IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COLLEEN ROSS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 20-971-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.

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MEMORANDUM OPINION

November 29, 2021
Wilmington, Delaware

Christopher J. Burke
BURKE, United States Magistrate Judge

Plaintiff Colleen Ross ("Plaintiff" or "Ms. Ross") 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"). (D.I. 22) For the reasons that follow, the Court DENIES St. Jude's Motion.

I. BACKGROUND

A. Factual Background

Ms. Ross, a New York resident, injured her lower back in August 2009 while operating an off-road four-wheel vehicle. (D.I. 15 at ¶¶ 4, 76) Her lower back pain progressed to pain that radiated down her left leg. (*Id.* at ¶ 76) An MRI study of Ms. Ross's lumbar spine revealed a left paracentral disc herniation compressing the left S1 nerve root at the L5-S1 disc level. (*Id.*)

In April 2011, Ms. Ross underwent a left L5-S1 hemilaminectomy and discectomy. (*Id.* at ¶ 77) One year later, she experienced a sudden severe reoccurrence of pain in her low back and left leg. (*Id.* at ¶ 78) Ms. Ross was referred to a pain management clinic with a diagnosis of "post-laminectomy failed back syndrome" after it was determined that she was not a candidate for lumbar fusion surgery. (*Id.*) Ms. Ross tried several opioid and non-opioid medications, as well as a series of transforaminal epidural steroid injections, all without relief. (*Id.* at ¶ 79)

From 2013 through March 2018, Ms. Ross continued to work as a cook and waitress while experiencing daily pain. (*Id.* at ¶ 80) In March 2018, she sought treatment at a local emergency department upon experiencing a sudden worsening of her radicular low back pain. (*Id.*) Ms. Ross eventually lost her job due to this pain. (*Id.*)

On January 3, 2019, Ms. Ross saw Dr. Hemant Kalia, an interventional pain specialist, who diagnosed her with complex regional pain syndrome ("CRPS") and recommended treatment through advanced neuromodulation. (*Id.* at ¶ 81) Ms. Ross proceeded with a spinal cord stimulator trial on May 31, 2019, which was performed by Dr. Vidyasagar Mokureddy in Elmira, New York. (*Id.* at ¶¶ 84, 87) A St. Jude representative was also present to perform the device's initial programming. (*Id.* at ¶ 87) The trial went well, with the device reducing Ms. Ross's chronic pain level by approximately 75% and allowing her to become more active. (*Id.*) Ms. Ross decided to proceed with a permanent implant of a St. Jude spinal stimulator device (i.e., the Proclaim™ 7 Elite Model 3662—hereinafter referred to as the "Proclaim" or the "SCS device"—and Model 3186 Octrode leads IPG). (*Id.* at ¶¶ 10, 87)

The surgery took place on August 23, 2019 in Elmira, New York. (*Id.* at ¶ 88) Dr. Mokureddy surgically implanted the leads while Dr. Georgois Hatzoudis, a general surgeon, implanted the IPG into a surgically-created pocket in Ms. Ross's right buttock. (*Id.*) A St. Jude representative was also present. (*Id.* at ¶ 89) Although the St. Jude representative was responsible for performing the initial programming of the SCS device, he forgot to bring the new patient programmer to the hospital. (*Id.*) As a result, Ms. Ross was unable to adjust the stimulation of the device during her hospital stay and the following weekend. (*Id.*)

Right from the beginning, Ms. Ross obtained little to no relief of her pain. (*Id.* at ¶¶ 90-92, 95) St. Jude representatives subsequently attempted to re-program the SCS device on several occasions without success. (*Id.*) On September 11, 2019, Ms. Ross saw a nurse practitioner at Dr. Mokureddy's office. (*Id.* at ¶ 92) Ms. Ross reported that her pain was 10 out of 10 and that she had turned off the SCS device because at times she felt a burning sensation or electrical feeling around the IPG site. (*Id.*) She would experience these sensations even when the device

was turned off. (*Id.*) Ms. Ross underwent x-rays that revealed that the right lead had migrated inferiorly from its original placement. (*Id.*)

Over the next few weeks, Ms. Ross continued to experience burning at the IPG site and sudden electrical shocks that traveled from the IPG site up the leads into her mid-back area. (*Id.* at ¶ 93) Ms. Ross informed her St. Jude representative of these episodes; the representative told her that he had never heard of anything like this before and suggested that her nerves were still recovering from the implant surgery and were forming a pocket around the device. (*Id.*)

