IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

Randy Warstler,

Plaintiff,

v.

Medtronic, Inc., *et al.*,

Defendants.

Case No. 3:16CV00385

ORDER

This is a products liability action against defendant Medtronic, Inc. (Medtronic). Plaintiff alleges that the Medtronic-manufactured device implanted in his body was defective, causing him serious injuries. Plaintiff brings his claims pursuant to Ohio law.

Jurisdiction is proper under 28 U.S.C. § 1332.

Pending is defendant Medtronic's motion to dismiss for failure to state a claim. (Doc. 6). Plaintiff has filed a response (Doc. 13) to which defendant has replied. (Doc. 14).

For the reasons that follow, I grant defendant's motion.

Background

Defendant Medtronic manufactures many different devices, but at issue in this case is the SynchroMed® II Programmable Drug Infusion System (SynchroMed II).

SynchroMed II is a prescription medical device–specifically, a programmable drug infusion system implanted in the body for drug delivery. Each SynchroMed II includes an infusion pump, connected to a thin, flexible catheter, that enables storage and delivery of medicine.

Pursuant to the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360c *et seq.*–an amendment to the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*–SynchroMed II is a Class III medical device.[1]

Under the FDCA and MDA, all medical devices, including SynchroMed II, are subject to Food and Drug Administration (FDA)-imposed regulations concerning design, manufacture, labeling, marketing, and sale. Specifically, as a Class III device, SynchroMed II–in its original form–was subject to the FDA's rigorous Premarket Approval Process (PMA), which, as its name suggests, requires prior FDA approval for a device to enter the market. § 360e

To receive PMA, manufacturers submit information about their device's proposed design, manufacture, and labeling. Based on these submissions and a comprehensive review, the FDA determines whether a device is suitable for the market, granting PMA only if there is "reasonable assurance" of the device's "safety and effectiveness." § 360e(d). This "safety and effectiveness" determination involves a risk-benefit analysis; the FDA "weig[hs] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." § 360c(a)(2)(C). The FDA either grants or denies PMA, § 360e(d)(1)(A) or, alternatively, places sale and distribution restrictions on the device as a condition to approval. § 360e(d)(1)(B)(ii).

---

[1] The MDA imposes different levels of federal oversight depending on the risks presented by a particular device. § 360c(a)(1)(A)-(C). Class I devices receive the lowest level of oversight: "general controls." § 360c(a)(1)(A). Class II devices, in addition to "general controls," are subject to "special controls." § 360c(a)(1)(B). Class III devices, the category in which SynchroMed II falls, receive the most federal oversight.

A device receives Class III designation "if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness," *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 317 (2008), and the device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "presents a potential unreasonable risk of illness or injury." § 360c(a)(1)(C)(ii).

PMA does not, however, allow manufacturers to then proceed without oversight. Rather, Class III device manufacturers must obtain FDA permission to make "any change to a device subject to an approved application . . . that affects safety or effectiveness." § 360e(d)(5)(A)(i). To make such a change, the manufacturer must submit for FDA approval an application for *supplemental* approval. Then, an evaluation similar to the initial application occurs. § 360e(d)(5)(A)(i)-(ii).

In addition to the restrictions on post-PMA changes, FDA regulations subject manufacturers to reporting requirements. § 360i. These include reporting new clinical investigations or scientific studies that the manufacturer knows of or reasonably should know of, 21 C.F.R. § 814.84(b)(2). In addition, the manufacturer must report incidents where the device either may have caused or contributed to death or serious injury or malfunctioned in such a way that would likely cause or contribute to death or serious injury if it happened again. § 803.50(a).

In this case, the FDA granted PMA to the original version of SynchroMed II, and the device entered the market in 1988. SynchroMed II was approved for the following uses:

- The chronic epidural/intrathecal infusion of Infumorph (preservative-free ziconotide sterile solution) for the management of pain;
- The chronic intrathecal infusion of Baclofen (Lioresal) for the management of severe spasticity; and
- The chronic intravascular infusion of floxuridine (FDUR) and methiotrexate for the treatment of primary or metastic cancer.

