IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KATHLEEN M. FREED and RICHARD FREED,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 17-1128-CJB
ST. JUDE MEDICAL, INC., ST. JUDE MEDICAL S.C., INC., ABBOTT LABORATORIES, INC., and ADVANCED NEUROMODULATION SYSTEMS, INC., d/b/a ST. JUDE MEDICAL NEUROMODULATION DIVISION,	)	
Defendants.	)	

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Brian M. Rostocki and Benjamin P. Chapple, REED SMITH LLP, Wilmington, DE; J. David Bickham, REED SMITH LLP, San Francisco, CA; Lisa M. Baird, REED SMITH LLP, Miami, FL, Attorneys for Defendants.

MEMORANDUM OPINION

February 1, 2019
Wilmington, Delaware

Christopher J. Burke

BURKE, United States Magistrate Judge

Plaintiffs Kathleen M. Freed and Richard Freed ("Plaintiffs" or "the Freeds") bring this products liability action against Defendants St. Jude Medical, Inc., St. Jude Medical S.C., Inc., Abbott Laboratories, Inc. and Advanced Neuromodulation Systems, Inc., d/b/a St. Jude Medical Neuromodulation Division (collectively, "St. Jude" or "Defendants"). Presently before the Court is St. Jude's "Motion to Dismiss Plaintiffs' Amended Complaint[,]" filed pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motion"). (D.I. 20) For the reasons that follow, the Court GRANTS-IN-PART St. Jude's Motion.

I. BACKGROUND

A. Factual Background

St. Jude manufacturers a variety of medical devices, including the Protégé 16-Channel IPG Spinal Cord Stimulator Catalogue Number 3789, Lot Number 4699346 (hereinafter, "the SCS device"). (D.I. 19 (hereinafter, "First Amended Complaint" or "FAC") at ¶ 7) The SCS device is implanted in patients suffering from chronic lower back and lower extremity pain. (*Id.*)

In 2001, following the submission of a premarket approval ("PMA") application and review, the United States Food and Drug Administration ("FDA") issued an approval for the commercial distribution of the Genesis and Eon Family of Neurostimulation (IPG) Systems, manufactured by St. Jude. (*Id.* at ¶ 8)[1] In March 2014, the FDA issued an approval to change the name of a device in this family, the Eon Mini IPG, to the Protégé Model 3789 (i.e., the SCS device). (*Id.* at ¶ 11)

Mrs. Freed has suffered from chronic lower back and left lower extremity pain since before October 17, 2014. (*Id.* at ¶ 17) She has received various surgical and non-surgical

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[1] The PMA process will be discussed in more detail below in Section III.A.

treatments providing only modest overall relief of her pain. (*Id.*) On or about July 14, 2014, Mrs. Freed underwent a trial placement of an SCS device. (*Id.* at ¶ 18) A St. Jude representative was present during the procedure, and this representative told Mrs. Freed that she would be "very happy" with the SCS device. (*Id.*) Mrs. Freed's physician subsequently recommended that Mrs. Freed undergo surgery to have an SCS device permanently implanted for management of her chronic pain. (*Id.*) After conducting internet research (including on St. Jude's website) regarding the SCS device and alternative devices, Plaintiffs decided that Mrs. Freed would proceed with permanent implantation of the SCS device in her body. (*Id.*)

On October 17, 2014, Mrs. Freed underwent the implantation procedure at Christiana Hospital in Newark, Delaware. (*Id.* at ¶ 19) Dr. Kennedy Yalamanchili surgically implanted the neurostimulator and battery components of the SCS device in the soft tissues of Mrs. Freed's left buttocks. (*Id.*) A St. Jude representative was present at Christiana Hospital during the procedure. (*Id.*) Thereafter, Mrs. Freed met regularly with representative(s) of St. Jude and her physician(s) regarding the SCS device's performance. (*Id.* at ¶ 20)

On or about June 12, 2015, Mrs. Freed underwent further exploratory and fusion surgery on her lumbar spine by Dr. Yalamanchili at Christiana Hospital. (*Id.* at ¶ 21) Shortly thereafter, Dr. Yalamanchili prescribed the use of a bone growth stimulator to assist the healing process. (*Id.*)

When Mrs. Freed began using the bone stimulator, she experienced discomfort in her left buttocks where the neurostimulator and battery components of the SCS device had been implanted. (*Id.* at ¶ 22) The discomfort progressed such that the SCS device began giving off severely painful electrical shocks and a burning sensation throughout her left buttocks. (*Id.*) Mrs. Freed stopped using the SCS device. (*Id.*) On August 5, 2015 she went to the Emergency

Department at the Easton Hospital in Easton, Maryland due to persistent severe burning pain in her left buttocks. (*Id.*) Mrs. Freed spoke to a St. Jude representative present at the Emergency Department. (*Id.*)

Mrs. Freed then consulted with Dr. Yalamanchili and a St. Jude representative, and a medical decision was made to surgically remove the SCS device. (*Id.* at ¶ 23) On August 17, 2015, Dr. Yalamanchili performed the surgery at the Upper Bay Surgery Center in Elkton, Maryland. (*Id.*) A representative of St. Jude was present, and took possession of the neurostimulator and battery components that had been removed. (*Id.*) Plaintiffs allege that Mrs. Freed has experienced and will continue to experience severe pain and suffering and emotional distress due to the implementation of the SCS device into her body. (*See, e.g.*, *id.* at ¶ 37)

B. Procedural History

Plaintiffs filed a Complaint in the Superior Court of the State of Delaware that was removed to this Court on August 11, 2017; that Complaint asserted state law claims for injuries allegedly sustained as a result of the implementation of the SCS device. (D.I. 1) With the case now in this Court, St. Jude moved to dismiss Plaintiffs' Complaint, arguing that, *inter alia*, Plaintiffs' state law claims are preempted by federal law. (D.I. 4; D.I. 5) On September 15, 2017, United States District Judge Mark A. Kearney[2] granted St. Jude's motion without prejudice to Plaintiffs' ability to file an amended complaint. *Freed v. St. Jude Medical, Inc.*, CIVIL ACTION NO. 17-1128, 2017 WL 4102583 (D. Del. Sept. 15, 2017) (hereinafter, "*Freed I*").[3] On that same date, the parties jointly consented to the Court's authority to conduct all

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[2] At that time, this case was assigned to Judge Kearney, a judge with the United States District Court for the Eastern District of Pennsylvania. Judge Kearney was sitting as a Visiting Judge in this District when the case was assigned to him.

[3] The Court assumes familiarity herein with the *Freed I* decision.

proceedings in this case, including trial, the entry of final judgment, and all post-trial proceedings. (D.I. 18)

On October 2, 2017, Plaintiffs filed the currently operative First Amended Complaint ("FAC"). (D.I. 19) In the FAC, Plaintiffs have asserted claims under Delaware law for breach of express warranty (Count I), breach of implied warranties of merchantability and fitness for a particular purpose (Counts II and III, respectively), the manufacture and/or sale of a dangerous chattel (Count IV), and loss of consortium (Count V). (*Id.*) In lieu of filing an Answer, on October 16, 2017, St. Jude filed the instant Motion, (D.I. 20), arguing that: (1) Plaintiffs' claims remain preempted by federal law; and (2) as to all of their claims, Plaintiffs have not otherwise stated a plausible claim for relief pursuant to Federal Rule of Civil Procedure 12(b)(6), (D.I. 21). The Motion was fully briefed on November 6, 2017. (D.I. 26)

II. STANDARD OF REVIEW

The sufficiency of pleadings for non-fraud cases is governed by Federal Rule of Civil Procedure 8, which requires "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, accepting "all of the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Id.* at 210-11. Second, the court determines "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). A plausible claim does more than merely allege entitlement to relief; it must also demonstrate the basis for that "entitlement with its facts." *Id.* Thus, a claimant's "obligation to provide the 'grounds' of his

'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In assessing the plausibility of a claim, the court must "'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.'" *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).[4]

III. DISCUSSION

In *Freed I*, as noted above, Judge Kearney granted St. Jude's motion to dismiss the original Complaint without prejudice to file an amended complaint. In doing so, he found that the original Complaint did "not plausibly allege the facts necessary to avoid federal preemption[.]" *Freed I*, 2017 WL 4102583, at *1. In the instant motion, St. Jude asserts that while the *Freed I* decision "outlined the defects in the initial Complaint . . . Plaintiffs' [FAC] still has not cured the fundamental problems" and that preemption requires dismissal of Plaintiffs' claims with prejudice. (D.I. 21 at 1-2) Additionally, St. Jude asserts that Plaintiffs "still have not [otherwise] adequately stated any claim under [*Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)] and [*Ashcroft v. Iqbal*, 556 U.S. 662 (2009)], and some of their causes of action must also be dismissed on state law grounds." (*Id.* at 2)

The Court will first set out the relevant law regarding federal preemption as it relates

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[4] In resolving a motion to dismiss, a court may consider not only the allegations in the complaint, but also, *inter alia*, exhibits attached to the complaint, documents integral to or explicitly relied upon in the complaint, and matters of public record. *See, e.g., In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *Quest Integrity USA, LLC v. Clean Harbors Indus. Servs., Inc.*, C.A. No. 14-1482-SLR, Civ. No. 14-1483-SLR, 2015 WL 4477700, at *2 (D. Del. July 22, 2015).

to medical devices. Then, the Court will assess whether Plaintiffs' amended claims in the FAC warrant dismissal on the various grounds pressed by St. Jude.

A. Preemption

Preemption is a concept based on the Supremacy Clause of the United States Constitution. *See Hillsborough Cty. v. Automated Med. Labs.*, 471 U.S. 707, 712 (1985); *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 242 (3d Cir. 2008). It provides that a conflicting state law will be trumped by its federal counterpart. *Hillsborough*, 471 U.S. at 712-13; *Fellner*, 539 F.3d at 242-43. Preemption may be express or implied. *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983).

Enacted in 1976, the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA") established the federal regulatory regime for medical devices (an area that had previously been left to the states). *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008). Pursuant to the MDA, medical devices are classified into three categories, depending on the risks that they present. *Id.* at 316-17. Class III devices, like those at issue in this case, receive the greatest amount of federal oversight; they are devices used "'in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,'" or that "'present[] a potential unreasonable risk of illness or injury.'" *Id.* at 317 (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).[5] The rigorous process of federal review that new Class III medical devices undergo for the evaluation of safety and effectiveness is known as "premarket approval" (or PMA). 21 U.S.C. § 360e; *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 766 (3d Cir. 2018).

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[5] It is undisputed that the SCS device at issue in this lawsuit is a Class III device. (D.I. 21 at 3; D.I. 25 at 7)

Once a Class III device has received premarket approval, the manufacturer is not permitted to change design specifications, manufacturing processes or labeling that would affect safety or effectiveness without permission from the FDA. *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). A manufacturer seeking to make such changes must submit an application for supplemental premarket approval ("PMA Supplement") to the FDA; it must then await approval pursuant to the same rigorous standard of review that is applied during the initial PMA application process. *Id.*

The MDA also imposes reporting requirements on manufacturers following the PMA process. Manufacturers are required to "inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of . . . and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred[.]" *Id.* (citing 21 C.F.R. §§ 803.50(a), 814.84(b)(2)).

The MDA contains an express preemption provision. It provides that state laws "which relate[] to the safety or effectiveness of [a Class III medical] device" and are "different from, or in addition to" federal requirements under the MDA, are expressly preempted. 21 U.S.C. § 360k(a) ("Section 360k(a)" or "Section 360k"); *see also Shuker*, 885 F.3d at 767 ("The [MDA's] comprehensive and tiered approval procedures for medical devices leave only limited room for additional state regulation, especially considering the statute contains a broad express preemption provision."). Class III device manufacturers receive express preemption protections because the devices have undergone premarket approval, and thus such devices have been found to satisfy federal requirements applicable to the device. *Shuker*, 885 F.3d at 767; *see also Riegel*, 552 U.S. at 318 ("The FDA spends an average of 1,200 hours reviewing each [Class III medical device

application], and grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness[.]'") (quoting 21 U.S.C. § 360e(d)). In light of Section 360k(a), the Supreme Court of the United States has construed the MDA as protecting Class III device manufacturers from liability under state law tort claims if the manufacturer has complied with federal regulatory requirements. *See Riegel*, 552 U.S. at 323-24; *see also, e.g.*, *Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010) ("Generalized common law theories of liability . . . are precisely the type of claims the MDA sought to preempt."); *Millman v. Medtronic*, Civil Action No. 14-cv-1465, 2015 WL 778779, at *5 (D.N.J. Feb. 24, 2015) ("As stated by one court, '*Riegel* is loud and clear: if a manufacturer complies with the premarket approval, it gets a free pass on [products liability and implied breach of warranty] claims.'") (citation omitted).

However, "state laws are not shut out entirely" when it comes to claims against Class III device manufacturers. *Shuker*, 885 F.3d at 768. The MDA's express preemption provision does not apply to "parallel" claims—that is, to claims premised on state requirements that merely incorporate federal requirements and therefore are not "different from, or in addition to," federal requirements. *Id.* (internal quotation marks and citations omitted); *see also Riegel*, 552 U.S. at 330 (noting that Section 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") (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)); *Hart v. Medtronic, Inc.*, Civil Action No. 1:16-cv-05403 (JBS-AMD), 2017 WL 5951698, at *4 (D.N.J. Nov. 30, 2017) (explaining that *Riegel* recognized that "claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's premarket approval are not preempted. . . . because they merely parallel federal requirements—that is, they

do not add to or differ from federal requirements, which is the cornerstone of" the MDA's medical device preemption).

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court established a two-step form of analysis for determining whether a claim is expressly preempted pursuant to the MDA. 552 U.S. at 321-22. First, the court must determine whether the FDA has established requirements applicable to the medical device at issue. Here, that step is not at issue, for it is undisputed that the SCS device is a Class III device, and the Supreme Court has held that any Class III device receiving PMA approval from the FDA will satisfy this first step in the analysis. *Id.* at 322 ("Premarket approval . . . imposes 'requirements' under the MDA[.]"); *Hart*, 2017 WL 5951698, at *3.[6] Second, the court must determine whether the plaintiffs' state law claims relate to safety and effectiveness and impose requirements that are "different from, or in addition to"

[6] In connection with St. Jude's motion to dismiss the original Complaint, Plaintiffs had argued that the battery of the SCS device was a separate component from the device itself, and that to the extent that the battery component of the device caused Mrs. Freed's injuries, such allegations would not be preempted by Section 360k(a) of the FDCA. (D.I. 14 at 9-13) In *Freed I*, however, Judge Kearney ruled that Plaintiffs did not actually plead that the battery was separate and distinct from the SCS device itself, such that it underwent a separate review process from the pulse generator. *Freed I*, 2017 WL 4102583, at *4-5. Judge Kearney also noted that Plaintiffs did not cite to any cases in which the battery in a spinal stimulation device was deemed to be separate from the device for preemption purposes. *Id.* at *4. Accordingly, Judge Kearney concluded that based on the then-current allegations in the original Complaint, the "[d]evice includes the battery and is subject to federal regulation and the MDA's express preemption." *Id.* at *5. The Court notes that the FAC does now include an allegation stating that 21 C.F.R. § 807.65 exempts manufacturers of raw materials or components from FDA regulation, and that upon information and belief, "the battery used in the SCS device is a component part manufactured by another and . . . is not subject to FDA regulation." (FAC at ¶ 13) However, in their answering brief in opposition to the Motion, Plaintiffs simply assert that it is undisputed that the "SCS [device] implanted in Mrs. Freed's body is a Class III device." (D.I. 25 at 7) They make no argument that preemption does not apply here as to the battery. Thus, the Court considers it undisputed that the first step in the preemption analysis has been satisfied; Plaintiffs have waived any argument to the contrary.

those imposed by federal law. *Riegel*, 552 U.S. at 321-22 (internal quotation marks and citation omitted). If they do, those claims are expressly preempted. *Id.* at 330.