Ms. Ross also had multiple experiences in which the SCS device interacted with other electronic devices near her. (*Id.* at ¶ 94) On one occasion, an anti-theft sensor at a Wal-Mart caused a sudden burning/shocking sensation at the IPG site. (*Id.*) Ms. Ross's St. Jude representative interrogated the device after these experiences and reported that everything was "'good.'" (*Id.*)

On October 28, 2019, Ms. Ross sought a second opinion with Dr. Adam Carcini. (*Id.* at ¶ 96) She reported that the SCS device had provided a small amount of relief at most, but that she had also experienced "'adverse effects'" such as pain at the IPG site and episodes of "'overstimulation.'" (*Id.* (internal quotation marks omitted)) Dr. Carcini ordered thoracic x-rays that showed that the leads had migrated away from their original placement and that the IPG device had flipped inside its pocket. (*Id.*)

Ms. Ross followed up with the nurse practitioner in Dr. Mokureddy's office in December 2019 and again in January 2020. (*Id.* at ¶¶ 97-98) She reported pain at the IPG site and in the area of the leads, estimated that the SCS device had been reprogrammed approximately 20 times with little to no relief of her pain, and said that she had to turn off the SCS device every 3-4 days

as a result of these issues. (*Id.*) The nurse practitioner instructed Ms. Ross to turn off the SCS device and contact Dr. Hatzoudis regarding possible explantation surgery. (*Id.* at ¶ 98)

On February 5, 2020, Ms. Ross saw Dr. Hatzoudis and agreed to have the IPG and leads removed. (*Id.* at ¶ 99) Dr. Hatzoudis performed the explantation surgery on February 18, 2020. (*Id.*) Ms. Ross has continued to experience periodic burning and shocking sensations at the site where the IPG was located even following the explantation surgery. (*Id.* at ¶ 100)

B. Procedural History

Plaintiff filed this action on July 22, 2020. (D.I. 1) On January 28, 2021, Ms. Ross filed the currently operative Amended Complaint ("FAC"). (D.I. 15) In the FAC, Plaintiff has asserted claims under New York law for strict product liability for manufacturing defect (Count I); negligent manufacture (Count II); strict product liability for failure to warn (Count III); negligent failure to warn (Count IV)[1] and breach of express warranty (Count V). (*Id.* at ¶¶ 101-61) In lieu of filing an answer, on February 18, 2021, St. Jude filed the instant Motion. (D.I. 22) The Motion was fully briefed on March 18, 2021. (D.I. 34)[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*

[1] Plaintiff's two failure to warn claims in the FAC are 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. 29 at 1) The Court will refer to these two claims collectively as the "failure to warn" claims.

[2] The parties have consented to the Court's jurisdiction to conduct all proceedings in the case, including trial, the entry of final judgment and all post-trial proceedings. (D.I. 12)

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

The Court here writes primarily for the parties, who are well familiar with the issues in this case. In doing so, the Court assumes familiarity with its December 23, 2020 and October 27, 2021 Memorandum Opinions in the related case *Guinn v. St. Jude Med., LLC* (hereinafter, "*Guinn*"), Civil Action No. 20-71-CJB (D.I. 50 (hereinafter, "*Guinn I*"); D.I. 77 (hereinafter, "*Guinn II*")) (D. Del), which are relevant to the Court's decision here.

To briefly summarize, in *Guinn*, the plaintiff asserts claims under Washington state law against St. Jude for, *inter alia*, strict liability based on defective construction and failure to warn; the claims there all relate to the Proclaim device (i.e., the same device at issue here). (*Guinn II* at 3) The crux of the plaintiff's claims in *Guinn* are that the Proclaim implanted in her body in August 2016: (1) was defective, in that it caused the 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 the plaintiff of these defects. (*See id.*) St. Jude moved to dismiss the original complaint in that case, and the Court granted that motion, dismissing without prejudice the plaintiff's claims. (*Guinn I* at 19) Those claims relied heavily on facts regarding recalls and patient complaints that did not relate to the Proclaim—and that instead related to different St. Jude devices, including certain IPG devices (the "predicate devices") and certain cardiac defibrillator devices. (*See id.* at 9) However, in her original complaint, the plaintiff had failed to plead sufficient facts explaining why such recalls/complaints were relevant; instead, the pleaded facts only made clear 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)

