UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

CARISSA SULLIVAN,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 4:20 CV 344 CDP
	)	
MEDTRONIC, INC., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

Plaintiff Carissa Sullivan has cerebral palsy and spastic quadriplegia. To reduce her muscle spasticity, Sullivan had a SynchroMed II Programmable Implantable Infusion Pump System ("SynchroMed") implanted in her abdomen. The SynchroMed administers a programmed amount of medication (here, baclofen) into the intrathecal space of her spine and is made by defendants ("Medtronic"). Sullivan's SynchroMed failed in 2015, causing injuries from baclofen withdrawal and requiring a pump replacement surgery. Sullivan alleges that the pump failure was caused by manufacturing defects and brings Missouri state law claims for strict liability, negligence, and breach of implied warranty of merchantability. She also seeks punitive damages.

Before me now is Medtronic's Rule 12(b)(6) motion to dismiss. Medtronic argues that Sullivan's claims are preempted by the 1976 Medical Device

Amendments to the Food, Drug and Cosmetic Act. Medtronic also argues that even if the claims are not preempted, Sullivan has failed to state plausible claims for relief. Because I find that the claims are not preempted and that they meet federal pleading requirements, I will deny Medtronic's motion.

Motion to Dismiss Standard

The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint. When considering a 12(b)(6) motion, the court assumes the factual allegations of a complaint are true and construes them in favor of the plaintiff. *Neitzke v. Williams*, 490 U.S. 319, 326–27 (1989). Rule 8(a)(2), Fed. R. Civ. P., provides that a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." In *Bell Atlantic Corp. v. Twombly*, the Supreme Court clarified that Rule 8(a)(2) requires complaints to contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." 550 U.S. 544, 555 (2007); accord *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). Specifically, to survive a motion to dismiss, a complaint must contain enough factual allegations, accepted as true, to state a claim for relief "that is plausible on its face." *Twombly*, 550 U.S. at 570. The issue in considering such a motion is not whether the plaintiff will ultimately prevail, but whether the plaintiff is entitled to present evidence in support of the claim. *See Neitzke*, 490 U.S. at 327.

Background Facts

Sullivan was first implanted with a SynchroMed pump in 2005. That device functioned normally until the end of its lifecycle in 2011. On August 29, 2011, Sullivan's original SynchroMed was replaced with a new SynchroMed pump bearing model number 8637-40 (serial number NGV453274H) and model number 8578 sutureless pump connector (serial number N280915008). She retained her original catheter. The device functioned normally at first, but on March 5, 2015, Sullivan began complaining of increased stiffness and the sensation of feeling bugs crawling on her. The SynchroMed alarm began to beep, and plaintiff alleges that the motor in her pump was stalling, seizing, or otherwise failing to deliver baclofen medication as programmed, causing baclofen withdrawal. (First Amended Complaint, Doc. #31 at Paragraph 11).

The next day, Sullivan went to the emergency room and was admitted with a diagnosis of acute withdrawal secondary to baclofen pump failure with symptoms of tremors, pruritus, shortness of breath, tachycardia, elevated blood pressure, and hyperthermia. Doctors initiated drug withdrawal protocol. A Medtronic representative examined Sullivan's pump at the hospital and confirmed it was not functioning. Sullivan's doctors recommended "urgent replacement" of her SynchroMed. On March 7, 2015, Sullivan had pump replacement surgery. Both the Medtronic pump and the sutureless catheter connector were replaced with new

Medtronic components. The surgeon noted that "there was evidence of a catastrophic pump failure with a rotor stall that had occurred that could not be remedied by cycling her pump off/on." Sullivan alleges that, as a result of her baclofen withdrawal, she has severe and permanent injuries, including being unable to void through her urethra, impaired speech, an uncontrollable stutter, and panic attacks. Sullivan alleges that her baclofen withdrawal was caused by manufacturing defects in her SynchroMed which caused the pump to experience motor stalls or seizure. She brings the following three claims under Missouri common law: Strict Liability—Manufacturing Defect (Count I); Negligence—Manufacturing Defect (Count II); and Breach of the Implied Warranty of Merchantability (Count III). She also seeks punitive damages (Count IV).

