IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

Pamela Williams, et al.,

Plaintiffs

v.

Boston Scientific Corporation,

Defendant

Case No. 3:12CV1080

ORDER

This is a product liability case in which defendant, Boston Scientific Corporation (BSC), has moved to dismiss plaintiffs', Pamela and Robert Williams[1], first amended complaint under Fed. R. Civ. P. 12(b)(6). For the reasons that follow, I grant the motion in part and deny it in part.

BSC manufactured and sold two medical devices later implanted in Pamela on January 29, 1998, to treat urinary incontinence. The devices were "ProteGen," made of woven polyester fabric coated with bovine collagen, and "Vesica," which included pins, suture material, and other components used in conjunction with the ProteGen. By the time of Pamela's surgery, BSC marketed both items together in a "Vesica Kit," also known as a vaginal sling.

In 2008, Pamela had episodes of occasional stress urinary incontinence. She so informed her doctor, who offered no medical treatment at that time. Around June 2011, she began having vaginal bleeding, increased incontinence, and, in July, began experiencing lower-left abdominal pain. She began treating with the doctors who had conducted her surgery ten years earlier.

[1] Plaintiffs are husband and wife.

On December 13, 2012, a doctor at the Cleveland Clinic verified Pamela had an exposed vaginal sling that required resection. The following February, that doctor concluded Pamela had two centimeters of exposed anterior vaginal mesh from the Vesica vaginal sling. She underwent surgery to remove the vaginal-sling-eroded tissue on February 9, 2012. Pamela's doctor found that the mesh was extruding and non-adherent to tissue.

Pamela contends that the sling, due to its collagen coating, was "erosive," and caused the physiological injuries and resulting surgery.

Aside from these details about Pamela's medical history and experience with BSC's products, the complaint alleges BSC was on notice from physicians working on development of the vaginal sling that use of synthetic materials was problematic. They had concerns about the erosive qualities of synthetics. BSC continued its development of the sling despite the notice.

Without conducting animal studies, and, in view of the fact that the FDA had already approved the Vesica bone anchoring system, BSC filed a 510K application with the FDA in August 1996. BSC anticipated marketing the product in December 1996.

BSC encountered manufacturing delays. To counter the financial effect of those delays in getting the product to market, BSC decided to forgo its original plans to provide the product to a select group of doctors so they could monitor its performance before its widespread distribution.

After the initial launch of the device into the market in early 1997, BSC created an "Incontinence Team" to meet monthly to review its incontinence projects. During a November 18, 1997, meeting participants voiced concerns about the bioincompatibility of the ProteGen, as evidenced by a large number of reported complaints and complications. Among these was ProteGen's failure to promote the type of "tissue in-growth" that BSC had represented and described

to urologists in its sales and marketing materials.

By the end of 1997, before Pamela had her surgery, the FDA had received fifty-eight medical device reports regarding ProteGen. In addition, BSC began undertaking studies to develop a new sling. By March 1998, BSC had decided to replace ProteGen with a successor product, the ProteGen II. It decided to continue selling the original product until it developed the successor sling.

Around January 20, 1999, BSC received a consultant's report. The report informed BSC that the complication rate for the ProteGen, as reported in medical literature, was higher than other implant materials. The report stated that woven polyester fabric coated with bovine collagen could not be ruled out as a cause for the complications.

About a year later, on January 22, 1999, BSC announced a voluntary recall of 25,000 ProteGen devices.

On the basis of these factual contentions, Pamela asserts, in generally conclusory terms, several causes of action: negligence; defective manufacture; defective design; marketing defect; breach of warranty; failure to warn; strict product liability; fraud; and violation of the Ohio Consumer Sales Practices Act. Her husband, Robert, seeks recovery for loss of consortium. Plaintiffs request an award of punitive damage and attorneys' fees.

In its motion to dismiss, BSC asserts two overarching challenges and, as well, contends that none of the individual counts successfully state claims against it. I first consider the overarching challenges based on the two statute of limitations and the *Iqbal/Twombly* doctrine; I then address the contentions regarding each separate count in the complaint.

