IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

CHRISTINE MCGEE,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 21-639
	)	
JOHNSON & JOHNSON,	)	
ETHICON, INC., and	)	
MENTOR WORLDWIDE LLC,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

The above-captioned matter involves product liability claims concerning breast implants, brought pursuant to Pennsylvania law by Plaintiff Christine McGee ("Plaintiff") against Defendants Johnson & Johnson ("J&J"), Ethicon, Inc. ("Ethicon"), and Mentor Worldwide, LLC ("Mentor") (collectively, "Defendants"). Plaintiff, who received Mentor's MemoryShape Siltex textured breast implants, alleges that she suffered damages as a direct and proximate result of the negligent and wrongful conduct of Defendants in connection with such implants. (Docket No. 20, ¶ 1). Presently before the Court is the Motion to Dismiss Plaintiff's Amended Complaint for failure to state a claim upon which relief can be granted, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, and brief in support thereof filed by Defendants (Docket Nos. 21; 22), the brief in opposition filed by Plaintiff (Docket No. 27), and Defendants' reply (Docket No. 28). The parties have also filed several notices of supplemental authority and responses thereto (Docket Nos. 29-34; 38-41). On May 16, 2023, the Court held oral argument on the motion to dismiss, after which the parties filed post-argument memoranda and supplemental submissions. (Docket Nos. 42-44; 46-48).

For the reasons set forth herein, Defendants' motion is granted in part and denied in part.

I. BACKGROUND

As alleged in the Amended Complaint, Plaintiff is a resident of Pennsylvania, and J&J is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. (Docket No. 20, ¶¶ 6-7). J&J's corporate family structure includes a multitude of wholly owned subsidiaries and affiliated companies, including Ethicon (a New Jersey corporation with its principal place of business in Somerville, New Jersey) and Mentor (a Delaware limited liability company with its principal place of business in Santa Barbara, California, and its headquarters in Irvine, California). (*Id.* ¶¶ 8-11). Mentor is a manufacturer of breast implants, and it touts itself as the global leader in aesthetic medicine and the United States market leader in breast aesthetics. (*Id.* ¶¶ 13-14).

On or about July 3, 2013, genetic testing revealed that Plaintiff, who has a significant family history of breast cancer and ovarian cancer, tested positive for the BRACI deleterious gene mutation. (Docket No. 20, ¶ 44). On January 9, 2017, as a precaution against developing breast cancer, Plaintiff underwent a bilateral total mastectomy followed by bilateral immediate reconstruction with implantation of Mentor's MemoryShape Siltex textured breast implants (the "Siltex implants"). (*Id.* ¶¶ 11, 45). On May 30, 2019, Plaintiff underwent a right breast ultrasound due to acute swelling of her breast, and the radiologist's impression was that an implant had ruptured. (*Id.* ¶ 46). On June 4, 2019, Plaintiff underwent surgery and replacement of her Siltex implants with a similar model of implants. (*Id.* ¶ 47). After the surgery, results of Plaintiff's surgical pathology showed breast implant-associated anaplastic large cell lymphoma ("BIA-ALCL" or "ALCL"), a rare form of cancer, with tumor cells in the fibrinous exudate of the capsule. (*Id.* ¶ 48). Therefore, on July 17, 2019, Plaintiff underwent surgery again to remove the Siltex implants. (*Id.* ¶ 50). According to Plaintiff, she suffered tremendously from the pain of her explant

surgery, symptoms of her BIA-ALCL, and recovery. (*Id.* ¶ 53). Prior to her development, diagnosis, and treatment of ALCL, Plaintiff enjoyed an active, full life and did not experience the symptoms that arose after the Siltex breast implants were placed in her body; but afterward, Plaintiff endured pain, swelling, and embarrassment because of her deformed chest. (*Id.* ¶ 54).

On May 13, 2021, Plaintiff filed her Complaint against Defendants in this matter. (Docket No. 1). On July 19, 2021, Defendants filed a motion to dismiss Plaintiff's Complaint. (Docket No. 10). On August 2, 2021, Plaintiff filed her Amended Complaint (the operative complaint here), in which she alleges that the Siltex implants that she received caused her to develop BIA-ALCL as a direct and proximate result of the negligent and wrongful conduct of Defendants' violations of the Federal Drug Administration ("FDA") laws, regulations, and requirements applicable to manufacturing, warnings, and post-marketing requirements. (Docket No. 20, ¶¶ 1, 2).

According to the Amended Complaint, the Siltex implants that Plaintiff received have a textured surface, and "[s]ometimes, in contravention with its federal requirements, the peeling away of the polyurethane foam stamp leaves residual polyurethane debris on the surface of the Siltex implants and causes pores and larger than intended cavities." (Docket No. 20, ¶ 243 (emphasis in original)). Plaintiff alleges that this debris that remains on the implants, which is recognized as a foreign body and triggers a T-cell lymphoma, is not part of the FDA-approved design for the MemoryShape Siltex implants. (*Id.* ¶¶ 244, 246). Plaintiff further avers that Defendants failed to comply with various FDA post-approval reporting requirements. (*Id.* ¶¶ 3, 302). Plaintiff alleges that Defendants were aware of complaints about BIA-ALCL related to their Siltex implants, but they took no action, did not properly report adverse events, and allowed the

nonconforming product to continue to be released into the stream of commerce. (*Id.* ¶¶ 38, 51, 85, 89, 96, 164, 168-69).

Plaintiff's Amended Complaint alleges four separate Counts against all Defendants under Pennsylvania law: (1) Strict Liability for Manufacturing Defect; (2) Breach of Implied Warranties; (3) Strict Liability for Failure to Warn; and (4) Negligence. (Docket No. 20, ¶¶ 241-306). Defendants have filed their motion to dismiss Plaintiff's Amended Complaint for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Defendants' motion has been fully briefed, oral argument has been held, and the motion is ripe for decision.

II. STANDARD OF REVIEW

In considering a Rule 12(b)(6) motion to dismiss, the factual allegations contained in the complaint must be accepted as true and must be construed in the light most favorable to the plaintiff, and the court must "'determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.'" *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) (quoting *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)); *see Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 563 n.8 (2007). While Federal Rule of Civil Procedure 8(a)(2) requires only "a short and plain statement of the claim showing that the pleader is entitled to relief," the complaint must "'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Phillips*, 515 F.3d at 231 (quoting *Twombly*, 550 U.S. at 555 (internal citation omitted)). Moreover, while "this standard does not require 'detailed factual allegations,'" Rule 8 "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* (quoting *Twombly*, 550 U.S. at 555); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555).

It should be further noted, therefore, that in order 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.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). The Supreme Court has noted that a "claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). The standard "'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element." *Phillips*, 515 F.3d at 234 (quoting *Twombly*, 550 U.S. at 556). Moreover, the requirement that a court accept as true all factual allegations does not extend to legal conclusions; thus, a court is "'not bound to accept as true a legal conclusion couched as a factual allegation.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555 (internal citation omitted)).

III. LEGAL ANALYSIS

In support of their motion to dismiss Plaintiff's Amended Complaint pursuant to Rule 12(b)(6), Defendants argue: that all of Plaintiff's claims, which involve a "Class III PMA medical device," are expressly preempted pursuant to the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); that such claims are impliedly preempted by federal law; and that none of the claims constitute a viable "parallel" claim that fits through the "narrow gap" between express and implied preemption. Defendants also argue that Plaintiff's claims do not satisfy applicable pleading requirements as to all three Defendants because the Amended Complaint "lumps" Defendants together and does not distinguish among their purported acts and omissions. While Plaintiff opposes Defendants' motion, in the course of the parties' briefing and oral argument, she has made certain concessions regarding her claims. Because of the overlapping nature of the

parties' arguments, the Court will first address Defendants' preemption arguments in the order that they were presented in briefing and during oral argument, and then the Court will address whether Plaintiff has adequately pled claims against all Defendants.

A. Defendants' Motion to Dismiss Plaintiff's Claims on Preemption Grounds

In their motion to dismiss, Defendants first argue that all of Plaintiff's claims, because they involve a "Class III PMA medical device," are preempted by federal law. In this regard, the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, establishes a federal regulatory regime granting the FDA authority to regulate medical devices. *See Riegel v. Medtronic, Inc.*, 552 U.S. at 315-16. The MDA creates three classes of medical devices, categorizing such devices based "on the risks they present." *Id.* at 316. The most stringent controls apply to Class III devices under the MDA, which require premarket approval ("PMA") by the FDA before they enter the market. *See id.* at 317-18.

Generally, before marketing a Class III medical device, "the manufacturer must submit a PMA application that the FDA can grant 'only after it determines that a device offers a reasonable assurance of safety and effectiveness.'" *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, 537 F. Supp. 3d 679, 706 (D.N.J. 2021) (quoting *Riegel*, 552 U.S. at 323). The "rigorous" PMA process requires that a manufacturer submit an application containing specific information and data about the safety and efficacy of the device, which the FDA then scrutinizes, examining the design specifications, manufacturing processes, and labeling proposed by the manufacturer. *See Riegel*, 552 U.S. at 317-18. Once the PMA is granted by the FDA, the MDA forbids the manufacturer from making, "without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety

or effectiveness." *Id.* at 319. Approved devices are also subject to ongoing reporting requirements related to safety, so a manufacturer must inform the FDA about studies or investigations and incidents where the device caused or could have caused serious injury. *See id.* The FDA then retains authority to withdraw its approval based on such information. *See id.* at 319-20.

The MDA contains an "express preemption" provision, which ensures that FDA oversight of PMA medical devices is not controverted by state law. That provision provides as follows:

> [N]o 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.

21 U.S.C. § 360k(a). The Supreme Court held in *Riegel* that state laws are expressly preempted by the MDA if "(1) the Federal Government has established 'specific requirements applicable to a particular 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." *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 484 (W.D. Pa. 2012) (quoting *Riegel*, 552 U.S. at 321-23). Section 360k(a) does not, however, "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations [because] the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330.

The MDA also contains an "implied preemption" provision, in that it specifically indicates that all actions to enforce FDA requirements concerning medical devices "shall be by and in the name of the United States." 21 U.S.C. § 337(a). In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001), the United States Supreme Court explained that Section 337 "leaves

no doubt" that federal law bars suit by private litigants "for noncompliance with the medical device provisions." Therefore, even if not expressly preempted, a claim is impliedly preempted if it is cognizable only because of the FDCA's provisions. *See id.* at 348, 353. In other words, "[i]mplied preemption under the MDA bars claims seeking to enforce an exclusively federal requirement that is not grounded in traditional state tort law." *Glennen v. Allergan, Inc.*, 247 Cal. App. 4th 1, 10-11 (2016); *see McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 814-15 (E.D. Pa. 2016).

Thus, express preemption and implied preemption create a "narrow gap" through which a state law claim must fit in order to escape preemption. *Gross*, 858 F. Supp. 2d at 492-93. Specifically, a plaintiff "'must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)),'" and "'must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted by *Buckman*).'" *McLaughlin*, 172 F. Supp. 3d at 815 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (emphasis in original)). Therefore, to survive preemption, a plaintiff's claim "must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." *Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F. Supp. 3d 403, 411 (D. Del. 2014) (internal quotation marks and citation omitted).

1. <u>Counts One & Four: Plaintiff's Manufacturing Defect Claims</u>

In her Amended Complaint, Plaintiff alleges that Defendants are liable under Pennsylvania law – based on strict liability at Count One and negligence at Count Four – for Plaintiff's injuries because the Siltex breast implant that caused her BIA-ALCL had a manufacturing defect. (Docket No. 20, ¶¶ 241-66, 292-306). In their motion to dismiss, Defendants argue that Plaintiff's manufacturing defect claims under Counts One and Four are both preempted by federal law.

As a Class III medical device, Mentor's MemoryShape Siltex breast implants had to go through the FDA's PMA application and approval process, discussed, *supra*.[1] (Docket No. 20, ¶¶ 31, 35). Nevertheless, Plaintiff specifically avers in her Amended Complaint that "**Mentor was required, but failed, to remove any manufacturing material that could adversely affect the device's quality, pursuant to 21 C.F.R. § 820.70(h),"** and that such **"failure left *unintended* particles on Christine McGee's breast implants that caused chronic inflammation and caused or contributed to the development of ALCL."** (*Id.* ¶ 245 (emphasis in original)). Plaintiff contends that such *adulterated* medical devices are *not* subject to preemption, and that Defendants' violations of federal requirements run parallel to Plaintiff's traditional Pennsylvania-based manufacturing defect claims. (*Id.* ¶¶ 247, 249, 256). Thus, Plaintiff avers in Count One that Defendants are strictly liable for, among other things, manufacturing their breast implant products in a manner that differed from the specifications agreed to by the FDA, by failing to follow the FDA's Current Good Manufacturing Practice requirements ("CGMPs")[2] and Quality System Regulations ("QSRs"), and by failing to meet the applicable standard of care by not complying with applicable federal regulations and manufacturing protocols approved by the FDA. (*Id.* ¶ 248). In Count Four, Plaintiff asserts that Defendants were also negligent, under Pennsylvania law, in manufacturing breast implants without controlling the texturing process and by leaving residual problematic debris on the devices. (*Id.* ¶ 294). Plaintiff maintains that her claims add no additional requirements to those required by the FDA. (*Id.* ¶¶ 250, 298).

---

[1] Additionally, Mentor was required to abide by ongoing requirements to conduct post-approval studies and report adverse events to the FDA. (Docket No. 20, ¶¶ 32, 42, 58, 84).

[2] CGMPs, set forth in Title 21 of the Code of Federal Regulations, Part 820 (entitled "Quality System Regulation"), "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1). CGMPs exist in order "to ensure that finished devices will be safe and effective and otherwise in compliance with the [FDCA]." *Id.*

In their motion, Defendants argue that Plaintiff's defective manufacturing claims at Counts One and Four of the Amended Complaint should both be dismissed because: (1) Plaintiff's manufacturing defect claims are really design defect claims, which are clearly preempted; (2) Plaintiff has not identified a specific regulatory violation at issue here, as is required; (3) Plaintiff's claims are insufficient to the extent they are based on alleged violations of the FDA's CGMPs; and (4) Plaintiff cannot plead a causal nexus between any alleged violation of a federal requirement and her injuries. (Docket No. 22 at 22-25). The Court will address these arguments in turn.

a. Allegations of a Manufacturing Defect or a Design Defect

In response to Defendants' first argument – that Plaintiff is alleging a preempted design defect claim – Plaintiff maintains that she is, in fact, alleging a *manufacturing* defect claim, and not a *design* defect claim. Plaintiff indicates that she does not, as Defendants argue, contend that *all* Siltex implants are defective, but rather, she alleges that her manufacturing defect claim is limited to *some* instances of "manufacturing gone awry." (*See, e.g.,* Docket No. 20, ¶ 243 ("***Sometimes***, in contravention with its federal requirements, the [peeling process] leaves residual polyurethane debris on the surface of the Siltex implants." (emphasis in bold added, underlining in original))). Plaintiff argues that her Amended Complaint thus includes allegations that "Mentor, **at times**, engaged in shoddy workmanship when executing the approved manufacturing and control processes (i.e., FDA required removal of debris and following a system of checks and balances)" and produced defective implants "with **varying degrees** of nonconformance and **varying degrees** of potential for harm." (Docket No. 27 at 19 (emphasis added)).

Plaintiff asserts that the Pennsylvania Supreme Court has adopted Section 402A of the Restatement (Second) of Torts as the law of strict products liability in Pennsylvania. (Docket No.

27 at 19 (citing *Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 746 (W.D. Pa. 2004); *Harsh v. Petroll*, 840 A.2d 404, 417-18 (Pa. Commw. Ct. 2003) ("Regarding a manufacturing defect claim, a plaintiff would have to prove similar evidence, e.g., that the manufacturing process was defective, etc."); *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 371 (Pa. 2014) (explaining that the standard for manufacturing defect cases is that "something went wrong in the manufacturing process," and "the resulting product was not as safe as intended")). Accordingly, Plaintiff emphasizes that here she is alleging "deviations" in the manufacturing process, a breach of the duty to "exercise reasonable care in manufacturing the products without deviations and defects," and manufacturing breast implants that did "not conform to specification." (Docket No. 20, ¶¶ 115, 265, 122-25). Plaintiff also notes that the alleged harms "directly resulted from the variations from the approved design and manufacturing specifications," and that "[h]ad Mentor utilized CGMPs and complied with QSRs, and undertaken the manufacturing process in an appropriate manner, it would have consistently produced a product in conformity with its approved specifications." (*Id.* ¶ 133).

Upon consideration of the parties' arguments, the Court agrees with Plaintiff's contention that her Amended Complaint challenges the execution of Mentor's manufacturing of its Siltex implants, and not the actual design of the implants (which Plaintiff admits would be a design defect claim and would certainly be preempted). *See, e.g., In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, MDL No. 05-1708, 2007 WL 1725289, at *8 (D. Minn. June 12, 2007) (finding that, where claims alleged that a device was not manufactured in accordance with FDA-approved manufacturing process requirements, the plaintiff's manufacturing claims were not preempted); Docket No. 27-6 at 28 (attaching *In re Allergan Biocell Textured Breast Implant Prod. Liab. Litig.*, Master Case No. BER-L-5064-20, slip op. (N.J. Super. Ct. May 4, 2021) (finding that a deviation

from specifications and processes constitutes a manufacturing defect)). As Plaintiff indicates, she is not alleging that all implants like the ones she received are defective, and that the design and/or manufacture process is thus defective; but rather, Plaintiff is alleging that certain implants deviated from the approved manufacturing process since they contained debris, which led to her ALCL. Therefore, despite Defendants' argument to the contrary, the Court finds that Plaintiff is alleging a manufacturing defect claim, not a design defect claim, in her Amended Complaint. Accordingly, her claims at Counts One and Four are not subject to preemption based on Plaintiff alleging a design defect.

b. Allegations of a Regulatory Violation

In their related second and third arguments regarding Plaintiff's manufacturing defect claims, Defendants contend that Plaintiff has not identified an appropriate specific regulatory violation that Mentor violated, so such claims cannot survive preemption. According to Defendants, merely alleging in a conclusory fashion that a defendant violated various laws and regulations, or that a defendant produced a nonconforming device, does not sufficiently establish that the defendant violated a federal requirement in order to state a claim. (Docket No. 22 at 23 (citing *Conley v. St. Jude Med., LLC*, 482 F. Supp. 3d 268, 280 (M.D. Pa. 2020) (holding that manufacturing defect claims were preempted where the plaintiffs "failed to allege any specific violations of federal law that might establish a parallel state duty," and "neither identifie[d] a specific manufacturing defect, nor specifically allege[d] how [the defendant's] practices ran afoul of FDA requirements")). Defendants argue that, "[t]o survive preemption, 'a plaintiff must allege that the defendant violated *a particular federal specification* referring to the device at issue, or *identify specific PMA requirements* that have been violated.'" (*Id.* (quoting *Ebrahimi v. Mentor Worldwide LLC*, No. CV 16-7316, 2018 WL 2448095, at *4 (C.D. Cal. May 25, 2018) (finding

the plaintiff's allegations insufficient where she alleged that her implants suffered from "poor quality of workmanship and patch defects" because that "sheds little light on how the manufacturing of the Implants failed to adhere to FDA specifications"))).

In response, Plaintiff asserts that state law claims based on allegations of a manufacturer's failure to comply with CGMPs or device-specific PMA specifications can survive preemption, and she argues that she has alleged enough at the present stage of the litigation in this particular case. (Docket No. 27 at 20 (citing *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 898-899 (M.D. Pa. 2017) (finding that the plaintiff's manufacturing defect claim, which alleged that a device was manufactured out of specification, was not preempted); *Sullivan v. Medtronic, Inc.*, 498 F. Supp. 3d 1106, 1113 (E.D. Mo. 2020) (citing *Silver* with approval); *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 363-64 (D. Del. 2019) (finding that the plaintiff's allegations plausibly alleged a negligent manufacturing claim))). In reply, Defendants argue, essentially, that Plaintiff's allegations here are just too conclusory and general in nature.

The Court finds that, given the information to which Plaintiff has access at this early point in the litigation, the Amended Complaint adequately alleges specific regulatory violations for Plaintiff's manufacturing defect claims at Counts One and Four to survive preemption at the motion to dismiss stage. Defendants argue that Plaintiff must allege a violation of a particular federal specification referring to the device at issue, or that she must identify a specific PMA requirement that has been violated, and the Court notes that – at a minimum – Plaintiff has in fact cited a specific CGMP that is particularly relevant to the facts alleged here: 21 C.F.R. § 820.70(h), which requires "removal of . . . manufacturing material" that can have an adverse effect on quality,

such as the debris that Mentor failed to remove from Plaintiff's implants.[3] (Docket Nos. 27 at 22; 20, ¶¶ 139, 245).

Plaintiff notes that this CGMP has previously been found to be specific enough to fit through the narrow gap to preclude preemption. *See Gross v. Stryker*, 858 F. Supp. 2d at 496 (explaining that in *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440-41 (6th Cir. 2010), the Court of Appeals for the Sixth Circuit held that the plaintiff's citation to 21 C.F.R. § 820.70(h) was a sufficient foundation on which to base a parallel claim, emphasizing that that CGMP was distinguishable from the "general allegations" that the plaintiff claimed were violated in *Gross*). The Court agrees with the *Howard* Court's view that this CGMP requires actual removal of manufacturing material when it adversely affects the device's quality. *See id.* (citing *Howard*, 382 F. App'x at 441; 21 C.F.R. § 820.70(h)); *see also D'Addario v. Johnson & Johnson*, No. 19-15627, 2021 WL 239395, at *5 (D.N.J. Jan. 18, 2023) (noting that the plaintiffs pled a failure to remove debris from Stiltex implants in violation of 21 C.F.R. § 820.70(h) in pleading a plausible manufacturing defect claim); *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, 537 F. Supp. at 714 (finding that the plaintiffs' textured breast implant claim, alleging that debris remained on the product, stated a manufacturing defect claim).

Moreover, while Defendants argue that Plaintiff should cite to specific violations of the PMA, the Court notes that Plaintiff has indicated that a more detailed citation to a violated regulation would require access to Mentor's confidential PMA documents, which she has not received at this point in the litigation. In light of the parties' arguments and the prior case law that has been presented and discussed at length in briefing and during oral argument, the Court concludes that, at this juncture and based on the facts of this case and the information that is

[3] The Court notes that, in her Amended Complaint, Plaintiff also cites to additional allegedly violated CGMPs, including 21 C.F.R. § 820.50(a) and 21 C.F.R. § 820.90(a). (Docket No. 20, ¶¶ 121, 125).

currently available to Plaintiff, Plaintiff has "pled sufficiently given the amount of information to which she had access." *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010). Accordingly, Plaintiff's manufacturing defect claims at Counts One and Four are not subject to preemption based on Plaintiff's failure to allege specific violations of federal law in order to establish a parallel state duty.

c. Allegations of a Causal Nexus

Fourth, Defendants argue that Plaintiff's manufacturing defect claims should be dismissed because she has not pled a causal nexus between the violation of a federal requirement and her injuries. In response, Plaintiff asserts that she clearly alleged causation here since she avers: that, for years, Mentor received complaints of BIA-ALCL related to their Siltex implants, but it ignored such complaints and took no corrective or preventative action; that, consequently, certain Siltex implants containing unintended residue continued to be produced; that, rather than disposing of nonconforming implants, Mentor unlawfully allowed those products to be released into the stream of commerce; and that Plaintiff had such nonconforming products implanted into her body and later suffered from BIA-ALCL. (Docket No. 27 at 21-22). Based on such allegations, the Court finds that Plaintiff has adequately pled causation.

Accordingly, the Court finds that Plaintiff's manufacturing defect claims at Counts One and Four of the Amended Complaint should not be dismissed for failure to plead a causal connection between an alleged violation of a federal requirement and her injuries.

2. Count Two: Breach of Implied Warranties

In Count Two of her Amended Complaint, Plaintiff seeks damages from Defendants for breach of implied warranties under Pennsylvania law. (Docket No. 20, ¶¶ 267-81). Defendants argue that this claim is preempted, and thus is not permitted under Pennsylvania law. (Docket

Nos. 22 at 32; 28 at 15). Plaintiff admits that the law is unsettled in this area. (Docket No. 27 at 30). Furthermore, during oral argument, Plaintiff's counsel conceded that this claim is really "kind of the same thing as a negligence claim," which Plaintiff alleges at Count Four. (Docket No. 42; Oral Argument regarding Defendants' motion to dismiss, held on May 16, 2023 ("Oral Argument")[4]). Upon consideration of the split in authority in this area, the Court concludes that "[w]ith such an unclarity, the Court will 'opt for the interpretation[] that restrict[s] liability,' *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 253 (3d Cir. 2010), and therefore finds Plaintiff['s] implied warranty claims not viable in Pennsylvania." *In re Allergan Biocell Textured Breast Implant Prod. Liab. Litig.*, 537 F. Supp. 3d at 749–50.

Accordingly, Plaintiff's claim of breach of implied warranties at Count Two of the Amended Complaint will be dismissed with prejudice.

3. Count Three: Strict Liability for Failure to Warn

In her Post-Argument Statement Memorandum, Plaintiff concedes that her failure to warn claims based on the adequacy of the FDA-approved warnings for Mentor's Siltex breast implants are preempted for the reasons stated in the November 23, 2021, Order issued in the California *Allergan Biocell Textured Breast Implant Cases*, filed in this case as supplemental authority (Docket No. 31, Judicial Council Coordinated Proceeding No. 5104, slip op. (Cal. Super. Ct. County of L.A. Nov. 23, 2021)). (Docket No. 44 at 1).

Accordingly, Count Three of the Amended Complaint, which alleges a strict liability claim against Defendants for failure to warn, will be dismissed with prejudice.

[4] An official transcript of the hearing during which oral argument was held has not been produced as of this date. Therefore, the Court discusses the testimony presented by reference to an unofficial draft of the transcript.

4. Count Four: Negligence

In Count Four of her Amended Complaint, Plaintiff alleges claims of negligence based on a number of different acts and/or omissions of Defendants, including negligent manufacturing, failure to timely report adverse events to the FDA, and failure to warn. (Docket No. 20, ¶¶ 292-306). In the course of briefing and oral argument, however, Plaintiff has narrowed the grounds upon which she wishes to pursue this negligence claim. As discussed, *supra*, Section III.A.1, to the extent Count Four alleges negligent manufacturing, such portion of Plaintiff's negligence claim survives Defendants' motion to dismiss. Also as discussed, *supra*, Section III.A.3, Plaintiff concedes that her failure to warn claims are preempted, so to the extent Count Four alleges negligence for failure to warn, such portion of Plaintiff's negligence claim will be dismissed. Nevertheless, Plaintiff argues that her negligent failure to report claim is "conceptually different" from her failure to warn claims and is *not* preempted under Third Circuit authority, so to the extent Count Four alleges negligence for the failure to report adverse events to the FDA, Plaintiff asks that such claim not be dismissed. (Docket Nos. 44 at 1; 46 at 2). Thus, at this juncture, Plaintiff has clarified that she wishes to pursue two specific sub-claims within her negligence claim at Count Four: (1) negligence based on a manufacturing defect, discussed, *supra*; and (2) negligence based on the failure to report adverse events to the FDA, discussed next.[5]

a. Defendants' Argument: No Parallel Pennsylvania State Law Duty

In moving to dismiss Plaintiff's negligence claim to the extent it is based on the failure to report, Defendants argue that the Amended Complaint does not identify a parallel Pennsylvania

[5] Although Plaintiff includes in her negligence claim at Count Four an allegation of failure to conduct adequate post-marketing surveillance to determine the safety of Mentor's implants (Docket No. 20, ¶ 303), Plaintiff apparently does not intend that allegation to constitute a separate negligence sub-claim, as that allegation is not included (or even mentioned) in Plaintiff's framing of sub-claims (within her negligence claim) that she intends to prove going forward in this litigation.

state law duty, imposed upon manufacturers and sellers, to report adverse events to a federal agency such as the FDA. Defendants contend that Plaintiff's failure to report claim is therefore impliedly preempted because it is "simply an attempt by [a] private part[y] to enforce the MDA, [a] claim[] foreclosed by [21 U.S.C.] § 337(a) as construed in *Buckman*." (Docket Nos. 22 at 26; 28 at 11 (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d at 1205-06)).

b. Plaintiff's Response: Pennsylvania Law Imposes a Duty to Report Adverse Events

Plaintiff does not dispute that the Amended Complaint does not refer to a specific parallel state law regarding a duty to report adverse events to the FDA. However, in opposing Defendants' motion to dismiss, Plaintiff argues that the Court should rely upon a line of cases that stand for the proposition that failing to report adverse events to the FDA supports a parallel Pennsylvania law claim for negligence. (Docket Nos. 27 at 32; 44 at 1 (citing to *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013); *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889 (M.D. Pa. 2017); *Freed v. St. Jude Medical, Inc.*, 364 F. Supp. 3d 343 (D. Del. 2019); *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, 537 F. Supp. 3d 679 (D.N.J. 2021)).

First, in support of her argument that her failure to report claim is not preempted, Plaintiff cites to *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889 (M.D. Pa. 2017). In considering a failure to report claim in *Silver*, the District Court for the Middle District of Pennsylvania found "no binding jurisprudence on whether a Pennsylvania failure to warn claim premised upon the manufacturer's failure to report to the FDA is expressly preempted by the MDA." 236 F. Supp. 3d at 899. The *Silver* court therefore looked to *McLaughlin v. Bayer Corporation*, 172 F. Supp. 3d 804, 837 (E.D. Pa. 2016), a decision from the District Court for the Eastern District of Pennsylvania that involved a nearly identical situation. *See Silver*, 236 F. Supp. 3d at 899. The *Silver* court noted that the

McLaughlin court, in turn, had relied primarily on a decision by the Court of Appeals for the Ninth Circuit, *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. 2013). *See* 236 F. Supp. 3d at 899. In *Stengel*, the Ninth Circuit, considering Arizona law, found that a parallel Arizona state law imposed a duty to warn third parties, so there was no federal preemption of a claim for failure to warn based upon failure to report to the FDA. *See Silver*, 236 F. Supp. 3d at 899-900.

In its analysis, the *Silver* court explained that, as in *McLaughlin*, the plaintiff had provided evidence that Pennsylvania imposes such a duty. *See id.* at 900. The *Silver* court also noted that the plaintiff, like the plaintiff in *McLaughlin*, cited to a Pennsylvania Superior Court case, *Phillips v. A.P. Green Refractories Co.*, 630 A.2d 874 (Pa. Super Ct. 1993), which (according to the *Silver* court) had adopted Section 388 of the Restatement (Second) of Torts, including comment n. *See id.* The *Silver* court cited the portion of comment n to Section 388 that provides:

> [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.

Id. (quoting *Phillips*, 630 A.2d at 882, and citing Restatement (Second) of Torts, § 388 cmt. n).

The *Silver* court then concluded that the duty set forth in that section of the Restatement is parallel to FDA reporting requirements because it may impose liability for the failure to report to the FDA. *See id.* Accordingly, the *Silver* court found that the plaintiff's claims in that case were not preempted by federal law. *See id.*

In further support of her argument that her failure to report claim is not preempted, Plaintiff cites to *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 359-60 (D. Del. 2019). In *Freed*, a case decided under Delaware law, the District Court for the District of Delaware reviewed the *Silver* and *McLaughlin* opinions. *See id.* The *Freed* court commented that Pennsylvania has adopted Section 388, which imposes a duty on a manufacturer to warn a third party of a product's dangerous

propensities where there is reasonable assurance that the information will reach those whose safety depends on such information. *See id.* at 359. The *Freed* court noted that Delaware has also adopted Section 388 and that the defendant's argument that the plaintiffs had not cited any Delaware law establishing a duty to report adverse events to the FDA was without merit. *See id.* at 360.

Finally, Plaintiff cites to *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, 537 F. Supp. 3d 679 (D.N.J. 2021), in support of her argument that her failure to report claim is not preempted. In *Allergan*, the District Court for the District of New Jersey simply included Pennsylvania in a list of jurisdictions that ostensibly allow a failure to warn claim based on a device manufacturer's inadequate reporting to the FDA under state law tort principles. *See id.* at 731. The *Allergan* court cited to *Silver* and *McLaughlin* in support of such proposition, but it included no analysis of those cases. *See id.*

c. Defendants' Reply: No Pennsylvania Courts Have Recognized a Claim for Failure to Report Adverse Events to the FDA

In replying to Plaintiff's argument that her failure to report claim is not preempted, Defendants emphasize that *no Pennsylvania court* has held that the Commonwealth recognizes a common law claim based on a failure to report adverse events to the FDA. (Docket No. 47 at 2). Moreover, Defendants contend that the cases that Plaintiff cites rely on erroneous precedent, those cases apply a standard that has not yet been explicitly adopted by Pennsylvania courts, and such cases ignore Third Circuit precedent holding that there is no Pennsylvania common law duty to report adverse events to a federal agency. (*Id.*).

In warning that Plaintiff's cited line of cases relies on erroneous precedent, Defendants alert the Court to the fact that *Silver* relied on *McLaughlin*, which in turn relied on *Stengel*, which erroneously predicted that Arizona would recognize a parallel state law duty for a manufacturer to

warn the FDA of adverse events. Specifically, the prediction in *Stengel* was later proven wrong in *Conklin v. Medtronic, Inc.*, 431 P.3d 571 (Ariz. 2018), where the Arizona Supreme Court found that Arizona law requires medical device manufacturers to convey warnings to prescribing physicians – *not* to the FDA, as the court had found in *Stengel*. *See id.* at 577 (stating that the plaintiff "cites no authority, and we are aware of none, for the proposition that Arizona law requires a manufacturer to warn a federal agency").

In addition to asserting that *Silver* and *McLaughlin* rely on erroneous precedent, Defendants point out that those cases also both rely, questionably, on Section 388 of the Restatement (Second) of Torts, comment n, otherwise known as the "sophisticated user doctrine." Defendants note that such doctrine – which is, in actuality, a *defense* rather than a *duty* – is limited to the transmission of warnings "to the third person through whom the chattel is supplied," and not through warnings to a regulatory agency like the FDA. In fact, comment n provides more fully:

> *n. Warnings given to third person.* Chattels are often supplied for the use of others, although the chattels or the permission to use them are not given directly to those for whose use they are supplied, as when a wholesale dealer sells to a retailer goods which are obviously to be used by the persons purchasing them from him, or when a contractor furnishes the scaffoldings or other appliances which his subcontractor and the latter's servants are to use, or when an automobile is lent for the borrower to use for the conveyance of his family and friends. In all such cases the question may arise as to whether the person supplying the chattel is exercising that reasonable care, which he owes to those who are to use it, **by informing the third person through whom the chattel is supplied** of its actual character.
>
> **Giving to the third person through whom the chattel is supplied** all the information necessary to its safe use is not in all cases sufficient to relieve the supplier from liability. It is merely a means by which this information is to be conveyed to those who are to use the chattel. The question remains whether this method gives a reasonable assurance that the information will reach those whose safety depends upon their having it. All sorts of chattels may be supplied for the use of others, through all sorts of third persons and under an infinite variety of circumstances. This being true, it is obviously impossible to state in advance any set of rules which will automatically determine in all cases **whether one supplying a chattel for the use of**

> **others through a third person** has satisfied his duty to those who are to use the chattel **by informing the third person** of the dangerous character of the chattel, or of the precautions which must be exercised in using it in order to make its use safe.

Restatement (Second) of Torts § 388 cmt. n (emphasis added).

Defendants further note that the Pennsylvania case that purportedly first adopted the sophisticated user doctrine, *Phillips v. A.P. Green Refractories Co.*, 630 A.2d 874 (Pa. Super. Ct. 1993) – to which both the *Silver* and the *McLaughlin* plaintiffs cited – involved foundry workers who were exposed to silica, rather than the manufacture and sale of a medical device, so the factual situations of the cases are extremely different. Furthermore, in handling the appeal of *Phillips*, the Supreme Court of Pennsylvania commented that it did not have to rule on "the merits of importing the negligence-based 'sophisticated user' defense embodied in § 388 of the Restatement (Second) of Torts into our strict liability law," and that the "analysis of whether a § 388 defense may be raised in a strict liability action must thus await a future case." *Phillips v. A-Best Prods. Co.*, 665 A.2d 1167, 1172 (Pa. 1995). Therefore, Defendants argue, *Silver* and the other cases cited by Plaintiff, which rely on *Stengel* and Section 388, rest on a shaky foundation and do not clearly indicate the existence of a duty imposed on manufacturers under Pennsylvania law to report adverse events to regulatory agencies such as the FDA.

Defendants also cite to a number of cases in support of their argument that no such duty to report exists under Pennsylvania law, including *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701 (3d Cir. 2018), in which the Court of Appeals for the Third Circuit relied on *Buckman*, 531 U.S. at 348 (noting that it had held that state law fraud-on-the-FDA claims were impliedly preempted by federal law) to find the plaintiff's "failure-to-notify-the-FAA" claim to be preempted by federal law. *See Sikkelee*, 907 F.3d at 716-17 (involving the alleged failure to report known product defects to the Federal Aviation Administration); *see also In re Medtronic, Inc., Sprint*

Fidelis Leads, 623 F.3d at 1205-06 (holding that the plaintiff's claim based on a failure to provide the FDA with adverse event reports was impliedly preempted, where the district court had noted that the plaintiff only asserted state law claims as generalized common law theories); *White v. Medtronic, Inc.*, No. 16-2638, 2016 WL 4539494, at *3 (E.D. Pa. Aug. 31, 2016) (holding that, to the extent the defendants failed to warn the FDA of dangers, there was no parallel duty imposed on manufacturers and sellers under Pennsylvania law to report to a federal agency); *Conley v. St. Jude Med., LLC*, 482 F. Supp. 3d 268, 279-80 (M.D. Pa. 2020) (dismissing the plaintiff's failure to report adverse events claim as preempted and inadequately pled); *Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F. Supp. 3d 403, 412 (D. Del. 2014) (holding, in a case involving a Class III PMA device, that there was no parallel Delaware state law claim for failure to report adverse events to the FDA, and dismissing the plaintiff's claims as preempted); *Bennett v. Teva Pharms. USA, Inc.*, No. 19-2126, 2021 WL 797834, at *4 (D. Del. Mar. 2, 2021) (finding the plaintiff's failure to report claims to be preempted and observing that "Section 388 also says nothing about an obligation to report adverse events to the FDA," but that "[s]uch an obligation, to the extent it exists, would arise from the FDA's own regulations").

d. Conclusion: Plaintiff's Negligence Claim Based on Failure to Report Adverse Events to the FDA is Preempted

Upon consideration of the parties' arguments and the law presented, the Court is not persuaded that Pennsylvania law imposes a duty upon manufacturers and sellers to report adverse events to the FDA. As discussed above, the cases cited by Plaintiff, including *Silver*, *McLaughlin*, and *Allergan*, do not currently rest on sound precedent as the prediction regarding Arizona law set forth in *Stengel* has been ruled erroneous, and as this Court finds that those courts' reliance on Section 388 (including comment n), considered alone, is insufficient to establish the existence of a duty imposed on Defendants under Pennsylvania law to report adverse events to the FDA. Even

assuming that Pennsylvania has adopted Section 388, in light of Third Circuit authority and decisions by our sister courts, discussed, *supra*, the Court is not convinced that Section 388 (or comment n thereto) creates a duty to report adverse events to the FDA under Pennsylvania law. *See Sikkelee*, 907 F.3d at 716-17; *Conley*, 482 F. Supp. 3d at 279-80; *White*, 2016 WL 4539494, at *3.

Therefore, the Court finds that Plaintiff's failure-to-report-based negligence claim – as that portion of Plaintiff's negligence claim is currently pled in the Amended Complaint – is not a "parallel" Pennsylvania state law claim that is exempt from federal preemption. Accordingly, to the extent that Plaintiff's negligence claim at Count Four is based on Defendants' failure to report adverse events to the FDA, that claim is dismissed. Such dismissal is without prejudice to amendment of the Amended Complaint with facts sufficient to support a claim upon which relief can be granted.

Accordingly, Defendants' motion to dismiss Plaintiff's negligence claim at Count Four of the Amended Complaint is granted in part and denied in part. The motion is granted to the extent that it seeks the dismissal of Plaintiff's negligence claim based on a failure to warn and a failure to report adverse events to the FDA, and the motion is denied to the extent that it seeks the dismissal of Plaintiff's negligence claim based on a manufacturing defect. Plaintiff's negligence claim based on Defendants' alleged failure to warn is dismissed with prejudice, and Plaintiff's negligence claim based on Defendants' alleged failure to report adverse event to the FDA is dismissed without prejudice.

B. Defendants' Motion to Dismiss for Failure to Satisfy Applicable Pleading Requirements

In support of their motion to dismiss, Defendants also argue that the Court should dismiss all of Plaintiff's claims for failure to state a claim because she does not satisfy the applicable

pleading requirements. According to Defendants, Plaintiff "lumps all defendants together in an undifferentiated fashion and fails to distinguish among their purported acts and omissions and their specific roles in bringing about Plaintiff's alleged injury." (Docket No. 22 at 32). Defendants assert that "Plaintiff directs the same conclusory and generic allegation against *each* defendant – i.e., that each defendant is responsible for 'the research, testing, development, design, licensing, manufacture, packaging, labeling, distribution, sale, [and] marketing' of the Mentor MemoryShape Breast Implants." (*Id.* (quoting Docket No. 20, ¶ 1) (emphasis added by Defendants)). Defendants contend that Plaintiff thereafter repeatedly refers to "Defendants" as a collective throughout the Amended Complaint and that, by doing so, she fails to provide fair notice of the basis of her claims as against each individual Defendant. (*Id.*).

