IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KATHLEEN M. FREED, *et al.*	:	**CIVIL ACTION**
	:	
v.	:	
	:	**NO. 17-1128**
ST. JUDE MEDICAL, INC., *et al.*	:	

MEMORANDUM

KEARNEY, J. **September 15, 2017**

A patient suffering injury allegedly caused by a medical device approved by the Food and Drug Administration must carefully plead her products liability claim to fit within the narrow gap of claims where the federal approval does not preempt her state law products liability claim. Her complaint is the governing document although we may take judicial notice of the federal approvals. When the complaint does not plausibly allege the offending aspect of the approved device is not covered by the federal approval nor plausibly allege how her claims are different from or in addition to the federal requirements, we cannot find she avoids federal preemption. Today, we review a complaint which does not plausibly allege the facts necessary to avoid federal preemption but, subject to good faith obligations, the patient may be able to plead facts necessary for a products liability claim not preempted by the federal approvals. In the accompanying Order, we grant the device manufacturer's motion to dismiss the patient's products liability claims without prejudice for the patient to timely file an amended complaint.

I. Pleaded Facts

Christiana Hospital doctors surgically implanted a neurostimulator and battery components of a spinal cord stimulator device (the "Device") into the soft tissue of Kathleen Freed's left buttocks to address chronic lower back and lower extremity pain.[1]

The St. Jude Defendants[2] designed, manufactured, marketed, distributed, and/or sold the Device for implantation in patients suffering from chronic lower back and lower extremity pain.[3] Mrs. Freed did not receive information or warning of any defects, faults, or contraindications regarding the Device.[4]

Mrs. Freed alleges the Device "started giving off severely painful electrical shocks and a burning sensation throughout the left buttocks."[5] Her doctors removed the Device.[6] Mr. and Mrs. Freed then sued St. Jude alleging state law breach of express warranty, breach of the implied warranty of merchantability and fitness for a particular purpose, manufacture or sale of dangerous chattel, and loss of consortium.

II. Analysis[7]

St. Jude moves to dismiss, arguing: federal law expressly and impliedly preempts the Freeds' state law claims; the complaint fails to meet the pleading standards of *Twombly* and *Iqbal*; the claims are barred by St. Jude's warranty disclaimer; and, the derivative loss of consortium claim fails because the other claims fail. St. Jude additionally requests we take judicial notice of Food and Drug Administration ("FDA") approval letters and the device's Limited Warranty.[8]

A. We take judicial notice of FDA approval letters only.

We first address St. Jude's request we take judicial notice of three exhibits: a November 21, 2001 FDA approval letter for the Device (Exhibit 1); a March 21, 2014 approval letter

supplementing the premarket approval application of the Device (Exhibit 2); and the Limited Warranty for the Protégé Device (Exhibit 3).[9]

Under Federal Rule of Evidence 201, we may take judicial notice of "a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned."[10] We may also consider "an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document."[11]

The FDA approval letters "can be accurately and readily determined" from the FDA's website, a source "whose accuracy cannot reasonably be questioned." The Freeds do not object to the FDA approval letters or question the authenticity of these documents.[12] We take judicial notice of St. Jude's Exhibits 1 and 2 because they are publically available on the FDA's website and are indisputably authentic.[13]

St. Jude argues we should also take judicial notice of the Limited Warranty for the Device because it is a document upon which the complaint necessarily relies and is central to the Freeds' breach of warranty claims. St. Jude argues the Limited Warranty cannot be reasonably disputed. We disagree. Rule 201 allows judicial notice of a fact "that is not subject to reasonable dispute" and where it can be "accurately and readily determined from sources whose accuracy cannot be reasonably questioned." Unlike the FDA's website, we have nothing to determine the source of this document and whether its accuracy "cannot be reasonably questioned." We have only the Declaration of St. Jude's counsel swearing the Limited Warranty is a "true and correct copy" of the Limited Warranty and "which [counsel is] informed and believe accompanied the Protégé Spinal Cord Stimulator used" by Mrs. Freed.[14]

