IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HAROLD R. BERK,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 23-10 (JLH)
	)	
TERUMO MEDICAL CORPORATION, *et al.*,	)	
	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

Harold R. Berk, Port St. Lucie, Florida, *Pro Se* Plaintiff.

Allison L. Texter, Esq., and Mollie F. Benedict, Esq., Swartz Campbell LLC, Wilmington, Delaware. Counsel for Defendants Terumo Medical Corporation, Terumo Americas Holding, Inc., Terumo Puerto Rico LLC, and Terumo Latin America Corporation.

September 30, 2024
Wilmington, Delaware

HALL, U.S. District Judge:

I. INTRODUCTION

Plaintiff Harold R. Berk, proceeding *pro se*, filed this case on January 4, 2023. (D.I. 1.) The operative pleading is Plaintiff's Second Amended Complaint, which asserts state law claims against Defendants Terumo Medical Corporation, Terumo Americas Holding, Inc., Terumo Puerto Rico, LLC, and Terumo Latin America Corporation. (D.I. 44 ("SAC").) Defendants moved to dismiss the SAC. (D.I. 45, 59.) After the motion was fully briefed (D.I. 46, 52, 53), the Court reassigned the case to me.

In addition to the pending motion to dismiss the SAC, there are ten other pending motions: Plaintiff's motion for leave to file sur-reply (D.I. 54), which is granted; Plaintiff's motion to allow Plaintiff limited discovery (D.I. 62); Plaintiff's motion for leave to file a third amended complaint (D.I. 71); Plaintiff's motion to take deposition (D.I. 78); Plaintiff's motion for teleconference to resolve discovery dispute (D.I. 79); Defendants' motion to quash non-party subpoena (D.I. 80); Plaintiff's motion to strike motion to quash (D.I. 83); Plaintiff's amended motion to strike motion to quash (D.I. 84); Plaintiff's motion for oral argument on pending motions (D.I. 87); and Plaintiff's motion for protective order (D.I. 88).

II. BACKGROUND

For purposes of ruling on Defendants' motion to dismiss, the Court accepts as true the following allegations in the SAC. Plaintiff was an attorney for 51 years and retired as of July 1, 2022. On December 23, 2021, at the HCA Florida Lawnwood Hospital in Fort Pierce, Florida, Plaintiff underwent a transcatheter aortic valve replacement (TAVR) procedure to insert a new aortic valve in his heart. At the end of the procedure, medical staff placed a Terumo Angio-Seal

in Plaintiff's left femoral artery. (SAC at 4-6.) Plaintiff was discharged from the hospital on December 24, 2021. Later that day, Plaintiff experienced sudden, severe internal bleeding, which caused intense pain and abnormal expansion in his left thigh and groin area. (*Id.* at 7.)

Plaintiff returned to the hospital, where he was readmitted and given at least one blood transfusion. By that time, Plaintiff had developed a hematoma in his groin, measuring 17 cm across, which caused him intense and continuous pain. (*Id.* at 8-9.) Approximately twelve days after Plaintiff was readmitted to the hospital, he received the first of five surgeries, which were intended to drain the hematoma and repair the thigh and groin area. The five surgeries took place over the course of two weeks, during which Plaintiff received approximately eight blood transfusions. After the surgeries, Plaintiff spent time in an isolation unit because he contracted COVID-19, and then he was transferred to Lawnwood Rehabilitation Hospital for physical and occupational therapy. (*Id.* at 10-11.)

Plaintiff was discharged and returned home on or about February 15, 2022. As of the filing of the Second Amended Complaint, Plaintiff continued to have balance problems and difficulty walking, allegedly resulting from "the long-term hospitalization and his movement limitations from the surgeries and the hematoma." (*Id.* at 11-12.) Plaintiff's medical expenses relating to the hematoma exceed $1 million. (*Id.* at 12.)

Plaintiff contacted Defendants about the incident. Defendant Terumo Medical Corporation filed a Manufacturer and User Facility Device Experience (MAUDE) Adverse Event Report with the Food and Drug Administration (FDA), which reported its receipt of a letter from Plaintiff

regarding the incident. The report listed the "device problem" as "Loosening of Implant Not Related to Bone In-Growth (4002)." (*Id.* at 13-14; D.I. 44-1 at 1.)[1]

The Terumo Angio-Seal is a Class III medical device approved pursuant to the FDA's premarket approval ("PMA") process. (SAC at 18.) In 2018, Terumo recalled two lots of product that were purportedly released for distribution prior to the completion of all required validation and lot acceptance activities. (*Id.* at 18-19.) The SAC does not allege that the device used on Plaintiff in 2021 was subject to any recall.