Since SynchroMed II's initial application and approval, the FDA has approved numerous supplements (*i.e.,* changes) to the original device. One such supplement is plaintiff's Model 8637 SynchroMed II pump and Model 8590-1 SynchroMed mesh pouch, for which the FDA granted PMA on September 12, 2003. Like all Class III devices, SynchroMed II remains subject to FDA oversight.

Plaintiff's need for the allegedly defective device resulted from a boating accident in 1980, which caused neuropathy in his right leg. In 1998, physicians implanted an infusion pump in plaintiff to manage pain. In July 2013, plaintiff received a replacement SynchroMed II pump. At that time, physicians also inserted a mesh pouch as part of the SynchroMed II.

Plaintiff alleges this replacement pump was defective and caused the injuries for which he now seeks recovery.

Medtronic designed the replacement SynchroMed II pump to pump pain medication through a catheter into the spinal cavity. Plaintiff alleges that the replacement SynchroMed II allowed medication "to leak out of the pump into Plaintiff's abdominal cavity." (Doc. 1, ¶26). Plaintiff discovered the SynchroMed II pump's failure and the resulting leakage when doctors treated him on February 26, 2014.

The leakage led to an infection in the pump pocket site, necessitating several surgeries. Plaintiff asserts that a March, 2014 operative report stated he had an "[i]nfected mesh status post removal of the morphine pump and mechanical complication of the pump." (*Id.* ¶28). An April, 2014 report listed preoperative and postoperative diagnoses as "Failure of implanted medical device." (*Id.*).

Plaintiff also asserts that the pain medication that leaked into his abdominal cavity injured his bowel and internal organs, causing damage to his left leg and the left side of his body. As noted above, the injury which initially required implantation of the SynchroMed II was in plaintiff's right leg; as a result of defendant's allegedly defective device, plaintiff's left leg is now damaged.

Finally, plaintiff asserts that the leaking medication caused the mesh pouch to dissolve, making the pouch and catheter wrap around his bowel and abdominal tissue and ultimately absorb

the tissue. The tubing remains absorbed into the mesh, which remains wrapped around plaintiff's large bowel and left kidney. According to plaintiff, continued treatment of this condition requires loss of at least eight inches of his large bowel, eighteen inches of his small bowel, and his left kidney.

As a result of the damage caused by the alleged defect, plaintiff brought this products liability suit, asserting seven state law claims against defendant under Ohio law.[2]

According to defendants, MDA § 360k(a) expressly preempts plaintiff's state law claims, and MDA § 337(a) impliedly preempts any claims based in federal law.

Standard of Review

A complaint must contain a "short and plain statement of the claim showing the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

To survive a motion to dismiss under Rule 12(b)(6), the complaint "must contain sufficient factual matter, accepted as true, to state a claim that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

In ruling on a motion to dismiss, I may consider "the Complaint and any exhibits attached thereto, public records, items appearing in the record of the case and exhibits attached to defendant's motion to dismiss so long as they are referred to in the Complaint and are central to the claims contained therein." *Bassett v. Nat'l Collegiate Athletic Ass'n*, 528 F.3d 426, 430 (6th Cir. 2008).

---

[2] Plaintiff's claims are: 1) manufacturing defect; 2) failure to warn; 3) breach of express warranty; 4) breach of implied warranty; 5) negligent misrepresentation; 6) negligence; and 7) fraudulent misrepresentation and omission.

Discussion

There are three varieties, one express and two implied, of federal preemption. *Bibbo v. Dean Witter Reynolds, Inc.*, 151 F.3d 559, 562-63 (6th Cir. 1998); *Casden v. Burns*, 504 F. Supp. 2d 272, 280 n.7 (N.D. Ohio 2007).