The parallel claim exception to preemption requires more than just the use of certain terminology; a plaintiff "cannot simply incant the magic words 'Defendant violated FDA regulations' in order to avoid preemption." *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 598 (D.N.J. 2015) (certain internal quotation marks, brackets and citations omitted); *see also Smith v. Depuy Orthopaedics, Inc.*, Civil Action No. 11-4139 (JAP), 2013 WL 1108555, at *12 (D.N.J. Mar. 18, 2013) ("[B]road references to federal regulations in pleadings are insufficient [to properly plead a parallel claim].") (internal quotation marks and citations omitted). Rather, a plaintiff must plead "facts showing action or inaction in [the] defendants' efforts to take part in the PMA process or implement its results." *Smith*, 2013 WL 1108555, at *12 (internal quotation marks, brackets and citation omitted). In sum, a "parallel claim," like any other claim, is subject to the pleading standards of *Twombly* and *Iqbal*. *Hart*, 2017 WL 5951698, at *5.

Moreover, in addition to the MDA's express preemption clause, the MDA provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), the Supreme Court construed this provision as barring suits by private litigants "for noncompliance with the medical device provisions." 531 U.S. at 349 n.4. To avoid implied preemption under *Buckman*, a claim must assert violation of a state tort duty that also violates some FDA requirement. *See Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 775 (5th Cir. 2011). That is, the conduct on which the plaintiffs' claim is premised must be the type of conduct that would traditionally give rise to liability under state law, and that would give rise to liability under state law even if the FDCA

had never been enacted. *Yosowitz v. Covidien LP*, 182 F. Supp. 3d 683, 690 (S.D. Tex. 2016); *see also, e.g.*, *Bull v. St. Jude Med., Inc.*, CIVIL ACTION NO. 17-1141, 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018) ("State law claims that allege liability based on a common law tort theory and which parallel federal law claims . . . are not impliedly preempted under *Buckman*."). If the defendant's conduct is not of this type, then (regardless of how the plaintiff has labeled the claim) the claim is impliedly preempted under *Buckman* because the plaintiff is effectively suing for a violation of the FDCA. *Yosowitz*, 182 F. Supp. 3d at 690.

B. Analysis of the FAC's Claims

In *Freed I*, Judge Kearney concluded that Plaintiffs' state law claims, as alleged in the original Complaint, were all expressly preempted by federal law because they were all theories of liability relating to the safety or effectiveness of the SCS device and Plaintiffs failed to plead facts sufficient to show that the claims did not impose requirements that were "different from, or in addition to" those imposed by federal law. Plaintiffs had conceded that their original Complaint failed to reference specific federal regulations, but they had argued that "their claims are parallel to federal requirements, pointing [in their briefing] to federal regulations pertaining to labeling and compliance with good manufacturing practices post-approval[.]" *Freed I*, 2017 WL 4102583, at *6. But ultimately, Plaintiffs' "fail[ure] to plead the Device failed to comply with a federal regulation" doomed the claims of the original Complaint. *Id.*

With the instant Motion, St. Jude contends that Plaintiffs' FAC is "hardly different" from their original Complaint. (D.I. 21 at 2) While St. Jude acknowledges that Plaintiffs' FAC now cites to federal regulations, (D.I. 26 at 2), it asserts that Plaintiffs "still have not 'plausibly allege[d] the facts necessary to avoid federal preemption[,]'" (D.I. 21 at 2 (quoting *Freed* I, 2017 WL 4102583, at *1); *see also* D.I. 26 at 2-3). St. Jude also argues that Plaintiffs do not otherwise

plead sufficient facts to make out plausible claims under the *Twombly/Iqbal* pleading standard. For these reasons, according to St. Jude, the FAC must be dismissed with prejudice. (D.I. 21 at 1-2)

Below, the Court will assess each of Plaintiffs' claims, in the order they are listed in the FAC.

1. Breach of Express Warranty (Count I)

St. Jude argues that Plaintiffs' breach of express warranty claim in Count I remains preempted. Section 2-313 of Title 6 ("Section 2-313") of the Delaware Code explains that an express warranty by the seller is created as follows:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the description.
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> (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

Del. Code tit. 6, § 2-313(1); *see also Freed I*, 2017 WL 4102583, at *6 n.42. However, under Delaware law, "an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty." Del. Code tit. 6, § 2-313(2).

St. Jude asserts that Count I still lacks any allegations of a violation of a federal regulation and otherwise fails to explain how such a federal regulation imposes duties that are parallel to Delaware law. (D.I. 21 at 10-11; D.I. 26 at 3-5) Additionally, St. Jude asserts that

even setting preemption aside, Plaintiffs' breach of express warranty claim is not adequately pleaded under *Twombly/Iqbal*.

Turning to the substance of Count I's breach of express warranty claim, what is the express warranty that St. Jude purportedly made to Plaintiffs? Plaintiffs' FAC includes the following allegations (with the language that is not in the original Complaint, but that was added in the FAC, emphasized):

> 18. On or about July 14, 2014 Mrs. Freed underwent a trial placement of a St. Jude spinal cord stimulator system. A representative from St. Jude was present during this procedure. *The representative informed Mrs. Freed that she would be "very happy" with the SCS device. Plaintiffs relied upon this statement in deciding to proceed with the trial. . . . Before deciding to proceed with permanent implantation of the SCS device Plaintiffs did their own research on the internet as to both the SCS device and other alternative devices. Based on what they read on St. Jude's website Plaintiffs were satisfied that the SCS device was safe and of good quality. Plaintiffs relied upon the information on St. Jude's website in deciding to proceed with the permanent implant. . . .*
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> 25. Through its marketing materials, *its website*, the statements of its representatives, and the published materials provided to *Mrs. Freed and* physicians such as *Drs. Ganesh Balu and* Kennedy Yalamanchili, St. Jude expressly *affirmed as fact and/or promised* that the SCS device was free of defects, designed for safe use in the management of chronic low back and lower extremity pain, safe for implantation in the human body, *and in conformity with the sample or model that had been used on a trial basis before the permanent implantation.*

(FAC at ¶¶ 18, 25) In reading the above allegations, it becomes clear that the FAC only details the *actual substance* of one statement that is said by Plaintiffs to amount to an express warranty: the statement made to Mrs. Freed by an unnamed St. Jude sales representative prior to Mrs. Freed's trial placement of the SCS device (i.e., that Mrs. Freed would be "very happy" with the

device). That is the only fleshed-out allegation that could possibly provide the basis for this claim. And so it is the only allegation that the Court will further assess below.[7]

As to that statement, the Court agrees with St. Jude that the sales representative's alleged warranty amounts to nothing more than the giving of an opinion; thus, it cannot create an express warranty. (D.I. 26 at 3 n.2) The parties cited to no Delaware state caselaw that examines what

