

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
DANVILLE DIVISION

LOIS LORRAINE ADKINS,)
) Case No. 4:07CV00053
 Plaintiff,)
)
 v.) **MEMORANDUM OPINION**
)
)
 CYTYC CORPORATION, et al.,)
)
) By: Jackson L. Kiser
 Defendants.) Senior United States District Judge
)

Before me is Defendants' *Motion to Dismiss*. I heard oral argument on this motion on June 17, 2008, it has been fully briefed by the parties, and it is now ripe for decision. For the reasons given below, I will **GRANT** the *Motion to Dismiss* with leave for Plaintiff to amend her *Complaint* with respect to her claim of negligence by the Defendants' representative.

I. STATEMENT OF FACTS AND PROCEDURAL HISTORY

I take the facts to be as stated in Plaintiff's *Complaint* and with all reasonable inferences drawn in her favor. Lois Lorraine Adkins ("Adkins") filed her complaint against Defendants on November 14, 2007. The heart of Adkins's Complaint concerns the effects of a device called the NovaSure, used during a surgical procedure called endometrial ablation, which was performed on Adkins. The device emits a flow of radio frequency energy which vaporizes and causes coagulation in the endometrium. This procedure and this device are jointly used to treat menorrhagia, an abnormally heavy and prolonged menstrual period at regular intervals from which some women suffer.

On November 14, 2005, Adkins underwent a endometrial ablation procedure with the NovaSure device, performed by Dr. Jason Leslie Ensminger, her gynecologist,

at Danville Regional Medical Center ("DRMC"). A corporate representative of Defendants was in the operating room during the procedure and advised and directed Dr. Ensminger on the proper way to measure the size of Adkins' uterus and to test the integrity of her uterine wall, which is necessary before using the device. These tests indicated that the plaintiff did not have a uterine perforation or a uterine wall measuring less than four centimeters in size, conditions which would preclude use of the device according to the Defendants' corporate representative.

During the ensuing ablation procedure, Adkins suffered a thermal burn to her sigmoid colon from the NovaSure device, and post-procedure she was found to have a perforation across the dome of her uterus and a uterus that in fact measured two centimeters. Dr. Ensminger had measured her uterus at 4.5 centimeters prior to beginning the procedure, relying on the representations of the corporate agent of Defendants for how to perform the measurement.

Adkins has now sued in this District Court, alleging breach of implied warranty of merchantability, breach of express warranty, negligence through inadequate design and negligent warnings or instruction of the surgeon by defendants' corporate representative.

II. STANDARD OF REVIEW

Dismissal under Rule 12(b)(6) of the Federal Rules of Civil Procedure is limited to "the extraordinary case where the pleader makes allegations that show on the face of the complaint some insuperable bar to relief." *Browning v. Vecellio & Grogan, Inc.*, 945 F. Supp. 930, 931 (W.D. Va. 1996) (internal quotation omitted). When considering a motion to dismiss, "the court should accept as true all well-pleaded allegations" and

construe those allegations in the light most favorable to the plaintiff. *Mylan Labs, Inc. v. Matkar*, 7 F.3d 1130, 1134 (4th Cir. 1993). While the complaint need not provide detailed factual allegations, the basis for relief in the complaint must state “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1965 (2007). Assuming the factual allegations in the complaint are true, they “must be enough to raise a right to relief above the speculative level,” or else dismissal is appropriate. *Id.*

III. DISCUSSION

This case arises under this Court’s diversity jurisdiction, pursuant to 28 U.S.C. § 1332. This *Motion to Dismiss* essentially argues that each of Adkins’s four common law claims of breach of warranty of merchantability, express warranty, negligent design and manufacture, and negligence on an agency theory, are preempted by the 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act (“MDA”), 21 U.S.C. § 360c, et seq. The Defendants argue that after the United States Supreme Court decided *Riegel v. Medtronic*, 128 S. Ct. 999 (2008), Adkins’s claims for common-law negligence and breach of warranty are preempted. I agree, and therefore I will dismiss all those causes of action that sound in negligence or breach of a duty related to the design, manufacturing, and labeling of the NovaSure device. However, Plaintiff has also pled a cause of action implicating the direct actions of Cytyc’s representative during the surgery in negligently instructing the operating physician. This claim is not governed by *Riegel’s* preemption holding. Since this claim as pled in the Complaint does not satisfy the requirements of *Twombly*, I will dismiss it without prejudice, with leave to amend.