We cannot say the Limited Warranty submitted by St. Jude is an "undisputedly authentic document" on which the Freeds base their claims. The Freeds object to the Limited Warranty, arguing it is not subject to judicial notice at the pleading stage and it is not a document attached to or referenced in their complaint. The Freeds concede they assert a breach of express warranty claim, but argue they do not refer or rely on the disclaimer language. The Freeds' warranty claims are based on St. Jude's marketing materials and we have no information the Limited Warranty is part of its marketing materials. We will not take judicial notice of the Limited Warranty (Exhibit 3).

B. The Medical Device Amendments and express preemption.

1. The FDA's premarket approval process for the Device.

The Medical Device Amendments of 1976 ("MDA")[15] requires FDA approval of medical devices intended for human use, establishing levels of oversight for medical devices depending on the risks they prevent.[16] Class III devices receive the most federal oversight, requiring a "rigorous regime" of premarket approval.[17] The FDA grants premarket approval "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness,'" after weighing "'any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'"[18] The Device is a Class III device.[19]

On November 21, 2001, the FDA granted premarket approval for the Device subject to certain conditions.[20] The conditions include approving labeling before commercial distribution and "adverse reaction and device defect reporting" requiring the manufacturer to report to the FDA any information concerning adverse reactions, side effects, injuries, or sensitivity reactions attributable to the Device not addressed by the Device's labeling or addressed by the Device's labeling but "occurring with unexpected severity or frequency."[21]

2. The MDA's express preemption provision.

The MDA expressly preempts state law claims challenging the safety and effectiveness of a medical device granted premarket approval by the FDA]:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[22]

The Supreme Court in *Riegel* defined the two steps we must use in deciding whether federal law preempts state law claims regarding a Class III device: "(1) the Federal Government has established requirements applicable to the device and (2) the plaintiff's claims are based on state requirements related to safety and effectiveness that are 'different from, or in addition to' the federal requirements."[23]

In the first step, we determine whether the FDA established requirements applicable to the Device. If there are FDA requirements applicable to the Device, we must then determine whether the Freeds' products liability claims are "different from, or in addition to" the FDA's safety and effectiveness requirements for the Device. Our court of appeals cautions "[g]eneralized common law theories of liability . . . are precisely the type of claims the MDA sought to preempt."[24]

3. Did the FDA establish requirements for the Device?

The FDA's approval of the Device identified its components: "the Model 3608 pulse generator, the Model 3850 patient programmer, the Model 1232 programming wand and the Model 1210 patient magnet."[25] The pulse generator implanted in Mrs. Freed is powered by an

internal battery.[26] The approval letter does not specifically mention the battery used to power the pulse generator as a component of the Device.

St. Jude asserts the first prong of the *Riegel* test is "irrefutably met" because the FDA granted premarket approval for the Device in its approval letter. The Freeds disagree. Although they allege injuries caused by the "device" generally, the Freeds contend the battery is "primarily at issue." The Freeds argue their allegations "relate (in large part) to the battery component" of the Device, pointing to allegations of injury resulting from a warming and burning sensation and electrical shocks emanating from the battery,[27] and "*to the extent* the battery component of the [Device] caused injury, those allegations fall outside the scope of" the MDA's express preemption provision.[28] It appears the Freeds continue to maintain both the Device and the battery caused injury.

To support their theory the battery caused injury, the Freeds argue the FDA's approval letter does not list the battery used to power the pulse generator as a component of the Device. Although not pleaded, the Freeds contend the battery is separate and distinct from the Device itself and is not the subject of the FDA's premarket approval process. The Freeds do not cite a case where the battery in a spinal stimulation device is found to be separate from the Device, specifically the pulse generator component.

