Misrepresentation (count 4)**

Although Plaintiffs allege "negligent misrepresentation" against Defendants, "by definition 'misrepresentation' includes concealment of facts by fraud." Cruz v. Mylan, Inc., No. 8:09-cv-1106-T-17EAJ, 2010 U.S. Dist. LEXIS 13563, at \*7 (M.D. Fla. Feb. 17, 2010). Under Florida law, the elements of such a claim are: "(1) the defendant made a misrepresentation of material fact that he believed to be true but which was in fact false; (2) the defendant was negligent in making the statement because he should have known the representation was false; (3) the defendant intended to induce the plaintiff to rely . . . on the misrepresentation; and (4) injury resulted to the plaintiff acting in justifiable reliance upon the misrepresentation." Lee Mem. Hosp. Sys. v. Blue Cross & Blue Shield of Fla., Inc., No. 2:16-cv-901-FtM-38MRM, 2017 U.S. Dist. LEXIS 47805, at \*52 (M.D. Fla. Feb. 22, 2017). And, "because negligent misrepresentation sounds in fraud, the facts supporting the claim must be plead with particularity." Id.

Here, Plaintiffs have included factual allegations that

satisfy each required element for the misrepresentation claim, and they have done so with sufficient particularity to meet the strictures of Rule 9. Plaintiffs allege that Defendants misrepresented that the Bard CK Hernia Patch was safe and effective for its intended use and omitted information showing that the product was not safe. (Doc. # 15 at ¶¶ 11, 16, 17, 40, 45, 53, 56, 59, 74, 150, 159, 160, 165, 166, 170). Plaintiff also allege that Defendants were negligent in making those statements and with respect to key omissions and that Defendants were well aware that the patch was dangerous to patients and defectively designed. (Id. at ¶¶ 10, 12, 13, 14, 15, 35, 36, 37, 41, 46, 47, 50, 51, 52, 55, 60, 61, 64, 75, 77, 91, 97, 156, 157, 161, 162, 168). Likewise, Plaintiffs allege that Defendants made the misrepresentations and omissions directly to the public, to the Plaintiffs, and to healthcare providers in an effort to induce them to choose the Bard Patch. (Id. at ¶¶ 151-155, 157-158, 167, 169, 171). Finally, Plaintiffs allege that Mrs. Hamblen relied on the misrepresentations and omissions and had the Patch implanted, which caused her physical, emotional, and financial injury. (Id. at ¶¶ 19, 67, 68, 69, 70, 71, 72, 96, 104, 172, 173).

In Cubbage v. Novartis Pharmaceuticals Corporation, No. 5:16-cv-129-Oc-30PRL, 2016 WL 3595747, (M.D. Fla. July 5, 2016), the court denied a motion to dismiss a negligent

misrepresentation claim in a case with similar factual allegations. There, the plaintiff alleged that Novartis “misrepresented to healthcare providers and the public that [the drug] was proper for its intended use and more effective and safe than other treatments . . . and Novartis knew that [the drug] was less safe than other treatments and not fit for its proper and intended use.” Id. at \*11. The plaintiff also alleged that Novartis’s misrepresentations were located on the drug’s labels and package inserts and “were also communicated by the oral representations of Novartis’s sales representatives.” Id. The Cubbage court found that these allegations met Rule 9’s specifications: “Plaintiff has alleged sufficient factual matter to satisfy the requirement[s]” of Rule 9. Id.

This Court reaches the same result. Plaintiffs’ negligent misrepresentation claim asserts that Defendants made the misrepresentations and omissions through “promotional and marketing campaigns as well as through direct representations made by their sales representatives/territory managers to healthcare providers, and by Defendants’ surgeon trainers to healthcare providers and surgeons.” (Doc. # 15 at ¶ 150). The Amended Complaint identifies Territory Manager Michael Baldwin as one of the individuals who misrepresented the safety and reliability of the Patch. (Id. at ¶¶ 150-151, 156). The Amended Complaint also explains that Defendants “ran a direct

to consumer campaign for National Hernia Awareness Month" in which they offered hernia screenings but did not communicate "the dangers and defects" of the Patch to consumers. (Id. at ¶ 158). Likewise, Plaintiffs claim that the Instructions for Use accompanying the Patch did not provide any information about the dangers associated with the "risk of the plastic ring breaking." (Id. at ¶ 161). These allegations satisfy Rule 9. The Motion to Dismiss is therefore denied as to count four.

**B. Fraud (count 5)**

To state a claim for fraud under Florida law, a Plaintiff must allege: "(1) a false statement concerning a material fact; (2) the representor's knowledge that the representation is false; (3) an intention that the representation induce another to act on it; and (4) consequent injury by the party acting in reliance on the representation." Byrnes v. Small, 142 F. Supp. 3d 1262, 1266 (M.D. Fla. 2015). Plaintiffs set the tone for their fraud claim against Defendants by alleging: "Defendants fraudulently presented Ms. Hamblen, her physicians, and the general public that the Bard CK Patch was a safe and effective hernia repair product and concealed the dangerous and defective elements identified herein of the Bard CK Patch." (Doc. # 15 at ¶ 176). Count five is replete with detailed allegations that support Plaintiffs' fraud claims,

including: (1) that "Defendants did not timely or adequately apprise the public and physicians of the defects or dangers inherent in the Bard CK Patch, including the Bard CK Patch implanted in Ms. Hamblen, despite Defendants' knowledge that the hernia repair products had failed due to the defects described herein" (Id. at ¶ 16); and (2) "Following the market introduction of the Bard CK Patches, including the Bard CK Patch implanted in Ms. Hamblen, Defendants began to receive actual notice of failures of the plastic ring; rings were breaking. Defendants actively and intentionally concealed this notice of the defective and dangerous condition from the public, Ms. Hamblen, her physicians and the FDA." (Id. at ¶ 40).