On February 20, 2008, the Supreme Court decided *Riegel v. Medtronic*, which held that common-law causes of action in products liability cases against medical devices that had received premarket approval from the Food and Drug Administration (“FDA”) were preempted. *See Riegel*, 128 S. Ct. at 1002, 1010-11. Specifically, the holding in *Riegel* applies to Class III devices under the Food and Drug Administration’s (“FDA”) regulatory scheme, devices which require premarket approval and have ongoing reporting requirements for their manufacture and sale. *See id.* at 1003. Holding that any requirement of state law “different from, or in addition to” the strictures imposed by the FDA was preempted, the Court in *Riegel* dismissed a products liability claim against the manufacturer of a Class III device. *Id.* at 1010.

It is undisputed here that the NovaSure is an FDA Class III medical device that has received premarket approval from the FDA. Because the FDA has approved the design, manufacturing process, and labeling of the NovaSure device as appropriate and reasonably safe, a negligence finding under state common law would impose requirements that differ from those imposed by the FDA on Cytoc. Therefore, the three claims of Adkins challenging the safety or effectiveness of the NovaSure device are preempted under *Riegel*.

This does not entirely resolve the matter. Adkins has also pled that “defendants’ corporate representative” had “a duty to ensure that the NovaSure device was operating correctly and that Dr. Ensminger followed the proper procedures when using the NovaSure device.” Complaint ¶¶ 30-31. Adkins states that “[n]otwithstanding that duty, the defendants’ corporate representative failed to take the necessary steps to ensure that the plaintiff was not injured, that the NovaSure device was operating correctly and that

Dr. Ensminger followed the appropriate procedures.” Complaint ¶ 32. This claim, which appears to charge negligence to Defendants by way of their representative’s direction of the surgery and pre-operative procedures, potentially states a claim for relief under Virginia tort law.

The FDA does not regulate interactions between corporate representatives and physicians on-site at a particular surgery, and where it does not mandate special physician training for a drug, it does not specify how such an interaction at surgery must be performed. These localized situations are traditional matters for the common law, not the FDA’s regulatory approval process. Such a claim does not challenge the design, manufacture, and labeling of the NovaSure device so as to implicate *Riegel* preemption, but rather challenges negligence by a corporate agent acting as a *de facto* physician’s assistant during a surgical procedure.

The *Complaint’s* agency theory for liability, however, does not give any facts that explain what Defendants’ representative did or failed to do as part of his alleged duty, such that more than mere suspicion of a cognizable right of action is created. *Twombly*, 127 S. Ct. at 1965. Instead, the *Complaint* merely charges that defendants’ agent failed to “take the necessary steps” to protect Adkins from the NovaSure device. Those necessary steps are left entirely to the imagination of the Court, and there is no link offered between such vague steps and causation of Adkins’s damages.

Notably, the possibility of device failure is not ruled out, such that it is just as likely upon reading the pleadings as true that faults in the NovaSure device were the cause of Adkins’s damages rather than negligent instruction by the representative. Where there are two explanations for the damages complained of within the four

corners of the *Complaint*, one of which would allow recovery if true and the other of which could not allow any recovery due to preemption, a plaintiff has failed to state a claim for relief if she has not given any facts to make it more plausible that it was the former rather than the latter. *See generally id.* Here, Adkins's claim fails for just such ambiguity, and must be dismissed, though with leave to amend.¹

IV. CONCLUSION

For the reasons stated above, I will **GRANT** Defendants' *Motion to Dismiss*. Plaintiff's cause of action against Cytoc for the negligence of its agent during the surgery is also dismissed, but without prejudice and with leave to amend the *Complaint* on that theory of recovery only.

The Clerk is directed to send a copy of this *Memorandum Opinion* and the accompanying *Order* to all counsel of record.

Entered this 3rd day of July, 2008.

s/Jackson L. Kiser
Senior United States District Judge

¹ Because the main focus of the *Complaint* was upon a standard products liability negligence theory – a theory effectively destroyed by the intervening *Riegel* decision – plaintiff's secondary theory of liability was not drafted as thoroughly as her other claims. Without argument *contra* from Defendants at the hearing, Adkins requested leave to amend. I will grant such leave, given the circumstances and to prevent prejudice to Adkins.