**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| JEFFREY L. MELLOTT and VITTORIA M. MELLOTT, | ) | |
| Plaintiffs, | ) | |
| v. | ) | Civil Action No. 19-1779-CJB |
| ST. JUDE MEDICAL, LLC, formally known as St. Jude Medical, Inc., and ABBOTT LABORATORIES, INC., | ) | |
| Defendants. | ) | |

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**MEMORANDUM OPINION**

November 16, 2020
Wilmington, Delaware

Christopher J. Burke
**BURKE, United States Magistrate Judge**

Plaintiffs Jeffrey L. Mellott and Vittoria Mellott ("Plaintiffs") bring 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 Plaintiffs' Complaint, filed pursuant to Federal Rule of Civil Procedure 12(b)(6) (the "Motion"). (D.I. 12) For the reasons that follow, the Court GRANTS-IN-PART St. Jude's Motion in the manner set out below.

## I. BACKGROUND

### A. Factual Background

#### 1. History of the Relevant Devices

St. Jude designs, manufactures, markets, distributes, and/or sells a variety of medical devices, including: (1) the Eon implantable pulse generator (IPG), serial number 3832006 ("Device 1") and (2) the Protégé 16-Channel IPG Spinal Cord Stimulator, Model 3771 IPG, serial number 15194885 ("Device 2"). (D.I. 2 at ¶¶ 10-11) Devices 1 and 2 are a part of the Genesis family of neurostimulator devices approved by the United States Food and Drug Administration ("FDA"). (*Id.* at ¶ 12)

St. Jude filed its original premarket approval ("PMA") submission package[1] for the Genesis Neurostimulation (IPG) System with the FDA on April 3, 2001. (*Id.* at ¶ 13) On November 21, 2001, the FDA issued an approval for the commercial distribution of the Genesis and Eon family of Neurostimulation (IPG) Systems, designed and manufactured by St. Jude. (*Id.* at ¶ 16) On March 4, 2005, the FDA issued an approval for the commercial distribution of the Eon Neurostimulation System, Model 3716. (*Id.* at ¶ 18)

[1] The PMA process will be discussed in more detail below in Section III.A.

In 2006, St. Jude submitted an application for supplemental premarket approval ("PMA Supplement") of the Eon Mini™ Neurostimulation System, Model 3788; [redacted] (*Id.* at ¶ 19) On March 28, 2008, the FDA issued an approval for the commercial distribution of the Eon Mini IPG Neurostimulation System, Model 3788. (*Id.* at ¶ 23) 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 ¶ 24) Otherwise, the Protégé Model 3789 device remained the same as the Eon Mini IPG. (*Id.*)

[redacted] (*Id.* at ¶ 21) There have been numerous patient complaints and related recall campaigns regarding the Genesis and Eon family of neurostimulation devices since 2001, further discussed *infra*, including three recalls initiated by St. Jude in 2011 and two recalls issued by the FDA in 2012. (*Id.* at ¶¶ 28-32, 34) In July 2012, 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 ¶ 33) [redacted] (*Id.* at ¶ 35)

**2. Mr. Mellott's Experience with Device 1 and Device 2**

On November 26, 2011, while working as a police officer for the City of Baltimore Police Department, Mr. Mellott injured his lower back when he came into contact with a live electrical wire while engaged in a foot pursuit of a suspect. (*Id.* at ¶ 43) Thereafter, Mr. Mellott came under the care of neurosurgeon Clayton Dean, M.D. (*Id.* at ¶ 44) Despite undergoing physical therapy, epidural steroid injections (administered by David Maine, M.D.) and anterior and posterolateral fusion surgery (performed by Dr. Dean), Mr. Mellott continued to experience severe low back and left leg pain. (*Id.* at ¶¶ 44-46)

On August 8, 2012, Dr. Maine evaluated Mr. Mellott for a spinal cord stimulator (or "SCS") trial; after Mr. Mellott agreed to proceed, on October 29, 2012, Dr. Maine performed the percutaneous placement of a St. Jude SCS trial lead at Mercy Medical Center in Baltimore, Maryland. (*Id.* at ¶ 46) A St. Jude employee was present during the procedure to assist with initial programming of the trial device. (*Id.*) On November 12, 2012, Mr. Mellott had an office visit with Dr. Dean during which he reported "'near complete'" resolution of his pain and improved sleep; Mr. Mellott also indicated that he wished to proceed with a permanent SCS implantation. (*Id.* at ¶ 47)

On December 12, 2012, Dr. Dean surgically implanted Device 1 in Mr. Mellott's body. (*Id.* at ¶ 48) Dr. Dean placed the Eon IPG in a surgically-created pocket in the superolateral aspect of Mr. Mellott's right pelvis, with the lead wires passing through a tunneling device to the T9-10 spinal interspace. (*Id.*) A St. Jude employee was present during the procedure. (*Id.*) Device 1 worked well "[f]or the most part[;]" Mr. Mellott had returned to a regular fitness program by December 2013, and was back to work full duty as a detective in September 2014. (*Id.* at ¶ 49)

On or about July 21, 2014, Mr. Mellott received a "Dear Patient" letter from St. Jude that advised him of the "'potential for excessive warmth or heating at the implant site during charging of Eon™ Spinal Cord Stimulators'" and offered a replacement charger "'which has been redesigned to address this concern.'" (*Id.* at ¶ 50) Mr. Mellott had not experienced any such problems with Device 1 up to that point. (*Id.*) Over two years later, on September 29, 2016, Mr. Mellott returned to Dr. Maine's office, reporting that during the last month or two he had experienced problems with his IPG. (*Id.* at ¶ 51) Among these were that the IPG became extremely hot when charged for over 20 minutes, and that at times the stimulation would suddenly increase automatically and then spontaneously shut off (requiring the IPG to be manually restarted). (*Id.*)[2] Mr. Mellott had communicated with a St. Jude representative regarding these problems and the device was "'interrogated[,]'" but Mr. Mellott was not made aware of any testing results. (*Id.*) Dr. Dean recommended that the IPG be replaced and noted that there had been a recall on the model IPG that had been implanted in Mr. Mellott. (*Id.*)

On October 3, 2016, Mr. Mellott returned to Dr. Dean's office, accompanied by a St. Jude employee. (*Id.* at ¶ 52) Dr. Dean indicated in a Progress Note from the visit that Mr. Mellott had been "'diagnosed by the St. Jude Company [sic] and Dr. [] Maine as having a failed spinal neurostimulator pulse generator'"; Dr. Dean recommended that the old battery be explanted, the lead wires be tested to ensure they were working properly and that a new IPG be implanted. (*Id.*)

[2] While the Complaint indicates that this visit was with Dr. Dean, Plaintiffs' answering brief clarifies that the note of this visit was actually authored by Dr. Maine and that Plaintiffs "will seek to amend the Complaint accordingly." (D.I. 17 at 3 n.5)

On October 6, 2016, Dr. Dean explanted Device 1 and implanted Device 2 into Mr. Mellott's body at Mercy Medical Center in Baltimore. (*Id.* at ¶ 53) Following the surgery, Mr. Mellott missed three weeks of work and then returned in a "'light duty'" capacity. (*Id.* at ¶ 54)

Beginning sometime in 2017, Device 2 began to turn on and off spontaneously without any advance notice, which would cause Mr. Mellott to experience pain in his back and left leg. (*Id.* at ¶ 55) Mr. Mellott informed his St. Jude representative of these problems, but the representative was unable to identify the source of the problems despite multiple attempts. (*Id.* at ¶ 56) St. Jude reprogrammed the device to remain "'on'" at all times, and instructed Mr. Mellott to use his magnet (an emergency fail-safe accessory) to "'kill'" the device if it delivered any uncomfortable or painful stimulation. (*Id.*) Thereafter, Device 2 continued to malfunction. (*Id.*)

By September 2018, Mr. Mellott had been on light duty status with the City of Baltimore Police Department for almost two years. On or about September 30, 2018, his superior officer informed Mr. Mellott that he was not permitted to continue working as a police officer because of the problems he had experienced with Device 1 and Device 2. (*Id.* at ¶ 57) Mr. Mellott was placed on a medical suspension pending a later hearing. (*Id.*) On June 27, 2019, Mr. Mellott attended a hearing before a Hearing Examiner with the City of Baltimore Fire and Police Employees Retirement System; the Hearing Examiner concluded that the malfunction of Device 2 prevented Mr. Mellott from performing his duties and that Mr. Mellott was eligible for line-of-duty disability retirement. (*Id.* at ¶ 58)[3]

[3] Plaintiffs' Complaint describes this hearing as occurring on June 27, 2018, but in light of the facts, it appears that the hearing likely occurred in 2019, since Mr. Mellott was placed on a medical suspension pending a later hearing on his status in September 2018. (D.I. 2 at ¶¶ 57-58)

### B. Procedural History

Plaintiffs filed the Complaint on September 23, 2019, asserting state law claims for strict product liability (Count I), negligent manufacture based upon Restatement (Second) of Torts Section 395 ("Section 395") (Count II at ¶ 72 and Count IV),[4] failure to warn based upon Restatement (Second) of Torts Section 388 ("Section 388") (Count III) and loss of consortium (Count V). (D.I. 2 at ¶¶ 60-108) In lieu of filing an Answer, on November 20, 2019, St. Jude filed the instant Motion. (D.I. 12) Briefing on the Motion (which includes a supplemental letter brief filed by Plaintiffs as well as three notices of supplemental authority submitted by St. Jude) was completed on November 5, 2020. (D.I. 40) The Court[5] 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. 43 (hereinafter, "Tr."))

