**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION | Case No. 2:19-md-2921-BRM-ESK<br>MDL No. 2921<br><br>JUDGE BRIAN R. MARTINOTTI<br>JUDGE EDWARD S. KIEL<br><br>**OPINION** |

**MARTINOTTI, DISTRICT JUDGE**

Before this Court are three motions by Defendants Allergan, Inc. and Allergan USA, Inc. ("Allergan"): (1) Motion to Strike/Dismiss Plaintiffs' Consolidated Class Action Complaint ("CAC") (ECF No. 118) and every other class action complaint filed in a lawsuit that is part of this Multi District Litigation ("MDL") pursuant to Fed. R. Civ. P. 12(b)(6) and 12(f) (ECF No. 171-2); (2) Motion to Dismiss Plaintiffs' complaints on preemption grounds pursuant to Fed. R. Civ. P. 12(b)(6) (ECF No. 171-1); and (3) Motion to Dismiss Plaintiffs' Master Long Form Personal Injury Complaint ("PIC") (ECF No. 119) on non-preemption grounds and every other complaint filed in a lawsuit that is part of this MDL and alleges personal injury damages pursuant to Fed. R. Civ. P. 8(a), 9(b) and 12(b)(6) (ECF No. 171-3). Plaintiffs filed Oppositions to Allergan's Motions. (ECF Nos. 216, 219, 220.) Allergan filed a Notice of Supplemental Authority. (ECF No. 224.) Plaintiffs responded to Allergan's Notice. (ECF No. 225.) Allergan filed Replies in support of its Motions. (ECF Nos. 236, 237, 238.) Allergan filed a second Notice of Supplemental Authority. (ECF No. 246.) Plaintiffs responded to Allergan's second Notice. (ECF No. 250.) Having reviewed the parties' submissions filed in connection with the Motions



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and having heard oral argument on December 14, 2020 (ECF No. 261),[1] for the reasons set forth below and for good cause having been shown, Allergan's Motion to Strike/Dismiss CAC (ECF No. 171-2), Motion to Dismiss Plaintiffs' complaints on preemption grounds (ECF No. 171-1), and Motion to Dismiss PIC (ECF No. 171-3) are **GRANTED IN PART and DENIED IN PART**.

For the ease of the reader, the Court has included a table of contents:

[1] Following oral argument, the Court permit simultaneous supplemental briefing, which was filed by Plaintiffs and Allergan on January 5, 2021. (ECF Nos. 262, 263.)

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## I. BACKGROUND

### A. Factual Background

Plaintiffs and class members are patients who had Allergan's BIOCELL textured breast implants and tissue expanders[2] (together, "the BIOCELL implants") implanted into their bodies. (ECF No. 119 at ¶ 1.) Many of the Plaintiffs are breast cancer survivors or women having undergone prophylactic mastectomies, who were implanted with the BIOCELL implants in reconstructive surgery. (*Id.* at ¶ 8.) Plaintiffs allege the BIOCELL implants cause Breast-Implant Associated Anaplastic Large Cell Lymphoma ("BIA-ALCL"), a cancer of the immune system that develops in the area around an implant, often between the implant and the surrounding scar tissue. (*Id.* at ¶¶ 1, 27.) BIA-ALCL frequently presents as a late-onset seroma in the breast, which is an accumulation of fluid between the capsule and the implant, resulting in swelling of the breast. (ECF No. 118 at ¶ 138.) Left untreated, BIA-ALCL can spread through the body and be fatal. (*Id.*) Symptoms of BIA-ALCL can arise even after the implant is removed. (*Id.* at ¶ 139.) Diagnostic procedures for detecting BIA-ALCL include computed tomography scans, magnetic resonance imagings, and fluid sampling. (*Id.* at ¶ 140.) BIA-ALCL is treated with the surgery to remove the implant and the surrounding capsule and tissue, and may require other treatments such as reconstructive surgery, chemotherapy, and radiation. (ECF No. 119 at ¶ 29.) Some of the Plaintiffs have been diagnosed with BIA-ALCL, others have had their implants removed, and others still have BIOCELL implants in their bodies. (*Id.* at ¶ 8.)

This case involves dozens of recalled models of the BIOCELL implants. (*Id.* at ¶ 41.) Many models were sold pursuant to three pre-market approvals ("PMAs") that Allergan received

[2] A tissue expander is an empty breast implant gradually filled with saline until the breast tissue expands to the desired size. A second surgery is performed to remove the tissue expander and insert a permanent breast implant. (ECF No. 119 at ¶ 4.)

from the United States Food and Drug Administration ("FDA") on May 20, 2000, on November 17, 2006, and on February 20, 2013. (*Id.* at ¶ 53.) Plaintiffs allege these PMAs contained Conditions of Approval, requiring Allergan to (among other things) conduct studies of the devices' safety, report adverse events to the FDA, and revise the labeling to add warnings when necessitated by new safety information. (*Id.* at ¶¶ 59–61.) Other models, including the BIOCELL tissue expanders, were approved through the much less rigorous § 510(k) process. (*Id.* at ¶ 52.) Still others were approved for use in investigative studies under the Investigational Device Exemption ("IDE"). (*Id.* at ¶ 50.)

For over 20 years, Allergan and its predecessor companies marketed and sold the BIOCELL Implants. (ECF No. 118 at ¶¶ 112–37.) To texturize the implant shell, Allergan allegedly employed a "salt loss" manufacturing process. (*Id.* at ¶¶ 13, 167.) The process applies solid particles of cubic salt over the implant shell surface, embedding the particles within. (*Id.*) The implant is then covered with another silicone layer, which is scrubbed off, and the shell is washed. (*Id.*) Plaintiffs state the FDA-approved manufacturing specifications require all solid particles be scrubbed off and dissolved. (*Id.* at ¶ 168.) Plaintiffs allege Allergan performs the final scrubbing process manually, which leaves solid particles and other residues on the implants' surface. (*Id.* at ¶ 169.) Plaintiffs claim these particles, residues, the implant's increased surface area resulting from the texturizing process, and the chronic friction that occurs between the body's tissues and the implant cause inflammation, increased T-cell activity, malignant T-cell transformation and, ultimately, BIA-ALCL. (*Id.* at ¶ 170.)

Allergan recalled the BIOCELL implants in July 2019 after the FDA found they posed a heightened risk of BIA-ALCL. (*Id.* at ¶¶ 138, 191–92.) Plaintiffs claim Allergan's textured implants increase the risk of BIA-ALCL by 3,000 times. (*Id.* at ¶ 158.) The FDA has concluded

"the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately six times the risk of BIA-ALCL with textured implants from other manufacturers." (*Id.* at ¶ 193.) According to the FDA, 246,831 BIOCELL Implants have been recalled in the United States. (*Id.* at ¶ 386.)

As early as 1997, some women were reported to have developed BIA-ALCL after receiving the BIOCELL Implants. (*Id.* at ¶ 141.) Over the course of the next two decades, the number of reported cases of BIA-ALCL associated with the BIOCELL Implants continued to mount. (*Id.* at ¶¶ 141–45, 149, 154–57.) Through this period, Allergan allegedly concealed the risks of BIA-ALCL by failing to appropriately submit adverse event reports to the FDA or otherwise disclose to the public complete and accurate safety information regarding the BIOCELL Implants. (*Id.* at ¶ 209–20.)

On July 29, 2019, the FDA issued a Class I Recall notice. (*Id.* at ¶ 2.) According to the FDA, the continued distribution of the BIOCELL Implants "would likely cause serious, adverse health consequences and potentially death from BIA-ALCL." (*Id.* at ¶ 193.) Allergan refuses to pay the implants' users for the cost of explant surgeries to remove the implants or for ongoing monitoring and testing for BIA-ALCL. (*Id.* at ¶ 198.)

**B. Procedural History**

This litigation began as a series of actions filed in judicial districts throughout the country. (ECF No. 144 at 1.) By Order dated December 18, 2019, the United States Judicial Panel on Multidistrict Litigation transferred several of those matters to the District of New Jersey, thereby creating MDL No. 2921. (ECF No. 1.) The Panel has continued to transfer cases since that time, and Plaintiffs have directly filed others, such that this MDL currently consists of more than 562 member cases. (ECF No. 144 at 1–2.)

On May 26, 2020, Liaison Counsel for Plaintiffs and Co-Lead Plaintiffs' Counsel filed the PIC. (ECF No. 119.) The complaint asserts: claims for manufacturing defect, based on strict liability (Count I) and negligence (Count II); claims for failure to warn, based on strict liability (Count IV) and negligence (Count V); claims for general negligence (Count III) and breach of the implied warranty of merchantability (Count VII), primarily based on the aforementioned defects; claims for negligent misrepresentation (Count VI) and breach of express warranty (Count VIII), based on false representations and warranties Allergan allegedly made regarding the safety of the BIOCELL implants. (ECF No. 216 at 29.) The complaint also asserts a claim for survivorship and wrongful death on behalf of representatives of decedents who died after being implanted with the BIOCELL implants (Count XI), loss of consortium on behalf of the spouses of those implanted with the BIOCELL implants (Count XII), and punitive damages (Count XIII). (*Id.* at 29–30.)

On May 26, 2020, certain Plaintiffs filed the CAC. (ECF No. 118.) In addition to certain claims also asserted in the PIC (strict liability and negligent failure to warn, strict liability and negligent manufacturing defect, strict liability and negligent design defect (for non-PMA devices), and breach of implied warranty of merchantability), the CAC asserts claims for medical monitoring (Counts 300–05), violations of state consumer fraud and deceptive trade practices acts (Counts 330–82), unjust enrichment (Counts 383–436), declaratory judgment declaring that releases signed by certain class members are unenforceable (Counts 437–38), and rescission of those releases (Count 439). (ECF No. 216 at 30.) The CAC also seeks equitable relief in the form of a court-ordered medical monitoring program funded by Allergan. (*Id.*)

On August 7, 2020, Allergan filed a Motion to Strike/Dismiss Plaintiffs' CAC and every other class action complaint pursuant to Fed. R. Civ. P. 12(b)(6) and 12(f) (ECF No. 171-2),

Motion to Dismiss Plaintiffs' complaints on preemption grounds pursuant to Fed. R. Civ. P. 12(b)(6) (ECF No. 171-1), and a Motion to Dismiss Plaintiffs' PIC and every other complaint on non-preemption grounds pursuant to Fed. R. Civ. P. 8(a), 9(b) and 12(b)(6) (ECF No. 171-3). On October 7, 2020, Plaintiffs filed an Opposition to Allergan's Motion to Dismiss Plaintiffs' PIC and CAC on preemption grounds. (ECF No. 216.) On October 9, 2020, Plaintiffs filed an Opposition to Allergan's Motion to Strike/Dismiss Plaintiffs' CAC (ECF No. 219) and an Opposition to Allergan's Motion to Dismiss Plaintiffs' PIC and CAC on non-preemption grounds (ECF No. 220). On October 14, 2020, Allergan filed a Notice of Supplemental Authority. (ECF No. 224.) On October 15, 2020, Plaintiffs responded to Allergan's October 14, 2020 Notice. (ECF No. 225.) On November 8, 2020, Allergan filed a Reply in Support of its Motion to Dismiss Plaintiffs' PIC on non-preemption grounds (ECF No. 236), a Reply in Support of its Motion to Dismiss Plaintiffs' CAC (ECF No. 237), and a Reply in Support of its Motion to Dismiss Plaintiffs' PIC and CAC on non-preemption grounds (ECF No. 238). On November 20, 2020, Allergan filed another Notice of Supplemental Authority. (ECF No. 246.) On November 24, 2020, Plaintiffs responded to Allergan's November 20, 2020 Notice. (ECF No. 250.)

On December 14, 2020, the Court held oral argument on the motions (ECF No. 261) and permitted simultaneous supplemental briefing, which were filed on January 5, 2020 (ECF Nos. 262, 263). On January 27, 2021, Allergan filed a third Notice of Supplemental Authority. (ECF No. 267.) On January 28, 2021, Plaintiffs responded to Allergan's January 27, 2021 Notice. (ECF No. 268.) On February 10, 2021, Allergan filed a fourth Notice of Supplemental Authority. (ECF No. 271.) On February 11, 2021, Plaintiffs responded to Allergan's February 11, 2021 Notice. (ECF No. 273.)

## II. LEGAL STANDARD

### A. Rule 12(b)(6)

In deciding a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a district court is "required to accept as true all factual allegations in the complaint and draw all inferences in the facts alleged in the light most favorable to the [plaintiff]." *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 228 (3d Cir. 2008). "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted). However, the plaintiff's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." *Id.* (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). A court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan*, 478 U.S. at 286 (citations omitted). Instead, assuming the factual allegations in the complaint are true, those "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555 (citing *Papasan*, 478 U.S. at 286).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for misconduct alleged." *Id.* This "plausibility standard" requires the complaint allege "more than a sheer possibility that a defendant has acted unlawfully," but it "is not akin to a probability requirement." *Id.* (citing *Twombly*, 550 U.S. at 556). "Detailed factual allegations" are not required, but "more than an unadorned, the defendant-harmed-me accusation" must be

pled; it must include "further factual enhancement" and not just conclusory statements or a recitation of the elements of a cause of action. *Id.* (citing *Twombly*, 550 U.S. at 555, 557).

"Determining whether a complaint states a plausible claim for relief [is] . . . a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* (citing Fed. R. Civ. P. 8(a)(2)). However, courts are "not compelled to accept 'unsupported conclusions and unwarranted inferences,'" *Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007) (citing *Schuylkill Energy Res. Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997)), nor "a legal conclusion couched as a factual allegation." *Papasan*, 478 U.S. at 286 (citations omitted).

While, as a general rule, the court may not consider anything beyond the four corners of the complaint on a motion to dismiss pursuant to Rule 12(b)(6), the Third Circuit has held that "a court may consider certain narrowly defined types of material without converting the motion to dismiss to a summary judgment motion, including items that are *integral to or explicitly relied upon* in the complaint ." *Coulter v. Doerr*, 486 F. App'x 227, 228 (3d Cir. 2012) (citing *In re Rockefeller Ctr. Props. Sec. Litig.*, 184 F.3d 280, 287 (3d Cir. 1999)).

**B. Rule 12(f)**

A court may, upon motion or *sua sponte*, "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "The purpose of a motion to strike is to simplify the pleadings and save time and expense by excising from a plaintiff's complaint any redundant, immaterial, impertinent, or scandalous matter which will not have any possible bearing on the outcome of the litigation." *Garlanger v. Verbeke*, 223 F.

Supp. 2d 596, 609 (D.N.J. 2002) (citations and internal quotations omitted). However, "[b]ecause of the drastic nature of the remedy, . . . motions to strike are usually 'viewed with disfavor' and will generally 'be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues.'" *Id*. (citing *Tonka Corp. v. Rose Art Indus., Inc.*, 836 F. Supp. 200, 217 (D.N.J. 1993)); *see also Weske v. Samsung Elecs., Am., Inc.*, 934 F. Supp. 2d 698, 702 (D.N.J. 2013) (explaining that motions to strike are extremely disfavored). "A court possesses considerable discretion in disposing of a motion to strike under Rule 12(f)." *Kim v. Baik*, No. 06-3604, 2007 U.S. Dist. LEXIS 13553, 2007 WL 674715, at *5 (D.N.J. Feb. 27, 2007) (citing *River Rd. Dev. Corp. v. Carlson Corporation-Northeast*, No. 89-7037, 1990 U.S. Dist. LEXIS 6201, 1990 WL 69085, at *2 (E.D. Pa. May 23, 1990)). In short, this is not the time to decide motions *in limine*. The issue to be resolved is whether there is some harm will result from permitting something to be alleged at all—a high bar.

**C. Rule 23**

"The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Wal-Mart Stores v. Dukes*, 564 U.S. 338, 348, 131 S. Ct. 2541, 180 L. Ed. 2d 374 (2011) (citing *Califano v. Yamasaki*, 442 U.S. 682, 700–701, 99 S. Ct. 2545, 61 L. Ed. 2d 176 (1979).). "To invoke this exception, every putative class action must satisfy the four requirements of Rule 23(a) and the requirements of either Rule 23(b)(1), (2), or (3)." *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 590 (3d Cir. 2012). A class may be certified pursuant to Rule 23(a) when:

> (1) the class is so numerous that joinder of all members is impracticable;
> (2) there are questions of law or fact common to the class;

> (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
> (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). These four requirements are customarily referred to as: (1) numerosity; (2) commonality; (3) typicality; and (4) adequate representation. *Dukes*, 564 U.S. at 349. In addition, Rule 23(b)(3) requires that "questions of law or fact common to class members predominate over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). These requirements are known as "predominance" and "superiority," respectively. *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 310 (3d Cir. 2008). Additionally, when certification is sought under Rule 23(b)(3), the Third Circuit has found that a prerequisite to an analysis of the Rule 23(a) requirements is the proposed class "must be currently and readily ascertainable based on objective criteria." *Marcus*, 687 F.3d at 592–93 (citations omitted).

"[T]he requirements set out in Rule 23 are not mere pleading rules." *Hydrogen Peroxide*, 552 F.3d at 316 (citing *Szabo v. Bridgeport Machs., Inc.*, 249 F.3d 672, 675–77 (7th Cir. 2001)). "A court may 'delve beyond the pleadings to determine whether the requirements for class certification are satisfied,'" and conduct a "preliminary inquiry into the merits." *Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 306 (3d Cir. 2011) (citing *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 167 (3d Cir. 2001)). "The party seeking certification bears the burden of establishing each element of Rule 23 by a preponderance of the evidence." *Marcus*, 687 F.3d at 591 (citing *Hydrogen Peroxide*, 552 F.3d at 307). This requires "actual" not "presumed" conformance with Rule 23's requirements. *Id.* (citing *Hydrogen Peroxide*, 552 F.3d at 326). "Class certification is proper only 'if the trial court is satisfied, after a rigorous analysis, that the

prerequisites' of Rule 23 are met." *Hydrogen Peroxide*, 552 F.3d at 309 (citing *Gen. Tel. Co. of Sw. v. Falcon*, 457 U.S. 147, 161, 102 S. Ct. 2364, 72 L. Ed. 2d 740 (1982)).

## III. DECISION

### A. Allergan's Motion to Dismiss on Preemption Grounds (ECF No. 171-1)

Allergan argues Plaintiffs' claims trigger express and implied preemption and are mostly foreclosed by the Medical Device Amendments ("MDA"). (ECF No. 171-1 at 34.) Plaintiffs counter that their claims regarding Allergan's violations of its duties under state law parallel federal requirements and therefore are not preempted. (ECF No. 216 at 31.) The Court will conduct the preemption analysis according to the principles discussed below.

"Preemption is an affirmative defense that the defendant has the burden to prove." *Lupian v. Joseph Cory Holdings LLC*, 905 F.3d 127, 130 (3d Cir. 2018) (citing *In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 n.6 (3d Cir. 2016)). "The question whether a certain state action is pre-empted by federal law is one of congressional intent." *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 96 (1992) (citing *Allis-Chalmers Corp. v. Lueck*, 471 U.S. 202, 208 (1985)). "Such a determination of congressional intent and of the boundaries and character of a pre-empting congressional enactment is one of federal law." *International Longshoremen's Ass'n. v. Davis*, 476 U.S. 380, 388 (1986). "The law of the transferee forum applies . . . to federal questions, though the Court may give the law of the transferor forum 'close consideration.'" *United States v. Bristol-Myers Squibb Co. (In re Plavix Mktg., Sales Practice & Prods Liab. Litig.)*, 332 F. Supp. 3d 927, 936 (D.N.J. 2017) (citing *In re Nazi Era Cases Against German Defendants Litig.*, 320 F. Supp. 2d 204, 214 (D.N.J. 2004), *aff'd*, 153 F. App'x 819 (3d Cir. 2005)); *see also Becnel v. Anco Insulations, Inc.*, No. 08-84556, 2011 U.S. Dist. LEXIS 9920, at *7 (E.D. Pa. Jan. 28, 2011) ("[T]he MDL transferee court applies the federal law of the

circuit where it sits.") (citations omitted). Accordingly, the Court will primarily apply the federal law from this District and the Third Circuit on the issue of preemption.

The law relating to the field of medical devices presents a unique set of preemption issues. Congress introduced the MDA, 21 U.S.C. § 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act ("FDCA") to establish a new regulatory regime implemented by the FDA on "various levels of oversight for medical devices, depending on the risks they present." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). "Class I devices pose the least risks, Class II devices are 'more harmful,' and Class III devices pose the greatest risks." *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 765 (3d Cir. 2018) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996); 21 U.S.C. § 360c(a)(1)). "Class III devices receive 'the most federal oversight,' and Class I and II devices receive much less." *Id.* (citing *Riegel*, 552 U.S. at 316–17). 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." *Riegel*, 552 U.S. at 323 (citing 21 U.S.C. §360e(d)). However, "[a] new device need not undergo premarket approval if the FDA finds it is 'substantially equivalent' to another device exempt from premarket approval." *Id.* (citing 21 U.S.C. § 360c(f)(1)(A)). The FDA "review of devices for substantial equivalence is known as the § 510(k) process, named after the statutory provision describing the review." *Id.* Class I and Class II devices and most Class III devices are subject to the § 510(k) process. *Id.* at 317; *Shuker*, 885 F.3d at 767.

A state law product liability or tort claim relating to a medical device may be expressly or impliedly preempted by the MDA. The MDA "contains a broad express preemption provision," which:

> [P]roclaims 'no State . . . may establish or continue in effect with respect to a device . . . any requirement' that 'is different from, or

> in addition to,' any federal requirement and that relates either 'to the safety or effectiveness of the device' or 'to any other matter' included in a federal requirement applicable to the device.

*Shuker*, 885 F.3d at 767 (citing 21 U.S.C. § 360k(a)). That is to say, "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (citing 21 U.S.C. § 360k(a)(1)). Therefore, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id*. The implied preemption issue is explained in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), where the Supreme Court "under the auspices of the MDA" foreclosed a state common law fraud-on-the-FDA tort claim. *Sullivan v. Novartis Pharms. Corp.*, 602 F. Supp. 2d 527, 535 (D.N.J. 2009) (citing *Buckman*, 531 U.S. 341). "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: 'All such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.'" *Buckman*, 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a)).

Allergan insists there are four principles that determine whether a state law product liability or tort claim avoids preemption under the MDA. (ECF No. 261 at 9:1–2.) First, if the controlling state law provides something mandatory where the federal law makes it discretionary, then the state law requires something different from or in addition to the federal requirements. *Id*. at 9:7–10. Second, to avoid preemption, a device specific requirement must have been breached and that device specific requirement has to come from the PMA. *Id*. at 9:14–17. Third, to avoid preemption, genuine equivalence is required between the federal regulation and the parallel state law. *Id*. at 10:1–4. Fourth, implied preemption is triggered when the source of the state law duty

in fact is in the federal regulations, which are critical to the state law claims. *Id*. at 10:9–13. However, these four principles add nothing to the preemption analysis the Court just discussed.

The first principle merely restates the express preemption inquiry under *Riegel*, which holds "state requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (citing 21 U.S.C. § 360k(a)(1)).

The second principle refers to the first prong in the two-step framework for the express preemption inquiry under *Riegel*: (1) whether the federal requirements are applicable to the specific device at issue, and (2) if so, whether the controlling state law requires something different from or in addition to the federal one, and relates to the safety and effectiveness of the device. *Id*. at 321–22. But the Court need not consider the first prong here. The BIOCELL implants are approved under one of the three regulatory paths: (1) the PMA, (2) the IDE, and (3) § 510(k). The PMA imposes requirements specific to a Class III device. *Horn v. Thoratec Corp.*, 376 F.3d 163, 171–72 (3d Cir. 2004); *Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 452 (D.N.J. 2003). The IDE is also device-specific. *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3d Cir. 1994) (citing 21 U.S.C. § 360j(g)(2)(A)) ("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."). Because the PMA and the IDE are device-specific federal requirements, the first prong is met for Plaintiffs' claims concerning PMA/IDE-approved BIOCELL implants, so that the Court need only examine the second prong. As for § 510(k), even though its review process is device-specific, "§ 510(k) does not trigger preemption." *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 747 (E.D. Pa. 2007) (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493–94 (1996)). As a result, a preemption analysis

for Plaintiffs' claims concerning § 510(k)-approved BIOCELL implants is unnecessary. Because either the first prong is inconsequential or no preemption analysis is necessary in analyzing Plaintiffs' claims, the Court need not examine the first prong or apply the two-step framework under *Riegel*.

The third principle also adds nothing new to the express preemption inquiry under *Riegel*. "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." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (citing *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)). In other words, genuine equivalence is found if the controlling state law requires something "different from, or in addition to" the federal requirements.

The fourth principle is essentially restating the implied preemption inquiry under *Buckman*, which prohibits a private enforcement of the FDCA. *Buckman*, 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a)).

In conclusion, Plaintiffs' allegations of Allergan's violations of state law duties, if in parallel with federal requirements and not amounting to a private enforcement of the FDCA, are not preempted.

**1. Failure to Warn Claims**

**a. Plaintiffs' Label-Based Failure to Warn Claims Are Expressly Preempted**

Allergan claims Plaintiffs' attacks on the adequacy of Allergan's FDA-approved labels would require something different from, or in addition to, what the controlling federal regulations mandate, and therefore cannot survive express preemption. (ECF No. 171-1 at 41.) In particular, Allergan argues Plaintiffs' misbranding claims are preempted, as they have the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling

requirement, and are different from, or in addition to, the FDA requirement. (ECF No. 238 at 21–22.) Allergan also states Plaintiffs cannot assert a claim for Allergan's failure to change the label through a Changes Being Effected ("CBE") supplement, because the CBE regulation permits, but does not require, such a change. (ECF No. 171-1 at 53–54.) Allergan maintains any claim that would convert the permissive CBE process into a mandatory submission is expressly preempted, as such a claim is necessarily "different from or in addition to" the FDA's regulatory scheme. (ECF No. 238 at 20.)

Plaintiffs counter their label-based failure to warn claims are not preempted, because they are based on Allergan's violations of parallel state law. (ECF No. 216 at 34.) Plaintiffs contend Allergan has a separate duty under state law to warn consumers of the risk of developing BIA-ALCL by patients with the use of BIOCELL implants. (*Id.* at 34–35.) Plaintiffs suggest such a state law duty parallels with two independent federal law requirements: (1) the PMAs for the BIOCELL implants require Allergan to submit a PMA supplement when unanticipated adverse effects or increases in the incidence of anticipated adverse effects necessitate a labeling modification, including, if permitted, a CBE submission; and (2) the FDCA misbranding provisions require Allergan to update its labeling that is false or misleading. (*Id.* at 35–37.) Plaintiffs insist, when the CBE regulation applies, the PMA requires Allergan to act before the FDA approves the label change. (ECF No. 263 at 7.) The Court disagrees.

"The MDA expressly pre-empts state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008) (citing 21 U.S.C. § 360k(a)(1)). "[O]nce there is any device-specific requirement (as there always is for Class III devices receiving PMA), then all state law claims are preempted if they differ from or add to any federal requirements applicable to the device."

*McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 814 n.5 (E.D. Pa. 2016). "To the extent that [the plaintiff] asserts a failure to warn claim based only on [the defendant's] failure to comply with FDA regulations, however, such a claim is not expressly preempted." *Mendez v. Shah*, 28 F. Supp. 3d 282, 300 (D.N.J. 2014) (citing *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011)). That is to say, if Plaintiffs' label-based failure to warn claims differ from or add to *any* requirement in either the PMAs or the FDCA's misbranding provisions, the claims will be expressly preempted.

Here, Plaintiffs allege Allergan failed to comply with requirements in the PMAs for the BIOCELL implants. (ECF No. 216 at 35.) In particular, Plaintiffs claim the CBE regulations direct and require Allergan to update the warnings on the BIOCELL implants, which Allergan allegedly fails to do in violation of the PMAs. (ECF No. 119 at ¶¶ 63–64.) However, as discussed below, the CBE process is not mandatory.

The PMAs require Allergan to submit a PMA supplement for the FDA to review and approve before making any change affecting the safety or effectiveness of the device, unless made through the CBE process. (ECF No. 119 at ¶ 61.) This CBE exception "allows a manufacturer to 'add or strengthen a contraindication, warning, [or] precaution' without pre-approval from the FDA." *Nelson v. Biogen Idec, Inc.*, No. 12-7317, 2018 U.S. Dist. LEXIS 70283, at *37 (D.N.J. April 25, 2018) (citing *Wyeth v. Levine*, 555 U.S. 555, 614 (2009)). "Nevertheless, if the manufacturer can show clear evidence that the FDA would not have approved the labeling change, the CBE exception does not apply." *Id.* (citing *Wyeth*, 555 U.S. at 571). In other words, "[t]he CBE procedure is permissive, not mandatory." *Brooks v. Mentor Worldwide, LLC*, No. 19-2088-KHV, 2019 U.S. Dist. LEXIS 161820, at *13 (D. Kan. Sep. 23, 2019), *aff'd* 985 F.3d 1272 (10th Cir. 2021) (citations omitted); *see also* 21 C.F.R. §814.39(d)(1)

("After FDA approves a PMA, any change . . . to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device *may be* placed into effect by the applicant prior to . . . a written FDA order approving the PMA supplement provided that: (i) The PMA supplement and its mailing cover are plainly marked 'Special PMA Supplement - Changes Being Effected.'").

Here, Plaintiffs have not alleged Allergan's failure to comply with any FDA labeling requirement. Though the CBE process allows Allergan to update the label of its implants, Allergan is not obligated to do so, because the CBE process is not mandatory. However, Plaintiffs' label-based failure to warn claims would require Allergan to update warnings on the implants' label. This amounts to a state law duty that differs from or adds to the federal requirements in the PMAs, which triggers express preemption. *See Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1280 (10th Cir. 2021) (citations omitted) ("And absent a federal requirement that [a medical device manufacturer] do so, federal law expressly preempts any state-law duty requiring a manufacturer to update its labeling."); *In re: Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010) ("Even if federal law allowed [the defendant] to provide additional warnings, as [the plaintiff] alleged, any state law imposing an additional requirement is preempted by § 360k."); *Heisner v. Genzyme Corp.*, No. 08-C-593, 2010 U.S. Dist. LEXIS 21339, at *7–8 (N.D. Ill. March 8, 2010) (concluding the MDA preempts all negligence and strict liability claims turning on the defendant's failure to provide supplemental warnings because CBE is not mandatory); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) ("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."). The PMA

requirement that a PMA supplement "be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling . . . modification" (ECF No. 119 at ¶ 61) does not mandate a change of label. Instead, the PMA only requires a submission to the FDA, which, depending on the FDA's decision, may or may not translate into a mandatory label change. Therefore, 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, though this alleged failure may support other theories for a failure to warn claim. Accordingly, the Court concludes Plaintiffs' label-based failure to warn claims are expressly preempted.

**b. Plaintiffs' Report-Based Failure to Warn Claims Are Not Preempted**

Allergan argues Plaintiffs' accusation of Allergan's alleged failure to make proper adverse event reports to the FDA is not based on any parallel state law duty, and is therefore expressly preempted. (ECF No. 171-1 at 43.) Allergan maintains Plaintiffs' allegations of Allergan's method of reporting as inadequate is similarly expressly preempted, because there is no state law duty to warn grounded in a method of reporting to the FDA. (*Id.* at 48–49.) Allergan explains the adverse event information that made its way into the MAUDE database accessible by physicians does not correspond to a warning to physicians about any specific report or risk, as it is the FDA that decides whether to exercise its regulatory prerogative to publish the information in the first place or take some other action. (ECF No. 262 at 11–12.) Allergan also insists Plaintiffs' report-based failure to warn claims are impliedly preempted, because Plaintiffs, as private persons, cannot base their warning claims on the purported breach of a federal duty, and any attempt to recognize such a duty would impermissibly interfere with the federal statutory scheme's requirements. (ECF No. 171-1 at 49–50.)

Plaintiffs argue their report-based failure to warn claims are not preempted, because these state law claims parallel the FDA requirements regarding the reporting of adverse safety information. (ECF No. 216 at 40.) Plaintiffs cite numerous court decisions holding a device manufacturer can violate its state law duty to warn by failing to report adverse safety information to the FDA. (*Id.* at 41–45.) Plaintiffs allege Allergan's improper submission to the FDA of Alternative Summary Reports ("ASRs"), which contain a series of alphanumeric codes (not a narrative description) and are not made publicly available for years, rather than Medical Device Reports ("MDRs"), which contain a full narrative description of the event and are published in the FDA's MAUDE database every month, violates both the state law duty to warn patients or their physicians and the parallel federal requirements. (*Id.* at 51–52.) The Court agrees.

Here, for the preemption inquiry, the Court will not conduct a state-by-state analysis to examine whether Plaintiffs' report-based failure to warn claims are based on a parallel state law duty. The Court determines, and the parties agree, preemption should be examined at the federal level, rather than on a state-by-state basis. (ECF No. 261 12:11–15, 24:13–16); *see also Buquer v. City of Indianapolis*, No. 1:11-cv-00708-SEB-MJD, 2012 U.S. Dist. LEXIS 31830, at *16 (S.D. Ind. March 9, 2012) ("[P]reemption must be considered on a national and not a state-by-state basis."). This avoids an across-the-board dismissal of report-based failure to warn claims in all jurisdictions, if some jurisdictions recognize a report-based duty to warn not different from or in addition to federal reporting requirements.

"In states that recognize failure to report claims, . . . a manufacturer's failure to report adverse events to the FDA can form the basis of a parallel claim that survives preemption." *Nunn v. Mentor Worldwide, LLC*, No. 19-56391, 2021 U.S. App. LEXIS 3286, at *3 (9th Cir. Feb. 5, 2021) (citations omitted); *see also Sewell v. Mentor Worldwide, LLC*, 2021 U.S. App. LEXIS

3276, at *4 (9th Cir. Feb. 5, 2021) (same); *Vieira v. Mentor Worldwide, LLC*, No. 19-56394, 2021 U.S. App. LEXIS 3279, at *3 (9th Cir. Feb. 5, 2021) (same); *Billetts v. Mentor Worldwide, LLC*, 2021 U.S. App. LEXIS 3272, at *3–4 (9th Cir. Feb. 5, 2021) (same). Accordingly, the Court declines to dismiss Plaintiffs' report-based failure to warn claims on preemption grounds, and will conduct a state-by-state analysis in Part III.B.5, *infra*, to examine the claims' viability in different jurisdictions. This is consistent with the precedents in the Third Circuit, as discussed below.

The Restatement (Second) of Torts 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." Restatement (Second) of Torts § 388 cmt. n (1965). This Restatement may establish a device manufacturer's traditional state law duty to warn by reporting adverse safety events to the FDA.[3] *Freed v. St. Jude Med.*, Inc., 364 F. Supp. 3d 343, 358–60 (D. Del. 2019); *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017); *Richardson v. Bayer Healthcare Pharm. Inc.*, No. 4:15-cv-00443-BLW, 2016 WL 4546369, at *8 (D. Idaho Aug. 30, 2016); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016). The underlying rationale of a report-based failure to warn claim is that the FDA reporting regulations "are related to the manufacturer's duty to provide the [FDA] with information regarding a device's safety and effectiveness, which is then disseminated to the public." *Freed*, 364 F. Supp. 3d at 358 n.13 (citing *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770–71 (5th Cir. 2011)). "A manufacturer's failure to provide such information to the FDA

[3] The Court is not holding the Restatement establishes a duty to warn for every state. Here, the Restatement only provides a theory that allows a state failure to warn claim to survive express preemption. It is up to each State to decide whether to adopt the Restatement as the basis for a state law duty to warn.

is a parallel violation of a state duty . . . to provide reasonable and adequate information regarding a product's risks." *Id.* (citing *Hughes*, 631 F.3d at 770–71). "[T]he FDA may be reasonably relied upon to disclose information regarding medical device failures through the publicly accessible database when provided with that information." *Silver*, 236 F. Supp. 3d at 900. Accordingly, Plaintiffs' report-based failure to warn claims are not expressly preempted.

For implied preemption, the Court is bound by the Third Circuit's interpretation of the holdings in *Buckman*. The application of *Buckman* "is often limited to 'fraud-on-the-agency' claims and not extended to claims based on state law tort principles." *Mendez v. Shah*, 28 F. Supp. 3d 282, 291 (D.N.J. 2014) (citing *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010)); *see also Freed*, 364 F. Supp. 3d at 352 (citing *Hughes*, 631 F.3d at 775) ("To avoid implied preemption under *Buckman*, a claim must assert violation of a state tort duty that also violates some FDA requirement."); *Bull v. St. Jude Med., Inc.*, No. 17-1141, 2018 U.S. Dist. LEXIS 115730, at *27 (E.D. Pa. July 12, 2018) ("State law claims that allege liability based on a common law tort theory and which parallel federal law claims . . . are not impliedly preempted under *Buckman*."). A failure to warn claim that "can be established solely by evidence of fraud on the agency is [impliedly] preempted." *Chester v. Boston Sci. Corp.*, No. 16-02421, 2017 U.S. Dist. LEXIS 26676, at *27 (D.N.J. Feb. 27, 2017) (citing *Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1056 (N.J. 2012)); *see also Stout v. Advanced Bionics, LLC*, No. 2:11cv1061, 2013 U.S. Dist. LEXIS 203717, at *13 (E.D. Pa. Sept. 19, 2013) (concluding the plaintiffs' negligence claims based on the device manufacturer's failure to obtain supplemental PMA approval for a change of supplier are "disguised fraud-on-the-FDA claims" and impliedly preempted, because the "approval is an administrative requirement created by the FDA, not a substantive safety requirement of state law"). Here, Plaintiffs' report-based failure to warn claims are based on state

law tort principles illustrated in § 388 of the Restatement (Second) of Torts, and not solely based on Allergan's alleged fraud on the FDA. Such an alleged violation of the state law duty to "warn physicians about the risks of [a medical device] based on the failure to fully comply with its federal duty to report all adverse events to the FDA" represents "a traditional state failure to warn theory premised on alleged non-compliance with federal regulations—that it is not impliedly preempted under *Buckman*." *Bull*, 2018 U.S. Dist. LEXIS 115730, at *28.

Accordingly, the Court finds Plaintiffs' report-based failure to warn claims are not preempted.