The cases cited by the Freeds do not support their argument the battery component is not expressly preempted. For example, in *Michael v. Shiley, Inc.*, our court of appeals found all state law claims preempted by the MDA except for the state law claims for express warranty based on the manufacturer's packaging and fraud based on the manufacturer's advertising and promotional materials sent to physicians.[29] *Michael* did not hold a component part of an FDA approved device escapes the preemptive force of the MDA. The Court of Appeals for the Sixth

Circuit's decision in *Jacobs v. E.I. Dupont de Nemours & Co.* is inapposite. There, the court addressed the specific question of whether a supplier of raw materials used in a medical device can invoke MDA preemption.[30] Here, there is no allegation the battery is "raw material" and outside the scope of MDA preemption. Similarly, *Lake v. TPLC*[31] does not support the Freeds' argument. In *Lake*, the plaintiff brought claims for injury allegedly caused by a cardiac pacemaker and pacemaker leads manufacturer by defendant Teletronics. The pacemaker underwent the FDA's premarket approval process, while the leads underwent a more relaxed premarket process where the FDA found the lead "substantially equivalent" to devices already on the market. The court found claims involving the lead were not preempted by the MDA, rejecting Teletronics' argument the premarket approval of the pacemaker should be considered the equivalent to premarket approval of the leads, and thus preempted. The court found Teletronics' argument "would seem to depend on the scope and scale and the evaluation of the system."[32]

We are left with no allegations the battery underwent a separate review process from the pulse generator to bring it outside the scope of MDA preemption. Based on the allegations as currently pleaded, we find the Device includes the battery and is subject to federal regulation and the MDA's express preemption.

4. Are the Freeds' claims based on parallel federal requirements?

We next determine the second prong of the *Riegel* test – whether the Freeds' state law claims impose requirements different from, or in addition to, federal requirements. Under the second prong, the Freeds' claims will be preempted under the MDA "only to the extent that they are 'different from, or in addition to,' the requirements imposed by federal law."[33] Preemption

does not apply where a state's law "parallels" federal requirements.[34] A "parallel" claim "must show a link between a specific violation of an FDA regulation and the plaintiffs' injury."[35]

St. Jude argues none of the Freeds' state law claims parallel the federal scheme and they otherwise fail to plead facts the Device failed to comply with federal requirements. The Freeds concede their complaint "does not reference specific federal regulations" and ask for leave to amend their complaint. Nevertheless, the Freeds argue their claims are parallel to federal requirements, pointing to federal regulations pertaining to labeling and compliance with good manufacturing practices post-approval raises questions whether St. Jude complied with federal requirements.[36] The problem is the Freeds, by their own admission, fail to plead the Device failed to comply with a federal regulation.[37]

Restatement § 388 claim.

The Freeds argue their claim under Delaware law for "manufacture or sale of dangerous chattel"[38] in which they allege St. Jude breached its duty of care to Mrs. Freed for failing to inform or warn of the Device's "dangerous propensity" runs parallel to federal regulations. The Freeds do not allege St. Jude failed to report problems with the Device to the FDA as required by federal regulation. Any additional warnings imposed by Delaware law would be expressly preempted by the MDA. We distinguish cases allowing common law claims under § 388 of the Restatement of Torts outside the scope of federal preemption. For example, in *Silver v. Medtronic, Inc.*, the court found the MDA did not preempt a failure to warn claim based on Pennsylvania's adoption of § 388 of the Restatement.[39] In *Silver,* the manufacturer argued the plaintiff's failure to warn claim expressly preempted to the extent it attempted to hold the manufacturer liable for its alleged failure to warn outside the FDA's requirements. The court rejected the manufacturer's preemption argument because plaintiff's failure to warn claim rested

on allegations the manufacturer failed to report problems with the device to the FDA as required by federal regulation. The court found the claim did not seek to impose additional warning requirements on the manufacturer, but ran parallel to FDA warning requirements.[40]

Here, the Freeds do not allege St. Jude failed to comply with FDA regulation. We cannot find their § 388 claim, as currently pleaded, is parallel to any federal regulation.[41]

Breach of express warranty and implied warranties.