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[7] The only other representations that Plaintiffs rely on with respect to their breach of express warranty claim are the above-referenced statements from Defendants' website. (D.I. 25 at 16) Plaintiffs acknowledge, however, that they do not know and cannot recall the "specific representations made to Mrs. Freed . . . contained in any website materials . . . made available to her at the time." (*Id.* at 16 n.7) Plaintiffs nevertheless assert that what they have pleaded about those website representations is sufficient to make out a claim for breach of express warranty. They argue that these referenced statements amount to a representation from St. Jude that Plaintiffs would have "a general satisfaction with the quality and safety of the SCS device." (*Id.* at 16) The Court cannot agree. As St. Jude points out, if "affirmations of fact and promises were made to, and relied on, by Ms. Freed—by definition—she should know exactly what those were." (D.I. 21 at 14) And in the absence of anything more being alleged about exactly what these representations were, the Court cannot know what statements made on the website are supposed to have "satisfied [Plaintiffs] that the SCS device was safe and of good quality[.]" Thus, the Court cannot, *inter alia*, assess whether such statements were specific enough that they amount to more than just the expression of opinion (so as to sufficiently plead a claim under Delaware law). *Cf. Shuker v. Smith & Nephew PLC*, Civil Action No. 13-6158, 2015 WL 1475368, at *12 (E.D. Pa. Mar. 31, 2015) (finding the plaintiffs' breach of express warranty claim to be inadequately pleaded where, *inter alia*, the plaintiffs failed to adequately describe the content of the warranty); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 707 (S.D. Tex. 2014) ("While conceptually an express warranty claim could avoid express preemption, what is missing from [the plaintiff's] complaint, in its current form, is a description of what specific warranties [the defendant] made to [the plaintiff] or her physicians[.]"); *Killen v. Stryker Spine*, Civil Action No. 11-1508, 2012 WL 4482371, at *14 (W.D. Pa. Aug. 21, 2012) ("Without factual support, description of a specific promise that became the basis of a bargain, or a showing that the promise was directed at her, [the plaintiff's] express warranty claim cannot escape dismissal."); *Doughtery v. C.R. Bard, Inc.*, Civil Action No. 11-6048, 2012 WL 2940727, at *9 n.15 (E.D. Pa. July 18, 2012) (explaining that to allege sufficient facts to support an inference that an express warranty was created, the plaintiff should include "the specific source of the alleged warranty (e.g., a publication or package insert) and the specific statements made"); *Parker v. Howmedica Osteonics Corp.*, Civil Action No. 07-02400 (JLL), 2008 WL 141628, at *6 (D.N.J. Jan. 14, 2008) (finding that allegations that the express warranties came in the form of publicly made "written and verbal assurances of safety" and press releases and promotional information "intended to create demand" for the medical device at issue constituted "exactly the type of 'bald assertions' that fail to give" the defendant fair notice of what the claim is and the grounds upon which it rests).

amounts to a statement of opinion for purposes of Section 2-313. (D.I. 25 at 17; D.I. 26 at 3 & n.2) But at least one court assessing the statute has opined that a statement amounts to more than mere "'seller's talk' or puffing" if it is "product-specific and not overly broad or vague." *Matter of L.B. Trucking, Inc.*, 163 B.R. 709, 720 (Bankr. Del. 1994); *cf. Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 945 (3d Cir. 1993) ("Puffery is an exaggeration or overstatement expressed in broad, vague, and commendatory language."); *Airborne Health, Inc. v. Squid Soap, LP*, C.A. No. 4410-VCL, 2010 WL 2836391, at *8 (Del. Ch. July 20, 2010) (noting, in assessing whether a party made a false representation of material fact, that "puffery" is "a 'vague statement' boosting the appeal of a service or product that, because of its vagueness and unreliability, is immunized from regulation") (certain internal quotation marks and citation omitted). The St. Jude sales representative's statement that Mrs. Freed would be "very happy" with the SCS device amounts to the promotion of a vague, subjective opinion. It is decidedly unclear as to what it is about the SCS device that, according to the representative, Mrs. Freed would be "very happy" with. Thus, it is impossible to pin down the nature of the specific fact or promise that the representative was making to Mrs. Freed about the device and/or how the device would perform. *See, e.g.*, *Arthur v. Medtronic, Inc.*, 123 F. Supp. 3d 1145, 1151 (E.D. Miss. 2015) (finding, in assessing a motion to dismiss, that plaintiff's breach of express warranty claim failed where it rested on allegations that defendants' sales representatives told her surgeon that it was "appropriate to use Infuse for her surgery," even though it had not been approved for such uses, as such a statement "amount[s] to no more than opinion[,]" since it was "not capable of determination"); *Rapid Models & Prototypes, Inc. v. Innovated Solutions*, Civil No. 14-277 (NLH/KMW), 2015 WL 4914477, at *5 (D.N.J. Aug. 18, 2015) (assessing a motion to dismiss and holding that an allegation in the complaint stating that the device was the "most robust system in the industry" was a highly

subjective, non-specific statement of opinion that could not create an express warranty) (internal quotation marks and citation omitted).[8] Count I should thus be dismissed with prejudice.[9]

2. Breach of Implied Warranty of Merchantability and Breach of Implied Warranty of Fitness for a Particular Purpose (Counts II and III)

St. Jude asserts that Plaintiffs' claims for breach of implied warranty of merchantability (Count II) and breach of implied warranty of fitness for a particular purpose (Count III)[10] remain preempted because they repeat, nearly verbatim, the implied warranty allegations found in the original Complaint. (D.I. 21 at 11) The only new allegations in the FAC for these claims are found in italics below:

> 33. *Through its marketing materials, its website, the statements of its representatives, and the published materials provided to Mrs. Freed and her physicians*, St. Jude impliedly warranted that the SCS device was of merchantable quality and fit for the ordinary

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[8] *Cf. Gammel v. Hewlett-Packard Co.*, 905 F. Supp. 2d 1052, 1071 (C.D. Cal. 2012) (finding, in assessing securities fraud claims, that a remark that "'we're very happy with the [TouchPad] ramp [and] we'll continue to invest very aggressively,' qualifies as puffery") (citation omitted) (alterations in original).

[9] Because the Court has determined that Plaintiffs have not sufficiently pleaded a breach of express warranty claim due to the failure to allege anything more than the seller's expression of opinion or commendation regarding the goods, the Court need not assess whether a claim based on the representation would be preempted by Section 360k.

[10] To make out a claim of breach of the implied warranty of merchantability under Delaware law, a plaintiff must prove: (1) that a merchant sold the goods; (2) which were defective at the time of sale; (3) causing injury to the ultimate consumer; (4) the proximate cause of which was the defective nature of the goods; and (5) that the seller received notice of the injury. *Reybold Grp., Inc. v. Chemprobe Techs., Inc.*, 721 A.2d 1267, 1269 (Del. 1998). To support a claim of breach of the implied warranty of fitness for a particular purpose under Delaware law, a plaintiff must show that: (1) he had a special purpose for the goods; (2) the seller knew or had reason to know of that purpose; (3) the seller knew or had reason to know the buyer was relying upon the seller's superior skill to select goods that fulfilled that purpose; and (4) the buyer in fact relied upon the seller's skill. *See Emmons v. Tri Supply & Equip. Inc.*, C.A. No. N10C-09-172 EMD, 2013 WL 4829272, at *5 (Del. Super. Ct. July 29, 2013) (citing Del. Code tit. 6, § 2-315).

