UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

DAWN M. ENGLE — Plaintiff

v. — Civil Action No. 3:19-cv-909-RGJ

MEDTRONIC, INC.; MEDTRONIC USA, INC.; MEDTRONIC LOGISTICS, LLC; and MEDTRONIC PUERTO RICO OPERATIONS CO. — Defendants

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MEMORANDUM OPINION & ORDER

Defendants Medtronic, Inc., Medtronic Logistics, LLC, and Medtronic Puerto Rico Operations Co. (collectively "Medtronic") move to dismiss Plaintiff Dawn Engle's ("Engle") first amended complaint pursuant to Fed. R. Civ. P. 12(b)(6). [DE 24 ("Motion")]. Medtronic USA, Inc. joined in the motion to dismiss. [DE 25]. Engle responded to the Motion, [DE 27], and Medtronic replied. [DE 29]. This matter is ripe. For the following reasons, Medtronic's Motion to Dismiss [DE 24] is **GRANTED in part** and **DENIED in part** as set forth below.

BACKGROUND

The Court accepts the facts in Engle's Amended Complaint [DE 19] as true for the present Motion. *See Total Benefits Plan. Agency, Inc. v. Anthem Blue Cross & Blue Shield*, 552 F.3d 430, 434 (6th Cir. 2008) (when considering a motion to dismiss, courts must presume all factual allegations in the complaint to be true and make all reasonable inferences in favor of the non-moving party). Engle presents four state law claims against Medtronic, including: strict liability

for a manufacturing defect, negligent manufacturing defect, negligence per se, and breach of express warranty.[1] [DE 19].

A. The SynchroMed II Device

The allegedly defective device at the heart of Engle's claims is the SynchroMed II Device ("Device"). [DE 19 at 130]. "The . . . Device is a programmable drug infusion system implanted in the body for drug delivery." [*Id.*]. After the Device is implanted, it

> remains under the skin. A clinician measures a precise amount of medication and injects the medication into the pump's reservoir fill port. The medication passes through a reservoir valve and into the pump reservoir. At normal body temperatures, pressurized gas, used as a propellant, is stored below the reservoir and it expands and exerts constant pressure on the reservoir. This pressure pushes the medication into the pump tubing. The battery-powered electronics and motor gears deliver a programmed dose of medication through the tubing out through a catheter port and into a catheter. Medication delivery then continues through the catheter tubing and into the intrathecal space of a patient.

[*Id.*]. "Each catheter has a pre-attached strain relief sleeve, a connector pin, and a sutureless pump connector (also known as a revision kit) that connects to the . . . pump." [*Id.* at 131]. The Device is "a Class III medical device, approved by the U.S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) process[.]" [*Id.*]. The Device "is FDA-approved solely for the following uses:" chronic intrathecal infusion of a "preservative-free morphine sulfate sterile solution" or a "preservative-free ziconotide sterile solution[,]" or a "baclofen injection[.]" [*Id.* at 131-32].

B. Engle's Device

Engle had "a history of chronic lower back pain[,]" so in October 2018, Dr. Nair (not a party to this suit) implanted a Device into Engle's body. [*Id.* at 132]. Engle's Device "comprised

[1] Engle withdraws her claim of breach of implied warranty of Merchantability. [DE 27 at 382]. Additionally, Engle's claim for punitive damages (Count VI) is "actually a prayer for relief, not a separate cause of action[.]" *Baird v. Bayer Healthcare Pharm.*, No. 6:13-077-DCR, 2013 WL 5890253, at *10 (E.D. Ky. Oct. 31, 2013).

of a model no. 8637-20 pump (serial no. NGP652204H) and a model no. 8780 Ascenda-brand catheter (lot no. N824310006)." [*Id.*]. The Device "was initially intended to deliver a programmed amount of morphine medication into her spine to alleviate her chronic lower back pain." [*Id.*]. In the months following her Device implant, Engle suffered "weakness and fatigue, followed by a return of significant back pain[,]" and because of that pain, Dr. Nair "altered [Engle]'s medication to hydromorphone" in January 2019. [*Id.* at 132-33]. Over the next months, Engle continued to suffer "periods of extreme weakness, fatigue, and lethargy, coupled with periods of significant pain." [*Id.* at 133]. During a routine pump refill procedure in July 2019, Engle's pump contained one-sixth of the medicine it should have contained. [*Id.*]. At a follow-up procedure later that month, Engle's pump again contained less medicine that it should have, "leading Dr. Nair to conclude that the pump and catheter were not working properly." [*Id.*].