The Freeds argue the MDA's preemption provision does not apply to their breach of express warranty claim because it arises from the parties' contract and the warranties are the basis of their bargain with St. Jude. Under Delaware law, a claim for breach of express warranty is based on state statute.[42]

The Freeds rely on case law holding express warranties arise from the parties' representations, not from operation of state law and, consequently, not preempted by the MDA. For example, in *Davenport v. Medtronic, Inc.*, the court found the MDA did not preempt plaintiff's express warranty claim because plaintiff based his claim on a limited warranty applicable to the device.[43] The court held "[t]he MDA preemption clause does not preempt an express warranty claim based on a warranty that is a product of the parties' bargain because any 'requirements' imposed by the warranty are created by the warrantor and not imposed by state law as required for MDA preemption."[44] The Freeds cite *McLaughlin v. Bayer Corp.* to support their argument.[45] *McLaughlin* is distinguishable on its facts. In *McLaughlin*, the court found the MDA did not expressly preempt the breach of express warranty claim because the claim, as pleaded, arose from alleged contracts between the parties.[46] We have no such allegations here. Ultimately, the court found the complaint failed to sufficiently allege any circumstances "under which *each* Plaintiff read or saw *each* particular warranty, or how that warranty came to be a

basis of each Plaintiff's bargain with Bayer."[47] The court dismissed the breach of express warranty claim because it failed to allege a plausible breach of express warranty.[48]

The Freeds do not plead the basis of their express warranty claim. In their response to St. Jude's motion, the Freeds argue their complaint does not "refer to or rely upon the disclaimer language" of the Limited Warranty, but do not clarify or explain the basis of the warranty claim.[49] We cannot determine, based on the complaint and the Freeds' brief, whether their breach of express warranty claim arises from state requirements or a contract between the parties. Even if we found the Freeds' breach of express warranty claim arose from the Freeds' bargain with St. Jude, there is nothing in the complaint plausibly alleging such a claim, including an allegation the Freeds relied on the warranty, a required element under Delaware law.[50]

The Freeds similarly fail to explain the basis of their breach of the implied warranties of merchantability and fitness for a particular purpose. For the reasons explained in finding the breach of express warranty defective, we find the implied warranties claim does not articulate parallel claims.

Adulterated Device.

Finally, the Freeds argue the MDA "does not preempt claims that the implanted device was adulterated." Class III devices not receiving premarket approval are "adulterated."[51] An "adulterated" device is defined as one where "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements."[52] FDA regulations prohibit the manufacturing, packaging, storing, labeling, distribution, or advertising "in a manner that is inconsistent with any conditions to approval specified in the [premarket approval] order for the device."[53]

The Freeds argue their allegations of burns and shocks in the implant area and "the recall campaign evidence" creates a reasonable inference the Device "was adulterated but nevertheless made it through the manufacturing and quality control process regulated by the [premarket process]." We disagree the complaint makes this allegation or that a reasonable inference of adulteration could be drawn from the complaint. We will not allow "recall campaign evidence" – presumably recall notices attached as exhibits to the Freeds' response – to amend the complaint. The complaint simply fails to allege the Device is "adulterated." There are no allegations of how the Device became adulterated in violation of federal regulation and we cannot determine the contours of any adulteration claim. It is additionally unclear which of the Freeds' five state law claims purport to articulate an adulteration claim to determine whether the state law claim or claims are parallel to the federal scheme or are different from or add to the federal scheme for purposes of our preemption analysis.

C. Implied preemption

St. Jude also argues even if the Freeds' claims survive express preemption, their claims are impliedly preempted. The Freeds' response does not address the implied preemption argument.

