IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

Suzy Wells, Plaintiff, vs. Allergan USA, Inc. and Medicis Aesthetics, Inc., Defendants.	)	Civil Action No. 6:12-3509-TMC **OPINION & ORDER**

This matter is before the court on the defendants', Allergan USA, Inc. ("Allergan"), and Medicis Aesthetics, Inc. ("Medicis"), respective motions to dismiss (ECF Nos. 47, 48) the plaintiff's amended complaint (ECF No. 46). After considering the record, the court grants the defendants' motions to dismiss.

I. Background

The defendants manufacture the medical aesthetic products Juvederm and Restylane, injectable gel dermal fillers. Both products are Class III medical devices, approved by the Food and Drug Administration ("FDA") through the premarket approval ("PMA") process under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.*, to the Food, Drug & Cosmetic Act ("FDCA"). The plaintiff, Suzy Wells ("Wells"), originally filed this action in state court, alleging that the defendants manufactured, distributed, and sold medical devices that were defective, unreasonably dangerous, and failed to contain adequate warnings when, after using the defendants' products, she suffered an immune system reaction that produced lesions in her lips and Lyme-disease-like symptoms.

The defendants removed the action to federal court and moved to dismiss on the grounds that Wells's claims were preempted by federal law and that, even if not preempted, Wells failed to state a claim. (ECF No. 8.) In response, Wells moved to amend her complaint to cure the pleading deficiencies. (ECF No. 30.) The court granted the motion and she filed her amended complaint, alleging causes of action for negligence, strict liability, breach of warranty, unfair trade practices, negligent misrepresentation, and post-manufacture failure to warn. (ECF No. 46.) The defendants responded with separate motions to dismiss raising essentially the same grounds: preemption and failure to adequately state a claim.[1]

II. Legal Standard

Under the federal rules, each pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Accordingly, pursuant to Federal Rule of Civil Procedure 12(b)(6), a claim should be dismissed when the complaint fails to allege facts upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When considering a motion to dismiss, the court should "accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff." *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993). However, "the pleading standard . . . demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). Thus, the rules require more than "labels and conclusions," "a formulaic recitation of the elements of a cause of action," or "naked assertions devoid of further factual enhancement." *Id.* at 678.

[1] Pursuant to the local rules, this court is not required to hear oral argument on motions. Local Rule 7.08, DSC. However, to provide the plaintiff another opportunity to present her position, the court scheduled a hearing on the motions for November 18, 2013. Then, on motion from plaintiff's counsel, the court continued that hearing until January 9, 2014, a date agreed upon by counsel for both sides. The court noticed the hearing on December 3, 2013, providing counsel over one month's notice. Yet, plaintiff's counsel failed to appear for the hearing. The court has thoroughly reviewed the record in this case and the motions are fully briefed. Accordingly, the court declines to schedule another hearing and will, instead, decide the motions before it on the briefs.

In sum, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Bell Atlantic v. Twombly*, 550 U.S. 544, 570 (2007)). And, for a claim to have facial plausibility, the plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556).

III. Discussion

Restylane and Juvederm are both Class III medical devices under the MDA and, as such, are subject to a rigorous premarket approval process. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). During that process, the FDA evaluates everything about the device, from labeling to safety. *See Walker v. Medtronic, Inc.*, 670 F.3d 569, 572-73 (4th Cir. 2012). And, once a device receives PMA, federal law forbids the manufacturer to make "changes in design specifications, manufacturing processes, labeling, or any other attribute that would affect safety or effectiveness" without FDA approval. *Reigel*, 552 U.S. at 319. The law also requires manufacturers to "report to the FDA when an approved device 'may have caused or contributed to a death or serious injury' or malfunctioned in a way that would make it likely to do so in the future,'" *Walker*, 670 F.3d at 574 (citing 21 U.S.C. § 360i(a)(1)), and "periodically inform the FDA about data from clinical studies or scientific literature related to the device," *id.* (citing 21 C.F.R. § 814.84(b)).

In addition, the FDA retains exclusive enforcement authority over the manufacturers pursuant to the FDCA. Thus, while private individuals "may report wrongdoing and petition the agency to take action," *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001) (citing 21 C.F.R. § 10.30), Congress has made clear that there is no private right of action under

the FDCA and that all actions to enforce the statute "shall be by and in the name of the United States." *Id.* at 349 n.4 (quoting 21 U.S.C. § 337(a)).

The FDA's exclusive enforcement right is reinforced by the MDA's express preemption clause, providing that no state may impose "any requirement" relating to the safety or effectiveness of a medical device that is "different from, or in addition to, any requirement applicable . . . to the device" under federal law. 21 U.S.C. § 360k(a). Courts have overwhelmingly interpreted this clause to bar common law tort claims against Class III device manufacturers, finding that those claims seek to impose different or additional requirements for purposes of § 360k(a). *See Riegel*, 552 U.S. at 322-25; *Walker*, 670 F.3d at 577.

