UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

KELLY PAINTER-HART, et al.,	)	
	)	
Plaintiffs,	)	Case No. 3:20-cv-418
	)	
v.	)	Judge Atchley
	)	
	)	Magistrate Judge McCook
SIENTRA, INC.,	)	
	)	
Defendant.		

MEMORANDUM AND ORDER

Before the Court is a Motion to Dismiss for Failure to State a Claim [Doc. 22] filed by Defendant Sientra, Inc. Plaintiffs Kelly Painter-Hart and Seth Hart responded [Doc. 27] and Defendant replied. [Doc. 29]. Additionally, Plaintiffs and Defendant have filed supplemental authority and briefing in support of their positions. [Docs. 34, 35, 37, 38, 44, 45, 46, 47, 53, 54]. For the reasons below, Defendant's Motion to Dismiss [Doc. 22] is **GRANTED**.

I. FACTUAL BACKGROUND

This is a products liability action related to breast implants that were used in Plaintiff Painter-Hart's breast reconstruction surgery. [Doc. 1].[1]

A. Medical Device Classification and PMA Process

In 1976, Congress introduced the Medical Device Amendments ("MDA) to the Federal Food, Drug, and Cosmetic Act ("FDCA"). The MDA established a comprehensive regulatory regime for medical devices to be implemented by the Food and Drug Administration ("FDA").

[1] For consistency and ease of reference, record citations are to the CM/ECF-stamped document and page number, not to the internal pagination of any filed document. Where possible, citation is made to more specific subdivisions within a document.

Before the MDA was enacted, "states individually were left to regulate medical devices. Now, Congress has swept back some state obligations and imposed a regime of detailed federal oversight." *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 850 (W.D. Tenn. 2015) (internal citations omitted).

Under the MDA, medical devices receive varying levels of scrutiny from the FDA depending on the risks they present. Class III medical devices incur the highest level of federal oversight under 21 U.S.C. § 360(c)(1)(C); and must receive FDA approval before entering the market through a process known as "premarket approval" ("PMA"). *Id*. Manufacturers must submit a PMA application for FDA approval, including, among other things, "full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for the manufacture, processing, and when relevant, packing and installation of such device; samples or device components required by the FDA; and a specimen of the proposed labeling." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008) (internal citations omitted).

The FDA spends an average of 1,200 hours reviewing PMA applications; and will only grant premarket approval if it determines that there is "reasonable assurance" of the device's "safety and effectiveness." *Id*. Once a device has received premarket approval, it "may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner…inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80. Therefore, a manufacturer seeking to make such changes must apply for supplemental premarket approval ("PMA Supplement"); and must then await FDA approval pursuant to the

same rigorous standard of review that is applied during the initial PMA process. 21 U.S.C. § 360(e)(d)(6); 21 C.F.R. § 814.39(a).

B. Sientra's Breast Implants

Defendant Sientra, Inc. ("Sientra") manufactures and sells medical devices, including silicone gel breast implants. [Doc. 1 at ¶ 4]. Defendant's breast implants are Class III medical devices that underwent the PMA process. [Doc. 23 at 9].

In March 2012, the FDA approved Defendant's PMA application for silicone gel breast implants. [Docs. 1 at ¶ 17; 23-1]. Defendant's PMA application included safety and efficacy information, proposed labeling and warnings, and a description of the proposed manufacturing process. [Doc. 23 at 13]. Upon receiving FDA approval, Defendant was allowed to begin distributing the silicone gel breast implants in accordance with specific conditions outlined in the PMA approval letter. [Doc. 1 at ¶ 17]. The PMA conditions required submission of various reports to the FDA: annual reports, adverse event reports, and post-approval study reports with particular data requirements. [Docs. 1 at ¶¶ 17-18; 23-1]. Additionally, Defendant was subject to general FDA regulations, including Current Good Manufacturing Processes ("CGMP"), Quality System Regulations ("QSRs"), and requirements regarding contractor selection, testing, and quality control. [Doc. 1 at ¶¶ 19, 22].

