UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

LLOYD L. POTOLICCHIO, *Plaintiff*, v. MEDTRONIC, INC., *et al.*, *Defendants*.	)	Case No. 1:15-cv-122 Judge Travis R. McDonough Magistrate Judge Christopher H. Steger

MEMORANDUM OPINION

Before the Court is Defendants Medtronic, Inc., Medtronic USA, Inc., Medtronic Sofamor Danek USA, Inc., and Medtronic Puerto Rico Operations Co.'s (collectively "Medtronic") motion for judgment on the pleadings. (Doc. 8.) Plaintiff responded (Doc. 13), and Medtronic replied (Doc. 15). For the reasons set forth below, the Court will **GRANT** Medtronic's motion. (Doc. 8.)

I. BACKGROUND

The Medical Device Amendments of 1976 ("MDA") 21 U.S.C. § 360c *et seq*. set up a three-tiered classification system for medical devices according to the risks the devices present. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–17 (2008). Class III is the most stringently regulated classification. *Id*. at 317. New Class III devices must be approved by the FDA before they can be sold in a process called premarket approval ("PMA"). *Id.* at 317–18.

Medtronic manufactures the Synchromed II Implantable Infusion System ("Synchromed II"), a medical device that utilizes an implanted pump to deliver medication directly into the

intrathecal area (the area of fluid surrounding the spinal cord) through a catheter. (Doc. 1-1, at 17–19.) The FDA has approved the Synchromed II under the premarket approval process.[1]

On February 7, 2007, a Synchromed II system was implanted into Plaintiff to deliver pain medication. (Doc. 3, at 6.) In the system implanted into Plaintiff, the catheter was a Model 8709 Intrathecal Catheter. (Doc. 3, at 6.) On September 14, 2011, Plaintiff's original pump was replaced. (Doc. 1-1, at 20; Doc. 3, at 6.) At some point in the late spring or early summer of 2013, the tip of the catheter fractured, causing both overdosing and underdosing of Plaintiff's medication. (Doc. 1-1, at 20.) Plaintiff began to experience severe insomnia, hallucinations, and memory loss. (*Id*.) Because of his deteriorated physical and mental state, Plaintiff was unable to care for himself or to communicate his problems effectively. (*Id*.) On May 19, 2014, a CT scan revealed the fractured catheter. (*Id*.)

Plaintiff filed this action in Hamilton County Circuit Court on April 6, 2015, alleging strict products liability, negligence, failure to warn, and breach of express and implied warranty. (*Id*. at 17–23.) Medtronic timely removed (Doc. 1) and filed this motion for judgment on pleadings based on express and implied preemption, as well as failure to state a claim (Doc. 8). The Court held a Rule 16 Conference on April 1, 2016. (Doc. 20.) Following the conference, the Court granted Plaintiff limited discovery by allowing Plaintiff to serve one Rule 30(b)(6) notice. (Doc. 27.) Plaintiff, however, failed to take advantage of this opportunity and instead filed a request for an extension approximately one week after the Court's deadline had expired. (Doc. 28.) Plaintiff made no showing of good cause, and the Court denied the request and

[1] In his response, Plaintiff appears to dispute whether the device is PMA approved. (Doc. 13, at 6–7.) Based on documents of which the Court can take judicial notice, the Synchromed II is a PMA-approved medical device. (Docs. 9-1, 9-2, 9-3, 9-4.) *See also McBride v. Medtronic, Inc.*, No. CIV.A. 13-377, 2013 WL 3491085, at *2 (W.D. La. July 10, 2013) (taking judicial notice that the Synchromed II infusion system is a PMA-approved device).

granted Medtronic's request for a stay pending a ruling on the motion for judgment on the pleadings. (Doc. 31.) The motion for judgment on the pleadings is now ripe for review.

II. STANDARD OF REVIEW

On a motion under Rule 12(c), the standard is the same as that for a motion under Rule 12(b)(6). The Court must accept all well-pleaded material allegations of the pleadings of the opposing party as true, and it may grant the motion only if the moving party is nevertheless clearly entitled to judgment as a matter of law. *JPMorgan Chase Bank, N.A. v. Winget*, 510 F.3d 577, 581 (6th Cir. 2007). For purposes of this determination, the Court construes the complaint in the light most favorable to the nonmoving party and assumes the veracity of all well-pleaded factual allegations in the nonmovant's pleading. *Thurman v. Pfizer, Inc.*, 484 F.3d 855, 859 (6th Cir. 2007). This assumption of veracity does not, however, extend to bare assertions of legal conclusions, *Iqbal*, 556 U.S. at 679, nor is the Court "bound to accept as true a legal conclusion couched as a factual allegation[,]" *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

