IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BETTY L. BISHOFF

Plaintiff,

v. // **CIVIL ACTION NO. 1:09CV171**
(Judge Keeley)

MEDTRONIC INCORPORATED
Defendant.

MEMORANDUM OPINION AND ORDER GRANTING DEFENDANT'S MOTION TO DISMISS [DKT. NO. 31], AND DENYING AS MOOT DEFENDANT'S MOTION FOR SUMMARY JUDGMENT [DKT. NO. 11]

I. INTRODUCTION

Pending before the Court is the motion of the defendant, Medtronic, Inc. ("Medtronic"), to dismiss the amended complaint of the plaintiff, Betty L. Bishoff ("Bishoff"). For the reasons that follow, the Court concludes that Bishoff has failed to adequately plead her claims for negligence per se, manufacturing defect, and breach of express warranties. Moreover, the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA") preempt her claim for breach of an implied warranty of fitness for a particular purpose. See 21 U.S.C. § 360c et seq.

II. FACTUAL AND PROCEDURAL HISTORY

On December 23, 2009, Bishoff filed a pro se complaint alleging that she had experienced "repeated inappropriate shock therapy" from a Sprint Quattro Lead ("Quattro Lead"), causing "constant pain in [her] shoulder and left arm." On April 12, 2010, Medtronic, the manufacturer of the Quattro Lead, moved for summary judgment against Bishoff's claims (dkt. no. 11). Bishoff subsequently retained counsel, and, on June 21, 2010, filed an amended complaint (dkt. no. 30).

Bishoff's amended complaint alleges that, on or about December 25, 2007, she experienced repeated shocks due to a fracture in the Quattro Lead of her InSync II Marquis Defibrillator. The amended complaint alleges further that, in early 2007, Medtronic became aware of fracturing problems in a product similar to the Quattro Lead, the Sprint Fidelis Lead ("Fidelis Lead"), and recalled that device in October 2007. After learning about the Fidelis Lead recall, Bishoff reportedly became concerned "that she may have one of the defective leads," and contacted a representative at Medtronic who "informed [Bishoff] that her lead was fine and not subject to the recall."

Despite this reassurance, Bishoff alleges that Medtronic knew that one out of every one hundred of its Quattro Lead devices would fail thirty months after implantation. Bishoff asserts that Medtronic failed to provide her with this information, and that her Quattro Lead failed approximately forty-seven months after implantation. Based on these allegations, Bishoff seeks to recover damages based on theories of (1) negligence per se, (2) manufacturing defect, (3) breach of expressed warranties, and (4) breach of an implied warranty of fitness for a particular purpose.

III. STANDARD OF REVIEW

When reviewing a motion to dismiss, a court must accept the factual allegations in the plaintiff's complaint as true. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949-50 (2009). Only a complaint that states a plausible claim for relief, however, will survive a motion to dismiss. Id. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," do not satisfy this requirement. Id. at 1949.

IV. DISCUSSION

As a threshold matter, Bishoff did not file a response opposing Medtronic's motion to dismiss and, accordingly, pursuant to Federal Rule of Civil Procedure Rule 41(b), the Court, in its

discretion, may dismiss Bishoff's claims for failure to prosecute. See Mitchell v. First Century Bank, Inc., No. 2:08-cv-6, 2008 WL 4145517 (N.D.W. Va. Sept. 8, 2008) (recognizing that a district court has discretion to dismiss an action based on a plaintiff's failure to prosecute). "It is recognized, however, that courts should not apply such an unforgiving and relentless sanction simply because a motion to dismiss goes unopposed." Mitchell at 2 (citing Reizakis v. Loy, 490 F.2d 1132, 1135 (4th Cir. 1974). Here, the Court need not address this issue further because, as discussed below, Bishoff's claims are either inadequately pleaded under the applicable Federal Rules of Civil Procedure or are preempted by the MDA.

A. The MDA and Federal Preemption of State Law Claims

Under the MDA, the Food and Drug Administration ("FDA") applies a high level of scrutiny and review to Class III[1] medical devices. This review is known as the Premarket Approval ("PMA") process. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344 (2001). Through the PMA process, the FDA must weigh the "probable benefit to health from the use of the device against any

[1] Medtronic asserts throughout its motion to dismiss that its Quattro Lead is a class III device and Bishoff fails to assert otherwise.

probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). Pursuant to this, the FDA sometimes approves potentially life-threatening devices if they "offer great benefits in light of available alternatives." Riegel v. Medtronic, Inc., 552 U.S. 312, 318 (2008).

