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Superior Court of New Jersey, Law Division
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Prepared by the court

IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCT LIABILITY LITIGATION

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: BERGEN COUNTY

MASTER CASE NO. BER-L-5064-20

CASE NO. 634

OPINION

Before this court in this Multi-County Litigation ("MCL") is Defendants Allergan, Inc. and Allergan USA, Inc.'s (collectively, "Allergan" or "Defendants") Motion to Dismiss Plaintiffs' Master Long Form Complaint on Preemption Grounds ("Motion") pursuit to R. 4:6-2 predicated on 21 U.S.C. § 360(k) and 21 U.S.C. § 337(a).[1] Plaintiffs opposed the Motion and Defendants replied. This court has carefully considered the parties' submissions. Oral argument was held on March 12, 2021. For the reasons set forth below and for good cause having been shown, Defendants' Motion is **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

This action arises out of Allergan's BIOCELL product line of textured breast implants and tissue expanders (collectively, "BIOCELL Product Line") that allegedly caused Plaintiffs to develop, or become at risk of developing, breast-implant associated anaplastic large cell lymphoma ("BIA-ALCL"), a subtype of non-Hodgkin's lymphoma. Allergan's breast implants have

[1] The United States Supreme Court has held that preemption is a question of law, and "one for a judge to decide, not a jury." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019). As preemption is an affirmative defense, Allergan has the burden of proof. *See In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 n.6 (3d Cir. 2016).

textured surfaces, by design, and are filled with either saline or silicone gel. (Compl. ¶ 3.) Tissue expanders are temporary inflatable implants that stretch skin and muscle to create space for breast implants. (*Id.* ¶¶ 4, 8, 41.) Like Allergan's breast implants, the tissue expanders also have textured surfaces. (*Id.* ¶¶ 4; 34.)

In 1987, Allergan, through its predecessor, introduced its first textured breast implants, the McGhan RTV Saline-Filled Mammary Implants ("McGhan RTV"). (*Id.* ¶¶ 3, 36.) The McGhan RTV implants were originally cleared for use through the 510(k) regulatory process. (*Id.* ¶¶ 3, 5.) In August 1999, the Food & Drug Administration ("FDA") issued a final rule requiring all saline-filled implants to receive Premarket Approval ("PMA") rather than clearance through the 510(k) process. (*Id.* ¶ 40.) Allergan's predecessor filed a PMA application to reclassify the McGhan RTV implants. (*Id.*) In May 2000, FDA approved the application and granted PMA for the McGhan RTV implants. (*Id.*)

In May 2000, FDA also granted PMA for the first segment of textured BIOCELL implants, the saline-filled breast implants. (*Id.* ¶¶ 40, 47.) In November 2006, FDA granted PMA for the second segment of textured BIOCELL implants, the silicone-filled breast implants. (*Id.* ¶ 57.) In February 2013, FDA granted PMA for the third segment of textured BIOCELL implants, the highly cohesive anatomical shaped silicone-filled breast implants. (*Id.* ¶ 59.) According to Plaintiffs, the PMAs for the BIOCELL implants included Conditions of Approval. (*Id.* ¶¶ 48-62.) The Conditions of Approval include specific obligations—such as requiring long-term post-approval studies for assessment of safety data and clinical performance—and general obligations—such as compliance with federal disclosure requirements and medical device reporting regulations. (*Id.*)

Allergan also manufactured McGhan BioDimensional Silicone-Filled BIOCELL Textured Breast Implant Style 153 ("Style 153"). (*Id.* ¶¶ 34, 39.) FDA granted Allergan an Investigational Device Exemption ("IDE") for the Style 153 implants to be studied in FDA-regulated clinical trials. (*Id.*) The Style 153 implants never received FDA approval and were discontinued before being marketed. (*Id.*) Allergan also manufactured two tissue expanders. Both products are Class II medical devices that were granted 510(k) clearance by FDA in 2011 and 2015, respectively. (*Id.* ¶¶ 5, 41.)

In 2013, a warning related to anaplastic large cell lymphoma was added to the BIOCELL implants label. (*Id.* ¶¶ 63, 64.) In July 2019, Allergan announced a global recall of its BIOCELL Product Line and discontinued its marketing and sale of the products. (*Id.* ¶¶ 2, 31.) The announcement followed a request by FDA to initiate the recall based on the emerging risk of BIA-ALCL associated with the BIOCELL Product Line. (*Id.* ¶ 31.) According to FDA, "the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S." (*Id.*) In May 2020, FDA issued a warning letter to Allergan regarding its failure to comply with PMA post-approval study requirements. (*Id.* ¶¶ 66-68.)

In sum, Plaintiffs' Master Long Form Complaint raises allegations involving five different breast implants and two different tissue expanders. Three of Allergan's breast implants received PMA, one received IDE, and one was reclassified to PMA after initially being cleared through the 510(k) process. Both of Allergan's tissue expanders were cleared through the 510(k) process. Plaintiffs bring the following Counts: (1) manufacturing defect; (2) failure to warn; (3) breach of express warranty; (4) design defect; (5) negligence; (6) consumer fraud; (7) wrongful death; and

(8) loss of consortium.[2] Allergan now moves to dismiss all claims based on federal preemption. Before addressing the parties' arguments on all counts, this court will first discuss the governing regulatory framework applicable to medical devices.

II. REGULATORY FRAMEWORK

The Medical Device Amendments ("MDA") of 1976, 21 U.S.C. § 360c et. seq., to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et. seq.*, "imposed a regime of detailed federal oversight" that authorized FDA to regulate medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Under the MDA, medical devices are categorized into one of three regulatory classes—Class I, Class II, or Class III—based on their level of risk and the controls needed to reasonably assure their safety and effectiveness. 21 U.S.C. § 360c. Class III medical devices are subject to Premarket Approval, a comprehensive and rigorous process that receives the highest level of regulatory scrutiny and arduous federal oversight compared to that of other medical devices. *Id.* §§ 360c(a)(1)(C); 360e. The PMA regime imposes federal requirements specific to individual devices. *See Riegel*, 552 U.S. at 323 ("[P]remarket approval is specific to individual devices."). In contrast, Class II medical devices receive clearance through the Section 510(k) process, a "limited form of review" with a far less exhaustive submission process. *See Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 767 (3d Cir. 2018) (citing 21 U.S.C. § 360(k); 21 C.F.R. § 807.87). FDA clearance of a Class II device rests on a finding that the device is

[2] Prior to filing any responsive pleadings, Allergan produced core PMA files relating to the breast implant devices involved in this litigation. Allergan also produced FDA regulatory submissions, including several PMA Supplements of its BIOCELL Product Line. Plaintiffs then served Allergan with a subpoena to depose a corporate representative to obtain additional information and develop a discovery plan. On October 8, 2020, Allergan filed a motion for a protective order, seeking to preclude Plaintiffs from deposing their corporate representative. Subsequently, Allergan filed this Motion to Dismiss Plaintiffs' Master Long Form Complaint on preemption grounds. On October 30, 2020, this court granted Allergan's motion for a protective order and stayed discovery until a decision was rendered on Allergan's motion to dismiss.

"substantially equivalent" to an approved preexisting medical device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996).

As part of the PMA process, a manufacturer must provide FDA with, among other requirements:

> full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a 'full statement' of the device's 'components, ingredients, and properties and of the principle or principles of operation'; 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of, such device'; samples or device components required by the FDA; and a specimen of the proposed labeling. § 360e(c)(1). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, 21 CFR § 814.44(a) (2007), and may request additional data from the manufacturer, § 360e(c)(1)(G).