"Implied preemption is based on the fact that any suit to enforce the [Food, Drug, and Cosmetic Act] 'shall be by an in the name of the United States.'" [54] In *Buckman Co. v. Plaintiffs' Legal Comm.*, the Supreme Court held "fraud [on the FDA] claims exist solely by virtue of the FDCA disclosure requirements" and are impliedly preempted by federal law as they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives."[55] St. Jude concedes the Freeds must allege parallel claims to survive implied preemption, leaving only a "narrow gap" for conduct violating the Food, Drug and

Cosmetic Act but not because the conduct violates this act.[56] As set forth above, we cannot determine whether the complaint as currently pleaded alleges parallel claims.

III. Conclusion

The Freeds do not presently allege facts necessary to overcome federal preemption arising from FDA's approval of the Device. They may be able to do so with an amendment. In the accompanying Order, we grant St. Jude's motion to dismiss without prejudice to the Freeds timely filing an amended complaint.

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[1] ECF Doc. No. 1-1 (Complaint) at ¶ 10.

[2] *Id.* at ¶¶ 7, 10. Defendants are St. Jude Medical, Inc., St. Jude Medical, S.C., Inc., Abbott Laboratories, Inc., and Advanced Neuromodulation Systems, Inc. d/b/a St. Jude Medical Neuromodulation Division (collectively, "St. Jude"). *Id.* at ¶¶ 2-5. The Device sold by St. Jude is the Protégé 16-Channel IPG Spinal Cord Stimulator implanted in Mrs. Freed.

[3] *Id.* at ¶ 7.

[4] *Id.*

[5] *Id.* at ¶ 13.

[6] *Id.* at ¶ 14.

[7] In deciding a motion to dismiss under Rule 12(b)(6), we accept all well-pleaded allegations in the complaint as true and draw all reasonable inferences in favor of the non-moving party, but we "are not compelled to accept unsupported conclusions and unwarranted inference, or a legal conclusion couched as a factual allegation." *Castleberry v. STI Group*, 863 F.3d 259, 263 (3d Cir. 2017) (quoting *Morrow v. Balaski*, 719 F.3d 160, 165 (3d Cir. 2013)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Edinboro Coll. Park Apartments v. Edinboro Univ. Found.*, 850 F.3d 567, 572 (3d Cir. 2017) (quoting *In re Vehicle Carrier Serv. Antitrust Litig.*, 846 F.3d 71, 79 n.4 (3d Cir. 2017)). A claim satisfies the plausibility standard when the facts alleged "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Maiden Creek Assoc., L.P. v. U.S. Dep't of Transp.*, 823 F.3d 184, 189 (3d Cir. 2016) (quoting *Ascroft v. Iqbal*, 556 U.S. 662, 678 (2009)). While the plausibility standard is not "akin to a 'probability requirement,'" there nevertheless must be more than a "sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). "Where a complaint pleads facts that are 'merely consistent with' a defendant's

liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

Our Court of Appeals requires us to apply a three-step analysis under a 12(b)(6) motion: (1) "it must 'tak[e] note of the elements [the] plaintiff must plead to state a claim;'" (2) "it should identify allegations that, 'because they are no more than conclusions, are not entitled to the assumption of truth;'" and, (3) "[w]hen there are well-pleaded factual allegations, [the] court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Connelly v. Lane Construction Corp.*, 809 F.3d 780, 787 (3d Cir. 2016) (quoting *Iqbal*, 556 U.S. at 675, 679).

[8] ECF Doc. Nos. 6, 7. We confine our analysis to the preemption question and will not address St. Jude's arguments the complaint fails to meet pleading standards.

[9] ECF Doc. No. 7.

[10] Fed.R.Evid. 201(b).

[11] *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

[12] *See* ECF Doc. No. 14-1 at Exhibits 3, 4.

