UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

SUSAN DORSEY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 3:08-0731**
	)	**Judge Echols**
ALLERGAN, INC. and ALLERGAN SALES, LLC,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM

This is a products liability action in which Plaintiff Susan Dorsey claims Defendants Allergan Inc.'s and Allergan Sales LLC's Style 20 silicone breast implants are unreasonably dangerous. Defendants have filed a Motion for Summary Judgment (Docket Entry No. 33) which has been fully briefed by the parties (Docket Entry Nos. 43 and 46).

I. FACTUAL BACKGROUND

For the most part, the relevant facts are undisputed. Those facts are as follows.

In April 1991, the Food and Drug Administration ("FDA") began requiring breast implant manufacturers to obtain specific premarket approval by the FDA for any silicone breast implantation. That same year, McGhan Medical Corporation ("McGhan"), a predecessor corporation to Allergan, Inc., applied for premarket approval for various styles of implants. The FDA denied approval of the application for use of such devices for the augmentation of healthy female breasts, but also determined there was a public health need for the devices to be available for reconstruction patients.

In April 1992, the FDA entered into an agreement with McGhan setting forth the

requirements for McGhan to conduct clinical trials of the silicon implant devices for use in reconstruction patients. Under the Agreement, the FDA required that any clinical trial protocols be approved by the FDA and local Institutional Review Boards. The FDA also required McGhan to take all reasonable steps to insure that it received informed consent from all patients prior to implantation of any device on a form consistent with that which had previously been approved by the FDA, and McGhan was to make sure all products were labeled consistent with the agreement and the terms of the approved protocols. McGhan was also required to submit data from the trials in accordance with an agreed schedule and take reasonable steps to ensure that participating physicians complied with the protocols. Further, McGhan was required to cooperate with the FDA's review of the application and monitoring of the clinical trials. The FDA also retained the power to terminate the study at any time if the data showed that continuation of the study was not necessary to, or in the interest of, the public health.

In March 1998, the FDA approved McGhan's study protocol which was submitted pursuant to the 1992 Agreement, subject to the FDA's inspection of McGhan's manufacturing facilities. In the same letter indicating approval, the FDA stated that McGhan's facility in Arklow, Ireland had been inspected and was found to be in compliance with regulations and therefore that facility could export silicone gel-filled mammary prostheses into the United States. McGhan was further informed that it could begin enrolling patients in the study. This study was referred to as the adjunct study. The FDA approved the addition of the Style 20 implants to the adjunct study on June 5, 2002.

In addition to the adjunct study involving reconstruction patients, McGhan also submitted an application for an investigational device exemption ("IDE") for use of the same devices for breast augmentation. The breast augmentation clinical trial was referred to as the "core" study and was

approved by the FDA in 1998.

As the studies progressed, the FDA continued its oversight and considered a large volume of material submitted about the core and adjunct studies submitted by McGhan each year. The submissions in both included detailed manufacturing, chemical, physical, toxicological, and clinical information. McGhan noted that while the adjunct study was not being conducted under an IDE, the submissions it made relative thereto were structured to follow FDA guidelines for IDE clinical study annual reports.

On November 7, 2005, Plaintiff signed a consent form to enter the McGhan Silicone Filled Breast Implant Adjunct Clinical Study. The consent was on a form approved by the FDA and indicated that the use of the implants was investigational and not FDA approved.

Plaintiff received Style 20 implants on November 9, 2005, and had the implants removed on September 29, 2006. The Style 20 implants received premarket approval from the FDA on November 17, 2006.

Plaintiff claims that prior to receiving the Style 20 implants, she was healthy and lived a healthy lifestyle.[1] She claims that when she explored the possibility of receiving silicone implants at the age of fifty, she was assured from doctors at Vanderbilt University Medical Center ("Vanderbilt") that silicone implants were safe and had been used for the past 30 years. She paid a $6,000 participation fee to participate in the adjunct study and receive the implants.

Plaintiff alleges that immediately following the surgery, she began to experience severe neck, back and left shoulder pain, heart palpitations, achy joints, fatigue, insomnia, difficulty swallowing,

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[1]Approximately a decade before the Style 20 implantation, Plaintiff underwent surgery to implant saline implants. She had no discomfort or pain with those implants.

metallic taste in mouth, twitching muscles and memory loss. Plaintiff also claims to have suffered numerous neurological symptoms, including vision loss, depth perception problems, ringing in her ears, and numbness in her hands and feet. The pain and discomfort allegedly was so severe as to keep Plaintiff from working or engaging in social activities.