The MDA also preempts device regulations established by states or political subdivisions which differ from, or are greater than, the safety requirements imposed by the PMA process. 21 U.S.C. § 360k(a). Since the Supreme Court decided Riegel, courts have routinely held that state law claims for strict products liability, negligence, negligence per se, breach of warranty, failure to warn and manufacturing-and-design-defect are preempted. See In re Medtronic, Inc. Sprint Fidelis Leads Products Liab. Litig., 592 F. Supp.2d 1147, 1152 (D. Minn. 2009) (collecting cases). Courts, however, also have recognized that "Riegel left open a back door for plaintiffs: claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA are not preempted." Id.

B. Negligence per se and Manufacturing Defect

Bishoff alleges that Medtronic failed to manufacture, assemble, test or inspect her Quattro Lead in accordance with the

requirements of the PMA process. While such allegations, if proven, might allow Bishoff to avoid preemption, she fails to support them with adequate facts.

For a medical device claim to survive a motion to dismiss, a plaintiff must provide enough factual detail to notify the defendant of the grounds on which her claim rests. See Sprint Fidelis Leads, 592 F. Supp.2d at 1152 . An allegation that a medical device manufacturer failed to comply with FDA regulations, without more, does not satisfy the pleading requirements of Rule 8(a). Id. To survive a motion to dismiss, the plaintiff's complaint must contain enough factual support to describe how the device manufacturer failed to comply with federal standards. Id.

In Sprint Fidelis Leads, the plaintiffs alleged that Medtronic used welding techniques that failed to comply with the FDA's regulations. Id. When reviewing this claim, the district court held that the plaintiffs had failed to establish a manufacturing defect claim that was plausible on its face because they had failed to identify how or why any FDA regulations prohibited the welding technique described in their complaint. Id.

In this case, Bishoff alleges without any factual support that Medtronic failed to comply with the PMA process and failed to

assemble Bishoff's device in the manner required by the FDA's regulations. Without specific factual support in her complaint identifying how or why Medtronic failed to comply with the PMA process, however, Bishoff's allegations of negligence per se and manufacturing defect fail to state a plausible claim under Rule 8(a). See In Re Sprint Fidelis Leads, 592 F. Supp.2d at 1158.

C. Breach of Express Warranties

Bishoff also alleges that Medtronic provided false representations to her and made express warranties by providing assurances of safety that exceeded the requirements of the PMA process. As to this issue, one court recently observed that "the federal courts are divided as to whether breach of express warranty claims are preempted by" the MDA. Parker v. Stryker Corp., 584 F. Supp.2d 1298, 1302 (D. Colo. 2008). This Court need not resolve that issue at this time, however, because Bishoff's express warranty claim is inadequately pleaded.

The complaint contains only generalized statements alleging that Medtronic breached an express warranty by stating that her Quattro Lead was "fine" and not subject to a recall. Taken at face value, these bare statements fail to establish the creation of an express warranty that Medtronic's product met safety standards

exceeding the requirements of the PMA process or the FDA's regulations. Because Bishoff has not explained how these statements created an express warranty, she fails to state a plausible claim for breach of express warranties under Rule 8(a). See Parker, 584 F. Supp. 2d at 1303.

D. Breach of Implied Warranty of Fitness for a Particular Purpose

Finally, Bishoff's claim for breach of an implied warranty of fitness for a particular purpose fails because it is preempted under 21 U.S.C. § 360k(a). Completion of the PMA process results in the FDA's approval of a medical device for sale and manufacture. See Riegel, 552 U.S. at 317-18. To state a claim for breach of an implied warranty of fitness for a particular purpose under West Virginia law, Bishoff would need to establish that her device was unfit for its intended purpose. See W. Va. Code § 46-2-315; Jones, Inc. v. W. A. Wiedebusch Plumbing & Heating Co., 201 S.E.2d 248, 257 (W. Va. 1973). The FDA's approval of Medtronic's device through the PMA process belies such a claim and preempts any claim that Bishoff's device was unfit for its intended purpose. See In re Sprint Fidelis Leads, 592 F. Supp.2d at 1164.

V. CONCLUSION

The Court **GRANTS** Medtronic's motion to dismiss (dkt. no. 31), and **DISMISSES WITHOUT PREJUDICE** Bishoff's claims for (1) negligence per se, (2) manufacturing defect, and (3) breach of express warranties. It further **DISMISSES WITH PREJUDICE** her claim for breach of the implied warranty of fitness for a particular purpose and **DENIES AS MOOT** Medtronic's motion for summary judgment (dkt. no. 11).

It is so **ORDERED.**

The Court **DIRECTS** the Clerk to prepare a separate judgment order pursuant to Fed. R. Civ. P. 58(a), and to transmit copies of both orders to counsel of record, and to strike this case from its active docket.

DATED: November 22, 2010.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE