IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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

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

MEMORANDUM OPINION

October 11, 2019
Wilmington, Delaware

Christina A. Burke

BURKE, United States Magistrate Judge

Plaintiffs Kathleen M. Freed and Richard Freed ("Plaintiffs" or "the Freeds") bring this products liability action against Defendants St. Jude Medical, Inc., St. Jude Medical S.C., Inc., Abbott Laboratories, Inc. and Advanced Neuromodulation Systems, Inc., d/b/a St. Jude Medical Neuromodulation Division (collectively, "St. Jude" or "Defendants"). Presently before the Court is St. Jude's "Motion to Dismiss Plaintiffs' Second Amended Complaint[,]" filed pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motion"). (D.I. 42) For the reasons that follow, the Court DENIES St. Jude's Motion.

I. BACKGROUND AND STANDARD OF REVIEW

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 February 1, 2019 Memorandum Opinion (hereinafter, "*Freed II*"), and incorporates that summary herein by reference. (D.I. 34 at 2-5) The Court will only set out additional background facts as needed, in light of the current case posture.

After the Court granted-in-part and denied-in-part St. Jude's Motion to Dismiss the First Amended Complaint ("FAC") in *Freed II*,[1] Plaintiffs filed their Second Amended Complaint ("SAC") on April 9, 2019. (D.I. 39)[2] In lieu of filing an Answer, on May 9, 2019, St. Jude filed

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[1] Specifically, the Court dismissed Plaintiffs' breach of warranty claims with prejudice and denied St. Jude's motion with respect to Plaintiffs' negligent manufacturing claim. (D.I. 34 at 33) With respect to Plaintiffs' failure to warn claim, the Court dismissed that claim without prejudice to Plaintiffs' ability to file a further amended complaint that would: (1) address the FAC's deficient pleading with regard to the element of causation; and (2) make it expressly clear that such claim is based on Restatement (Second) of Torts § 388. (*Id.*)

[2] In addition to setting out claims for negligent manufacturing and failure to warn, (D.I. 39 at ¶¶ 70-85), Plaintiffs' SAC also includes three claims relating to breach of warranty, (*id.* at ¶¶ 47-69). The SAC recognizes that these claims were dismissed with prejudice in *Freed II*, (*id.* at 16 n.1, 17 n.2, 18 n.3), but Plaintiffs nevertheless included them in their SAC "to preserve them for appeal purposes[,]" (D.I. 45 at 3 n.2).

the instant Motion. (D.I. 42) The Motion was fully briefed on June 18, 2019, (D.I. 48), and the Court heard oral argument on the Motion on October 8, 2019.

The Court additionally 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 also set out in *Freed II*. (D.I. 34 at 5-12)

II. DISCUSSION

The Court will address St. Jude's arguments with respect to Plaintiffs' negligent manufacturing claim and failure to warn claim in turn.

A. Negligent Manufacturing

With respect to their negligent manufacturing claim, Plaintiffs allege in the SAC that, *inter alia*: (1) St. Jude manufactured and/or sold a variety of spinal cord stimulator devices ("SCS device(s)") with components including batteries that were defective and that caused injury to patients like Mrs. Freed, (D.I. 39 at ¶ 83); (2) St. Jude has conducted recall campaigns in the past for various such devices and their components, including batteries, (*id.* at ¶¶ 27, 84); and (3) St. Jude manufactured and/or sold to Mrs. Freed an SCS device that was adulterated or that was otherwise nonconforming with certain identified good manufacturing practices ("GMPs") required by the FDA, (*id.* at ¶¶ 81 (citing 21 U.S.C. § 351), 85; *see also id.* at ¶ 35 (citing 21 C.F.R. §§ 820.90(a), 820.100(a)(3)). Importantly, Plaintiffs made these *same* allegations in their FAC. (*See, e.g.*, D.I. 19 at ¶¶ 12, 16, 48, 50-52) Indeed, at oral argument, St. Jude's counsel acknowledged that in substance, Plaintiffs' negligent manufacturing claim in their SAC is the same as it was in their FAC.

Nevertheless, in the instant Motion, St. Jude asserts that Plaintiffs' negligent manufacturing claim should now be dismissed with prejudice for two reasons. First, St. Jude

argues that the recalls that Plaintiffs rely upon cannot support a viable claim for negligent manufacturing, sufficient to survive the affirmative defense of preemption, because those recalls relate to prior devices (i.e., the Genesis and Eon family of neurostimulator devices) with different FDA Premarket Approvals ("PMAs") that predate the March 2014 PMA for the Protégé, the device at issue. (D.I. 43 at 9-11; D.I. 48 at 2-3) Second, St. Jude argues that Plaintiffs' reliance on GMP regulations cannot serve as the basis for a federal violation sufficient to survive preemption, because such GMPs are vague and open-ended, and thus create standards that are different from, or in addition to, those required by federal requirements. (D.I. 43 at 15-16; D.I. 48 at 6-9) St. Jude did not raise either of these arguments in its prior Motion to Dismiss the FAC. (*See* D.I. 34 at 33 n.20; D.I. 43 at 15 n.5; D.I. 48 at 9-10)

Plaintiffs respond that these two arguments "should have been raised in [Defendants'] Motion to Dismiss the FAC" but were not, and therefore "have been waived by Defendants" at this Rule 12(b)(6) stage. (D.I. 45 at 3; *see also id.* at 11-12, 17) The Court agrees.

Federal Rule of Civil Procedure 12(g)(2) states that: "[e]xcept as provided in Rule 12(h)(2) or (3), a party that makes a motion under this rule must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion." Fed. R. Civ. P. 12(g)(2). When St. Jude filed its previous motion to dismiss the FAC, it could have made these same two arguments for dismissal (regarding a claim that was the same in substance in that complaint), as even its counsel acknowledged during oral argument here. But it did not. Thus, pursuant to Rule 12(g)(2), St. Jude should not be allowed to raise these previously-available arguments in a subsequent Rule 12(b)(6) motion. *See Leyse v. Bank of Am. Nat'l Ass'n*, 804 F.3d 316, 320-22 & n.5 (3d Cir. 2015) (finding that when defendant filed a second Rule 12(b)(6) motion to dismiss asserting that the plaintiff lacked statutory standing, but

where defendant could have and did not raise such a defense in its prior Rule 12(b)(6) motion, the district court committed "error" in nevertheless considering that statutory standing argument); *Sunoco Partners Mktg. & Terminals L.P. v. Powder Springs Logistics, LLC*, Civil Action No. 17-1390-LPS-CJB, (D.I. 322 at 5-7) (D. Del. Aug. 7, 2019) (finding a motion to dismiss waived as to certain claims because the original complaint contained those claims, but defendant's prior motion to dismiss that original complaint did not seek to dismiss those claims) (citing cases).[3] Therefore, St. Jude's Motion with respect to Plaintiffs' negligent manufacturing claim is denied.

B. Failure to Warn

As noted above, in *Freed II*, the Court found Plaintiffs' failure to warn claim to be insufficiently pleaded because "Plaintiffs did not adequately plead a causal nexus between St. Jude's alleged failure to report adverse events (on the one hand) and Mrs. Freed's injuries (on the other." (D.I. 34 at 27) To that end, the FAC did not "allege that had St. Jude reported certain adverse events to the FDA, this information would have reached Mrs. Freed's physicians (and ultimately her) and would have impacted Mrs. Freed's decision to have the SCS device

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[3] The Court recognizes that, as St. Jude argues, (D.I. 48 at 10), Rule 12(g)(2) (by way of its citation to Rule 12(h)(2)) would still permit it to make these arguments in subsequent motions, such as a Rule 12(c) motion for judgment on the pleadings. Fed. R. Civ. P. 12(h)(2). And it is true that some other courts in this same position have, for efficiency's sake, nevertheless gone on to consider the plausibility of claims that (under a strict reading of Rule 12(g)(2)) should live on to fight another day. (D.I. 48 at 10 (citing cases)); *see also Sunoco*, (D.I. 322 at 6-7). But the United States Court of Appeals for the Third Circuit has pretty clearly stated that in these circumstances, the Court should "enforce Rule 12(g)(2)" and decline to commit "error" by analyzing the claims under *Twombly/Iqbal*, even if the Court's "failure to do so is [harmless and thus] not a ground for reversal[.]" *Leyse*, 804 F.3d at 321-22 & n.5 (explaining that taking this path, "over the long term, . . . may motivate defendants to consolidate their arguments in a single pre-answer motion"). Thus here, pursuant to the Third Circuit's guidance, the appropriate path is to deny the instant Motion as to these arguments for dismissal.