**2. Plaintiffs' Manufacturing Defect Claims Are Not Preempted**

Allergan concedes claims for manufacturing defects, when properly alleged, may not be expressly or impliedly preempted, but contends Plaintiffs' manufacturing defect claims fail for several reasons. (ECF No. 171-1 at 57.) First, Allergan argues Plaintiffs have not alleged its BIOCELL implants deviate from an FDA-approved manufacturing process or attendant FDA-approved device specifications, and therefore must be dismissed. (*Id.* at 60.) Allergan contends the FDA could not have intended these allegedly dangerous particles to be on a medical device. (ECF No. 262 at 15.) Second, Allergan maintains Plaintiffs' allegations, disguised in "manufacturing defect" clothing, are actually aimed at the PMA-approved processes by which all of Allergan's devices are manufactured, and should be preempted as an effort to change what federal regulation commands. (ECF No. 171-1 at 61.) Third, Allergan states the Current Good Manufacturing Practices ("CGMPs"), the quality system requirements ("QSRs"), and FDCA's adulteration provisions are not device-specific, and cannot serve as parallel federal requirements. (ECF No. 262 at 14.) Allergan argues the CGMPs are too vague to create identifiable federal requirements and supply a federal parallel to Plaintiffs' manufacturing defect claims. (ECF No.

238 at 38–39.) In addition, Allergan argues Plaintiffs' adulteration allegations are preempted, because they do not resemble any common law manufacturing defect claim, and exist solely by virtue of the FDA requirements. (ECF No. 171-1 at 65.)

Plaintiffs counter they have alleged manufacturing defects in the BIOCELL implants. (ECF No. 216 at 55.) For example, Plaintiffs allege the debris, including silicone particles, on the implants' surface is not an intended part of the design for the BIOCELL implants. (*Id.*) Plaintiffs suggest the Court should not entertain Allergan's argument that the implants' design may not call for surfaces littered with debris, because Allergan has not produced all the documents from its PMA submissions. (ECF No. 263 at 10 n.6.) Plaintiffs further allege violations of CGMPs by Allergan in the manufacturing process. (ECF No. 216 at 56.) Plaintiffs state their manufacturing defect claims also parallel the FDCA's prohibition on marketing an adulterated device, and therefore are not preempted. (*Id.* at 65.) The Court agrees.

"To the extent that the [manufacturing defect] claim is a hardware failure because the device did not conform to the standards of other units, and also violated federal regulations and procedures in manufacturing, then it would be parallel claim and would not be preempted." *Mendez v. Shah*, 28 F. Supp. 3d 282, 298–99 (D.N.J. 2014) (citations omitted); *see also Nunn v. Mentor Worldwide, LLC*, No. 19-56391, 2021 U.S. App. LEXIS 3286, at *3 (9th Cir. Feb. 5, 2021) (citing *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1112 (9th Cir. 2019)) ("For [Plaintiffs'] manufacturing defect claims to survive express preemption under the MDA, Plaintiffs must allege that Defendants 'deviated from a particular premarket approval or other FDA requirement applicable to the Class III medical device.'"); *Sewell v. Mentor Worldwide, LLC*, 2021 U.S. App. LEXIS 3276, at *5 (9th Cir. Feb. 5, 2021) (same); *Vieira v. Mentor Worldwide, LLC*, No. 19-56394, 2021 U.S. App. LEXIS 3279, at *4 (9th Cir. Feb. 5, 2021) (same); *Billetts v. Mentor*

*Worldwide, LLC*, 2021 U.S. App. LEXIS 3272, at *4–5 (9th Cir. Feb. 5, 2021) (same). "However, if the [defendant's] device was manufactured in compliance with its PMA, then any claim of manufacturing defect would not parallel a federal claim and would be preempted." *Mendez*, 28 F. Supp. 3d at 299 (citing *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1207 (8th Cir. 2010)). Also, "it would be an injustice to penalize a plaintiff for alleging, through no fault of her own, what turned out to be insufficient facts about the manufacturing process of a device that caused injury," as the manufacturer's agreements with the FDA "that would provide the necessary factual specificity are confidential, and available only to the defendants and the FDA." *Killen v. Spine*, No. 11-1508, 2012 U.S. Dist. LEXIS 141639, at *23–24 (W.D. Pa. Aug. 21, 2012) (citations omitted).

> [I]n this unique set of circumstances, where [the plaintiff] has advanced facts that suggest the existence [of] parallel claims, but does not have access to the confidential information to specifically plead the alleged violation of FDA regulations, fairness compels that some leniency be afforded plaintiff from the stringent *Twombly/Iqbal* pleading standards to allow this claim to proceed.

*Id*. at *24–25. Here, Plaintiffs allege the debris in the BIOCELL implants is not a part of the PMA-approved design for the BIOCELL implants, and therefore constitutes a deviation from the design in violation of the PMAs. (ECF No. 216 at 55.) Therefore, Plaintiffs have advanced facts suggesting plausible manufacturing defects in the BIOCELL implants, and fairness compels some leniency be afforded to Plaintiffs in asserting their manufacturing defect claims. Accordingly, the Court declines to dismiss Plaintiffs' manufacturing defect claims at this stage.

Alternatively, the CGMPs and the FDCA's adulteration provisions could also serve as parallel federal requirements.

"[C]iting to the FDA's Current Good Manufacturing Practices ("CGMP") could present a parallel federal claim." *Mendez v. Shah*, 94 F. Supp. 3d 633, 638 (D.N.J. 2015); *see also Killen*,

2012 U.S. Dist. LEXIS 141639, at *21 (rejecting "the blanket position that CGMPs can never serve as the basis for a parallel claim"). To survive preemption, the plaintiff must identify "what regulations under the CGMPs . . . parallel [the plaintiff's] state law claim," *Mendez*, 94 F. Supp. 3d at 639, and should not "simply provide a 'laundry list of alleged CGMP violations,'" which is "too general to be capable of enforcement." *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 897 (E.D. Pa. 2017) (holding the CGMP violations alleged qualify as federal regulations from which a parallel state claim may be made, because the FDA warning letters delineate specific deviations of the defendant's devices from specific CGMPs). Otherwise, "a comparison cannot be made" between the plaintiff's state law claims and relevant federal obligations to determine if the state law "requirements with respect to the device are 'different from, or in addition to,' the federal ones." *Mendez*, 94 F. Supp. 3d at 369. Here, Plaintiffs have alleged Allergan's violations of specific CGMP regulations. (ECF No. 119 at ¶¶ 129–39.) In particular, Plaintiffs allege Allergan "violated state law and parallel federal requirements set forth at 21 C.F.R. § 820.30 by failing to," among other things, "test production units under actual or simulated use conditions." (*Id*. at ¶ 132.) Section 820.30(g), which requires a device manufacturer "to test products under actual or simulated use conditions[,] is specific enough to support a parallel [state law] claim." *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 686 (W.D. Ky. 2013) (citing 21 C.F.R. § 820.30(g)). Therefore, Plaintiffs have identified federal parallels for their manufacturing defect claims based on the CGMPs.

The FDCA's adulteration provisions state a medical device is adulterated if "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with" the CGMP requirements. 21 U.S.C. §§ 351(h), 360j(f). That is to say, adulteration is found if specific CGMP violations are identified. Since Plaintiffs have specified

the CGMP regulations that Allergan allegedly violates, Plaintiffs can assert manufacturing defect claims based on Allergan's alleged violation of the FDCA's adulteration provisions. *See Silver*, 236 F. Supp. 3d at 898–99 (concluding the plaintiff asserts a parallel manufacturing defect claim, because the plaintiff "alleges that [the defendant] breached his Pennsylvania common law duty to exercise reasonable care in manufacturing the Device in failing to ensure that the Device conformed to its own PMA specifications and complied with CGMPs," resulting in an "'adulterated' device [that] was unreasonably dangerous and caused him harm").

Finally, the Court need not consider implied preemption here, because Allergan does not challenge Plaintiffs' manufacturing defect claims based on implied preemption. Accordingly, with parallel federal requirements in the implants' PMAs, CGMPs, and the FDCA's adulteration provisions, the Court finds Plaintiffs' manufacturing defect claims are not preempted.

**3. Plaintiffs' Negligence *Per Se* Claims Are Not Preempted**

Allergan argues Plaintiffs' negligence *per se* claims, which are based solely on the violation of the FDCA, are improper attempts at private FDCA enforcement and should be impliedly preempted. (ECF No. 171-1 at 65–66.) Plaintiffs maintain state-created causes of action that invoke negligence *per se* based on FDCA violations are not preempted. (ECF No. 216 at 72.) The Court agrees with Plaintiffs and finds negligence *per se* claims are not preempted.

"[T]he doctrine of *per se* liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort." *In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 781, 791 (3d Cir. 1999) (citing *Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc.*, 720 F. Supp. 714, 716 (N.D. Ill. 1989)). "[T]he FDCA or its accompanying regulations" can be invoked to "establish the standard or duty which defendants allegedly failed to meet." *Id.* (citing *Grove*

*Fresh Distribs.*, 720 F. Supp. at 716); *see also Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 554 (E.D. Pa. 2006) ("Here, Plaintiff's negligence *per se* claim is premised on the alleged violation of the FDCA."). "[T]he FDCA does not preempt state common law claims 'such as negligence.'" *Polt v. Sandoz, Inc.*, No. 16-2362, 2017 U.S. Dist. LEXIS 228038, at *5 n.1 (E.D. Pa. July 7, 2017) (citing *Orthopedic Bone Screw*, 193 F.3d at 792).

Therefore, the FDCA and the FDA regulations may set the basis for Plaintiffs' negligence *per se* claims. Because Plaintiffs' negligence *per se* claims "invoke the statutory violations to prove defendants' liability for a separate underlying tort," instead of "contending the violations themselves form a cause of action," they are not impliedly preempted. *Id.* at *4 n.1 (citing *Orthopedic Bone Screw*, 193 F.3d at 791).

**4. Plaintiffs' Claims Concerning Investigational Devices Used In An Approved Clinical Trial Are Preempted**

Allergan argues Plaintiffs' claims concerning its investigational devices (McGhan Textured Breast Implant, Style 153), and post-PMA claims against its reclassified devices (McGhan RTV® Saline-Filled Mammary Implant), are expressly and impliedly preempted. (ECF No. 171-1 at 69–70.) Plaintiffs contend there is no preemption when these investigational devices are used outside an approved clinical trial. (ECF No. 261 at 37:7–9, 38:6–10.) The Court finds Plaintiffs' claims concerning Allergan's investigational devices used in an approved clinical trial are preempted.

As Allergan concedes, whether a device enjoys PMA approval when used for a particular patient governs the availability of preemption. (ECF No. 171 at 73.) Therefore, Plaintiffs' post-PMA claims against Allergan's reclassified devices, which had the PMA approval when used by Plaintiffs, are treated no differently from the claims against the PMA-approved devices as

discussed previously. However, Plaintiffs' claims concerning Allergan's investigational devices, which have not received PMAs, must be analyzed separately.

"To obtain the data to support an application for premarket approval, a manufacturer may use the device in clinical trials under active FDA supervision pursuant to the FDCA's Investigational Device Exemption ("IDE") provisions and accompanying federal regulations." *Orthopedic Bone Screw*, 193 F.3d at 786 (citing 21 U.S.C. § 360j(g)). The FDA approves an IDE investigation "only upon a determination that the device is sufficiently safe and effective for investigative use on human beings." *Hunsaker v. Surgidev Corp.*, 818 F. Supp. 744, 752 (M.D. Pa. 1992) (citing *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir. 1992)). "A jury determination that the device is not sufficiently safe and effective would not only be contrary to the experimental purposes of the exemption, but, more important[ly], would directly conflict with the FDA's contrasting judgment." *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 545 (3d Cir. 1994) (citing *id*. at 752–53). "Therefore, state tort law invoked to challenge the safety or effectiveness of a [device] which is part of an FDA investigation is federally preempted." *Id*. (citing *Hunsaker*, 818 F. Supp. at 753). Such "state tort claims run counter to the important public policy, recognized by Congress, of promoting scientific inventions." *Id*. at 546. However, the state law claims concerning investigational devices used outside an approved clinical trial are not preempted under the IDE. *English v. Mentor Corp.*, 67 F.3d 477, 480 (3d Cir. 1995) ("The FDA had initially granted an Investigational Device Exemption to [the defendant], permitting it to test its prosthesis on human subjects; [the plaintiff], however, did not receive a device as part of an IDE test study and thus [the defendant] cannot rely on IDE regulations in support of its argument that [plaintiff's] state tort claims are preempted."), *vacated on other grounds*, 518 U.S. 1030 (1996); *see also Caccia v. Biomet, Inc.*, No. 3:13-CV-73 RLM, 2013

U.S. Dist. LEXIS 119124, *12–13 (N.D. Ind. Aug. 21, 2013) (rejecting the argument that "a manufacturer that obtains IDE status for a device to be used in a controlled investigational setting is, during the time the study is being conducted, exempt from liability for use of that device outside the clinical trial"). Therefore, Plaintiffs' claims challenging the safety or effectiveness of Allergan's investigational devices used in an approved clinical study are expressly preempted.

**5. Plaintiffs' Negligent Failure to Warn Claims Alleging Allergan's Failure to Conduct Post-PMA Clinical Studies Are Preempted**

Allergan contends Plaintiffs' claims alleging Allergan failed to conduct post-PMA clinical studies are expressly preempted, because there is no state law duty that requires Allergan to undertake the studies. (ECF No. 171-1 at 56.) Allergan maintains such a requirement exists solely by virtue of the FDA's regulatory oversight and Allergan's PMA-based obligations. (*Id*.) Plaintiffs counter they are asserting negligent failure to warn claims for Allergan's alleged violation of FDA regulations and the PMA orders, which require Allergan to conduct post-PMA studies regarding the safety of BIOCELL implants. (ECF No. 216 at 75.) The Court disagrees and finds these claims to be preempted.