Ultimately, Engle's Device "had been overinfusing significant amounts of medicine into her body, causing a rollercoaster of overdose symptoms followed by underinfusion and withdrawal symptoms" that necessitated the removal of her Device. [*Id.*]. Engle attributes the over and underinfusion to her pump "miscalculat[ing] drug reservoir levels and drug dispensing rates and/or experienc[ing] motor stalls," and to her catheter "occlud[ing], kink[ing], and/or disconnect[ing] from the pump." [*Id.*]. Engle's Device was removed in August 2019 and replaced with a device made by a different manufacturer. [*Id.*].

STANDARD

Federal Rule of Civil Procedure 12(b)(6) instructs that a court must dismiss a complaint if the complaint "fail[s] to state a claim upon which relief can be granted[.]" Fed. R. Civ. P. 12(b)(6). To state a claim, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). As stated, when considering a motion

to dismiss, courts must presume all factual allegations in the complaint to be true and make all reasonable inferences in favor of the non-moving party. *Total Benefits Plan. Agency, Inc.*, 552 F.3d at 434 (citation omitted). "But the district court need not accept a bare assertion of legal conclusions." *Tackett v. M&G Polymers, USA, LLC*, 561 F.3d 478, 488 (citation omitted). "A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertion[s] devoid of further factual enhancement." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks and citation omitted).

To survive a motion to dismiss, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). "A complaint will be dismissed . . . if no law supports the claims made, if the facts alleged are insufficient to state a claim, or if the face of the complaint presents an insurmountable bar to relief." *Southfield Educ. Ass'n v. Southfield Bd. Of Educ.*, 570 F. App'x 485, 487 (6th Cir. 2014) (citing *Twombly*, 550 U.S. at 561-64).

DISCUSSION

Medtronic seeks dismissal of Engle's Amended Complaint, arguing that each of her claims is either "expressly preempted . . . and/or inadequately pleaded[.]" [DE 24 at 336]. Engle argues that her "claims are not preempted by federal law[] because they thread the narrow gap between express and implied preemption insofar as they are based on state-law claims which parallel federal manufacturing requirements," and that her "claims are otherwise adequately pleaded[.]" [DE 27 at 382].

A. PMA and Preeemption

> In 1976, Congress enacted the [Medical Device Amendments ("MDA")] in order to provide for the safety and effectiveness of medical devices intended for human use. Under the MDA's regulatory structure, medical devices are categorized into three classes, based on the level of risk that they pose. *See* 21 U.S.C. § 360c(a)(1). Those devices presenting minimal risks are placed in Classes I and II. *See* 21 U.S.C. § 360(a)(1)(A) and (B). Those devices which either 'present a potential unreasonable risk of illness or injury' or are 'for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health' are classified as Class III devices. 21 U.S.C. § 360c(a)(1)(C).

White v. Stryker Corp., 818 F. Supp. 2d 1032, 1034 (W.D. Ky. 2011). It is undisputed that "[t]he SynchroMed II Device is a Class III medical device." [DE 19 at 134; DE 24 at 331].

> Prior to marketing and sale, a Class III device must undergo 'premarket approval to provide reasonable assurance of its safety and effectiveness.' 21 U.S.C. § 360c(a)(1)(C). The premarket approval, or "PMA," process is considered lengthy and rigorous. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (describing the PMS process as a 'rigorous one,' and noting that the FDA spends an average of 1,200 hours on each PMA submission). The manufacturer must submit a detailed PMA application that contains: full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information. *See* 21 U.S.C. § 360e(c).

White, 818 F. Supp. 2d at 1034. "Devices that receive the PMA and comply with its requirements are entitled to the benefit of the MDA's express preemption provision[.]" *Id.* at 1036. The preemption provision reads:

> [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 Act [21 U.S.C. §§ 301 *et seq.*] 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 Act [21 U.S.C. §§ 301 *et seq.*].

21 U.S.C. § 360k(a). The Supreme Court explained that "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law[,]" so the preemption provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel v. Medtronic, Inc.*, 552 U.S. 314, 330 (2008).

