IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KRIS A. CHECK,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 20-329-CJB
	)	
ST. JUDE MEDICAL, LLC, formally known as St. Jude Medical, Inc., and ABBOTT LABORATORIES, INC.,	)	
	)	
Defendants.	)	

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MEMORANDUM OPINION

December 4, 2020
Wilmington, Delaware

Christopher J. Burke

BURKE, United States Magistrate Judge

Plaintiff Kris A. Check ("Plaintiff" or "Ms. Check") brings this products liability action against Defendants St. Jude Medical, LLC and Abbott Laboratories, Inc. (collectively, "St. Jude" or "Defendants"). Presently before the Court is St. Jude's motion to dismiss Plaintiff's Complaint, filed pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motion"). (D.I. 10) For the reasons that follow, the Court GRANTS-IN-PART St. Jude's Motion in the manner set out below.

I. BACKGROUND

A. Factual Background

1. History of the Relevant Devices

St. Jude designs, manufactures, markets, distributes, and/or sells a variety of medical devices, including the Eon Mini™ Neurostimulation System (the "Eon Mini" or "Eon Mini IPG"), serial number 14136951. (D.I. 2 at ¶¶ 10-11) The Eon Mini is among the Genesis family of neurostimulator devices approved by the United States Food and Drug Administration ("FDA"). (*Id.* at ¶ 11)

St. Jude filed its original premarket approval ("PMA") submission package for the Genesis Neurostimulation (IPG) System with the FDA on April 3, 2001. (*Id.* at ¶ 12) On November 21, 2001, the FDA issued an approval for the commercial distribution of St. Jude's Genesis and Eon family of Neurostimulation (IPG) Systems. (*Id.* at ¶ 15) On March 4, 2005, the FDA issued an approval for the commercial distribution of the Eon Neurostimulation System, Model 3716. (*Id.* at ¶ 17)

In 2006, St. Jude submitted a PMA supplement for approval of the Eon Mini IPG, Model 3788; [redacted]

[redacted] (*Id.* at ¶ 18) On March 28, 2008, the FDA issued an approval for the commercial distribution of the Eon Mini IPG, Model 3788. (*Id.* at ¶ 22)

[redacted] (*Id.* at ¶ 20) There have also been numerous patient complaints and related recall campaigns regarding the Genesis and Eon family of neurostimulation devices since 2001. (*Id.* at ¶ 24) For example, St. Jude initiated three recalls relating to the Eon Mini in 2011. (*Id.* at ¶¶ 25-27) Two of these three recalls related to a defect in the battery; this defect was associated with complaints of patients losing the ability to communicate with or recharge the IPG, resulting in loss of pain relief and in explant surgery. (*Id.* at ¶¶ 25-26) The third recall related to patient complaints of warmth at the implant site during charging of the device. (*Id.* at ¶ 27) For its part, the FDA initiated a Class 2 Device recall for the Eon Mini charging system on July 26, 2012, after receiving patient reports of discomfort associated with heating at the device site while using the charging system to charge the device. (*Id.* at ¶ 28) On the same date, St. Jude issued a "Dear Physician" letter regarding the loss of the ability of the IPG device to communicate or recharge as a result of an inner battery weld issue. (*Id.* at ¶ 29 (internal quotation marks omitted)) On September 24, 2012, the FDA initiated a Class 2 Device recall for the Eon Mini relating to three lots of Eon Mini IPGs manufactured in April 2012 that included an internal battery with the potential to contact the internal microcontroller, which had resulted in a sudden brief surge in painful stimulation. (*Id.* at ¶ 30) [redacted]

[redacted] (*Id.* at ¶ 31)

2. Ms. Check's Experiences with the Eon Mini IPG

Ms. Check, a Pennsylvania resident, is a self-employed pet groomer and certified sports official. (*Id.* at ¶¶ 4, 41) She has suffered from low back and left leg pain for many years. (*Id.* at ¶ 41) In 1988 and 2001, Ms. Check underwent laminectomy surgeries on her lumbar spine to address her pain. (*Id.*)

In 2003, Dr. Robert Corba implanted a St. Jude Genesis model spinal cord stimulator ("SCS") device into Ms. Check's body. (*Id.*) This device reduced Ms. Check's back and leg pain, which allowed her to remain active in daily activities. (*Id.*) The device was not rechargeable, so Ms. Check underwent at least two surgical procedures to replace the battery between 2003 and 2010. (*Id.*)

In July 2012, the Genesis device had reached the end of its life, and Dr. Corba recommended that Ms. Check replace the device. (*Id.* at ¶ 42) Ms. Check met with her St. Jude representative, Joe Schroeder, to discuss her available options. (*Id.*) Mr. Schroeder explained to Ms. Check that St. Jude had developed a new rechargeable device—the Eon Mini SCS. (*Id.*) According to Mr. Schroeder, the battery would last up to 10 years before it needed to be replaced, and the device would only need to be recharged every three weeks. (*Id.*) In reliance on this discussion, Ms. Check elected to have the Eon Mini IPG device implanted into her body. (*Id.*)

On August 20, 2012, at the Surgery Center of Allentown in Allentown, Pennsylvania, Dr. Corba surgically removed Ms. Check's Genesis device and replaced it with an Eon Mini IPG.