The Court is not aware of, and Plaintiffs do not identify, any legal authority suggesting the existence of a parallel state law duty to warn resulting from post-PMA studies. On the contrary, some courts have explicitly rejected such a duty to warn as impliedly preempted. *See, e.g., Nunn v. Mentor Worldwide, LLC*, No. 19-56391, 2021 U.S. App. LEXIS 3286, at *4 (9th Cir. Feb. 5, 2021) ("[T]o the extent Plaintiffs base their failure to warn claims on [the device manufacturer's] alleged failure to properly conduct the post-approval studies, Plaintiffs' claims are impliedly preempted because Plaintiffs do not identify a parallel state law duty to conduct post-approval studies."); *Sewell v. Mentor Worldwide, LLC*, 2021 U.S. App. LEXIS 3276, at *4–

5 (9th Cir. Feb. 5, 2021) (same); *Vieira v. Mentor Worldwide, LLC*, No. 19-56394, 2021 U.S. App. LEXIS 3279, at *4 (9th Cir. Feb. 5, 2021) (same); *Billetts v. Mentor Worldwide, LLC*, 2021 U.S. App. LEXIS 3272, at *4 (9th Cir. Feb. 5, 2021) (same); *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1281 (10th Cir. 2021) (citations omitted) ("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."); *Ebrahimi v. Mentor Worldwide LLC*, No. 16-7316-DMG (KSx), 2017 U.S. Dist. LEXIS 153840, at *12 (C.D. Cal. Sept. 15, 2017) (citing *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 881 (N.D. Cal. 2013)) ("[T]o the extent [the plaintiff] bases her failure-to-warn claim on [the device manufacturer's] failure to comply with the federal requirement to complete the six post-approval studies, the claim is impliedly preempted."). Therefore, the Court concludes Plaintiffs' negligent failure to warn claims alleging Allergan's failure to conduct post-PMA clinical studies are preempted.

**6. Plaintiffs' Implied Warranty Claims Are Not Preempted**

Allergan argues an implied warranty claim targeting the safety and effectiveness of a PMA-approved medical device is expressly preempted. (ECF No. 171-1 at 36.) Allergan maintains it is following federal law, and therefore any claim premised on alleged faults in the FDA-approved design is expressly preempted. (ECF No. 238 at 43.) Plaintiffs counter their implied warranty claims are not preempted, because they parallel violations of federal law: the BIOCELL implants are not merchantable due to the violations of federal requirements regarding manufacturing and labeling. (ECF No. 216 at 71.) The Court agrees these claims are not preempted.

"State law claims for breach of implied warranty may be preempted to the extent that they impose new or additional requirements on manufacturers beyond the federal regulations

governing the medical device at issue." *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 356 (D. Del. 2019) (citations omitted). But a state law claim for breach of implied warranty is "viable," "to the extent [it] seek[s] recovery for conduct that may also have violated the FDCA." *In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 781, 792 (3d Cir. 1999). Here, Plaintiffs' claims are not imposing requirements that are different from, or in addition to, the federal ones. Instead, Plaintiffs claim the BIOCELL implants are not merchantable solely because of Allergan's alleged failure to comply with the FDA regulations and the FDCA's adulteration provisions. (ECF No. 119 at ¶ 240.) Therefore, Plaintiffs' claims are not expressly preempted, because they parallel violations of federal law. *C.f. Freed*, 364 F. Supp. 3d at 356 (dismissing the plaintiff's state law claims for breach of implied warranty as expressly preempted, because the plaintiff does not allege violation of any federal regulations or plead facts setting out the specifics of the breaches at issue); *Bentzley v. Medtronic, Inc.*, 827 F. Supp. 2d 443, 454 (E.D. Pa. 2011) (finding express preemption of the plaintiff's implied warranty of merchantability claim that asserts the defendant's medical device is "not merchantable for its intended use because of its tendency to infuse the incorrect dosage of insulin," which represents a standard different from, or in addition to, the federal requirements); *Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 455 (D.N.J. 2003) (concluding the MDA preempts the plaintiff's implied warranty claims, which "impose safety and effectiveness requirements . . . that, if successful, would differ from, or impose additional requirements to, those requirements established by the FDA on [the defendant's] device").

The Court need not address the issue of implied preemption, which Allergan does not raise. Accordingly, the Court concludes Plaintiffs' implied warranty claims are not preempted.

**7. Plaintiffs' Claims for Negligent Misrepresentation, Breach of Express Warranty, and Breach of State Consumer Fraud and Deceptive Trade Practice Statutes Are Not Preempted**

Allergan argues, for Plaintiffs' warranty or misrepresentation claims to survive preemption, they must be supported by allegations of Allergan's representations occurring outside the approval process and going beyond what the device's labeling encompasses, which Plaintiffs have not pled. (ECF No. 262 at 15–16.) Allergan stresses Plaintiffs allege no specific statements of Allergan that formed the basis of any purported bargain entered by Plaintiffs or that materially deviated from language approved by the FDA. (*Id*. at 16.) Plaintiffs assert several of their misrepresentation-based claims are not preempted, because Allergan did not argue in its opening brief that these claims were preempted, thereby waiving such preemption arguments. (ECF No. 216 at 68.) The Court agrees the claims are not preempted.

"Absent compelling circumstances not present here, failure to raise an argument in one's opening brief waives it." *Anspach v. City of Philadelphia*, 503 F.3d 256, 258 n.1 (3d Cir. 2007) (citations omitted); *see also Holk v. Snapple Bev. Corp.*, 575 F.3d 329, 337 n.5 (3d Cir. 2009) ("An issue is waived unless a party raises it in its opening brief."). Preemption arguments are not except from this waiver rule. *See Eagle Sys. v. Asaro-Angelo*, No. 18-11445, 2019 U.S. Dist. LEXIS 127972, at *9 (D.N.J. July 31, 2019). Allergan did not argue in its opening brief that Plaintiffs' claims for negligent misrepresentation, breach of express warranty, and breach of state consumer fraud and deceptive trade practice statutes were preempted, and has not explained why it could not have done so. Therefore, Allergan has waived the preemption arguments against these claims.

Notwithstanding the waiver, these claims are not preempted. As discussed in Part III.B.6.a, *infra*, the PIC has at least sufficiently alleged a misleading promotional YouTube video

that Allergan authored concerning the safety features of its Natrelle Breast Implants, which constitutes an off-label representation not approved by the FDA. Therefore, Plaintiffs' claims for negligent misrepresentation, breach of express warranty, and breach of state consumer fraud and deceptive trade practice statutes are supported by adequate factual allegations. To the extent these claims are based on Allergan's statements not approved by the FDA, they are not preempted. *Hart v. Medtronic, Inc.*, No. 1:16-cv-05403, 2017 U.S. Dist. LEXIS 196837, at *14 (D.N.J. Nov. 30, 2017) (citations omitted) ("An express warranty claim is not preempted under the MDA if a Plaintiff can show that Defendants made 'voluntary statements' that were 'not approved by the FDA or mandated by the FDA about the use or effectiveness' of a medical device."); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 827 (E.D. Pa. 2016) (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008)) ("Plaintiffs can potentially allege cognizable and parallel misrepresentation claims at least insofar as they allege [the defendant] made false or misleading statements . . . that were inconsistent with specific statements in approved FDA materials."); *Morton v. Allegran, Inc.*, No. 14-cv-1312, 2015 U.S. Dist. LEXIS 188871, at *9–10 (D.N.J. April 2, 2015) (recognizing the plaintiff's claims for negligent misrepresentation and breach of state consumer fraud statute, if adequately pleaded, may satisfy "a narrow exception for a 'parallel' claim, e.g., 'a damages remedy for claims premised on a violation of FDA regulations'" to avoid preemption under the MDA); *Horn v. Thoratec Corp.*, 376 F.3d 163, 168 (3d Cir. 2004) (citing *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1325–31 (3d Cir. 1995)) ("[The plaintiff's] claims for breach of express warranty (based on the [device's] packaging materials) and fraud (based on the manufacturer's advertisements and promotional materials), neither of which were the subject of the FDA's PMA approval, were held not to be preempted."); *Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 456 (D.N.J. 2003) (citing *Michael*, 46 F.3d at

1328) ("[A]ny express warranty claims that are based on representations made by [the device manufacturer] concerning non-FDA approved promotional and advertising materials also are not preempted by the MDA because those claims arise out of a private contractual agreement rather than 'a product of state action.'").

Finally, both parties agree Plaintiffs' claims concerning Allergan's tissue expanders and implants sold before the 2000 PMA are not preempted. (ECF No. 119 at ¶ 43; ECF No. 171-1 at 22; ECF No. 261 at 37:7–8.) Indeed, Allergan's tissue expanders and pre-PMA implants were sold through the 510(k) process (ECF No. 119 at ¶¶ 5, 43, 46), which does not trigger preemption. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493–94 (1996).

In conclusion, the Court finds the following Plaintiffs' claims are preempted and therefore dismissed: (1) label-based failure to warn claims; (2) claims challenging the safety or effectiveness of Allergan's investigational devices used in an approved clinical trial; and (3) negligent failure to warn claims based on Allergan's alleged failure to conduct post-PMA clinical studies. The above preemptions, however, do not apply to Plaintiffs' claims concerning Allergan's tissue expanders and implants sold before the 2000 PMA, as set forth above and as agreed upon by the parties. (ECF No. 119 at ¶ 43; ECF No. 171-1 at 22; ECF No. 261 at 37:7–8.)

**B. Allergan's Motion to Dismiss on Non-Preemption Grounds (ECF No. 171-3)**

Allergan argues Plaintiffs raise novel state law personal injury claims that have not been authorized by a state statute or adopted by any state's highest court, and this Court should not recognize such claims under the *Erie* doctrine. (ECF No. 171-3 at 10.) Allergan maintains, when confronted with open questions of state law liability, federal courts in this Circuit must opt for the interpretation that restricts liability, rather than expands it, until the state's highest court decides differently. (ECF No. 236 at 6.) However, Allergan concedes the Court need not rely

solely on the decisions of a state's highest court in interpreting state laws. (ECF No. 261 at 64:20–21.) Plaintiffs contend the *Erie* doctrine does not mandate the dismissal of all the state claims not recognized by that state's highest court. (ECF No. 220 at 17.) Instead, they assert, if the state's highest court has not spoken, district courts sitting in diversity must predict what the state's highest court would decide. (*Id.* at 17–18.) The Court agrees the *Erie* doctrine does not mandate dismissal.

"Under the *Erie* doctrine, federal courts sitting in diversity apply state substantive law and federal procedural law." *Gasperini v. Ctr. for Humanities*, 518 U.S. 415, 427 (1996). "A state is not without law save as its highest court has declared it." *West v. AT&T Co.*, 311 U.S. 223, 236 (1940). "There are many rules of decision commonly accepted and acted upon by the bar and inferior courts which are nevertheless laws of the state although the highest court of the state has never passed upon them." *Id.* "In those circumstances a federal court is not free to reject the state rule merely because it has not received the sanction of the highest state court." *Id.* "State law is to be applied in the federal as well as the state courts and it is the duty of the former in every case to ascertain from all the available data what the state law is and apply it." *Id.* at 237. "In predicting how a matter would be decided under state law," a federal court should examine: "(1) what the [State's] Supreme Court has said in related areas; (2) the decisional law of the [State's] intermediate courts; (3) federal appeals and district court cases interpreting state law; and (4) decisions from other jurisdictions that have discussed the issues we face here." *Hughes v. Long*, 242 F.3d 121, 128 (3d Cir. 2001) (citing *Boyanowski v. Capital Area Intermediate Unit*, 215 F.3d 396, 406 (3d Cir. 2000)). "[W]here 'two competing yet sensible interpretations' of state law exist," a federal court "should opt for the interpretation that restricts liability, rather than expands it, until the Supreme Court of [the State] decides differently." *Travelers Indem. Co. v.*

*Dammann & Co.*, 594 F.3d 238, 253 (3d Cir. 2010) (citing *Werwinski v. Ford Motor Co.*, 286 F.3d 661, 680 (3d Cir. 2010)). Therefore, even if a state's highest court has not decided whether a particular state law claim exists, the Court will predict what the state's highest court may decide by looking into other relevant legal authorities.