## II. STANDARD OF REVIEW

The sufficiency of pleadings for non-fraud cases is governed by Federal Rule of Civil Procedure 8, which requires "a short and plain statement of the claim showing that the pleader is

[4] While Plaintiffs' Complaint labels Count II as a claim for "[f]ailure to [w]arn" based upon Section 395, (D.I. 2 at 19 (emphasis omitted)), Plaintiffs' answering brief explained that this Count was "mistakenly designated" as such and that instead, Count II is a negligent manufacture claim, (D.I. 17 at 1 n.2). However, in the main, Count II's allegations appear to reflect the elements of a failure to warn claim. (D.I. 2 at ¶¶ 73-82) Plaintiffs' Complaint also includes an additional count (Count IV) labeled "[n]egligent [m]anufacture." (*Id.* at 25 (emphasis omitted)) In a September 3, 2020 letter, Plaintiffs explained that because Maryland courts have adopted Section 395 as a part of common law, there is no legal or substantive difference between Count II and Count IV and that they should be combined for purposes of Defendants' Motion and for the litigation more broadly. (D.I. 39 at 3) Because Plaintiffs will be given the opportunity to amend their Complaint (as is discussed below), Plaintiffs should correct their Complaint so that it alleges one negligent manufacture count.

[5] On November 14, 2019, 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. 11)

entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). First, the court separates the factual and legal elements of a claim, accepting "all of the complaint's well-pleaded facts as true, but [disregarding] any legal conclusions." *Id.* at 210-11. Second, the court determines "whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). A plausible claim does more than merely allege entitlement to relief; it must also demonstrate the basis for that "entitlement with its facts." *Id.* Thus, a claimant's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In assessing the plausibility of a claim, the court must "construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler*, 578 F.3d at 210 (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).[4]

## III. DISCUSSION

With its Motion, St. Jude asserts that each of Plaintiffs' claims must be dismissed because Plaintiffs have failed to plausibly plead specific facts necessary to avoid federal preemption or to otherwise state a claim for relief. (D.I. 13 at 1) St. Jude also argues that Plaintiffs' claims based

[4] In resolving a motion to dismiss, a court may consider not only the allegations in the complaint, but also, *inter alia*, exhibits attached to the complaint, documents integral to or explicitly relied upon in the complaint, and matters of public record. *See, e.g.*, *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *Quest Integrity USA, LLC v. Clean Harbors Indus. Servs., Inc.*, C.A. No. 14-1482-SLR, Civ. No. 14-1483-SLR, 2015 WL 4477700, at *2 (D. Del. July 22, 2015).

on Device 1 are barred by Maryland's three-year statute of limitations for personal injury claims. (*Id.* at 3)[6]

The Court will first set out the relevant law regarding federal preemption as it relates to medical devices. Then, the Court will assess whether Plaintiffs' claims warrant dismissal on the various grounds pressed by St. Jude.

**A. Preemption**

Preemption is a concept based on the Supremacy Clause of the United States Constitution. *See Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712-13 (1985); *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 242 (3d Cir. 2008). It provides that a conflicting state law will be trumped by its federal counterpart. *Hillsborough*, 471 U.S. at 712-13; *Fellner*, 539 F.3d at 242. Preemption may be express (i.e., explicitly stated in a federal statute's language) or implied (i.e., implicitly contained in the statute's structure and purpose). *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983).

Enacted in 1976, the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA") established the federal regulatory regime for medical devices (an area that had previously been left to the states). *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008). Pursuant to the MDA, medical devices are classified into three categories, depending on the risks that they present. *Id.* at 316-17. Class III devices, like those at issue in this case, receive the greatest amount of federal oversight; they are devices used "'in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,'" or that "'present[] a potential unreasonable risk of illness or injury.'" *Id.* at 317

[6] The parties agree that Maryland law supplies the substantive state law for this case. (D.I. 13 at 3 & n.1; D.I. 17 at 1 n.3)

(quoting 21 U.S.C. § 360c(a)(1)(C)(ii)).[5] The rigorous process of federal review that new Class III medical devices undergo for the evaluation of safety and effectiveness is known as "premarket approval" or "PMA." 21 U.S.C. § 360e; *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 766 (3d Cir. 2018).

Once a Class III device has received premarket approval, the manufacturer is not permitted to change design specifications, manufacturing processes or labeling that would affect safety or effectiveness without permission from the FDA. *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). A manufacturer seeking to make such changes must submit an PMA Supplement to the FDA; it must then await approval pursuant to the same rigorous standard of review that is applied during the initial PMA application process. *Id.*

The MDA also imposes reporting requirements on manufacturers following the PMA process. Manufacturers are required to "inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of . . . and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred[.]" *Id.* (citing 21 C.F.R. §§ 803.50(a), 814.84(b)(2)).

The MDA contains an express preemption provision. It provides that state laws "which relate[] to the safety or effectiveness of [a Class III medical] device" and are "different from, or in addition to" federal requirements under the MDA, are expressly preempted. 21 U.S.C. § 360k(a) ("Section 360k(a)" or "Section 360k"); *see also Shuker*, 885 F.3d at 767 ("The [MDA's] comprehensive and tiered approval procedures for medical devices leave only limited room for

[5] It is undisputed that the SCS devices at issue in this lawsuit are Class III devices. (D.I. 2 at ¶ 12; D.I. 13 at 5; D.I. 17 at 4)

additional state regulation, especially considering the statute contains a broad express preemption provision."). Class III device manufacturers receive express preemption protections because the devices have undergone premarket approval, and thus such devices have been found to satisfy federal requirements applicable to the device. *Shuker*, 885 F.3d at 767; *see also Riegel*, 552 U.S. at 318 ("The FDA spends an average of 1,200 hours reviewing each [Class III medical device application], and grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness[.]'") (quoting 21 U.S.C. § 360e(d)). In light of Section 360k(a), the Supreme Court of the United States has construed the MDA as protecting Class III device manufacturers from liability under state law tort claims if the manufacturer has complied with federal regulatory requirements. *See Riegel*, 552 U.S. at 323-24; *see also, e.g.*, *Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010) ("Generalized common law theories of liability . . . are precisely the type of claims the MDA sought to preempt."); *Millman v. Medtronic*, Civil Action No. 14-cv-1465, 2015 WL 778779, at *5 (D.N.J. Feb. 24, 2015) ("As stated by one court, '*Riegel* is loud and clear: if a manufacturer complies with the premarket approval, it gets a free pass on [products liability and implied breach of warranty] claims.'") (citation omitted).

However, "state laws are not shut out entirely" when it comes to claims against Class III device manufacturers. *Shuker*, 885 F.3d at 768. The MDA's express preemption provision does not apply to "parallel" claims—that is, to claims premised on state requirements that merely incorporate federal requirements and therefore are not "different from, or in addition to," federal requirements. *Id.* (internal quotation marks and citations omitted); *see also Riegel*, 552 U.S. at 330 (noting that Section 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,'

rather than add to, federal requirements") (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)); *Hart v. Medtronic, Inc.*, Civil Action No. 1:16-cv-05403 (JBS-AMD), 2017 WL 5951698, at *4 (D.N.J. Nov. 30, 2017) (explaining that *Riegel* recognized that "claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's premarket approval are not preempted. . . . because they merely parallel federal requirements—that is, they do not add to or differ from federal requirements, which is the cornerstone of" the MDA's medical device preemption).

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court established a two-step form of analysis for determining whether a claim is expressly preempted pursuant to the MDA. 552 U.S. at 321-22. First, the court must determine whether the FDA has established requirements applicable to the medical device at issue. Here, that step is not at issue, for it is undisputed that the SCS devices at issue here are Class III devices, and the Supreme Court has held that any Class III device receiving PMA approval from the FDA will satisfy this first step in the analysis. *Id.* at 322 ("Premarket approval . . . imposes 'requirements' under the MDA[.]"); *Hart*, 2017 WL 5951698, at *3. Second, the court must determine whether the plaintiffs' state law claims relate to safety and effectiveness and impose requirements that are "different from, or in addition to" those imposed by federal law. *Riegel*, 552 U.S. at 321-22 (internal quotation marks and citation omitted). If they do, those claims are expressly preempted. *Id.* at 330.

The parallel claim exception to preemption requires more than just the use of certain terminology; a plaintiff "cannot simply incant the magic words 'Defendant violated FDA regulations' in order to avoid preemption." *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 598 (D.N.J. 2015) (certain internal quotation marks, brackets and citations omitted); *see also Smith v. Depuy Orthopaedics, Inc.*, Civil Action No. 11-4139 (JAP), 2013 WL 1108555, at

*12 (D.N.J. Mar. 18, 2013) ("[B]road references to federal regulations in pleadings are insufficient [to properly plead a parallel claim].") (internal quotation marks and citations omitted). Rather, a plaintiff must plead "facts showing action or inaction in [the] defendants' efforts to take part in the PMA process or implement its results." *Smith*, 2013 WL 1108555, at *12 (internal quotation marks, brackets and citation omitted). In sum, a "parallel claim," like any other claim, is subject to the pleading standards of *Twombly* and *Iqbal*. *Hart*, 2017 WL 5951698, at *5.

Moreover, in addition to the MDA's express preemption clause, the MDA provides that all actions to enforce FDA requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), the Supreme Court construed this provision as barring suits by private litigants "for noncompliance with the medical device provisions." 531 U.S. at 349 n.4. To avoid implied preemption under *Buckman*, a claim must assert violation of a state tort duty that also amounts to a violation of some FDA requirement. *See Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 775 (5th Cir. 2011). That is, the conduct on which the plaintiffs' claim is premised must be the type of conduct that would traditionally give rise to liability under state law, and that would give rise to liability under state law even if the FDCA had never been enacted. *Yosowitz v. Covidien LP*, 182 F. Supp. 3d 683, 690 (S.D. Tex. 2016); *see also, e.g.*, *Bull v. St. Jude Med., Inc.*, CIVIL ACTION NO. 17-1141, 2018 WL 3397544, at *9 (E.D. Pa. July 12, 2018) ("State law claims that allege liability based on a common law tort theory and which parallel federal law claims . . . are not impliedly preempted under *Buckman*."). If the defendant's conduct is not of this type, then (regardless of

how the plaintiff has labeled the claim) the claim is impliedly preempted under *Buckman* because the plaintiff is effectively suing for a violation of the FDCA. *Yosowitz*, 182 F. Supp. 3d at 690.[7]

### B. Analysis of the Complaint's Claims

The Court will address St. Jude's arguments with respect to Plaintiffs' strict liability claim, negligent manufacturing claim, and failure to warn claim in turn. Then it will take up St. Jude's statute of limitations defense.

#### 1. Strict Product Liability Claim

Count I of Plaintiffs' Complaint asserts a strict product liability claim. (D.I. 2 at ¶¶ 60-70)[8] St. Jude argues that Plaintiffs' strict product liability claim must be dismissed because it is expressly preempted and inadequately pleaded. (D.I. 13 at 11-12; D.I. 25 at 4; Tr. at 58-60)

One of St. Jude's arguments is that the Count does not allege that any federal regulation was violated. (D.I. 13 at 11; D.I. 25 at 4) Thus, according to St. Jude, the claim does not articulate how it avoids imposing requirements that are "different from, or in addition to" those imposed by federal law, and it is therefore expressly preempted.

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[7] A district court may grant a defendant's Rule 12(b)(6) motion asserting preemption as an affirmative defense, so long as the allegations in the complaint (and the remainder of the record that the Court may consider at the pleading stage) clearly suffice to establish that ground. *See In re Asbestos Prods. Liability Litig. (No. VI)*, 822 F.3d 125, 133 n.6 (3d Cir. 2016); *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1341 (10th Cir. 2015); *see also Jones v. Bock*, 549 U.S. 199, 215 (2007). The defendant bears the burden to show that a claim is preempted. *In re Asbestos Prods.*, 822 F.3d at 133 n.6.

[8] In Maryland, a plaintiff must prove the following elements to recover for strict product liability: "(1) the product was in defective condition at the time that it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause of the injuries, and (4) that the product was expected to and did reach the consumer without a substantial change in its condition." *Great N. Ins. Co. v. Balt. Gas & Elec. Co.*, Civil No. SAG-19-2429, 2019 WL 6732966, at *2 (D. Md. Dec. 11, 2019) (quoting *Phipps v. Gen Motors Corp.*, 363 A.2d 955, 959 (Md. 1976)).

St. Jude is correct. Plaintiffs' strict product liability claim does fail to identify any specific federal regulations that were violated. (D.I. 2 at ¶¶ 60-70) Nor did Plaintiffs explain to the Court how the claim can otherwise be understood to amount to a parallel claim. Indeed, even after St. Jude pointed out this deficiency in its opening brief, (D.I. 13 at 11), Plaintiffs' answering brief ignored the point, (D.I. 17 at 13-14; D.I. 25 at 4). In order for a state law claim to avoid express preemption, it must be premised on a violation of FDA regulations. And if a Complaint's allegations for a particular count facially demonstrate that there is no such violation alleged, then the claim is subject to dismissal on preemption grounds. *See, e.g.*, *Rowe v. Mentor Worldwide, LLC*, 297 F. Supp. 3d 1288, 1300 (M.D. Fl. 2018) (finding that a strict liability manufacturing defect claim was expressly preempted, where the plaintiff never identified any specific federal regulations that were violated, such that the complaint failed to state a parallel claim); *cf. Freed v. St. Jude Med., Inc.*, CIVIL ACTION NO. 17-1128, 2017 WL 4102583, at *6 (D. Del. Sept. 15, 2017) (finding that the plaintiffs' claim pursuant to Section 388 was preempted, where it did not allege that "St. Jude failed to comply with [any] FDA regulation"). The Court therefore GRANTS St. Jude's motion with respect to this claim.

**2. Negligent Manufacturing Claim**

With respect to their negligent manufacturing claim, Plaintiffs allege that, *inter alia*: (1) St. Jude manufactured and/or sold SCS devices with components including batteries that were defective and that caused injury to patients like Mr. Mellott, (D.I. 2 at ¶ 98); (2) St. Jude has conducted recall campaigns in the past (i.e., in 2011 and 2012) for Eon/Eon Mini devices[9] and their components, including batteries, (*id.* at ¶¶ 29-31, 99); and (3) St. Jude manufactured and/or sold to Mr. Mellott SCS devices (Device 1 and Device 2) that were "adulterated" pursuant to 21

[9] In this subsection, the Court will often refer to these products as "Eon" devices.

U.S.C. § 351, in that they did not conform to certain identified good manufacturing practices ("GMPs") required by the FDA, specifically, 21 C.F.R. § 820.90(a) and 21 C.F.R. § 820.100(a)(3), (*id.* at ¶¶ 42, 96, 100).

St. Jude articulates a number of bases for why this claim should be dismissed. The Court will address them in turn.

**a. Whether Recalls of the Eon Exempt Plaintiffs' Claims from Preemption**

First, St. Jude makes a few arguments about the relevance (or lack thereof) of Plaintiffs' allegations regarding the recalls of the Eon products. As an initial matter, St. Jude argues that the "mere fact of [a] recall" relating to a medical device like the Eon does not create a presumption that the device's manufacturer violated FDA requirements; it says this is particularly true where, as here, the device's PMA remained in place during and after the recall. (D.I. 13 at 9-10; D.I. 25 at 2) In support, St. Jude cites to, *inter alia*, *Erickson v. Boston Sci. Corp.*, 846 F. Supp. 2d 1085 (C.D. Cal. 2011). (D.I. 13 at 9; D.I. 25 at 2) The *Erickson* Court stated that "[m]any courts have recognized that product recalls do not create a presumption that FDA requirements have been violated[.]" 846 F. Supp. 2d at 1093 (citing *Blanco v. Baxter Healthcare Corp.*, 70 Cal. Rptr. 3d 566, 580 (Cal. Ct. App. 2008); *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liability Litig.*, 592 F. Supp. 2d 1147, 1155 (D. Minn. 2009)).