The Medical Device Amendments

In 1976, Congress passed the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act (FDCA). *See* 21 U.S.C. § 360c et seq. The amendments authorized the FDA to "regulate the safety and effectiveness of medical devices." *In re Medtronic, Inc.*, 623 F.3d 1200, 1203 (8th Cir. 2010). Through the amendments, which were a response to proliferation (and frequent failure) of medical devices entering the market, Congress "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 Medtronic, Inc. v. Lohr*, 518

U.S. 470, 476 (1996) (MDA was enacted in "response to the mounting consumer and regulatory concern").

The MDA classifies medical devices into three groups (Classes I, II, and III) based on the degree of risk they pose. In general, Class III devices—as the most dangerous—are subject to the highest level of scrutiny by the FDA. This manifests in a rigorous, comprehensive inquiry called "premarket approval," or PMA. *See Lohr*, 518 U.S. at 477 (noting that it takes the FDA an average of 1,200 hours to review an application for premarket approval). An applicant seeking PMA for a Class III device must supply information to the FDA, including a description of the device, clinical safety trials, methods of product testing, design of the device and manufacturing controls, outcome evaluation, and proposed labeling. (First Am. Compl. Doc. #31 at ¶ 27). The FDA does not conduct independent testing on a medical device in a PMA application. (*Id.*). Following PMA, an applicant must comply with certain FDA requirements and federal regulations, including those set out in 21 C.F.R. Pt. 803, 21 C.F.R. Pt. 820, and 21 U.S.C. §§ 351–52. (*Id.*, at ¶ 29). The holder must also comply with specifications imposed during the PMA process for the device. (*Id.*, at ¶ 78).

SynchroMed's PMA and Subsequent History with the FDA

SynchroMed is a Class III, premarket-approved device. (*Id.* at ¶ 26). The FDA approved the original SynchroMed in 1988 (PMA P860004) and has granted

supplemental approval for numerous modifications and improvements to the device. (*Id.* at ¶ 22, 23). SynchroMed is FDA-approved for the intrathecal infusion of baclofen. (*Id.* at ¶ 25).

Starting in 2006, the FDA issued Medtronic a series of warning letters identifying federal manufacturing and quality control violations at their manufacturing plants with respect to SynchroMed. (*Id.* at ¶ 35, 36). On April 27, 2015, the U.S. Department of Justice and U.S. Department of Health and Human Services filed a complaint requesting a permanent injunction, leading to a court ordered consent decree "imposing a moratorium on the manufacture, sale, and distribution" of SynchroMed. (*Id.* at ¶ 33). Since receiving PMA, SynchroMed has been subject to at least 72 recalls. (*Id.* at ¶ 34).

The warning letters issued by the FDA identified "significant deviations" from Current Good Manufacturing Practices (CGMPs), codified at 21 C.F.R. § 820, committed by Medtronic while manufacturing SynchroMed. (*Id.* at ¶ 38). The letters outlined specific CGMPs that Medtronic failed to follow. (*Id.*). Due to these deviations, SynchroMed was found to be "adulterated" or "misbranded." (*Id.* at ¶¶ 37, 41, 45, 49). The FDA also notified Medtronic on multiple occasions that the violations "may be symptomatic of serious underlying problems in [Medtronic's] manufacturing and Quality Assurance systems." (*Id.* at ¶¶ 43, 47, 52). Since 2008,

the FDA has issued nineteen Class I and II recall actions for SynchroMed to address federal violations. (*Id.* at ¶ 68).