**1. The Court Will Review the PIC with Leniency**

As a threshold matter, Plaintiffs state Allergan's motion to dismiss on non-preemption grounds is premature at this stage. (ECF No. 220 at 20.) Plaintiffs claim an MDL master complaint is an administrative tool to assist discovery and allows a court to decide on common issues of fact or law. (*Id.*) Plaintiffs contend a master complaint does not set forth any Plaintiff's specific facts, and does not necessarily include complete recitations of the factual bases and claims a Plaintiff may assert, which makes dismissal of any specific claim alleged in the PIC premature. (*Id*. at 21.) Therefore, Plaintiffs maintain, any ruling on the PIC would have to take the individually filed complaints into account. (*Id*. at 22.) Plaintiffs suggest the decision on matters specific to each Plaintiff and its State should be left for later proceedings. (*Id*.) Allergan insists the Court should narrow Plaintiffs' claims where Plaintiffs have failed to state a claim upon which relief can be granted. (ECF No. 236 at 8.) Allergan asks the Court to apply Rules 8 and 12. (*Id*. at 10.) For the reasons set forth below, the Court will apply some leniency in reviewing the PIC.

In an MDL, "parties may elect to file a master complaint and a corresponding consolidated answer, which supersede prior individual pleadings." *Gelboim v. Bank of Am. Corp.*, 574 U.S. 405, 413 n.3 (2015). "In such a case, the transferee court may treat the master pleadings as merging the discrete actions for the duration of the MDL pretrial proceedings." *Id*. "No merger occurs, however, when the master complaint is not meant to be a pleading with legal

effect but only an administrative summary of the claims brought by all the plaintiffs." *Id*. "When plaintiffs file a master complaint of this variety, each individual complaint retains its separate legal existence." *In re Refrigerant Compressors Antitrust Litig.*, 731 F.3d 586, 590 (6th Cir. 2013). "Where defendants bring a motion to dismiss that raises issues common to all plaintiffs, however, the administrative nature of a Master Complaint does not necessarily preclude 12(b)(6) motion practice." *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, No. 11 C 5468, 2012 U.S. Dist. LEXIS 117239, at *21–22 (N.D. Ill. Aug. 16, 2012). "[W]hen the information that may or may not support Plaintiffs' claims is largely within the control of the Defendants," the court may "assess the sufficiency of plaintiffs' claims with substantial leniency." *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-1928-MIDDLEBROOKS, 2009 U.S. Dist. LEXIS 65481, at *71 (S.D. Fla March 4, 2009).

Here, Plaintiffs consider the PIC as "an administrative method to set forth common facts and potential claims which individual Plaintiffs . . . may assert against Allergan." (ECF No. 119 at 4.) The individual Short Form Complaint to be filed by each Plaintiff will adopt the pleadings in the PIC. Therefore, in this motion to dismiss inquiry, the Court will not afford special leniency in reviewing such "common facts" as presented in the PIC. However, the Court will review, with substantial leniency, the facts that may be specific to each individual Plaintiff or largely within the control of Allergan. In other words, the lack of potentially individualized factual allegations of Plaintiffs, such as causation of individual Plaintiffs' injuries, will not be a ground for dismissal. The Court understands each Plaintiff may allege in its Short Form Complaint facts not mentioned in the PIC.

**2. The Court Will Not Scrutinize Whether Plaintiffs Have Sufficiently Alleged Present Injuries in the PIC**

Allergan contends Plaintiffs not diagnosed with BIA-ALCL do not have a legally cognizable injury to bring this MDL (ECF No. 171-3 at 11), which is formed for the very specific injury of BIA-ALCL (ECF No. 261 at 49:18–24). Allergan claims any alleged injuries without clinical significance are merely potential precursors to a harm that may never be realized (ECF No. 236 at 11). Allergan maintains most states do not recognize tort claims for an "increased risk" or "fear of developing a disease due to exposure" without a currently manifest physical injury. (ECF No. 171-3 at 11–12.) As for medical monitoring, Allergan suggests most states reject it as a relief, and the few states that allow medical monitoring as a relief or a cause of action require the plaintiff to first demonstrate a legally cognizable injury. (*Id*. at 12.) Plaintiffs claim to have sustained physical injuries even if they are not diagnosed with BIA-ALCL; such injuries include: (1) tissue damage; (2) a collection of fluid built up under the skin (called a "seroma"); (3) unchecked T-cell proliferation; (4) malignant T-cell mutation; and (5) chronic physiologic inflammation. (ECF No. 220 at 25.) Additionally, Plaintiffs claim to have sustained injuries in the diagnostic procedures to detect BIA-ALCL, and the surgeries to remove the BIOCELL implants from their bodies and, in some cases, replace it with a non-defective implant. (*Id*. at 25–26.) Finally, Plaintiffs seek damages for emotional distress, which includes the fear of cancer. (*Id*. at 27.)

The Court finds the question of whether present injuries exist is a factual issue specific to each individual Plaintiff, and should not be scrutinized at this stage. Each Plaintiff is entitled to allege its own present injuries, including the diagnosis of BIA-ALCL, separately in the Short Form Complaint. Accordingly, the Court will not dismiss Plaintiffs' claims, including the

requests for the relief of medical monitoring, fear of or increase risk of cancer, based on a failure to allege present injuries in the PIC.

**3. Plaintiffs' Manufacturing Defect Claims Should Not Be Dismissed**

Allergan contends Plaintiffs fail to identify a single manufacturing defect for the manufacturing defect claims, but rather attack the manufacturing process of the BIOCELL implants and allege the textured surface of every device is defective as a result of that process. (ECF No. 171-3 at 14–15.) Allergan relies on *Coba* to argue these claims actually target the design defect of the BIOCELL implants and therefore should be dismissed. (*Id.* at 15 (citing *Coba v. Ford Motor Co.*, 932 F.3d 114, 123–24 (3d Cir. 2019)).) Plaintiffs claim to have described in the PIC that the BIOCELL implants deviate from their intended and approved design specifications. (ECF No. 220 at 29.) The Court agrees.

The alleged manufacturing defects in the BIOCELL implants involve individualized factual issues, as the actual implant used, including its possible defects, is unique to each Plaintiff. Further, the product information of the implants is primarily within the control of Allergan. Therefore, at this stage, the Court will not dismiss Plaintiffs' manufacturing defect claims solely based on an insufficiency of manufacturing defects alleged in the PIC.

Even an exhaustive Rule 12(b)(6) analysis does not warrant dismissal of Plaintiffs' manufacturing defect claims. 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," and "cannot simply demonstrate a defect or a malfunction and rely on *res ipsa loquitur* to suggest only . . . that the thing speaks for itself." *Nunn v. Mentor Worldwide, LLC*, No. 19-56391, 2021 U.S. App. LEXIS 3286, at *4 (9th Cir. Feb. 5, 2021) (citing *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1112 (9th Cir. 2019)); *Sewell v. Mentor Worldwide, LLC*, 2021 U.S. App. LEXIS 3276, at *5 (9th Cir. Feb. 5, 2021) (same);

*Vieira v. Mentor Worldwide, LLC*, No. 19-56394, 2021 U.S. App. LEXIS 3279, at *4–5 (9th Cir. Feb. 5, 2021) (same); *Billetts v. Mentor Worldwide, LLC*, 2021 U.S. App. LEXIS 3272, at *4–5 (9th Cir. Feb. 5, 2021) (same). Allergan concedes a manufacturing defect is "a deviation from the manufacturer's intended specifications that renders the device unreasonably dangerous." (ECF No. 171-3 at 14–15.) The PIC has alleged exactly that. For example, Plaintiffs allege Allergan's scrubbing process used different brushes and un-validated methods that violated PMA requirements, and resulted in a defectively manufactured surface with particle residues unintended by the product specifications approved by the FDA, causing severe harm to patients. (ECF No. 119 at ¶ 118.) Allergan argues the PMA does not specify a prohibition of the surface particles (ECF No. 261 at 43:8–10), but this does not make the particles a part of the FDA-approved product specifications.

Even if Allergan is correct that Plaintiffs fail to specifically allege a deviation of the implants from their PMA-approved specifications, as discussed in Part III.A.2, *supra*, fairness compels some leniency be afforded to Plaintiffs in asserting their manufacturing defect claims at this stage, because Plaintiffs may not have access to the confidential information to specifically plead Allergan's deviations. Accordingly, the Court declines to dismiss Plaintiffs' manufacturing defect claims based on a potentially inadequate identification of deviations from the PMA-approved specificications.

Finally, *Coba* is inapposite here. The defects in *Coba* involved the delamination of a vehicle's fuel tank coatings, "whereby particles of the tank lining would separate from the underlying metal and mix with the vehicle's fuel." *Coba*, 932 F.3d at 117. The delamination was caused by the exposure of the fuel tank coatings to "the acetic and formic acids in fuel," which the coatings could not "tolerate." *Id*. at 123. In other words, in *Coba*, the defects associated with

delamination, including the particles of the tank lining, were not a part of the fuel tank in its manufactured form; instead, the defect resulted from the erosions of the fuel tank after it was manufactured, and was caused by an external matter, i.e., the fuel. The *Coba* court decided the fuel tank defect was a design defect. *Id*. But this is different from the alleged defects in the BIOCELL implants, which involve unintended surface particles in the implants' manufactured form.

Accordingly, the Court will not dismiss Plaintiffs' manufacturing defect claims.

#### 4. Plaintiffs' Negligence *Per Se* Claims Are Not Viable in Some Jurisdictions

Allergan insists Plaintiffs' negligence *per se* claims fail for multiple independent reasons. (ECF No. 171-3 at 15.) Allergan explains many states do not recognize any negligence *per se* claim, or do not allow a negligence *per se* claim based on alleged FDCA or CGMP violations. (*Id*. at 16–18.) Plaintiffs argue the FDCA can be and is actually recognized as the basis for a negligence *per se* claim. (ECF No. 220 at 36–39.) The Court finds Plaintiffs cannot assert an FDCA/CGMP-based negligence *per se* claim in some jurisdictions.

The following jurisdictions do not allow any negligence *per se* claim or an FDCA/CGMP-based negligence *per se* claim concerning a prescription device:

- Alaska. *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200–01 (Alaska 1992) (affirming a lower court's decision not to give a negligence *per se* instruction in action against a prescription drug manufacturer, where the negligence *per se* claim is under the misbranding provisions of Alaska's Food, Drug, and Cosmetics Act, because the state statute, using the same languages in FDCA's misbranding provisions, is too vague to define a reasonable standard of care). Though *Shanks* did not conclude that no provision of FDCA/CGMP could form the basis

of a negligence *per se* claim, the Court does not discern any legal authority in Alaska that recognizes an FDCA/CGMP-based negligence *per se* claim concerning a prescription device.

- Arkansas. *Central Okla. Pipeline, Inc. v. Hawk Field Services, LLC*, 400 S.W.3d 701, 712 (Ark. 2012) (citing *Shannon v. Wilson*, 947 S.W.2d 349 (Ark. 1997)) ("Under Arkansas law, the violation of a statute is only evidence of negligence and does not constitute negligence *per se*.").

- Colorado. *Liby v. City Park Family*, No. 2011-CV-436, 2012 Colo. Dist. LEXIS 781, at *12 (D. Colo. Feb. 27, 2012) ("[T]he FDCA and its underlying regulations cannot serve as a basis for a negligence *per se* claim."). Plaintiffs argue *Franklin* recognized the viability of FDCA/CGMP-based negligence *per se* claims. (ECF No. 220-1 at 96 (citing *Franklin v. Medtronic, Inc.*, No. 09-cv-02301-REB-KMT, 2010 U.S. Dist. LEXIS 71069 (D. Colo. May 12, 2010)).) The Court does not read such a ruling into *Franklin*. The *Franklin* court found the plaintiff's negligence *per se* claim was preempted, because "the underlying allegations [were] far too conclusory and factually deficient to state a plausible 'parallel' claim," and were only "facially 'premised on a violation of FDA regulations.'" *Franklin*, 2010 U.S. Dist. LEXIS 71069, at *30. But this does not mean, if the plaintiff in *Franklin* sufficiently alleged a violation of FDA regulations, its negligence *per se* claim would surely be viable. The *Franklin* court did not analyze other factors under Colorado law that may preclude FDCA/CGMP-based negligence *per se* claims, such as those considered in *Liby* in rejecting FDCA-based negligence *per se* claims. *Liby*, 2012 Colo. Dist. LEXIS 781, at *5–6.

- Connecticut. *Norman v. Bayer Corp.*, No. 3:16-cv-00253 (JAM), 2016 U.S. Dist. LEXIS 96993, at *14 (D. Conn. July 26, 2016) (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001)) (concluding the plaintiff's negligence *per se* claim based on "several

FDA statutes and regulations . . . arise[d] directly and wholly derivatively from the violation of federal law," and "is therefore subject to implied preemption").

- Florida. *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1200 (M.D. Fla. 2013) (citations omitted) ("As with Plaintiff's claims . . . for negligence *per se* and failure to warn, Plaintiff's attempt to recast a claim for violation of the FDCA as a state-law negligence claim is impliedly barred by § 337(a)."); *McClelland v. Medtronic, Inc.*, No. 6:11-CV-1444-Orl-36KRS, 2012 U.S. Dist. LEXIS 152197, at *12–13 (M.D. Fla. 2012) (citations and internal quotations omitted) ("[U]nder Florida law, the violation of a statute can only give rise to civil liability if the statute indicates an intention to create a private cause of action. The FDCA expressly provides that all actions to enforce the Act shall be by and in the name of the United States. This language evidences legislative intent to prohibit a private right of action for a violation of the FDCA. Therefore, Plaintiff cannot assert a negligence *per se* claim based on violations of the FDCA or the FDA's implementing regulations.").