> purposes for which such devices are implanted in the human body *within the meaning of 6 Del. C. 2-314.*
>
> 34. *Mrs. Freed relied upon their representations in deciding to have the SCS device implanted in her body.*

(FAC at ¶¶ 33-34; *see also id.* at ¶¶ 41-42) St. Jude argues that these claims still lack any allegations of a violation of a federal regulation and are expressly preempted since they seek to impose state law requirements that are different from, or in addition to, federal requirements. (D.I. 21 at 11)

State law claims for breach of implied warranty may be preempted to the extent that they impose new or additional requirements on manufacturers beyond the federal regulations governing the medical device at issue. *Riegel*, 128 S. Ct. at 1009-10; *Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301, 308 (E.D. Pa. 2009), *aff'd*, 388 F. App'x 169 (3d Cir. 2010); *see also Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 482 (W.D. Pa. 2012).[11] In *Freed I*, Judge Kearney explained that in the original Complaint, Plaintiffs "fail[ed] to explain the basis" of their breach of implied warranty claims in that they had not pleaded facts sufficient to demonstrate why that claim was not preempted by Section 360k. *Freed I*, 2017 WL 4102583, at *7. The FAC does not resolve this deficiency. Counts II and III do not allege violation of any federal regulations, nor do they plead facts setting out the specifics of the breaches at issue. Moreover, in those counts, Plaintiffs do not further "explain" how such implied warranty claims may escape preemption here. Additionally, Plaintiffs' answering brief is of no help, since it does not even address St. Jude's arguments as to the claims for breach of implied warranty. Though the brief

[11] Unlike express warranties which arise from the representations of the parties that are made the basis of the bargain, implied warranties "arise by operation of state law." *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1325 (3d Cir. 1995) (internal quotation marks, citation and brackets omitted), *overruled on other grounds by Lohr*, 518 U.S. at 495.

has a section entitled "Plaintiffs' Warranty Claims[,]" that section solely argues why Plaintiffs' *express warranty* claims should be allowed to proceed; the section is silent with respect to the claims for breach of implied warranty. (*See* D.I. 25 at 15-17)

For all of these reasons, the Court finds that Counts II and III should be dismissed with prejudice. *See Cavender v. Medtronic, Inc.*, Case No. 3:16-CV-232, 2016 WL 6599744, at *6 (N.D. Ind. Nov. 8, 2016) (dismissing a claim for breach of implied warranties where the complaint did not allege "exactly what . . . implied warranties Medtronic extended and how they were breached (and whether and how they were relied upon)").

3. Count IV

Plaintiffs assert that subsumed within Count IV of their FAC (titled "Manufacture or Sale of a Dangerous and/or Adulterated Chattel") are claims that the SCS device was: (1) dangerous or defective as a result of a failure to inform or warn of its dangerous propensities (the "failure to warn" claim); and (2) negligently manufactured. (D.I. 25 at 10) St. Jude moves for dismissal of both types of claims.

In Count IV, Plaintiffs now allege that, *inter alia*: (1) St. Jude had manufactured or sold a variety of spinal cord stimulator devices with components including batteries that caused bodily injury to patients like Mrs. Freed; (2) St. Jude has conducted recall campaigns for various such devices; (3) the SCS device implanted in Mrs. Freed was defective; and (4) St. Jude failed to properly warn Mrs. Freed of the relevant hazards as mandated by the FDA in various regulations, including 21 C.F.R. §§ 801.109, 814.39 and 814.82(a)(9). (FAC at ¶¶ 50-52, 54)

Moreover, in an earlier section of the FAC, Plaintiffs included additional allegations (not in the original Complaint) fleshing out these assertions in Count IV. For example, Plaintiffs

allege there, (FAC at ¶ 12), that the Genesis and Eon family of neurostimulator devices has been the subject of numerous recall campaigns since 2001, including:

- On May 24, 2011, St. Jude initiated a recall for the Eon Mini IPG device to address a defective battery following reports that the battery was causing an inability to communicate with or recharge the device. (*Id.*)

- On December 19, 2011, St. Jude initiated a recall following 112 similar complaints of the device losing its ability to communicate with or recharge the unit, resulting in the device's failure to relieve pain and subsequent explant. (*Id.*)

- On that same date, St. Jude initiated a second recall in light of 110 complaints of warmth or heating at the implantable pulse generator (or "IPG") implant site during charging for the Eon IPG and 116 similar reports involving the Eon Mini IPG. (*Id.*)

- On September 4, 2012, St. Jude initiated a recall for the Eon Mini IPG manufactured in April 2012 that "could potentially exhibit a sudden, brief surge in stimulation that would be felt by the patient as uncomfortable or painful[,]" and St. Jude recognized that the internal battery could come into contact with the internal microcontroller board. (*Id.* (internal quotation marks omitted))

- On July 26, 2012, St. Jude initiated three separate recalls relating to certain Eon devices after receiving numerous reports in which "discomfort [was] associated with heating around the device site while patients are using the charging system to charge their spinal cord stimulator." (*Id.* (internal quotation marks omitted)) Three patients suffered burn injuries at the site of implantation. (*Id.*)

The FAC also includes new allegations further describing a manufacturer's duty (pursuant to 21 C.F.R. §§ 801.109 and 814.39) to submit a PMA supplement for any proposed labeling changes that affect the safety of the device, and its duty to submit an Adverse Reaction Report or Device Defect Report to the FDA (pursuant to 21 C.F.R. § 814.82(a)(9)) soon after it receives knowledge of an adverse reaction or injury that is attributable to the device that has not been addressed by the device's labeling. (*Id.* at ¶¶ 9, 14, 15) Plaintiffs further allege in the FAC that

while St. Jude has submitted 109 supplements to the original PMA approval for the Genesis family of devices, none of the supplements relate to the battery component of the SCS device. (*Id.* at ¶¶ 10, 14, 15) And they allege that there is no indication that St. Jude submitted any Adverse Reaction Reports or Device Defect Reports before or after the SCS device was implanted into Mrs. Freed's body. (*Id.* at ¶ 15)

With the specifics of Count IV's allegations now set out, the Court will address St. Jude's challenges to Plaintiffs' failure to warn and negligent manufacturing claims.

a. Failure to Warn Claim

Although the FAC does not expressly make this clear, Plaintiffs' failure to warn claim under Delaware law is premised on Section 388 of the Restatement (Second) of Torts ("Section 388"), s*ee* (D.I. 14 at 16); *Freed I*, 2017 WL 4102583, at *6 & n.38, which has been adopted by Delaware courts, *see, e.g.*, *Ramsey v. Georgia S. Univ. Advanced Dev. Ctr.*, 189 A.3d 1255, 1261 (Del. 2018); *Graham v. Pittsburgh Corning Corp.*, 593 A.2d 567, 569 (Del. Super. Ct. 1990).[12] St. Jude asserts that Plaintiffs' failure to warn claim remains preempted, because while the FAC adds a list of allegedly-violated federal regulations, it still lacks factual allegations necessary to support these assertions. (D.I. 21 at 11-12)

[12] Section 388 ("Chattel Known to be Dangerous for Intended Use") states that "[o]ne who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person whose use it is supplied, if the supplier (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and (c) *fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.*" Restatement (Second) of Torts § 388 (emphasis added).