The July 17, 2012 warning letter states that Medtronic violated 21 C.F.R. § 820.100(a) by failing to establish adequate procedures for corrective and preventive action, including failing to identify "the actions to correct and prevent recurrence of nonconforming product" outlined in "GCAPA[1] 1485, opened October 26, 2007, [which] relates to motor corrosion resulting in device field failure (motor stall). Within the Investigation Report for SynchroMed II Pump Corrosion (NDHF1119-88863), it states 'corrosion . . . can result in partial or complete removal of gear teeth.' This can 'seize' the motor altogether or 'gear wheel . . . will continue to rotate, but there may be no drug delivery in the region of missing teeth.' . . . This GCAPA includes 567 complaints and has not been closed." (*Id.* at ¶ 50). This same letter also details Medtronic's failure to "adequately evaluate" "eleven of 11 closed complaints involving motor stalls with unknown cause and no returned product." (First Am. Compl. Ex. 6). On December 13, 2012, the FDA issued recall number Z-0497-2013 for SynchroMed to address the increased risk of motor stall. (*Id.* at Ex. 14). The FDA initiated recall number Z-0896-2018 on August 9, 2017, to address motor stalls due to corrosion. (*Id.* at Ex. 8). As part of the recall, Medtronic issued a Medical Device

[1] CAPA stands for Corrective and Preventative Action.

Safety Notification to healthcare professionals, detailing the rates of pump survivability specific to non-recoverable motor stall over a period of six years. (*Id.* at Ex. 9). The letter states that shaft wear is the most common contributing factor to motor stall. (*Id.*).

On April 27, 2015, the United States Department of Justice and the United States Department of Health and Human Services filed a complaint in the United States District Court for the District of Minnesota for a permanent injunction against Medtronic with respect to manufacture of the SynchroMed. (*Id.* at ¶ 56). The complaint alleges that Medtronic is well aware that its practices violate the FDCA. (*Id.* at ¶ 57, Ex. 15). The complaint further alleges that Medtronic continues to violate 21 U.S.C. §§ 331(a) and (k) by introducing adulterated devices into commerce. (*Id.* at ¶ 60). On April 27, 2015, the Court signed a consent decree of permanent injunction preventing the manufacture and distribution of SynchroMed. (*Id.* at ¶ 62). Sullivan alleges that Medtronic continues to produce, distribute, and sell SynchroMed in violation of the consent decree. (*Id.* at ¶ 66).

The MDA and Federal Preemption

The MDA expressly preempts certain state laws. Subject to some unrelated exceptions, "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."

21 U.S.C. § 360k(a). The United States Supreme Court has articulated a two-part test for applying the express preemption principles codified in Section 360k of the MDA. *See Riegel*, 552 U.S. at 321–22. The test requires the court to examine the particular federal laws and regulations applicable to the device in question and compare them to the state claims the plaintiff wishes to bring. First, a court must determine whether "the Federal Government has established requirements" applicable to a particular device. Second, the court must determine whether a plaintiff's claims "are based upon [state] 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.* If the Court answers both questions in the affirmative, the state laws are expressly preempted by the MDA. *Id.* at 321-23. However, "§ 360k 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." *Id.* at 330.

Premarket approval is a federal "requirement" that meets the first prong of the test for Section 360k preemption. *Riegel*, 552 U.S. at 322–23 (PMA was

"specific to individual devices" and "focused on safety, not equivalence."). As for the second prong of the Section 360k preemption test, included in the meaning of "state requirements" subject to federal preemption are common law causes of action, such as negligence and strict liability. *Id.* at 323-244.

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court construed § 337(a) of the MDA—which provides that all actions to enforce FDA requirements "shall be by and in the name of the United States"—"as barring suits by private litigants 'for noncompliance with the medical device provisions.'" *In re Medtronic*, 623 F.3d at 1204 (quoting *Buckman*, 531 U.S. at 349 n. 4). The Eighth Circuit Court of Appeals has read *Buckman* and *Riegel* together to create only a "narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *Id.* (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). As such, a plaintiff "must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic*, 623 F.3d at 1204 (quoting *Riley*, 625 F. Supp. 2d at 777) (italics in original).

