IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

EDWARD WALLS and	:	
TONYA CHAVIS-WALLS,	:	
Plaintiffs,	:	
	:	**CIVIL ACTION**
v.	:	**No. 19-3690**
	:	
MEDTRONIC, INC., et al.,	:	
Defendants.	:	

McHUGH, J. **December 16, 2019**

MEMORANDUM

This is a product liability action brought by Plaintiff Edward Walls and his wife against Medtronic, Inc., Medtronic USA, Inc., and Physio-Control, Inc. Plaintiffs allege that two Activa deep brain stimulators and one deep brain stimulator lead—surgically implanted in Mr. Walls to treat neurological disorders—were defective, lacked adequate instructions and warnings, and were negligently designed and produced.

Defendants move to dismiss, asserting that because the devices were subject to a full Premarket Approval (PMA) process by the Food and Drug Administration (FDA) under the Medical Device Amendments to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 360c *et seq.*, Plaintiffs' claims are therefore preempted pursuant to *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). In their response, Plaintiffs have failed to overcome the obstacles presented by *Riegel*. The Complaint will therefore be dismissed, though such dismissal is without prejudice to Plaintiffs' ability to assert claims that might be consistent with the federal statutory scheme.

I. BACKGROUND

A. Statutory and Regulatory Framework for Medical Devices

When Congress passed the Medical Device Amendments to the FDCA, it created a comprehensive "regime of detailed federal oversight." *Riegel*, 552 U.S. at 316. Congress also specified in the MDA 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).

The MDA also "established various levels of oversight for medical devices, depending on the risks they present."[1] *Riegel*, 552 U.S. at 317. Devices that are "purported or represented to be for a use in supporting or sustaining human life" or "present a potential unreasonable risk of illness or injury" are designated "Class III" devices. 21 U.S.C. § 360c(a)(1)(C)(ii). Except for devices "substantially equivalent" to one that is already exempt, any new Class III device must receive premarket approval from the FDA, which is the most stringent form of FDA review for devices. *Riegel*, 552 U.S. at 317 (internal citations and quotation marks omitted). Obtaining "[p]remarket approval is a 'rigorous' process." *Id*. (internal citation omitted). The FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* at 318 (quoting 21 U.S.C. § 360e(d)).

[1] In distinguishing the applicable levels of oversight under the MDA, the Third Circuit has explained that:

> Approval procedures for new medical devices under the Medical Device Amendments vary depending on a device's class designation. The statute divides devices into three classes "based on the risk that they pose to the public" and applies more rigorous prerequisites to devices that pose greater risks. Because Class I devices pose the least risks, Class II devices are "more harmful," and Class III devices pose the greatest risks, Class III devices receive "the most federal oversight," and Class I and II devices receive much less.

Shuker v. Smith & Nephew, PLC, 885 F.3d 760, 765-66 (3d Cir. 2018) (internal citations omitted).

B. The Premarket Approval Process

As described by the Second Circuit in *Riegel*, a manufacturer seeking premarket approval must submit:

> a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information.

Riegel v. Medtronic, Inc., 451 F.3d 104, 109 (2d Cir. 2006) (citing 21 U.S.C. § 360e(c)), *aff'd*, 552 U.S. 312 (2008).

The Premarket Approval process involves "'weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). It includes review of a device's proposed labeling to "evaluate … safety and effectiveness under the conditions of use set forth on the label," *id*. (citing § 360c(a)(2)(B)), and "determine that the proposed labeling is neither false nor misleading," *Id*. (citing § 360e(d)(1)(A)). If the FDA concludes that a device's proposed design, manufacturing methods, or labeling needs revision, it can require such revisions before approval. *Id.* at 319 (citing 21 C.F.R. § 814.44(e)).

Even after approval, a Class III device remains subject to scrutiny after reaching the market. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Any change in the device requires a PMA Supplement, which is subject to the same rigorous standards as an initial PMA application. *Id*.

(citing 21 C.F.R. § 814.39(c)); *see also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000).

Defendants here cite to and attach FDA records accessible online that demonstrate their products were subject to a full Class III Premarket Approval process. Def. Mot. to Dismiss, Ex. 1, ECF 3-2, at 1-16. Plaintiffs have not questioned the validity of those records, and I am satisfied that it is proper for me to take judicial notice of them. Federal Rule of Evidence 201(b)(2); *In re Egalet Corp. Sec. Litig.*, 340 F. Supp. 3d 479, 497 (E.D. Pa. 2018).

Against this backdrop, I now turn to the arguments Defendants raise in their Motion to Dismiss.

II. STANDARD OF REVIEW

In this Circuit, motions to dismiss under Federal Rule of Civil Procedure 12(b)(6) are governed by the well-established standard set forth in *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009).

III. DISCUSSION

Defendants are correct that *Riegel* mandates dismissal of all of Plaintiffs' claims. Def. Mot. to Dismiss, ECF 3-1, at 7-10. In *Riegel*, the plaintiff asserted state-law product liability claims, including strict liability, breach of implied warranty, and negligence. 552 U.S. at 320. The existence of a comprehensive regulatory scheme, coupled with the language of § 360k(a), led the Supreme Court to conclude that state law tort claims are preempted to the extent that they invite a court or jury to impose requirements different than those endorsed by the FDA as part of its Premarket Approval process. *Id*. at 330. It therefore held each of the plaintiff's state law claims were expressly preempted. *Id*.

