IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

JASON SILVER,	:	1:16-cv-1682
	:	
Plaintiff,	:	Hon. John E. Jones III
	:	
v.	:	
	:	
MEDTRONIC, INC, MEDTRONIC PUERTO RICO OPERATIONS, CO, AND MEDTRONIC LOGISTICS, LLC,	:	
	:	
Defendants,	:	

MEMORANDUM & ORDER

February 21, 2017

Presently pending before the Court is a motion to dismiss (the "Motion") filed by Defendants Medtronic, Inc, Medtronic Puerto Rico Operations, Co, and Medtronic Logistics, LLC.[1] (collectively "Medtronic") (Doc. 9). Plaintiff Jason Silver brings seven counts against Medtronic arising out of the alleged malfunction of a Medtronic device, the SynchroMed II.[2] (Doc. 1). The Motion has been fully briefed (Docs. 11, 14, 15) and is therefore ripe for our review. For the reasons that follow, the Motion shall be granted in part and denied in part.

[1] Plaintiff named "Medtronic Nueromodulation" as a Defendant, but Medtronic asserts that this is just a division of Medtronic, Inc., as opposed to a separate legal entity. (Doc. 9, p. 1). Plaintiff also named Defendant "Medtronic Puerto Rico Operations, Inc," but Defendants state that its name is "Medtronic Puerto Rico Operations, Co." (*Id*.). Plaintiffs did not contest these statements and we shall refer to the Defendants in this way and direct the Clerk to remove Medtronic Nueromodulation as a separate Defendant.

[2] Plaintiff brings seven claims numbered Counts I, II, III, V, VI, VII, VIII. There is no Count IV. We will refer to each of Plaintiff's claims by the number assigned to it in his Complaint.

I. BACKGROUND

Plaintiff Jason Silver filed a Complaint against Medtronic on August 12, 2016. (Doc. 1). Plaintiff brings the following causes of action arising out of the alleged malfunction of Medtronic's product, the SynchroMed II Device (the "Device"): manufacturing defect, failure to warn, negligence, breach of express warranty, breach of implied warranties, negligent misrepresentation, and violation of Pennsylvania's unfair trade practices and consumer protection law.

In accordance with the standard of review applicable to a motion to dismiss, the following facts are derived from Plaintiff's Complaint. (Doc. 1).

Plaintiff is a fifty-two year old man with diagnosed cervical radiculopathy and cervicalgia. (*Id*., at ¶¶ 10, 12). On December 7, 2012, Plaintiff had the Device, comprised of a pump and an intrathecal catheter, implanted in his abdomen. (*Id*., at ¶ 13). The Device is a programmable drug infusion system that delivers medication into the intrathecal space of the patient's spine. (*Id*., at ¶¶ 22, 25). It is implanted and remains under the skin. (*Id*., at ¶ 25).

For several months after the Device was implanted, Plaintiff's pain improved. (*Id*., at ¶14). However, in the summer of 2014, the Device overdelivered pain medication and caused Plaintiff severe pain, nausea, and lack of mobility. (*Id*.). On August 12, 2014, Plaintiff underwent a procedure to remove the Device due to its malfunction. (*Id*., at ¶ 15).

The Device is a Class III medical device approved by the Food and Drug Administration ("FDA") through the Pre-Market Approval ("PMA") process in 1988. (*Id*., at ¶ 23). PMA is the FDA's process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. (*Id*., at ¶ 29). The applicant must supply information to the FDA in a PMA application. (*Id*., at ¶ 30). The information includes: "a) device description, b) clinical safety trials, c) methods of its product testing, d) design of the device and specific manufacturing controls, e) outcome evaluation, and f) proposed labeling." (*Id*.). Medtronic submitted a PMA application and the Device was approved under PMA 860004. (*Id*., at ¶ 23). Since the original approval, the FDA has approved many changes to the Device. (*Id*.). Following PMA approval, the holder must comply with certain FDA requirements and federal regulations, including those set out in 21 C.F.R. § 801, *et seq*., 21 C.F.R. § 803, *et seq*., 21 C.F.R. § 814, *et seq*., 21 C.F.R. § 806, *et seq*., 21 C.F.R. § 820, *et seq*., and 21 U.S.C. §§ 351-52. (*Id*., at ¶¶ 31, 66). The holder must also comply with specifications imposed during the PMA process for the Device. (*Id*., at ¶ 66).