*Erickson* is not all that helpful to St. Jude. For one thing, Plaintiffs are not alleging that the fact of a product recall, *in and of itself*, means that the manufacturer has necessarily violated FDA requirements (or that the fact of a recall means there is some kind of "presumption" to this effect at the pleading stage). Instead, Plaintiffs cite to the recall campaigns as one part of a larger evidentiary whole that lead to the plausible conclusion that St. Jude's devices were negligently manufactured. Neither *Erickson*, nor any of the cases to which it cites for support, suggest that

recalls of a medical device at issue are *wholly irrelevant* to a plaintiff's state law product liability claims. And indeed, courts that have allowed similar claims to survive the pleading stage have relied on allegations relating to product recalls (coupled with other allegations). *See, e.g.*, *Hill v. Abbott Labs.*, C/A No. 6:19-cv-01011-DCC, 2020 WL 4820243, at *2, *5 (D.S.C. Aug. 19, 2020) (denying defendant's motion to dismiss negligence and manufacturing defect claims on the basis of preemption, where the allegations included that the FDA had issued a recall due to the defect at issue); *Green v. Medtronic, Inc.*, CIVIL ACTION FILE NO. 1:19-CV-3242-TWT, 2020 WL 4577713, at *3 (N.D. Ga. May 1, 2020) (finding that a plaintiff's proposed amendment regarding a negligent manufacturing claim would not be futile, where the plaintiff's complaint included allegations of multiple recalls involving defendant's products (as well as allegations relating to FDA inspections of defendant's plants that turned up violations)); *Cline v. Advanced Neuromodulation Sys., Inc.*, 17 F. Supp. 3d 1275, 1284 (N.D. Ga. 2014) (denying a motion to dismiss a negligent manufacturing claim, where plaintiff's complaint included allegations of recalls that appeared to describe the plaintiff's alleged device failure).

Next, St. Jude argues that because the recalls referenced in Plaintiffs' Complaint relate to Device 1 (the Eon), they cannot serve to bolster a claim with respect to Device 2 (the Protégé). This is so, according to St. Jude, because: (1) the recalls relate to a different device (i.e., the Eon, not the Protégé), and after those recalls, the Protégé went through the FDA's rigorous PMA process in 2014, such that the FDA had then blessed the Protégé as being safe and effective; and (2) the recalls regarding the Eon did not involve the same problem that Mr. Mellott experienced with the Protégé. (D.I. 13 at 10-11; D.I. 25 at 2-3)

As to the former issue, the Court has already considered and rejected St. Jude's position in a related case. *See Freed v. St. Jude Med., Inc.*, Civil Action No. 17-1128-CJB, 2019 WL

5102643, at *4 (D. Del. Oct. 11, 2019) ("*Freed III*"). The same reasoning applies here. Plaintiffs' Complaint alleges that at St. Jude's request, the FDA approved a labeling identification that simply changed the name of the Eon Mini IPG to the Protégé Model 3789 (and that also implemented certain software modifications). (D.I. 2 at ¶ 24) Otherwise, the Complaint alleges, Device 2 "remained the same" as the Eon Mini Neurostimulation System. (*Id.*; *see also id.* at ¶¶ 10, 16, 18, 19) In light of these allegations, it is at least plausible that Device 2 did not undergo the FDA's "rigorous" PMA process in March 2014 (and that instead, all the FDA did then was to approve a name change and some software modifications to the product). And it is also plausible that Device 2 "is in fact the same device as the Eon Mini with a different name[,]" and that, therefore, recalls and patient complaints relating to the Eon/Eon Mini devices could have relevance to claims regarding the Protégé device. (D.I. 17 at 9-10; *see also* Tr. at 112-13)

However, St. Jude is correct that the Eon recalls and associated patient complaints described in the Complaint seem to relate to problems that are different than what Mr. Mellott experienced with Device 2. (D.I. 13 at 11 n.6; D.I. 25 at 2) Mr. Mellott's problem with Device 2 was that, sometime in 2017, it "began to turn on and off spontaneously" without any advance notice, and that when the "IPG turned itself off" Mr. Mellott would experience pain in his back and leg. (D.I. 2 at ¶ 55) In attempting to link this problem with allegations relating to any of the Eon product recalls referenced in the Complaint, Plaintiffs point to the Complaint's paragraphs 29 and 33; those paragraphs, in turn, describe St. Jude's May 24, 2011 recall relating to the Eon Mini Model 3788 and St. Jude's follow up "Dear Physician" letter relating to that recall. (*Id.* at ¶¶ 29, 33 (cited in D.I. 17 at 7); Tr. at 112) This recall/letter involved user complaints that the IPG "los[t] the ability to communicate with or recharge the IPG, resulting in loss of pain

relief[.]" (D.I. 2 at ¶ 29; *see also id*. at ¶ 33) Yet the Complaint does not sufficiently explain how *that* problem is related to the problem Mr. Mellott experienced with Device 2. In other words, it is not clear to the Court that "the IPG[] losing the ability to communicate with or recharge the IPG" is the same thing as, or is somehow linked to, the IPG turning on and off spontaneously. It could be that it is, but if so, the Complaint should make this clearer. For now though, in light of the Complaint's allegations, the Court cannot find that the recall evidence bolsters Plaintiffs' allegations that Device 2 (i.e., the Protégé device) violated FDA regulations, which in turn caused Mr. Mellott injury. And because Plaintiffs' negligent manufacturing claim relies heavily on the recall evidence to set out a plausible claim as to Device 2, Plaintiffs' allegations are insufficient with respect to that device.

**b. St. Jude's Remaining Arguments Relating to Negligent Manufacture**

In light of the Court's conclusion above, it will analyze St. Jude's remaining arguments as to this claim only with regard to Plaintiffs' allegations regarding Device 1. Beyond the recall issue, St. Jude asserts that the negligent manufacturing claim as to Device 1 should be dismissed for two reasons. The Court will address them in turn.

First, St. Jude argues that Plaintiffs' allegations are wanting because they allege only *in a conclusory fashion* that Mr. Mellott's devices suffered from a manufacturing defect. This is assertedly because Plaintiffs: (1) simply allege that the Device 1 was "'defective'" without saying more; and (2) fail to make a link between any specific defect and Mr. Mellott's injuries. (D.I. 13 at 17; D.I. 25 at 8-9) The Court disagrees. Plaintiffs' Complaint describes a history of specific problems with the battery component of the Eon family of devices. More particularly, it alleges:

(1) In May 2011, St. Jude initiated a recall relating to the Eon Mini due to a defect in the IPG's battery, which was caused by weld failures that led the batteries to leak electrolyte, which in turn prevented them from holding a charge. (D.I. 2 at ¶ 29)

(2) In December 2011, St. Jude initiated a recall relating to the Eon Mini IPGs, due to the negative battery strap of the internal IPG battery coming into contact with the microprocessor board, which resulted in a short to the IPG battery that caused the device to go into failure mode. (*Id.* at ¶ 30)

(3) In December 2011, St. Jude initiated a recall relating to the Eon IPG and the Eon Mini IPG, due to complaints of warmth or heating at the implant site while the device was charging, and noted in the accompanying "Dear Physician" letter that "[a] greater percentage [of IPGs] may be affected[.]" (*Id.* at ¶ 31)

(4) In July 2012, the FDA initiated a recall relating to the Eon Mini charging system due to complaints of heating while the device was charging. (*Id.* at ¶ 32)

(5) In July 2012, St. Jude issued a "Dear Physician" letter that identified a need to maintain and replace certain tools more frequently during the internal battery welding process, in order to avoid battery weld cracks. (*Id.* at ¶ 33)

(6) In September 2012, the FDA initiated a recall for three lots of Eon Mini IPGs because the internal battery had the potential to contact the internal microcontroller, causing a sudden brief surge in painful stimulation. (*Id.* at ¶ 34)

From these allegations it is plausible to infer that Device 1 suffered from manufacturing defects relating to the battery component—defects that caused the IPG to surge noticeably, to lose power for no apparent reason, or to become extremely hot and to cause pain. (*Id.* at ¶¶ 98-100; *see also* D.I. 17 at 11) And in the Complaint, Plaintiffs allege that thereafter, in 2016, Mr. Mellott experienced problems with Device 1 that were consistent with such defects: that "when charging the IPG for longer than 20 minutes it would become extremely hot, at times so hot that he could not touch it[,]" and that "at times the stimulation would suddenly increase automatically and then spontaneously shut off[,]" all of which forced him to have the device explanted. (D.I. 2 at ¶¶ 51,

98, 102) And, at least with regard to Mr. Mellott's complaints about excessive heat flow, the Complaint further explains that in July 2014, Mr. Mellott had received a letter from St. Jude informing him of the "'potential for excessive warmth or heating at the implant site during charging of'" the device, and offering him a replacement charger. (*Id.* at ¶ 50) These allegations are sufficient, in that they explain: (1) what is the asserted problem with the device, (2) what part of the device suffers from a defect, (3) (in many cases) what particular manufacturing issue led to the defect; and (4) how the defect relates to the particular harm suffered by Mr. Mellott.[10] *See, e.g.*, *Green*, 2020 WL 4577713, at *3 (finding that plaintiff's amended complaint stated a sufficient claim for negligent manufacturing defect, where it plausibly alleged "that the same manufacturing, process, and control issues that the FDA identified with respect to the [d]efendants' various other pump and catheter systems also caused a defect in the [p]laintiff's specific device"); *Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 821, 832, 836-37 (W.D. Ky. 2014) (finding that a negligent manufacturing claim was sufficiently pleaded and not preempted where the plaintiff alleged that shortly after he was implanted with a Riata lead, he began to experience recurring unexplained episodes of defibrillator discharge in which he received electrical shocks from the defibrillator, and that he was advised by his doctors that "'his Riata lead showed signs of inside-out erosion of the conductors'") (internal citation omitted).