Riegel, 552 U.S. at 318. FDA grants PMA only if the manufacturer has provided "reasonable assurance" that the device is safe and effective under the conditions of use included on the label and determined that the proposed label is not false or misleading. 21 U.S.C. § 360e(d)(2). "FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323.

Even after receiving PMA, "FDA may impose postapproval requirements." 21 C.F.R. § 814.82(a). Manufacturers must comply with certain Medical Device Reporting ("MDR") requirements, 21 U.S.C. § 360i(a)(1); 21 C.F.R. § 803.50(a), including:

> 1) inform the FDA of new clinical investigations or scientific studies concerning the device about which the manufacturer knows or reasonably should know, 21 C.F.R. § 814.84(b)(2); and 2) 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, 21 U.S.C. § 803.50(a).

Cornett v. Johnson & Johnson, 211 N.J. 362, 381-82 (2012) (citing *Riegel*, 552 U.S. at 319-20). Manufacturers must also submit adverse events reports, which are made publicly available through an online database called the Manufacturer and User Facility Device Experience ("MAUDE").[3] 21 C.F.R. §§ 803.10; 803.50. Moreover, "FDA has the power to withdraw [PMA] based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Cornett*, 211 N.J. at 382 (citing *Riegel*, 552 U.S. at 323); 21 U.S.C. §§ 360e(e)(1); 360h(e). Further, "[o]nce approved, the device may be manufactured, advertised, and distributed to the public, but those marketing activities may not be done in a manner 'inconsistent with . . . the [premarket] approval order for the device.'" *Shuker*, 885 F.3d at 766 (citing 21 C.F.R. § 814.80).

In addition, a manufacturer may seek an IDE to conduct clinical studies and collect data on a medical device prior to obtaining approval. *See* 21 C.F.R. § 812.1. "An approved . . . IDE permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device." *Id.* Similar to the PMA process, a manufacturer seeking to obtain IDE status for a particular device must comply with specific federal requirements. *Id.* § 812.20; *see also Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3d Cir. 1994) ("Persons seeking an exemption from pre-market approval for a particular medical device (an 'investigational device exemption' or 'IDE') must apply to the FDA for permission to undertake clinical investigations.").

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[3] *See* U.S. FDA, MAUDE — Manufacturer and User Facility Device Experience, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

III. LEGAL STANDARD

On a motion to dismiss pursuant to R. 4:6-2(e), the court must treat all factual allegations as true and must carefully examine those allegations "to ascertain whether the fundament of a cause of action may be gleaned even from an obscure statement of claim. . . ." *Printing Mart-Morristown v. Sharp Elec. Corp.,* 116 N.J. 739, 746 (1989). "In evaluating motions to dismiss, courts consider allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim." *Banco Popular N. Am. v. Gandi*, 184 N.J. 161, 183 (2005). Courts may take judicial notice of determinations by federal agencies and need not accept allegations "which are contradictory to facts of which the court takes judicial notice." *Mianulli v. Gunagan*, 32 N.J. Super. 212, 215 (App. Div. 1954); *Rivelli v. MH & W Corp.*, 383 N.J. Super. 69, 75 (App. Div. 2006).

After a thorough examination, should the court determine that such allegations fail to state a claim upon which relief can be granted, the court must dismiss the claim. *Printing Mart*, 116 N.J. at 746. It is simply not enough for a party to file mere conclusory allegations as the basis of its complaint. *See Scheidt v. DRS Techs., Inc.*, 424 N.J. Super. 188, 193 (App. Div. 2012); *see also Camden Cty. Energy Recovery Assocs., L.P. v. New Jersey Dept. of Envtl. Prot.*, 320 N.J. Super 59, 64 (App. Div. 1999), *aff'd o.b.* 170 N.J. 246 (2001) ("Discovery is intended to lead to facts supporting or opposing an asserted legal theory; it is not designed to lead to formulation of a legal theory."). However, "[a]t this preliminary stage of the litigation the Court is not concerned with the ability of plaintiffs to prove the allegation contained in the complaint." *Printing Mart*, 116 N.J. at 746.

Under the New Jersey Court Rules, a complaint may only be dismissed for failure to state a claim if, after an in-depth and liberal search of its allegations, a cause of action cannot be gleaned from even an obscure statement in the Complaint, particularly if additional discovery is permitted.

R. 4:6-2(e); *see Pressler, Current N.J. Court Rules*, Comment 4.1.1. to Rule 4:6-2(e), at 1348 (2010) (citing *Printing Mart*, 116 N.J. at 746). Moreover, "the court should assume that the nonmovant's allegations are true and give that party the benefit of all reasonable inferences." *NCP Litigation Trust v. KPMG LLP*, 187 N.J. 353, 365 (2006); *Banco Popular No. America*, 184 N.J. at 165-66; *Fazilat v. Feldstein*, 180 N.J. 74, 78 (2004). The "test for determining the adequacy of a pleading [is] whether a cause of action is suggested by the facts." *Printing Mart*, 116 N.J. at 746. However, "a court must dismiss the plaintiff's complaint if it has failed to articulate a legal basis entitling plaintiff to relief." *Sickles v. Carbot Corp.*, 379 N.J. Super. 100, 106 (App. Div. 2005).

IV. DISCUSSION

Allergan argues that Plaintiffs' claims are either expressly or impliedly preempted because they "(i) do not show a violation of federal law; (ii) have no counterpart in established state law; or (iii) are based solely on federal duties of care." (Defs.' Br. at 18.) Plaintiffs argue that their state-law claims are not preempted because they require "nothing of Allergan that was different from or in addition to the federal law requirements applicable to the BIOCELL implants." (Pls.' Opp'n Br. at 1.) Before delving into Plaintiffs' specific state-law claims, this court will first discuss the scope of federal preemption in the context of Class III medical devices approved through the PMA process.

A. Express and Implied Federal Preemption

In enacting the MDA, Congress included an express preemption clause to the FDCA for medical devices approved by FDA through the PMA process. 21 U.S.C. § 360k(a). The clause provides, in relevant part:

> [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 and 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). Under federal law, the MDA preempts state-law requirements when FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements." *Perez v. Nidek Co.*, 711 F.3d 1109, 1117 (9th Cir. 2012) (quoting 21 C.F.R. § 808.1(d)). The MDA, however, does not prevent States "from providing a damages remedy for claims premised on a violation of FDA regulations [where] the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (citing *Lohr*, 518 U.S. at 495). "The 'overarching concern' behind this provision is 'that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest.'" *Shuker*, 885 F.3d at 767 (citing *Lohr*, 518 U.S. at 500).

In *Riegel v. Medtronic, Inc.*, the Supreme Court set forth a two-step process for considering the applicability of express preemption to a particular device, finding a court must determine: (1) "whether the Federal Government has established requirements applicable to" the device; and (2) whether the state-law claims being asserted against a manufacturer are based on requirements "different from, or in addition to," federal requirements related to safety and effectiveness of the device. 552 U.S. at 321-22 (citing 21 U.S.C. § 360k(a)). In the context of Class III devices, the first step of the inquiry is automatically satisfied because the PMA regime inherently imposes federal requirements on manufacturers of medical devices. *Id.* at 322 ("Premarket approval . . .

imposes 'requirements' under the MDA. . . ."); *Cornett*, 211 N.J. at 384. Thus, the express preemption inquiry turns on whether a state-law claim imposes requirements "different from, or in addition to," federal requirements. *Id.* at 321.