Starting in 2006, the FDA issued Medtronic a series of warning letters identifying federal manufacturing and quality control violations at their manufacturing plants. (*Id*., at ¶ 32). 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 the Device. (*Id*.).

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 the Device. (*Id*., at ¶ 36). The letters outlined specific CGMPs that Medtronic failed to follow. (*Id*.). Due to these deviations, the Device was found to be "adulterated" or "misbranded." (*Id*., at ¶¶ 36, 37, 39). The FDA also notified Medtronic on multiple occasions of several manufacturing defects in the Device. (*Id*., at ¶¶ 41, 46). Since 2008, the FDA has issued nineteen Class I recall actions for the Device to address federal violations. (*Id*., at ¶ 48).

In addition to manufacturing issues and violations of CGMPs, the FDA notified Medtronic of the following failure to follow their PMA:

> "Regulatory approval was received for Supplement 136 to PMA P860004 on December 15, 2011 to change the design of SC Catheter models 8709 SC, 8731 SC, 8596 SC, and Revision Kit model 8578 to mitigate a known field issue associated with CAPA 1507-SC Catheter Occlusion. This design change was implemented via ECO 12-00985, date March 6, 2012, and the new revisions of Catheter models were released to the field in September 2012. However, the previous SC catheter models which do not conform to the current design have continued to be distributed and have been attributed to 60 complaints of catheter occlusion since September 2012."

(*Id*., at ¶ 47).

On April 27, 2015, the United States Department of Justice and the United States Department of Health and Human Services filed a complaint for a permanent injunction against Medtronic with respect to manufacture of the Device. (*Id*., at ¶ 52). The complaint alleges that Medtronic is well aware that their practices violate the Act, presumably referring to the CGMPs. (*Id*., at ¶ 53). The complaint alleged that Medtronic continued to violate 21 U.S.C. §§ 331(a) and (k) by introducing adulterated devices into commerce. (*Id*., at ¶ 56). On April 27, 2015, the Court signed a consent decree of permanent injunction preventing the manufacture and distribution of the Device. (*Id*., at ¶ 58). According to Plaintiff, Medtronic continues to produce, distribute, and sell the Device in violation of the consent decree. (*Id*., at ¶ 60).

II. STANDARD OF REVIEW

In considering a motion to dismiss pursuant to Rule 12(b)(6), courts "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (quoting *Pinker v. Roche Holdings, Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)). In resolving a motion to dismiss pursuant to Rule 12(b)(6), a court generally should consider only the allegations in the complaint, as

well as "documents that are attached to or submitted with the complaint, . . . and any matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case." *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006).

A Rule 12(b)(6) motion tests the sufficiency of the complaint against the pleading requirement of Rule 8(a). Rule 8(a)(2) requires that a complaint contain a short and plain statement of the claim showing that the pleader is entitled to relief, "in order to give the defendant fair notice of what the claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). While a complaint attacked by Rule 12(b)(6) motion to dismiss need not contain detailed factual allegations, it must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To survive a motion to dismiss, a civil plaintiff must allege facts that "raise a right to relief above the speculative level…." *Victaulic Co. v. Tieman*, 499 F.3d 227, 235 (3d Cir. 2007) (quoting *Twombly*, 550 U.S. at 555). Accordingly, to satisfy the plausibility standard, the complaint must indicate that defendant's liability is more than "a sheer possibility." *Iqbal*, 556 U.S. at 678. "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the

line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

Under the two-pronged approach articulated in *Twombly* and later formalized in *Iqbal*, a district court must first identify all factual allegations that constitute nothing more than "legal conclusions" or "naked assertions." *Twombly*, 550 U.S. at 555, 557. Such allegations are "not entitled to the assumption of truth" and must be disregarded for purposes of resolving a 12(b)(6) motion to dismiss. *Iqbal*, 556 U.S. at 679. Next, the district court must identify "the 'nub' of the … complaint – the well-pleaded, nonconclusory factual allegation[s]." *Id.* Taking these allegations as true, the district judge must then determine whether the complaint states a plausible claim for relief. *See id.*

However, "a complaint may not be dismissed merely because it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits." *Phillips*, 515 F.3d at 231 (citing *Twombly*, 550 U.S. at 556-57). Rule 8 "does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Id.* at 234.