However, there is one narrow exception to this rule. Plaintiffs may bring claims directly against device manufacturers if their state law claims parallel federal law, i.e., do not impose requirements that are different from, or in addition to, those already imposed on the manufacturers by federal law. District courts within the Fourth Circuit have found that a well-pleaded parallel claim must at least (1) identify the federal requirement applicable to the device with which it allegedly failed to comply and (2) explain how that violation of a federal requirement caused the plaintiff's injury. *See, e.g., Smith v. St. Jude Med. Cardiac Rhythm Mgmt. Div.*, Civil Case No. CCB-12-1746, 2013 WL 1104427, at *4 (D. Md. March 13, 2013); *Ali v. Allergan USA, Inc.*, No. 1:12CV115, 2012 WL 3692396, at *8 (E.D. Va. Aug. 23, 2012); *Viserta v. St. Jude Med., Inc.*, C.A. No. 8:11CV505, 2012 WL 667814, at *4 (D.S.C. Feb. 29, 2012); *Bishoff v. Medtronic Inc.*, Civil Action No. 1:09CV171, 2010 WL 4852650, at *2 (N.D.W. Va. Nov. 22, 2010); *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *14-15 (M.D.N.C. Aug. 5, 2009).

In this case, Wells does not seem to dispute that preemption applies, but asserts that she is bringing a parallel claim. However, the court finds that the Amended Complaint fails to adequately plead specific facts as to how either defendant violated federal requirements or how those violations caused Wells's injuries. Instead, Wells offers only barebones, conclusory allegations. For example, Counts I-IV include the following language or a slight variation: "By containing these defects, the [sic] Juvederm and Restylane failed to comply with and operate in terms of their Pre-Market Approval from the Food & Drug Administration, approved in FDA Applications P050047 and P020023, as well as all other relevant supplemental applications." (ECF No. 46, Am. Compl. ¶¶ 12, 16, 21, 29.) However, the Amended Complaint does not identify specific device defects or violations of any specific PMA terms. Without specific factual support for her allegations, Wells's Amended Complaint fails to state a plausible claim and must be dismissed.

Wells contends that she cannot plead additional facts without access to confidential PMA documents and urges the court to allow this case to proceed to discovery.[2] In support of this argument, Wells relies almost exclusively on *Walker v. Medtronic, Inc.*, Civil Action No. 2:08-00317, 2008 WL 4186854 (S.D.W. Va. Sept. 9, 2008). *Walker*, however, is fairly unique in its timing. While the parties were already engaged in discovery and the district court was considering a motion for summary judgment, the Supreme Court decided *Riegel*. The court found that the plaintiff had not adequately alleged the type of claim that would survive *Riegel*, but allowed her to amend to correct the deficiency. After the plaintiff amended her complaint, the court granted summary judgment for the defendants on the ground that the plaintiff's claims

[2] The court held a telephonic status conference on this issue on October 16, 2013. At that point, all briefing on the motions to dismiss had been filed and the court decided, for the sake of efficiency and fairness, to stay all deadlines, including discovery, until it could resolve the motions to dismiss. (ECF No. 64.) As noted, the motions were scheduled for hearing on November 18, 2013, but thereafter continued on motion of the plaintiff.

were preempted. *See Walker v. Medtronic, Inc.*, Civil Action No. 2:08-00317, 2010 WL 4822135 (S.D.W. Va. Nov. 24, 2010).

The Fourth Circuit affirmed the district court's decision in an order that has helped outline the requirements for pleading parallel claims after *Riegel* – the same requirements the court relies on today. *See Walker v. Medtronic, Inc.*, 670 F.3d 569, 578-81 (4th Cir. 2012). Now, following *Riegel*'s guidance, courts can ascertain earlier in the litigation whether a plaintiff has a proper parallel claim, thus saving the parties from engaging in expensive and unnecessary discovery.[3] The court declines to lower the pleading standards for this case.

IV. Conclusion

For the foregoing reasons, Allergan's motion to dismiss (ECF No. 47) and Medicis's motion to dismiss (ECF No. 48) are both GRANTED. Accordingly, this case is DISMISSED. Dismissal is without prejudice to the plaintiff's right to potentially pursue relief based on a properly pled and sufficiently supported parallel claim and with prejudice as to any claim premised on standards different from or in addition to the standards imposed by federal law.

IT IS SO ORDERED.

s/Timothy M. Cain
United States District Judge

January 13, 2014
Anderson, South Carolina

NOTICE OF RIGHT TO APPEAL

The parties are hereby notified of the right to appeal this order pursuant to Rules 3 and 4 of the Federal Rules of Appellate Procedure.

[3] In addition, the court has reviewed the discovery requests that plaintiff's counsel submitted following the telephonic status conference (ECF No. 66-1) and finds that much of the requested information is publicly available on the FDA's website.