Following *Riegel*, the New Jersey Supreme Court clarified the parameters of express preemption, explaining: "[Section] 360k(a) preempts state law claims only when: 1) there is a federal requirement specific to a particular device; 2) a state law requirement relates to the safety or effectiveness of a device or to any other matter included in a requirement applicable to the device; and 3) a state requirement is different from or in addition to a federal requirement." *Cornett*, 211 N.J. at 384 (citing *Lohr*, 518 U.S. at 500-02). Conversely, Section 360k(a) does not preempt "a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA." *Perez*, 711 F.3d at 1117 (citing *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013)); *see also Cornett*, 211 N.J. at 384 ("Parallel state claims are not preempted because they do not impose additional requirements or burdens on the manufacturer."). Notwithstanding, the preemption analysis does not end there—a parallel state-law claim may still be impliedly preempted.

Under the FDCA, 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 Committee*, the Supreme Court held that "the Federal Government rather than private litigants . . . are authorized to file suit for noncompliance with the medical device provisions." 531 U.S. 341, 349 n.4 (2001). Relying on *Buckman*, the New Jersey Supreme Court addressed "the circumstances in which parallel state claims will be preempted," explaining "if the claim depends on the alleged violation of a federal requirement, it is functionally equivalent to a claim grounded solely on the federal violation." *Cornett*, 211 N.J. at 385 ("[A] traditional state law cause of action is one that provides

the required elements of a state cause of action with no reference to federal requirements as the measure of the reasonableness or wrongfulness of the manufacturer's conduct."). Thus, to avoid implied preemption, a parallel state-law claim may not "exist solely by virtue of the FDCA . . . requirements." *Perez*, 711 F.3d at 1119 (quoting *Buckman*, 531 U.S. at 353).

In sum, to escape both express and implied preemption—"[t]he 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 implied preempted under *Buckman*)." *Perez*, 711 F.3d at 1120 (citing *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)). Having outlined the scope of express and implied preemption, this court now turns to the specific state-law claims asserted by Plaintiffs.[4]

B. Failure to Warn Claims

Plaintiffs raise a variety of allegations in support of their failure to warn claims. Allergan argues Plaintiffs' warning-based claims are preempted as they are an "attack [on] the adequacy of its FDA-approved warnings, the content of its FDA-mandated reporting, or the method of reporting itself." (Defs.' Br. at 18.) Plaintiffs argue their warning-based claims are "not an attack on the FDA approved labeling," but rather are focused on Allergan's alleged "failure to discharge its

[4] This court notes, Count V of Plaintiffs' Master Long Form Complaint is a claim for negligence. Plaintiffs assert their negligence claim "to the extent the Court deems the conduct at issue not to fall within the PLA claims for manufacturing defect, design defect, or failure to warn." (Compl. ¶ 171.) The present motion is limited only to issues of federal preemption. Indeed, the parties have not addressed the sufficiency of Plaintiffs' negligence claim outside of the federal preemption context. Accordingly, this court makes no determination at this time as to whether the PLA subsumes Plaintiffs' negligence claim. For the purposes of this motion, this court's preemption findings as to the strict liability-based claims for failure to warn, manufacturing defect, and design defect also applies to the negligence-based claims predicated upon failure to warn, manufacturing defect, and design defect.

parallel state and federal obligations to take steps to strengthen the warnings when that became necessary after the BIOCELL line began to be sold." (Pls.' Opp'n Br. at 16.) As an initial matter, the New Jersey Supreme Court held that challenges to "the adequacy of the information required by the FDA during the PMA process and label approved by the agency" are preempted. *Cornett*, 211 N.J. at 389. To the extent Plaintiffs premise their failure to warn claims on this theory, the claims are preempted.[5] However, to the extent Plaintiffs premise their failure to warn claims on alleged misconduct after the PMA process, this court is instructed by *Cornett*.

1. Plaintiffs' Failure to Warn Claims Based on Deliberate Nondisclosure are Not Preempted.

Under the New Jersey Product Liability Act ("PLA"), a manufacturer is not liable "for harm caused by a failure to warn if the product contains an adequate warning or instruction" about its dangers. N.J.S.A. 2A:58C-4. The PLA defines an adequate warning as "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product." *Cornett*, 211 N.J. at 387 (citing N.J.S.A. 2A:58C-4). In *Cornett*, the New Jersey Supreme Court spoke on the rebuttable presumption of adequacy that attaches to FDA-approved labels and the heightened pleading requirement for maintaining a failure to warn claim. 211 N.J. at 387-88. The Court explained a device manufacturer that complies with FDA requirements is granted "a

[5] This court recognizes there are three segments of BIOCELL implants, one approved in May 2000, the second approved in November 2006, and the third approved in February 2013. (Compl. ¶ 42.) Thus, the period for when challenges to the label are preempted will apply differently to each segment depending on its approval date. Plaintiffs' claims challenging the label are preempted if those claims are based on the adequacy of information required by FDA during the PMA process prior to the product's approval date. For example, claims asserted against the second segment of BIOCELL implants, approved in November 2006, are preempted if those claims are based on information required by FDA during the PMA process prior to November 2006. Likewise, claims asserted against the third line of BIOCELL implants, approved in February 2013, are preempted if those claims are based on information required by FDA during the PMA process prior to February 2013.

rebuttable presumption that the labeling is adequate." *Id.* at 388. In turn, plaintiffs seeking to overcome this presumption must satisfy stricter pleading requirements. *Id.* Specifically, a plaintiff asserting a failure to warn claim based on an inadequate label must plead specific factual allegations of "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects," or "manipulation of the post-market regulatory process." *Id.* (citing *Rowe v Hoffman-La Roche, Inc.*, 189 N.J. 615, 626 (2007); *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 24 (1999); *McDarby v. Merck & Co.*, 401 N.J. Super. 10, 62 (App. Div. 2008)). In the context of Class III medical devices, the New Jersey Supreme Court tied the pleading requirements for overcoming the PLA rebuttable presumption to the pleading requirements for overcoming express preemption, concluding "[t]his pleading specificity also serves to permit a determination whether a failure to warn claim is preempted by the MDA or is a permissible parallel state claim." *Id.*

As discussed above, to avoid express preemption, a state-law claim must be: (1) premised on a violation of FDA regulations; and (2) based on state common law duties parallel to but not in addition to federal requirements. *See Cornett*, 211 N.J. at 385 ("[T]o escape preemption, the state claim premised on a violation of FDA regulations must be based on state common law duties parallel to but not in addition to federal requirements."). Plaintiffs' state-law claim must be based on conduct prohibited by the FDCA. If the state-law claim is based on conduct not prohibited by the FDCA, then the claim imposes requirements "different from, or in addition to," federal requirements, and is thus preempted. *See Perez*, 711 F.3d at 1118 (explaining that in *Riegel*, "because the plaintiffs alleged that the device violated state tort law *notwithstanding* compliance with the federal requirements, the state claims were preempted" (emphasis added)). On the other hand, if the state-law claim is based on conduct prohibited by the FDCA, then the state-law claim premised on that conduct is not expressly preempted by the MDA. *See Riley v. Cordis Corp.*, 625

F. Supp. 2d 769, 776 (D. Minn. 2009). To avoid implied preemption, Plaintiffs' state-law claim must "rely[] on traditional state tort law which had predated the federal enactments." *Buckman*, 531 U.S. at 353. As the New Jersey Supreme Court reiterated, "a failure-to-warn claim alleging that the defendants withheld information from or made misrepresentations to the general public and the medical community about the safe use of the medical device at issue fell 'within a traditional area of state concern and regulation.'" *In re Reglan Litig.*, 226 N.J. 315, 339 (2016) (quoting *Cornett*, 211 N.J. at 390). If pled with specificity, this claim also overcomes the PLA rebuttable presumption of adequacy. *Cornett*, 211 N.J. at 390.