III. DISCUSSION

Medtronic moves for dismissal on four grounds: all claims are expressly preempted by federal law, all claims are impliedly preempted by federal law,

certain claims are inadequately pleaded, and Counts VI and VIII are barred by independent state law grounds. (Doc. 11, p. 6). We will first analyze the federal preemption issue and then discuss each count in turn.

A. Federal Preemption

The Medical Device Amendments of 1976 ("MDA"), codified at 21 U.S.C. § 360, *et. seq*., established a three-tiered classification system for medical devices, arranged according to the risks presented. *Riegel v. Medtronic, Inc*., 552 U.S. 312, 317 (2008). Class III devices receive the most stringent federal oversight, which is why they are subject to the rigorous PMA process. *Id*. "The FDA spends an average of 1,200 hours reviewing each application, and grants premarket approval only if there is 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id*., at 318 (quoting 21 U.S.C. § 360(e)(d)) (internal citation omitted). The MDA "swept back some state obligations and imposed a regime of detailed federal oversight." *Id*., at 316. In order to "preserve the FDA's regulatory authority over medical devices", *Morgan v. Medtronic, Inc*, 172 F. Supp. 3d 959, 965 (S.D. Tex. 2016), the MDA includes an express preemption provision that 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."

21 U.S.C. § 360k(a). The Supreme Court considered this preemption provision in *Riegel v. Medtronic, Inc*, 552 U.S. 312 (2008) and established a two-step analysis to determine whether a state-law claim regarding a Class III medical device is preempted by federal law. The Court "held that state laws are preempted by the MDA if: (1) the Federal Government has established 'specific requirements applicable to a particular device'; and (2) the plaintiff's claims are based on 'state requirements' related to safety and effectiveness that are 'different from, or in addition to' the federal requirements." *Gross v. Stryker Corp*., 858 F. Supp. 2d 466, 484 (W.D. Pa. 2012) (quoting *Riegel*, 552 U.S. at 321–23). "Included in the meaning of 'state requirements' subject to federal preemption are common law causes of action, such as negligence, strict liability, and breach of implied warranty." *Id*.

The parties do not dispute that the first prong of the *Riegel* test is satisfied. (Doc. 14, p. 8). The Device was subject to premarket approval and is thus governed by the specific requirements set forth in the PMA, as well as federal regulations. (Doc. 1, ¶¶ 23, 31). Whether Plaintiff's claims are expressly preempted by federal law, therefore, "requires the court to evaluate whether the state requirements underlying the plaintiff's claims relate to the

device's safety and effectiveness and are 'different from or in addition to' the federal requirements." *Gross*, 858 F. Supp. 2d at 488 (quoting 21 U.S.C. § 360(k)).

Plaintiff's claims undoubtedly meet the first requirement: his claims arise out of alleged issues with the safety and effectiveness of the Device. However, Medtronic asserts that Plaintiff's claims are based on state law that is different from or additional to federal law. (Doc. 11, p. 9). In response, "Plaintiff asserts that his pump was manufactured ***in violation of federal law*** and parallel state law, was nonconforming with FDA-approved standards making it misbranded and adulterated and therefore defective." (Doc. 14, p. 8).

The Supreme Court made expressly clear in *Reigel* that state law claims are not universally preempted:

> "State 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. § 360k(a)(1). Thus, § 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."

Riegel, 552 U.S. at 330 (emphasis added). Plaintiff's claims of federal violations stem from FDA warning letters to Medtronic following inspections of Medtronic's Minneapolis and Puerto Rico manufacturing facilities. (Doc.