After receiving FDA approval through the PMA process, Defendant began selling its silicone gel breast implants, both textured and smooth varieties, to plastic surgeons in the United States and Canada. [Doc. 1 at ¶¶ 4, 16, 24-26]. At all times relevant to this litigation, Defendant contracted with Silimed Industria de Implantes LTDA ("Silimed"), a Brazilian company, to manufacture Defendant's implants in accordance with the PMA specifications approved by the FDA. [*Id*. at ¶¶ 17-18, 26-27, 38].

C. Plaintiff's Claims

In November 2013, Plaintiff Painter-Hart had a double mastectomy in Knoxville, Tennessee; and Defendant's textured silicone gel breast implants were used for her breast reconstruction surgery. [*Id*. at ¶ 7]. Plaintiff claims neither she, nor her plastic surgeon, were informed of any increased risks associated with the breast implants or the use of a medical device manufactured in Brazil, nor of any quality control issues that could impact her health, safety, or well-being. [*Id*. at ¶¶ 8, 10].

In September 2019, Plaintiff returned to her surgeon with complaints of swelling in her right breast. [*Id*. at ¶ 11]. Plaintiff's surgeon ordered an ultrasound to evaluate the possibility of breast implant associated anaplastic large cell lymphoma ("BIA-ALCL"). [*Id*.]. In October 2019, an oncologist confirmed the presence of BIA-ALCL in Plaintiff's right breast. [*Id*. at ¶ 12]. In November 2019, Plaintiff's breast implants were removed. [*Id*. at ¶ 13]. Plaintiff has since required, and will continue to need, medical care, testing, and monitoring related to her BIA-ALCL. [*Id*. at ¶ 14].

II. PROCEDURAL BACKGROUND

Plaintiff claims that Defendant's silicone gel breast implants caused her to develop BIA-ALCL, as they were defective, unreasonably dangerous, and/or adulterated, and were not manufactured in compliance with applicable laws, regulations, and/or standards. [*Id*. at ¶ 15]. Plaintiff and her husband assert three products liability claims under Tennessee law: (1) Strict Liability—Failure to Warn; (2) Strict Liability—Manufacturing Defect; and (3) Negligence. [*Id*. at 20-27].[2]

[2] Plaintiffs also assert a claim for breach of express and implied warranties. [Doc. 1 at 27-29]. However, in briefing the instant motion, Plaintiffs have agreed to dismiss their breach of warranty claims. [Doc. 27 at 25].

In response, Defendant filed the Motion to Dismiss now before the Court. [Doc. 22]. Defendant claims Plaintiffs' state law claims are preempted by federal law; and alternatively, Plaintiffs have failed to state plausible claims for relief. [*Id*.].

III. STANDARD OF REVIEW

A Rule 12(b)(6) motion to dismiss tests the sufficiency of the complaint by arguing the allegations establish no claim for which relief can be granted. Fed. R. Civ. P. 12(b)(6). In considering a motion to dismiss under Rule 12(b)(6), the Court "must construe the complaint in the light most favorable to the plaintiff, accept all of the complaint's factual allegations as true, and determine whether the plaintiff undoubtedly can prove no set of facts in support of his claim that would entitle him to relief." *Engler v. Arnold*, 862 F.3d 571, 574-75 (6th Cir. 2017) (internal quotations omitted).

"The [plaintiff's] factual allegations, assumed to be true, must do more than create speculation or suspicion of a legally cognizable cause of action; they must show entitlement to relief." *League of United Latin Am. Citizens v. Bredesen*, 500 F.3d 523, 527 (6th Cir. 2007). "Mere labels and conclusions are not enough; the allegations must contain 'factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Id.* at 575 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. Furthermore, the Court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

"In evaluating a motion to dismiss, [the Court] 'may consider the complaint and any exhibits attached thereto, public records, items appearing in the record of the case and exhibits attached to defendant's motion to dismiss so long as they are referred to in the complaint and are central to the claims contained therein.'" *Ryniewicz v. Clarivate Analytics*, 803 F. App'x. 858, 863

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