Here, FDA granted PMA to the first line of BIOCELL implants in May 2000. (Compl. ¶ 47.) FDA issued the PMA order with Conditions of Approval. (*Id.* ¶ 48.) The Conditions of Approval impose specific requirements, such as to comply with federal disclosure requirements and medical device reporting regulations. (*Id.* ¶¶ 48-62.) The federal disclosure requirements and reporting regulations impose a duty 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.* ¶ 45 (citing 21 C.F.R. § 803.50).) The Conditions of Approval also specify that Allergan must submit written reports to FDA "after the applicant receives or has knowledge of information concerning . . . any adverse reaction, side effect, [or] injury . . . that is attributable to the device and (a) has not been addressed by the device's labeling or (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency." (*Id.* ¶ 50.) Plaintiffs contend Allergan failed to comply with these federal requirements.

Specifically, Plaintiffs allege Allergan deliberately concealed or failed to disclose the risk of contracting BIA-ALCL by not complying with medical device reporting regulations or federal

disclosure requirements imposed by the PMA. (*Id.* ¶¶ 20-23; 27-28; 51-53; 62-64.) Plaintiffs contend that by 2007, years prior to submitting its first adverse event report to FDA, Allergan had after-acquired information that BIOCELL implants were associated with development of BIA-ALCL. (*Id.* ¶¶ 20; 23; 27.) Plaintiffs allege Allergan received complaints from physicians regarding BIOCELL implants and the risk of contracting BIA-ALCL but failed to report that information to FDA. (*Id.* ¶ 27.) Plaintiffs allege Allergan manipulated post-market reporting data related to cases of BIA-ALCL that were diagnosed years before being reported to FDA. (*Id.* ¶¶ 20; 27; 28; 60; 66; 78; 83.) Based on the foregoing, Plaintiffs' failure to warn claim satisfies the pleading specificity required to overcome the PLA rebuttable presumption.

Likewise, Plaintiffs have sufficiently pled a permissible state-law claim based on breach of a state-law duty that parallels a duty imposed by federal law. Federal law imposes a duty on manufacturers to comply with post-market federal disclosure requirements. New Jersey law parallels those duties by incorporating compliance with federal regulations as a prerequisite to the presumed adequacy of the label. *See Cornett*, 211 N.J. at 388 ("Defendants who comply with FDA requirements are granted a rebuttable presumption that the labeling is adequate."). Because the only two possible bases for rebutting the presumption—(1) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects; or (2) manipulation of the post-market regulatory process—are premised on conduct that violates the FDCA, a failure to warn claim based on that conduct is not preempted by the MDA. To be sure, parallel claims are "claims premised on state requirements that merely incorporate applicable federal requirements, and therefore not 'different from, or in addition to,' federal requirements." *Shuker*, 885 F.3d at 768 (citing *Lohr*, 518 U.S. at 494-95). Plaintiffs' failure to warn claims premised on deliberate nondisclosure to FDA of after-acquired information relating to the risk of contracting BIA-ALCL,

directly incorporates the federal requirement to "report to the FDA whenever [manufacturers] receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer . . . may have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a).

Accordingly, because Plaintiffs' failure to warn claims are premised on a violation of FDA regulations and based on New Jersey common law duties that are parallel to, but not in addition to, federal requirements, the claims are not preempted by the MDA. *See Cornett*, 211 N.J. at 385 ("[T]o escape preemption, the state claim premised on a violation of FDA regulations must be based on state common law duties parallel to but not in addition to federal requirements."); *see also Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1279 (10th Cir. 2021) ("[T]o survive preemption, a plaintiff must plead conduct that (1) violates the FDCA (because state law may not impose additional or different duties) and (2) would be actionable under state law independently of the FDCA (because a plaintiff may not seek to enforce the FDCA)."); *Riley*, 625 F. Supp. 2d at 777 ("For a state-law claim to survive, then, the 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.").

Moreover, to the extent Allergan argues that a state-law failure to warn claim is preempted because it requires Allergan to warn physicians and patients, a requirement Allergan contends is different from or in addition to federal requirements, this court disagrees. New Jersey law requires manufacturers to disclosure newly acquired information of harmful effects to FDA, a duty parallel to federal disclosure requirements under the FDCA and applicable federal regulations. *See Rowe*, 189 N.J. at 626 ("[A]bsent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of

a failure-to-warn claim." (citing *Perez*, 161 N.J. at 25)). As the Supreme Court explained in *Lohr*, "[n]othing in § 360k denies [a State] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at 495. While a manufacturer can be held liable for withholding information from the general public and medical community about the safe use of its medical device, liability is only imposed if the manufacturer violates common-law duties, either through deliberate nondisclosure of material information to FDA or manipulation of the post-market regulatory process. *See In re Accutane* 235 N.J. at 274 (reiterating the "general directive that federal regulations are of the utmost significance in determining whether a 'manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its product.'" (quoting *Perez*, 161 N.J. at 24)). When those duties parallel federal requirements, New Jersey law provides a right to recover a traditional damages remedy. Thus, because Plaintiffs have adequately pled a state-law failure to warn claim premised on a violation of FDA regulations, the MDA does not prevent Plaintiffs from pursuing a traditional damages remedy.[6] *Riegel*, 552 U.S. at 330 (finding that the MDA "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations"); *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 600 (D.N.J. 2015).

[6] To note, a review of the New Jersey Model Civil Jury Charges for a failure to warn claim indicates that a product is defective if the product "fails to contain an adequate warning or instructions." *Model Jury Charge (Civil)* 5.40C. New Jersey law grants a rebuttable presumption that the labeling is adequate. To overcome this presumption, a plaintiff must plead specific facts alleging deliberately concealment or nondisclosure of after-acquired knowledge of harmful effects or manipulation of the post-market regulatory process. There is no requirement in the Model Jury Charges to directly warn patients and physicians. Even where the Model Jury Charges explains that "[i]n the case of prescription drugs, the warning must be one that a reasonable prudent manufacturer would have provided to adequately communicate information on the dangers and safe use of the product to physicians," the charge is not adding a requirement to directly warn physicians and patients, but defining an adequate warning (i.e. one that communicates sufficient information to physicians). *Id.*

Notwithstanding the forgoing, this court makes no findings as to whether Plaintiffs have established their claims, but only that their claims have been adequately pled. This court adds the same caveat as the New Jersey Supreme Court added in *Cornett*: "If discovery reveals that the failure to warn claim is nothing more than a private action to enforce FDA statutes and regulations, or that plaintiffs' claim is no more than a challenge to the approval of the device or label, or that proof of fraud on the FDA is an element of their claim, . . . defendants may move for summary judgment, and the trial court should not hesitate to grant such relief." *Cornett*, 211 N.J. at 391 (citing *NCP Litig. Trust*, 187 N.J. at 384-85). Accordingly, if discovery reveals that Allergan did not violate the federal requirements set forth in the PMA, then there would be no violation of a federal requirement for Plaintiffs to premise their state-law failure to warn claim, and therefore would be preempted. Indeed, Plaintiffs can only maintain their failure to warn claims to the extent Allergan violated parallel federal disclosure requirements. *See Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) ("To the extent that [plaintiff] asserts a failure to warn claim based only on [the manufacturer's] failure to comply with FDA regulations, however, such a claim is not expressly preempted."); *Perez*, 711 F.3d at 1118 ("[F]ailure to warn the FDA was not preempted 'insofar as the state-law duty parallels a federal-law duty under the MDA.'" (quoting *Stengel*, 704 F.3d at 1233)); *Bausch v. Styker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010) ("Section 360k provides immunity for manufacturers of new Class III medical devices to the extent that they comply with federal law, but it does not protect them if they have violated federal law."); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) ("State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law."); *Sewell v. Mentor Worldwide, LLC*, No. 19-56393, 2021 U.S. App.