Discussion

1. Contentions Applicable to All Claims

A. Statute of Limitations

The parties agree that Ohio's two-year statute of limitations for personal injuries, O.R.C. § 2305.10, applies. They disagree, however, about when the limitations period began to run.

According to BSC, Pamela knew or should have known of her injury in 2008. BSC cites, as the limitations-triggering event, that Pamela then experienced a resumption of occasional stress urinary incontinence, and she knew or should have known the vaginal sling implanted ten years earlier (and that had, apparently, functioned since then without any indication of problems) was causing the incontinence.[2] Though Pamela told her doctor she had occasional stress incontinence, the physician did nothing in response. This, BSC claims, sufficed to alert Pamela that its device, if defective, had caused the return of that condition. Pamela argues that the statute was not triggered until her physician told her, in February, 2012, that the defective Vesica kit had likely caused her symptoms.[3]

"The discovery rule provides that a cause of action does not arise until the plaintiff knows, or by the exercise of reasonable diligence should know, that he or she has been injured by the conduct of the defendant." *Flagstar Bank, F.S.B. v. Airline Union's Mortg. Co.*, 128 Ohio St.3d 529,

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[2] BSC contends in its brief in support of its motion for summary judgment that, "[i]n plaintiff's own words she became aware in ***2008*** that the injuries of which she now complains were caused by Boston Scientific." (Doc. 23, at 4). That statement is a misleading misreading of plaintiffs' complaint, which actually reads: "In approximately 2008, Plaintiff told her family physician she had occasional stress urinary incontinence." (Doc. 18-1, ¶ 46).

[3] It is at least arguable that Pamela knew or should have known some months earlier, in either June 2011, when she began having vaginal bleeding, increased incontinence, or, in any event, some weeks later, in July, when she also began experiencing lower left abdominal pain. Even if so, that would not matter, as she still filed her complaint well within two years after that time.

(2011) (citing *Collins v. Sotka*, 81 Ohio St.3d 506, 507 (1998)). "The rule entails a two pronged test—*i.e*., actual knowledge not just that one has been injured but also that the injury was caused by the conduct of the defendant." *Id*. (citing *O'Stricker v Jim Walter Corp*., 4 Ohio St.3d 84, 90 (1983)).

That one may have some awareness, *Burgess v. Eli Lilly & Co.*, 66 Ohio St. 3d 59, (1993), or even suspect, *Grimme v. Twin Valley Cmty. Local Sch. Dist. Bd. of Educ*., 173 Ohio App.3d 460, (2007), a connection between injury and possible cause does not trigger the statute.

Nothing in the allegations as pled suggests, or provides the basis for a fair assumption that, Pamela knew enough in 2008 to connect her *occasional stress incontinence* with the injuries that the device, according to her complaint, ultimately caused. Moreover, her doctor was, apparently, so unconcerned that he did nothing in response to her complaints. Finally – a fact that BSC ignores entirely in its discussion of its statute of limitations claim – the multiple and severe symptoms that ultimately led to removal of the device did not manifest themselves until July, 2011.[4]

I find no merit whatsoever in BSC's claim that the statute of limitations began to run in 2008 when she had occasional (and apparently ultimately transient) stress urinary incontinence.[5]

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[4] BSC suggests, in effect, that plaintiffs should have filed a complaint within the next two years, when Pamela's sole allegation would have been that BSC's device caused occasional stress incontinence (about which her doctor did nothing). If that were all plaintiffs alleged – because that was all Pamela knew – would BSC accept that such contention met any standard of notice pleading, much less *Twombley/Iqbal*?

[5] BSC's reply raises, for the first time, the contention that the ten-year statute of repose, O.R.C. § 2305.10(C)(1) bars plaintiffs' suit. Arguments not raised in the opening brief are waived. *See, e.g., McPherson v. Kelsey*, 125 F.3d 989, 995-996 (6th Cir.1997). As stated in *Inland Waters Pollution Controls, Inc. v. Marra/Majestic Joint Venture*, 2009 WL 700773, *5 (N.D. Ohio) (citing *Novosteel SA v. U.S. Bethlehem Steel Corp*., 284 F.3d 1261, 1274 (Fed. Cir. 2002)):

B. *Twombly/Iqbal*

The second poisoned arrow in BSC's quiver is the contention that plaintiffs failed to meet the heightened pleading standard of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). I disagree.