Beginning in January 2006, Plaintiff consulted with numerous physicians in various fields in an effort to find the root of her medical problems. This quest lasted several months and involved countless doctor office visits, a trip to the emergency room, participation in a sleep study, and even cervical fusion of her spine.

On September 19, 2006, Plaintiff underwent a breast exam because she noticed hardness in her breasts. The examination revealed that both implants had contracted and on September 29, 2006, she underwent surgery to remove the Style 20 implants.

After removal of the implants, Plaintiff claims that her health improved and the majority of her neurological symptoms subsided, although some pain and cognitive issues lingered. Plaintiff further claims that laboratory testing "revealed three different oxidation levels of platinum in her system." (Complaint ¶ 33).[2]

Based on the foregoing, Plaintiff filed a one-count Complaint in the Circuit Court for Wilson County alleging that Defendants are liable on a theory of strict liability because the implants at issue were allegedly defective and/or unreasonably dangerous.[3] Defendants removed the action to this

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[2]The issue of platinum exposure, through platinum remaining on the implants after manufacturing, or seepage from the shell, or a rupture of the implant, was considered by the FDA during the approval process and found not to pose a significant risk.

[3]In the original Complaint filed in state court, Plaintiff identified the allegedly defective devices as a Style 153 implant manufactured by Inamed Corporation, a subsidiary of Allergan, Inc. However, in an Amended Complaint filed in state court, as well as in the filings in this Court, the

Court based upon diversity of citizenship. The Motion for Summary Judgment, which presents a discrete legal issue and has been filed relatively early in this case, followed.

II. STANDARD OF REVIEW

A party may obtain summary judgment if the evidence establishes there are not any genuine issues of material fact for trial and the moving party is entitled to judgment as a matter of law. See Fed. R. Civ. P. 56(c); Covington v. Knox County School Sys., 205 F.3d 912, 914 (6th Cir. 2000). The moving party bears the initial burden of satisfying the court that the standards of Rule 56 have been met. See Martin v. Kelley, 803 F.2d 236, 239 n.4 (6th Cir. 1986). The ultimate question to be addressed is whether there exists any genuine issue of material fact that is disputed. See Anderson v. Liberty Lobby, 477 U.S. 242, 248 (1986); Covington, 205 F.3d at 914 (citing Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986)). If so, summary judgment is inappropriate.

To defeat a properly supported motion for summary judgment, the nonmoving party must set forth specific facts showing that there is a genuine issue of material fact for trial. If the party does not so respond, summary judgment will be entered if appropriate. Fed. R. Civ. P. 56(e). The nonmoving party's burden of providing specific facts demonstrating that there remains a genuine issue of material fact for trial is triggered once the moving party shows an absence of evidence to support the nonmoving party's case. Celotex, 477 U.S. at 325. A genuine issue exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson, 477 U.S. at 248. In ruling on a motion for summary judgment, the Court must construe the evidence in the light most favorable to the nonmoving party, drawing all justifiable inferences in its favor. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

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device at issue has been identified as Style 20 implants manufactured by Allergan, Inc. and/or its predecessors.

III. LEGAL ANALYSIS

Defendants move for summary judgment solely on the grounds that Plaintiff's claim is preempted by federal law. Specifically, Defendants argue that the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et. seq., preempts Plaintiff's strict liability claim brought under state law. Prior to reaching the specific arguments raised by the parties, some review of the MDA is appropriate to place the arguments in context.

The MDA was enacted by Congress in 1976 and modified the Food, Drug and Cosmetics Act to allow the FDA to regulate medical devices. Medical devices under the FDA are divided into three classes (Class I, II, and III), with Class III being the most regulated. Kemp v. Medtronic, Inc., 231 F.3d 216, 221 (6th Cir. 2000). The parties in this case agree the Style 20 implant is a Class III device.

Under the regulations, Class III medical devices are those which are to be used for supporting or sustaining human life or that are of substantial importance in preventing impairment of public health, or those that present a potential unreasonable risk of illness or injury. See 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II). In Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), the United States Supreme Court reviewed the process for marketing a Class III device under the MDA:

> Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance," which is known as the "premarket approval," or "PMA" process, is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission. Hearings before the Subcommittee on Health and the Environment of the House Committee on Energy & Commerce, 100th Cong., 1st Sess. (Ser. No. 100-34), p. 384 (1987) (hereinafter 1987 Hearings); see generally Kahan, Premarket Approval Versus Premarket Notification: Different Routes to the Same Market, 39 Food Drug Cosm. L.J. 510, 512-514 (1984).