Here, Medtronic argues that Sullivan's claims are expressly preempted by the MDA. The parties do not dispute that the first prong of the *Riegel* test is

satisfied, as SynchroMed was subjected to PMA and is thus governed by the specific requirements set forth in the PMA. Medtronic argues that because Sullivan "has not pleaded facts plausibly establishing that Medtronic violated federal requirements in the manufacture of *her specific* pump and thereby caused her *specific injury*, her claims necessarily seek to impose state-law requirements 'different from, or in addition to,' federal device requirements, triggering preemption." (Doc. #23 at 7).

Medtronic posits that Sullivan's claims are really design defect claims which are expressly preempted as "attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device." *In re Medtronic*, 623 F.3d at 1206. In this case, however, Sullivan has pleaded claims for *manufacturing* defects, not *design* defects, and these claims are parallel state claims which survive preemption. Sullivan alleges that the SynchroMed implanted in her body was defective in that it was manufactured in violation of the PMA and the CGMP as set out in detail in the First Amended Complaint and that these manufacturing defects caused her device to fail. In *In re Medtronic*, the Eighth Circuit affirmed the district court's dismissal of plaintiffs' claims against Medtronic that its implantable cardiac defibrillators were defectively manufactured. 623 F.3d at 1206. In the district court, plaintiffs alleged that the manufacturing of their devices was defective because Medtronic failed to use welding techniques that complied with

the CGMPs. *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009). In the absence of allegations as to how the welding techniques failed to comply with the CGMPs, however, the district court concluded that such allegations were too generalized and vague and amounted to an attempt to impose requirements "different from, or in addition to" those required under federal law. *Id.*

In contrast, here Sullivan has pleaded not only particularized violations of CGMPs as detailed by the FDA's numerous warning letters to Medtronic (which detail the factual bases for such violations), but also that the manufacture of her device was in violation of the PMA specifications, which resulted in a defective device whose manufacture was not approved by the FDA. State law claims based on allegations of a manufacturer's failure to comply with device-specific PMA specifications survive preemption. *See Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 898-99 (M .D. Pa. 2017) (claim that SynchoMed was manufactured out of specification not preempted); *In re Medtronic Inc. Sprint Fidelis Leads*, 592 F. Supp. 2d at 1161 n.17 ("[A]n adequately pleaded claim that a specific device was not manufactured in accordance with its PMA specifications can survive preemption."); *Warren v. Howmedica Osteonics Corp.*, No. 4:10CV1346 DDN, 2011 WL 1226975, at *5 (E.D. Mo. Mar. 29, 2011) ("[B]ecause plaintiffs allege that defendants violated a federal requirement specific to the FDA's PMA approval

of [the device], plaintiffs' claims survive preemption.") (internal quotation marks and citation omitted); *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 988 (E.D. Mo. 2014) (allegations that manufacturing did not comply with PMA sufficiently alleges a specific federal violation). Although Medtronic disputes Sullivan's characterization of the recalls and warning letters from the FDA, these arguments go to Sullivan's ability to ultimately prove her claims of manufacturing defects, not whether she has adequately pleaded her claims to survive dismissal. As such, these arguments are an inappropriate basis for dismissal.