implanted in her body[,]" nor did it "explain how the reporting of such adverse events to the FDA would have prompted the FDA to take an action that would have made the information available to Mrs. Freed and her physician." (*Id.*) In their SAC, Plaintiffs added the following new allegations relevant to causation:

> 34. Upon information and belief the FDA publishes reports of adverse events and [reports made pursuant to Medical Device Reporting requirements] in a searchable database for use by the general public including physicians and patients. This reporting serves to notify the public of a potential problem with a device so the informed person can avoid the hazard or develop a solution to address it. . . .
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> 76. In the event that St. Jude had properly informed or notified the FDA of the SCS devices' hazards/risks/defects Mrs. Freed and/or her physicians would have learned about them and either chosen to implant a different neurostimulation system or taken steps to avoid the use of the SCS device in a specific manner or environment that created the risk of harm.

(D.I. 39 at ¶¶ 34, 76 (emphasis omitted))[4]

Notwithstanding these additional allegations, St. Jude argues that Plaintiffs still fail to adequately plead sufficient facts relating to the causation element for the SAC's failure to warn

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[4] During oral argument, Plaintiffs' counsel pointed out another allegation in the SAC (which was also included in the FAC in similar fashion) relevant to causation:

> 37. . . . . On or about July 23, 2014 . . . . [i]t was recommended that Mrs. Freed undergo surgery to permanently implant a St. Jude Spinal Cord Stimulator device for use in management of her chronic pain symptoms. Before deciding to proceed with permanent implantation of the SCS device Plaintiffs did their own research on the internet as to both the SCS device and other alternative devices. Based on what they read (or did not read) on the internet Plaintiffs were satisfied that the SCS device was safe and of good quality. Plaintiffs relied upon this information in deciding to proceed with the permanent implant.

(D.I. 39 at ¶ 37 (emphasis omitted))

claim, and that the claim should therefore be dismissed with prejudice. (D.I. 43 at 12-15; D.I. 48 at 4-6) During oral argument, St. Jude's counsel primarily argued that Plaintiffs' causation allegations remain deficient because the adverse events that Plaintiffs allege St. Jude had a duty to report pursuant to federal requirements (i.e., the various past recalls involving the Genesis and Eon family of neurostimulator devices) do not involve the *Protégé*, and instead were related to other previous products (i.e., the Eon Mini neurostimulation device). Indeed, St. Jude's counsel acknowledged that if this was a case relating to an *Eon device*, Plaintiffs' allegations with respect to causation would be at least "closer" to nudging over the line of plausibility.

However, this argument—that the allegations regarding causation are insufficient because they relate to the *wrong products*—was not clearly and explicitly raised in St. Jude's briefing on the Motion. (D.I. 43 at 12-15; D.I. 48 at 4-6) Therefore, St. Jude has waived this argument for purposes of this Motion. *See, e.g.*, *In re La Paloma Generating Co. LLC*, Civ. No. 17-1697-LPS, Civ. No. 19-17-LPS, 2019 WL 4674865, at *11 (D. Del. Sept. 24, 2019); *Horatio Washington Depot Techs. LLC v. TOLMAR, Inc.*, Civil Action No. 17-1086-LPS, 2018 WL 5669168, at *7 n.4 (D. Del. Nov. 1, 2018).

Nevertheless, even were the Court to consider the merits of that argument here (along with the other arguments as to lack of causation made in St. Jude's briefing) the Court would still conclude that Plaintiffs have set out just enough facts to establish a plausible claim for relief. That is, Plaintiffs' allegations are sufficient to plausibly allege a causal nexus between St. Jude's alleged failure to report adverse events and Mrs. Freed's injuries. In this regard, the SAC alleges that:

> (1) The FDA publishes reports of adverse events in a searchable database for use by the general public, including physicians and patients, and this database serves to notify the public of potential problems with a device, (D.I. 39 at ¶ 34);

(2) Plaintiffs did internet research regarding the Protégé and other devices before deciding to proceed with permanent implantation of the Protégé device, (*id.* at ¶ 37); and

(3) If St. Jude had properly informed the FDA of the hazards, risks and defects associated with the device (i.e., those associated with the recalls of certain St. Jude products), Mrs. Freed and/or her physicians would have learned about them and taken appropriate steps to avoid the risk of harm associated with the device, (*id.* at ¶ 76).

