IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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TINA M. WINKLER, et al.,

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Plaintiffs,

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v. Civil Action No. PX 18-00865

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MEDTRONIC, INC., et al.,

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Defendants.

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MEMORANDUM OPINION

Pending before the Court in this products liability action is Defendants Medtronic, Inc., and HeartWare, Inc.'s renewed motion to dismiss the Second Amended Complaint. ECF No. 67. The Court had previously permitted Plaintiffs to amend the Complaint one final time to cure their pleading defects. Having reviewed the pleadings and the Second Amended Complaint, the Court deems a hearing unnecessary. See Loc. R. 105.6. For the following reasons, the Second Amended Complaint is still insufficient to overcome preemption under the Medical Devices Act and is, therefore, dismissed with prejudice.

I. Background

In August of 2014, John C. Winkler ("Winkler") underwent an operation at Duke University Hospital in North Carolina to implant a HeartWare Ventricular Assistive System ("HVA") in his heart. ECF No. 9 ¶ 5. The purpose of the HVA was to serve as a "bridge" to provide life sustaining left ventricular function while Winkler waited for a heart transplant. Id. Two years prior, Medtronic's predecessor company, HeartWare, Inc., sought and obtained from the United States Food and Drug Administration ("FDA") premarket approval for the HVA. ECF No. 63 ¶ 5. The HVA is classified by the FDA as a Class III device subject to the agency's

most intensive review and approval process. Id.; Williams v. Smith & Nephew, Inc., 123 F. Supp. 3d 733, 736 (D. Md. 2015).

One of the HVA's component parts is the battery power supply. ECF No. 63 ¶ 4. The HVA includes two batteries connected to the device's controller. Id. One battery provides the power to the device while the other serves as a backup. Id. When the main battery source is depleted to less than 25% power, the HVA controller is designed to switch automatically to the backup battery supply. Id.

On January 4, 2015, the HVA device in Winkler experienced a tragic power failure. When the primary battery pack power fell below 25%, the HVA controller switched to the backup battery. Id. However, the backup battery had been fully depleted due to faulty power cells. Id. The HVA pump, therefore, stopped working and Winkler suffered cardiac arrest. Id. Winkler died on January 6, 2015. Id.

The Plaintiffs filed this action on January 4, 2018, in the Circuit Court for Montgomery County, Maryland. ECF No. 2 at 1. Defendants removed the matter to this Court and moved to dismiss the claims on preemption and limitations grounds. ECF Nos. 1, 30. This Court in its previous written opinion noted that the claims as pleaded were subject to dismissal on preemption grounds. ECF No. 54 at 8–9. However, the Court permitted Plaintiff a final opportunity to amend the Complaint to cure the pleading defects, if possible. Id. at 9. Winkler has now amended the claims and Medtronic renews it motion to dismiss. ECF Nos. 63, 67. Because Winkler failed to aver any facts demonstrating that the claims arose from Defendants'

violations of any FDA regulation, giving rise to a permissibly parallel claim, the Court grants Medtronic's motion to dismiss with prejudice.[1]

II. Standard of Review

In ruling on a motion to dismiss, a plaintiff's well-pleaded allegations are accepted as true and viewed in the light most favorable to the plaintiff. Mylan Labs., Inc v. Matkari, 7 F.3d 1130, 1134 (4th Cir. 1993). "However, conclusory statements or a 'formulaic recitation of the elements of a cause of action will not [suffice].'" EEOC v. Performance Food Grp., Inc., 16 F. Supp. 3d 584, 588 (D. Md. 2014) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). "Factual allegations must be enough to raise a right to relief above a speculative level." Twombly, 550 U.S. at 555. "'[N]aked assertions' of wrongdoing necessitate some 'factual enhancement' within the complaint to cross 'the line between possibility and plausibility of entitlement to relief.'" Francis v. Giacomelli, 588 F.3d 186, 193 (4th Cir. 2009) (quoting Twombly, 550 U.S. at 557).

The purpose of a motion to dismiss under Rule 12(b)(6) "is to test the sufficiency of the complaint." Presley v. City of Charlottesville, 464 F.3d 480, 483 (4th Cir. 2006) (citation and internal quotation marks omitted). A complaint need only satisfy the standard of Rule 8(a), which requires a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "Rule 8(a)(2) still requires a 'showing,' rather than a blanket assertion, of entitlement to relief." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 n.3 (2007). That showing must consist of more than "a formulaic recitation of the elements of a cause of

[1] Medtronic also argues that the claims must be dismissed as time barred. ECF No. 67. Because this argument is less than straightforward, and because the Court dismisses the claims as preempted, it declines to reach the limitations question.

action" or "naked assertion[s] devoid of further factual enhancement." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citations omitted).