The SAC alleges four causes of action. The First Cause of Action is styled, "Products Liability Manufacturing Defect." At bottom, it alleges that the device implanted in Plaintiff must have been manufactured through a process that violated "FDA approved design plans" and/or as a result of Defendants' failure to implement FDA-required quality control systems because it didn't work like it was supposed to. (*Id.* at 17-20.) The Second Cause of Action is styled, "Negligence." It alleges that Defendants were negligent in "plac[ing] a defective medical device in the marketplace" and "not instituting effective quality control systems" in accordance with FDA requirements. (*Id.* at 21-22.) The Third Cause of Action is styled, "Failure to Warn." It alleges that, although Plaintiff was provided with a Terumo brochure prior to his TAVR surgery, "which stated in a [f]ont smaller than 8 that bleeding or a hematoma could result," Defendants did not warn Plaintiff "that he could not stand up from a chair after the Angio-Seal implant" or that "he could . . . suffer the 17 cm hematoma and internal bleeding and blood loss that resulted from the

[1] The Court has considered Plaintiff's exhibits to the extent they are referenced in the SAC. *See Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006) ("In evaluating a motion to dismiss, we may consider documents that are attached to or submitted with the complaint . . . and any 'matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case.'" (quoting 5B Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure* § 1357 (3d ed. 2004))).

defective Terumo Angio-Seal." (*Id.* at 22-23.) The Fourth Cause of Action is styled, "New Jersey Products Liability Act," and it alleges that Defendants are "subject to . . . N.J. Stat. Ann. § 2A:58-C et seq., for manufacturing defects and inadequate warnings." (SAC at 23.)

III. LEGAL STANDARD

A defendant may move to dismiss a complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face when the complaint contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). A possibility of relief is not enough. *Id.* "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

In determining the sufficiency of the complaint, the court must assume all "well-pleaded facts" are true but need not assume the truth of legal conclusions. *Id.* at 679. "[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Twombly*, 550 U.S. at 558 (internal quotation marks omitted).

Because Plaintiff proceeds *pro se*, his pleading is liberally construed and his Complaint, "however inartfully pleaded, must be held to less stringent standards than formal pleadings drafted by lawyers." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007).

IV. DISCUSSION

Defendants argue that the SAC fails to state a claim for a number of reasons, including because it fails to plausibly allege a claim that is not pre-empted by federal law. I agree.

The Terumo Angio-Seal is a Class III medical device approved pursuant to the FDA's PMA process. As numerous courts have explained in exhaustive detail, the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360k(a), preempts state tort claims relating to the safety and effectiveness of medical devices subject to the PMA process if the state claims are based on state requirements related to safety and effectiveness "different from, or in addition to" the federal requirements. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008); *see also, e.g.*, *Williams v. Cyberonics, Inc.*, 388 Fed. App'x 169, 171 (3d Cir. 2010); *Estate of Benn v. Medtronic, Inc.*, No. 22-6522, 2023 WL 3966000, at *3 (D.N.J. June 13, 2023); *Marmol v. St. Jude Med. Ctr.*, 132 F. Supp. 3d 1359, 1363 (M.D. Fla. 2015); *In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litig.*, 592 F. Supp. 2d 1147, 1151-52 (D. Minn. 2009). As these courts have held, the MDA operates to preempt many state law theories of liability, including tort claims based on manufacturing and design defects, strict liability, negligence, failure to warn, and state consumer fraud statutes. *Id.*

The MDA does not preempt state law claims that "parallel," rather than add to federal requirements. *Riegel*, 552 U.S. at 330. However, as courts have explained, to state a plausible "parallel claim" that is not preempted, the complaint must either allege a claim under a state cause of action that provides a remedy for a violation of the FDCA, *see id.*, or plausibly allege that a manufacturer failed to adhere to the legal requirements and standards imposed by the device's PMA. *See Estate of Benn*, 2023 WL 3966000, at *3 (citing cases); *see also Williams*, 388 F. App'x

at 171-72 (affirming dismissal of complaint where the plaintiffs "fail[ed] to explain how the device deviated from the FDA requirements"); *In re Medtronic*, 592 F. Supp. at 1158 ("Plaintiffs cannot simply incant the magic words '[defendant] violated FDA regulations' in order to avoid preemption.").

Defendants argue that the state law causes of action alleged in the SAC are precisely the type of claims preempted by the MDA. I agree.[2]

Plaintiff contends that he states a claim that is not preempted because Defendants failed to comply with various FDA requirements in the process of manufacturing the device used on Plaintiff. But Plaintiff fails to explain how Defendants violated those requirements, nor does the SAC plausibly allege facts suggesting that they did. Plaintiff's argument seems to be that Defendants must have violated some PMA or federal requirement when they manufactured the device, otherwise it wouldn't have failed. But, as courts have recognized, the FDA engages in a cost-benefit analysis when it undertakes the PMA process, and it approves Class III devices that sometimes cause adverse events or otherwise don't work 100% of the time. *Riegel*, 552 U.S. at 318; *Banner v. Cyberonics, Inc.*, No. 08-741, 2010 WL 455286, at *4 (D.N.J. Feb. 4, 2010); *see also Weber v. Allergan, Inc.*, 940 F.3d 1106, 1114 (9th Cir. 2019) (explaining that as part of the PMA process, "the FDA performs a cost-benefit analysis and may approve devices knowing that they sometimes will fail"). The mere fact that a patient had an adverse event does not give rise to a plausible inference that the manufacturer violated PMA requirements or federal law when it manufactured the device.