LEXIS 3276, at *3 (9th Cir. Feb. 5, 2021) ("The MDA expressly preempts state law claims unless they are premised on a 'parallel' federal requirement.").

Further, Plaintiffs advance two different theories as the basis of their failure to warn claim: (1) the traditional failure-to-warn theory premised on the inadequacy of the product label; and (2) a purported failure-to-report-to-FDA theory premised on the method, means, and manner of reporting risks to FDA. (Pls.' Opp'n Br. at 16-45). While the distinction between the two theories is nuanced, as a matter of law, the latter theory is impliedly preempted because New Jersey does not recognize a standalone failure-to-report-to-FDA claim. *See In re Allergan BIOCELL Textured Breast Implant Prods. Liab. Litig.*, No. 2:19-md-2921-BRM-ESK, 2021 U.S. Dist. LEXIS 52380, at *92 (D.N.J. Mar. 19, 2021). Under the failure-to-warn theory of products liability, "the duty to warn is premised on the notion that a product is defective absent an adequate warning for foreseeable users that 'the product can potentially cause injury.'" *Clark v. Safety-Kleen Corp.*, 179 N.J. 318, 336 (2004) (quoting *Coffman v. Keene Corp.*, 133 N.J. 581, 593-94 (1993)). To prevail, a plaintiff must establish that a manufacturer had a duty to warn, and such duty was breached by the manufacturer's failure to provide an adequate warning. *James v. Bessemer Processing Co.*, 155 N.J. 279, 299 (1998). Plaintiffs' failure-to-warn claim premised on the inadequacy of the product label avoids implied preemption because the claim rests on independent, traditional state-law grounds. As such, there are state-law elements to a failure-to-warn claim apart from evidence of fraud on the FDA. *See Cornett*, 211 N.J. at 390 ("[T]o the extent plaintiffs' failure to warn claim is based on other allegations of wrong-doing apart from defendants' failure to comply with FDA disclosure requirements, it is not preempted.").[7] On the

[7] To the extent Allergan argues that "*Cornett* held that FDA-related 'disclosure requirement' claims were impliedly preempted under *Buckman*" (Defs.' Reply Br. at 11-12), Allergan misconstrues the New Jersey Supreme Court's holding. Indeed, *Cornett* did explain that

other hand, the failure-to-report-to-FDA claim "exist[s] solely by virtue" of fraud-on-the-FDA. *See Id.* at 389 ("[P]laintiffs' failure to warn claim is preempted and dismissed to the extent that it can be established *solely* by evidence of fraud on the agency." (emphasis in original)).

Accordingly, with respect to all devices, this court finds Plaintiffs' failure to warn claim founded on deliberate nondisclosure of material information from FDA is not preempted. *See Cornett*, 211 N.J. at 385-86 ("[W]hen the so-called fraud-on-the-FDA claim is founded on deliberate non-disclosure of material information or deliberate misrepresentations of known facts, the claim may not be preempted.").

2. Plaintiffs' Failure to Warn Claims Based on Updating the Product Label are Preempted.

Plaintiffs claim Allergan was required to strengthen the warnings of its BIOCELL implants through the Changes Being Effected ("CBE") regulation, 21 C.F.R. § 814.39(d). (Pls.' Opp'n Br. at 22.) Specifically, Plaintiffs argue "the PMA Conditions of Approval required [Allergan] to follow the [CBE] pathway and disseminate strengthened warnings." (*Id.*) Allergan argues Plaintiffs' warnings-based claims premised on updating the product label through the CBE regulation are preempted. (Defs.' Br. at 29.) Specifically, Allergan argues that because the CBE

"regardless of how a plaintiff styles a state claim, if the claim depends on the alleged violation of a federal requirement, it is functionally equivalent to a claim grounded solely on the federal violation, and is impliedly preempted." 211 N.J. at 385. However, here, the traditional failure-to-warn claim does not depend on violations of federal requirements; it is premised on violations of federal requirements to avoid express preemption. As explained in *Buckman*, to avoid implied preemption, the state-law claim must "rely[] on traditional state tort law which had predated the federal enactments in question." 531 U.S. at 353. In the absence of the FDCA, New Jersey still recognizes a failure-to-warn claim, which is, in fact, codified in the PLA. *See Cornett v. Johnson & Johnson*, 414 N.J. Super. 365, 396 (App. Div. 2010) ("While it is true that the 'misconduct' underlying plaintiffs' claims also constitutes a violation of federal regulations--indeed that is precisely why the claims are parallel--the suit was brought to vindicate plaintiffs' rights, not the FDA's. Plaintiffs adequately pled that claim."). However, absent the FDCA, New Jersey would not recognize a standalone failure-to-report-to-FDA claim. *See In re Allergan*, 2021 U.S. Dist. LEXIS 52380, at *92; *D'Addario v. Johnson & Johnson*, No. 19-15627, 2020 U.S. Dist. LEXIS 116760, at *12 (D.N.J. June 30, 2020).

process is permissive, a state duty mandating the process is 'different from, or in addition,' to federal requirement. (*Id.*) This court agrees with Allergan.

The CBE regulation permits a manufacturer to make interim changes to the product label "without prior FDA approval." *Albrecht*, 139 S. Ct. at 1673. As federal courts have concluded, the CBE process is permissive, not mandatory. *See Brooks*, 985 F.3d at 1280 ("Defendant could have changed its labeling without FDA approval by a permissive mechanism, but that mechanism is not mandatory."); *In re Medtronic, Inc.*, 623 F.3d at 1205 ("Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." (citing *McMullen*, 421 F.3d at 489)). Consequently, where a federal regulation makes a process voluntary, a state-law duty mandating the process imposes requirements "different from, or in addition to," federal requirements, and therefore is preempted by the MDA. *See In re Medtronic, Inc.*, 623 F.3d at 1205 ("Even if federal law *allowed* [defendant] to provide additional warnings, as Plaintiffs alleged, any state law *imposing* an additional requirement is preempted by § 360k." (emphasis in original)).

Here, Plaintiffs allege that Allergan failed to submit a PMA supplement through the CBE process to change or update the BIOCELL label after learning more about the risks of BIA-ALCL. (Compl. ¶ 50-52.) However, because the CBE process is permissive, an obligatory state-law requirement to update or change the product label would impose requirements in addition to those under federal law. *See McMullen*, 421 F.3d at 489 ("Because § 814.39 permits, but does not require, a manufacturer to provide interim supplemental warnings pending approval by the FDA, a common-law duty to provide such a warning imposes an additional obligation."). Thus, Plaintiffs' warnings-based claims premised on mandating use of the CBE process are expressly preempted. Moreover, to the extent Plaintiffs argue the Conditions of Approval require Allergan

to submit a PMA supplement through the CBE process, this court disagrees. Rather, the requirement imposed on Allergan in the Conditions of Approval is to submit a PMA supplement when following the CBE process, not mandating use of the CBE process to update or change the product label. (Compl. ¶ 55.) Indeed, this court concurs with the conclusion of the Honorable Brian R. Martinotti, U.S.D.J. in the related Multidistrict Litigation, "Plaintiffs cannot allege Allergan's failure to submit a PMA supplement to the FDA as the basis for their label-based failure to warn claims." *In re Allergan*, 2021 U.S. Dist. LEXIS 52380, at *36.