"When facing MDA preemption, a plausible cause of action requires, among other things, a showing that the alleged violation of state law parallels a violation of federal law[,]" which "requires some greater specificity in the pleadings." *White*, 818 F. Supp. 2d at 1037. The preemption analysis has two steps: "[f]irst, a court must determine whether 'the Federal Government has established requirements applicable to' the particular medical device[;]" if it has, "the court must determine whether plaintiff's state-law claims would impose 'requirements with respect to the device that are different from, or in addition to' the federal requirements, and relate to either the safety or effectiveness' or 'any other matter included in a requirement applicable to the device under'" the MDA. *Smith v. Zoll Med. Corp.*, 2020 U.S. Dist. LEXIS 230245, at *19 (W.D. Tenn. Dec. 8, 2020) (quoting *Spier v. Coloplast Corp.*, 121 F. Supp. 3d 809, 816 (E.D. Tenn. 2015)). "Claims involving a PMA device," like the SynchroMed II Device, "automatically satisfy the first condition." *Id.* So, "plaintiffs may not bring state-law claims challenging the design, manufacturing process, or labeling of a medical device that has been approved by the FDA via the PMA process." *Id.*

There remains question, however, as to whether it is "sufficient to allege that the Defendants violated FDA regulations by deviating from the FDA-approved processes and procedures in the PMA or, instead, [if] the Plaintiffs [must] identify the particular FDA regulations

and set forth facts pointing to the particular PMA requirements that are alleged to have been violated? The Court has found no clear answer to this question, as there appears to be case law supporting both possibilities." *Waltenburg v. St. Jude Medical, Inc.*, 33 F. Supp. 3d 818, 829 (W.D. Ky. 2014) (collecting cases). The Seventh Circuit cautioned that "[i]n applying [the *Iqbal* 'plausibility' standard] to claims for defective manufacture of a medical device in violation of federal law, . . . district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law." *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010). Thus, "[f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." *Id.* Following the Seventh Circuit's approach, this Court held in *Waltenburg* that the plaintiff sufficiently stated a claim where she alleged "that the [product was] defective because the actual manufacture of [that product] deviated from the specifications and protocols set forth in the federal regulations and the PMA." 33 F. Supp. 3d at 832.

B. Unapproved Use of the Device

Defendants argue that Engle "admits [that] her pump was used to deliver hydromorphone, an unapproved medication." [DE 24 at 341]. Engle responds that "defects in her pump were present on December 12, 2019, when [she] began to suffer weakness and fatigue, followed by a return of significant back pain, while she was initially using her pump to administer morphine—a drug for which the SynchroMed II device *is* indicated." [DE 27 at 394]. Thus, according to Engle, her pump failure began to occur while her Device was used for an approved purpose. [*Id.*].

"'[O]ff-label' usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001). However, "[w]hen a plaintiff is injured because her doctor used an FDA-approved device for an unapproved use, the plaintiff is asking the manufacturer to do something 'different from, or in addition to' federal law." *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 988 (D. Ariz. 2013) (criticized on other grounds, *see e.g.*, *Thorn v. Medtronic Sofamor Danek,. USA, Inc.*, 81 F. Supp. 3d 619, 627 (W.D. Mich. 2015)). This is because "[t]he doctor's off-label use is not a result of the manufacturer's conduct; indeed, the manufacturer in this situation is adhering to federal law." *Id.*

To the extent Engle's claims arise out of Device issues occurring after her doctor put hydromorphone into the Device, they are preempted. As acknowledged by Engle, the "Device is FDA-approved solely for" use with morphine, zinconotide, and baclofen, [*see* DE 19 at 131-32], and thus the Device is not approved for use with hydromorphone. So, when "Dr. Nair . . . altered [her] medication to hydromorphone starting January 14, 2019[,]" [*id.* at 133], her use of the device was no longer an FDA-approved use. *See Ramirez*, 961 F. Supp. 2d at 988. Even according to Engle, her Device "was used for the infusion of *unapproved* hydromorphone[.]" [DE 19 at 152] (emphasis added).

The Device is approved for use with three specific medications, and the Court cannot require that the Device operate properly with different or additional medications. *See* 21 U.S.C. § 360k(a). Engle's Amended Complaint acknowledges the known product defects that can arise when the Device is used with the unapproved medication hydromorphone, [DE 19 at 151-52], just like hers was used after January 14, 2019. Because the use of hydromorphone is not an approved FDA use for the Device, Engle's claims arising after her medication switch would impose requirements different from or in addition to the federal requirements already applicable

to the Device. As a result, Medtronic's Motion [DE 24] is **GRANTED in part** as to Engle's claims arising after her medication switch on January 14, 2019.