> Not all, nor even most, Class III devices on the market today have received premarket approval because of two important exceptions to the PMA requirement. First, Congress realized that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices. The statute therefore includes a "grandfathering" provision which allows pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA. See 21 U.S.C. § 360e(b)(1)(A); 21 CFR § 814.1(c)(1) (1995). Second, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market, the Act also permits devices that are "substantially equivalent" to pre-existing devices to avoid the PMA process. See 21 U.S.C. § 360e(b)(1)(B).

Id. at 477-78 (footnote omitted).

The MDA includes a provision that expressly preempts state law. This preemption provision, which is at the center of Defendants' Motion for Summary Judgment, states:

> "No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360c et seq.

Recently, the Supreme Court had occasion to address the MDA preemption clause in Riegel v. Medtronic, Inc., 128 S.Ct. 999 (2008). That case involved a catheter manufactured by defendant Medtronic which was a Class III device that had received FDA premarket approval. The suit arose after plaintiff's surgeon overinflated the catheter while performing a coronary angioplasty, causing the catheter to rupture. This led to heart blockage after which plaintiff was placed on life support and underwent emergency coronary bypass surgery. Plaintiff filed suit in state court, alleging a host of state law claims. On review, the Supreme Court affirmed dismissal of plaintiff's strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling,

marketing, and sale claims on the grounds that they were preempted by the MDA. The Court also "pre-empted a negligent manufacturing claim insofar as it was not premised on the theory that Medtronic violated federal law." Riegel, 128 S.Ct. at 1005-06.

In arriving at its conclusions, the Supreme Court established a two-part test to decide whether the MDA preempts a state claim. First, it must be determined whether the FDA has established requirements applicable to the medical device in issue. Second, it must be determined whether the state law claims are based on requirements "different from, or in addition to" the federal requirements, relating to safety and effectiveness or any requirement under the MDA. Id. at 1007.

In this case, Defendants assert that "[t]he Supreme Court's decision earlier this year in Riegel leaves no doubt that the Medical Device Amendments preempt plaintiff's state law claims." (Docket Entry No. 34 at 7). Plaintiff argues Riegel is distinguishable and not dispositive. Specifically, Plaintiff seeks to distinguish Riegel on the ground that the implant at issue in this case had not received premarket approval by the FDA at the time of surgery, whereas the catheter in Riegel had received premarket approval at the time of surgery. Plaintiff further argues that the Style 20 implants had not been granted clearance through the IDE exemption for use of the implants in reconstruction, as opposed to augmentation, surgery.

While this case is in fact distinguishable from Riegel with respect to the timing of the premarket approval, this is a distinction without a difference in the Court's view because within a month of removal of the implants from Plaintiff, the Style 20 implants did in fact receive premarket approval. Recall that in Riegel, the Supreme Court established a two-prong inquiry consisting of whether the FDA has established requirements applicable to the specific device at issue and whether a state law claim is based upon requirements which are different from or in addition to the federal

requirements. Both prongs of the inquiry must be answered in the affirmative in this case.

By approving the Style 20 implant, the FDA necessarily conducted a "federal safety review" and determined that the device was reasonably safe and effective. See, Riegel, 128 S.Ct. at 1007 (premarket approval "is safety review" and FDA approval is only given "after it determines that a device offers a reasonable assurance of safety and effectiveness."). For Plaintiff to prevail on a strict liability claim under Tennessee law, she would have to show that the product at issue, the Style 20 implant, was "in a defective condition or unreasonably dangerous at the time it left the control" of the Defendant, with "defective condition" being "defined as 'a condition of a product that renders it unsafe for normal or anticipatable handling and consumption.'" Mohr v. DaimlerChrysler Corp., 2008 WL 4613584 (Tenn. Ct. App. 2008)(citation omitted). However, Riegel specifically instructs that such claims are preempted under the MDA where a specific device has received premarket approval. Here, the subsequent approval by the FDA is a bar to Plaintiff's strict liability claim because the FDA has determined that the implants at issue are reasonably safe for consumers and there is no suggestion that the implants she received were somehow different than those ultimately approved by the FDA.

In this regard, Plaintiff's reliance upon the highly fractured opinion of the Supreme Court in the pre-Riegel case of Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) is misplaced. There, a husband and wife filed state law claims for negligence and strict liability after a pacemaker implanted in the wife failed and resulted in the wife having to undergo emergency surgery. The pacemaker at issue was a Class III device but had not been subject to the premarket approval process. Nevertheless, defendant argued that the pacemaker was substantially equivalent to a device which had been "grandfathered" into the MDA and that, as such, the state law claims were pre-

empted. The Supreme Court disagreed. In Riegel, the Supreme Court explained Lohr as standing for the proposition that "federal manufacturing and labeling requirements applicable across the board to almost all medical devices d[o] not preempt the common-law claims of negligence and strict liability" because such requirements which are non-specific to the device in question reflect "'entirely generic concerns about device regulation generally.'" Riegel, 128 S.Ct. at 1006 (quoting Lohr, 518 U.S. at 501). Here to the contrary, but as in Riegel, the specific device at issue has been found to be reasonably safe and effective. As in Riegel, Plaintiff's state law strict liability claim is preempted by the MDA.