(*Id.* at ¶ 43) Mr. Schroeder was present to assist with the initial programming of the new Eon Mini IPG. (*Id.*)

On July 8, 2013, Ms. Check reported to Dr. Corba's office that she was experiencing increased back pain, numbness in her left leg and difficulty communicating with the Eon Mini IPG. (*Id.* at ¶ 45) Dr. Corba advised her to come to his office immediately, and he ordered x-rays to assess the positioning of the device and its leads. (*Id.*) After the x-rays failed to identify a problem, Dr. Corba recommended that he surgically open the implant pocket to visually inspect Ms. Check's device. (*Id.*)

On August 7, 2013, Dr. Corba performed this procedure. (*Id.* at ¶¶ 10, 46) The IPG was lying in the proper position, which indicated that there had likely been an "early depletion" of the IPG battery. (*Id.* at ¶ 46 (internal quotation marks omitted)) Dr. Corba disconnected the device from the lead wires and replaced it with another Eon Mini IPG (hereafter, "the SCS device"). (*Id.*) Mr. Schroeder was present during the procedure and took possession of the explanted Eon Mini IPG, which was sent to St. Jude's facility in Plano, Texas for further analysis. (*Id.*) St. Jude provided Ms. Check with an Eon Mini Charging System to charge the device's rechargeable IPG. (*Id.* at ¶ 48) Plaintiff alleges that upon information and belief, this same charging system was the subject of the FDA's July 26, 2012 Class 2 recall. (*Id.*)

At no time before either the August 20, 2012 surgery or the August 7, 2013 surgery did any representative of St. Jude inform Ms. Check or Dr. Corba of the FDA's July 26, 2012 Class 2 recall or the relevant patient complaints that St. Jude was receiving with regard to the Eon Mini IPG. (*Id.* at ¶¶ 44, 47) The Complaint alleges that had they been informed of this information, Ms. Check would not have consented to the surgical implantation of the Eon Mini IPG, nor would Dr. Corba have agreed to implant the device. (*Id.*)

On June 29, 2018, Ms. Check saw Dr. Corba for a regularly scheduled visit. (*Id.* at ¶ 49) She reported worsening pain and new weakness in her left leg. (*Id.*) Dr. Corba ordered an x-ray of the SCS device's lead wires to rule out a lead fracture. (*Id.*) On July 6, 2018, Ms. Check reported to Dr. Corba that she was "'getting a shock sometimes'" from the SCS device and that it was "'not working like it used to[.]'" (*Id.*) On July 9, 2018, Dr. Corba's office provided Ms. Check with a telephone number for "Joe" at St. Jude and advised her to contact Joe regarding these issues. (*Id.*) When Ms. Check called the number, she was redirected to a different representative at "'Abbott[.]'" (*Id.*) Ms. Check eventually met with the new representative, who found nothing wrong with the SCS device and said that he could not explain why the device was not working properly. (*Id.* at ¶ 50)

On November 23, 2018, while charging the SCS device, Ms. Check "'felt something weird'" and noticed that the device had burned a dime-sized hole through her skin at the site of the IPG. (*Id.* at ¶ 51) The next day, Ms. Check saw her primary care physician who instructed her to take an oral antibiotic medication and to place gauze over the wound. (*Id.*) On November 28, 2018, Ms. Check visited with Dr. Corba; a St. Jude representative, David Falcheck, also attended the visit. (*Id.* at ¶ 52) Dr. Corba's progress note for that visit states:

> Representative from St. Jude today revealed that there should've been a new charging system sent to the patient a few years ago, there was a recall in which the charging time and voltage was changed she did not receive letter nor phone call from St. Jude.
>
> New charging system will be sent.
>
> She is to withhold charging until then.

(*Id.* (internal quotation marks omitted)) The Complaint alleges that upon information and belief, the St. Jude representative was here referring to the July 26, 2012 recall. This is the first time that Ms. Check and Dr. Corba were informed of the recall. (*Id.*)

Several days later, Ms. Check received a replacement charger for the SCS device from St. Jude. (*Id.* at ¶ 53) The Complaint alleges that she should have received this replacement charger after the July 26, 2012 recall, but did not. (*Id.*) Ms. Check began to use the replacement charger, but it took a very long time to charge the SCS device even with the new charger. (*Id.*) A new St. Jude representative, Brian Furlong, informed Ms. Check that it would take longer to charge the SCS over time and that at some point the programmer would indicate that it was time to replace the device. (*Id.*)

On December 3, 2018, Ms. Check sent an urgent e-mail to Dr. Corba to inform him that she had experienced two "'more shocks'" while using the SCS device. (*Id.* at ¶ 54) Dr. Corba instructed Ms. Check to turn off the device until it could be "'interrogated'" by a St. Jude representative. (*Id.*) On December 5, 2018, Ms. Check saw Dr. Corba with a St. Jude representative present. (*Id.* at ¶ 55) The SCS device was analyzed but no anomalies were found. (*Id.*) Dr. Corba recommended that the device be removed. (*Id.*)

At about this same time and continuing into January 2019, Ms. Check's SCS device began to automatically turn itself off several times per week. (*Id.* at ¶ 56) After exchanging e-mails with Mr. Furlong regarding this new problem, Ms. Check and Mr. Furlong met on February 18, 2019 at Mr. Furlong's office in Quakertown, Pennsylvania, so that Mr. Furlong could perform additional diagnostic testing on the SCS device. (*Id.*) Mr. Furlong reported that he had added some additional programs that he thought would help alleviate the problem. (*Id.*) However, Ms. Check's device continued to turn itself off at random times. (*Id.*)

On February 22, 2019, Ms. Check saw Dr. Stephen Falatyn for a surgical consultation at the recommendation of Dr. Corba. (*Id.* at ¶ 57) Dr. Falatyn noted that Ms. Check was suffering from intractable pain in her back and left leg and had an SCS that was "'running down and

shocking her back[.]'" (*Id.*) Dr. Falatyn recommended that Ms. Check undergo lumbar spine surgery with simultaneous removal of the SCS device and its leads. (*Id.*) On April 8, 2019, Dr. Falatyn performed this surgery on Ms. Check at the Lehigh Valley Hospital in Allentown, Pennsylvania. (*Id.*)

B. Procedural History

Plaintiff filed her Complaint on March 4, 2020. (D.I. 2) The Complaint asserts state law claims for strict product liability (Count I), failure to warn based upon Restatement (Second) of Torts Section 388 ("Section 388") (Count II), negligent manufacture (Count III), negligence (Count IV) and breach of express warranty (Count V). (*Id.* at ¶¶ 59-112) In lieu of filing an Answer, on April 27, 2020, St. Jude filed the instant Motion. (D.I. 10) Briefing on the Motion (which includes a supplemental letter brief filed by Plaintiff as well as four notices of supplemental authority submitted by St. Jude) was completed on November 5, 2020. (D.I. 37) The Court[1] heard telephonic argument on the Motion (as well as on pending motions to dismiss filed in two related cases) on August 26, 2020. (D.I. 35 (hereinafter, "Tr.")

II. STANDARD OF REVIEW

The Court hereby incorporates by reference the standard of review regarding Rule 12(b)(6) motions to dismiss for failure to state a claim, as well as its description of the legal requirements for federal preemption, all of which were set out in its November 16, 2020

[1] On October 2, 2020, the parties jointly consented to the Court's authority to conduct all proceedings in this case, including trial, the entry of final judgment, and all post-trial proceedings. (D.I. 36)

Memorandum Opinion in the related case *Mellott v. St. Jude Med., LLC*, Civil Action No. 19-1779-CJB (D. Del. Nov. 16, 2020) (D.I. 45 at 7-8, 9-14) (hereinafter, "November 16 MO").[2]

III. DISCUSSION

With its Motion, St. Jude asserts that each of Plaintiff's claims must be dismissed because Plaintiff has failed to plausibly plead specific facts necessary to avoid federal preemption or to otherwise state a claim for relief. (D.I. 11 at 1-4) The Court will assess whether Plaintiff's claims warrant dismissal on the various grounds pressed by St. Jude in turn.

As an initial matter, the Court notes that all of Plaintiff's claims relate to the SCS Device that was implanted in Plaintiff's body on August 7, 2013. St. Jude had understood the Complaint to be asserting claims relating to both Plaintiff's first Eon Mini device implanted in August 2012 as well as to her second Eon Mini device (i.e., the SCS Device) implanted in August 2013. Based on this understanding, St. Jude asserted in its opening brief that Plaintiff's claims relating to the first Eon Mini are barred by Pennsylvania's statute of limitations. (D.I. 11 at 17-18)[3] In response, however, Plaintiff clarified that the focus of her claims is on the second Eon Mini device. (D.I. 16 at 16; D.I. 19 at 1; Tr. at 132) St. Jude's statute of limitations argument is therefore DENIED as MOOT.

A. Strict Product Liability Claim

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[2] The Court assumes familiarity with the November 16 MO. In that case, Plaintiffs asserted claims relating to, *inter alia*, a St. Jude SCS device, the Protégé Model 3789, which was the same device as the Eon Mini IPG (at issue here) except that St. Jude had changed the name and implemented certain software modifications to the device in 2014. (November 16 MO at 3, 6)

[3] The parties agree that Pennsylvania law supplies the substantive state law for this case. (D.I. 11 at 3 n.1; D.I. 16 at 1 n.2)

Count I of Plaintiff's Complaint asserts a strict product liability claim. (D.I. 2 at ¶¶ 59-71) St. Jude argues that Plaintiff's strict product liability claim must be dismissed for two reasons: (1) it does not state a plausible parallel claim; and (2) it is barred by Pennsylvania law. (D.I. 11 at 2, 4, 8-9, 19; D.I. 19 at 9-10)

The Court agrees with St. Jude's first argument. Here, just as in *Mellott*, St. Jude contends that Plaintiff's strict liability claim fails to identify an alleged violation of FDA requirements of any type. (D.I. 11 at 8; November 16 MO at 14) In order for a state law claim to avoid express preemption, however, it must be premised on a violation of FDA regulations; therefore, if a count facially demonstrates that there is no such violation alleged, the claim is subject to dismissal. (November 16 MO at 15) And here, Plaintiff acknowledges that Count I does not list any violation of FDA regulations; instead, she notes that her Complaint only set out detailed allegations as to the relevant federal requirements at issue in *other* counts (i.e., Counts II and III) of the Complaint. (D.I. 16 at 7 & n.8) Since Count I contains no such allegations, St. Jude's Motion is GRANTED as to that Count (albeit without prejudice to Plaintiff's ability to file an amended pleading that attempts to correct the defect).

It is still necessary to address St. Jude's second argument for dismissal of this claim, because if St. Jude is correct that Plaintiff's strict product liability claim is barred by Pennsylvania law, then the claim would be subject to dismissal *with* prejudice. In Pennsylvania, Section 402A of the Restatement (Second) of Torts ("Section 402A") governs strict liability claims. *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 394-99 (Pa. 2014); *Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966). Pursuant to Section 402A, a plaintiff may recover based on a strict liability theory if his or her injury was caused by a product in "a defective condition unreasonably dangerous to the user or consumer[.]" Restatement (Second) of Torts § 402A; *see also Tincher*,

104 A.3d at 358. Three different types of defective conditions can give rise to a strict liability claim: design defect, manufacturing defect, and failure-to-warn defect. *Phillips v. A-Best Prods. Co.*, 665 A.2d 1167, 1170 (Pa. 1995). Plaintiff's strict product liability claim is based on an alleged manufacturing defect. (D.I. 16 at 6)[4]

St. Jude asserts that Plaintiff's strict liability claim is barred as a matter of law pursuant to comment k to Section 402A ("comment k"). (D.I. 11 at 19) Comment k provides that manufacturers of "[u]navoidably unsafe products" are exempted from strict liability when the product at issue is "properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it unreasonably dangerous." Restatement (Second) of Torts § 402A cmt. k (emphasis omitted). Comment k expressly applies to "many . . . drugs, vaccines, and the like, many of which . . . cannot legally be sold except to physicians, or under the prescription of a physician." *Id.* The Pennsylvania Supreme Court, in cases like *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014) and *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996), has held that comment k bars strict lability for claims alleging design defect and failure-to-warn defect in the context of prescription drugs. But that Court has yet to address whether comment k applies to strict liability claims alleging *manufacturing defects* in the drug context, nor has it addressed whether comment k applies to categorically bar *any type* of strict liability claim relating to *medical devices*. *See, e.g.*, *Keen v. C.R. Bard, Inc.*, — F. Supp. 3d —, 2020 WL 4873634, at *6-7 (E.D. Pa. Aug. 19, 2020); *see also* (D.I. 16 at 17). In the absence of such a decision by the Pennsylvania Supreme Court, a

[4] Plaintiff's answering brief first states that Plaintiff's strict product liability claim is based on both a manufacturing defect and a failure-to-warn defect. (D.I. 16 at 6) Later, however, Plaintiff argues only that Pennsylvania law does not preclude a strict liability *manufacturing defect* claim. (*Id.* at 16 ("PENNSYLVANIA DOES NOT PRECLUDE A STRICT LIABILITY MANUFACTURING DEFECT CLAIM") (certain emphasis omitted); *id.* at 16-19) Thus, Plaintiff appears to acknowledge that she is not asserting claims for strict liability design defect or strict liability failure to warn defect. (*See* D.I. 19 at 9 n.4)

federal court applying Pennsylvania's substantive law must predict how the Pennsylvania Supreme Court would decide the issue (i.e., whether comment k categorically bars Plaintiff's strict liability manufacturing defect claim raised regarding a medical device). *Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 45-46 (3d Cir. 2009). In doing so, it must "consider relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand." *Id.* (internal quotation marks and citation omitted); *see also Packard v. Provident Nat'l Bank*, 994 F.2d 1039, 1046-47 (3d Cir. 1993).

Courts are split on the issue of whether comment k's grant of immunity from strict liability extends to manufacturing defects in the medical device context. On the one hand, Plaintiff points to decisions that have allowed strict liability manufacturing defect claims to proceed under Pennsylvania law, (D.I. 16 at 18), while on the other hand, St. Jude points to cases that have predicted that the Pennsylvania Supreme Court would apply comment k to absolutely bar such claims, (D.I. 11 at 19; D.I. 19 at 9-10 & n.5; D.I. 27). *See also, e.g.*, *Lopez v. Ethicon Inc.*, CIVIL ACTION NO. 20-2694, 2020 WL 5569770, at *5 n.3 (E.D. Pa. Sept. 17, 2020) (noting that there is a split among federal courts regarding whether Pennsylvania law would bar a claim for strict liability based on a manufacturing defect) (citing cases); *Patchcoski v. W.L. Gore & Assocs., Inc.*, CIVIL ACTION NO. 3:19-1556, 2020 WL 4335016, at *6 (M.D. Pa. July 28, 2020) (same).

Cases in the latter camp point to the plain language of comment k, which specifically contemplates application to prescription products such as "drugs, vaccines, and the like, many of which . . . cannot legally be sold except to physicians, or under the prescription of a physician." Restatement (Second) of Torts § 402A cmt. k. This language could be read to encompass

prescription medical devices, which are, by definition, products that require a physician's prescription (just like prescription drugs do). *See Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 577 (E.D. Pa. 2019). These opinions also cite to case law that purportedly demonstrates that the Pennsylvania Supreme Court would apply comment k to bar strict liability claims with respect to medical devices. *Id.* at 577-78; *Harben v. Allergan USA, Inc.*, CIVIL ACTION NO. 18-1833, 2019 WL 9100175, at *4 (E.D. Pa. July 15, 2019). For example, these courts point to the Pennsylvania Supreme Court's decision in *Hahn*, and the *Hahn* Court's general statement that comment k "denies application of strict liability to products such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." *Hahn*, 673 A.2d at 889-90. They also cite to the Pennsylvania Superior Court's holding in *Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. Ct. 2006), which held that a plaintiff's strict liability manufacturing defect claim against a prescription medical device manufacturer, which involved allegations regarding an Implantable Neurological Electrical Pulse Generator, was barred by comment k. *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006). The *Creazzo* Court found "no reason why the same rational[e] [finding comment k] applicable to prescription drugs may not be applied to medical devices." *Id.*[5]

Having considered cases on both sides of the split, the Court joins with decisions in the former camp—i.e, those that have declined to dismiss a plaintiff's strict liability manufacturing

[5] The Court notes, however, that at least one federal district court—in concluding that the Pennsylvania Supreme Court would ultimately not agree with the decision in *Creazzo*—pointed out that the Pennsylvania Supreme Court has only cited to the *Creazzo* decision one time, and then only for an unrelated purpose relating to the spoliation of evidence. *Wagner v. Kimberly-Clark Corp.*, 225 F. Supp. 3d 311, 317 & n.7 (E.D. Pa. 2016) (citing *Pyeritz v. Commonwealth*, 32 A.3d 687, 692 n.5 (Pa. 2011)).

defect claim in the medical device context on the basis of comment k, without the benefit of a fully developed factual record. *See Patchcoski*, 2020 WL 4335016, at *12. These courts:

> predict that the Pennsylvania Supreme Court would not categorically extend *Hahn* and comment k to all prescription medical device manufacturers. . . . [and] predict[] that Pennsylvania's highest court would instead analyze comment k's applicability to prescription medical devices on a case-by-case basis, determined largely by each case's developed factual record and the individual characteristics of the medical device at issue.

Id. at *11 (internal quotation marks and citations omitted); *Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 652-53 (E.D. Pa. 2020); *Moultrie v. Coloplast Corp.*, Civil Action No. 18-231, 2020 WL 1249354, at *10 (W.D. Pa. Mar. 16, 2020).

In doing so, these courts have also cited the plain language of comment k in support. As noted above, comment k exempts a product from strict liability when it is "properly prepared." This reasonably suggests that a claim regarding a medical device that has *not* been "properly prepared" (the crux of a typical manufacturing defect claim) would fall outside the comment's scope. *See, e.g.*, *Wallace v. Bos. Sci. Corp.*, Civil No. 3:18-CV-01839, 2018 WL 6981220, at *7 (M.D. Pa. Nov. 29, 2018).[6]

These courts have also persuasively pointed to supporting caselaw. One such case is *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014). In *Tincher*, the Pennsylvania Supreme Court (in declining to adopt the Restatement (Third) of Torts Products Liability §§ 1, *et. seq*. as the standard for deciding products liability cases under Pennsylvania law) generally cautioned against courts creating categorical exemptions in the strict liability context. *Tincher*, 104 A.3d at

[6] Indeed, many courts in other jurisdictions (as well as commentators generally) agree that comment k's immunity from strict liability does not extend to manufacturing defects. *See, e.g.*, *Doughtery v. C.R. Bard, Inc.*, Civil Action No. 11-6048, 2012 WL 2940727, at *5 (E.D. Pa. July 18, 2012) (collecting cases).

396 ("Courts, which address evidence and arguments in individual cases, are neither positioned, nor resourced, to make the kind of policy judgments required to arrive at an *a priori* decision as to which individual products, or categories and types of products, should be exempt.") (emphasis in original). The *Tincher* Court explained that such decisions require an assessment and balancing of policies best left to the General Assembly. *Id.* Another such case is *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), wherein the Pennsylvania Supreme Court articulated its view that the *Hahn* Court had:

> applied a rather one-dimensional analysis in its adoption of a blanket approach to comment k in the first instance. For example, the terse opinion in *Hahn* does not so much as mention, let alone evaluate, the reasons why many other jurisdictions had interpreted comment k to require a case-by-case assessment concerning the availability of its protections.

85 A.3d at 452 n.21. This "cautionary language" in *Tincher* and *Lance* suggests that the Pennsylvania Supreme Court would not apply comment k to categorically exempt all medical devices from strict liability claims (including manufacturing defect claims). *See, e.g.*, *Gross v. Coloplast Corp.*, 434 F. Supp. 3d 245, 252 (E.D. Pa. 2020) ("*Tincher* and *Lance* discourage Pennsylvania courts from making such categorical decisions at all, especially briefly [and] especially on limited records[.]"); *see also Patchcoski*, 2020 WL 4335016, at *12.

For these reasons, the Court will not dismiss with prejudice Plaintiff's strict liability manufacturing defect claim on the ground that it is barred by comment k, without the benefit of a fully developed factual record (one it does not have at this early stage of the case).[7]

[7] The Court also notes that St. Jude's briefing was devoid of any analysis as to *why* the Pennsylvania Supreme Court would apply comment k to bar strict liability manufacturing defect claims. Instead, St. Jude simply implored the Court to "adopt the correct line of cases finding claims for strict lability manufacturing defect unavailable under comment k[,]" (D.I. 19 at 9; *see also* D.I. 11 at 19), without saying much about why those cases were "correct."

B. Failure to Warn Claim

Plaintiff's failure to warn claim is based on the same two theories that were at issue in the *Mellott* case: a "duty to supplement labeling" theory and a "failure to report adverse events" theory. (D.I. 2 at ¶¶ 75(d) & (f), 77; November 16 MO at 26; D.I. 19 at 2; Tr. at 133)

With respect to the duty to supplement labeling theory, St. Jude makes the same arguments for dismissal that it made in the *Mellott* case. (D.I. 11 at 9-13; D.I. 19 at 2-3; Tr. at 133) The Court incorporates by reference its analysis in *Mellott*. (November 16 MO at 26-28, 30 n.15) To the extent Plaintiff's allegations regarding this theory are premised on St. Jude's ability to supplement a label pursuant to 21 C.F.R. § 814.39(d), the theory survives in this case for the same reasons as it did in *Mellott.* And additionally, just as in *Mellott*, Plaintiff also notes that the "Conditions of Approval" issued by the FDA for the relevant device here expressly required that St. Jude submit certain reports to the FDA, if St. Jude became aware of any "adverse reaction [or] injury" attributable to its device that has "not been addressed by the device's labeling[.]" (D.I. 2 at ¶ 35 (internal quotation marks omitted); D.I. 16 at 9) Plaintiff alleges in the Complaint that St. Jude failed to timely and completely submit certain of these required reports. (D.I. 2 at ¶ 35; *see also id.* at ¶ 33)[8] This "Conditions of Approval" requirement also seems to establish a parallel duty to state law, and St. Jude's alleged failure to

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Plaintiff, meanwhile, did explain why the cases that declined to apply comment k to categorically bar all such claims are more persuasive. (D.I. 16 at 16-19)

[8] St. Jude's reply brief does not directly address the substance of the Conditions of Approval, or how the content of those conditions relate to its implied preemption argument. (D.I. 19 at 3-4)

abide by it is thus a separate basis on which Plaintiff's duty to supplement labeling theory is viable and not preempted.[9]

With respect to the failure to report adverse events theory, St. Jude presses similar arguments to those made in the *Mellott* case. (D.I. 11 at 10-13; D.I. 19 at 4-6) As in *Mellott*, where the state at issue (Maryland) had incorporated Restatement (Second) of Torts Section 388 ("Section 388") into its substantive law regarding failure to warn claims, (November 16 MO at 30), so too has Pennsylvania adopted Section 388 for cases involving such claims, (D.I. 16 at 8); *see also Gibbs v. H.A. DeHart & Son, Inc.*, No. 828 EDA 2013, 2014 WL 10575192, at *5 (Pa. Super. Ct. Sept. 17, 2014). And as the Court concluded in the November 16 MO, here a properly pleaded failure to warn claim based on Section 388 is not necessarily preempted by federal law—provided that it sets out plausible factual allegations as to why a manufacturer's failure to report adverse events to the FDA would have reached physicians (and ultimately the plaintiff), and would have impacted the plaintiff's decision to use the medical device at issue. (November 16 MO at 31-32)

However, just as in *Mellott*, Plaintiff has failed to plausibly plead this failure to report adverse events theory—specifically with regard to the element of causation. (D.I. 11 at 11-12; D.I. 19 at 5; November 16 MO at 33-35) Just like in *Mellott*, here Plaintiff says this theory is premised on the idea that had St. Jude regularly and adequately reported adverse events relating to the problems that Plaintiff experienced, such reports would have been "published by the FDA" on the FDA's MAUDE database. (D.I. 16 at 12) But from there, Plaintiff simply alleges that

[9] In *Mellott*, the Court did not substantively consider the plaintiffs' argument regarding the content of the Conditions of Approval because the Court had determined that the plaintiffs' allegations regarding St. Jude's failure to report adverse events were not accurately pleaded. (November 16 MO at 29-30)

had St. Jude "properly informed or notified the FDA" in this way, then she "and/or her physicians would have learned of [the device's true hazards/risks/defects via such reports] and either chosen to implant a different neurostimulation system or seek out other alternative medical treatment." (D.I. 2 at ¶¶ 77-78; *see also id.* at ¶¶ 32-33) However, such allegations (relating to *how it is* that Plaintiff and her physicians would have learned of these reports, and thereafter sought alternative treatment) suffer from the same lack-of-specificity problems as the Court set out in the November 16 MO. (November 16 MO at 34-35)

For these reasons, St. Jude's Motion as to the failure to warn claim will be granted to the extent the claim is premised on the failure to report adverse events theory. It will be denied to the extent the claim is premised on the duty to supplement labeling theory.

C. Negligent Manufacture Claim

With respect to her negligent manufacture claim, Plaintiff alleges that, *inter alia*: (1) St. Jude manufactured an SCS device with a nonconforming battery component or other electrical defect that caused injury to Plaintiff, (D.I. 2 at ¶¶ 85-88); (2) St. Jude has conducted recall campaigns in the past (i.e., in 2011) for Eon/Eon Mini devices and their components, including batteries, (*id.* at ¶¶ 25-27); (3) the FDA initiated two recalls in July and September 2012 relating to the Eon Mini Charging System and the internal battery of the Eon Mini device, (*id.* at ¶¶ 28, 30); and (4) St. Jude manufactured an SCS device that was implanted in Plaintiff, which was "adulterated" pursuant to 21 U.S.C. § 351[10] in that it did not conform to certain identified good manufacturing practices ("GMPs") required by the FDA, specifically, 21 C.F.R. § 820.90, 21

[10] This particular allegation is set out in Count I's strict product liability count. (D.I. 2 at ¶ 66)

C.F.R. § 820.100(a)(3), 21 C.F.R. § 820.50(a) and 21 C.F.R. § 820.80, (*id.* at ¶¶ 66, 85, 87).[11] St. Jude argues that Plaintiff's negligent manufacture claim fails because: (1) it does not adequately plead a manufacturing defect that caused Plaintiff's injuries; (2) it alleges that St. Jude was negligent in failing to comply with certain GMPs, which are too vague to sustain a parallel claim that survives preemption; and (3) it relies on recalls, which have "no bearing on the preemption analysis." (D.I. 11 at 14-15, 16-17)

The Court has already considered, and rejected, these same arguments in the November 16 MO. (*See* Tr. at 133 (St. Jude's counsel noting that with respect to this claim, "the arguments are the same as Mellott")) It will apply the same analysis here.

With respect to St. Jude's first argument, just as in the *Mellott* case, (November 16 MO at 19-21), Plaintiff's Complaint here describes a history of specific problems with the battery component of the Eon family of devices that mirror her own experiences with her Eon Mini device (i.e., the SCS Device), (D.I. 16 at 13). Indeed, because the *Mellott* case involved allegations about the same basic device (albeit with a different name) as that at issue here, the Complaint in *Mellott* set out the same past history of Eon family device problems found in Plaintiff's Complaint here. (November 16 MO at 19-20; D.I. 2 at ¶¶ 24-30) As the Court explained in *Mellott*, from these allegations, it is plausible to infer that: (1) Plaintiff's SCS

[11] Plaintiff also alleged violations of other GMPs in this Count. For example, she alleged a violation of 21 C.F.R. §§ 870(a) & (h). (D.I. 2 at ¶ 87(e) & (f)) St. Jude, however, pointed out that these GMPs apply to cardiovascular devices, not to neurostimulation devices like the SCS device at issue here. (D.I. 11 at 14) In response, Plaintiff indicated that these references were "typographical errors" and that Plaintiff intended to cite to 21 C.F.R. §§ 820.70(a) & (h). (D.I. 16 at 15 n.16) Additionally, Plaintiff alleged a violation of 21 C.F.R. § 850(a)(1), (D.I. 2 at ¶ 87(d)), but it appears that this should have been a reference to 21 C.F.R. § 820.50(a)(1), *see* (*id.* at ¶ 87(c); 21 C.F.R. § 820.50(a)(1)). Because these allegations appear to be made in error, the Court will not consider them here and Plaintiff should amend her Complaint to correct these errors.

Device suffered from manufacturing defects relating to the battery component and charging system (indeed, Plaintiff alleges that she received the same charging system that was the subject of the FDA's July 2012 recall); which resulted in (2) the loss of the ability to communicate with or recharge the IPG, heating at the implant site during charging, and sudden surges in painful stimulation. (November 16 MO at 20; D.I. 2 at ¶¶ 24-30, 48) And Plaintiff's Complaint alleges that in 2018, Plaintiff experienced harm consistent with these defects: her device lost power randomly, she experienced increased pain and shocks while using the device, and she suffered from a dime-sized burn in her skin at the site of the implant. (D.I. 2 at ¶¶ 49, 51, 54, 56, 57) These allegations sufficiently allege manufacturing defects that caused Plaintiff's injuries.

As for St. Jude's argument that GMPs cannot serve as a basis for a federal violation sufficient to survive preemption, in the November 16 MO, the Court explained why it disagrees with St. Jude's position. (November 16 MO at 21-26) And two of the same GMPs referenced in Plaintiff's Complaint here were also at issue in the November 16 MO (21 C.F.R. § 820.90 and 21 C.F.R. § 820.100). The Court stands by that analysis here.[12]

[12] As noted above, Plaintiff's Complaint here also references additional GMPs that were not at issue in *Mellott*, such as 21 C.F.R. § 820.50(a) (which requires manufacturers to establish and maintain adequate quality control requirements for the suppliers of its component parts and to adequately evaluate and select suppliers for component parts on the basis of their ability to meet specified requirements). And Plaintiff alleges that St. Jude's July 26, 2012 "Dear Physician" letter indicated that the IPG's loss of the ability to communicate or recharge came as a result of battery weld cracks, and that St. Jude had identified a need to more frequently maintain and replace certain tools during the internal battery welding process by a St. Jude supplier. (D.I. 2 at ¶ 29) With Plaintiff allegedly experiencing these same problems in 2018, it is plausible that after July 2012, St. Jude did not in fact ensure that its suppliers had addressed such issues and thus failed to comply with this GMP. *Cf. Brackin v. Medtronic, Inc.*, No. 17-cv-2101-SHL-cgc, 2017 WL 5957204, at *6 (W.D. Tenn. Sept. 14, 2017) (finding that the plaintiff sufficiently pleaded a parallel negligent manufacture claim, where the plaintiff alleged that the FDA had found that the defendant was in violation of certain GMPs, including Section 820.50(a), because for nearly two years pumps were manufactured utilizing an outdated step in the manufacturing process).

Third and finally, in the November 16 MO, the Court rejected the notion that recalls are wholly irrelevant to a plaintiff's state law product liability claim. (November 16 MO at 16-17) And here, the recall allegations in the Complaint seem to relate to problems that Plaintiff later experienced with her own SCS device. So the Court can consider them as to this claim.

Taken as a whole, the allegations plausibly set out a negligent manufacturing claim that is not preempted. Therefore, the Court denies St. Jude's Motion as it relates to Plaintiff's negligent manufacture claim.

D. Negligence Claim

Count IV of Plaintiff's Complaint asserts a claim for negligence. (D.I. 2 at ¶¶ 92-104) With this claim, Plaintiff asserts that St. Jude was negligent in: (1) failing to send Plaintiff or her physician a July 21, 2014 "Dear Patient" letter that informed patients of the potential for excessive heating at the implant site during charging of Eon SCS devices and that offered a replacement charger and/or (2) failing to otherwise notify Plaintiff and her physician of the letter's content. (*Id.* at ¶¶ 98, 100; Tr. at 142-43) After Plaintiff's SCS device burned a hole through her skin while using the charging system in 2018, Plaintiff alleges that St. Jude admitted that Plaintiff should have received the replacement charger years earlier. (D.I. 2 at ¶ 99)

St. Jude counters that this claim reads like a claim for negligent failure to warn (that is, that St. Jude failed to propound different or additional warnings as to its device). (D.I. 11 at 15; D.I. 19 at 8; Tr. at 133 (St. Jude's counsel asserting that this negligence claim is "just another way of saying that [St. Jude] failed to warn, because patient letters like dear doctor letters are considered patient labeling")) Plaintiff's claim for negligence, according to St. Jude, therefore "broadly challenges the safety and effectiveness of [Plaintiff's] Eon Mini, and is expressly preempted[.]" (D.I. 11 at 15-16; *see also* D.I. 19 at 8) In support, St. Jude cites to *PLIVA v.*

Mensing, 564 U.S. 604, 623-24 (2011), for the proposition that "Dear Doctor" letters "are equivalent to product labeling[.]" (D.I. 19 at 8)

Perhaps St. Jude's argument would hold some weight if Plaintiff's claim alleged that St. Jude *should have* sent patients a Dear Patient letter warning of the potential for excessive warmth at the implant site during charging of the device, but did not.[13] But that is not what Plaintiff is alleging. Rather, Plaintiff's negligence claim is premised on the fact that St. Jude *did* issue such a letter, and offered a replacement charger as a solution to the problem, but that St. Jude was negligent in *failing to send* this letter to *Plaintiff*. (D.I. 16 at 15; Tr. at 142-43) The Court therefore agrees with Plaintiff that this is a tort claim "based on alleged conduct apart from the MDA" that is not subject to preemption. (D.I. 16 at 15); *cf. Killen v. Stryker Spine*, Civil Action No. 11-1508, 2012 WL 4498865, at *5 (W.D. Pa. Sept. 28, 2012) (finding that plaintiff's fraud and misrepresentation claims against the defendant, which related to follow-up care, were not "within the scope of the applicable federal regulations and are not preempted by the MDA").

The Court therefore denies St. Jude's Motion to dismiss Plaintiff's negligence claim.