Accordingly, with respect to the devices approved through the PMA process, this court finds Plaintiffs' warnings-based claims premised on changing the product label through the CBE process are preempted.[8]

3. Plaintiffs' Failure to Warn Claims Based on Failure to Conduct Post-Approval Clinical Studies are Preempted.

Plaintiffs claim Allergan failed to conduct post-sale clinical studies. (Compl. ¶¶ 59-62.) Allergan argues such claims are preempted because "New Jersey law imposes no duty for Allergan to undertake FDA-mandated studies." (Defs.' Br. at 31.) Plaintiffs concede that they "do not plead a separate cause of action based on Allergan's failure to conduct adequate post-approval clinical studies." (Pls.' Opp'n Br. at 49.) Thus, there are no preemption issues to address with regard to that issue. Nonetheless, to the extent Plaintiffs premise their failure to warn claims on Allergan's alleged failure to properly conduct post-approval clinical studies, "Plaintiffs' claims are impliedly preempted because Plaintiffs do not identify a parallel state law duty to conduct post-approval studies." *Billetts v. Mentor Worldwide, LLC*, No. 19-56398, 2021 U.S. App. LEXIS 3272, at *4 (9th Cir. Feb. 5, 2021); *Sewell*, 2021 U.S. App. LEXIS 3276, at *4-5 (same); *Nunn v.*

[8] To be clear, with respect to devices approved through the 510k process, this court finds Plaintiffs' warnings-based claims are not preempted.

Mentor Worldwide, LLC, No. 19-56391, 2021 U.S. App. LEXIS 3286, at *4 (9th Cir. Feb. 5, 2021) (same); *see also Brooks*, 985 F.3d at 1281 ("Federal law thus impliedly preempts Plaintiffs' claims based on alleged failures to properly conduct post-approval testing and reporting as attempts to enforce the MDA."); *In re Allergan*, 2021 U.S. Dist. LEXIS 52380, at *53-54. Moreover, to the extent Plaintiffs premise their warning-based claims on a failure to identify additional adverse events had Allergan conducted its post-approval studies differently, such claims are too speculative and insufficient to state a parallel state-law claim for failure to warn. *See Nunn*, 2021 U.S. App. LEXIS 3286, at *2; *Vieira v. Mentor Worldwide, LLC,* No. 19-56394, 2021 U.S. App. LEXIS 3279, at *4 (9th Cir. Feb. 5, 2021); *D'Addario v. Johnson & Johnson*, No. 19-15627, 2021 U.S. Dist. LEXIS 63183, at *20 (D.N.J. Mar. 31, 2021).

Accordingly, with respect to all devices, this court finds Plaintiffs' warnings-based claims premised on Allergan's alleged failure to conduct post-approval clinical studies are preempted.[9]

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[9] Of note, this court's holding on the failure to warn claim is consistent with that in *D'Addario* and *In re Allergan*. 2020 U.S. Dist. LEXIS 116760; 2021 U.S. Dist. LEXIS 52380. As explained by the Honorable Brian R. Martinotti, U.S.D.J., Plaintiffs cannot premise their label-based failure to warn claims on Allergan's alleged failure to submit a PMA Supplement to FDA, though Plaintiffs may premise their failure to warn claims on other theories that are traditionally recognized under state law. 2021 U.S. Dist. LEXIS 52380, at *36. Under New Jersey law, and as explained in *Cornett*, a failure to warn claim premised on deliberate nondisclosure is a basis founded in state law that is not preempted by the MDA. Indeed, this court concurs with the holdings in *D'Addario* and *In re Allergan*, that New Jersey does not recognize a separate cause of action for failure to report to FDA. However, to the extent Plaintiffs premise their failure to warn claims on allegations that overcome the rebuttable presumption, such as deliberate nondisclosure, Plaintiffs' failure to warn claim is grounded on a traditional state-law basis recognized under New Jersey law. In other words, Plaintiffs need to rely on a traditional basis of state law for their failure to warn claim. A failure to report to FDA is not a traditional basis of state law because such a theory is aimed to vindicate the rights of FDA. However, a failure to warn theory based on deliberate nondisclosure is derived from the NJPLA which is aimed to vindicate the rights of Plaintiffs. Thus, a failure to warn claim premised on this theory is not preempted. Unlike the allegations in *D'Addario* or the allegations in *In re Allergan*, Plaintiffs here have alleged and argued deliberate nondisclosure of after-acquired information of harmful effects as their basis for their failure to warn claim, a basis that is soundly premised in New Jersey state law.

C. Manufacturing Defect Claims

Allergan argues the manufacturing defect claims are preempted because "Plaintiffs have not alleged that their [] breast implant devices deviated from their FDA-approved design at the time they were shipped and implanted." (Defs.' Br. at 34.) Plaintiffs argue "the BIOCELL implants were manufactured such that the device failed to conform to the FDA-approved design specifications, in particular with regard to the exterior surface." (Pls.' Opp'n Br. at 7.)

Under New Jersey law, a product is defectively manufactured if it "deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae." N.J.S.A. 2A:58C-2(a). To establish a manufacturing defect claim, "a plaintiff must prove that the product was defective, that the defect existed when the product left the manufacturer's control, and that the defect proximately caused injuries to the plaintiff, a reasonably foreseeable or intended user." *Myrlak v. Port Authority of N.Y. and N.J.*, 157 N.J. 84, 97 (1999). Under federal law, a manufacturer of a medical device approved through the PMA process is required to "comply with manufacturing controls outlined at 21 C.F.R § 814.20(b)(4) and § 820." *Gomez v. Bayer Corp.*, No. A-0680-18T4, 2020 N.J. Super. Unpub. LEXIS 92, at *30 (N.J. App. Div. Jan. 14, 2020) (citing *Cornett v. Johnson & Johnson*, 414 N.J. Super. 365, 386 (App. Div. 2010)). "These controls require the manufacturer to submit to the FDA a complete description of the methods used in . . . the manufacture . . . of the device." *Id.* Thus, for a state-law manufacturing defect claim to avoid preemption, "a plaintiff must make some showing that the medical device was not manufactured in accordance with FDA standards." *Williams v. Cyberonic, Inc.*, 654 F. Supp. 2d 301, 306 (E.D. Pa. 2009), *aff'd* 388 F. App'x 169 (3d Cir. 2010); *Riegel*, 552 U.S. at 323 ("FDA requires a device that has received [PMA] to be made with almost no deviations from the

specifications in its approval application."); *In re Allergan*, 2021 U.S. Dist. LEXIS 52380, at *67-68 ("To sufficiently plead a manufacturing defect claim, Plaintiffs must allege Allergan 'deviated from a particular premarket approval or other FDA requirement applicable to the Class III medical device'" (citing *Nunn*, 2021 U.S. App. LEXIS 3286, at *4)).

