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 motion to dismiss. ECF No. 30. After a motions hearing, the parties submitted supplemental letter pleadings. ECF Nos. 52, 53. Upon consideration of the parties' arguments, the Court grants in part and denies in part Defendants' motion to dismiss. The Court also will allow Plaintiffs twenty-one days to file a final Amended Complaint to cure the pleading defects as discussed in this opinion, if possible.

## I. Background[1]

In August of 2014, John C. Winkler ("Winkler") underwent an operation at Duke University Hospital in North Carolina to have a Left Ventricular Assistive Device ("LVAD") implanted in his heart. ECF No. 9 ¶ 5. The purpose of the LVAD was to serve as a "bridge" to provide life sustaining left ventricular function while Winkler waited for a heart transplant. Id. On January 4, 2015, the LVAD unexpectedly lost power. Id. The backup systems intended to

[1] In considering Defendants' motion to dismiss, the Court relies upon the facts alleged in the amended complaint. See Philips v. Pitt County Memorial Hosp., 572 F.3d 176, 180 (4th Cir. 2009). All facts are viewed in the light most favorable to Plaintiffs.

insure the operation of the LVAD also failed, and Winkler suffered a cardiac arrest and died on January 6, 2015. Id.

On January 4, 2018, Winkler's children and spouse ("Plaintiffs") filed suit in the Circuit Court for Montgomery County against HeartWare, Inc. and its parent company Medtronic, Inc. ("Defendants") as the manufacturers of the LVAD. See ECF No. 2. Plaintiffs assert five claims against both defendants: negligent design (Count I), negligent manufacture (Count II), breach of warranty (Count III), strict liability (Count IV), and wrongful death (Count V). ECF No. 9.

On March 30, 2018, Defendants removed the action to this Court pursuant to 28 U.S.C. § § 1332, 1441. ECF No. 1. Defendants now move to dismiss Plaintiffs' Amended Complaint, arguing that Medtronic bears no liability because it did not own HeartWare at the time of Winkler's death, and that Plaintiffs' claims are time-barred under the Virginia wrongful death statute. Defendants also assert Plaintiffs' claims are preempted under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 360k. Finally, Defendants contend that dismissal is warranted because Plaintiffs have failed to plead facts to support their theory of liability.

## II. Standard of Review

In ruling on a motion to dismiss, a plaintiff's well-pleaded allegations are accepted as true and the complaint is viewed in the light most favorable to the plaintiff. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). "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 Twombly, 550 U.S. at 555). "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 action" or "naked assertion[s] devoid of further factual enhancement." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citations omitted).

## III. Analysis

The Court finds at the outset that Plaintiffs have averred sufficient facts to support personal jurisdiction over Defendants, and on a basic level, to allow the allegations to proceed. [2] However, Plaintiffs' Amended Complaint does not provide sufficient detail for the Court to determine the applicable limitations period to certain claims or whether any of the claims are preempted. The Court addresses each issue in turn.

### A. Applicable Statute of Limitations

Defendants contend that the Amended Complaint must be dismissed because the Plaintiffs have not filed suit within the two-year limitations period applicable to wrongful death actions under Virginia law. Va. Code Ann. § 8.01-244. Plaintiffs argue that the action is

[2] While Medtronic contends that claims against it should be dismissed for lack of personal jurisdiction because it did not acquire HeartWare until after Winkler's death, Medtronic offers no argument for why successor liability should not apply. See City of Richmond, Va. v. Madison Mgmt. Grp., Inc., 918 F.2d 438, 454 (4th Cir. 1990) ("If the successor is to stand thus in the place of the predecessor, it must do so for all purposes, including personal jurisdiction in the first instance." (internal citation omitted)).

correctly filed under Maryland's wrongful death statute which provides a three-year limitations period for such claims, Md. Code Ann., Cts. & Jud. Proc. § 3-904(g)(1), and that even though Winkler died elsewhere, the Maryland limitations period applies. The Court cannot agree with either party at this juncture.

Plaintiffs' Amended Complaint avers that the LVAD's design and manufacture defects caused Mr. Winkler's death. In diversity cases, the Court applies the choice of law rules of the state in which it sits. Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496–97 (1941). "In a Maryland wrongful death action, based upon a wrongful act occurring outside of Maryland, the Maryland wrongful death statute itself specifies which jurisdiction's law shall govern." Jones v. *Prince George's Cty*., 378 Md. 98, 107 (2003). More particularly, when the wrongful act occurs outside of Maryland, "a Maryland court shall apply the substantive law of that jurisdiction."[3] Md. Code Ann., Cts. & Jud. Proc. § 3-903.

