IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAMREN GUINN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 20-71-CJB
	)	
ST. JUDE MEDICAL, LLC, formerly known as St. Jude Medical, Inc., and ABBOTT LABORATORIES, INC.,	)	
	)	
Defendants.	)	

David G. Culley, TYBOUT, REDFEARN & PELL, Wilmington, DE, Attorney for Plaintiff.

Brian M. Rostocki, REED SMITH LLP, Wilmington, DE; J. David Bickham, REED SMITH LLP, San Francisco, CA; Michael K. Brown, REED SMITH LLP, Los Angeles, CA; Lisa M. Baird, REED SMITH LLP, Miami, FL, Attorneys for Defendants.

MEMORANDUM OPINION

December 23, 2020
Wilmington, Delaware

Christopher J. Burke
BURKE, United States Magistrate Judge

Plaintiff Camren Guinn ("Plaintiff" or "Ms. Guinn") 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" or the "Motion to Dismiss"). (D.I. 14) For the reasons that follow, the Court GRANTS St. Jude's Motion in the manner set out below.

I. BACKGROUND

A. Factual Background

1. History of Genesis and Eon Family of Neurostimulation Devices

St. Jude designs, manufactures, markets, distributes, and/or sells a variety of medical devices, including the Proclaim 7 spinal cord stimulator device and Octrode leads (the "SCS Device"). (D.I. 2 at ¶ 10) The SCS Device 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) Then in March 2014, the FDA issued an approval to change the name of the Eon Mini IPG to the Protégé Model 3789, as well as to implement certain software modifications to sync the Patient Programmer with the new Protégé device. (*Id.* at ¶ 23) Otherwise, the Protégé Model 3789 device remained the same as the Eon Mini IPG. (*Id.*)

On November 2, 2015, the FDA approved a PMA supplement for the commercial distribution of the Proclaim™ IPG ("Proclaim"). (*Id.* at ¶ 24) St. Jude marketed the Proclaim as a "MR-compatible, software upgradeable, and recharged-free spinal cord stimulator powered by a hermetically sealed battery within a titanium case." (*Id.*) The Complaint alleges that "[u]pon information and belief[,]" the Proclaim utilizes a lithium battery that is "materially the same as the lithium battery used in the predecessor Eon/Eon Mini/Protégé neurostimulator devices." (*Id.*) St. Jude represented to the public in press releases and other marketing materials that the Proclaim's lithium battery would last up to 10 years before needing to be replaced. (*Id.* at ¶ 25)

2. Patient Complaints, Recalls and Related Activity

Since 2001, there have been numerous patient complaints, related recall campaigns and other similar activity regarding the Genesis and Eon family of neurostimulation devices, as well as other St. Jude devices. (*Id.* at ¶ 27)

[redacted] (*Id.* at ¶ 20) Thereafter, St. Jude initiated three recalls relating to the Eon Mini in 2011.

(*Id.* at ¶¶ 28-30) Two of these 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 ¶¶ 28-29) The third recall, which also occurred in 2011, related to patient complaints of warmth or heating at the implant site during charging of the device. (*Id.* at ¶ 30) For its part, the FDA initiated a Class II Device recall ("Class II 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 ¶ 31) 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 ¶ 32 (internal quotation marks omitted)) [redacted] (*Id.* at ¶ 33)

On October 11, 2016, the FDA published a Safety Communication regarding the premature battery depletion of the lithium battery that was utilized in St. Jude's Implantable Cardioverter Defibrillator ("ICD") and Cardiac Resynchronization Therapy Defibrillator ("CRT-D") devices. (*Id.* at ¶ 34) Plaintiff alleges that "[u]pon information and belief" the lithium battery used in those defibrillator devices is materially the same as the lithium battery used to power the Proclaim. (*Id.*) The October 11, 2016 Safety Communication indicated that deposits of lithium called "'lithium clusters'" could form within the lithium battery, creating abnormal electrical connections leading to premature battery failure. (*Id.*)

On September 12, 2017, St. Jude initiated a Class II recall for the Proclaim regarding an error in measuring the difference between the battery indicator status and the actual battery's

longevity. (*Id.* at ¶ 35) St. Jude also issued a related "Dear Physician" letter in which it reported "incidents in which the elective replacement indicator (ERI) in some devices has triggered earlier than intended[.]" (*Id.* (internal quotation marks omitted))

On April 11, 2018, the FDA issued a Safety Communication approving the use of a "Firmware" software by St. Jude to address the rapid battery depletion issue reported in the FDA's October 11, 2016 Safety Communication regarding the defibrillator devices. (*Id.* at ¶ 36)

3. Ms. Guinn's Experiences with the SCS Device

Ms. Guinn is a resident of the State of Washington. (*Id*. at ¶ 4) In October 2009, she began to experience low back pain that radiated into her left buttock and leg, down to her foot. (*Id.* at ¶ 48) The following month, Ms. Guinn underwent a left L5 and S1 laminectomy, removal of a large disc herniation and decompression of the cauda equina. (*Id.*) Thereafter, she experienced fair resolution of her left leg pain. (*Id.*)

In 2014, Ms. Guinn began to experience right leg pain and weakness that progressively worsened. (*Id.* at ¶ 49) On December 19, 2014, Ms. Guinn underwent a right L5-S1 microdiscectomy. (*Id.*) Her symptoms continued after surgery, and on June 24, 2015, Ms. Guinn underwent lumbar decompression and anterior fusion/instrumentation surgery of the L5-S1 disc space. (*Id.*) She continued to experience low back and leg pain following these surgeries. (*Id.* at ¶ 50)

In early 2016, Ms. Guinn began to see Dr. Arash Motaghi, a pain management physician. (*Id.*) He eventually recommended that Ms. Guinn undergo a trial with a St. Jude spinal cord stimulator device. (*Id.*) After a "'very positive'" trial, Ms. Guinn agreed to proceed with a permanent implantation. (*Id.*)

On August 4, 2016, Dr. Motaghi surgically implanted the SCS Device in Ms. Guinn's left buttock and surgically tunneled the leads from the IPG through the epidural space to the T6 through T8 levels of her spine. (*Id.* at ¶ 51) The procedure took place at the Kadlec Regional Medical Center in Richland, Washington. (*Id.*) A St. Jude representative was present during the surgery to assist with the initial programming of the device. (*Id.*)

Ms. Guinn had a positive experience with the SCS Device until December 2017, a year and a half after implantation. (*Id.* at ¶ 52) At that time, the IPG transmitted a "yellow" signal indicating that it had a "low battery life[,]" which occurred much sooner than would have been anticipated in light of the battery's expected longevity. (*Id.* (internal quotation marks omitted)) At Dr. Motaghi's request, St. Jude representative Mike Jensen checked the device, in order to determine whether it was in fact at the "'end-of-life'" stage. (*Id.*) St. Jude then analyzed data from the device and determined that a software update to the device's programmer would extend its battery life for at least another year. (*Id.*)

On several occasions, Ms. Guinn experienced a sensation of warmth at the implantation site. (*Id.* at ¶ 53) She reported each experience to her St. Jude representative, who responded that it was not something that St. Jude had heard about before. (*Id.*) In late April 2019, Ms. Guinn experienced an episode of intense heat and burning in her left buttock at the site of the IPG. (*Id.* at ¶ 54) The burning pain was more intense and lasted longer than she had experienced before. (*Id.*) Approximately one week later, the pain in Ms. Guinn's legs had returned. (*Id.*) She attempted to connect the programmer to the SCS Device but received a "'cannot connect'" message on the programmer. (*Id.*) On May 1, 2019, Ms. Guinn informed Lindsey John, her St. Jude representative, about this problem; Ms. John in turn attempted to update the software in the programmer. (*Id.* at ¶ 55) The problem persisted, however. (*Id.*) On

May 23, 2019, another St. Jude representative "'interrogated'" the SCS device, informed Ms. Guinn that the battery was dead, and recommended that the IPG be replaced. (*Id.* at ¶ 56)

On June 26, 2019, Dr. Motaghi surgically removed and replaced the IPG. (*Id.* at ¶ 57) Testing of the original leads revealed the presence of high impedance levels which indicated that one or both of the Octrode leads had been compromised. (*Id.*) Following the surgery, and while Ms. Guinn was still in the recovery room, Dr. Motaghi informed her that the leads were "'fried'" and needed to be replaced. (*Id.* at ¶ 58) On July 3, 2019, Dr. Motaghi saw Ms. Guinn and again determined that the Octrode leads were not working properly. (*Id.* at ¶ 59)

On August 7, 2019, Dr. Motaghi surgically explanted the second IPG and the original Octrode leads, surgically tunneled two new Octrode leads through the epidural space to the T7-T9 vertebral levels, and then surgically implanted a new IPG in a newly created pocket at the midline of Ms. Guinn's back. (*Id.* at ¶ 60) A St. Jude representative was present during the surgery. (*Id.*)

B. Procedural History

Plaintiff filed her Complaint on January 17, 2020. (D.I. 2) In lieu of filing an Answer, on March 11, 2020, St. Jude filed the instant Motion. (D.I. 14) Briefing on the Motion (which includes a supplemental letter brief filed by Plaintiff as well as three notices of supplemental authority submitted by St. Jude) was completed on November 5, 2020. (D.I. 49) 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. 48 (hereinafter, "Tr.”))

[1] On September 25, 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. 47)

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 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

The Court will first address what types of claims Plaintiff is pursuing via her Complaint. The Complaint, on its face, includes three Counts. (D.I. 2) The Complaint refers to Count I as a claim for "STRICT PRODUCT LIABILITY" and to Count III as a claim for "NEGLIGENT MANUFACTURE." (*Id.* at 18, 22 (emphasis omitted)) However, St. Jude pointed out in its opening brief that Washington's Product Liability Act ("WPLA" or "the Act") created a single cause of action for product-related harms, thus precluding claims sounding in product liability that are not stated under the WPLA. (D.I. 15 at 19-20 (citing cases))[3] Plaintiff then acknowledged that the WPLA operates to "bring all claims of strict liability and negligence under one umbrella" and that "it would [therefore] be appropriate to consider Count I . . . and Count III . . . as one single claim" under the WPLA—i.e., as a "claim for strict liability based on

[2] The Court assumes familiarity with the November 16 MO. In that case, the plaintiffs asserted claims relating to two St. Jude SCS devices, the Eon implantable pulse generator (IPG), serial number 3832006 and the Protégé Model 3771, which was the same device as the Eon Mini IPG. (November 16 MO at 2-6) The Court also assumes familiarity with its December 4, 2020 Memorandum Opinion in the related case *Check v. St. Jude Med., LLC*, Civil Action No. 20-329-CJB (D. Del. Dec. 4, 2020) (D.I. 38) (hereinafter, "December 4 MO"). In that case, the plaintiff asserted claims relating to the Eon Mini IPG. (December 4 MO at 4-9)

[3] The parties agree that Washington law supplies the substantive state law for this case. (D.I. 15 at 1; D.I. 22 at 1 n.2)

the defective construction of a product[.]" (D.I. 22 at 8; *see also id.* at 2, 20; D.I. 24 at 9)[4] The Court will treat it as such in the discussion below.[5] As for Count II of Plaintiff's Complaint, it asserts a claim for failure to warn under the WPLA. (D.I. 2 at ¶¶ 76-86) Plaintiff's failure to warn claim here 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 ¶ 79(d)-(f); D.I. 22 at 17-19; D.I. 24 at 5-6)

Now understanding the two claims that Plaintiff puts forward, the Court turns to St. Jude's arguments for dismissal. With its Motion, St. Jude asserts that both 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 viable claim for relief. (D.I. 15 at 1-4)

Both of Plaintiff's claims undisputedly rely heavily on facts relating to recalls (and associated patient complaints) regarding St. Jude devices *other than* the Proclaim: St. Jude's Eon and Eon Mini IPGs and its ICD and CRT-D cardiac defibrillator devices. Plaintiff relies on these recalls/associated complaints to support her assertion that St. Jude violated federal regulations—and that such federal violations also amount to violations of Washington state law. (D.I. 22 at 10-11 (Plaintiff explaining that her strict liability claim allegations are sufficient

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[4] As St. Jude noted, the WPLA is the exclusive remedy under Washington state law for claims asserting that a product caused a plaintiff harm. *Mesecher v. Lowes Cos., Inc.*, NO. 2:17-CV-299-RMP, 2018 WL 793613, at *2 (E.D. Wash. Feb. 8, 2018). The Act preempted common law theories of negligence in product liability claims, creating a single cause of action for product-related harms. *Luttrell v. Novartis Pharms. Corp.*, 894 F. Supp. 2d 1324, 1342 (E.D. Wash. 2012). Under the WPLA, to recover on a claim of strict liability based on defective construction against a product manufacturer, a plaintiff must prove that "the claimant's harm was proximately caused by the fact that the product was not reasonably safe in construction[.]" Wash. Rev. Code Ann. § 7.72.030(2).

[5] However, because Plaintiff will be given the opportunity to amend her Complaint (as is discussed below), Plaintiff should correct her Complaint so that it alleges a single claim for strict liability based on defective construction.

because "she points to the evidence of prior-battery related recalls . . . . [that] create a reasonable inference that the manufacturer violated federal requirements in the manufacture (construction) of the device that harmed Ms. Guinn"); *id*. at 19 (Plaintiff acknowledging that her failure to warn claim relies on the Complaint's allegations relating to recalls of the Eon, Eon Mini and cardiac defibrillator devices); D.I. 15 at 17; D.I. 24 at 2; D.I. 26 at 4 ("Plaintiff's entire Complaint depends on the suggestion that this Court can infer a federal violation with respect to her Proclaim based on her allegations of recalls in these other devices.")).[6]

In light of this, one of St. Jude's arguments for dismissal encompasses both of Plaintiff's claims. That is, St. Jude asserts that Plaintiff's allegations regarding recalls/associated complaints involving St. Jude's Eon, Eon Mini and ICD and CRT-D defibrillator devices cannot help establish a plausible claim that Plaintiff's *Proclaim device* violated FDA requirements—and that absent reliance on such allegations, no viable claims exist. (D.I. 15 at 3-4, 17-19; D.I. 24 at 2-5; Tr. at 125, 128-30) The Court first addresses this threshold issue.

Plaintiff's strict liability defective construction claim alleges that Ms. Guinn's SCS Device was defective and unreasonably dangerous to her because: (1) "its battery component became prematurely depleted"; (2) "its battery component caused warmth, heat, and burning at the IPG site"; and (3) "the Octrode leads fractured or failed during their ordinary use[.]" (D.I. 2 at ¶¶ 68-70) The Complaint further alleges that these problems amounted to a violation of federal regulations, in that St. Jude manufactured and/or sold to Ms. Guinn an SCS device that

[6] St. Jude has also filed a motion to strike portions of Plaintiff's Complaint with respect to the Complaint's allegations "regarding recalls and adverse events related to devices other than Plaintiff's Proclaim SCS[,]" (the "Motion to Strike"), (D.I. 17; D.I. 18 at 1), which has been fully briefed, (D.I. 18; D.I. 21; D.I. 26). Plaintiff's answering brief in opposition to the Motion to Dismiss "incorporates . . . her argument as to the relevancy of" these recall-related allegations. (D.I. 22 at 9 n.11) Accordingly, the Court will herein make reference to the briefing on the Motion to Strike in addition to the briefing on the Motion to Dismiss.

was "adulterated" pursuant to 21 U.S.C. § 351, as it did not conform to certain FDA-identified good manufacturing practices ("GMPs") including 21 C.F.R. § 820.90 and 21 C.F.R. § 820.100(a)(3). (*Id.* at ¶¶ 72, 91(a)-(c))[7] And in explaining why she has sufficiently linked the problems she faced with the SCS Device to evidence of the device's defective construction, Plaintiff points to additional pleaded facts, including:

> (1) The prior recalls for the Eon/Eon Mini and ICD and CRT-D defibrillator devices, which were related to those devices' failure to communicate or recharge the IPG, warmth or heating at the implant site or premature depletion of the devices' lithium battery.; and
>
> (2) Her allegation that "[u]pon information and belief" the lithium battery used in the Proclaim device is "materially the same" as the lithium battery used in those other devices.

(*Id*. at ¶¶ 24, 28-34 (*cited in* D.I. 22 at 9-10))

As for Plaintiff's failure to warn claim, Plaintiff alleges that Plaintiff's SCS Device was "defective and dangerous in regards to the design, manufacture, or use of its battery component[,]" and that St. Jude failed to adequately warn Plaintiff and her physicians of the device's dangerous condition. (*Id.* at ¶ 80) More specifically, as was noted above, Plaintiff asserts that St. Jude failed to warn both by: (1) failing to "correct or change its labeling, including its warnings/instructions, so as to adequately inform or warn Ms. Guinn and her

[7] Plaintiff also alleged violations of other GMPs in her Complaint. For example, she alleged violations of 21 C.F.R. §§ 870(a) & (h). (D.I. 2 at ¶ 91(f) & (g)) 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. 15 at 16) 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. 22 at 14 n.15) Additionally, Plaintiff alleged a violation of 21 C.F.R. § 850(a)(1), (D.I. 2 at ¶ 91(e)), but it appears that this should have been a reference to 21 C.F.R. § 820.50(a)(1), *see* 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 (if she wishes to continue to press such allegations) amend her Complaint to correct these errors.

physicians of the relevant hazards as mandated by 21 C.F.R. § 814.39 and § 814.82(a)(9)" and (2) failing to accomplish the "timely and complete submission of Adverse Event Reports and Medical Defect Reports concerning the relevant hazards to the FDA[.]" (*Id.* at ¶¶ 79(a)-(b), (d)-(f), 82) And in Plaintiff's answering brief, she acknowledges that these failure-to-warn allegations necessarily rely on "the publication of the Eon, Eon Mini[], and cardiac defibrillator recalls"—in that: (1) the "cumulative publication" of the adverse events relating to all of these recalls, combined with adverse events relating to the Proclaim, should have prompted labeling changes to the Proclaim device and (2) had certain patient complaints associated with these recalls been reported to the FDA, they would have been uploaded on the FDA's MAUDE database, and such reports would have helped to later dissuade Plaintiff and her physicians from going forward with the implantation of the Proclaim device. (D.I. 22 at 19)

St. Jude's argument for dismissal here is that prior recalls related to *other* devices cannot serve as a plausible basis for inferring a defect or nonconformity in Plaintiff's *Proclaim* device. (D.I. 15 at 18-19; D.I. 18 at 4; D.I. 24 at 2, 10; Tr. at 128) For the reasons set out below, and in light of what is (and is not) pleaded in the Complaint, the Court agrees with St. Jude.

In two related cases—*Freed v. St. Jude Med., Inc.*, Civil Action No. 17-1128-CJB, 2019 WL 5102643 (D. Del. Oct. 11, 2019) and *Mellott*—the Court has previously wrestled with the issue of whether recalls and associated complaints relating to one SCS device model can be relevant to product liability claims relating to a different SCS device model. (*See, e.g.*, D.I. 22 at 7, 9-10; D.I. 24 at 3) In those cases, the Court found that prior recalls/associated complaints relating to Eon and Eon Mini devices could in fact have relevance to claims regarding the Protégé device. Importantly though, this conclusion was motivated by the plaintiffs' allegations that the FDA had issued an approval to change the name of the Eon Mini to the Protégé, and that

otherwise, the Protégé had "'remained the same'" as the Eon Mini. (November 16 MO at 18); *see also Freed v. St. Jude Med., Inc.*, Civil Action No. 17-1128-CJB, 2019 WL 5102643, at *4 (D. Del. Oct. 11, 2019).

But in those prior decisions, the Court was not suggesting that any recalls/associated complaints relating to any device manufactured by the same defendant—or even recalls/associated complaints regarding devices in the same "family" of devices as the product at issue—are *automatically* relevant to a plaintiff's product liability claims. If those recalls/associated complaints had to do with a different device, then a plaintiff would at least have to plead sufficient facts explaining why the recalls/complaints were relevant to the instant device too. The plaintiffs did that in *Freed* and *Mellott*.

The facts here are different, however.

For one thing, here Plaintiff could not and did not make a similar "only-the-name-changed" assertion with respect to the Proclaim device. (D.I. 15 at 18-19; D.I. 24 at 3) This is clear simply from comparing the Complaint's allegation relating to the Eon Mini and Protégé on the one hand (i.e., that in March 2014 "the FDA approved, at St. Jude's request, a labeling change to change the name of the Eon Mini IPG to the Protégé Model 3789" and to implement software modifications, but that otherwise "the device remained the same as the Eon Mini IPG") to its allegation relating to the Proclaim's approval on the other (i.e., that in November 2015, the FDA approved through a PMA supplement the commercial distribution of the Proclaim, which was marketed by St. Jude as a "MR-compatible, software upgradeable, and recharged-free spinal cord stimulator powered by a hermetically sealed battery within a titanium case"). (D.I. 2 at ¶¶ 23-24) In other words, the Complaint makes clear that the Eon/Eon Mini/Protégé devices and the Proclaim device are different devices, in more than name only.

Moreover, the Proclaim device is a *non-rechargeable* device. (*Id.* at ¶ 24) Yet the Eon and Eon Mini devices were *chargeable* devices. (*See, e.g., id.* at ¶¶ 19, 28, 30, 31) This is particularly important because according to the Complaint, the various problems that patients had with the Eon and Eon Mini devices related to what occurred (or did not occur) when the batteries in those devices were attempting to *recharge*:

> (1) In May 2011, St. Jude initiated a recall relating to the Eon Mini following complaints "of the IPGs losing the ability to communicate with or *recharge* the IPG" and identified the defect as weld failures "that caused the batteries to leak electrolyte *preventing them from holding a charge*[,]" (*id.* at ¶ 28 (emphasis added));
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> (2) In December 2011, St. Jude initiated a recall following complaints of the Eon Mini IPG losing the ability to "'communicate or *recharge* due to a workmanship issue'" which was determined to be the result of process variances in the positioning of the internal battery and printed circuit board that caused a short, (*id.* at ¶ 29 (emphasis added));
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> (3) In December 2011, St. Jude initiated a second recall following complaints of warmth or heating at the IPG implant site "*during charging*" of the Eon IPG and Eon Mini IPG, (*id.* at ¶ 30 (emphasis added));
>
> (4) In July 2012, the FDA initiated a Class II recall for St. Jude's Eon Mini after receiving reports of heating at the device site while patients were "*using the charging system to charge their device*[,]" (*id.* at ¶ 31 (emphasis added)); and
>
> (5) In July 2012, St. Jude issued a "Dear Physician" letter regarding the "loss of the ability of the IPG to communicate or *recharge* as a result of an inner battery weld issue[,]" (*id.* at ¶ 32 (emphasis added)).

As for St. Jude's ICD and CRT-D defibrillator devices, the Complaint makes it clear that those devices also differ from the Proclaim. After all, the defibrillator devices treat a completely different problem in a completely different part of the body—i.e., they "provide pacing for slow

heart rhythms and electrical shock or pacing to stop or interrupt dangerously fast heart rhythms[.]" (*Id.* at ¶ 34; *see also* D.I. 24 at 2-3)

Now, as noted above, it is true that despite these clear differences in the respective devices, Plaintiff nevertheless pleads that "[u]pon information and belief" the "lithium battery used in the Proclaim[device] is materially the same" as the lithium battery in the Eon/Eon Mini devices and in the ICD and CRT-D defibrillator devices. (D.I. 2 at ¶ 24; *see also id.* at ¶ 34) But as to this key allegation, the Complaint does not provide the necessary predicate information that would permit the Court to rely on an "upon information and belief" assertion. *See McDermott v. Clondalkin Grp.*, 649 F. App'x 263, 267-68 (3d Cir. 2016) (explaining that a plaintiff may plead "upon information and belief" but only "[w]here it can be shown that the requisite factual information is peculiarly within the defendant's knowledge or control" and "so long as there are no boilerplate and conclusory allegations and [p]laintiffs . . . accompany their legal theory with factual allegations that make their theoretically viable clam plausible") (internal quotation marks, citations and emphasis omitted). And in light of the manifest differences between the Proclaim device and these other St. Jude devices, as well as the fact that the alleged Eon/Eon Mini defects had to do with the recharging of those devices (while the alleged Proclaim defects could not have), the Court cannot find this "upon information and belief"-based allegation plausible. (Tr. at 129-30; D.I. 18 at 1) While Plaintiff argues that "[o]nly detailed discovery . . . can shed the necessary light" on these "battery issues[,]" (D.I. 21 at 6), in order to be entitled to obtain that discovery, Plaintiff must first plead enough facts to push her allegations over *Twombly* and *Iqbal*'s plausibility line, *see, e.g.*, Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense[.]"); *see also, e.g.*, *Sisk v. Sussex Cnty.*, Civil Action No. 11-121-RGA, 2012 WL 1970879, at *12 (D. Del.

June 1, 2012) ("[B]efore Plaintiff is entitled to engage in discovery, she must state some facts that would support a plausible claim; merely stating that such facts might be uncovered during discovery is insufficient to survive a motion to dismiss."). She has not done so here as to this "same battery" allegation.

Therefore, the Court will not consider any of the pleaded facts about the prior Eon/Eon Mini/cardiac defibrillator recalls in assessing the plausibility of Plaintiff's clams about what happened with her Proclaim device. *See Teixeria v. St. Jude Med. S.C., Inc.*, 193 F. Supp. 3d 218, 228 (W.D.N.Y. 2016) (concluding, in resolving a motion to dismiss, that allegations relating to problems including a recall with an earlier model of lead, the Riata, were irrelevant to the plaintiff's claims regarding the Durata lead, which had a "different design and structure" than the Riata lead); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282 (E.D.N.Y. 2009) (explaining, in resolving a motion to dismiss, that the plaintiff failed to demonstrate a cognizable link between the defendant's federal violations and the plaintiff's injury where, *inter alia*, the plaintiff cited to recalls instituted by defendants that did not include the device at issue or any of its components).

So with the allegations regarding these recalls stripped away, what is left in Plaintiff's Complaint that is specific to the history of the *Proclaim*? The Complaint alleges the following in that regard:

> (1) In September 2017, St. Jude initiated a recall for the Proclaim "reflecting an error in measuring the difference between the battery indicator status and the actual device (battery) longevity[,]" (D.I. 2 at ¶ 35);
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> (2) The FDA's MAUDE database of Adverse Event Reports for the Proclaim has identified a number of reports, submitted from 2016-19, relating to: (a) warmth/heating/burning/shocking at the IPG site and (b) premature battery depletion. The Complaint alleges that "[u]pon information and belief" the total number of such events have been "grossly underreported" by St. Jude, (*id.* at ¶¶ 37, 38);

> (3) In 2018 and 2019, the FDA published reports on its MAUDE database regarding the Proclaim becoming inoperable or unable to communicate with the patient programmer, (*id.* at ¶ 39); and
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> (4) The FDA's MAUDE database included a number of adverse event reports in 2014-19 about the Octrode lead, which described lead fractures/failures from 2014-19, (*id.* at ¶ 40).

Although St. Jude devoted substantial resources in its Motion to Dismiss briefing to the argument that Plaintiff's Eon/Eon Mini/ICD and CRT-D defibrillator recall evidence should be entirely discounted, (D.I. 15 at 3, 17-19; D.I. 24 at 2-5), and St. Jude filed a separate Motion to Strike any allegation relating to these recalls, (D.I. 17), in Plaintiff's briefing, she never explained why her claims should survive *even if the recall evidence was ignored*. Instead, Plaintiff simply asserted that these recall-related allegations were relevant, that they should be considered, and that (together with the Complaint's other allegations) they established plausible parallel state law-based claims that avoid preemption. (D.I. 22 at 7, 9-11, 19-20; D.I. 21 at 5-6) As a result, there is nothing in Plaintiff's briefing that explains why the claims should still endure even if the Eon/Eon Mini/defibrillator recall allegations are set aside.

Despite this, the Court has considered the Proclaim-related allegations on their own. Having done so, it cannot conclude that they suffice to set out plausible, non-preempted claims under the WLPA for strict liability defective manufacture or failure to warn.

For one thing, the evidence regarding the sole recall involving the Proclaim is not helpful. That recall was related to a problem with the battery indicator—i.e., that it would wrongly indicate that the battery was depleted *before the battery had actually reached that stage*. (D.I. 2 at ¶ 35) But this problem does not appear to be related to any of the harms that Plaintiff suffered. Plaintiff's problems with the Proclaim's battery stemmed from the fact that her device: (1)

demonstrated excessive "heat generation" and that (2) its battery *actually became* "premature[ly] . . . deplet[ed]." (D.I. 22 at 16 n.17; *see also* D.I. 2 at ¶¶ 52-56; D.I. 24 at 5)

It is a closer call regarding the pleaded evidence as to the Proclaim adverse event reports. On the one hand, those reports appear to relate to problems similar to those that Plaintiff experienced with her Proclaim. (D.I. 2 at ¶¶ 37-40, 52-54, 56-59) But on the other hand, as St. Jude points out, (D.I. 24 at 9-10), the fact that an adverse event occurs regarding a device does not necessarily mean that the device is defective or that St. Jude needed to warn others about it. The Court also notes that most of the adverse events that Plaintiff cites in her Complaint occurred or were filed after Plaintiff first had the SCS device implanted in August 2016. (D.I. 2 at ¶¶ 37-40, 51) And with Plaintiff having made no argument in her briefing as to why these adverse event reports alone would suffice to establish a plausible, non-preempted claim as to either Count, the Court cannot yet see how Plaintiff has sufficiently set out such a claim.[8]

Accordingly, St. Jude's Motion as to both claims is granted.[9]

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[8] Moreover, with regard to Plaintiff's "failure to report adverse events" theory in Count II, that theory suffers from an additional fatal defect. Just like the similar clams in the *Mellott* and *Check* cases, here Plaintiff never specifically alleges *how or why* it is that if certain unsubmitted adverse event reports about the Proclaim had actually been provided to the FDA, Plaintiff and her physicians would have learned of such reports and thereafter sought alternative treatment. (November 16 MO at 33-35; December 4 MO at 17-18) (Indeed, it appears that to this day, Ms. Guinn has a Proclaim device implanted in her body.). (D.I. 2 at ¶ 60; Tr. at 127; D.I. 15 at 5 & n.4)

[9] The Court notes that St. Jude made some additional arguments as to why Plaintiff's claims were preempted. By way of example, St. Jude argued that Plaintiff's manufacturing defect claim cannot be based on a violation of federal GMPs, (D.I. 15 at 16), or that an FDA recall can never have any bearing on the preemption analysis, (*id.* at 17-18). The Court has considered and rejected St. Jude's positions in its prior opinions, (November 16 MO at 16-17, 21-26; December 4 MO at 20-21), and it affirms its conclusions with respect to these overlapping issues here. It does the same with regard to other issues raised by St. Jude here that the Court has previously addressed in those other opinions.

IV. CONCLUSION

For the reasons set out above, the Court GRANTS the Motion.[10] 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 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 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).

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 30, 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

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St. Jude does make an additional unique argument with respect to Plaintiff's "failure to report adverse events" theory in Count II. There it notes that in other related cases, the Court has previously found such a claim not to be preempted, because: (1) the relevant state law at issue in those cases had adopted the Restatement (Second) of Torts § 388 ("Section 388"); and (2) the Court found that Section 388's requirements were identical to or genuinely equivalent to FDA adverse event-reporting requirements. (D.I. 24 at 6-7; *see also* D.I. 15 at 15 n.9) But St. Jude notes that in this case, Washington law is at issue, and that Washington has not expressly adopted Section 388 for failure-to-warn claims. (D.I. 24 at 6-7) For her part, Plaintiff had explained that Washington state law "has adopted the legal equivalent" of Section 388. (D.I. 22 at 15-17) And in its reply brief, St. Jude did not counter by articulating how Washington state law was any different than Section 388 (or how Plaintiff's analysis on this front was incorrect). (D.I. 24 at 7; Tr. at 126) In light of the lack of a clear back-and-forth between the parties on this issue, and because (in light of its decision above) the Court need not resolve this question now, it declines to do so here.

[10] In light of this conclusion, the Court DENIES AS MOOT St. Jude's Motion to Strike. (D.I. 17)

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.