Express preemption arises when Congress "expresses a clear intent to pre-empt state law in the language of the statute." *Bibbo, supra,* 151 F.3d at 562.

"Field preemption"–one form of implied preemption–results when "Congress indicates an intent to occupy exclusively an entire field of regulation." *Id.* This may occur with "a federal regulatory scheme that is 'so pervasive as to make reasonable the inference that [it] left no room for the States to supplement it.'" *Id.* (citing *Fidelity Fed. Savings and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982)).

"Conflict preemption"–the other form of implied preemption–occurs "either where it is impossible to comply with both federal and state law, or where state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress' as reflected in the language, structure and underlying goals of the federal statute at issue." *Id.* at 562-63 (quoting *Fidelity Fed. Savings and Loan Ass'n, supra,* 458 U.S. at 153).

A. Express Preemption

Prior to the MDA's enactment, the states primarily governed medical devices. *Medtronic, Inc v. Lohr*, 518 U.S. 470, 475-76 (1996). This drastically changed with the MDA, due largely in part to the statute's express preemption provision, which states:

> Except as provided in subsection (b) of this section, no 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.

§ 360k(a).

Congress intended § 360k(a) to be a "general prohibition on non-Federal regulation" of medical devices. H.R. Rep. No. 94-853, at 12. This was to ensure "that innovations in medical device technology are not stifled by unnecessary restrictions" and to shield manufacturers from the "undu[e] burdens" of "differing requirements . . . imposed by jurisdictions other than the Federal government." *Id*. at 45. Ultimately limiting the role of private plaintiffs and state tort law, the MDA "swept back some state obligations and imposed a regime of detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008); *see also Aaron v. Medtronic, Inc.*, 2016 WL 5242957, *5 (S.D. Ohio) ("As an alternative to private tort suits, Congress granted the FDA extensive authority to police device manufacturers . . . .") (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001)).

While "[t]he Supreme Court has interpreted § 360k(a) to preempt most common-law tort duties," *Howard v. Sulzer Orthopedics, Inc.,* 382 F. App'x 436, 439 (6th Cir. 2010), it does not preempt all state law claims concerning medical devices. According to the Supreme Court, "[n]othing in § 360k denies [states] the right to provide a traditional damages remedy for violations of common-law duties when those duties *parallel federal requirements.*" *Lohr*, *supra,* 518 U.S. at 495 (emphasis added).

This "narrow gap" in § 360k(a) allows state law claims premised on a violation of FDA regulations to avoid express preemption. *Riegel, supra,* 552 U.S. at 331. "[T]he state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* (citing *Lohr, supra,* 518 U.S. at 495); *see also Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010) ("The Supreme Court thus has made clear that section 360k protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law."); *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1205 (8th Cir. 2010) (holding that state law claims "'premised on a violation of FDA regulations'" merely "'parallel'" federal requirements) (quoting *Riegel*, *supra*, 552 U.S. at 330 and *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)).

Simply put, "'state tort suits that allege, as the basis of their claim, that the approved FDA requirements have not been met are not preempted." *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig.*, 455 F. Supp. 2d 709, 718 (N.D. Ohio 2006) (quoting *Martin v. Medtronic, Inc.*, 254 F.3d 573, 583 (5th Cir. 2001)).

I note, however, that "[a]rmed with the Supreme Court's ruling in *Reigel*, courts have held that '[p]arallel claims must be *specifically stated in the initial pleadings.* A plaintiff must allege that '[t]he defendant violated a particular federal specification referring to the device at issue.'" *Schmidt v. Boston Scientific Corp.*, 2016 WL 1274824, *3 (N.D. Ohio) (quoting *Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (quoting *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009))) (emphasis added); *see also Wolicki-Gables, supra,* 634 F.3d at 1301 ("'To properly allege parallel claims, the complaint must set forth facts' *pointing to specific PMA*

requirements that have been violated.") (quoting *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008)) (emphasis added).[3]

Accordingly, I apply a two-part test to determine whether plaintiff's state law claims are preempted. *See, e.g., Wolicki-Gables*, *supra,* 634 F.3d at 1300-01; *In re Medtronic, Inc., Spring Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010); *Thorn v. Medtronic Sofamor Danek, USA, Inc.*, 81 F. Supp. 3d 619, 623-24 (W.D. Mich. 2015).