In response, Plaintiffs explain that a "number of courts" have allowed failure to warn claims to proceed over preemption arguments where the plaintiff's allegations were based on the manufacturer's failure to comply with FDA regulations—such as a manufacturer's failure to report serious injuries and adverse events relating to the device (as is required by the FDA). (D.I. 25 at 14-15 (citing cases)) One such decision is *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013). In that case, the United States Court of Appeals for the Ninth Circuit concluded that when a failure to warn claim is based on the manufacturer's "'continuing duty 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[,]'" such a claim would not be preempted by the MDA. *Stengel*, 704 F.3d at 1232-33. This was because the relevant Arizona state law at issue in the case imposed a duty for a manufacturer to warn "a third party such as the FDA" of product dangers, and allowed that a warning to a third party satisfies this duty if there is "reasonable assurance that the information will reach those whose safety depends on their having it." *Id.* at 1233 (internal quotation marks and citation omitted). This Arizona state-law duty was thus said to "parallel[] a federal-law duty under the MDA." *Id.*[13] In *Freed I*, Judge Kearney recognized this line of caselaw. But he concluded that Plaintiffs' failure to warn claim was insufficient

[13] The United States Court of Appeals for the Fifth Circuit has also reached a similar conclusion, explaining that a plaintiff's failure to warn claim alleging that the manufacturer failed to report serious injuries and malfunctions of a medical device as required by federal regulations was not expressly preempted. *Hughes*, 631 F.3d at 770-71. The Fifth Circuit explained that these regulations are related to the manufacturer's duty to provide the FDA with information regarding a device's safety and effectiveness, which is then disseminated to the public. *Id.* A manufacturer's failure to provide such information to the FDA is a parallel violation of a state duty (there, a duty provided by Mississippi law) to provide reasonable and adequate information regarding a product's risks. *Id.*

because the original Complaint did "not allege St. Jude failed to report problems with the Device to the FDA as required by federal regulation." *Freed I*, 2017 WL 4102583, at *6.

St. Jude challenges the FAC's failure to warn claim in various ways, which the Court will take up below.

i. Defendants' Argument that the Court Should Not Follow the *Stengel* Line of Caselaw

One of St. Jude's arguments with respect to Plaintiffs' failure to warn claim is that the Court should not follow the *Stengel* line of caselaw. (D.I. 26 at 6-7) St. Jude sets out two reasons for its argument in this regard.

First, St. Jude asserts that while the *Stengel* Court was considering an Arizona law that "contemplates a warning to a third party such as the FDA[,]" *Stengel*, 704 F.3d at 1233, "Plaintiffs here have not cited any *Delaware law* which establishes a duty to warn—or report adverse events to—a government agency such as the FDA[,]" (D.I. 26 at 7 (emphasis added)). St. Jude thus asserts that if Plaintiffs are making a claim in Count IV for failure to report adverse events to the FDA, that necessarily is a claim that arises solely under the FDCA, and thus it would be impliedly preempted. (*Id.*)

It does not appear that the United States Court of Appeals for the Third Circuit has directly addressed this issue.[14] However, other district courts in this Circuit have concluded that

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[14] Recently, after briefing had closed on the instant Motion, the Third Circuit issued its decision in *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760 (3d Cir. 2018). *Shuker* addressed how courts should apply Section 360k(a)'s express preemption provision to claims challenging the design and manufacturer of a medical device comprised of multiple components, some of which were from Class III medical devices and some of which were from other classes of medical devices. While the Third Circuit found the plaintiff's failure to warn claims to be preempted, there the claims on appeal did not appear to allege that the manufacture failed to report problems with the device to the FDA. *Shuker*, 885 F.3d at 775. The plaintiffs had earlier asserted a claim based on the defendants' failure to report to the FDA adverse events associated with the use of a medical device; however, the district court found that such claim was not

state law failure to warn claims premised on Section 388, which focus on a manufacturer's failure to report adverse events to the FDA, are not preempted. *See, e.g.*, *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 899-900 (M.D. Pa. 2017); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 837-38 (E.D. Pa. 2016). These courts were analyzing Pennsylvania state law; Pennsylvania, in turn, has adopted Section 388 and imposes a duty on a manufacturer to warn a third party of a product's dangerous propensities, where there is reasonable assurance that the information will reach those whose safety depends on such information.[15] These courts have ruled that this duty is "parallel to FDA reporting requirements because it may impose liability [on manufacturers] for the failure to report to the FDA." *Silver*, 236 F. Supp. 3d at 900; *see also McLaughlin*, 172 F. Supp. 3d at 838. The *Silver* Court also explained that the FDA may be reasonably relied upon to disclose information regarding medical device failures to product

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sufficiently pleaded because: (1) plaintiffs did not specify the adverse events that the defendants failed to report; and (2) plaintiffs did not plead facts supporting a plausible inference that had the undisclosed adverse events been reported to the FDA, such information would have reached the plaintiff's physician in time to prevent the plaintiff's injuries. *Shuker*, 2015 WL 1475368, at *15-16. The district court thus dismissed this claim with prejudice. *Id.* at *16. On appeal, the plaintiffs did not attempt to revive the claim, and instead rested on amended claims involving off-label promotion that were asserted in their Third Amended Complaint. *Shuker*, 885 F.3d at 774 n.13.

[15] Pennsylvania state courts have explained that comment n to Section 388 provides that:

> [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 v. A.P. Green Refractories Co., 630 A.2d 874, 882 (Pa. Super. Ct. 1993) (citing Restatement (Second) of Torts § 388 cmt. n) (cited in *Silver*, 236 F. Supp. 3d at 900).

users, in that the FDA posts such information to a publicly accessible database as a means of warning the public and physicians. *Silver*, 236 F. Supp. 3d at 899-900.

To be sure, it would have been better if Count IV had made specific reference to Section 388. But in light of the fact that Delaware has also adopted Section 388, and in light of the substance of Count IV's allegations, the Court concludes that St. Jude's argument that Plaintiffs have not cited any *Delaware law* that establishes a duty to report adverse events to the FDA is without merit.

Second, St. Jude argues that the *Stengel* line of caselaw should not be followed because *Stengel* and its progeny wrongly *assume* that the reporting of a device's adverse events to the FDA would reach physicians (and in turn, the patients)—thus satisfying Section 388's requirement that there be a reasonable assurance that the warning at issue will reach those whose safety depends on it. (D.I. 26 at 7) As discussed above, courts like *Silver* that follow *Stengel* have reasoned that "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." *Silver*, 236 F. Supp. 3d at 899 (internal citation omitted). Yet other courts have pushed back against this line of reasoning. Those courts have asserted that adverse event reports "are not automatically made public" because while the FDA "'*may* disclose' adverse-event reports, it is not required to do so." *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005 (S.D. Ohio 2016) (citing 21 C.F.R. § 803.9(a)) (emphasis in original) (certain quotation marks and citations omitted); *see also, e.g.*, *Pinsonneault v. St. Jude Med., Inc.*, 953 F. Supp. 2d 1006, 1016 (D. Minn. 2013).

In the Court's view, if a complaint includes factual allegations that address *why* it is plausible that a manufacturer's failure to report adverse events to the FDA would have reached physicians (and ultimately the plaintiff) and would have impacted the decision to use the medical

device at issue, then such allegations would address the concern expressed by this latter group of courts. *See Mayer v. Belichick*, 605 F.3d 223, 229 (3d Cir. 2010) (explaining that under Rule 12(b)(6), courts must "accept all factual allegations in the complaint as true, construe the complaint in the light most favorable to the plaintiff, and ultimately determine whether plaintiff may be entitled to relief under any reasonable reading of the complaint"). While the FAC does not currently include such allegations, those allegations relate to the causal nexus element of a failure to warn claim, which the Court will discuss in more detail below.

ii. Defendants' Arguments that the Failure to Warn Claim is Inadequately Pleaded

The Court next turns to St. Jude's various arguments as to why the failure to warn claim is insufficiently pleaded.