In response, Plaintiff states that the Amended Complaint alleges that: (1) Defendants manufactured, sold, and marketed Mentor breast implants; (2) Defendants acted in concert with one another; (3) Defendants each profited from the design, manufacture, marketing and sale of Mentor's implants; (4) the implants' Instructions for Use are provided by J&J for its "Johnson & Johnson Medical Devices Companies;" and (5) Defendants acted as the alter ego of each other, engaged in a civil conspiracy, and ratified each other's acts. (Docket No. 27 at 30-31). Plaintiff further argues that J&J and Ethicon are proper defendants here simply because she is bringing claims of deceptive marketing against related entities operating under a single brand. (*Id.* at 31 (citing *In re Riddell Concussion Reduction Litig.*, 77 F. Supp. 3d 422, 432 (D.N.J. 2015), and *Pennsylvania v. Think Fin., Inc.*, No. 14-cv-7139, 2016 WL 183289, at *12 (E.D. Pa. Jan. 14, 2016))).

In reply, Defendants reiterate their argument that, regardless of Plaintiff's characterization of her claims, the Amended Complaint is legally deficient because it lumps all Defendants together

and fails to distinguish among their alleged acts and omissions and their specific roles in causing Plaintiff's alleged injury. (Docket No. 28 at 15). Defendants emphasize that Plaintiff does not – and cannot – allege any facts showing that J&J or Ethicon are responsible for the design, manufacture, labeling, or sale of Mentor's implants. (*Id.*). Further, Defendants explain that Plaintiff's proffered general argument – that J&J and Ethicon are proper Defendants here for all her claims simply because she is bringing claims of deceptive marketing against related entities operating under a single brand – is not supported by Third Circuit authority. (*Id.* at 15-16).

Upon consideration of the parties' arguments and taking as true all of the allegations contained in the Amended Complaint in accordance with the proper procedure for adjudicating Rule 12(b)(6) motions, the Court finds that Plaintiff has not adequately alleged her claims against J&J and Ethicon. As Defendants indicate, in the Amended Complaint's 306 paragraphs, Plaintiff includes many allegations against Mentor specifically, she states other allegations against Defendants as a group, and she occasionally mentions J&J or Ethicon specifically. With regard to her allegations against J&J and Ethicon specifically, Plaintiff argues – at most – that they (perhaps along with Mentor) engaged in deceptive marketing. Plaintiff does not state a claim for deceptive marketing in her Amended Complaint, however, nor has she indicated how allegations of deceptive marketing are relevant to her claims of strict liability or negligence for a manufacturing defect at Counts One and Four.[6]

Other than the limited specific conduct of J&J and Ethicon that Plaintiff alleges, she also argues that J&J and Ethicon are both liable for the acts of each other and of Mentor under an alter ego theory. To the extent Plaintiff alleges that J&J, Ethicon, and Mentor "acted in all aspects as the agent and alter ego of each other" (Docket No. 20, ¶ 21) and are liable for each other's acts

[6] As discussed, *supra*, Counts Two and Three, as well as Count Four to the extent it is based on the failure to warn or the failure to report adverse events to the FDA, are being dismissed on other grounds.

under an alter ego theory, the Court notes that Pennsylvania "does not allow recovery unless the party seeking to pierce the corporate veil on an alter-ego theory establishes that the controlling corporation wholly ignored the separate status of the controlled corporation and so dominated and controlled its affairs that its separate existence was a mere sham." *Culbreth v. Amosa (Pty) Ltd.*, 898 F.2d 13, 14 (3d Cir. 1990) (citing *In re Penn Cent. Sec. Litig.,* 335 F. Supp. 1026, 1035 (E.D. Pa. 1971); *Ashley v. Ashley,* 393 A.2d 637, 641 (Pa. 1978)). In other words, Pennsylvania requires "a threshold showing that the controlled corporation acted robot- or puppet-like in mechanical response to the controller's tugs on its strings or pressure on its buttons." *Id.* at 15. Here, while Plaintiff makes conclusory allegations in her Amended Complaint presumably related to Defendants' alter ego status, she does not plead sufficient facts to support such theory of liability.

Accordingly, since the Court finds that the allegations of the Amended Complaint are not sufficient to state claims at Counts One and Four against J&J and Ethicon – either based on their own actions or based on the actions of all Defendants under an alter ego theory of liability – to the extent those claims are made against J&J and Ethicon, they will be dismissed without prejudice, and the Court will permit Plaintiff an opportunity to further amend her Amended Complaint in this regard.

IV. CONCLUSION

In summary, Defendants' motion to dismiss Plaintiff's Amended Complaint for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6) is **granted in part and denied in part**.

To the extent the motion seeks the dismissal of Count One, the motion is **denied**.

To the extent the motion seeks the dismissal of Count Two, the motion is **granted**, and Plaintiff's breach of implied warranties claim is **dismissed with prejudice**.

To the extent the motion seeks the dismissal of Count Three, the motion is **granted**, and Plaintiff's claim of strict liability for failure to warn is **dismissed with prejudice**.

To the extent the motion seeks the dismissal of Count Four, the motion is **granted in part and denied in part**. The motion is **denied** to the extent it seeks the dismissal of Plaintiff's negligence claim based on a manufacturing defect. The motion is **granted** to the extent it seeks the dismissal of Plaintiff's negligence claim based on a failure to warn, and that claim is **dismissed with prejudice**. The motion is **granted** to the extent it seeks the dismissal of Plaintiff's negligence claim based on the failure to report adverse events to the FDA, and that claim is **dismissed without prejudice** to amendment of the Amended Complaint with sufficient facts to state a claim upon which relief can be granted.

To the extent the motion seeks the dismissal of J&J and Ethicon as Defendants at all Counts, the motion is **granted** and the claims against J&J and Ethicon are **dismissed without prejudice** to amendment of the Amended Complaint with sufficient facts to state a claim against those Defendant(s) upon which relief can be granted.

An appropriate Order follows.

s/ W. Scott Hardy
W. Scott Hardy
United States District Judge

Dated: July 26, 2023

cc/ecf: All counsel of record