Second, St. Jude argues that Plaintiffs' Complaint does not plead facts that establish a sufficient *violation of federal requirements* relating to manufacture of Device 1, and thus the

[10] The Court recognizes that, at least with regard to the Eon IPG's propensity to heat up and cause pain at the implant site, Plaintiffs do not identify a specific manufacturing problem (e.g., a particular wire that was faulty, or a particular subcomponent of the IPG that was defective) that may have led to this heating issue. But the Court is not convinced that, at this stage, all of that detail is necessarily required of Plaintiffs. (*See* Tr. at 108-10) The Court can at least see how it is plausibly alleged that there was some type of manufacturing problem that had to have led to this defective condition, and at this point in the case, that is enough.

claim is expressly preempted. (D.I. 13 at 17-18; D.I. 25 at 9) St. Jude asserts that Plaintiffs' reliance on certain GMPs cannot serve as the basis for a federal violation, sufficient to survive its preemption defense. (D.I. 13 at 18-19; D.I. 25 at 9; Tr. at 41, 44, 46-48, 53-54) Again here, the Court cannot agree with St. Jude.

To be sure, as the Court has observed in a prior opinion, some courts have found negligent manufacture claims that rely on the violation of a GMP to be preempted. These courts so conclude in light of their view that GMPs are "vague, open-ended and susceptible to an individual manufacturer's interpretation, thereby creating potentially varying standards that are 'different from, or in addition to' those required by federal requirements." *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 364 n.20 (D. Del. 2019) (hereinafter, "*Freed II*") (citing *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 197-98 (E.D.N.Y. 2015)).[11] However, the Court disagrees with the conclusion that these courts have reached.

After all, some GMPs, like those at issue here, do include requirements that bear some relation to the manufacturing process for Class III devices. And those GMPs have the force of federal law. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 555 (7th Cir. 2010). Moreover, many other courts have concluded that negligent manufacture claims that rely on GMPs can avoid preemption. *See, e.g.*, *id.* at 554-56; *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440 (6th Cir. 2010); *Santoro v. Endologix Inc.*, Case No. 3:19-CV-01679-YY, 2020 WL 6295077, at

[11] The Court notes, however, that in at least one such case cited by St. Jude, (D.I. 38), *Conley v. St. Jude Med., LLC*, — F. Supp. 3d —, 2020 WL 5087889 (M.D. Pa. Aug. 28, 2020), the relevant pleading (unlike the Complaint here) did not cite to any *specific* GMPs. *See, e.g.*, *Conley v. St. Jude Med., LLC*, — F. Supp. 3d —, 2020 WL 5087889, at *5 & n.4 (M.D. Pa. Aug. 28, 2020) (explaining that general citations to GMPs are not specific enough to state a parallel claim) (citing cases); *see also* (*Conley v. St. Jude Med., LLC*, Civil Action No. 20-286, D.I. 11-1 at ¶ 38 (M.D. Pa. Mar. 30, 2020) (the seven-page pleading in the *Conley* case, which alleged only that the "Defendant sold the Plaintiff an adulterated or otherwise non-conforming DRG stimulator as required by the good manufacturing practices of the FDA.")).

*5-6 (D. Or. Oct. 6, 2020) (citing cases); *Canary v. Medtronic, Inc.*, Case No. 16-11742, 2017 WL 1382298, at *5-8 (E.D. Mich. Apr. 18, 2017) (citing cases). These courts have often pointed out that: (1) Section 360(k)'s reference to the type of federal "requirement" that is sufficient to implicate a preemption analysis is broad enough to encompass GMPs; and (2) a holding that GMPs are too vague to support a non-preempted claim would leave injured patients without any remedy for what could amount to harmful violations of federal law. *See Bausch*, 630 F.3d at 554-44. The Court is persuaded that these courts' decisions are correct, and that a claim like this one can avoid preemption, so long as "the plaintiff has identified specific []GMPs that the defendant device manufacturer has allegedly violated . . . and . . . the plaintiff's allegations, accepted as true, demonstrate that the plaintiff was injured as a result of the manufacturer's breach of a []GMP-based duty." *Canary*, 2017 WL 1382298, at *8.

Here, Plaintiffs' Complaint references two specific GMPs that St. Jude is alleged to have violated (along with a related statute, 21 U.S.C. § 351): 21 C.F.R. § 820.90(a) (which requires that manufacturers "establish and maintain procedures to control product that does not conform to specified requirements" that shall address "identification, documentation, evaluation, segregation, and disposition of nonconforming product") and 21 C.F.R. § 820.100(a)(3) (which requires a manufacturer to "[i]dentify the action(s) needed to correct and prevent reoccurrence of nonconforming product and other quality problems"). (D.I. 2 at ¶ 42; D.I. 17 at 12-13; Tr. at 100, 104-05) And the Complaint also alleges that St. Jude had, at various points from 2011 through 2014, described its own failure to establish and maintain sufficient procedures that might have helped to avoid the alleged defects at issue:

> (1) In May 2011, St. Jude "identified a need to improve process control" following a review of its battery suppliers' manufacturing processes, which related to the defect in the Eon

Mini IPG's battery that had caused the IPG to lose the ability to communicate or to recharge. (D.I. 2 at ¶ 29)

(2) In December 2011, after initiating the recall relating to the Eon Mini IPG's ability to communicate or recharge, St. Jude retrained all manufacturing operators and inspectors regarding procedures related to the Eon Mini IPG's battery, so as to "ensure the effectiveness of the improved manufacturing and inspection instructions, and that process variations are not affecting our currently manufactured product[.]" (*Id.* at ¶ 30) St. Jude also acknowledged that it was considering "[a]dditional manufacturing process controls[.]" (*Id.*)

(3) In December 2011, in response to a second recall relating to warmth or heating at the Eon Mini IPG's implant site, St. Jude announced that it had taken corrective action by revising directions for use in the product labeling and that it would continue to monitor complaints to determine if that action was sufficient. (*Id.* at ¶ 31)

(4) In July 2012, St. Jude identified a need for its supplier to maintain and replace certain tools more frequently during the internal battery welding process for an Eon IPG, and that this related to the loss of the IPG's ability to communicate or recharge. (*Id.* at ¶ 33)

(5) In July 2014, St. Jude offered a replacement charger that was redesigned to address the potential for excessive heating at the implant site during charging of Device 1. (*Id.* at ¶ 50)

Each of these instances appear to be an example of St. Jude attempting to revise its procedures relating to the Eon IPG, or to correct and prevent reoccurrence of problems with its products' non-conformance to expected outcomes. But despite these efforts, the Complaint alleges that in 2016, Mr. Mellott experienced problems with his device—problems similar in nature to the problems described above. (*Id.* at ¶ 51)

In the Court's view, these allegations make it at least plausible that St. Jude violated the specific GMPs described in the Complaint. (D.I. 17 at 12-13; Tr. at 101, 104-05, 106-09) That is, they allow for the inference that in the time period leading up to Mr. Mellott receiving Device

1, St. Jude (as it had arguably failed to do in the past) did not "establish and maintain procedures to control product that does not conform to specified requirements" or appropriately "[i]dentify the action(s) needed to correct and prevent reoccurrence of nonconforming product and other quality problems." Admittedly, the relevant GMPs are pretty broadly worded. But they exist. Companies are obligated to abide by them. And the FDA can and at times does determine that such companies have actually violated such GMPs. It therefore stands to reason that, with help from the Court, a factfinder in this case could also make that same determination—just as that factfinder would be required to do so in assessing whether a defendant has violated some purportedly "more specific" federal regulation.[12] Therefore, the Complaint's reliance on the alleged violation of these GMPs is not a basis for dismissal of this claim on preemption grounds as to Device 1. *See, e.g.*, *Frey v. Bayer Corp.*, CASE NO. 3:20-CV-41 (CDL), 2020 WL 5995587, at *2-3 (M.D. Ga. Oct. 9, 2020) (finding that plaintiff's negligent manufacturing claim was not preempted, where she alleged that defendants "negligently failed to manufacture her Essure device in a manner consistent with federal requirements [including 21 C.F.R. § 820.90 and 21 C.F.R. § 820.100] and that this failure resulted in a manufacturing defect that caused her injuries"); *Green*, 2020 WL 4577713, at *2 (finding that the plaintiff's amended claim for negligent manufacturing defect was not preempted where the plaintiff "has now identified the

[12] *Cf. Bausch*, 630 F.3d at 556 ("We recognize the possibility that there may be some room for interpretation of the applicable federal requirements, and it is at least conceivable that a jury deciding a common law claim might apply those requirements more stringently than the FDA intended. That danger is defendants' best argument in favor of their distinction between general requirements and concrete, product-specific requirements. We are not persuaded. First, the meaning of the FDA's requirements will present questions of law for the court to decide, not questions of fact for a jury to decide. Second, those questions of law will be questions of federal law, subject to the usual processes for reconciling conflicting views.").

specific laws and regulations that she alleges that the Defendants violated [including 21 C.F.R. § 820.100(a)(3)] in the manufacture and distribution of the [d]evice").

