IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ALBERT F. HECK	:	
	:	
v.	:	CIVIL NO. CCB-07-2101
	:	
AMERICAN MEDICAL SYSTEMS, INC.	:	

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MEMORANDUM

Now pending before the court is a motion to dismiss filed by defendant American Medical Systems, Inc. ("AMS") against the plaintiff Dr. Albert F. Heck. Dr. Heck is suing AMS over its medical implant device, the AMS Sphincter 800 ("AMS 800"). Having allowed Dr. Heck an opportunity to amend his original complaint after granting AMS' first motion to dismiss for failure to state a claim, the court must now determine whether Dr. Heck's amended complaint can survive this second dismissal motion. The issues in this case have been fully briefed and a hearing was held on April 30, 2008. For the reasons stated below, AMS' motion will be granted.

BACKGROUND

Because the court is considering a motion to dismiss, the factual background of the case is taken entirely from Dr. Heck's amended complaint. This medical products liability case centers around an allegedly defective artificial urinary sphincter device, the AMS 800, that was surgically implanted in Dr. Heck on October 22, 2004. (Amended Compl. at ¶ 3.) According to the amended complaint, the AMS 800 "was warranted as good and in functional condition," and upon its insertion, Dr. Harvey Schonwald, the urologist, "activated the artificial sphincter several times with resulting proper action." (*Id.* at ¶¶ 4, 5.) Following the procedure, Dr. Heck was compelled to visit his urologist on November 2, November 29, December 14, and December 21 of 2004, because the device was "not functioning properly." (*Id.* at ¶ 6.) Dr. Heck states that

"[w]ithout any warning or knowledge on the part of the urologist who implanted the sphincter device manufactured by the Defendant, there was a defective valve implanted in the Plaintiff's body which required its surgical removal on January 11, 2005 . . . for 'non-functioning artificial urinary sphincter with subsequent erosion of the urethra.'" (*Id.* at ¶ 7.) The amended complaint summarily concludes that AMS was negligent in manufacturing the device and liable for furnishing a defective product. (*Id.* at ¶ 12.) As a result of the product defect, Dr. Heck asserts that he "suffered pain, discomfort, and embarrassment because of the failure of the defective artificial sphincter to function and allow him to live a normal physical and emotional life without the pain and embarrassment of urinary retention." (*Id.* at ¶ 9.)

The original complaint, filed on August 7, 2007, was dismissed by the court for its failure to specify the theories of recovery under which Dr. Heck is proceeding, the elements of his cause of action(s), and the facts that lead him to assert there was a defect in the product and/or negligence in the manufacturing. The court noted that the conclusory allegations in the complaint failed to put the defendant on notice of the claim(s) Dr. Heck sought to bring before the court and the reasons he may be entitled to relief. *See Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955, 1965 (2007). Despite being afforded an opportunity to amend his complaint, Dr. Heck has still failed to articulate in a clear fashion the theories he is asserting and the underlying facts necessary to satisfy the elements of his cause of action(s). Dr. Heck did little to explain or cure these deficiencies during the April 30, 2008 hearing, but rather continued offering vague theories possibly sounding in tort or product liability law. The court will address these issues in turn.

ANALYSIS

"The purpose of a Rule 12(b)(6) motion is to test the sufficiency of a complaint; importantly, a Rule 12(b)(6) motion does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Edwards v. City of Goldsboro*, 178 F.3d 231, 243 (4th Cir. 1999) (internal quotation marks and alterations omitted). When ruling on such a motion, the court must "accept the well-pled allegations of the complaint as true," and "construe the facts and reasonable inferences derived therefrom in the light most favorable to the plaintiff." *Ibarra v. United States*, 120 F.3d 472, 474 (4th Cir. 1997). To survive a motion to dismiss, a complaint must "in light of the nature of the action . . . sufficiently allege[] each element of the cause of action so as to inform the opposing party of the claim and its general basis." *Chao v. Rivendell Woods, Inc.*, 415 F.3d 342, 348 (4th Cir. 2005). Following the Supreme Court's ruling in *Twombly*, 127 S.Ct. at 1965, "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." "Once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Id.* at 1969 (quoted in *Goodman v. Praxair*, 494 F.3d 458, 466 (4th Cir. 2007)). Moreover, the "plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 1964-65.

As a threshold matter, despite the court's clear notice that the original complaint failed to specify which theories Dr. Heck was pursuing, the amended complaint does little to resolve this defect. The amended complaint continues to state legally operative terms in a conclusory fashion, but then fails to articulate the theory being pursued, the elements of that theory, and the

facts that establish those elements. For example, the amended complaint baldly concludes that the AMS 800 was "defective"; the defendant was "negligent" in the manufacture of the device; the device was "warranted as good and in functional condition"; and that the defendant is liable for the defective device that was "used without any warning or knowledge of the surgeon [*sic*]" who performed the procedure. The amended complaint thus includes language that could sound in tort, contract, or product liability law. A viable complaint must offer more than these unsubstantiated "labels and conclusions," *Twombly*, 127 S.Ct. at 1964-65, even under the more relaxed standard prior to *Twombly*. The amended complaint, quite simply, does not sufficiently put the defendant on notice of the claim(s) Dr. Heck seeks to bring before this court and the reasons he may be entitled to relief.