First, "[I] must determine whether the Federal Government has established requirements applicable to [the device at issue]" *Riegel, supra,* 552 U.S. at 321. If so, then I must determine whether the state law claims impose "requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22 (quoting § 360k(a)); *see also Hafer v. Medtronic Inc.*, 99 F. Supp. 3d 844, 855-56 (W.D. Tenn. 2015).

If these conditions apply, then § 360k(a) preempts plaintiff's state law claims.

---

[3] To the extent plaintiff argues he is unable to identify the federal provisions or requirements or the Ohio statutes which defendant violated without discovery, I find this argument not well taken. Without discovery, plaintiff has access to information sufficient to discover defendant's violations, if any. *See Schmidt v. Boston Scientific Corp.*, 2016 WL 1274824, *3 (N.D. Ohio).

First, plaintiff has access to and control over his own medical records, which would include information concerning the specific SynchroMed II device he received as a replacement and now argues caused his injuries. Second, plaintiff has access to the FDA website, which describes the PMA approval process for SynchroMed II.

Thus, plaintiff "could have, with reasonable effort, described the federal requirements that have allegedly been violated and any parallel state statute." *Id.; see also Johnson v. Eli Lilly and Co.*, 2015 WL 1120009, *3 (S.D. Ohio) (holding plaintiff's mere allegations that a prescription medication "was not made in accordance with [defendant's] specifications or performance standards" insufficient to survive dismissal) (internal citation and quotation marks omitted); *Frey v. Novartis Pharm. Corp.*, 642 F. Supp. 2d 787, 792 (S.D. Ohio 2009) (rejecting argument that without discovery, plaintiff could not specify the specific manufacturing defect in the drug).

1. The Federal Government Has Established Requirements Applicable to Medtronic's SynchroMed II

The device at issue understandably meets the first inquiry: the PMA provides the framework for regulating the SynchroMed II as a Class III medical device. The Court in *Riegel* specifically held that "[p]remarket approval . . . imposes [federal] 'requirements'" as that term is used in § 360k(a). *Id.* at 322; *see also id.* at 322-23 ("Unlike general labeling duties, premarket approval is *specific to individual devices*.") (emphasis added). This is so, the court reasoned, 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, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323.

As discussed above, SynchroMed II originally received PMA in 1988, allowing entry into the market, and received subsequent approval *via* more than 200 supplemental applications. The FDA's evaluation that led to PMA was specific to SynchroMed II, requiring the device to be manufactured with "almost no deviations from the specifications in its approval application." *Id.*

Thus, the FDA's PMA established federal requirements applicable to SynchroMed II.

2. Warstler Bases His Claims on Ohio Requirements "Different From, or In Addition To" Federal Requirements and That Relate to Safety and Effectiveness[4]

Because the FDA's grant of PMA to SynchroMed II established federal requirements, plaintiff can proceed with his state law claims only if the state law requirements on which he bases his claims parallel (*i.e.,* are not "different from, or in addition to") the FDA-imposed requirements.

[4] All of plaintiff's claims clearly relate to the "safety and effectiveness" of SynchroMed II. Therefore, I address only whether plaintiff bases each of his claims on Ohio requirements "different from, or in addition to" the federal ones to determine whether the claim is preempted.

"Any state-law requirement imposed on FDA-regulated medical devices that is 'different from, or in addition to' FDA requirements is expressly preempted and cannot support a Complaint." *Aaron, supra,* 2016 WL 5242957 at *7 (quoting § 360k(a)).

a. Count One: Manufacturing Defect

Plaintiff raises a manufacturing defect claim against defendant, arguing defendant is strictly liable for any manufacturing defects in its SynchroMed II device.