Therefore, the Court GRANTS St. Jude's Motion to the extent it seeks dismissal of Plaintiffs' negligent manufacture claim with respect to Device 2, and DENIES the Motion to the extent it seeks dismissal of the claim with respect to Device 1.

### 3. Failure to Warn Claim

Plaintiffs' failure to warn claim is based on two theories: first, that St. Jude failed to sufficiently update or change its labeling (the "duty to supplement labeling" theory); and second, that St. Jude failed to report adverse events to the FDA (the "failure to report adverse events" theory). (D.I. 2 at ¶¶ 74(d), 76; D.I. 17 at 14-17; Tr. at 85-86) The Court will assess St. Jude's arguments for dismissal of each theory in turn.

#### a. Duty to Supplement Labeling Theory

In its opening brief, St. Jude argued that any state law failure to warn claim that is based on the premise that a manufacturer had a duty "to ask the FDA for authorization to modify [a] PMA-required label" is preempted because this duty is one that "'exist[s] solely by virtue of the FDCA'" and may be enforced only by "'the Federal Government rather than private litigants.'" (D.I. 13 at 13 (quoting *Buckman*, 531 U.S. at 349 n.4, 353))[13] In further articulating its preemption argument, St. Jude asserts that Plaintiffs' claim assumes that the mere submission of a PMA Supplement would have resulted in the modification of the labeling of Device 1 and Device 2, and that this is wrong because any such modification would still be subject to the

[13] *Buckman* held that the plaintiff's state-law fraud-on-the-FDA claims were impliedly preempted because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration" and to allow fraud-on-the-FDA claims under state tort law would conflict with the "FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Buckman*, 531 U.S. at 348, 350.

FDA's approval of the application. (*Id.*) According to St. Jude, this type of state law claim is impliedly preempted, because the mere possibility that the FDA might have approved a labeling change if St. Jude had submitted a PMA Supplement is insufficient to prevent federal and state law from conflicting. (*Id.*)

In support of its argument, St. Jude cites to *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618-19 (2011). (*Id.*) In that case, the plaintiffs asserted product liability claims against generic drug manufacturers, in light of the fact that the plaintiffs developed a severe neurological disorder after using the manufacturers' drug. *Mensing*, 564 U.S. at 608-10. The plaintiffs alleged that the defendants were liable under state tort law for failing to change their labels to adequately warn persons of the risk of developing that disorder, were they to use the drug long-term. *Id*. at 610. For their part, the generic drug manufacturers argued that plaintiffs' claims were preempted by federal law. The manufacturers explained that federal law required them to use the same labeling as their brand-name counterparts, which meant that it was "impossible" for them to simultaneously comply with both federal law and with their alleged duty under state tort law. *Id*. The Supreme Court agreed with the defendants that the plaintiffs' claims were preempted, finding "impossibility" in the circumstances before it. *Id.* at 618. The *Mensing* Court explained that if one took the plaintiffs' allegations as true, then while state law imposed on the generic drug manufacturers a duty to use a safer, stronger label, federal law "demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels." *Id.* Thus, the Court explained, "it was impossible for the [defendants] to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same." *Id.* The question for impossibility is "whether the private party could independently do under federal law what state law requires of it." *Id.* at 620. And under the circumstances before the *Mensing* Court, while it

was "possible" that had the defendants "asked the FDA for help," the defendants might have eventually succeeded in strengthening their labels (if and only if the FDA and the brand-name manufacturer changed the brand-name label), to allow such "conjectures" to prevent preemption under these circumstances would essentially render preemption meaningless. *Id.* at 620-21, 623.

In the Court's view, St. Jude's argument—that *Mensing* dictates a finding of preemption here—stretches the holding of *Mensing* too far. This case does not involve a generic drug manufacturer, nor the federal laws governing such a manufacturer. (Tr. at 76; *see also* D.I. 17 at 17) As another district court put it when a medical device manufacturer attempted to rely on *Mensing* in arguing that the plaintiff's design defect claims were preempted, "[t]he impossibility in *Mensing* arose from the unique 'duty of sameness' imposed on generic drugs, which has no corollary in the medical device context." *Mullins v. Ethicon, Inc.*, 147 F. Supp. 3d 478, 484 (S.D.W.V. 2015). Rather, unlike in *Mensing*, under federal law, pursuant to 21 C.F.R. § 814.39(d)(2) ("Section 814.39"), a manufacturer of a medical device is permitted to add to or strengthen its labels unilaterally, without waiting for prior approval from the FDA. (D.I. 17 at 17; *see also* D.I. 2 at ¶ 36) Section 814.39 provides that after the FDA approves a PMA, a manufacturer may place into effect a change to the label to reflect newly acquired information that enhances the safety of the device, prior to the receipt of a written FDA order approving a PMA Supplement to that effect. 21 C.F.R. §§ 814.39(d)(1)-(2). Under these circumstances, the Court cannot find that the "impossibility" that was present in *Mensing* (and that led to a finding of preemption) is present here.[14]

[14] The Court agrees with Plaintiffs that the present circumstances are more similar to cases involving a brand name manufacturer's duty to supplement its label. (D.I. 17 at 17; D.I. 39 at 2 & n.1; Tr. at 76-77, 79-80) For example, in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), the plaintiffs filed state law failure to warn claims against a brand name manufacturer of a drug for failing to change its label to add a warning about the risk of atypical

Plaintiffs have a separate argument as to why their duty to supplement labeling theory should survive, which is based on the content of certain "Conditions of Approval" issued by the FDA. (D.I. 13, ex. 1 at 5; *see also* D.I. 2 at ¶ 37; D.I. 39 at 3; Tr. at 84) But both because this duty to supplement labeling theory will otherwise survive for the reasons set out above, and because the content of the pleadings regarding the "Conditions of Approval" issue may change in any future amended complaint (in light of the Court's analysis regarding the failure to report

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femoral fractures associated with using the drug. 139 S. Ct. at 1675. The Supreme Court explained that because the FDA's relevant regulation (the "CBE regulation") permitted (though did not require) a drug manufacturer to change a label in certain circumstances in order to reflect newly acquired information, without first obtaining prior approval from the FDA, then a "drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." *Id*. at 1679. This was so, even though the FDA reviews CBE submissions and could ultimately reject label changes after the manufacturer has made them. *Id.*; *see also Allbright v. Teva Pharms. USA, Inc.*, 290 F. Supp. 3d 1321, 1327 (S.D. Fla. 2017) ("There are several processes by which a brand name manufacturer may update labels, *some unilateral and some requiring FDA approval*. Thus, courts examining whether state common law obligations of a brand name manufacturer are preempted by federal law have generally found that obligations placed on brand name manufacturers and *avenues to fulfill those obligations allowed by the FDA* do not pose the direct conflict as required to find preemption.") (emphasis added). Under these circumstances, a manufacturer can only establish the impossibility preemption that was found in *Mensing* with "'clear evidence that the FDA would not have approved a change'" to the label. *Lyons v. Boehringer Ingelheim Pharms., Inc.*, — F. Supp. 3d — , 2020 WL 5835125, at *7 (N.D. Ga. Sept. 29, 2020) (quoting *Wyeth v. Levine*, 555 U.S. 555, 571 (2009)). Here, Section 814.39 provides a manufacturer of a medical device the same ability to strengthen its warnings prior to obtaining approval from the FDA as did the CBE regulation in *Merck Sharp & Dohme Corp*. (*See* D.I. 17 at 17; D.I. 39 at 2 & n.1); *see also In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 896 (D. Minn. 2006). Although the preemption analyses in cases involving drug manufacturers is a little different from that here, (Civil Action No. 20-329-CJB, D.I. 16 at 12), the lessons drawn from the Supreme Court's analysis in the cases above are helpful to Plaintiffs' position.