[13] *See* Declaration of Brian M. Rostocklin in Support of Defendants' Request for Judicial Notice at ¶¶ 2, 3 (ECF Doc. No. 7). Courts in this District regularly take judicial notice of FDA records. *See e.g. Scanlon v. Medtronic Sofamor Danek USA, Inc.*, 61 F.Supp. 3d 403, 413 n. 16 (D.Del. 2014) (taking judicial notice of FDA document titled "Important Medical Information" available on the FDA's website); *Clements v. Sanofi-Aventis, U.S., Inc*, 111 F.Supp. 3d 586, 592 n. 2 (D. N.J. 2015) (taking judicial notice of FDA's premarket approval of Class III medical device); *Starks v. Coloplast Corp.*, No. 13-3872, 2014 WL 617130, at *1 n.3 (E.D. Pa. Feb. 18, 2014) (taking judicial notice of public records of the FDA attached to defendant manufacturer's motion to dismiss); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F.Supp.2d 751, 755 n. 2 (E.D.Pa.2003) (taking judicial notice of FDA's published reports posted on FDA's website).

[14] ECF Doc. No. 7 at ¶ 4.

[15] 21 U.S.C. § 360 *et seq.*

[16] *Riegel v. Medtronic, Inc.*, 552, U.S. 312, 315 (2008). Medical devices fall into one of three categories. 21 U.S.C. § 360c. Class I devices such as bandages and examination gloves are subject to "general controls" and receive the lowest level of oversight. *Riegel*, 552 U.S. at 316. Class II devices, such as powered wheelchairs and surgical drapes, are those which cannot be classified as Class I because the general controls are "insufficient to provide reasonable assurance of the safety and effectiveness of the device" and require "special controls" to provide safety assurances including performance standards, post-market surveillance, and patient registries. *Id.* at 316 -17.

[17] *Id.* at 317.

[18] *Id.* at 318 (quoting 21 U.S.C. §§ 360c(a)(2)(C), 360e(d)).

[19] Although they do not plead it in their complaint, the Freeds assert "[t]here is no dispute that the [Device] implanted in Mrs. Freed's body is a Class III device." ECF Doc. No. 14 at 6.

[20] FDA approval is not alleged in the complaint. However, both parties attach the FDA's November 21, 2001 approval letter to their briefing. The FDA issued its November 21, 2001 approval letter to Advanced Neuromodulation Systems, Inc. The Freeds allege Advanced Neuromodulation Systems, Inc. is an entity doing business as St. Jude Medical Neuromodulation Division. ECF Doc. No. 1 at ¶ 5. At the time the FDA issued its approval letter, the Device was known as the Genesis Neurostimulation (IPG) System. *See* ECF Doc. No. 7-1, Exhibit 1. At some point, the name of the Genesis device changed to the Eon Mini IPG. There is no explanation by the parties how and when the device changed from the Genesis system to the Eon Mini system. On March 21, 2014, the FDA issued an approval to change the name from the Eon Mini systen to the Protégé model used by Mrs. Freed. *See* ECF Doc. No. 7-1 at Exhibit 2.

[21] *See* ECF Doc. No. 7-1 at Exhibit 1.

[22] 21 U.S.C. § 360k(a).

[23] *Williams v. Cyberonics, Inc.*, 388 F.App'x 169, 171 (3d Cir. 2010) (quoting *Riegel*, 552 U.S. 321-22)).

[24] *Williams*, 388 F.App'x at 171 (citing *Riegel*, 552 U.S. at 325 and *Horn v. Thoratec Corp.*, 376 F.3d 163, 173 (3d Cir. 2004)).

[25] ECF Doc. No. 7-1, Exhibit 1.

[26] ECF Doc. No. 14 at 3, n.3.

[27] ECF Doc. No. 1 at ¶¶ 13, 14.

[28] ECF Doc. No. 14 at 13 (emphasis added).