Dr. Heck's opposition brief further illustrates the ambiguous nature of the amended complaint. Despite language in the amended complaint that appears to invoke negligence or contract theories, Dr. Heck's opposition brief characterizes his claim as one for strict liability only, citing *Phipps v. General Motors Corp.*, 363 A.2d 955 (Md. 1976). Although *Phipps* adopts the theory of strict liability found in the Restatement (Second) of Torts § 402A, 363 A.2d at 963, Dr. Heck does not, in his amended complaint or opposition brief, provide factual support to satisfy the elements of that theory. Under Maryland law, to prevail in a strict liability action, the claimant must establish that "(1) the product was in defective condition at the time that it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause of the injuries, and (4) that the product was expected to and did reach the consumer without substantial change in its condition." *Id.* at 958. A claimant should specify at least one of three possible reasons a product may be defective: "First, there

may be a flaw in the product at the time the defendant sold it, making the product more dangerous than was intended . . . Second, a producer of a product may fail to warn adequately of a risk or hazard related to the way a product was designed . . . Finally, a product may be defective in its design." *Simpson v. Standard Container Co.*, 527 A.2d 1337, 1339-40 (Md. Ct. Spec. App. 1987) (citing *Prosser and Keeton on the Law of Torts § 99* (W. Keeton 5th ed. 1984)).

Here, Dr. Heck has failed to articulate a clear strict liability theory or offer any evidence to support such a theory. First, Dr. Heck's amended complaint does not identify how the AMS 800 was defective. Instead, it contains vague language that does not specify whether the device was flawed at the time AMS sold it, whether AMS failed to warn adequately of a risk related to the product,[1] or whether the device was defective in its design. Second, rather than pleading facts that establish the necessary elements of a strict liability claim, Dr. Heck either offers evidence that plainly contradicts the viability of his theory, or fails to offer any evidence at all. The first element of a strict liability claim is that the product be in a defective condition at the time it leaves the possession of the seller. Dr. Heck's amended complaint, however, implies that the AMS 800 was not defective when it left the seller, because the product was activated several times by the surgeon, after it was implanted, "with resulting proper action." (Amended Compl. at ¶ 5.) Moreover, the amended complaint fails to suggest that the AMS 800 was unreasonably dangerous. Finally, Dr. Heck makes no showing that the AMS 800 reached him without substantial change in its condition. To the contrary, Dr. Heck's amended complaint would imply that the device may have been altered after its insertion since, according to the urologist, it

[1] AMS, in fact, suggests that the product comes with "a clear warning that the outcome of the surgery may be unsuccessful and that there is a risk of the need of additional surgery to remove or replace the device." (Def.'s Mem. at 9.)

originally appeared to function properly. Furthermore, even after the April 30, 2008 hearing, it appears Dr. Heck is unable to locate the allegedly defective device, and will therefore have significant difficulty proving the original condition of the device or that it was defective. (*See* Def.'s Reply Mem. at 3.) The only evidence Dr. Heck offers to support his product defect claim is an affidavit from his physician, Dr. Schonwald, who simply concludes that the valve in the device was "defective." (Amended Compl. at Ex. 3, Schonwald Aff.) These unsubstantiated legal conclusions are insufficient to state a viable cause of action.

Although Dr. Heck appears to assert in his opposition brief that he is only attempting to bring a strict product liability claim against AMS, the court will briefly discuss, for the sake of completeness, the insufficiency of any potential negligence or contract theories. First, Dr. Heck's amended complaint, which contains numerous references to AMS' allegedly negligent conduct, fails to articulate how AMS was, in fact, negligent. *See Bobo v. State*, 697 A.2d 1371, 1375 (Md. 1997) ("The basic elements of a negligence claim are: (1) a duty or obligation under which the defendant is to protect the plaintiff from injury; (2) breach of that duty; and (3) actual loss or injury to the plaintiff proximately resulting from the breach."). More specifically, the amended complaint does not suggest how AMS breached its duty to Dr. Heck or how that breach may have caused him harm. Second, Dr. Heck's amended complaint states in conclusory fashion that the AMS 800 "was warranted as good and in functional condition." (Amended Compl. at ¶ 4.) To the extent that statement sounds in contract law, Dr. Heck has not specified the elements of, or factual support for, a breach of warranty claim. *See generally Rite Aid Corp. v. Levy-Gray*, 894 A.2d 563, 570-72 (Md. 2006) (discussing Maryland law on breach of warranty claims). Dr. Heck was given the opportunity to amend his original complaint in order to put AMS on notice

as to the nature of this lawsuit and, quite simply, he has failed to do so. In sum, the amended complaint does not specify the theories of recovery under which Dr. Heck is proceeding, the elements of his cause of action(s), and the facts that lead him to assert there was a defect in the product, negligence in the manufacturing, and/or a breach of contract.

For all the above reasons, the motion to dismiss will be granted. A separate order follows.

April 30, 2008
Date

/s/
Catherine C. Blake
United States District Judge

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ORDER

For the reasons stated in the accompanying Memorandum, it is hereby **ORDERED** that:

1. The defendant's motion to dismiss the amended complaint (docket entry no. 18) is **GRANTED**; and

2. The Clerk shall **CLOSE** this case.

April 30, 2008
Date

/s/
Catherine C. Blake
United States District Judge