1, ¶ 30). In the warning letters, the FDA outlines Medtronic's violations of CGMPs at both facilities. (Doc. 1, ex. 2-5). Importantly, the warning letters do not simply list the CGMPs that Medtronic violated, but provide specific factual information regarding how Medtronic failed to adhere to the CGMPs. (*See id.*).

Medtronic argues that CGMPs do not provide a parallel "federal requirement" to excuse Plaintiff's claims from preemption because they are too general and inherently flexible. (Doc. 11, p. 12). Several courts have dismissed claims premised on violations of CGMPs for this very reason.[3] Courts have held that "[t]he CGMPs are guidelines that do not create a federal requirement, and a claim based on alleged failure to comply with the guidelines fails to plead violation of a federal requirement. To permit a claim that mandates compliance with such 'vague' standards effectively imposes 'different, or additional' requirements, and is preempted by § 306." *Pearsall v. Medtronics, Inc*., 147 F. Supp. 3d 188, 198 (E.D.N.Y. 2015) (internal citation omitted). Courts reason that the "purposefully broad," "intentionally vague and open-ended nature" of these regulations prevent their use as a basis for parallel claims. *Ilarraza v. Medtronic*, Inc., 677 F. Supp. 2d 582,

[3] *See*, e.g., *In re Medtronic Inc. Sprint Fidelis Leads Prods. Liab. Litig*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009); *James v. Diva Int'l, Inc.*, 803 F. Supp. 2d 945, 950–51 (S.D. Ind. 2011); G*ross*, 858 F. Supp. 2d at 495-96.

588 (E.D.N.Y. 2009). Ultimately, the courts have found that reliance on broad CGMPs cannot withstand the pleading requirements of *Twombly*, 550 U.S. at 555. *Ilarraza*, 677 F. Supp. 2d at 588 ("Where, as here, the plaintiff has done nothing more than recite unsupported violations of general regulations, and fails to tie such allegations to the injuries alleged, the complaint is properly dismissed [under *Twombly*]."); *Horowitz v. Stryker Corp*., 613 F. Supp. 2d 271, 280 (E.D.N.Y. 2009) ("Plaintiff's generalized allegations" cannot withstand *Twombly* standard); *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig*., 623 F.3d 1200, 1206 (8th Cir. 2010) (upholding District Court's conclusion that "general allegations of failure to comply with CGMPs" does not survive *Twombly* standard).

However, other courts have allowed claims based on CGMP violations to proceed. *See Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010); *Howard v. Sulzer Orthopedics, Inc*., 382 F. App'x 436 (6th Cir. 2010). The Sixth Circuit allowed a Plaintiff to rely on a CGMP violation because the Plaintiff identified a particular CGMP that was allegedly violated and it was one that "is not so vague as to be incapable of enforcement." *Howard*, 382 F. App'x at 440. The Seventh Circuit followed suit, stating "[l]ike the Sixth Circuit in *Howard*, we do not see a sound legal basis for defendants' proposal to distinguish between general requirements and 'concrete, device-specific'

requirements." *Bausch*, 630 F.3d 546, 555 (7th Cir. 2010). The court emphasized that Section 360k offers a preemption defense based on "any requirement" under federal law, and CGMPs are legally binding requirements on PMA manufacturers. *Id*. Further, the court noted that compliance with CGMPs are "obviously vital to producing safe and effective medical devices," and disallowing claims based on noncompliance would leave injured patients without a remedy. *Id*., at 555-556. Finally, the court noted that the plaintiff alleged that the FDA specifically found the defendant in noncompliance with CGMPs regarding noncomforming products and product specifications. *Id*., at 556.