[29] 46 F.3d 1316, 1319, 1325, 1329-30 (3d Cir. 1995). The passage cited by the Freeds supports preemption. In *Michael*, the plaintiff argued the absence of specific regulations on heart valves proves the lack of FDA regulation, a requirement for preemption. Our court of appeals disagreed, finding the "absence of regulations relating specifically to hear valves is not dispositive as long as the [Defendant's] valve was subject to 'any requirement applicable under [the MDA] to the device.'" 46 F.3d at 1324 (quoting 21 U.S.C. § 360k(a)(1)). The court found the valve subject to MDA requirements. *Id.* The entire passage, excised by the Freeds, reads: "Even though these generally applicable regulations do not rise to the level of specificity present in the case of some other devices regulated by the FDA, we conclude that they present "specific requirements applicable to a particular device under the act." 21 C.F.R. § 808.1(d). ***They therefore constitute***

proper bases for pre-emption under § 360k." *Id.* (emphasis added). The Freeds regrettably omit this emphasized sentence in their argument.

[30] 67 F.3d 1219 (6th Cir. 1995). In *Jacobs*, the plaintiff brought a products liability action against DuPont alleging injury resulting from Teflon used in an implant to replace her jaw joint. DuPont manufactured Teflon and other entity manufacturer the implant. The Sixth Circuit held plaintiff's claims were not preempted by the MDA because the FDA never issued regulations specific to the jaw joint implant or even classified the device until years after plaintiff received her implant and, as to the raw material argument, the language of the preemption provision in the MDA applies only to medical devices, not raw materials. *Id.* at 1236. *Jacobs* is factually distinguishable.

[31] 1 F.Supp. 2d 84 (D. Mass. 1998).

[32] *Id.* at 86.

[33] *Riegel*, 552 U.S. at 330 (quoting § 360k(a)(1)).

[34] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); *Riegel*, 552 U.S. at 330.

[35] *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F.Supp. 3d 586, 598 (D.N.J. 2015) (citations omitted).

[36] For example, the Freeds argue Mrs. Freed received "a non-conforming" Device which "raises an issue as to whether Defendants complied with" federal good manufacturing practices regulation. But the Freeds do not make these allegations.

[38] The Freeds assert their claim in Count IV is based on the Restatement (Second) of Torts, § 388 – "Chattel Known to be Dangerous for Intended Use."

[39] 236 F.Supp. 3d 889, 899-900 (M.D. Pa. 2017).

[40] *Id.* at 899-900.

[41] Because we focus our analysis on whether the complaint as currently pleaded articulates a parallel claim, we do not address St. Jude's argument the "manufacture or sale of dangerous chattel" states a claim under Delaware law, including the "learned intermediary" argument.
[42] *Bell Sports, Inc. v. Yarusso*, 759 A.2d 582,592 (De. 2000). The statute provides:

(1) Express warranties by the seller are created as follows:

(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
(b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

(c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

6 Del.C. § 2-313(1).

[43] 302 F.Supp.2d 419, 433 (E.D.Pa. 2004).

[44] *Id.* (citing *Steele v. Depuy Orthopaedics, Inc.,* 295 F.Supp. 2d 439, 455-56 (D.N.J. 2003)).

[45] 172 F.Supp. 3d 804 (E.D. Pa. 2016).

[46] *Id.* at 823-24.

[47] *Id.* at 824.

[48] *Id.* at 823-24.

[49] ECF Doc. No. 14 at 20, n.14.

[50] *Dilenno v. Libbey Glass Div., Owens-Illinois, Inc.*, 668 F.Supp. 373, 376 (D. Del. 1987).

[51] 21 U.S.C. § 351(f).

[52] *Id.* at § 351(h).

[53] 21 C.F.R. § 814.80.

[54] *Scanlon v. Medtronic Sofamor Danek USA, Inc.*, 61 F.Supp.3d 403, 410 (D.Del. 2014) (quoting 21 U.S.C. §337(a)).

[55] 531 U.S. 341, 350, 353 (2001).

[56] ECF Doc. No. 5 at 9, n.7 (quoting M*cLaughlin*, 172 F.Supp. 3d at 815). As explained by the court in *McLaughlin*, "*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by §360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*). *McLaughlin*, 172 F.Supp.3d at 815 (quoting *In re Medtronic, Inc. Sprint Fidelis Leads Prod. Liab. Litig.*, 623 D.3d 1200, 1204 (8th Cir. 2010)).