Because plaintiff fails to assert facts suggesting defendant deviated from any specific FDA-prescribed manufacturing requirement, I conclude that § 360k(a) expressly preempts his manufacturing defect claim.

Plaintiff does not allege that the actual manufacture of the SynchroMed II device he received deviated from the FDA's requirements relating to production of the device. *See, e.g., Aaron, supra* 2016 WL 5242957 at *9. Therefore, "'to prevail on this claim, Plaintiff[] would need to establish that the [SynchroMed II device] should have been designed in a manner *different* than that approved by the FDA.'" *Id.* (quoting *Beavers-Gabriel v. Medtronic, Inc.,* 15 F. Supp. 3d 1021, 1040 (D. Haw. 2014) (emphasis in original)).

The Supreme Court in *Riegel* clearly foreclosed any such claim, holding that § 360k(a) preempts "claims of strict liability," 552 U.S. at 320, as they would establish manufacturing requirements "different from, or in addition to" any federal requirements for SynchroMed II. § 360k(a).

In *Aaron*, the court reached the same conclusion with respect to a design defect claim, holding it was "'the exact type of claim that is expressly preempted under § 360k(a).'" 2016 WL 5242957 at *8 (quoting *Caplinger v. Medtronic, Inc.,* 921 F. Supp. 2d 1206, 1222 (W.D. Okla.

2013)). There, the court held that "a state-law claim that would require a medical device to have a design *different from that approved by the FDA through the PMA process* is a frontal 'attack[] on the risk/benefit analysis that led the FDA to approve' the device." *Id.* (quoting *Bryant, supra,* 623 F.3d at 1206) (emphasis added).

This is precisely what plaintiff's manufacturing defect claim improperly seeks to do.

First, there is no allegation that defendant did not produce plaintiff's SynchroMed II device according to FDA specifications *per* the PMA. Thus, allowing plaintiff to proceed with his manufacturing defect claim effectively results in a holding that an FDA-approved manufacturing process could nevertheless be legally insufficient and expose defendant to liability. As the court in *Aaron* concluded, this decision would "enchroach[] on federal regulatory authority that 21 U.S.C. § 360k(a) was specifically designed to prevent." *Id.* at *10.

Further, I disagree with plaintiff's attempt to avoid preemption by alleging violations of Good Manufacturing Practices (GMP).[5]

In *Howard, supra,* 382 F. App'x at 440, the Sixth Circuit rejected the defendant-manufacturer's argument that the GMP at issue was unenforceable as a basis for plaintiff's negligence *per se* claim. In reaching this conclusion and allowing plaintiff to proceed on this state law claim, the Sixth Circuit emphasized the fact that the plaintiff identified a specific GMP that he believed defendant violated. The court emphasized that "the particular GMP that [plaintiff] cites is not so vague as to be incapable of enforcement." *Id*.

[5] Good Manufacturing Practices are FDA regulations based upon manufacturing standards that apply to every FDA-regulated medical device. *See generally* 21 C.F.R. § 820.

The parties disagree on the accuracy and significance of the Sixth Circuit's holding in *Howard.* I decline to address that issue because the specificity of the core allegation in *Howard* is greater than the allegation in plaintiff's complaint; moreover, plaintiff fails to show a causal connection between his vaguely alleged GMP violations and his injuries.

First, unlike the plaintiff in *Howard,* plaintiff alleges generally that "Medtronic violated the federal manufacturing regulations and Current Good Manufacturing Practices (CGMPs) with regards to the SynchroMed® II Device." (Doc. 1, ¶46). To evidence these alleged GMP violations, plaintiff references FDA inspection notices, warning letters, and recalls of certain component parts. Despite these references, plaintiff fails to identify a GMP that "is not so vague as to be incapable of enforcement." *Howard, supra,* 382 F. App'x at 440.