Here, Plaintiff did not simply provide a "laundry list of alleged CGMP violations", as Medtronic argues. (Doc. 11, p. 12). Instead, Plaintiff cites to FDA warning letters that delineate specific CGMPs and exactly how Medtronic was in noncompliance. (Doc. 1, ex. 2-5). The letters provide specific facts to support the FDA's conclusion that Medtronic was in violation of certain CGMPs. There is nothing vague or open ended about these asserted violations, and as the FDA warning letters demonstrate, the CGMP violations alleged are certainly not too general to be capable of enforcement. Thus, we hold that the CGMP violations alleged qualify as "federal regulations" from which a parallel state claim may be made. These

allegations undoubtedly establish violations of federal regulations sufficient to withstand *Twombly*'s plausibility pleading standard. So long as Plaintiff's state claims are premised upon these federal regulations and parallel state law, rather than duties that differ from or add to this regulatory framework, Plaintiff's claims are not expressly preempted.

Medtronic next argues that Plaintiff's claims are impliedly preempted as well. Medtronic relies the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) for the proposition that 21 U.S.C. § 337(a) impliedly preempts "any private action seeking to enforce the FDCA and its implementing regulations." (Doc. 11, p. 16). This argument is easily rejected.

In *Buckman*, the plaintiffs brought suit alleging that a regulatory consultant to the manufacturer of a medical device made fraudulent representations to the FDA in order to obtain premarket approval. *Buckman*, 531 U.S. at 343. The Court found that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives," and were thus impliedly preempted. *Id*., at 350. Importantly, however, the Court specifically distinguished its holding for fraud-on-the-FDA claims from claims based "on traditional state tort law principles of the duty of care owed by the producer."

Id. at 352. The Court referenced its prior decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, where it held that the MDA did not preempt common law tort claims against the manufacturer of a pacemaker premised on violations of the FDA. There, the Court reasoned that because the common law tort claims arise from the manufacturer's alleged failure to use reasonable care in the production of a product, not solely FDA violations, they would not be impliedly preempted. *Lohr*, 518 U.S. at 481; *Buckman*, 531 U.S. at 352. As these are the exact types of claims asserted by Plaintiff here, we easily reject Medtronic's implied preemption argument. Plaintiff's claims arise by virtue of FDA violations that allegedly represent failures of parallel state common law duties.

Having disposed of Medtronic's implied preemption argument, and the overriding argument that the violations alleged by Plaintiff do not constitute violations of "federal regulations", we now turn to each claim to analyze whether it properly states a parallel claim to survive dismissal.

B. Count I- Manufacturing Defect

Plaintiff alleges that Medtronic "had a duty under Pennsylvania law to use reasonable care in the manufacture of their products," which includes compliance with their own PMA specifications and federal regulations. (Doc. 1, ¶ 67). Plaintiff alleges that Medtronic breached his Pennsylvania common

law duty to exercise reasonable care in manufacturing the Device in failing to ensure that the Device conformed to its own PMA specifications and complied with CGMPs. (*Id*., at ¶ 68). As a result of these violations, Plaintiff alleges that his "adulterated" device was unreasonably dangerous and caused him harm. (*Id*., at ¶¶ 69-74). Regarding preemption, it is clear that Plaintiff is asserting a parallel claim, as he alleges that the Device is unreasonably dangerous *because of* the federal failures, rather than in spite of them.

Medtronic argues that, even if Plaintiff's theories support a parallel claim, Count I must fail because "Plaintiff cannot show that any of the regulatory actions cited in his Complaint" plausibly caused his injuries. (Doc. 11, p. 13). We disagree. Plaintiff has cited to the FDA warning letters, including three specifically outlining failures of CGMPs at the Minneapolis, Minnesota manufacturing facility. (Doc. 1, ex. 3-5). Plaintiff has further alleged that his Device was manufactured in that facility and was subject to those failures. (Doc. 1, ¶ 36). Finally, Plaintiff alleged that his Device failed because it was "manufactured out of specification" and was "adulterated" due to the federal violations. (*Id*., at ¶ 73). Taking Plaintiff's allegations as true, as we must, he has certainly pled a plausible claim of manufacturing defect. Thus, we will deny Medtronic's motion to dismiss Count I.