St. Jude first argues that Plaintiffs' allegations are "too general and vague" because they do "not identify any supposed adverse event that [D]efendants supposedly had a duty to report[.]" (D.I. 26 at 6) But, as was described above, the FAC *does* now list specific federal requirements with which St. Jude purportedly failed to comply. (FAC at ¶ 54) And it *does* also list the adverse events that Plaintiffs allege St. Jude had a duty to report, pursuant to these requirements (i.e., the various recalls involving the Genesis and Eon family of neurostimulator devices, and the related complaints of battery defects, pain, discomfort and burning). (*Id.* at ¶¶ 12, 15) And it *does* allege that "there is no indication" that St. Jude actually "complied with or took action to supplement its labeling or notify patients . . . of the specific hazards alleged in this Complaint" and that there is no indication that St. Jude submitted any required adverse event report to the FDA. (*Id.* at ¶¶ 14-15) Thus, St. Jude's assertions of deficient pleading in this regard are without merit. *See, e.g.*, *A.F. By & Through Fogel v. Sorin Grp. USA, Inc.*, — F. Supp. 3d —, 2018 WL 4680022, at *5-7 (S.D.N.Y. Sept. 28, 2018) (finding that the plaintiffs

plausibly alleged a failure to warn claim where, *inter alia*, plaintiffs alleged specific deficiencies in the timeliness and content of the defendants' reports to the FDA regarding the device's adverse effects and identified FDA regulations requiring such reports, including 21 C.F.R. § 814.82); *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742-43 (D. Md. 2015) (finding that plaintiffs' failure to warn claim was not preempted and was plausibly pleaded, where the complaint alleged that defendant had the duty to comply with the PMA requirements set out in the device's approval order and enclosed conditions of approval but failed to comply with those duties, as defendant received over 600 adverse event reports yet delayed production of the reports to the FDA and followed up on only two percent of them); *cf. Chester v. Boston Sci. Corp.*, Civil Action No. 16-02421 (FLW), 2017 WL 751424, at *9 (D.N.J. Feb. 27, 2017) (finding that plaintiff did not plausibly allege a violation of an FDA regulation sufficient to state a parallel claim where it provided a "laundry list" of FDA regulations with which defendants were obligated to comply, including 21 C.F.R. § 814.39, but did not plausibly plead how, if or when defendants violated any of the listed regulations).

St. Jude next argues that Plaintiffs did not adequately plead a causal nexus between St. Jude's alleged failure to report adverse events (on the one hand) and Mrs. Freed's injuries (on the other). (D.I. 26 at 6) Here, the Court agrees with St. Jude.

The FAC does not allege that had St. Jude reported certain adverse events to the FDA, this information would have reached Mrs. Freed's physicians (and ultimately her) and would have impacted Mrs. Freed's decision to have the SCS device implanted in her body. Relatedly, the FAC does not explain how the reporting of such adverse events to the FDA would have prompted the FDA to take an action that would have made the information available to Mrs. Freed and her physician. Courts recognize that a plaintiff making this type of failure to warn

claim must allege that the plaintiff would not have utilized the medical device at issue had the manufacturer disclosed the allegedly withheld information. *See, e.g.*, *Bull*, 2018 WL 3397544, at *9 (finding that plaintiff's claim plausibly alleges the requisite causal nexus between defendant's alleged violation of its duty to report adverse events and the plaintiff's injury, where the plaintiff alleged that had information regarding adverse events been made publicly available prior to the implantation of the device, she and her physicians would not have chosen to implant the device).[16] Thus, the claim is insufficiently pleaded on this ground.

St. Jude argues that dismissal of Plaintiffs' claims should be with prejudice at this juncture. However, the causation issue was not addressed by the *Freed I* Court, and therefore the Court will permit Plaintiffs one final opportunity to amend their failure to warn claim in this regard.[17] In

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[16] *See also Gravitt v. Mentor Worldwide, LLC*, 289 F. Supp. 3d 877, 891 (N.D. Ill. 2018) (finding that plaintiff's failure to warn claim was adequately pleaded where, *inter alia*, as to causation, the complaint plausibly alleges that the plaintiff would not have consented to an implant procedure had she known the true risk of device rupture, and that, were her physicians to have been informed of those risks, they would not have recommended that she undergo the procedure); *Martin v. Medtronic, Inc.*, No. 1:15-cv-00994-DAD-MJS, 2017 WL 4574160, at *7 (E.D. Cal. Oct. 13, 2017) (dismissing the plaintiff's failure to warn claim because the complaint did not allege facts addressing how any failure to report certain adverse events to the FDA ultimately caused plaintiff's injury); *Fisk v. Medtronic, Inc.*, Case No. 3:17-CV-032 JD, 2017 WL 4247983, at *7 (N.D. Ind. Sept. 25, 2017) (finding that the plaintiff adequately pleaded a causal connection between a violation of a federal requirement and her injury with respect to her failure to warn claim, where she alleged that had the defendant timely notified the FDA of the known problems and defects, she and her doctors would have learned of those dangers and would have removed the medical device); *McLaughlin*, 172 F. Supp. 3d at 836-38 (denying the defendant's motion to dismiss the plaintiff's negligent failure to warn claim where, *inter alia*, the complaint alleged that the plaintiffs would not have had the medical device implanted if the defendant had disclosed the withheld information); *cf. Hughes*, 631 F.3d at 776 (explaining that a Mississippi negligence claim could only succeed if plaintiff could prove that the defendant's violation caused the plaintiff's injury, and that the plaintiff's primary causation theory with respect to the failure to warn claim was that if the manufacturer had reported the true number of injuries and malfunctions caused by the device at issue, such information would have appeared in the FDA's internet database and in medical journals, and with such information the plaintiff would not have chosen the device as a treatment option).

[17] In light of this holding, the Court will not address St. Jude's argument that Plaintiffs' failure to warn claim is barred by the learned intermediary doctrine because there are

doing so, Plaintiffs should also make expressly clear that this claim is based on Restatement (Second) of Torts § 388, which has been adopted by Delaware law.

b. Negligent Manufacturing

As noted above, Plaintiffs also assert that "[s]ubsumed" in Count IV is a claim for negligent manufacturing. (D.I. 25 at 10) St. Jude retorts that no such claim exists in the FAC. (D.I. 26 at 8)

In order to make out a negligent manufacture claim under Delaware law, a plaintiff must plead the nature of the defect, the specific cause of the defect, the duty owed by the defendant to its customers, the breach of the duty by the defendant and damages resulting from the breach. *See Rinaldi v. Iomega Corp.*, No. 98C-09-064-RRC, 1999 WL 1442014, at *7 (Del. Super. Ct. Sept. 3, 1999); *see also Baylis v. Red Lion Grp., Inc.*, 214 F. App'x 193, 196 (3d Cir. 2007) (explaining that under Delaware law, "a plaintiff in a products liability case must show a defect in the product [that existed at the time of the sale] and that the defect was the proximate cause of the injury"). To be sure, it would have been better if Count IV had used clearer signposts indicating that Plaintiffs intended to assert such a claim. (D.I. 26 at 8) But in the Court's view, although Count IV is not a model of clarity, it does enough to make out the basic contours of a negligent manufacturing claim.

Count IV contains allegations that as a manufacturer of the SCS device, St. Jude owed a duty to Mrs. Freed not to supply a dangerous product to her, and that St. Jude manufactured and/or sold to her such a device—one that was adulterated or otherwise nonconforming with the good manufacturing practices required by the FDA. (FAC at ¶¶ 49, 52, 54) The FAC also includes

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no allegations that a stronger or different warning would have altered the treatment decision by Mrs. Freed's physician. (D.I. 21 at 16-17)

facts identifying the nature of the alleged defect in the product that is said to have caused a breach of this duty (that the neurostimulator and battery components of the device caused Mrs. Freed discomfort in her left buttocks, to the point where the device caused "severely painful electrical shocks and a burning sensation"). (*Id.* at ¶ 22) And it describes multiple prior recalls of the Genesis and Eon family of neurostimulator devices relating to the battery component of the device, which were driven by patient complaints of discomfort or injury similar to those felt by Mrs. Freed. (*Id.* at ¶ 12) Taking all allegations as true, as the Court must at this stage, a reasonable inference can be drawn that Plaintiffs have a viable claim that St. Jude negligently manufactured the SCS device.