The elements of fraudulent misrepresentation and fraud are similar and the allegations contained in the Amended Complaint that support the fraudulent misrepresentation claim, discussed at length above, likewise support the fraud claim. Plaintiffs allege that Defendants made false statements regarding the Patch being safe and effective. (Id. at ¶¶ 11, 16, 17, 40, 45, 53, 59, 74, 176, 177, 179, 180, 181, 185, 186, 188, 190, 191, 192, 194). Plaintiffs also claim that Defendants knew that the statements were false and were aware that the Patch was unsafe and unfit for its intended purpose. (Id. at ¶¶ 10, 12-15, 35-37, 41, 46-47, 50-52, 55, 60-61, 64,

75, 77, 91, 97, 175, 184, 189, 195, 197, 199, 203, 206). Plaintiffs contend that the misrepresentations were made to Mrs. Hamblen, doctors, and others to induce them to choose the Patch for hernia repair. (Id. at ¶¶ 196, 198, 200, 204-205). And, after Mrs. Hamblen chose the Patch, its implantation caused her to suffer various injuries. (Id. at ¶¶ 19, 67, 68, 69, 70, 71, 72, 96, 104, 201, 207). The lengthy Complaint sets forth sufficiently detailed allegations to support the fraud claim. The Court finds that Rule 9 has been satisfied and denies the Motion to Dismiss.

### **C. Learned Intermediary Doctrine**

The Court recognizes that Defendants advocate for dismissal of both counts four and five under the learned intermediary doctrine. But, the Court determines that this discussion should be had at the summary judgment stage, because it entails a potentially fact intensive inquiry. See In re Trasylol Products Liability Litigation, MDL -1928, No. 08-cv-80386, 2011 U.S. Dist LEXIS 57057 (S.D. Fla. May 23, 2011)(granting summary judgment in favor of drug company on negligence and fraud claims under the learned intermediary doctrine after evaluating all of the evidence and finding a lack of proximate cause); Levine v. Wyeth, Inc., No. 8:09-cv-854-T-33AEP, 2010 WL 5137424 (M.D. Fla. Dec. 10, 2010)(analyzing the learned intermediary doctrine at the

summary judgment stage when plaintiff claimed that an acid reflux medication caused an incurable neurological disorder); Kaufman v. Pfizer Pharms., Inc., No. 1:02-cv-22692, 2010 U.S. Dist. LEXIS 146552, at \*15 (S.D. Fla. Nov. 23, 2010) ("The undersigned tends to agree that application of the learned intermediary doctrine at [the motion to dismiss] stage of the proceedings would be premature.").

**D. FDUTPA and Law of Rhode Island**

In the Motion to Dismiss, Defendants recognize that Plaintiffs' Amended Complaint does not state a claim for violation of the Florida Deceptive and Unfair Trade Practices Act, but that the Amended Complaint suggests that Plaintiffs may be seeking relief under the consumer protection statutes of one or more states. (Doc. # 18 at 8). Defendants point out that the FDUTPA expressly states that it does not apply to a "claim for personal injury or death or a claim for damages to property other than the property that is the subject of the consumer transaction." Fla. Stat. § 501.212(3). In response to the Motion to Dismiss, Plaintiffs make no response with respect to the FDUTPA. The Court accordingly determines that Plaintiffs concede that they cannot seek relief under the FDUTPA.

In addition, Plaintiffs mention in response to the Motion to Dismiss that a choice of law determination has not yet been

made in this case, and that it is unclear whether the law of Florida or Rhode Island applies. (Doc. # 23 at 12). However, both sides have provided case law only from the Eleventh Circuit and from Florida state courts. Neither party included a discussion of the law of Rhode Island on any disputed issue. If either party contends that the law of Rhode Island applies, it should provide the Court with operative law and choice of law briefing. In addition, the parties are directed to file a joint status report by December 28, 2017, explaining why the present case has not be transferred to the consolidated multidistrict litigation In re: Kugel Mesh Hernia Repair Patch Litigation, No. 007-470-MDL.

Accordingly, it is

**ORDERED, ADJUDGED, and DECREED:**

- (1) Defendants Davol, Inc. and C. Bard Inc.'s Motion to Dismiss, in Part, Plaintiffs' Amended Complaint (Doc. # 18) is **DENIED**.
- (2) Defendants are directed to respond to the Amended Complaint by December 28, 2017.
- (3) The parties are directed to file a joint status report by December 28, 2017, explaining why the present case has not be transferred to the consolidated multidistrict litigation In re: Kugel Mesh Hernia Repair Patch Litigation, No. 007-470-MDL.

**DONE** and **ORDERED** in Chambers in Tampa, Florida, this 15th  
day of December, 2017.

  
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VIRGINIA M. HERNANDEZ COVINGTON  
UNITED STATES DISTRICT JUDGE