C. Count II- Failure to Warn

In Count II, Plaintiff alleges that Medtronic breached its "duty to disclose to users and purchasers, including the FDA, of potentially dangerous risks involved in their product's use" through their failures to report known problems, consumer generated adverse events, and malfunctions of the Device, and failure to submit mandated Medical Device Reports to the FDA. (Doc. 1, ¶¶ 79-80).

Medtronic argues that Plaintiff's failure to warn claim is expressly preempted to the extent that it attempts to hold Medtronic liable for not providing additional warnings outside of FDA requirements. (Doc. 11, pp. 9-10). Plaintiff does not respond to this portion of Medtronic's argument, likely because Plaintiff is well aware that the imposition of additional warning requirements would be expressly preempted by the MDA. Upon review of Count II, it is clear that Plaintiff's claim rests on Medtronic's alleged failures to report problems with the Device to the FDA as mandated by 21 C.F.R § 803, *et. seq*., which requires Class III device manufacturers to "report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports." 21 C.F.R. § 803.1; (Doc. 1, ¶¶ 78-80). Thus, the claim does not seek to impose additional warning requirements on Medtronic and would not be expressly preempted.

Medtronic argues that Plaintiff's claim cannot rest on its alleged failure to report to the FDA because it is expressly preempted, the reports do not constitute

"warnings", and the reports are not automatically disclosed to the public. Beginning with express preemption, Medtronic argues that a Pennsylvania failure to warn claim imposes additional or different requirements on PMA device manufacturers because it requires manufacturers to provide warnings to the physicians, whereas federal law requires only that the manufacturer submit information to the FDA. (Doc. 11, p. 10). Plaintiff responds that Medtronic "misses the point" because, in practice, the FDA posts the manufacturer's Medical Device Reports to a publicly accessible database as a means of warning the public and physicians. (Doc. 14, pp. 10-11).

While there is no binding jurisprudence on whether a Pennsylvania failure to warn claim premised upon the manufacturer's failure to report to the FDA is expressly preempted by the MDA, Plaintiff points to the well-reasoned decision of our sister court in the Eastern District. In *McLaughlin v. Bayer Corporation*, the court faced an essentially identical situation wherein the complaint set forth a failure to warn claim against a PMA manufacturer based on its failure to report adverse events to the FDA. *McLaughlin v. Bayer Corp*., 172 F. Supp. 3d 804, 837 (E.D. Pa. 2016). The court relies primarily on the *en banc* decision of the United States Court of Appeals for the Ninth Circuit in *Stengel v. Medtronic Inc*., 704 F.3d 1224 (9th Cir. 2013). In *Stengel*, the Ninth Circuit found no preemption of a failure to warn claim based upon FDA reporting failures because the parallel state law

imposed a duty to warn a third party where there was "reasonable assurance that the information will reach those whose safety depends on their having it." *Stengel*, 704 F.3d at 1233. Because state law imposed a duty to warn third parties, the court found it parallel to the federal reporting requirements of the FDA. *Id*.

Just as in *McLaughlin*, Plaintiff here provides evidence that Pennsylvania law imposes such a duty. *McLaughlin*, 172 F. Supp. 3d at 838; (Doc. 14, p. 11). Both cite to *Phillips v. A.P. Green Refractories Co*., 630 A.2d 874 (Pa. Super. Ct. 1993) where the Pennsylvania Superior Court adopted Section 388 of the Restatement (Second) of Torts, including comment n. (Doc. 14, p. 11). Comment n provides:

> "[A] supplier's duty to warn is discharged by providing information about the product's dangerous propensities to a third person upon whom it can reasonably rely to communicate the information to the ultimate users of the product or those who may be exposed to its hazardous effects.

Phillips, 428 Pa. Super. Ct. at 182 (*citing* Restatement (Second) of Torts § 388, comment n). This duty is parallel to FDA reporting requirements because it may impose liability for the failure to report to the FDA. Comment n also disposes of Medtronic's argument that Count II must fail because FDA reporting does not constitute "warnings" and they are not automatically disclosed to the public; the comment makes clear that a duty to warn is discharged by providing "information about the product's dangerous propensities," which undoubtedly encompasses

Medtronic's alleged failures to report known problems, adverse events and malfunctions, and the comment does not require the third party to disclose the warnings, but rather be reasonably relied upon to do so. We easily conclude that the FDA may be reasonably relied upon to disclose information regarding medical device failures through the publicly accessible database when provided with that information. As such, we will follow our sister court and reject Medtronic's express preemption argument. Thus, we will deny Medtronic's motion to dismiss Count II.