That leaves the question of whether Plaintiffs have pleaded sufficient facts to demonstrate that their negligent manufacturing claim is not preempted by federal law. This type of claim would not be expressly preempted if the factual allegations pleaded violations of federal regulations (which, in turn, cause a violation of state common law duty to use due care in manufacturing goods). *See, e.g.*, *Godelia v. Doe 1*, 881 F.3d 1309, 1319 (11th Cir. 2018); *Silver*, 236 F. Supp. 3d at 898 (finding that the plaintiff's manufacturing defect claim was not preempted where "it is clear that [p]laintiff 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") (emphasis in original).[18]

In *Freed I*, the Court found that Plaintiffs had not pleaded sufficient facts to avoid preemption. The Court explained that FDA regulations prohibit, *inter alia*, the manufacturing of a

[18] Nor is such a claim impliedly preempted. *See, e.g.*, *Silver*, 236 F. Supp. 3d at 898 (concluding that where 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).

product in a manner that is inconsistent with applicable FDA requirements, and it noted that Plaintiffs had *argued* in their briefing that their "allegations of bu[rn]s and shocks in the implant area and the 'recall campaign evidence' creates a reasonable inference the [SCS] Device 'was adulterated but nevertheless made it through the manufacturing and quality control process regulated by the [premarket process].'" *Freed I*, 2017 WL 4102583, at *7 (certain alterations in original). The *Freed I* Court concluded, however, that the *original Complaint* made no such allegation; moreover, the Court explained that it would "not allow 'recall campaign evidence'—presumably recall notices attached as exhibits to the Freeds' respons[ive brief]—to amend the complaint." *Id.* The original Complaint "simply fail[ed] to allege the Device is 'adulterated'" and did not include any allegations regarding *how* the Device became adulterated in violation of federal regulation. *Id.*

In the FAC, as was previously described above, Plaintiffs do now include additional facts that describe multiple recalls of the Genesis and Eon family of neurostimulator devices, which relate to the battery component of the device. (FAC at ¶ 12) And in Count IV of the FAC, they now allege that 21 U.S.C § 351 "defines a device as adulterated if it was not in all respects in conformity with the standard approved by the FDA[,]" and that "St. Jude manufactured and/or sold to Mrs. Freed an SCS device that was *adulterated or otherwise nonconforming* with the good manufacturing practices required by the FDA." (*Id.* at ¶¶ 48, 52 (emphasis added)) Plaintiffs also newly allege that St. Jude failed to comply with the good manufacturing practices ("GMP") "as mandated by the FDA in 21 C.F.R. § 820.1 *et seq.*" in manufacturing and selling to Mrs. Freed an SCS device that was adulterated within the meaning of 21 U.S.C. § 351. (*Id.* at ¶ 54(g)-(h))[19]

[19] Earlier in the FAC, Plaintiffs had further described the relevant GMPs, alleging that St. Jude was bound by 21 C.F.R. § 820.90(a), which requires each manufacturer to "establish and maintain procedures to control product that does not conform to specified requirements" and 21

The Court finds that in the FAC, Plaintiffs have sufficiently addressed the concern articulated by the *Freed I* Court. That is, they now include allegations that can be fairly read to assert that the battery component of the SCS device (by itself, or in conjunction with the neurostimulator) was adulterated or defective. (D.I. 25 at 12) While technically Count IV refers to the SCS device as a whole as having been "adulterated[,]" (FAC at ¶ 54(h)), the additional allegations in the remainder of the FAC help the reader draw the reasonable inference that these particular components of the device were adulterated due to federal violations. *See, e.g.*, *Silver*, 236 F. Supp. 3d at 898-99 (finding that the plaintiff pleaded a plausible claim of manufacturing defect where the complaint cited to FDA warning letters, alleged that his device was manufactured in a facility where other devices with failures had been manufactured, and alleged that his device failed because it was manufactured out of specification and was adulterated due to failures to comply with GMPs); *see also Shuker v. Smith & Nephew PLC*, Civil Action No. 13-6158, 2015 WL 1475368, at *17 (E.D. Pa. Mar. 31, 2015) (finding that manufacturing defect allegations were insufficient, where while the plaintiff pleaded that the device was recalled, the plaintiff did not plead facts suggesting that the recall was associated with a manufacturing problem, and instead suggested that the recall was due to data indicating that the device was not performing satisfactorily within a system); *cf. Bausch v. Stryker Corp.*, 630 F.3d 546, 559 (7th Cir. 2010) (concluding that the plaintiff had pleaded a plausible parallel manufacturing defect claim where the claim alleged the device was implanted in the patient's body six days after the FDA informed the defendant that a device component was "'adulterated due to manufacturing methods . . . not in conformity with industry and regulatory standards'" and where the implanted device was later

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C.F.R. § 820.100(a)(3), which requires manufacturers to "[i]dentify the action(s) needed to correct and prevent reoccurrence of nonconforming product and other quality problems." (*Id.* at ¶ 16 (internal quotation marks omitted))

recalled).[20] In sum, the Court finds that Plaintiffs' allegations plausibly allege a negligent manufacturing claim.

4. Conclusion

In light of the foregoing, the Court will dismiss Plaintiffs' breach of warranty claims (found in Counts I, II and III) with prejudice. As to Count IV's failure to warn claim, as explained above, the Court will permit Plaintiffs the opportunity to file one further amended complaint that addresses the causation issue/preemption and that makes clear that this claim is based on Section 388. Finally, as to Count IV's negligent manufacturing claim, the Court denies the Motion.[21]

IV. CONCLUSION

For the reasons set out above, the Court GRANTS-IN-PART and DENIES-IN-PART the Motion to Dismiss, as described above.

An appropriate Order follows.

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[20] While the above-referenced courts have permitted negligent manufacture claims like Plaintiffs' to not be preempted, the Court notes that some courts have found such claims to be preempted and have dismissed them. These latter courts have concluded that GMPs are vague, open-ended and susceptible to an individual manufacturer's interpretation, thereby creating potentially varying standards that are "different from, or in addition to" those required by federal requirements. *See, e.g.*, *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 197-98 (E.D.N.Y. 2015). St. Jude did not raise this specific GMP-related preemption issue in its briefing, however, (*see* D.I. 21 at 11-12; D.I. 26 at 8-9), and therefore the Court will not assess it here.

[21] Because the Court has not granted St. Jude's motion in its entirety, St. Jude's argument that Count V's loss of consortium claim "depends on the other claims and falls along with them" is not a basis to dismiss the claim. (D.I. 21 at 17)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KATHLEEN M. FREED and RICHARD FREED, Plaintiffs, v. ST. JUDE MEDICAL, INC., ST. JUDE MEDICAL S.C., INC., ABBOTT LABORATORIES, INC., and ADVANCED NEUROMODULATION SYSTEMS, INC., d/b/a ST. JUDE MEDICAL NEUROMODULATION DIVISION, Defendants.	)	Civil Action No. 17-1128-CJB

ORDER

At Wilmington, Delaware this **1st** day of **February, 2019**:

For the reasons stated in the Memorandum Opinion issued this same date, IT IS HEREBY ORDERED that Defendants' Motion to Dismiss, (D.I. 20), is: (1) GRANTED with prejudice regarding Counts I, II and III; (2) GRANTED without prejudice regarding the failure to warn claim found in Count IV; and (3) DENIED regarding the negligent manufacturing claim found in Count IV, and the loss of consortium claim in Count V.

Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE