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, Attorneys for Defendants.

MEMORANDUM OPINION

October 27, 2021
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 Amended Complaint[,]" filed pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motion" or the "Motion to Dismiss"). (D.I. 65) For the reasons that follow, the Court DENIES St. Jude's Motion.

I. BACKGROUND

The Court here writes primarily for the parties, who are well familiar with the issues in this case. The Court has previously provided an overview of the relevant background regarding this matter in its December 23, 2020 Memorandum Opinion (hereinafter, "*Guinn I*"), and incorporates that summary herein by reference. (D.I. 50 at 2-7) The Court will only set out additional background facts as needed, in light of the current case posture.

The Court granted St. Jude's motion to dismiss the original Complaint in *Guinn I*, dismissing without prejudice Plaintiff's claims for strict liability based on defective construction and failure to warn. (*Id.* at 19) Those claims relied heavily on facts regarding recalls and patient complaints that did not relate to the Proclaim™ IPG (the device at issue in this action, hereinafter referred to as the "Proclaim")—and that instead related to different St. Jude devices, including the Eon and Eon Mini IPG devices (the "predicate devices") as well as certain cardiac defibrillator devices. (*See id.* at 9) The Court explained that in order for recalls/associated complaints relating to a different device to be relevant to Plaintiff's claims about the Proclaim, "[P]laintiff would at least have to plead sufficient facts explaining why" such recalls/complaints were relevant. (*Id.* at 13) But the allegations in Plaintiff's original Complaint failed to establish

such a link; instead, they made clear only that there were real differences among the respective devices. (*Id.* at 13-15) And with the Complaint's allegations regarding these recalls/complaints then stripped away, the Proclaim-related allegations that remained failed to set out plausible, non-preempted claims. (*Id.* at 16-18) To that end, the Court noted that: (1) Plaintiff had made allegations regarding only a single recall involving the Proclaim, and that recall implicated a problem with the battery indicator that was not related to the harms that Plaintiff had suffered; and (2) Plaintiff had simply failed to explain why the allegations regarding Proclaim-related adverse event reports ("AERs") alone would be sufficient to state a claim. (*Id.*)

Plaintiff then filed her Amended Complaint ("FAC") on January 22, 2021. (D.I. 58) In addition to setting out claims for strict liability based on defective construction (the "defective construction" claim) and failure to warn (the "failure to warn" claim) under the Washington Product Liability Act ("WPLA"), (*id.* at ¶¶ 96-122),[1] Plaintiff's FAC also includes a claim for breach of express warranty under the WPLA, (*id.* at ¶¶ 123-33). The crux of Plaintiff's defective construction and failure to warn claims is that the Proclaim device implanted in Plaintiff's body in August 2016: (1) was defective, in that it caused Plaintiff to experience excessive heating at the IPG site and premature battery depletion, ultimately resulting in the loss of communication with the device; and (2) that St. Jude failed to adequately supplement the Proclaim's labeling to warn Plaintiff of these defects. (*Id.* at ¶¶ 85-88, 90, 102-03, 118; *see also* D.I. 70 at 1-2, 7 n.7, 13)

In lieu of filing an Answer, on February 8, 2021, St. Jude filed the instant Motion. (D.I. 65) The Motion was fully briefed on March 15, 2021. (D.I. 74)

[1] Plaintiff's failure to warn claim in her FAC is based on a "failure to supplement product's labeling" theory; she is no longer pressing a failure to warn claim based on a "failure to report adverse events" theory. (D.I. 70 at 2)

II. STANDARD OF REVIEW

The Court incorporates by reference the legal principles regarding motions to dismiss filed pursuant to Federal Rule of Civil Procedure 12(b)(6), and those regarding the legal doctrine of preemption, all of which were set out in its 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).

III. DISCUSSION

St. Jude moves to dismiss Plaintiff's defective construction and failure to warn claims, arguing that the FAC does not remedy the deficiencies identified in *Guinn I*.[2] (*See* D.I. 66 at 1-2) In its briefing, St. Jude does not make unique arguments for dismissal as to these two types of claims. Instead, St. Jude notes that as to both claims, Plaintiff is primarily relying on two types of allegations: (1) recall/complaint-related allegations regarding the St. Jude predicate devices and defibrillator devices; and (2) certain Proclaim-specific allegations. St. Jude then argues that both types of allegations are wanting, and that whether these two types of allegations are considered separately or together, they cannot suffice to set out plausible defective construction or failure to warn claims.

The Court disagrees. Below, in explaining why this is so, the Court will take up St. Jude's arguments for dismissal as to both types of allegations in turn.

A. Recalls/Complaints Relating to Other Devices

In *Guinn I*, the Court explained that the Complaint's allegations relating to recalls/complaints relating to devices other than the Proclaim were insufficient because:

[2] St. Jude does not seek dismissal of Plaintiff's breach of express warranty claim. (D.I. 66 at 1, 4; D.I. 70 at 2 n.3)

(1) The predicate device-related recalls described therein seemed to involve, at least for the most part, problems that occurred when the batteries in those devices were attempting to recharge, while the Proclaim device is a non-rechargeable device. (D.I. 50 at 14);

(2) The defibrillator devices described in that Complaint treat a completely different problem in a completely different part of the body than does the Proclaim, (*id.*); and

(3) The allegation that the Proclaim's lithium battery is materially the same as the lithium battery in the predicate devices and the defibrillator devices was made "[u]pon information and belief," yet the prior Complaint failed to provide the necessary predicate information for such an allegation to be sufficient, (*id.* at 15).

In opposing St. Jude's Motion, Plaintiff asserts that the FAC "sets forth additional factual allegations intended to address the Court's concerns as to the relevant similarities between the Proclaim device and St. Jude's other devices." (D.I. 70 at 1, 10) The FAC contains nearly 40 entirely new paragraphs of allegations; it also adds other new content to paragraphs that were found in the original Complaint. (D.I. 2; D.I. 58)

St. Jude contends that the FAC still fails to establish "how the devices themselves (or their design or manufacture) are similar enough to warrant the use of non-Proclaim allegations to plausibly show that the Proclaim violated FDA requirements." (D.I. 74 at 5; *see also id.* at 2; D.I. 66 at 6-7) For the following reasons, the Court does not agree.

To be sure, as St. Jude notes, (D.I. 66 at 6-7), in a number of places the FAC makes clear that there are differences between the Proclaim device and St. Jude predicate devices/defibrillator devices. For example, the FAC explains that [redacted] (D.I. 58 at ¶ 33 (internal quotation marks and emphasis omitted) The FAC also alleges [redacted]

[redacted] (*Id.* at ¶ 30 (internal quotation marks omitted)) The FAC also asserts that St. Jude's premarket approval ("PMA") supplement for the Proclaim noted that, [redacted] And with regard to the defibrillator devices, the FAC notes that these serve a different function than neurostimulation devices like the Proclaim, in that they "provide pacing for slow heart rhythms and electrical shock or pacing to stop or interrupt dangerously fast heart rhythms." (*Id.* at ¶ 66)

But the FAC *also* now includes allegations establishing the many similarities between the Proclaim and the predicate devices/defibrillator devices, such as the following:

(1) In applying for approval of the Proclaim by the United States Food and Drug Administration ("FDA"), [redacted] (*Id*. at ¶¶ 32-33 (internal quotation marks and emphasis omitted));

(2) [redacted] (*Id.* at ¶ 35 (internal quotation marks and emphasis omitted);

(3) [redacted]

[redacted] (*Id.* (emphasis omitted));

(4) [redacted] (*Id.* at ¶ 37);

(5) [redacted] (*Id.* at ¶¶ 38-39);

(6) [redacted] (*Id.* at ¶¶ 40, 42-43);

(7) [redacted] (*Id.* at ¶¶ 45-48 (internal quotation marks omitted));

(8) These hazards are the same or materially similar to those identified during the development and subsequent use of the predicate devices. (*Id.* at ¶¶ 14, 17-18, 23-24, 27, 49); and

(9) Patients who have been implanted with both the predicate devices and the Proclaim have experienced these hazards. (*Id.* at ¶¶ 50-51, 60-61, 65, 69-73)

Accepting the FAC's allegations as true, then, and construing the FAC's allegations in the light most favorable to Plaintiff (as the Court must at this stage), the Court agrees with Plaintiff that the allegations render it at least plausible that "the battery and microelectric circuitry used in the Proclaim device is materially the same in its *functionality, performance, and hazards/defects*" as in St. Jude's other predicate devices/defibrillator devices. (D.I. 70 at 10 (emphasis in original)) That is, the allegations in sum demonstrate that: (1) St. Jude's neurostimulation devices (including the Proclaim) and implantable cardiac defibrillator devices use a battery component and microelectric circuitry to power the device; (2) the Proclaim's "design and functional features" are based on the predicate devices; (3) the Proclaim's "mechanical packaging, microelectronic and battery chemistry" is "based on the same technology" as that utilized in the predicate devices and defibrillator devices; [redacted] and (6) customers had similar reported problems with both the predicate devices and the Proclaim device. (*Id.* at 10-12) Admittedly, the FAC could be clearer, for example, as to what it means for the Proclaim to have circuitry or battery chemistry that are "based on the same technology" as that in predicate devices/defibrillator devices, or for the Proclaim to have "design and functional features" that are "based on" predicate devices. (*See* D.I. 66 at 7-8) But we are at the pleading stage. And at least

at this stage, Plaintiff has alleged facts that, if taken as true, seem like they could establish that the battery components and microelectric circuitry in these other devices are sufficiently similar to that in the Proclaim. Thus, it seems plausible that, to the extent that prior recall/complaint-related evidence about predicate devices/defibrillator devices relate to the same problems that Plaintiff experienced with her Proclaim device, then that evidence is relevant to the Motion.[3]

The question then becomes, *is* Plaintiff relying on prior recall/complaint allegations in her FAC that *do* bear relation to the problems that Plaintiff herself experienced with the Proclaim?

In her briefing, Plaintiff appeared to indicate that she is relying on five paragraphs of her FAC that contain prior recall allegations: paragraphs 60-61, 64, 66 and 68. (D.I. 70 at 7-8 & n.7)[4] And for the reasons set out below, the Court concludes that this reliance is appropriate:

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[3] St. Jude counters by arguing that the above allegations about similarities between the Proclaim and other St. Jude devices are "so general in nature" that they could apply to essentially all implantable medical devices, as well as to other battery-operated devices like flashlights and motor vehicles. (D.I. 74 at 3-4) But contrary to the suggestion in Defendants' briefing, (*id.* at 3), Plaintiff's allegation here is not just that the Proclaim and the predicate devices/defibrillator devices simply all have *some type* of battery and microelectric circuitry (and thus can suffer from the same hazards). [redacted] That is more than simply an "all the devices have a battery and circuitry"-type of argument.

[4] In her briefing, Plaintiff disclaimed reliance on prior recall allegations in two paragraphs of the FAC: paragraphs 62-63. (D.I. 70 at 7 n.7 (citing D.I. 58 at ¶¶ 62-63)) These two paragraphs describe December 2011 and July 2012 recalls of the Eon and Eon Mini, following complaints of heating at the implant site during the *charging* of those devices. (D.I. 58 at ¶¶ 62-63) As the Court has previously noted in its December 23, 2020 Memorandum Opinion regarding Defendants' motion to dismiss the original Complaint, it is not clear why this recall evidence is relevant to Plaintiff's allegations, since the Proclaim utilizes a *non-rechargeable* battery. (D.I. 50 at 14; *see also* D.I. 70 at 7 n.7) The Court will not consider the allegations in paragraphs 62 and 63 in resolving this Motion.

- With regard to paragraphs 60-61 and 64, these describe evidence relating to 2011 and 2012 recalls involving the Eon Mini. The Complaint explains that these recalls were prompted by numerous customer complaints about, *inter alia*, the fact that the battery in the Eon Mini lost the ability to "communicate" with the IPG, resulting in a loss of pain relief and subsequent explant surgery. (D.I. 58 at ¶¶ 60-61, 64) Plaintiff, in turn, has alleged that she had problems with her Proclaim device in 2019 stemming from the inability to get her programmer to connect to the IPG, due to the fact that the device's battery was "'dead.'" (*Id*. at ¶¶ 88, 90)[5]

- With regard to paragraphs 66 and 68, these describe the FDA's publication in 2016 and 2018 of Safety Communications relating to the "premature battery depletion" of the lithium battery used to power certain of St. Jude's defibrillator devices. (*Id.* at ¶¶ 66, 68) And Plaintiff alleges that in 2017, her Proclaim device had signaled that it was suffering from "low battery life" that occurred "much sooner than the expected and warranted longevity of the battery." (*Id*. at ¶ 86 (emphasis omitted))

Additionally, as noted above, the FAC also includes other allegations about customer complaints—via its citations to relevant Risk Assessments, Risk Management Reports, Risk Tables, patient complaints and AERs—asserting that the predicate devices caused problems like excessive heating at the implant site, reduced battery life, or loss of all communication between the battery and the IPG. (D.I. 70 at 13 (citing D.I. 58 at ¶¶ 14, 17-18, 21-24, 27, 69-70)) The

[5] St. Jude notes that in these paragraphs relating to the 2011 and 2012 recall evidence, the FAC states that these recalls were also prompted by customer complaints that the Eon/Eon Mini's battery failed to "recharge[.]" (D.I. 58 at ¶¶ 60-61, 64; *see also* D.I. 74 at 3 n.2) As stated above in footnote 4, the Court agrees with St. Jude that, because the Proclaim has a non-rechargeable battery, Plaintiff has not shown how these complaints relating to the "recharg[ing]" process would be relevant to the injuries Plaintiff has suffered. But in her briefing, Plaintiff pointed out that this recall evidence did not *only* relate to customer complaints about "recharg[ing]"—it *also* relates to complaints about the devices' failure to "communicate" with their battery. (D.I. 70 at 7 n.7) The Court can now see how these latter type of complaints would seem to be relevant here, as set out above.

FAC pleads that Plaintiff dealt with these same issues with regard to the Proclaim. (D.I. 58 at ¶¶ 86, 88, 90)

Therefore, the Court will take into account the above-referenced allegations in resolving this Motion. These are not the only allegations the Court considers as to plausibility here, however, as the Court will further discuss below.

B. Proclaim-Specific Allegations

The Court turns next to the FAC's Proclaim-specific allegations. They too help to plausibly establish Plaintiff's claims.[6]

Certain of these allegations relate to the Proclaim's Risk Table. As noted above, the FAC explains how, during development of the Proclaim, St. Jude analyzed the device for its potential hazards and risks by looking at the hazard analyses and complaint data for the predicate devices, and published these in a March 2015 report, which included a Risk Table. (*Id*. at ¶¶ 40, 42-44 & ex. A) The Risk Table identifies as potential hazards, *inter alia*, [redacted] (*Id.* at ¶¶ 45-48 (internal quotation marks omitted))

[6] Plaintiff's FAC includes one allegation (that had also been in Plaintiff's original Complaint) relating to a recall of the Proclaim device itself; the recall was prompted by an error in measuring the difference between the device's battery indicator status and the actual longevity of the battery. (D.I. 58 at ¶ 67) However, the Court explained in *Guinn I* that this problem does not appear to be related to the harms that Plaintiff actually suffered. (D.I. 50 at 17-18) And Plaintiff acknowledges in her brief that "there exists no relevant recall history (thus far) for the Proclaim[.]" (D.I. 70 at 6) Thus, this allegation does not impact the Court's analysis here.

St. Jude argues that these allegations are irrelevant because they describe *possible* risks that St. Jude then mitigated (thus leading the FDA to grant the PMA for the Proclaim device). (D.I. 66 at 10-11; D.I. 74 at 6, 8) But as Plaintiff retorts, just because St. Jude was required to take steps to mitigate these risks before its Proclaim product was to be sold, that does not mean that these risks were in fact entirely eliminated. And other allegations in the FAC establish that these hazards *actually occurred* in both the predicate devices and in the Proclaim. (D.I. 70 at 13)[7] These allegations include those relating to Plaintiff's own experience with the Proclaim, (D.I. 58 at ¶¶ 86-88, 90), as well as to those relating to AERs for the Proclaim, (*id.* at ¶¶ 71-73).

Plaintiff also relies on certain allegations relating to the Proclaim's AERs. In response, St. Jude contends that the mere existence of AERs relating to a device does not mean that a device is defective or that St. Jude was required to warn about such defects. (D.I. 66 at 12; D.I. 74 at 9-10) However, the Court agrees with Plaintiff that, taken together with the other allegations of the FAC, the allegations describing AERs for the Proclaim at minimum help to support a plausible claim that the Proclaim was defective when implanted in Plaintiff. (D.I. 70 at 13) This is true even with respect to AER data generated after the device was implanted in Plaintiff. (*Id.* ("[E]vidence of the Proclaim's real life results, as predicted by St. Jude's own hazard analyses, provides powerful post hoc evidence of the SCS device's condition when sold

[7] St. Jude also contends that because the FDA approved the PMA based on the submitted documents including the Risk Table, then any claims based on such materials are preempted, since any other outcome would amount to a challenge to the FDA's determination of the safety and effectiveness of the device. (D.I. 66 at 11; D.I. 74 at 9) The Court is not persuaded. Plaintiff's point is that the Risk Table demonstrates that St. Jude had identified certain risks relating to the Proclaim that *then subsequently actually occurred*; thus, these allegations help to support Plaintiff's claims that: (1) the Proclaim device implanted in Plaintiff suffered from defects that led to similar harm for Plaintiff; and (2) St. Jude should have supplemented its label to warn patients of the hazards associated with premature battery depletion, battery overheating and burning and lead failure.

to Ms. Guinn.")); *cf.*, *Gordon v. B. Braun Med. Inc.*, Case No. 1:19-cv-121, 2020 WL 1491378, at *8 (S.D. Ohio Mar. 27, 2020) ("[B]ased on the facts Plaintiff has alleged in the complaint, the Court finds that the filter plausibly exhibited either a design or manufacturing defect. This can be inferred from the outcome—the filter's tilt—in combination with the adverse MAUDE reports and other reports cited by the Plaintiff.").

Taken together with the above-referenced recall/complaint allegations as to predicate devices/defibrillator devices, the Proclaim-specific allegations in the FAC establish plausible parallel claims that survive preemption.[8]

IV. CONCLUSION

[8] Plaintiff's answering brief concludes by arguing that the FAC more specifically connects the defects that Plaintiff experienced to alleged violations of federal requirements (and that the allegations therefore establish plausible parallel claims for the Proclaim). (D.I. 70 at 14-15 & nn.10-14) For example, with respect to Plaintiff's defective construction claim, the FAC alleges that St. Jude manufactured and/or sold to Plaintiff a Proclaim that was "adulterated" pursuant to 21 U.S.C. § 351, in that it did not conform to certain identified good manufacturing practices ("GMPs") required by the FDA, including 21 C.F.R. § 820.90(a) and 21 C.F.R. § 820.100(a)(3). (D.I. 58 at ¶¶ 81, 106, 110) And in connection with Plaintiff's failure to warn claim, the FAC alleges that, for example, St. Jude failed to supplement its label to adequately warn Plaintiff's physicians of the hazards of the Proclaim device in violation of regulations including 21 C.F.R. § 801.109 and 21 C.F.R. § 814.39(d)(2). (*Id.* at ¶¶ 75, 118) Plaintiff also points to the Risk Tables of the predicate devices and Proclaim, which identified the hazards that Plaintiff experienced and related them to, *inter alia*, manufacturing errors and inadequate labeling, as lending further support for her claims. (*Id.* at ¶¶ 14, 17, 23, 45-48) Finally, Plaintiff contends that these alleged violations of federal regulations parallel state law requirements under the WPLA. (*Id.* at ¶¶ 97-101, 116-17)

The Court agrees, and indeed, St. Jude does not fight back with respect to Plaintiff's argument here, except to contend that the Risk Tables cannot show that the Proclaim violated federal regulations. (D.I. 74 at 8-9) To that point, though, Plaintiff is not relying solely on the Risk Tables to show that St. Jude violated federal requirements. (D.I. 70 at 14-15) Rather, Plaintiff's point is that the Risk Tables demonstrate that if a device causes excessive heating, for example, then possible causes of any excessive heating-related damage that Plaintiff suffered in could be manufacturing errors and inadequate labels/warnings, which are at least relevant to Plaintiff's claims here. (*Id.*) In sum, the Risk Tables are one piece of a larger puzzle that collectively, plausibly establishes Plaintiff's claims.

For the reasons set out above, the Court DENIES the Motion.

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 Memorandum Opinion. Any such redacted version shall be submitted no later than **November 1, 2021** for review by the Court. It should be accompanied by a motion for redaction that shows that the presumption of public access to judicial records has been rebutted with respect to the proposed redacted material, by including a factually-detailed explanation as to how that material is the "kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Opinion.