D. Count III- Negligence

Plaintiff's negligence claim is very similar to Count I for manufacturing defect, evidenced by the fact that Medtronic argues against both Counts I and III simultaneously in its brief. Accordingly, we will deny Medtronic's motion to dismiss Count III for the same reasons: the claim alleges that Medtronic breached its Pennsylvania common law duty to exercise reasonable care in its failure to comply with federal regulations (Doc. 1, ¶¶ 89-90), that the failure to follow federal regulations resulted in the Plaintiff receiving an adulterated device (*Id*., at ¶ 94), and that the device caused his injuries. (*Id*.). Considering the specific federal violations alleged through the FDA warning letters, and taking Plaintiff's allegations as true, Plaintiff has properly pled a plausible claim for negligence.

E. Count V -Breach of Express Warranty

Medtronic argues that "any warranty claim that challenges the safety or effectiveness of a medical device that has received premarket approval . . . is expressly preempted by § 360k(a)" because it would require a finding that the device is not safe and effective, contrary to the finding made by the FDA in granting premarket approval. (Doc. 11, pp. 13-14).

Plaintiff's breach of express warranty claim is beyond the scope of federal preemption. As the Eastern District recognized in *Bentzley v. Medtronic, Inc.*, 827 F. Supp. 2d 443, 454 (E.D.Pa. 2011), "[e]xpress warranties, as distinguished from implied warranties, do not independently arise by operation of state law." Pennsylvania law considers an express warranty as a part of the contract between the parties. *Goodman v. PPG Indus*., 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004). "Importantly, the parties, not the state" define the substantive obligations that make up an express warranty claim. *Bentzley*, 827 F. Supp. 2d at 454-455. Thus, a claim for breach of express warranty "does not involve a state 'requirement' and is not preempted by MDA." *Id*., at 455. Therefore we will deny Medtronic's motion to dismiss Count V for breach of express warranty.

F. Count VI- Breach of Implied Warranties

Plaintiff advances both a claim for breach of the implied warranty of fitness for a particular purpose and breach of the implied warranty of merchantability.

(Doc. 14, p. 13). Medtronic argues that Count VI should be dismissed because it is preempted by the MDA and barred by Pennsylvania law. (Doc. 11, pp. 13, 14, 20).

Medtronic points to *Horsmon v. Zimmer Holdings, Inc*., 2011 WL 5509420 (W.D. Pa. 2011) and *Kee v. Zimmer, Inc*., 871 F. Supp. 2d 405 (E.D. Pa. 2012) for the proposition that Pennsylvania courts "bar claims against device manufacturers based on the implied warranties of merchantability and fitness for a particular purpose." (Doc. 11, p. 20). As noted in *Kee*, the Pennsylvania Supreme Court has not yet adopted this holding, but the Pennsylvania Superior Court has done so and numerous federal district courts have predicted that the Pennsylvania Supreme Court would adopt it as well if presented with the chance. *Kee*, 871 F. Supp. 2d at 409 (citing cases).

Plaintiff failed to address Medtronic's Pennsylvania law argument for Count VI's dismissal. As such, we will accept Medtronic's and other courts' interpretations that Pennsylvania would not allow an implied warranty claim against a medical device manufacturer. Because this issue is dispositive, we will not consider the federal preemption arguments and shall dismiss Count VI.

G. Count VII- Negligent Misrepresentation

Medtronic moves to dismiss Plaintiff's negligent misrepresentation claim because it is preempted by the MDA and Plaintiff has not adequately pled a

misrepresentation claim under Federal Rule of Procedure 9(b). (Doc. 11, pp. 14, 19). Plaintiff does not address Medtronic's adequacy of pleading argument.