The foregoing analysis necessarily means that Plaintiff cannot pursue her strict liability claim. Nevertheless, the Court will address Plaintiff's argument that the FDA had not granted clearance of the device at issue under the IDE for use of the implants in reconstruction patients. That is, Plaintiff argues that while Defendants were granted an IDE for use of implants in Defendants' core study involving augmentation patients, the same cannot be said about the adjunct study.

In advancing her arguments, Plaintiff asserts "[t]here are no cases on point in this matter as no court has addressed the issue presented here; namely, preemption in the context of a device involved in an adjunct study." (Docket Entry No. 43 at 12). While Defendants do not directly contest this assertion, the Fifth Circuit in Lewis v. Intermedics Intraocular, Inc., 1997 WL 256768 at *10 (5th Cir. 1997)(unpublished) was presented with a case in which "Plaintiffs ask us to hold as a matter of law that adjunct studies are not concerned with safety and effectiveness; and are therefore outside the scope of an IDE[.]" Addressing that argument, the Fifth Circuit wrote:

> We cannot agree with Plaintiffs' interpretation. First, we are not convinced that adjunct studies are outside the scope of the MDA or the regulations. It is

> impossible to overlook the fact that Intermedics' investigatory plan includes an adjunct study group that will be monitored less than the core study group and that this plan was approved by the FDA. Also, we refuse to engraft onto the MDA or applicable regulations a judicially-created distinction between core and adjunct studies, especially when there is no clear congressional intent on the question. The statements cited by Plaintiffs do evidence a concern about adjunct studies; but, that is all they evidence. Second, Medtronic provides the test for all claims of MDA preemption, regardless of whether the device in question has been made available to the public pursuant to premarket approval, a finding of substantial equivalence, or an IDE. Whether Plaintiffs' claims are preempted turns on the device-specificity of the federal and state requirements at issue, not whether the claim arose out of an adjunct or a core study.

Id. Here, regardless of whether the Style 20 implant was a part of the core or adjunct study, the FDA has approved its use and therefore Plaintiff's claim is preempted.

Further, Plaintiff's suggestion that the implants at issue received less scrutiny because they were a part of the adjunct as opposed to the core study is belied by the very evidence Plaintiff sets forth for her assertion that the Style 20 implant was a part of the adjunct study. Specifically, Plaintiff points to the annual progress report which McGhan submitted to the FDA on April 16, 2001 and which stated, "Although this study is not being conducted under an IDE, this amendment is structured to follow FDA guidance for IDE clinical study annual reports and also to provide additional information requested by the FDA and agreed to by McGhan Medical[.]" (Docket Entry No. 37-5). Thus, regardless of how it was characterized (as a clinical or adjunct study), the record suggests that the information given to the FDA was consistent with the IDE protocol in the core study and Plaintiff has provided absolutely no evidence which would suggest otherwise. This lack of evidence is underscored by the fact that the FDA had approved an IDE relative to the core study for the same devices, including Style 20 implants, that were being used in the adjunct study. Unquestionably, state products liability claims with respect to an FDA approved investigational device are preempted because to hold otherwise "would thwart the goals of safety and innovation."

Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090, 1100 (6th Cir. 1997).

Moreover, the FDA imposed numerous restrictions on the devices used in the adjunct study including, but not limited to, informed consent, submission of data, protocols submitted to and approved by the FDA, investigation of any misuse or improper application of the device, and FDA monitoring of the trials. While there was not enough information to allow general marketing at the time, the FDA found there was a public health need for such a trial and the benefits of such trials outweighed the risk to patients. See, Chambers v. Osteonics Corp., 109 F.3d 1243, 1248 (7th Cir. 1997)(where FDA has "decided, rightly or wrongly, that a particular device can be sold, subject only to requirements, procedural in character and designed to assure this experimental distribution was in fact a worthwhile experiment," state law claims for strict liability and breach of warranty are preempted).

Given the evidence in the record, the Court determines that Plaintiff's strict liability claim is preempted. Accordingly, Defendants' Motion for Summary Judgment will be granted.

IV. CONCLUSION

On the basis of the foregoing, Defendants' Motion for Summary Judgment (Docket Entry No. 33) will be granted and this case will be dismissed. An appropriate Order will be entered.

ROBERT L. ECHOLS
UNITED STATES DISTRICT JUDGE