Even assuming plaintiff properly identifies a specific GMP that defendant allegedly violated, he asserts no facts linking an alleged GMP violation, recall, or FDA regulatory action to the injuries he claims that the specific device implanted in his body in 2013 caused. *See e.g., Frere v. Medtronic, Inc.*, 2016 WL 1533524, *6 (C.D. Cal.) (dismissing complaint based on similar GMP allegations because plaintiff included "only conclusory allegations that the purported irregularities or failure to warn caused [the plaintiff's] injuries"); *Anderson v. Boston Scientific Corp.*, 2013 WL 632379, *2 (S.D. Ohio) ("[T]he complaint contains no factual allegations that can support a plausible inference of causation."); *Anthony v. Stryker Corp.*, 2010 WL 1387790, *4 (N.D. Ohio) (dismissing complaint because the plaintiff "did not plead any facts that would lead this court to plausibly infer that [the manufacturer's] noncompliance with FDA regulations led to his injury").

Accordingly, § 360k(a) expressly preempts plaintiff's manufacturing defect claim.

b. Count Two: Failure to Warn

Plaintiff also alleges that defendant is liable for plaintiff's injuries due to defendant's failure to warn of SynchroMed II's dangers.

I conclude, again, that § 360k(a) expressly preempts plaintiff's failure to warn claim.

First, to the extent plaintiff alleges Ohio law required defendant to provide any warning other than or beyond that which the FDA required as part of its PMA, I look no further than the statutory language: § 360k(a) expressly preempts such a claim due to it inconsistency with federal law. *See Riegel, supra,* 552 U.S. at 329 ("[360k(a)] [s]urely . . . would pre-empt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings.").

Second, plaintiff argues that he premises his failure to warn claim on defendant's failure "to monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product." (Doc. 13, at 11). Specifically, plaintiff argues defendant had a duty to warn "patients, their doctors, the medical community, and the FDA of the device's risks and dangers." (*Id.*). I disagree.

Section 360i(a)(1) outlines the adverse event reporting requirement for manufacturers or importers of medical devices–they must: "report[ ] whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices . . . may have caused or contributed to a death or serious injury."

Unlike the FDA's adverse event reporting requirement, Ohio law imposes no duty to report adverse events to the FDA. Simply put, the federal reporting duty is not "equal to, or substantially

identical to" and, therefore, not "parallel" to the state law duty to warn patients or their physicians. *Lohr, supra,* 518 U.S. at 496-97 (holding that a state law claim that "merely provides another reason for manufacturers to comply with *identical existing 'requirements' under federal law*" avoids preemption) (emphasis added); *Otis-Wisher v. Medtronic, Inc.,* 616 F. App'x 433, 434 (2d Cir. 2015); *Wolicki-Gables*, *supra,* 634 F.3d at 1300; *Millman v. Medtronic*, 2015 WL 778779, *4 n.2 (D.N.J. 2015) ("To state a 'parallel' claim, a plaintiff must allege (1) the violation of a specific federal requirement applicable to the device; (2) the violation of *an identical state-law duty*; and (3) that the predicate federal violation caused his or her injuries.") (emphasis added).

As a result, plaintiff's allegation that defendant failed to satisfy a duty to warn does not state a parallel claim.

Further, I note that a manufacturer's mandatory adverse event report to the FDA does not function as a warning. While the FDA "*may* disclose" adverse event reports to the public, it has no obligation to do so. 21 C.F.R. § 803.9(a) (emphasis added). Thus, adverse-event reports "are not automatically made public." *Pinsonneault v. St. Judge Med, Inc.*, 953 F. Supp. 2d 1006, 1016 (D. Minn. 2013); *see also Cline v. Advanced Neuromodulation Sys., Inc.,* 17 F. Supp. 3d 1275, 1286 (N.D. Ga. 2014) ("[T]he FDA's disclosure of [adverse event reports] to the public is not guaranteed."). That adverse-event reports are not warnings further evidences that the federal duty to submit these reports is not "equal to, or substantially identical" to a state law duty to warn patients, their doctors, or the medical community, as plaintiff suggests. *Lohr, supra,* 518 U.S. at 496-97. Therefore, an alleged failure to submit adverse event reports to the FDA fails to support a parallel state law failure to warn claim.