Plaintiffs submit that the statute of limitations question is procedural, not substantive. Plaintiffs are incorrect. "Since the wrongful death statute created a new liability not existing at common law . . . . [t]he period of limitations is part of the substantive right of action." Knauer v. Johns-Manville Corp., 638 F. Supp. 1369, 1375–76 (D. Md. 1986) (quoting Slate v. Zitomer, 275 Md. 534, 542 (1975)). See also Kielar v. Granite Const. Co., 647 F. Supp. 2d 524, 529 (D. Md. 2009) (applying another jurisdiction's wrongful death statute of limitations as substantive law). Accordingly, this Court shall apply the limitations period of the jurisdiction where the wrongful act occurred. Farwell v. Un, 902 F.2d 282, 287 (4th Cir. 1990) ("[T]he Maryland statute specifically identifies the locus of the 'wrongful act' rather than the locus of death as the critical choice of law determinant in wrongful death actions with multi-state connections.").

[3] Pursuant to the statute, "'[w]rongful act' means an act, neglect, or default including a felonious act which would have entitled the party injured to maintain an action and recover damages if death had not ensued." Md. Code Ann., Cts. & Jud. Proc. § 3-901(e).

In a products liability claim where the manufacture or design defect is the averred cause of death, the "wrongful act" takes place where the alleged defective design or manufacture of the device occurred. See Kielar, 647 F. Supp. 2d at 528 (Louisiana law applied to wrongful death products liability claim where death occurred in Maryland and plaintiffs had not introduced evidence that the equipment was designed or manufactured outside of Louisiana); Desrosiers v. MAG Indus. Automation Sys., LLC, No. WDQ-07-2253, 2010 WL 4116991, at *2 (D. Md. Oct. 19, 2010) (Wisconsin law applied to wrongful death defective design claim where death occurred in Maryland and product was manufactured in Wisconsin).

The Amended Complaint pleads no facts about where the LVAD device was manufactured or designed. Accordingly, the Court cannot assess which limitations period applies to the wrongful death claim based on the LVAD's defective manufacture or design. Plaintiffs will be afforded a final opportunity to amend the complaint to plead sufficient facts for the Court to ascertain the applicable limitations period. Plaintiffs are forewarned that failure to plead sufficient facts relevant to limitations will result in dismissal of the claims with prejudice.

**B. Survival Action**

To the extent Plaintiffs bring a survival action, that claim must be dismissed. "While the Maryland Wrongful Death statute specifically dictates the choice of law to be used in these circumstances [where the death occurred in another jurisdiction], the law is silent for claims brought under the Survival Statute." *Jones v. Prince George's Cty.*, Md., 541 F. Supp. 2d 761, 763 (D. Md. 2008), *aff'*d, 355 F. App'x 724 (4th Cir. 2009). Rather, for tort claims such as survivorship, this Court follows the lex loci delecti rule and applies the substantive law of the relevant jurisdiction. Id. (citing Cooper v. Berkshire Life Ins. Co., 148 Md. App. 41, 54 (2002)).

In contrast to Maryland's wrongful death statute, the place of injury for a common law survivorship action is "where the injury was suffered, not where the wrongful act took place." Vogel v. Morpas, No. RDB-17-2143, 2017 WL 5187766, at *7 (D. Md. Nov. 9, 2017) (quoting Baker v. Booz Allen Hamilton, Inc., Nos. 08-1152, 08-2321, 358 Fed. App'x. 476, 480-81 (4th Cir. Dec. 28, 2009)). If the last injury occurred outside Maryland, then the law of that jurisdiction applies. Lab. Corp. of Am. v. Hood, 395 Md. 608, 615–16 (2006). See also Williams v. Gyrus ACMI, Inc., 790 F. Supp. 2d 410, 414 (D. Md. 2011). Here, the last injury is the decedent's death. See *DiFederico v. Marriott Int'l, Inc*., 130 F. Supp. 3d 986, 990 (D. Md. 2015), *aff'd*, 677 F. App'x 830 (4th Cir. 2017) (Pakistani law would apply to survival action where alleged breach of duty occurred in Maryland, but damage was decedent's death in Pakistan).