[2] To the extent the parties dispute which state law(s) apply to Plaintiff's claims, I don't need to resolve that dispute because the result would be the same under any of the state laws mentioned by the parties.

Plaintiff points out that some Terumo devices were recalled in 2018. But there are no facts alleged to plausibly link the 2018 recall to anything that happened to Plaintiff in 2021.

Based on the foregoing, the Court will grant Defendants' motion to dismiss the Second Amended Complaint. (D.I. 45, 59.) As this is the first time the Court has evaluated Plaintiff's pleadings, Plaintiff will be given an opportunity to file a third amended complaint remedying the deficiencies discussed above. Plaintiff's pending motion for leave to file a third amended complaint, which was filed before the Court had a chance to rule on Defendants' motion to dismiss the SAC, will be denied without prejudice to refile (D.I. 71), in order to give Plaintiff an opportunity to remedy the deficiencies identified above. If Plaintiff chooses to again file a third amended complaint, he may not add any new claims; he may only amend the allegations in the SAC to remedy the deficiencies discussed in this Opinion. Plaintiff should be advised that filing a third amended complaint that fails to remedy the above-discussed deficiencies will likely result in dismissal with prejudice. Alternatively, if Plaintiff chooses not to timely file a third amended complaint, this case will be closed.

Because the Court is dismissing the SAC, Plaintiff's motion to allow Plaintiff limited discovery (D.I. 62), Plaintiff's motion to take deposition (D.I. 78), Plaintiff's motion for teleconference to resolve discovery dispute (D.I. 79), and Plaintiff's motion for a protective order regarding non-party discovery-related materials (D.I. 88) will all be denied without prejudice to reraise if and when Plaintiff files a pleading that states a claim. For the same reason, the Court will grant Defendants' motion to quash Plaintiff's non-party discovery-related subpoena (D.I. 80), and deny both Plaintiff's motion to strike Defendants' motion to quash (D.I. 83) and Plaintiff's

amended motion to strike Defendants' motion to quash (D.I. 84). Plaintiff's motion for oral argument on the pending motions (D.I. 87) will be denied.

V. CONCLUSION

For the above reasons, the Court will grant Defendants' motion to dismiss the Second Amended Complaint (D.I. 45, 59), Plaintiff's motion for leave to file sur-reply (D.I. 54), and Defendants' motion to quash non-party subpoena (D.I. 80). The Court will deny Plaintiff's motion for limited discovery (D.I. 62), Plaintiff's motion for leave to file a third amended complaint (D.I. 71), Plaintiff's motion to take deposition (D.I. 78), Plaintiff's motion for teleconference to resolve discovery dispute (D.I. 79), and Plaintiff's motion for a protective order (D.I. 88). Finally, the Court will deny Plaintiff's motion to strike motion to quash (D.I. 83), Plaintiff's amended motion to strike motion to quash (D.I. 84), and Plaintiff's motion for oral argument on the pending motions (D.I. 87).

An appropriate Order will be entered.

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TERUMO MEDICAL CORPORATION, et al.,	)	
	)	
	)	
Defendants.	)	

ORDER

At Wilmington, this 30th day of September, 2024, consistent with the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that:

1. Defendants' motion to dismiss the Second Amended Complaint (D.I. 45, 59) is **GRANTED**.

2. Plaintiff's motion for leave to file sur-reply (D.I. 54) is **GRANTED**.

3. Plaintiff's motion to allow Plaintiff limited discovery (D.I. 62) is **DENIED.**

4. Plaintiff's motion for leave to file a third amended complaint (D.I. 71) is **DENIED** with leave to file an amended complaint **on or before October 30, 2024** that remedies the deficiencies identified in the Court's Memorandum Opinion. Plaintiff may not add any new claims. Should Plaintiff choose not to timely file a third amended complaint, the case will be closed.

5. Plaintiff's motion to take deposition (D.I. 78) is **DENIED**.

6. Plaintiff's motion for teleconference to resolve discovery dispute (D.I. 79) is **DENIED**.

7. Defendants' motion to quash non-party subpoena (D.I. 80) is **GRANTED**.

8. Plaintiff's motion to strike motion to quash (D.I. 83) is **DENIED**.

9. Plaintiff's amended motion to strike motion to quash (D.I. 84) is **DENIED**.

10. Plaintiff's motion for oral argument on pending motions (D.I. 87) is **DENIED**.

11. Plaintiff's motion for a protective order (D.I. 88) is **DENIED**.

The Honorable Jennifer L. Hall
United States District Judge