Accordingly, § 360k(a) expressly preempts plaintiff's failure to warn claim.

c. Counts Three and Four:
Breach of Express and Implied Warranties

Count Three alleges that defendant breached express warranties that SynchroMed II "was safe, effective, fit and proper for the intended or prescribed use and foreseeable uses." (Doc. 1, ¶92). Count Four alleges that defendant breached implied warranties that SynchroMed II "was of merchantable quality, was manufactured, packaged, or labeled in accord with FDA regulations, complied with applicable FDA regulations and approved specifications, was safe, effective, and fit for use for the ordinary purpose for which it was intended." (*Id.* ¶99).

In other words, plaintiff's breach of warranty claims challenge the safety and effectiveness of SynchroMed II, as warranted by defendant.

To succeed on these claims, a jury would need to find that SynchroMed II "was not safe and effective" as labeled. *See, e.g,. Gavin*, 2013 WL 3791612, at *15-16 (E.D. La.); *Hafer*, *supra,* 99 F. Supp. 3d at 863-64; *Caplinger, supra,* 921 F. Supp. 2d at 1222; *Lawrence v. Medtronic, Inc.*, 2013 WL 4008821, at *5 (D. Minn.).

Such a finding, however, would directly conflict with the FDA's initial PMA and its numerous supplements for SynchroMed II and the basis for its actions: namely, that "there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel, supra,* 552 U.S. at 318 (quoting § 360e(d)). Similarly, the court in *Aaron* stated:"the imposition of state-law liability for the alleged breach of a purported warranty as to the safety or effectiveness of medical device that has received premarket approval would effectively require that such a device be safer or more effective than demanded by the FDA." 2016 WL 5242957 at *10.

When plaintiffs have brought these types of claims, "[c]ourts have consistently found that state law claims for breach of warranties based on the safety or effectiveness of [a PMA] device, impose requirements that are different from, or in addition to federal regulations, and thus are preempted." *Thomas v. Alcon Labs.,* 116 F. Supp. 3d 1361, 1367 (N.D. Ga. 2013) (internal citation and quotation marks omitted); *see also Riegel,* 552 U.S. at 330 (affirming dismissal of plaintiff's state law claims for negligence, strict liability, and breach of implied warranty); *Hafer, supra,* 99 F. Supp. 3d at 863 (holding "allegations of a breached warranty of safety and effectiveness" were preempted); *Horn v. Boston Scientific Neuromodulation Corp.*, 2011 WL 3893812, *4-7 (S.D. Ga.) (holding plaintiff's state law claims for strict liability, negligence, and breach of implied warranty were preempted pursuant to *Riegel*); *Leonard v. Medtronic, Inc.*, 2011 WL 3652311, *6-11 (N.D. Ga.) (holding plaintiff's state law claims for negligence, strict liability, breach of implied and express warranty were preempted because plaintiff failed to allege legitimate parallel claims).

Simply put, plaintiff bases his breach of warranty claims on the safety or effectiveness of SynchroMed II and thereby seeks ultimately to hold defendant liable for violating requirements "different from, or in addition to" those the federal government has imposed.[6]

Accordingly, § 360k(a) expressly preempts plaintiff's claims for breach of express and implied warranties.