Here, Plaintiffs' manufacturing defect claim is premised on Allergan's alleged failure to comply with manufacturing requirements imposed by the PMA. Specifically, Plaintiffs allege Allergan "fail[ed] to manufacture the BIOCELL line in accordance with intended and approved design specifications and processes." (Compl. ¶ 6.) Specifically, Plaintiffs allege Allergan utilized a manufacturing scrubbing process, known as the salt-loss technique, that "required gentle agitation of the surface after a final layer of silicone was over-coated . . . for an intact, consistent surface," but "the scrubbing technique used by Allergan to manufacture BIOCELL implants and Natrelle 133 [e]xpanders . . . created a 'particle laden' environment on the implant surface . . . which exposed patients to particles that were shed into their tissue, caused chronic inflammation, and caused or contributed to the development of BIA-ALCL." (*Id.* ¶ 101.) Plaintiffs allege Allergan violated several manufacturing controls that require a manufacturer to establish and maintain procedures for removal of manufacturing material, or in this case, removal of debris on the surface of the implants that could adversely affect product quality. (*Id.* ¶ 114.) According to Plaintiffs, this amounts to an alleged "fail[ure] to output BIOCELL implants with external surfaces in compliance with the design specifications." (*Id.* ¶ 101.)

At this initial pleading stage, Plaintiffs have sufficiently pled a manufacturing defect claim premised on a violation of federal law and predicated on state law duties. Because FDA approved the design as part of the PMA process, any deviation from that design would violate federal requirements imposed by the PMA or under federal law. *See Gomez v. St. Jude Med. Daig Div.,*

Inc., 442 F.3d 919, 933 (5th Cir. 2006); *Bausch v. Styker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010); *Nunn*, 2021 U.S. App. LEXIS 3286, at *4-5; *In re Allergan*, 2021 U.S. Dist. LEXIS 52380, at *44. Plaintiffs' manufacturing defect claim identifies a specific manufacturing process utilized by Allergan—the salt-loss technique—and alleges Allergan deviated from design control procedures imposed under federal law that resulted in a specific manufacturing defect—the particle laden environment on the external surface. Plaintiffs' state-law manufacturing defect claim incorporates federal requirements on manufacturing controls to prevent the release of nonconforming product as it relates to the external surface of the implants and expanders that could affect the devices' safety. Moreover, with respect to all devices, Plaintiffs' manufacturing defect claims are not impliedly preempted because, as in *Lohr*, the claims "arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." *Buckman*, 531 U.S. at 352.[10]

To the extent Allergan relies on the decision in *D'Addario v. Johnson & Johnson*, the allegations in this case are distinguishable and this court's reasoning is consistent. No. 19-15627, 2020 U.S. Dist. LEXIS 116760, at *10 (D.N.J. June 30, 2020). Indeed, in *D'Addario*, the court dismissed the manufacturing defect claim, finding that "a federal requirement [was] not properly identified," and the plaintiffs "fail[ed] to allege how these violations [of numerous federal specifications] resulted in" their injuries.[11] Here, Plaintiffs have properly identified federal

[10] *Cornett*, 414 N.J. Super. at 398 ("The additional requirement that this [manufacturing defect] claim imposed on plaintiffs, proving that the deviations actually rendered the device unsafe or unsuitable for the intended uses, was acceptable because it narrowed the circumstances in which manufacturers could be liable compared to the federal scheme, instead of enlarging them.").

[11] Subsequently, the plaintiff in *D'Addario* amended her complaint and the defendant filed a similar motion to dismiss. The manufacturing defect claim replead in the amended complaint was dismissed because "Plaintiffs have not alleged actions or inactions by Defendants that deviate from the manufacturing process approved by the FDA." 2021 U.S. Dist. LEXIS 63183, at *18.

requirements that Allergan allegedly failed to comply with—manufacturing controls to remove external surface debris from the devices—and allege how deviating from those requirements resulted in their injuries—creating a "particle laden" environment that caused chronic inflammation and development of BIA-ALCL. *See Gomez*, 2020 N.J. Super. Unpub. LEXIS 92, at *30 ("A plaintiff's manufacturing defect claim that alleges the PMA device was 'adulterated due to failure to comply with federal regulations' is 'not preempted because a jury could find the defendants breached their duty of care to the plaintiff and that the product was unreasonably dangerous without imposing different or additional requirements.'" (citing *Cornett*, 414 N.J. Super. at 398)).

With respect to Allergan's argument that Plaintiffs are attempting to "disguise" a design defect claim into a manufacturing defect claim by "attack[ing] the process by which the devices are made . . . not the way a particular device was manufactured" (Defs.' Br. at 37), that argument is unpersuasive. Plaintiffs allege Allergan's scrubbing process deviated from manufacturing controls and specifications resulting in Plaintiffs' injuries. Regardless of whether it was a single instance or wholesale deviation, a deviation from specifications and processes constitutes a manufacturing defect. Notwithstanding, as with Plaintiffs' failure to warn claims, if discovery reveals that Allergan was in compliance with FDA-approved manufacturing specifications for their devices, then Allergan may move for summary judgment.[12] *Cornett*, 211 N.J. at 391 (citing *NCP Litig. Trust*, 187 N.J. at 384-85). However, at this initial pleading stage of the litigation, Plaintiffs

[12] To note, Allergan provided this court with excerpts from the manufacturing section of a PMA for one of its breast implant products. *See Banco Popular*, 184 N.J. at 183 (finding that a court may review a "document integral to . . . the basis of a claim" on a motion to dismiss). Relying on those excerpts, Allergan argues the FDA-approved specifications permit variability in its scrubbing process (Defs.' Reply Br. at 23.) Notwithstanding, the PMA excerpts do not address other manufacturing defect allegations pertaining to debris on the external surface of the BIOCELL implants that Plaintiffs allege is a deviation from the PMA-approved design.

have identified specific federal requirements related to the manufacturing of the device and alleged Allergan violated those manufacturing specifications. *See Printing Mart.*, 116 N.J. at 746 ("At this preliminary state of the litigation the Court is not concerned with the ability of Plaintiffs to prove the allegations contained in the complaint."); *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 837-38 (S.D. Ind. 2009) (holding that a manufacturing defect claim alleging the "manufacturer failed to adhere to the specifications imposed by a device's PMA" is not preempted at the pleading stage).

Accordingly, with respect to all devices, this court finds Plaintiffs' manufacturing defect claims are not preempted.

D. Design Defect Claims

Allergan argues that Plaintiffs' design defect claims are preempted because such claims would require changes to FDA-approved design imposed during the PMA process. (Defs.' Br. at 38). Concededly, Plaintiffs note that they "do not allege design defect claims for devices after their receipt of a PMA." (Pls.' Opp'n Br. at 60.) Indeed, it is well-settled that design defect claims against devices approved through the PMA process are preempted. *See Riegel*, 552 U.S. at 319 ("Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety and effectiveness."); *Cornett*, 414 N.J. Super. at 397 ("Because the PLA is a state law that provides a different standard for the adequacy of the device's design than the federal requirements, plaintiffs' design defect claim is not 'parallel' to them and is thus squarely within *Riegel's* preemption holding."); *Walker v. Medtronic, Inc.*, 670 F.3d 569, 580 (4th Cir. 2012) (holding design defect claims are "expressly preempted by the MDA as interpreted by *Riegel*"). With respect to the Style 153 implants, the express preemption clause

of the MDA extends to devices being studied under an IDE. *See Gile*, 22 F.3d at 542. Thus, to the extent the devices were used in approved clinical trials, Plaintiffs' design defect claims asserted against the Style 153 implants are preempted.