The plaintiff in *Guinn* then filed an amended complaint, which included additional factual allegations intended to address the Court's concerns discussed in *Guinn I*. (*See Guinn II* at 5) On October 27, 2021, the Court denied St. Jude's motion to dismiss that amended complaint. (*Id.* at 14) In doing so, the Court explained that the plaintiff's amended complaint: (1) sufficiently alleged facts that "if taken as true, seem like they could establish that the battery components and microelectric circuitry in [St. Jude's other predicate devices/defibrillator devices] are sufficiently similar to that in the Proclaim[;]" (2) includes allegations relating to prior recalls and patient complaints relating to the predicate devices/defibrillator devices, which were related to the same problems that the plaintiff herself had experienced with the Proclaim; and (3) includes Proclaim-specific allegations relating to the Proclaim's Risk Table and adverse event reports ("AERs") that (4) taken together, established plausible parallel claims that survive preemption. (*Id.* at 6-13)

Here, Ms. Ross filed her FAC after the Court issued *Guinn I*, with the parties "recogniz[ing] that Ms. Ross'[s] pleadings implicated many of the same claims and issues addressed" in *Guinn I.* (D.I. 29 at 1; *see also* D.I. 13 at 2) The FAC (like the plaintiff's amended complaint in *Guinn*) "avers additional factual allegations intended to address the Court's rulings in" *Guinn I.* (D.I. 29 at 1) St. Jude then filed the instant Motion, which seeks dismissal of Ms. Ross's strict product liability for manufacturing defect claim, her negligent manufacture claim and her two failure to warn claims. (D.I. 23 at 1)[3] In the Motion, which was

[3] St. Jude does not seek dismissal of Ms. Ross's breach of express warranty claim. (D.I. 23 at 1, 4; D.I. 29 at 1 n.1)

fully briefed before the Court issued *Guinn II*, St. Jude argues that "Plaintiff here filed [a FAC] with substantively the same new factual allegations as in the *Guinn* Amended Complaint, but these only serve to confirm that the Proclaim device is different from the earlier SCS devices, and that there are no allegations sufficient to state a parallel claim." (D.I. 23 at 2; *see also id.* at 6) St. Jude then makes the same arguments that it made in seeking to dismiss the plaintiff's amended complaint in *Guinn*—i.e., that Ms. Ross's recall/complaint-related allegations regarding St. Jude's predicate devices and Proclaim-specific allegations are wanting, and that whether considered separately or together, they fail to establish plausible strict product liability for manufacturing defect/negligent manufacture claims and failure to warn claims. (*Id.* at 6-13; D.I. 34 at 2-10)

However, having subsequently issued its decision in *Guinn II*, the Court notes that the same analysis/conclusions that it set out there also apply here. In this case, the FAC explains how after implantation of her Proclaim, Ms. Ross experienced burning sensations and pain at the site of the IPG; she obtained little to no relief of her pain even after many attempts were made to reprogram the device. (D.I. 15 at ¶¶ 50-51, 90, 92-93, 96-97) Moreover (and similar to the amended complaint in *Guinn*), the FAC includes allegations about St. Jude predicate devices that describe:

(1) the many similarities between the Proclaim and the other St. Jude predicate devices, (*id.* at ¶¶ 30-33, 35-39, 42-43);

(2) [redacted]

(3) patient complaints and AERs relating to pocket heating and burning at the IPG site, (*id.* at ¶¶ 22, 50, 65); and

(4) recalls and patient complaints relating to the IPGs losing the ability to communicate, resulting in loss of pain relief and warmth at the IPG site, (*id.* at ¶¶ 59-60, 63-64).

And, just as did the FAC in *Guinn*, the FAC here contains the following Proclaim-specific allegations:

(1) [redacted]

(2) Proclaim AERs from 2016 through 2020 reported burning, pain and shocking at the IPG site, as well as ineffective stimulation, (*id.* at ¶¶ 66-67); and

(3) FDA publications beginning in 2018 indicated reports of the Proclaim producing ineffective stimulation, (*id.* at ¶ 67).

For the same reasons as discussed in *Guinn II* (which the Court will not repeat here), these allegations are sufficient to establish plausible claims that the Proclaim implanted in Ms. Ross was defective and that St. Jude failed to supplement the labeling of the Proclaim to warn of such defects. (*See Guinn II* at 5-13) And for the same reasons discussed in *Guinn II*, these plausibly-pled claims survive preemption. (*Id.* at 13 & n.8; *see also* D.I. 29 at 13-15)

IV. CONCLUSION

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 **December 2, 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.