Medtronic also complains that Sullivan's allegations are not specific enough as to how her device was not manufactured in compliance with the PMA specifications, claiming that she fails to allege a plausible claim for relief. The Eighth Circuit has recognized "the care that courts must exercise in applying *Riegel*'s parallel claim principle at the pleading stage, particularly to manufacturing defect claims." *In re Medtronic*, 623 F.3d at 1207. Although Sullivan has not argued that she lacks access to the PMA,[2] the Court must be mindful not to hold Sullivan "to an impossible pleading standard." *Id.* at 1206; *see also id.* at 1209-14 (Melloy, J., concurring in part and dissenting in part). Unlike

[2] Medtronic argues that Sullivan's counsel has seen the PMA in another case, but the Court has no information as to whether that disclosure was subject to a protective order or the amount of documentation produced, and it declines to speculate on these issues or dismiss Sullivan's claims on this basis.

the plaintiffs in *In re Medtronic*, Sullivan has not "specifically disclaimed the need" for discovery to oppose the motion to dismiss, nor has she made a "belated request" for discovery. *See id.* at 1207. I find Sullivan's case distinguishable on that basis and reject Medtronic's argument that her First Amended Complaint should be dismissed as preempted because it lacks specificity. Sullivan has done more than simply allege that Medtronic has violated unspecified or generic federal regulations; she is entitled to conduct discovery to support her claims. I thus conclude that Sullivan's First Amended Complaint sufficiently alleges a specific federal violation.

The next issue is whether Sullivan's state law claims are "different from, or in addition to" federal requirements and, if not, whether such claims would give rise to liability under state law even if the FDCA had never been enacted.[3] *Riegel*, 552 U.S. at 321-23; *Buckman*, 531 U.S. at 353.

Count I of Sullivan's First Amended Complaint alleges a claim of strict liability for manufacturing defects under Missouri law. To make a submissible case, Sullivan has to prove:

> (1) the defendant sold a product in the course of its business; (2) the product was then in a defective condition, unreasonably dangerous when put to a reasonably anticipated use; (3) the product was used in a manner reasonably anticipated; and (4) the plaintiff was damaged as a direct result of such defective condition as existed when the product was sold.

[3] There is no dispute that the claims brought by Sullivan "relate to the safety or effectiveness" of the device.

Coterel v. Dorel Juvenile Group, Inc., 827 F.3d 804, 808 (8th Cir. 2016) (quoting *Columbia Mut. Ins. Co. v. Epstein*, 239 S.W.3d 667, 671 (Mo. Ct. App. 2007)). In Missouri, a manufacturing defect occurs when something goes wrong in the manufacturing process and the product deviates from its intended condition. *Gillan v. Wright Med. Tech. Inc.*, 396 F. Supp. 3d 844, 848 (E.D. Mo. 2019) (citing *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 791 (Mo. Ct. App. 2008)).

In support of this claim, Sullivan alleges that: the SynchroMed implanted into her abdomen was manufactured in deviation of the manufacturing specifications set out in the PMA and the specific CGMPs cited by the FDA in its numerous warning letters to Medtronic; these manufacturing defects rendered the SynchroMed adulterated under federal and Missouri law, which prohibits the manufacturing and sale of adulterated devices; the SynchroMed implanted into her abdomen was not reasonably safe for its intended use when it was implanted; the device was defective because the motor stalled and failed to deliver medication as programmed, it was adulterated under federal and state law, and failed when used as reasonably anticipated; and that as direct result of the SynchroMed's manufacturing defects, she was injured.

In support of her claim of negligent manufacturing defects[4] in Count II of her First Amended Complaint, Sullivan alleges: the SynchroMed implanted in her was manufactured in violation of federal and Missouri law as described in Count I; Medtronic owed her a duty under Missouri law to use reasonable care to manufacture the SynchroMed in compliance with federal requirements; Medtronic was negligent in failing to use reasonable care in manufacturing Sullivan's SynchroMed and manufactured her device in a way that did not comply with federal requirements, including the PMA requirements; and as a direct result of Medtronic's negligence, she was injured.

These claims as pleaded by Sullivan in Counts I and II of the First Amended Complaint do not attempt to impose responsibilities on Medtronic that are different from, or in addition to, the federal requirements, and sufficiently plead violations of parallel Missouri law such that they are not preempted.