As BSC correctly points out, to survive a motion to dismiss for failure to state a claim under *Twombly*, "[f]actual allegations must be enough to raise a right to relief above the speculative level,"550 U.S. at 555, and set forth "enough facts to state a claim to relief that is plausible on its face." *Id*. at 570. To meet this standard, the complaint must contain "more than labels or conclusions" or "a formulaic recitation of the elements of a cause of action." *Id*. at 555. Thus, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678.

This complaint meets the standard. It alleges more than sufficient detail to inform BSC of the nature of plaintiffs' claims and their factual underpinnings. Among these are that Pamela had one of BSC's devices surgically implanted at a time when BSC knew, or, at least, had a reasonable basis for knowing, that the device might cause an unusual rate of complications. Indeed, the

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> Raising the issue for the first time in a reply brief does not suffice; reply briefs reply to arguments made in the response brief—they do not provide the moving party with a new opportunity to present yet another issue for the court's consideration. Further the non-moving party ordinarily has no right to respond to the reply brief, at least until oral argument. As a matter of litigation fairness and procedure, then, we must treat [such issues] as waived.

complaint alleges that, even before those problems manifested themselves, BSC's scientists expressed concern about the possible safety of a component in one of the two devices in the vaginal sling kit. The complaint also alleges insufficient testing and failure to conduct a limited release to monitor the performance of the device before undertaking a nationwide marketing program. As a result, according to the complaint, the company sent, without adequate warning, a dangerous device into the marketplace.

All these failings, the complaint asserts, caused serious injuries to Pamela.

In essence, BSC contends that, to survive a *Twombly /Iqbal* challenge, plaintiffs must allege in greater detail what went wrong with the sling, and why it did so, after it was placed in her body. That sort of detail is not necessary at this stage. The complaint alleged two centimeters of exposed anterior vaginal mesh from the Vesica vaginal sling required Pamela to undergo surgery to have it removed. During surgery, Pamela's doctor found that the mesh was extruding and non-adherent to tissue. Pamela's contention that this relatively free-moving foreign object, present in the same area as her pain, caused her abdominal symptoms. Plaintiff need not further state exactly how or why the sling caused her internal injuries to state a claim plausible on its face.

Contrary to BSC's contention, I find the Seventh Circuit's observation in *Bausch v. Stryker Corp*., 630 F.3d 546, 558 (7th Cir.2010),[6] apt and applicable: "district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can be

[6] A Judge of this District quoted *Bausch* with approval in a case involving a different medical device produced by the defendant. *Cameron v. Boston Scientific Corp*., 2012 WL 1592535, *5, *Magistrate Judge's Report and Recommendation adopted*, 2012 WL 1592535 (N.D. Ohio).

expected to provide a detailed statement of the specific bases for her claim."

BSC demands, however, that a plaintiff, to beat back a motion to dismiss in a case such as this, must give more detail than Pamela did here about what went wrong and how it did so. To adopt this overly cribbed and unrealistic standard would, in many cases, effectively grant medical device manufacturers *de facto* immunity. Deploying the portcullis of *Twombley/Iqbal* in this ruthless manner would bar many plaintiffs with potentially successful claims from any fair chance of recovery.

I find no merit in BSC's contention that the factual allegations in the complaint fail to meet the *Twombley/Iqbal* requirements.

I turn now to BSC's challenges to the specific causes of action in the complaint. I agree that I should dismiss some, but not all, of them.

2. Challenges to Individual Claims

A. Negligence

BSC claims that Pamela has failed to state a claim for negligence. I disagree.

As stated in *Little v. Purdue Pharma, L.P.*, 227 F.Supp.2d 838, 848-849 (S.D. Ohio 2002) (citing *Freas v. Prater Constr. Corp., Inc*., 573 N.E.2d 27, 30 (Ohio 1991)), "to recover in an action for products liability based upon negligence, a plaintiff must show that the defendant owed him a duty, that the duty was breached and that the injury proximately resulted from the breach." The allegations in the complaint satisfy these requirements. Taken as true, those allegations show that BSC manufactured and distributed a device with erosive qualities that, in time, caused the device to fail, with injury proximately resulting. She also alleges foreseeability, in that early on BSC was on notice that use of artificial mesh might create problems.