The Court recognizes that there are certain federal court decisions, like that in *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009), which conclude that "a failure-to-warn claim cannot parallel [Section] 814.39(d) because [Section] 814.39(d) merely *permits* a device manufacturer to make a temporary change to a label whereas a successful failure-to-warn claim would *require* such a change." 625 F. Supp. 2d at 783 (emphasis in original). The Court, however, cannot square these decisions with the guidance provided by the Supreme Court, set out above. And so it declines to follow the lead of cases like *Riley* here. (D.I. 39 at 3)

adverse events theory below), the Court does not address the "Conditions of Approval" issue further here.[15]

**b. Failure to Report Adverse Events Theory**

Maryland has incorporated Section 388 into its substantive law. (D.I. 17 at 15-16); *Twombley v. Fuller Bush Co.*, 158 A.2d 110, 118 (Md. 1960). Plaintiffs' failure to warn claim is premised on Section 388. To that end, Plaintiffs allege that St. Jude knew that Device 1 and Device 2 were defective with respect to the battery components and/or the tendency to turn on and off without notice, but failed to report related adverse events to the FDA. (D.I. 2 at ¶¶ 87-88) St. Jude argues that this type of failure to warn claim, which generally alleges that if Defendants had reported "certain unspecified adverse events, Mr. Mellott's physicians 'would have learned of them and either chosen to implant a different neurostimulation system or seek

[15] As to St. Jude's other argument—that if state law would have required it to submit a PMA Supplement relating to a change of label, this would render such a claim impliedly preempted—the Court disagrees. In support of that conclusion, St. Jude cites to *Littlebear v. Advanced Bionics, LLC*, 896 F. Supp. 2d 1085 (N.D. Okla. 2012). (D.I. 25 at 5-6; Tr. at 15-16) In that case, the court found at the summary judgment stage that the plaintiff's claims, which were based on the defendant's failure to obtain supplemental PMA approval for a change in suppliers for the feedthru assembly portion of its medical device, were impliedly preempted because PMA approval "is an administrative requirement created by the FDA" and "no pre-existing state law duty existed requiring such supplemental approval." *Littlebear*, 896 F. Supp. 2d at 1088, 1092. If what *Littlebear* is saying is that any state law claim that incorporates facts relating to the PMA approval process is impliedly preempted, then the Court disagrees with its analysis. Moreover, that fact pattern in *Littlebear* (i.e., whether a defendant had to get FDA approval *for a change in suppliers for a product component*) seems like a different scenario than a claim alleging that: (1) St. Jude learned that the Eon family of devices were dangerous due to hazards associated with the battery overheating and turning on and off without notice, but (2) *failed to update or change its labeling to adequately warn* Plaintiffs of these defects as required by federal regulations. (*See* D.I. 2 at ¶¶ 85-88) The latter type of claim, at issue here, does seem to mirror a "pre-existing state law duty"—i.e., the contours of a Maryland state law failure to warn claim. (*Id.* at ¶ 84; D.I. 17 at 15 n.20); *see also, e.g., Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015) ("The Williamses' failure to warn claim tracks Maryland law's elements: Smith & Nephew learned new information about the BHR System's risks, yet failed to make reasonable efforts to issue an effective post-sale warning. And this claim is parallel to several federal duties imposed by the PMA[.]").

out other alternative medical treatment[,]'" is insufficient for a number of reasons. (D.I. 13 at 14 (quoting D.I. 2 at ¶ 89); *see also id*. at 14-17) The Court will address each of these reasons below.

First, St. Jude argues a duty to *warn physicians* does not parallel a duty to *report adverse events to the FDA*, thus preempting Plaintiffs' claim. (*Id.* at 14; D.I. 25 at 8) In *Freed II*, however, the Court examined and rejected this line of argument. (D.I. 17 at 15)[16] In that case, the Court found that a properly pleaded failure to warn claim based on Section 388 is not necessarily preempted by federal law, because it relies on a state-based duty that may run parallel to the manufacturer's obligation to comply with FDA reporting requirements. *Freed II*, 364 F. Supp. 3d at 359-60. To survive preemption, the Court explained that such a claim would have to set out factual allegations addressing "*why* it is plausible that a manufacturer's failure to report adverse events to the FDA would have reached physicians (and ultimately the plaintiff) and would have impacted the decision to use the medical device at issue[.]" *Id.* at 360 (emphasis in original).

Here, St. Jude argues that the line of cases that the Court cited in support of its holding in *Freed II*, which included *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) and cases relying on *Stengel* like *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889 (M.D. Pa. 2017) and *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804 (E.D. Pa. 2016), were wrongly decided. (D.I. 13 at 14; D.I. 25 at 8; Tr. at 19-21) St. Jude cites to *Conklin v. Medtronic, Inc.*, 431 P.3d 571 (Ariz. 2018) in support of this argument. In *Conklin*, the Arizona Supreme Court concluded that the *Stengel* Court had misinterpreted Arizona state law in concluding that the MDA did not expressly or impliedly preempt the plaintiffs' Arizona common law failure-to-warn claim—a

[16] The Court assumes familiarity with the *Freed II* decision.

claim that was based on the defendant's alleged failure to submit adverse event reports to the FDA. *Conklin*, 431 P.3d at 578-79. Instead, the *Conklin* Court concluded that while Arizona law would "recognize a claim for failure to provide an adequate warning to the patient directly or through certain third parties (including health care providers)" it would "not recognize a claim merely for failing to provide something like adverse event reports . . . to a government agency that has no obligation to relay the information to the patient." *Id*. at 579.

The Court is not persuaded by St. Jude's new argument. As Plaintiffs point out, (D.I. 17 at 15-16; Tr. at 88), Arizona substantive law has not adopted Section 388. Instead, *Conklin* noted that Arizona law: (1) had implicitly rejected Section 388's applicability; and (2) had instead adopted a portion of the Restatement (Third) of Torts, which mandated that the only third parties that a device manufacturer must warn of a foreseeable risk of harm are "'prescribing and other healthcare providers'" (i.e., not a federal agency like the FDA). *Conklin*, 431 P.3d at 577-78. Maryland, however, *has* adopted Section 388, as has Pennsylvania.[17] And *Silver* and *McLaughlin* both explain why the content of Comment n to Section 388 (which states that a supplier's duty to warn is discharged by providing information about the product's dangerous propensities to "a third person upon whom it can reasonably rely to communicate the information to the ultimate users of the product or those who may be exposed to its hazardous effects") is broad enough to encompass a supplier's provision of adverse event information to the FDA. *Silver*, 236 F. Supp. 3d at 900; *McLaughlin*, 172 F. Supp. 3d at 838. So the Court stands by its prior analysis with respect to this issue.[18]

[17] Pennsylvania was the applicable state law at issue in the *Silver* and *McLaughlin* decisions.

[18] The *Conklin* Court did suggest that even if Section 388 had been adopted by Arizona law, that would not have changed the result because: (1) Section 388 has not been

Second, while acknowledging that Plaintiffs "describe the adverse events that allegedly led to the Eon's recalls[,]" St. Jude argues that Plaintiffs' Complaint does not allege that St. Jude *failed to report* these adverse events. (D.I. 13 at 14; *see also* D.I. 25 at 6) Instead, St. Jude argues, Plaintiffs' Complaint just states in conclusory fashion that "[t]here is no indication that St. Jude submitted any such report(s) before or after Device 1 and Device 2 were implanted into Mr. Mellott's body." (D.I. 2 at ¶ 37)

By the time of oral argument, Plaintiffs had conceded that what they had alleged in their Complaint on this score was incorrect, in that "the defendants did submit some [relevant] adverse event reports with regard to these devices." (Tr. at 94) Therefore, according to Plaintiffs' counsel, what Plaintiffs really mean to be alleging here is that St. Jude "did not *adequately* report the prevalence or propensity of these problems." (*Id.* at 95 (emphasis added)) But of course Plaintiffs' current pleading does not make that allegation. Instead, it makes an allegation that even Plaintiffs have now acknowledged is not accurate (and therefore, in the Court's view, not plausible). To the extent that Plaintiffs wish to continue to pursue this type of failure to warn claim, they must amend their pleading accordingly.