After sorting the factual allegations from the legal conclusions, the Court next considers whether the factual allegations, if true, would support a claim entitling the plaintiff to relief. *Thurman*, 484 F.3d at 859. This factual matter must "state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Plausibility "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

III. ANALYSIS

As stated above, the MDA set up a three-tiered classification system for medical devices according to the risks the devices present, with Class III devices being the most stringently regulated classification. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–17 (2008). New Class III devices are subject to premarket approval ("PMA")—an exacting process that involves rigorous inspection of all components of a device. *Id.* at 317–18. The FDA spends an average of 1,200 hours reviewing each PMA application. *Id*. at 318. The FDA may grant a PMA application only if it finds "there is a 'reasonable assurance' of the device's 'safety and effectiveness'[.]" *Id*. at 318 (quoting § 360e(d)). To make this determination, the FDA weighs the probable benefits to health against the probable risk of injury from use. *Id*. Because this is a balancing test, the PMA process permits approval of devices even when they present great risk, so long as that risk is outweighed by the health benefit. *Id*.

Once a device has been approved through the PMA process, "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." *Id*. at 319. Any request for change must be submitted to the FDA as a supplemental application for premarket approval, which is evaluated along the same standards. *Id*.

When the MDA created the PMA process and the accompanying federal regulatory scheme, it replaced preexisting state obligations with "a regime of detailed federal oversight." *Id.* at 316. To effectuate this transition, the MDA contains an express pre-emption provision that provides:

> [N]o 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. § 360K(a). "The Supreme Court has interpreted § 360k(a) to preempt most common-law tort duties" reasoning that such duties would interfere with the premarket-approval-imposed federal requirements. *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 439 (6th Cir. 2010) (citing *Riegel*, 552 U.S. at 323–25). When the agency approves a device under the PMA process, it makes a determination that the device's health benefits outweigh any safety concerns. *Id*. To have a jury second guess that determination would undermine federal policy. *Id.* Section 360k preemption applies only to the extent state law requirements are "'different from, or in addition to' the requirements imposed by federal law" and does not apply to claims premised on state duties that "parallel" FDA regulations. *Riegel*, 552 U.S. at 440.

To determine whether a claim is preempted by the MDA, the Court employs a two-step process. *Riegel* 552 U.S. at 321–22. First, the Court must determine whether the federal government has established safety requirements for the device at issue. Second, the Court determines whether the plaintiff's claims are based on state law requirements that are "different from, or in addition to" the federal requirements. 21 U.S.C. § 360K(a). If the plaintiff's claim is based on state law requirements that are not "different from or in addition to" the federal law requirements but rather are the same as the federal requirements, the claim is a parallel claim and survives preemption. *Riegel*, 552 U.S. at 440.

It is important to remember that even parallel claims are not exempted from the causation requirements ordinarily applicable to the asserted causes of action. Merely pleading a violation of federal requirements is not enough; Plaintiff must also plead facts that show a causal connection between the alleged violation of the federal requirements and the injury suffered. *See Frere v. Medtronic, Inc.*, No. EDCV1502338BRODTBX, 2016 WL 1533524, at *7 (C.D. Cal.

Apr. 6, 2016) (dismissing the plaintiff's strict liability claims because the complaint did not "plausibly allege facts showing a causal connection between the alleged defect and Plaintiff's injuries"). In *Sadler v. Advanced Bionics, Inc.*, for example, the court found that the state law at issue incorporated FDA standards—particularly certain testing requirements. 929 F. Supp. 2d 670, 685–86 (W.D. Ky. 2013). Because the plaintiff had presented evidence that defendant did not conduct the testing as required, and that those testing failures could have resulted in the defect that caused the plaintiff's injury, the court held that he had pleaded a valid parallel claim. *Id*. at 686. By contrast, in *White v. Stryker Corp.*, the plaintiff alleged violations that resulted in a series of recalls related to the device at issue, but he did not allege that any recall pertained to the particular component that caused his injury. 818 F. Supp. 2d. 1032, 1040 (W.D. Ky. 2011). Because the plaintiff had not pleaded facts that tied the violations of federal law to his injury, the court dismissed his complaint. *Id*.

a. The Federal Government Has Established Safety Requirements for the Synchromed II.