BSC argues that Pamela did not specifically allege a standard of care or its breach. Any fair reading of this complaint indicates, even if only implicitly (but also, indisputably[7]) that BSC had a duty to manufacture a device that, when implanted in the human body, would not cause injury to those who received the device.

Pamela has stated a cause of action for negligence.

B. The Ohio Product Liability Act, O.R.C. § 2307.73(A)(1)

Plaintiffs claim the device violated the Ohio Product Liability Act (OPLA), O.R.C. § 2307.73(A)(1), due to defects in its design and marketing (*i.e.*, failure to warn).

To prevail on such claim, an injured plaintiff, in addition to showing proximate cause, must show either that the product was defective "in manufacture or construction . . . design or formulation . . . [or] due to inadequate warning or instruction, . . . [or] because it did not conform to a representation made by its manufacturer. O.R.C. § 2307.73(A)(1).

i. Design and Manufacturing Defects

Here, based on the facts set forth above, I conclude that Pamela has stated causes of action for defective design and manufacture. She pled, in more than conclusory terms, and has shown, according to her allegations, that BSC was on notice before producing their product of its risks, but did not alter its design.

The complaint also adequately alleges that the device, as manufactured, incorporated one or more components that, either singly or in combination, led to Pamela's injuries. This suffices, in

[7] I decline to read BSC's motion as suggesting it has no duty to produce devices without regard to their safety.

light of the facts alleged, to state a cause or causes of action for design and manufacturing defects.[8]

ii. Failure to Warn; Defective Marketing

Though plead as separate counts, Pamela' claims of failure to warn and defective marketing are based in the same essential contention: namely, BSC failed to provide an adequate warning as the risks of its use.

The Sixth Circuit stated the elements of a claim for breach of the duty to warn in a products liability case:

> The claim has three elements, each of which must be satisfied: (1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury that is proximately caused by the breach. Under Ohio law, the manufacturer of a prescription drug discharges its duty to warn about risks regarding prescription drugs if the manufacturer adequately warns the patient's doctor of those risks. When a plaintiff alleges that the warning given to a prescribing physician is inadequate, the plaintiff must prove his claim through expert medical testimony.

Graham v. American Cyanamid Co., 350 F.3d 496, 514 (6th Cir. 2003).

BSC contends that Pamela has not defined the warning that should have been given. However, she does not have a duty at *this* stage to be *that* precise. Instead, she must simply plead the three elements which *Graham* recites, and do so in accordance with *Twombly/Iqbal*.

Plaintiffs have done so here. The complaint alleges prior knowledge of the defect which, it also alleges, caused serious injury. There was, though, no warning. To the extent that some detail is necessary about the missing content, plaintiffs amply provide that detail:

> Specifically, Defendant did not provide sufficient or adequate warnings regarding, among other subjects: the device's propensity to erode, the rate and manner of erosion, the risk of chronic infections resulting from implantation, the risk of vaginal scarring, the risk of recurrent severe pelvic pain and other pain resulting from the implantation, the need for corrective or revisionary surgery to adjust or repair the

[8] Whether the defect leading to the injuries resulted precisely from either a design or manufacturing defect, or both (or neither) can best be ascertained following discovery.

> device, and the overall severity of complications that could arise as a result of implantation of the medical devices.

(Doc. 18-1 ¶ 84).

iii. Breach of Express and Implied Warranties

I agree with BSC, however, that Pamela has failed adequately to allege claims under OPLA (or otherwise) for breach of express or implied warranty.

(a). Express Warranty

With regard to a claim of breach of express warranty, plaintiffs must show: (1) the manufacturer made a representation as to a material fact concerning the quality of the manufacturer's product; (2) the product did not conform to that representation; (3) the plaintiff justifiably relied on that representation; and (4) the plaintiff's reliance on the representation was the direct and proximate cause of the plaintiff's injuries. *See, e.g.*, *Cervelli v. Thompson/Center Arms*, 183 F.Supp.2d 1032, 1045 (S.D. Ohio 2002).