In Count III, Sullivan brings a claim for breach of the implied warranty of merchantability,[5] which under Missouri law "a plaintiff must prove: (1) that a

[4] Under Missouri law, "in an action for negligence, generally, a plaintiff must allege ultimate facts which if proven, show: (1) the existence of a duty on the part of the defendant to protect the plaintiff from injury; (2) failure of the defendant to perform that duty; and (3) injury to the plaintiff resulting from such failure." *Redd v. DePuy Orthopaedics, Inc.*, 48 F. Supp. 3d 1261, 1270–71 (E.D. Mo. 2014). "Thus, in order to recover on a claim for negligent manufacture, . . . a plaintiff must establish that the defendant failed to use ordinary case to manufacture . . . the product to be reasonably safe . . . ." *Id.*

[5] While Medtronic is correct that some of Sullivan's allegations in Count III also refer to an implied warranty of fitness for a particular purpose, Count III is entitled "Breach of Implied

merchant sold goods, (2) which were not 'merchantable' at the time of the sale, (3) injury and damages to the plaintiff or his property (4) which were caused proximately or in fact by the defective nature of the goods, and (5) notice to the seller of the injury." *Johnsen v. Honeywell International Inc.*, No. 4:14CV594 RLW, 2015 WL 631361, at *5 (E.D. Mo. Feb. 12, 2015) (citing *Ragland Mills, Inc. v. General Motors, Corp.*, 763 S.W.2d 357, 360 (Mo. Ct. App. 1989)). Sullivan alleges that Medtronic impliedly warranted to her that her SynchroMed was fit for the ordinary purpose for which it would be used – namely, the intrathecal administration of baclofen, that Medtronic breached its implied warranty of merchantability because it sold her a defective device that was not in compliance with federal requirements, and that as a result of this breach of warranty the SynchroMed failed and damaged her. Here, where Sullivan alleges that the device was not fit for its intended purpose under Missouri law due to Medtronic failing to manufacture the SynchroMed in accordance with federal requirements, the alleged breach of warranty claim parallels the federal requirements for the device rather than imposing different or additional

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Warranty of Merchantability" and Sullivan's opposition brief makes clear that this claim is solely for breach of an implied warranty of merchantability, not one for breach of an implied warranty of fitness for a particular purpose. This case does not include a claim for breach of an implied warranty of fitness for a particular purpose, which under Missouri law has elements not alleged here, *see Johnsen*, 2015 WL 631361 at * 6, and any attempt by Sullivan to assert that Count III states a claim for breach of implied warranty of fitness for a particular purpose will be rejected by the Court.

requirements and is therefore not preempted by the MDA. *See Grubbs v. Medtronic, Inc.*, 2019 WL 3288263, at *4 (N.D. Ala. July 22, 2019) (claim that Medtronic breached implied warranty of merchantability by selling plaintiff SynchroMed which was not manufactured in accordance with federal requirements was not preempted by MDA).

Finally, Medtronic's request that Sullivan's claim for punitive damages be dismissed will be denied as the Court has concluded that her substantive claims are not preempted and survive dismissal. The Court also finds that the allegations in Sullivan's First Amended Complaint are sufficient to support her request for punitive damages at this time. Whether Sullivan will ultimately prevail on her request for punitive damages is not properly before me at this time.

Accordingly,

IT IS HEREBY ORDERED that defendants' motion to dismiss [23] is denied.

IT IS FURTHER ORDERED that defendants' motion for hearing [28] is denied as moot.

IT IS FURTHER ORDERED that the plaintiff's unopposed motion allowing substitution of name of defendant [25] is granted and the Clerk of Court is directed to substitute on the docket the correct name of "Medtronic Puerto Rico

Operations Co." for the defendant previously identified as "Medtronic Puerto Rico Operations, Inc."

This case will be set for a Rule 16 scheduling conference by separate Order.

CATHERINE D. PERRY
UNITED STATES DISTRICT JUDGE

Dated this 30th day of October, 2020.