And while it is true that Plaintiffs' allegations with respect to the recall history relate to the Eon Mini device, (*id.* at ¶ 27), Plaintiffs further allege that on March 21, 2014, the FDA approved a St. Jude PMA supplement, the effect of which was to simply change the name of the "Eon Mini" device to the "Protégé" device, and to implement certain software modifications related to this name change, (*id.* at ¶ 23; D.I. 45 at 9 n.9).[5] Taking all of this into account: (1) if adverse event reports regarding the allegedly defective components of the Eon Mini device at issue had been inputted into the FDA's database prior to Mrs. Freed's initial implantation procedure in 2014;[6] and (2) if it is true (as Plaintiffs assert) that the Eon Mini device and the Protégé device were

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[5] St. Jude attached to its opening brief the March 21, 2014 FDA PMA letter for the Protégé device. (D.I. 43, ex. 2) The content of that letter provides a basis to believe that the PMA supplement for the Protégé related only to "labeling modifications to change the name of the Eon Mini IPG to Protégé (Model 3789); labeling modifications to change the name of the Eon Mini LE Charge to Prodigy Charger (Model 3730); and minor software modifications to the Patent Programmer and Rapid Programmer (Model 3852) to recognize the device with the new Protégé device name and model number." (*Id.*) It is appropriate to consider the content of this document, which is available to the public, (D.I. 43-1 at 3), and which relates to allegations in the Complaint, (*see, e.g.*, D.I. 39 at ¶ 23), in deciding St. Jude's Motion. *See, e.g.*, *In re Chemed Corp., Shareholder Derivative Litig.*, Civil Action No. 13-1854-LPS-CJB Consolidated Action, 2019 WL 3215852, at *3 n.6 (D. Del. Feb. 26, 2019) ("Generally, courts faced with a motion to dismiss must limit their consideration solely to the complaint's allegations, attached exhibits, documents integral to or explicitly relied upon in the complaint, and matters of public record.") (citing cases).

[6] At oral argument, St. Jude's counsel acknowledged that though the FDA may not be required to input such adverse event reports into its database, it sometimes does so, and acknowledged that such inputted reports can be viewed thereafter by interested members of the public.

mechanically identical (and that the March 2014 FDA supplemental PMA action was focused on simply approving a name change to the product); then (3) it seems plausible that Mrs. Freed (whom we know was doing internet research on the Protégé device prior to her 2014 operation) and/or her physicians might have seen indication of such adverse events online in 2014, might have connected them to the Protégé device, and might thus have declined to go forward with implantation of the Protégé device in that year or thereafter.

It certainly would have been better for Plaintiffs had their new allegations in the SAC relating to causation been more robust. But nevertheless, construing Plaintiffs' allegations in the light most favorable to them (as the Court must at this nascent stage of the case), it is plausible that St. Jude's alleged failure to warn the FDA (and therefore Mrs. Freed) about alleged hazards, risks and defects relating to the device at issue could have caused Mrs. Freed's injuries.[7] Therefore, St. Jude's Motion with respect to Plaintiffs' failure to warn claim is denied.

III. CONCLUSION

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

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[7] *See, e.g.*, *Bull v. St. Jude Med., Inc.*, CIVIL ACTION NO. 17-1141, 2018 WL 3397544, at *2, *9 (E.D. Pa. July 12, 2018) (finding that causation was sufficiently pleaded where the complaint alleged that the FDA had published adverse events in a public, searchable databased called MAUDE, which is used by the general public to obtain safety data on medical devices, and had St. Jude reported certain relevant adverse events to the FDA, information regarding the risks of the device at issue would have reached plaintiff's doctors in time for them to select a different device); *Fisk v. Medtronic, Inc.*, Case No. 3:17-CV-032 JD, 2017 WL 4247983, at *7 (N.D. Ind. Sept. 25, 2017) (finding plaintiff's allegations of causation adequate where she alleged that defendant knew that the implanted device was defective and dangerous, and that had defendant timely notified the FDA of the known problems with the device, plaintiff and her doctors would have learned of them and removed the device); *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 187 (N.D.N.Y. 2014) (finding causation to be sufficiently pleaded where the complaint alleged that had defendants reported the adverse events at issue to the FDA, those reports would have reached the plaintiff's physician through the MAUDE public database, and where defendants did not contest that the FDA regularly publishes adverse reports such as those at issue).

An appropriate Order follows.