Third, St. Jude contends that Plaintiffs' theory suffers from a "weak causal chain[,]" in that the Complaint does not plead facts plausibly demonstrating that had such adverse events been reported, Mr. Mellott or his physician would have seen them and would have done

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extended to require a manufacturer to submit warnings to a governmental regulatory body; (2) a manufacturer cannot have a "reasonable assurance" that the information in adverse event reports will reach patients or their physicians; and (3) when the FDA does publicly release adverse event reports, it simply uploads them to a database, which patients and their physicians must then access and search. *Conklin*, 431 P.3d at 578. For the reasons discussed in *Freed II*, the Court does not agree with the *Conklin* Court's analysis in this regard. 364 F. Supp. 3d at 359-60.

something differently.[19] (D.I. 25 at 6-7; *see also* D.I. 13 at 15-16) On this score, the Complaint alleges that "the FDA publishes reports of adverse events . . . in a searchable database [the 'database'] for use by the general public including physicians and patients" that "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." (D.I. 2 at ¶ 41) That is a good start. But then the Complaint simply further alleges that "[i]n the event that St. Jude had properly informed and notified the FDA or Mellott's physicians of Device 1's and Device 2's hazards/risks/defects Mr. Mellott and/or his physicians would have learned of them and either chosen to implant a different neurostimulation system or seek out other alternative medical treatment." (*Id.* at ¶ 89) This allegation is simply a legal conclusion devoid of any meaningful factual content.[20] How or why is it plausible that Mr. Mellott or his physicians would have learned of these hazards/risks/defects if they had been disclosed to the FDA? Did Mr. Mellott do research in advance of his procedures about the devices, where he might have discovered these problems had they been reported? Did his physicians at the time regularly consult the FDA's searchable database that regularly publishes such reports? Is there some other link? The Complaint does not say. In the absence of such allegations, the Court agrees that Plaintiffs have not done enough

[19] As the Court explained in *Freed II*, "[c]ourts recognize that a plaintiff making this type of failure to warn claim must allege that the plaintiff would not have utilized the medical device at issue had the manufacturer disclosed the allegedly withheld information." *Freed*, 364 F. Supp. 3d at 361.

[20] In contrast, in *Freed III*, Plaintiffs' Complaint alleged that "Plaintiffs did internet research regarding the Protégé and other devices before deciding to proceed with permanent implantation of the Protégé device[.]" *Freed III*, 2019 WL 5102643, at *4; (*see also* Tr. at 30). This, together with other allegations in the Complaint, made it plausible that the plaintiffs might have seen indication of adverse events online and might have then declined to proceed with implantation of the Protégé device (though even then the Court noted that Plaintiffs' allegations related to causation could have been "more robust"). 2019 WL 5102643, at *5.

to plausibly allege that Mr. Mellott and/or his physicians would have learned of such adverse events (were they reported) as to Device 1 and Device 2.

Fourth, St. Jude argues that Plaintiffs' failure to report theory is even weaker with respect to their claim relating to Device 2. (D.I. 13 at 16) For the reasons already noted above, the allegations regarding causation as to both Device 1 and Device 2 regarding this type of claim are insufficient. But the Court agrees with St. Jude that the causation-related allegations as to Device 2 are even more attenuated than those as to Device 1. For one thing, as the Court explained above in Section III.B.2.a, it is not clear that the adverse events that led to recalls of Device 1 involved the same problem that Mr. Mellott experienced with Device 2. To the extent they did not, it would seem less plausible that any failure to report adverse events relating to Device 1's recalls actually caused Mr. Mellott to experience the types of problems he did with Device 2. Additionally, after Mr. Mellott began experiencing problems with Device 1 in 2016, Mr. Mellott's physician told him that there had been a recall relating to Device 1 and proceeded to implant Device 2 anyway. (D.I. 2 at ¶ 51) This could make it more difficult to plausibly allege that "the adverse events that led to Eon recalls [would have had an] effect on the implanting physician's choice to use" Device 2, had they been more fully reported. (D.I. 13 at 17; *see also* D.I. 25 at 7; Tr. at 29-31, 40-41)

The Court thus GRANTS-IN-PART St. Jude's Motion with respect to Plaintiffs' failure to warn claim.

**4. Statute of Limitations Issue**

St. Jude next argues that Plaintiffs' claims relating to Device 1 are time-barred. (D.I. 13 at 19-20; D.I. 25 at 9-10) Maryland law applies a three-year statute of limitations in products liability actions such as this one. *See* Md. Code Ann., Cts. & Jud. Proc. § 5-101; *Jeffries v.*

*Boston Sci. Corp.*, Case No. RWT 15-cv-3480, 2017 WL 2645723, at *2 (D. Md. June 20, 2017). The discovery rule applies to products liability cases in Maryland, under which the statute of limitations does not begin to run "until the plaintiff knows or through the exercise of due diligence should know of injury, its probable cause, and either manufacture wrongdoing or product defect." *Pennwalt Corp. v. Nasios*, 550 A.2d 1155, 1165 (Md. 1988); *see also Doe v. Maskell*, 679 A.2d 1087, 1090 (Md. 1996) (explaining that the discovery rule "holds that a cause of action 'accrues' when plaintiff knew or should have known that actionable harm has been done to him").

St. Jude argues that Plaintiffs knew (or should have known) that they had a potential cause of action with respect to Device 1 in July or August 2016, based on the Complaint's allegations that: (1) Mr. Mellott received a "Dear Patient" letter from St. Jude on or about July 21, 2014, which informed him of the potential for excessive heating at the implant site while the device was charging and offered a replacement charger; and (2) when Mr. Mellott saw his physician on September 29, 2016, Mr. Mellott reported that "during the past month or two" (i.e., sometime in either July or August of 2016), his Device 1 began to become extremely hot when charging; and (3) this in turn led to Mr. Mellott communicating with a St. Jude representative, who tested the device, but who thereafter never conveyed the results of that testing to Mr. Mellott. (D.I. 2 at ¶¶ 50-51) Based on these allegations, St. Jude asserts that in July or August 2016, Mr. Mellott knew or should have known that he had a cause of action when he began to experience the same problem with Device 1 that was identified in the 2014 "Dear Patient" letter. (D.I. 13 at 20; Tr. at 60-61) But Plaintiffs did not file their Complaint until September 23, 2019, just over three years after their claims with respect to Device 1 began to accrue, according to St. Jude. (D.I. 13 at 20)

Plaintiffs disagree. They counter that no claim accrued until Mr. Mellott's September 29, 2016 physician visit, when he learned that Device 1 had been recalled and that it would need to be surgically removed. (D.I. 17 at 19) According to Plaintiffs, only on this date did Mr. Mellott know the facts he needed in order to conclude that an actionable harm had been done to him: i.e., the fact of his injury; the cause of his injury; and wrongdoing and/or product defect on the part of St. Jude (i.e., in that the device had been recalled). (*Id.*; Tr. at 116-17)

The Court will not grant St. Jude's motion on this ground. A motion to dismiss based on an argument that a claim is time-barred should not be granted "unless it is clear from the facts and allegations on the face of the complaint that the statute of limitations has run." *Ferebee v. Dep't of Human Relations Comm'n*, Civil Action No. TDC-16-3803, 2018 WL 731682, at *3 (D. Md. Feb. 5, 2018) (internal quotation marks and citation omitted). Courts interpreting Maryland law have explained that decisions regarding the timeliness of claims subject to a discovery rule are generally "unsuited" to decision at the motion to dismiss stage, "because the determination of when a claim accrues under a discovery rule is fact-intensive[.]" *In re Smith & Nephew Birmingham Hip Resurfacing Hip Implant Prods. Liab. Litig.*, Master Docket No. 1:17-md-2775, 2020 WL 407136, at *1 (D. Md. Jan. 24, 2020); *see also Frederick Road Ltd. P'ship v. Brown & Sturm*, 756 A.2d 963, 974 (Md. 2000) (noting that application of the discovery rule "is ordinarily a question of fact for the jury" as it "generally requires the balancing of factual issues and the assessment of the credibility or believability of the evidence") (internal quotation marks and citation omitted). Here, the timing is very close—it is not as if St. Jude is arguing that Plaintiffs had the requisite knowledge years or even several months before they filed suit. And in light of the Complaint's allegations, it is at least plausible that Mr. Mellott did not know that he suffered an actionable harm until his physician informed him that his device had been recalled on

September 29, 2016. Mr. Mellott had received the "Dear Patient" letter two years before he began to experience any problems, and while St. Jude tested Mr. Mellott's device prior to the September 29 visit, thereafter St. Jude did not provide Mr. Mellott with any information regarding the results of those tests. While St. Jude may ultimately demonstrate that Plaintiffs were or should have been aware of the facts underlying their claim back in July or August 2016, the issue necessitates a fact-intensive inquiry that is not appropriate at this stage of the case.

### C. Nature of Dismissal

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

## IV. CONCLUSION

For the reasons set out above, the Court GRANTS-IN-PART and DENIES-IN-PART the Motion.[21] More specifically, the Motion is: (1) GRANTED as to Count I; (2) as to Counts II and IV, GRANTED with respect to the allegations regarding Device 2, and DENIED with respect to the allegations regarding Device 1; (3) as to Count III, GRANTED to the extent the claim is premised on the failure to report adverse events theory and DENIED to the extent the claim is premised on the duty to supplement labeling theory; and (4) DENIED as to Count V.

[21] Because the Court has not granted St. Jude's motion in its entirety, St. Jude's argument that Count V's loss of consortium claim fails because the other claims fail is not a basis to dismiss the claim. (D.I. 13 at 20)

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 **November 19, 2020** for review by the Court, along with a motion for redaction that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The Court will subsequently issue a publicly-available version of its Memorandum Opinion.