Here, the complaint fails to state facts showing, to any plausible extent, that BSC provided an express warranty to Pamela or anyone else, much less one of which they were aware and on which they relied. Here, at the very least, Pamela's claim fails under *Twombly/Iqbal*.

(b). Implied Warranty

The same is true, as BSC argues, with regard to Pamela's claim of breach of implied warranty. Pamela has not plausibly alleged reliance on any such warranty. Though there appears to be no Ohio case directly on point, *i.e.*,where an implied warranty relating to a medical device was at issue, I am satisfied that reliance is an element of her claim. *Cf. Kinstle v. J&M Manufacturing Co.* , 1977 WL 199565, 3 (Ohio App.) ("reliance by the buyer upon the seller's representations is one of the elements that give rise to liability for either express or implied warranty."); *Cervelli*, 183

F.Supp.2d at 1045.

C. Fraud

Pamelas' fraud claim fails for the same reason as the warranty claims: lack of a plausible claim of reliance on any purported misrepresentations. *See, e.g., Burr v. Board of County Comm'rs*, 23 Ohio St.3d 69, 73 (1986).

In addition, the complaint falls far short of meeting the requirements of Fed. R. Civ. P. 9(b). That Rule requires that a complaint state with "particularity the circumstances constituting fraud or mistake." In our Circuit this means alleging "the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Yuhasz v. Brush Wellman, Inc*., 341 F.3d 559, 563 (6th Cir. 2003).

None of that is stated here, and BSC is entitled to dismissal of this claim.

D. Ohio Consumer Sales Practices Act
O.R.C. § 1345.01(D)

Pamela claims BSC violated the Ohio Consumer Sales Practices Act (OCSPA), O.R.C. § 1345.01(D). The elements that a plaintiff must prove are "a material misrepresentation, deceptive act or omission" that impacted the decision to obtain the item at issue. "Whether it be termed an issue of reliance or an issue of proximate cause, an appropriate rule is that where the defendant is alleged to have made material representations or misstatements, there must be a cause and effect relationship between the defendant's acts and the plaintiff's injuries." *Reeves v. PharmaJet, Inc*., 2012 WL 380186, *5 (N.D. Ohio) (quoting *Lilly v. Hewlett–Packard Co.*, 2006 WL 1064063, *5 (S.D. Ohio 2006)). Pamela has not plausibly pled that she relied on any of the alleged misstatements.

Moreover, the device was not a "consumer good." *Reeves v. PharmaJet, Inc.*, 2012 WL

380186, *5 n. 2 (N.D. Ohio) (prescription medical device is not a consumer good under the OCSPA). The hospital, not Pamela, was, under the OCSPA, the "consumer" participating in a "consumer transaction." The statute provides that a "consumer transaction" is "a sale . . . or other transfer of an item of goods . . . to an individual for purposes that are primarily personal, family, or household, or solicitation to supply any of these things." O.R.C. §1345.01(A). A "consumer" under the OCSPA is a person who engages in a consumer transaction with a supplier. Thus, the hospital was the consumer. Pamela, accordingly, did not engage in a consumer transaction within the OCSPA's scope.

E. Loss of Consortium

Defendant bases its challenge to the husband's claim of loss of consortium on its claims that the complaint fails *in toto.* That not being so, he can proceed on that claim.

3. Punitive Damages/Attorneys' Fees and Costs

Determining now whether I should charge the jury as to punitive damages and consider an award of costs in the event it were to return such award would be premature. For now, I will overrule the defendant's attempt to exclude those options, without prejudice to renew.[9]

Conclusion

For the foregoing reasons, it is hereby

ORDERED THAT defendant's motion to dismiss (Doc. 22), be, and hereby is granted with regard to plaintiff's claims for breach of express and implied warranty, fraud, and violation

[9] It is my general, but not immutable, practice to withhold judgment on whether to allow the jury to consider an award of punitive damages until the final charge. Only then, most instances, am I in a position to determine whether the evidence warrants such charge.

of the Ohio Consumer Sales Practices Act; and otherwise denied (without prejudice as to the issues of punitive damages and attorneys' fees and costs).

So ordered.

/s/ James G. Carr
Sr. U.S. District Judge