- Georgia. *Green v. Medtronic, Inc.*, No. 1:19-CV-3242-TWT, 2020 U.S. Dist. LEXIS 145524, at *11 (N.D. Ga. May 1, 2020) (citing *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 U.S. Dist. LEXIS 93176, at *23 (N.D. Ga. Aug. 19, 2011)) ("Nor may a negligence per se claim be premised on breaches of duties created by the FDCA."); *Scoggins v. Floyd Healthcare Mgmt.*, No. 4:14-CV-00274-HLM-WEJ, 2016 U.S. Dist. LEXIS 201663, at *107 (N.D. Ga. June 10, 2016) (citing *Miller v. Chase Home Fin., LLC*, No. 2:10-CV-206-WCO, 2011 WL 10944693 (N.D. Ga. Oct. 6, 2011), *aff'd*, 677 F.3d 1113 (11th Cir. 2012)) ("[A] claim for negligence *per se* [under Georgia law] fails if the statute or regulation establishing the claimed legal duty does not provide a cause of action for damages for its violation."); *Horn v. Boston Sci. Neuromodulation Corp.*, No. CV409-074, 2011 U.S. Dist. LEXIS 102164, at *25

(S.D. Ga. 2011) ("[B]ecause [CGMPs] fail to provide any tangible or concrete standard, this Court agrees that to allow a violation of such a flexible standard to result in liability would, in itself, be imposing a standard 'different from, or in addition to' those imposed by the MDA. 21 U.S.C. § 360k(a)(1). Indeed, any claim based on the QSRs or similarly vague FDA regulations would fail under comparable reasoning.").

- Hawaii. *Sailola v. Mun. Servs. Bureau*, No. 13-00544 HG-RLP, 2014 U.S. Dist. LEXIS 93087, at *23 (D. Haw. July 9, 2014) (citing *Aana v. Pioneer Hi-Bred Intern., Inc.*, 65 F.Supp.2d 1157, 1175 (D. Haw. 2013)) ("Hawaii law does not recognize a negligence *per se* cause of action for violation of a statutory standard.").

- Indiana. *Bayer Corp. v. Leach*, 153 N.E.3d 1168, 1179 (Ind. Ct. App. 2020) (concluding the plaintiff's negeligence *per se* claim is impliedly preempted to the extent it is premised "on a standard imported from the Indiana FDCA," which "is specifically designed to parallel federal requirements" in the FDCA); *Cavender v. Medtronic, Inc.*, No. 3:16-CV-232, 2017 U.S. Dist. LEXIS 57376, at *17–18 (N.D. Ind. April 14, 2017) (finding the plaintiff's negligence *per se* claim based on federal regulations "is not a cognizable independent claim and is subsumed by the [Indiana Product Liability Act]").

- Kansas. *Brooks v. Mentor Worldwide, LLC*, No. 19-2088-KHV, 2019 U.S. Dist. LEXIS 161820, at *10 n.5 (D. Kan. Sept. 23, 2019), *aff'd* 985 F.3d 1272 (10th Cir. 2021) (citations omitted) ("Plaintiffs cannot recover under the theory of negligence *per se* based on violations of the FDCA. In Kansas, negligence *per se* 'is limited to violations of a statute where the legislature intended to create an individual right of action for injury arising out of a statutory violation.'").

- Kentucky. *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 681 (W.D. Ky. 2013) ("Plaintiffs' negligence *per se* claims, which are premised upon violations of federal law, are not cognizable as a matter of Kentucky law and must be dismissed.").

- Louisiana. *King v. Bayer Pharms. Corp.*, No. 09-0465, 2009 U.S. Dist. LEXIS 125802, at *11–12 (W.D. La. June 8, 2009) (citing *Jefferson v. Lead*, 106 F.3d 1245, 1251 (5th Cir. 1997)) ("Plaintiffs' claims against Defendants for strict liability, negligence and negligence *per se* are not viable as independent theories of recovery outside of the [Louisiana Products Liability Act] framework.").

- Maine. *Binette v. Dyer Library Ass'n*, 688 A.2d 898, 904 (Me. 1996) (citations omitted) ("Maine does not recognize the doctrine of negligence *per se*.").

- Maryland. *Webb v. Green Tree Servicing, LLC*, No. ELH-11-2105, 2012 U.S. Dist. LEXIS 79451, at *18 (D. Md. June 7, 2012) ("Maryland does not recognize the negligence *per se* doctrine.").

- Massachusetts. *Amoah v. McKinney*, No. 4:14-40181-TSH, 2016 U.S. Dist. LEXIS 191864, at *45 n.15 (D. Mass. Sept. 2, 2016) (citing *Juliano v. Simpson*, 962 N.E.2d 175, 179 (Mass. 2012)) ("[A] theory of negligence *per se* . . . is not recognized by Massachusetts law.").

- Michigan. *Barnes v. Birds Eye Foods, Inc.*, No. 1:10-cv-541, 2011 U.S. Dist. LEXIS 166587, at *15 (W.D. Mich. Sept. 26, 2011) ("Michigan law does not recognize negligence *per se* as an independent cause of action . . .").

- Minnesota. *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1152 (D. Minn. 2011) (citations omitted) ("A negligence-*per-se* claim that is predicated on an alleged

violation of the FDCA is, by definition, a claim that would give rise to liability under Minnesota law only because of the FDCA's enactment. Such a claim is preempted under *Buckman*.").

- Nebraska. *Scheele v. Rains*, 874 N.W.2d 867, 872 (Neb. 2016) (citations omitted) ("[T]he violation of a regulation or statute is not negligence per se, but may be evidence of negligence to be considered with all the other evidence in the case."); *Orduna v. Total Constr. Servs.*, 713 N.W.2d 471, 479 (Neb. 2006) (citations omitted) ("[T]he violation of a statute is not negligence per se, but is evidence of negligence.").

- Nevada. *Miller v. DePuy Spine, Inc.*, 638 F. Supp. 2d 1226, 1231 (D. Nev. 2009) (citations omitted) ("Congress has stated its intent that the FDCA and regulations thereunder be enforced only by the U.S. Government, . . . Nevada law [therefore] would not provide a damages remedy for any violation of FDA regulations," and will "refus[e] to impose negligence *per se* for violation of a statute in absence of legislative intent to impose civil liability.").

- New Hampshire. *Bartlett v. Mut. Pharm. Co.*, 731 F. Supp. 2d 135, 155 (D.N.H. 2010) (citations omitted) (predicting "the New Hampshire Supreme Court would not treat [the defendant's] violation of 21 C.F.R. § 314.80(b)[4] as establishing a *per se* breach of its duty of care, but rather would allow the jury to consider that violation as evidence of such a breach"). Though *Bartlett* did not conclude that no provision of FDCA/CGMP could form the basis of a negligence *per se* claim, the Court does not discern any legal authority in New Hampshire that recognizes an FDCA/CGMP-based negligence *per se* claim concerning a prescription device.

- New Jersey. *Green v. 712 Broadway, LLC*, No. 17-991, 2018 U.S. Dist. LEXIS 96657, at *18 (D.N.J. June 8, 2018) (citing *Sang Geoul Lee v. Won Il Park*, 720 F. App'x 663, 666 (3d Cir. 2017)) ("Under New Jersey law, a claim of negligence *per se* is supported by the

[4] The FDA regulation for postmarketing reporting of adverse drug experiences

violation of a statute or regulation, but only when that statute or regulation serves to impose direct tort liability on the person who offends it.").

- New Mexico. *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1240 (D.N.M. 2008) ("The Court is not certain how it could let proceed a negligence *per se* claim based on the FDCA and its regulations without interpreting and applying in some way the FDA's regulations. Because the Tenth Circuit has indicated that such a private cause of action for violation of the FDCA is foreclosed, [the defendant] is entitled to summary judgment as a matter of law on [the plaintiff's] negligence *per se* claim.").

- North Carolina. *Hill v. Danek Med., Inc.*, No. 4:96-CV-177-H1, 1998 U.S. Dist. LEXIS 21749, at *6 n.1 (E.D.N.C. Sept. 9, 1998) ("[T]o the extent that plaintiffs' complaint can be said to present a negligence *per se* claim for violations of the FDCA . . . a negligence *per se* claim is nothing but a disguised attempt at private FDCA enforcement, which is precluded by law.").

- North Dakota. *Mehl v. Canadian Pac. Ry.*, 417 F. Supp. 2d 1104, 1118 (D.N.D. 2006) (citing *Kimball v. Landeis*, 652 N.W. 2d 330, 336 (N.D. 2002)) ("North Dakota law does not recognize a claim for negligence *per se*.").

- Rhode Island. *State v. Purdue Pharma L.P.*, No. PC-2018-4555, 2020 R.I. Super. LEXIS 34, at *6 (R.I. Super. May 5, 2020) (citing *Salcone v. Bottomley*, 129 A.2d 635, 637 (R.I. 1957)) ("Rhode Island does not recognize negligence *per se* as a cause of action.").

- Texas. *Monk v. Wyeth Pharms., Inc.*, No. SA-16-CV-1273-XR, 2017 U.S. Dist. LEXIS 72477, at *23 (W.D. Tex May 11, 2017) ("Texas law likely does not recognize a cause of action for negligence per se based solely on the violation of the FDCA and FDA regulations."); *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex 2012) (citations omitted)

("[T]he FDCA and FDA regulations do not give rise to a negligence per se cause of action under the standard the Texas Supreme Court established in *Perry v. S.N.*, 973 S.W.2d 301, 41 Tex. Sup. Ct. J. 1162, (Tex. 1998).").

- Utah. *Colosimo v. Gateway Cmty. Church*, 424 P.3d 866, 882 n.82 (Utah 2018) ("So it is only after a statute or ordinance is adopted by the court as the standard of conduct of a reasonable person, thereby imposing a duty recognizable in tort, that a court will then determine whether a violation thereof constitutes prima facie evidence of negligence or negligence per se."); *Gaw v. State*, 798 P.2d 1130, 1135 (Utah Ct. App. 1990) ("The violation of a statute does not necessarily constitute negligence *per se* and may be considered only as evidence of negligence. The violation may be regarded as prima facie evidence of negligence, but is subject to justification or excuse.").

- Washington. *Veridian Credit Union v. Eddie Bauer, LLC*, 295 F. Supp. 3d 1140, 1150 (W.D. Wash. 2017) (citing RCW 5.40.050) ("In Washington, . . . the violation of a statute or the breach of a statutory duty is not considered negligence *per se*, but may be considered by the trier of fact only as evidence of negligence.").

- West Virginia. *Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, 2017 WL 275452, at *2 (S.D. W. Va. Jan. 19, 2017) (citations omitted) ("The plaintiff cannot properly state a negligence *per se* claim under the Food, Drug, and Cosmetics Act."); *Gillingham v. Stephenson*, 551 S.E.2d 663, 670 (W. Va. 2001) (citations omitted) ("In West Virginia a 'violation of a statute is prima facie negligence and not negligence per se.'"). Plaintiffs cite *Digitek*, where the court denied the defendant's motion to dismiss the plantiffs' FDCA-based negligence *per se* claim. (ECF No. 220-1 at 132 (citing *In re Digitek Prods. Liab. Litig.*, No. 2:08-md-01968, 2009 U.S. Dist. LEXIS 113947 (S.D.W. Va. Aug. 3, 2009)).) But *Digitek* involved an MDL

proceeding, where the court did not conduct a state-by-state analysis of the viability of the plaintiffs' claims. *Digitek*, 2009 U.S. Dist. LEXIS 113947, at *111. Therefore, *Digitek* said nothing about whether West Virginia recognized an FDCA/CGMP-based negligence *per se* claim.

The following jurisdictions allow an FDCA/CGMP-based negligence *per se* claim:

- Alabama. *Allen v. Delchamps, Inc.*, 624 So. 2d 1065, 1067–68 (Ala. 1993) (finding the FDCA may "establish a duty or standard of care" for the plaintiff's negligence *per se* claim).

- Arizona. *Conklin v. Medtronic, Inc.*, 418 P.3d 912, 920 (Ariz. Ct. App. 2019) (finding certain FDCA provisions and FDA regulations "may be adopted as a standard of conduct to support a negligence per se claim").

- California. *Bird v. Globus Med., Inc.*, No. 19-cv-1024-KJM-CKD, 2020 U.S. Dist. LEXIS 164480, at *16 (E.D. Cal. Sept. 4, 2020) ("Because plaintiffs' negligence per se claim is also based on a state law duty that appears to parallel federal law, it also is not preempted by the MDA."); *Mize v. Mentor Worldwide LLC*, 265 Cal. Rptr. 3d 468, 481 (Cal. Ct. App. 2020) (allowing the plaintiff to "pursue her negligence *per se* claim" based on the defendant device manufacturer's alleged "manufacturing defects and its failure to properly report adverse events to the FDA [that] caused her injuries" in violation of "the MDA and FDA regulations"); *Coleman v. Medtronic, Inc.*, 167 Cal. Rptr. 3d 300, 316 (Cal. Ct. App. 2014) (allowing the plaintiff's negligence *per se* claim based on FDCA violations); *Knoppel v. St. Jude Med., Inc.*, No. SACV 13-383 JVS (ANx), 2013 U.S. Dist. LEXIS 201072, at *19 (C.D. Cal. Sept. 24, 2013) (concluding "Plaintiffs have stated a claim for negligence per se," because "to the extent

Plaintiffs' negligence per se claim invokes federal statutes in order to articulate a standard of care for medical device manufacturing, it is not impliedly preempted").