The Court first must determine whether there are in fact federal requirements applicable to the device at issue. The Synchromed II is a PMA-approved medical device. (Docs. 9-1, 9-2, 9-3, 9-4.) *See also McBride v. Medtronic, Inc.*, No. CIV.A. 13-377, 2013 WL 3491085, at *2 (W.D. La. July 10, 2013) (taking judicial notice that the Synchromed II infusion system is a PMA-approved device). The PMA process involves the approval of all aspects of a device—specifically relating to safety and efficacy. Once a device is approved, the manufacturer cannot change any aspect of the device without getting supplemental approval from the FDA. 21 U.S.C. § 360e(d)(6)(A)(i). The PMA process, therefore, imposes federal requirements that the device conform precisely to the specifications set forth in the PMA process. *Riegel*, 552 U.S. at 323. The PMA process not only imposes requirements on the device as a whole, but also on the

individual components. *Hawkins v. Medtronic, Inc.*, No. 1:13-CV-00499 AWI SK, 2014 WL 346622, at *5 (E.D. Cal. Jan. 30, 2014) ("The requirements set forth in the premarket approval for the entire device are just as applicable to the components that together form the FDA-approved device as the device itself."); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 656–57 (S.D. Tex. 2010) (finding that PMA approval imposes requirements on the components as well as the device as a whole).

b. Plaintiff Has Not Pleaded Facts Causally Linking Parallel State-Law Claims with Violations of Federal Law.

State tort claims like those alleged by Plaintiff here can constitute state-law requirements. *Riegel*, 552 U.S. at 330. Such claims are preempted to the extent they are based on standards that differ from or add to requirements imposed by federal law. *Id*. They are not preempted, however, if they are based on violations of federal law (i.e. "parallel claims"). *Id*. And if a claim is based on a violation of federal law, the plaintiff must plead facts causally linking the federal violation to the injury suffered. *See, e.g.*, *Frere*, 2016 WL 1533524, at *7; *White*, 818 F. Supp. 2d. at 1040. Because Plaintiff has failed to plead such facts, the Court must **GRANT** Medtronic's motion for judgment on the pleadings.

A plaintiff may plead a parallel claim by showing that there was a violation of federal requirements, that the state law tort incorporated federal standards, and that the violation caused the plaintiffs injuries. *See, e.g.*, *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670 (W.D. Ky. 2013). Here, Plaintiff asserts that all of his claims are parallel claims.

Plaintiff's strict liability, negligence, and implied and express warranty claims are all premised on the violations of federal law set forth in warning letters and inspectional observations from the FDA. (Docs. 13-1, 13-2, 13-3.) However, Plaintiff fails to draw the necessary causal link between these violations and Plaintiff's injuries. As Medtronic points out,

none of those alleged violations relates to the Model 8709 Intrathecal Catheter that, Plaintiff alleges, caused his complications. (*See* Doc. 15 at 6–7.) Plaintiff's complaint suffers from the same defect as the complaint in *White*. The federal violations Plaintiff identifies do not relate to the Model 8709 Intrathecal Catheter—the component he alleges caused his injuries. Therefore, he fails to establish a causal link, and his claims are subject to dismissal. *Frere*, 2016 WL 1533524, at *7; *White*, 818 F. Supp. 2d. at 1040.

Plaintiff's failure-to-warn claim also fails, but for slightly different reasons. Plaintiff argues that Medtronic's failure to report adverse events to the FDA violates Medtronic's duties under the MDA and suffices for proof of a failure-to-warn claim. But Plaintiff's argument avoids the issue of whom Medtronic had a duty to warn. No Tennessee law requires Medtronic to warn the FDA about adverse events. Tennessee law requires manufacturers to warn physicians, but not the FDA. *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 701 (Tenn. 2011) ("In Tennessee, the learned intermediary doctrine is applicable in failure to warn suits where a physician is the intermediary between a defendant pharmaceutical or other medical product manufacturer and an injured patient."). Even if there were a requirement to notify the FDA, the allegedly omitted warnings have nothing to do with catheter breakage of the kind that Plaintiff alleges caused his injuries. Therefore, this claim is also subject to dismissal.

* * *

For the reasons set forth above, Medtronic is entitled to judgment on the pleadings on all of Plaintiff's claims. In response to Medtronic's motion, Plaintiff alternatively seeks leave to conduct discovery so that he can add the following claims 1) fraudulent concealment, misrepresentation and fraud, 2) negligent misrepresentation, 3) adulteration of the device and 4) negligence per se. (Doc. 13, at 1.) Relying heavily on a Seventh Circuit case, *Bausch v. Stryker*

Corp., 630 F.3d 546, 557 (7th Cir. 2010), Plaintiff argues he does not have access to the information he needs to be more specific in his above claims. (Docs. 13, 14.) The Court attempted to remedy Plaintiff's concerns by allowing him measured and appropriate access to discovery. (Doc. 27.) However, Plaintiff failed to take advantage of that opportunity. (Doc. 31.) Accordingly, to the extent Plaintiff seeks discovery, that request is denied.

IV. CONCLUSION

For the reasons set forth above, the Court will **GRANT** Medtronic's motion for judgment on the pleadings. An accompanying order will enter.

/s/ Travis R. McDonough
TRAVIS R. MCDONOUGH
UNITED STATES DISTRICT JUDGE