C. Sufficiency of Engle's Pleadings

Engle cites to a myriad of federal regulations, recalls, and FDA communications which she claims were violated during the manufacture of the Device.[2] [*See* DE 19 at 136-157]. Medtronic correctly argues that Engle does not make an effort to tie a majority of the cited violations to her specific Device. [DE 24 at 339]. However, "there has not yet been an opportunity for discovery, and [the plaintiff] never waived discovery. For her to plead with any more detail that her claims were 'based entirely on a specific defect in the [device] that existed outside the knowledge and regulations of the FDA,' she would need access to the confidential materials in the premarket approval application setting forth the medical device's specifications. This is simply not possible without discovery." *Bausch*, 630 F.3d at 561. After the parties have engaged in discovery and Engle is able to explicitly define the specific defect in her Device as well as the specific violation of federal law she attributes said defect to, the Court will be able to more accurately make a determination as to whether Engle's alleged harm was caused by a violation of federal regulations applicable to the Device.

Notably, "the FDA's recall of a PMA Class-III medical device does not give rise to a claim capable of surviving federal preemption." *Wheeler v. Frank*, Case No. 2010-cv-9016, 2012 Colo. Dist. LEXIS 2832, *4 (2012) (citing *In re Medtronic, Inc.*, 592 F. Supp. 2d 1147 (D. Minn. 2009)).

[2] Engle also cites a "Permanent Injunction against Medtronic preventing the manufacture, distribution, and sale of Medtronic SynchroMed Implantable Infusion Pump systems" as a regulation violated by Medtronic when it manufactured her Device. [DE 19 at 158-59]. However, this permanent injunction clearly imposes requirements "different from, or in addition to" the federal requirements applicable to the Device. *See* 21 U.S.C. § 360k(a). Medtronic is explicitly permitted to manufacture the Device pursuant to its PMA and 21 U.S.C. § 360k(a), so Medtronic's failure to cease manufacture is not a violation of federal law. Engle makes no contention that the Device lost PMA status. Therefore, Medtronic's purported violation of the permanent injunction is insufficient to establish a claim that avoids preemption under 21 U.S.C. § 360k(a).

This is because "[t]he FDA, too, recognizes the distinction between the recall of a device and the revocation of a device's PMA[.]" *In re Medtronic, Inc.*, 592 F. Supp. 2d at 1155. However, the Sixth Circuit has held that pleading a Good Manufacturing Process ("GMP") violation can properly state a parallel claim where the GMP cited "is not so vague as to be incapable of enforcement." *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed. App'x 437, 440 (6th Cir. 2010). In *Howard*, the GMP at issue was not so vague as to be incapable of enforcement because rather than "requir[ing] compliance with a validated cleaning *process*," the GMP "require[d] a specific *result*[.]" *Id.* at 440-41. So, where a GMP mandates a process but not an identifiable result, it is incapable of enforcement and therefore insufficient to state a parallel claim. Conversely, where a GMP mandates an identifiable result, it can be used to successfully establish a parallel claim and thus avoid PMA preemption.

After the parties have engaged in discovery, Engle will be required to connect a specific federal violation to her alleged defect in order to state a sufficient claim. Given the disagreement among courts[3] and the inability of PMA plaintiffs to gather all necessary information prior to engaging in discovery, *see Waltenburg*, 33 F. Supp. 3d at 832, the Court is not inclined to dismiss all of Engle's claims at this early stage. Therefore, Medtronic's Motion [DE 24] is **DENIED in part** as to Engle's claims arising before her switch to the unapproved medication on January 14, 2019.

[3] *See e.g.*, *Waltenburg*, 33 F. Supp. 3d at 829; *Franzese v. St. Jude Med., Inc.*, 2014 WL 2863087, at *3 (E.D.N.Y. June 23, 2014); *Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 403 (S.D.N.Y. 2013); *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901, 906 (S.D. Ohio 2012); *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 838-39 (S.D. Ind. 2009).

CONCLUSION

For the foregoing reasons, and being otherwise sufficiently advised, it is **ORDERED** that Medtronic's Motion to Dismiss [DE 24] is **GRANTED in part** as to Engle's claims arising after January 14, 2019, and **DENIED in part** as to her claims arising prior to January 14, 2019.

Rebecca Grady Jennings, District Judge
United States District Court
April 8, 2021

Copies to: Counsel of Record