Although the Amended Complaint is silent on where Mr. Winkler died, the parties do not dispute that he died in Virginia. ECF Nos. 40 at 7, 52 at 2, 53 at 1. The Court will take judicial notice of this fact. Virginia law does not recognize an independent survivorship action in addition to a wrongful death claim where "the person dies from the injury or the wrongful act." Jones, 541 F. Supp. 2d at 764–65 (D. Md. 2008). See also Va. Code Ann. §§ 8.01-25, -56; Adams v. NaphCare, Inc., No. 2:16-CV-229, 2016 WL 10455885, at *5 (E.D. Va. Dec. 19, 2016), report and recommendation adopted, 232 F. Supp. 3d 866 (E.D. Va. 2017) ("[T]he wrongful death statute [is] the exclusive statement of the grievances that Virginia will recognize when a tort victim dies of her injuries." (quoting El-Meswari v. Washington Gas Light Co., 785 F.2d 483, 491 (4th Cir. 1986))); Jones *v. Prince George's Cty*., Md., 355 F. App'x 724, 730 (4th Cir. 2009) (rejecting the argument that the court should depart from lex loci and allow recovery on both causes of action for public policy reasons). Accordingly, because Winkler died in

Virginia, the substantive applicable law dictates that his survivors may only pursue a wrongful death claim.[4] Further, as discussed above, the wrongful death claim will proceed only if Plaintiffs amend the Complaint sufficient to demonstrate the location of the negligent design or manufacture of the LVAD and that the claims were filed within that location's applicable limitations period. Cf. Wright v. Eli Lilly & Co., 65 Va. Cir. 485 (2004) ("[I]n Virginia today, there can be only one recovery for an injury that causes death, and that recovery belongs to the decedent's next of kin as specified in the wrongful death statute."). The survivorship action is dismissed.

**C. Preemption**

Defendants alternatively argue that Plaintiffs' claims are preempted under the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 360k. 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. The parties agree that the LVAD implanted in Winkler was a Class III device.

To obtain premarket approval by the Food and Drug Administration ("FDA"), Class III devices undergo a "rigorous process" of FDA scrutiny and review. Williams v. Smith & Nephew, Inc., 123 F. Supp. 3d 733, 736 (D. Md. 2015). 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

[4] Virginia does allow a survivorship claim to be pleaded in the alternative, averring that if Defendant's conduct did not cause death, it nonetheless caused separate injury not resulting in death. See Adams, 2016 WL 10455885, at *5 n.2. See also Centra Health, Inc. v. Mullins, 277 Va. 59, 78 (2009). Plaintiffs have only pleaded that Defendants' alleged misconduct caused Winkler's death, rendering this exception inapplicable.

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 (quoting 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, failure to comply with the Class III premarket approval directives with respect to the particular device. Riegel, 522 U.S. 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."). However, claims based on duties "different from, or in addition to" the federal requirements are preempted by federal law. Id. Accordingly, "for a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the [MDA] and (2) would give rise to a recovery under state law even in the absence of the [MDA]." Williams, 123 F. Supp. 3d at 746 (quoting Riley v. Cordis Corp., 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

The Amended Complaint is simply insufficient to ascertain whether the claims are preempted. For example, the Amended Complaint does not set forth the Class III requirements applicable to the LVAD. Nor does the Amended Complaint address whether Defendants deviated from any such requirements, and finally, whether such deviations were the proximate cause of Winkler's death. Cf. In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip

Implant Prod. Liab. Litig., 300 F. Supp. 3d 732, 740–41 (D. Md. 2018). Although Plaintiffs persist that a more robust pleading is impossible absent discovery, the Court disagrees. As discussed during the hearing, the FDA Class III information is publicly available through the FDA website, and Plaintiffs noted that they currently retain custody over the allegedly defective part of the specific LVAD that had been implanted in Winkler. With Plaintiffs exercising due diligence to amend their Complaint properly, "[t]he court is confident it can [evaluate preemption] during the motion to dismiss stage." Id. Accordingly, Plaintiffs are granted one opportunity to amend the Amended Complaint consistent with this Opinion.

## IV. Conclusion

For the foregoing reasons, Defendants' motion to dismiss is granted as to Plaintiffs' survivorship action. As to the remaining claims, Plaintiffs are to file a Second Amended Complaint within twenty-one days consistent with this Opinion. Defendants' motion is therefore denied without prejudice to refile a motion to dismiss or answer the Second Amended Complaint within the time allotted under the Federal Rules of Civil Procedure. A separate Order follows.

11/29/2018
Date

/S/
Paula Xinis
United States District Judge