E. Breach of Express Warranty Claim

Count V of Plaintiff's Complaint asserts a claim for breach of express warranty. (D.I. 2 at ¶¶ 105-12) Plaintiff alleges that: (1) St. Jude's representative made a verbal representation to Plaintiff that the Eon/Eon Mini device had a battery life up to 10 years and would only have to be recharged every three weeks; (2) Plaintiff relied upon these representations of fact in choosing to have the SCS device implanted in her body; (3) these representations constituted "express

[13] That was what plaintiffs argued in the *PLIVA* case—that the manufacturers "*could have used* 'Dear Doctor' letters to send additional warnings to prescribing physicians and other healthcare professionals" but did not. *PLIVA*, 564 U.S. at 615 (emphasis added).

warranties" that were breached when the battery component in the SCS device did not last up to 10 years and needed to be charged more frequently than every three weeks. (*Id.* at ¶¶ 106-08)

St. Jude argues that this claim warrants dismissal for two reasons. First, St. Jude asserts that the claim is preempted because it "goes to the safety and effectiveness of the device." (D.I. 19 at 9; *see also* D.I. 11 at 16; Tr. at 144) Second, St. Jude contends that the claim is insufficiently pleaded because the representation at issue is "too vague" to create an express warranty. (D.I. 11 at 20; D.I. 19 at 10)[14] Neither argument prevails.

With respect to St. Jude's first argument, courts in this Circuit have found that express warranty claims escape preemption because they do not involve a "state requirement" that fails to parallel a federal requirement. *See, e.g.*, *Conley v. St. Jude Med., LLC*, — F. Supp. 3d — , 2020 WL 5087889, at *6 (M.D. Pa. Aug. 28, 2020) (citing cases). This is because express warranties do not independently arise by operation of state law; instead, Pennsylvania law considers an express warranty to be part of the contract between the parties, such that the parties, not the state, define the substantive obligations that make up an express warranty claim. *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900–01 (M.D. Pa. 2017); *see also White v. Medtronic, Inc.*, CIVIL ACTION NO. 16-2638, 2016 WL 4539494, at *2-3 (E.D. Pa. Aug. 31, 2016).

[14] In its opening brief, St. Jude had also argued that under Pennsylvania law, a viable express warranty claim requires privity, which Plaintiff did not and cannot plead because implantable medical devices are not sold directly to patients. (D.I. 11 at 19) In response, Plaintiff pointed out that "Pennsylvania long ago abandoned privity requirements in the consumer product arena." (D.I. 16 at 19 (citing *Kassab v. Cent. Soya*, 246 A.2d 848 (Pa. 1968)); *see also, e.g.*, *Moscatiello v. Pittsburgh Contractors Equip. Co.*, 595 A.2d 1198, 1201 (Pa. Super. Ct. 1991) ("[A] manufacturer may be held liable in a breach of warranty suit for damages sustained by a consumer as a result of the purchase of a defective product, even in the absence of privity of contract between the manufacturer and the consumer.")) St. Jude seemed to give up on the argument in its reply brief, (D.I. 19 at 10), and thus the Court does not further address it here.

In making its second argument, St. Jude contends that the representation at issue in this case is "similar" to the allegation that the Court found wanting in *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343 (D. Del. 2019) (hereinafter, "*Freed II*"). (D.I. 11 at 20; D.I. 19 at 10) In that case, the Court dismissed with prejudice the plaintiffs' breach of express warranty claim. There, the claim relied on a statement made by a St. Jude sales representative prior to the plaintiff's trial placement of an SCS device, to the effect that the plaintiff would be "very happy" with the device. *Freed II*, 364 F. Supp. 3d at 354-55. The Court explained that this statement "amounts to the promotion of a vague, subjective opinion" that rendered it 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." *Freed II*, 364 F. Supp. 3d at 355.[15]

The Court does not agree that the representation at issue here is similar to the representation in *Freed II*. Here, St. Jude's representation is specific and objective: the Eon Mini device had a battery life up to 10 years, and would only have to be recharged every three weeks. (D.I. 2 at ¶ 106) The Court thus does not agree with St. Jude that Plaintiff's breach of express warranty claim is insufficiently pleaded on this ground.

For these reasons, the Court denies St. Jude's Motion to dismiss Plaintiff's breach of express warranty claim.

F. Nature of Dismissal

[15] Under Pennsylvania law, an express warranty is created through "any affirmation of fact or promise" made by a seller to a buyer; necessarily, if the alleged warranty is so vague as to not clearly amount to an "affirmation of fact or promise," then it cannot support a breach of express warranty claim. *See Kester v. Zimmer Holdings, Inc.*, No. 2:10-cv-00523, 2010 WL 2696467, at *10 (W.D. Pa. June 16, 2010); *cf. Brucker v. State Farm Mut. Auto. Ins. Co.*, 17cv00084, 2017 WL 7732876, at *3 (W.D. Pa. May 26, 2017).

Because it is not clear to the Court that allowing the opportunity to amend would be a futile act, because this is the first time the Court has found certain of Plaintiff's claims to be deficiently pleaded, and because leave to amend should be given freely "when justice so requires[,]" Fed. R. Civ. P. 15(a)(2), dismissal of the claims found wanting is without prejudice. Plaintiff shall be given leave to file a further amended complaint addressing the deficiencies outlined above within 14 days. *TriDiNetworks Ltd. v. Signify N. Am. Corp.*, Civil Action No. 19-1063-CFC-CJB, 2020 WL 2839224, at *5 (D. Del. June 1, 2020).

IV. CONCLUSION

For the reasons set out above, the Court GRANTS-IN-PART and DENIES-IN-PART the Motion. More specifically, the Motion is: (1) GRANTED as to Count I; (2) as to Count II, GRANTED to the extent the claim is premised on the failure to report adverse events theory and DENIED to the extent the claim is premised on the duty to supplement labeling theory; (3) DENIED as to Count III; (4) DENIED as to Count IV; and (5) DENIED as to Count V.

An appropriate Order follows.

Because this Memorandum Opinion may contain confidential information, it has been released under seal, pending review by the parties to allow them to submit a single, jointly proposed, redacted version (if necessary) of the document. Any such redacted version shall be submitted by no later than **December 9, 2020** for review by the Court, along with a motion for redaction that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Opinion.