Riegel established a two-step analysis. First, a court must determine whether "the Federal Government has established requirements applicable to" the particular medical device.

Id. at 321. If it has, then the court must determine whether the state law claims raised by the plaintiff impose "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements that relate to either (i) "safety or effectiveness" or (ii) "any other matter included in a requirement applicable to the device." *Id*. at 323 (citing § 360k(a)).

Applying the *Riegel* test to the Plaintiffs' claims here, I find that both prongs are satisfied. Claims involving PMA-approved Class III devices will automatically satisfy the first prong of the test because "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application." *Id*. Plaintiffs have not challenged that the deep brain stimulators and deep brain stimulator lead here are Class III devices that have received Premarket Approval. Thus, as Class III devices, the federal government has established requirements applicable to the devices. And, by definition, a common law product liability claim satisfies the second prong because it is based on the premise that the product required some change to render it safe for its intended use. *See id.* at 324-25; *Shuker*, 885 F.3d at 774 (3d Cir. 2018); *Horn v. Thoratexc Corp.*, 376 F.3d 163, 179 (3d Cir. 2004) (design, labeling, and instructions for device receiving PMA "were the subject of extensive consideration by the FDA" and rendered plaintiff's state law claims expressly preempted because they would impose conflicting requirements). Thus, under *Riegel*, claims such as those brought by Plaintiffs here are expressly preempted. *Id*. at 330.

Indeed, *Riegel* has been invoked by a broad array of federal courts to preempt claims involving products that went through the Premarket Approval process. *See*, *e.g.*, *Shuker*, 885 F.3d at 775 (dismissing negligence, strict liability, and breach of implied warranty claims); *Millman v. Medtronic*, 2015 WL 778779, at *6 (D.N.J. Feb. 24, 2015) (dismissing twelve state common-law claims regarding Medtronic's Activa device as preempted). Plaintiffs cite no

authority to undercut the application of *Riegel* and its progeny. Instead, they cite to cases where the product at issue was subject to the far less rigorous process of approval under §510(k) of the MDA, which the Supreme Court held did not result in preemption in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). *Riegel* was decided after *Lohr*, and it drew a clear distinction between the two processes.[2] The precepts of *Lohr* simply do not apply in this context where the device went through a full Premarket Approval process. Plaintiffs' claims sounding in strict liability and negligence are therefore preempted.

In answering the Motion to Dismiss, Plaintiffs for the first time raise three alternative theories of liability, none of which they pled in the Complaint. First, they observe that a manufacturer of a medical device can incur liability for promoting its use beyond a purpose approved by the FDA. Pls.' Ans. to Def. Mot. to Dismiss, ECF 4, at 9-10. But such a theory is undercut by Plaintiffs having already pled that the devices were inserted to treat Mr. Walls's tremors, Compl. ¶ 15, a use for which they were specifically approved.

Second, Plaintiffs cite to a notice of "Medical Device Correction" issued by Medtronic sometime in February 2013, before Mr. Walls's surgery on March 19, 2013, which they characterize as a "recall." ECF 4, at 6. The notice on its face is not a recall of the product but provides additional instruction to surgeons who made use of a lead cap when implanting the device. Plaintiffs suggest that the difficulties encountered by Mr. Walls could in some way relate to this post-sale correction, and they suggest that Medtronic violated a "state-law duty to provide an adequate warning about the use of the DBS and the recalled lead." *Id*. at 6. Whether

[2] In reaching its conclusion that Premarket Approval imposes "requirements," the Supreme Court explained that Premarket Approval is more robust than the § 510(k) review because Premarket Approval (1) focuses on safety, rather than equivalence; (2) entails a formal review for safety and efficacy; and (3) requires that devices enter the market "with almost no deviations from the specifications in its approval application." *Riegel*, 552 U.S. at 323.

Plaintiffs can establish such a claim is not squarely before me based on the Complaint here, but it should be noted that any post-sale duty to warn under Pennsylvania law is extremely narrow, *Walton v. Avco Corp.*, 610 A.2d 454, 459-60 (1992), and could be preempted even if Pennsylvania sought to impose such a duty on pharmaceutical suppliers. *Riegel*, 552 U.S. at 330.

Finally, Plaintiffs point out that not every claim is preempted in the case of products having received Premarket Approval. *Riegel* also held that Section 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id*. at 330 (citing *Lohr*, 518 U.S. at 495). But Plaintiffs have pled their claims in general terms, and they have not identified any violation of specific FDA regulations.

IV. CONCLUSION

For the reasons set forth above, Defendants' motion to dismiss will be **GRANTED**, but such dismissal must be without prejudice because I cannot definitively conclude that allowing Plaintiffs to amend the Complaint would be futile on the record before me. An appropriate order follows.

/s/ Gerald Austin McHugh
United States District Judge