However, because Section 360k does not apply to devices approved through the 510(k) process, state-law claims related to Allergan's tissue expanders and McGhan RTV pre-reclassification are not preempted. *See Shuker*, 885 F.3d at 767 ("Because manufacturers of Class I and Class II devices receive only § 510(k) approval and emerge from the approval process with no safety review specific to those devices, manufacturers do not receive the benefit of express preemption.") (citing *Lohr*, 518 U.S. at 492-94)). To the extent Allergan argues the 510(k) cleared devices are still subject to implied preemption, Allergan fails to adequately explain how Plaintiffs' design defect claims are not premised on independent, "traditional state tort law which had predated the federal enactments in question." *Buckman*, 531 U.S. at 353.

Accordingly, this court finds the defective design claims against the PMA products, BIOCELL implants and McGhan RTV implants post-reclassification, as well as the IDE products, the Style 153 implants, are preempted and therefore dismissed. The defective design claims against the 510(k) cleared devices are not preempted.

E. Breach of Express Warranty Claims and Consumer Fraud

Allergan argues Plaintiffs' breach of express warranty claims and consumer fraud claims are preempted. (Defs.' Br. at 19-21). Specifically, Allergan argues Plaintiffs' breach of express warranty claims are preempted because the MDA preempts express warranty claims based on the information contained in FDA-approved product labels and package inserts. (*Id.* at 19-20.) Allergan also argues Plaintiffs' consumer fraud claims are preempted "as attacks on FDA-approved labeling." (*Id.* at 21.) Plaintiffs argue their express warranty claim is not preempted because their claims are based on voluntary, non-PMA statements made by Allergan that

misrepresented the risk of the BIOCELL implants. (Pls.' Opp'n Br. at 61.) Plaintiffs also argue their consumer fraud claims are not preempted because Allergan made express and affirmative misrepresentation through non-PMA voluntary statements. (*Id.* at 62.)

Under New Jersey law, a claim for breach of express warranty has three elements: "(1) that Defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." *Snyder v. Farnam Companies, Inc.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011); N.J.S.A. § 12A:2-313. The MDA preempts "an express warranty claim based on the information contained in FDA approved product labels and package inserts." *See Gomez*, 2020 N.J. Super. Unpub. LEXIS 92, at *24. However, the MDA does not preempt a breach of express warranty claim "to the extent plaintiffs allege defendants have deviated from the labeling and instructions for use through voluntary statements to third parties in the course of its marketing efforts." *Cornett*, 211 N.J. at 393. Voluntary statements are "statements not approved by the FDA or mandated by the FDA about the use or effectiveness of the product." *Id.* at 392. With respect to the consumer fraud claims, the New Jersey Supreme Court held that "state law claims brought by individuals based on intentional misrepresentation to the FDA during or after the PMA process are barred . . . [because] only the federal government is authorized to sue for failure to comply with the MDA provisions, including providing false or misleading information." *Id.* at 385; *see also Perez*, 711 F.3d at 1119 ("Although [plaintiff] is not barred from bringing *any* fraud claim related to the surgeries, he cannot bring a claim that rests solely on the non-disclosure to patients of facts tied to the scope of PMA approval." (emphasis in original)). However, consumer fraud claims premised on voluntary statements that are not approved by FDA are not preempted.

Here, Plaintiffs have identified several voluntary statements made by Allergan that allegedly deviate from the warnings in the FDA-approved labels of the implants and expanders. Plaintiffs allege Allergan made "non-PMA statements" that downplayed the risk of BIA-ALCL in promotional materials. (Compl. ¶¶ 65; 75; 91; 150-152.) Specifically, Plaintiffs allege that "an Allergan spokesperson reported that a patient is more likely to be struck by lightning than to develop ALCL." (*Id.* ¶ 91.) Plaintiffs also allege Allergan made misleading statements in promotional YouTube videos that were not approved by FDA. (*Id.* ¶ 86.) At this stage, Plaintiffs have identified statements made on behalf of Allergan that arguably deviate from the product labels. Whether such a statement actually downplays the warnings of BIA-ALCL is not a question of law for this court to address in this motion to dismiss. It is sufficient that Plaintiffs identified a voluntary statement that specifically references the product's safety in a measurable way, such the likelihood of being struck by lightning is greater than the likelihood of developing BIA-ALCL, to adequately allege statements made in deviation to the product labeling and instructions. Thus, to the extent Plaintiffs rely on express and affirmative misrepresentations not approved by FDA, Plaintiffs' breach of express warranty and consumer fraud claims are not preempted.[13]

Accordingly, with respect to all devices, this court finds Plaintiffs' breach of express warranty claims and consumer fraud claims are not preempted.

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[13] In light of the New Jersey Supreme Court decision in *Sun Chem. Corp. v. Fike Corp.*, 243 N.J. 319 (2020), this court makes no determination at this time as to whether the PLA subsumes Plaintiffs' consumer fraud claims. Notably, the parties have not addressed the scope of the New Jersey Supreme Court's holding in *Sun Chem. Corp.* as it would apply to this case. Rather, the parties only focus on whether state-law claims are preempted by federal law. Therefore, this court focuses its inquiry into the consumer fraud claims through the lens of a preemption analysis only.

V. CONCLUSION

For the foregoing reasons, Allergan's Motion to Dismiss Plaintiffs' Master Long Form Complaint on Preemption Grounds is **GRANTED IN PART** and **DENIED IN PART.**

Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn based on Allergan's alleged failure to update the label of devices approved through the PMA process, other than Allergan's tissue expanders and implants sold before the 2000 PMA, are DISMISSED with prejudice.

Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn based on Allergan's alleged failure to conduct post-approval clinical studies are DISMISSED with prejudice.

With respect to the first segment of BIOCELL implants approved in May 2000, Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn are DISMISSED with prejudice to the extent that those claims are based on the adequacy of information required by FDA during the PMA process prior to the May 2000 approval date.

With respect to the second segment of BIOCELL implants approved in November 2006, Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn are DISMISSED with prejudice to the extent that those claims are based on the adequacy of information required by FDA during the PMA process prior to the November 2006 approval date.

With respect to the third segment of BIOCELL implants approved in February 2013, Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn are DISMISSED with prejudice to the extent that those claims are based on the adequacy of information required by FDA during the PMA process prior to the February 2013 approval date.

Plaintiffs' claims for strict liability (Count IV) and negligent (Count V) design defect asserted against the investigational devices used in approved clinical trials and devices approved through the PMA process are DISMISSED with prejudice.

Allergan's Motion, with respect to all devices, is DENIED as to Plaintiffs' claims for strict liability (Count II) and negligent (Count V) failure to warn based on deliberate nondisclosure to FDA of after-acquired knowledge of harmful effects or other grounds that overcome the rebuttable presumption.

Allergan's Motion, with respect to all devices, is DENIED as to Plaintiffs' claims for strict liability (Count I) and negligent (Count V) manufacturing defect.

Allergan's Motion is DENIED as to Plaintiffs' claims for strict liability (Count IV) and negligent (Count V) design defect asserted against Allergan's tissue expanders and implants sold before the 2000 PMA.

Allergan's Motion, with respect to all devices, is DENIED as to Plaintiffs' claims for breach of express warranty (Count III).

Allergan's Motion, with respect to all devices, is DENIED as to Plaintiffs' claims for consumer fraud (Count VI).

Plaintiffs' claims for wrongful death (Count VII) and loss of consortium (Count VIII) remain as they have not been challenged in this preemption motion and these claims are derivative in nature.

Date: May 4, 2021

HON. RACHELLE L. HARZ, J.S.C.