[6] To the extent plaintiff argues defendant's failure to adhere to FDA regulations and specifications breached an implied warranty, *see* Doc. 1, ¶99, he alleges no facts sufficient to support this claim. Because plaintiff fails to cite to specific PMA requirements or specifications with which defendant failed to comply, his attempt to assert a parallel claim fails.

d. Counts Five and Seven: Negligent Misrepresentation and Fraudulent Misrepresentation and Omission

In his misrepresentation claims, plaintiff alleges that defendant represented to him and to his medical providers that SynchroMed II was safe and effective despite having knowledge that the device was defective and dangerous.

Like plaintiff's breach of warranty claims, his misrepresentation claims also require a finding that SynchroMed II was unsafe or ineffective despite the FDA's PMA, which the FDA based primarily on its determination that the device was safe and effective. In other words, for these claims to prevail, a jury must make findings contrary to the FDA's PMA finding of safety and effectiveness. Such a finding would ultimately hold defendant liable for violating requirements "different from, or in addition to" those the federal government had established.

Also, there is nothing in either count alleging a violation of PMA requirements, further foreclosing any parallel claim argument.

Accordingly, § 360k(a) expressly preempts plaintiff's misrepresentation claims.

e. Count Six: Negligence

Finally, plaintiff brings a negligence claim, alleging defendant breached its duty to manufacture, label, market, distribute, supply, and sell products in such a way as to avoid harm to users. This breach, according to plaintiff, directly and proximately caused his injuries.

To dispose of this claim, I need look no further than the Supreme Court's opinion in *Riegel,* in which the Court held the plaintiff's negligence claim was preempted. 552 U.S. at 330; *see also Lohr, supra,* 518 U.S. at 503-05 (Breyer, J., concurring in part and concurring in judgment).

In *Riegel*, the plaintiff, like the plaintiff here, brought a negligence claim, alleging negligence "in the design, testing, inspection, distribution, labeling, marketing, and sale of the [medical device]." 552 U.S. at 320. Rejecting that attempt, the Court stated, "State tort law that requires manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Id.* at 325.

The same is true here. The FDA's PMA established the federal requirements with which defendant had to comply in manufacturing, labeling, marketing, distributing, supplying, and selling SynchroMed II. Imposing Ohio or common law negligence doctrine and a corresponding reasonableness standard would create duties that are "different from, or in addition to" the federal requirements applicable to SynchroMed II and would "disrupt the federal scheme" in that the FDA already evaluated SynchroMed II's safety and effectiveness and granted PMA. *Id.*

Accordingly, § 360k(a) preempts plaintiff's negligence claim.

B. Implied Preemption

Defendant argues, in the alternative, that even if § 360k(a) does not expressly preempt plaintiff's claims and even if plaintiff adequately pled a parallel claim, I must still dismiss *via* the FDCA's implied preemption provision–§ 337(a).

In addition to § 360k(a), § 337(a) of the FDCA includes a "no private right of action" clause, whereby all actions to enforce its requirements "shall be by and in the name of the United States." Simply put, the FDA–not a private citizen–has the right to investigate and pursue violations of the FDCA, its amendments, and corresponding regulations. To that end, the FDA has "a variety of enforcement options that allow it to make a measured response." *Buckman Co.*, *supra,* 531 U.S. at 349; *see also id.* at 349 n. 4 ("The FDCA leaves no doubt that it is the Federal Government rather

than private litigants who are authorized to file suit for noncompliance with the medical device provisions.").

Because I already concluded that the FDCA expressly preempts plaintiff's claims, I decline to address whether the Act impliedly preempts his claims as well.

Conclusion

Plaintiff asserts only state law claims. I conclude that the Medical Device Amendment's express preemption provision, 21 U.S.C. § 360k(a), applies and, additionally, that plaintiff fails to state plausible parallel claims allowing him to avoid preemption. As a result of statutory preemption, defendant's motion to dismiss is well taken.

It is, therefore,

ORDERED THAT: defendant's motion to dismiss (Doc. 6) be, and the same hereby is, granted.

So ordered.

/s/ James G. Carr
Sr. U.S. District Judge