III. Analysis

Defendants contend that Winkler has failed to cure the deficiencies in the Second Amended Complaint to avoid preemption under the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 360k. As previously discussed, the MDA imposes a "regime of detailed federal oversight" on medical devices. Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). The MDA provides for various tiers of scrutiny depending on a medical device's safety risks, with the most stringent oversight afforded to Class III devices. Id. at 316–17. Premarket approval by the FDA for Class III devices involves a "rigorous" process of FDA scrutiny and review. Williams, 123 F. Supp. 3d at 736. The FDA crafts each premarket approval process specifically for the individual medical device and conditions the sale and use of the device on the manufacturer's compliance with enumerated safety requirements. Riegel, 552 U.S. at 322–23. Where, as here, the FDA has issued premarket approval to a Class III device, that approval requires the device to be manufactured "with almost no deviations from the specifications in its approval application . . . [to] provide[] a reasonable assurance of safety and effectiveness." Id. at 323. As part of premarket approval, the FDA imposes oversight and monitoring requirements to ensure continued safe use of the device. Walker v. Medtronic, Inc., 670 F.3d 569, 574 (4th Cir. 2012).

Because the FDA had imposed a comprehensive regulatory scheme aimed at ensuring the safety of Class III devices, the MDA expressly preempts lawsuits based on "state requirements" that are "'different from, or in addition to, any requirement applicable . . . to the device' under federal law.'" Riegel, 552 U.S. at 321–22 (quoting 21 U.S.C. § 360k(a)(1)). Accordingly,

common law tort claims based on a violation of FDA regulations may go forward if the claims are based on, essentially, failures to comply with the FDA regulations applicable to the Class III premarket approval directives for the particular device. Id. at 330 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996) ("[T]he state duties in such a case 'parallel,' rather than add to, federal requirements.")). Claims that are "different from, or in addition to" the federal requirements are preempted by federal law. Id.

The Second Amended Complaint includes five causes of action: negligent manufacture, failure to warn, breach of warranty, strict liability, and wrongful death. ECF No. 63 ¶¶ 7–23. None of the claims, however, may proceed because the Plaintiffs have averred no facts by which this Court could plausibly infer any violations of the FDA requirements. The Second Amended Complaint adds no detail pertinent to this question. Indeed, the Second Amended Complaint includes one short paragraph relevant to the FDA process for the HVA that reads:

> On November 20, 2012, HeartWare, Inc. received premarket approval for the "HeartWare Ventricular Assistive System," as a Class III device from the United States Food and Drug Administration. The batteries for the HVA System are expected to function through a minimum of 500 charge and discharge cycles to provide patient support for at least one year. Defectively manufactured batteries which fail to hold a charge due to faulty cells violate the standards required by the FDA for premarket approval of the HVA systems.
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> ECF No. 63 ¶ 5.

The Second Amended Complaint otherwise asserts standard, garden variety, common law negligence claims, and provides no specificity as to the manner in which Defendants violated the FDA regulations applicable to this Class III device. Put differently, merely stating that the precise alleged failure of this device which allegedly caused Winkler's death also generally violated some non-specific FDA "standards" is simply insufficient for this Court to infer plausibly that the claims are parallel, and not in addition, to the pertinent FDA regulations. Cf.

In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig., 300 F. Supp. 3d 732, 737–39 (D. Md. 2018). If the Second Amended Complaint were deemed sufficient, then any time Plaintiffs asserted that the Defendants "violated FDA standards," without more, Plaintiffs could escape statutory preemption.

Plaintiffs argue in their response that an FDA recall issued in January 2016 saves the claim. However, none of the information surrounding this recall was included in the Second Amended Complaint. It is axiomatic that a Plaintiff cannot amend a complaint through a responsive pleading. See Mathis v. McDonough, No. ELH-13-2597, 2014 WL 3894133, at *25 (D. Md. Aug. 7, 2014). Ultimately, however, although the recall itself supports that which has already been pleaded—the HVA battery pack was defective—the recall does not shed any light on the applicable FDA regulations and how Defendants violated those regulations necessary to avoid preemption. Accordingly, the Complaint must be dismissed.

IV. Conclusion

For the foregoing reasons, Defendants' motion to dismiss is granted with prejudice. A separate Order follows.

11/15/2019
Date

/s/
Paula Xinis
United States District Judge

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ORDER

Based on the foregoing Memorandum Opinion, it is this 15th day of November 2019, hereby ORDERED that:

1. The Motion to Dismiss Second Amended Complaint filed by Defendants MEDTRONIC, INC., AND HEARTWARE, INC., (ECF No. 67) BE, and the same hereby IS, GRANTED with prejudice.
2. The Clerk is DIRECTED to TRANSMIT copies of the Memorandum Opinion and this Order to counsel for the parties and to CLOSE this case.

11/15/2019
Date

/s/
Paula Xinis
United States District Judge