District Courts in our Circuit have come to differing conclusions on whether Rule 9(b)'s heightened pleading requirements for fraud or mistake apply to claims of negligent misrepresentation. *Bors v. Johnson & Johnson*, No. CV 16-2866, 2016 WL 5172816, at *6 (E.D. Pa. Sept. 20, 2016).[4] Because Plaintiff's negligent misrepresentation claim fails even the more liberal standard of Rule 8, we need not decide the applicability of Rule 9(b).

In the eight paragraphs that comprise Count VII for negligent misrepresentation, Plaintiff fails to identify any specific representation that was allegedly negligent, instead generally referring to "representations" made by Medtronic and making conclusory allegations about their nature. (Doc. 1, ¶¶ 111-118). While the fact section of Plaintiff's complaint identifies several marketing representations made by the Defendant (*Id*., at ¶ 28), Medtronic, and this Court, have no way of knowing which representations were allegedly negligent and relied upon by Plaintiff and his medical providers. Indeed, this claim would even fail the outdated "notice" pleading of *Conley v. Gibson* and certainly fails the plausibility

[4] *Citing Cogswell v. Wright Med.Tech, Inc.*, 2015 WL 4393385, at *5 (W.D. Pa. July 16, 2015) (declining to apply Rule 9(b)'s heightened pleading standard to negligent misrepresentation claim); *Kramme v. Zimmer, Inc*., 2015 WL 4509021, at *5 (M.D. Pa. July 24, 2015) (applying pleading requirements of Rule 9(b) to negligent misrepresentation); *Sims v. Viacom, Inc*., 2009 WL 3856667 (E.D. Pa. Nov. 17, 2009).

standard of *Twombly*. Accordingly, the claim must be dismissed and we do not reach the preemption issue with respect to Count VII.

H. Count VIII- Pennsylvania Unfair Trade Practices and Consumer Protection Law

In Count VIII, Plaintiff alleges that Medtronic violated Pennsylvania's Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1, *et. seq*., by "knowingly and intentionally induc[ing] [Plaintiff] to use the SynchroMed II Device through the use of false and or/misleading representations and statements." (Doc. 1, ¶ 121). Medtronic moves for dismissal, arguing that the claim is preempted, inadequately pled under Rule 9(b), and barred by the learned intermediary doctrine. (Doc. 11, pp. 14-15, 19, 20). Plaintiff did not offer any response to the pleading or learned intermediary doctrine argument.

Again, we need not even consider Rule 9(b) to hold that Plaintiff's pleading of Count VIII is wholly inadequate. Just as in Count VII, Plaintiff's claims rest on allegedly misleading representations and statements, and yet he fails to point to any specific representation. The claim is entirely conclusory, stating generally that Medtronic made "false and misleading oral and written statements" that misled customers. (Doc. 1, ¶ 123(a)). In an attempt to provide examples, the complaint states that Medtronic made representations stating that the Device had certain characteristics that it did not, but again failed to point to any such representations or statements. (*Id*., at ¶ 123(b)-(d)). Count VIII cannot survive dismissal in face of

such factual deficiencies. As such, we will grant Medtronic's motion to dismiss Count VIII and need not reach the preemption or learned intermediary issues.

IV. CONCLUSION

For the foregoing reasons, Medtronic's motion to dismiss will be granted in part and denied in part.

NOW, THEREFORE, IT IS HEREBY ORDERED THAT:

1. Medtronic's motion to dismiss will be **GRANTED IN PART** and **DENIED** in part.
    a. The motion is **GRANTED** with respect to Counts VI, VII, and VIII.
    b. The motion is **DENIED** with respect to Counts I, II, III, and V.
2. The Clerk is directed to **TERMINATE** Medtronic Nueromodulation, Inc. as a Defendant in this action and **AMEND** Defendant "Medtronic Puerto Rico Operations, Inc." to "Medtronic Puerto Rico Operations, Co."

s/ John E. Jones III
John E. Jones III
United States District Judge