- Delaware. *Price v. Blood Bank of Del., Inc.*, 790 A.2d 1203, 1213 (Del. 2002) (ruling the "plaintiff is entitled to a negligence *per se* instruction if he establishes a factual basis for causation" despite "the general language of the FDA protocol" that underlies the plaintiff's negligence *per se* claim).

- District of Columbia. *Iacangelo v. Georgetown Univ.*, 580 F. Supp. 2d 111, 119–20 (D.D.C. 2008) (allowing the plaintiff's negligence *per se* claims based on alleged FDCA violations upon the plaintiff's "demonstrating that the statute creates a reasonable standard of care").

- Illinois. *Sellers v. Boehringer Ingelheim Pharms., Inc.*, 881 F. Supp. 2d 992, 1010 (S.D. Ill. 2012) (holding "the plaintiff has asserted facts sufficient to support a plausible claim for relief under the theory of negligence per se," because "the plaintiff has alleged that, under Illinois common law, [the defendant] owed a duty of care to the plaintiff and that the FDCA provides the definition for the standard of care owed to the plaintiff," and "the fact that there is no private right of action under the FDCA does not warrant dismissal of the plaintiff's negligence per se claims").

- Mississippi. *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 772 & n.8 (5th Cir. 2011) (concluding the plaintiff's negligence *per se* claim under Mississippi law based on the defendant's alleged violations of the FDA regulations is not expressly or impliedly preempted)

- Missouri. *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017) (finding the plaintiff's negligence *per se* claim "is grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product,

which [the plaintiff] argues [the defendant] breached by failing to meet the post-premarket approval reporting requirements listed in the MDA and the [defendant's device's] PMA."); *Mattingly v. Medtronic, Inc.*, 486 F. Supp. 2d 964, 969 (E.D. Mo. 2007) (finding the plaintiffs' negligence *per se* claim based on FDA regulations "could parallel similar federal requirements such that the claim could survive a preemption challenge").

- New York. *Henson v. Wright Med. Tech., Inc.*, No. 5:12-CV-805 (FJS/TWD), 2013 U.S. Dist. LEXIS 44295, at *16 (N.D.N.Y. March 28, 2013) (citing *Sita v. Danek Med.*, 43 F. Supp. 2d 245, 262 (E.D.N.Y. 1999)) ("[T]he Second Circuit has expressly recognized that a private cause of action for per se negligence arises under New York State law upon violation of the FDCA."); *Lawrence v. Sofamor, S.N.C.*, No. 95-CV-1507, 1999 U.S. Dist. LEXIS 12228, at *18 (N.D.N.Y. Aug. 2, 1999) (citing *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727, 733 (2d Cir. 1979)) ("Under New York law, a cause of action exists for negligence *per se* when the underlying claim is for misbranding, or otherwise illegally omitting product warnings required by the FDCA; that is, New York recognizes that a violation of a statute or regulation may serve as the basis for negligence *per se*.").

- Oklahoma. *Howard v. Zimmer, Inc.*, 299 P.3d 463, 465 (Okla. 2013) (holding the FDCA does not prohibit Oklahoma from recognizing a claim for negligence *per se* based on a violation of the MDA).

- Oregon. *Santoro v. Endologix Inc.*, No. 3:19-cv-01679-YY, 2020 U.S. Dist. LEXIS 200421, at *35 (D. Or. Oct. 6, 2020) (finding "plaintiff has alleged a cognizable claim of negligence *per se*" based on the FDCA concerning the defendant's PMA-approved medical device).

- Pennsylvania. *Polt v. Sandoz, Inc.*, 462 F. Supp. 3d 557, 569 (E.D. Pa. 2020) (citations omitted) ("[A]lthough the FDCA does not create a private cause of action, a violation of the FDCA can form the basis for a negligence *per se* claim.").

- South Carolina. *Fisher v. Pelstring*, 817 F. Supp. 2d 791, 824 (D.S.C. 2012) (allowing a negligence action in which the standard of care is defined by the FDA regulations).

- Tennessee. An FDA regulation that imposes specific substantive requirement concerning the safety and effectiveness of a medical device may form the basis of a negligence *per se* claim under Tennessee law. *See Spier v. Coloplast Corp.*, 121 F. Supp. 3d 809, 816 (E.D. Tenn. 2015) (citing *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 437, 441 (6th Cir. 2010)) ("[A] negligence per se claim based on a GMP violation constituted a non-preempted parallel claim."); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 698 (W.D. Tenn. 2011) ("If the CGMP regulation in question sets forth a specific and substantive standard of care that is intended to protect others, then it imposes a requirement on the manufacturer. As a result, the violation of that CGMP regulation may support a parallel claim and, incidentally, a negligence per se claim."); *c.f. King v. Danek Med.*, 37 S.W.3d 429, 457 (Tenn. Ct. App. 2000) (citing *Talley v. Danek Med., Inc.*, 179 F.3d 154, 161 (4th Cir. 1999)) ("The administrative requirement that a given device be approved by the FDA before being marketed—as opposed to a specific substantive requirement that a device be safe and effective—is only a tool to facilitate administration of the underlying regulatory scheme. Because it lacks any independent substantive content, it does not impose a standard of care, the breach of which could form the basis of a negligence per se claim.").

- Virginia. *Carmine v. Poffenbarger*, 154 F. Supp. 3d 309, 317 (E.D. Va. 2015) (allowing the plaintiff's negligence *per se* claim based on alleged violations of the FDCA);

*Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455, 461 (4th Cir. 1960) ("[A] violation of the Federal Food, Drug, and Cosmetic Act is negligence *per se* in Virginia . . . .").

- Wisconsin. *Valente v. Sofamor, S.N.C.*, 48 F. Supp. 2d 862, 876 (E.D. Wis. 1999) ("[I]f the plaintiffs could show causation, they could assert negligence *per se* claims against the defendants based on the defendants' alleged violation of FDCA regulations.").

Finally, the Court discerns no relevant legal authority in these states: Idaho, Iowa, Montana, Vermont, and Wyoming. The Court need not consider relevant legal authority in Ohio, because Plaintiffs do not allege a negligence *per se* claim under Ohio law. (*See* ECF No. 119 at ¶¶ 84–86.)

Therefore, Plaintiffs cannot assert negligence *per se* claims based on alleged FDCA/CGMP violations in the following jurisdictions: Alaska, Arkansas, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Rhode Island, Texas, Utah, Vermont, Washington, West Virginia, and Wyoming. These claims shall be dismissed.

**5. Plaintiffs' Report-Based Failure to Warn Claims Are Not Viable in Some Jurisdictions**

Allergan argues Plaintiffs' report-based failure to warn claims should be dismissed, because there is no state law duty to report adverse events to the FDA. (ECF No. 171-3 at 19.) Plaintiffs contend at least 15 states explicitly recognize a state law duty to warn via adverse event reporting, and most of the remaining states are also likely to recognize such a duty. (ECF No. 220 at 43–44.) The Court finds the state law duty to warn by reporting adverse events to the FDA is not recognized in some jurisdictions.

The following jurisdictions allow a failure to warn claim based on a device manufacturer's inadequate reporting to the FDA under state law tort principles:

- California. *Mize v. Mentor Worldwide LLC*, 265 Cal. Rptr. 3d 468, 479 (Cal. Ct. App. 2020) (citations omitted) ("A claim based on the failure to warn the FDA of adverse events is not preempted to the extent state tort law recognizes a parallel duty."); *Coleman v. Medtronic, Inc.*, 167 Cal. Rptr. 3d 300, 312 (Cal. Ct. App. 2016) ("[T]he duty to warn should not be so narrowly defined as to exclude a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers.").

- Delaware. *Freed v. St. Jude Med.*, Inc., 364 F. Supp. 3d 343, 358 n.13 (D. Del. 2019).

- Hawaii. *Beavers-Gabriel v. Medtronic, Inc.*, No. 13-00686 JMS-RLP, 2015 WL 143944, at *12 (D. Haw. Jan. 9, 2015) (citing *Tabieros v. Clark Equip. Co.*, 944 P.2d 1279, 1297–98 (Haw. 1997)) ("Hawaii law imposes a general duty of reasonable care on product manufacturers, and recognizes a cause of action for failure to warn. . . . Thus, this duty of care supplies a basis for Plaintiff's strict liability and negligence claims that arises independently of [the defendant's] duty to warn the FDA under federal law.").

- Illinois. *Gravitt v. Mentor Worldwide, LLC*, No. 17 C 5428, 2018 U.S. Dist. LEXIS 98198, at *33 (N.D. Ill. June 12, 2018) (citations omitted) ("[The defendant's] alleged underreporting [its medical device's] tendency to rupture implicates the state law duty of a manufacturer to inform regulators and the public when it has reason to know that a product is riskier than initially believed."); *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026, 1035 (N.D. Ill. 2016) ("The MDA sets standards for what, when, how, and to whom a manufacturer must report; it does not eviscerate the longstanding state-imposed duty to warn simply by

redefining the way medical device manufacturers satisfy that obligation. . . . Illinois has long recognized negligence and strict liability torts arising out of a failure to warn, placing a duty on a product manufacturer not to communicate directly with an end user, but to engage in 'reasonable conduct for the benefit' of the end user. Here, that reasonable conduct includes fully and correctly complying with FDA disclosure requirements.").

- Indiana. *McAfee v. Medtronic, Inc.*, No. 1:12-CV-417 RLM, 2015 U.S. Dist. LEXIS 74101, at *10–11 (N.D. Ind. June 4, 2015) (finding the plaintiff "stated plausible claims for relief" under Indiana state law "based on an alleged failure to warn the FDA" with adverse event reports).

- Idaho. *Richardson v. Bayer Healthcare Pharm. Inc.*, No. 4:15-cv-00443-BLW, 2016 WL 4546369, at *8 (D. Idaho Aug. 30, 2016) (citation omitted) (holding under Idaho law the manufacturer of a product may have a duty to forewarn a user of the product, which includes warnings and reports to the FDA in the context of Class III medical devices).

- Kentucky. *Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 839–40 (W.D. Ky. 2014) (finding to the extent the plaintiffs' failure to warn claim "is based on Defendants' failure to comply with FDA [reporting] regulations, that claim is not preempted by § 360k(a)" or impliedly preempted).

- Louisiana. *Gavin v. Medtronic, Inc.*, No. 12-0851 SECTION: "G"(5), 2013 U.S. Dist. LEXIS 101216, at *44 (E.D. La. July 19, 2013) (ruling the state law duty to provide adequate warnings and the FDA reporting requirements imposed by 21 C.F.R. § 803.50 are parallel).

- Maryland. *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015) (citations and internal quotations omitted) ("Maryland tort law recognizes that a duty to

warn can undergird a negligence case in a product liability action. Moreover, this duty to warn extends beyond the time of sale, and requires the manufacturer to make reasonable efforts to convey an effective warning. And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA.").

- Minnesota. *Angeles v. Medtronic, Inc.*, 863 N.W.2d 404, 419 (Minn. 2015) ("[The plainiffs' state law] claim is not expressly or impliedly preempted by federal law to the extent that [the plaintiffs] allege that [the defendant] failed to report adverse events to the FDA.").

- Mississippi. *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) (finding under Mississippi law "a failure to warn claim limited to an assertion that the defendant violated a relevant federal statute or regulation is 'parallel' to federal requirements").

- Missouri. *Williams v. Bayer Corp.*, 541 S.W.3d 594, 606 (Mo. Ct. App. 2017) ("[The plaintiff's] claim is not analogous to the 'fraud-on-the-FDA' theory that was rejected in *Buckman* and is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which [the plaintiff] argues [the defendant] breached by failing to meet the post-premarket approval reporting requirements listed in the MDA and the [device's] PMA.").

- Nevada. *Scovil v. Medtronic Inc.*, No. 2:14-CV-00213-APG-VCF, 2015 U.S. Dist. LEXIS 25708, at *19 (D. Nev. March 2, 2015) (finding Nevada law contains a parallel requirement that a medical device manufacturer report adverse events to the FDA as required by federal law).

- New York. *Barone v. Bausch & Lomb, Inc.*, No. E2017000711, 2019 N.Y. Misc. LEXIS 6423, at *6–7 (N.Y. Sup. Ct., Dec. 6, 2019) , *rev'd on other grounds*, 1055 CA 20-00048, 2021 N.Y. App. Div. LEXIS 657 (N.Y. App. Div. Feb. 5, 2021) (allowing a failure to warn claim

based on an alleged failure to comply with the parallel state and federal duty to report adverse events to the FDA concerning an implantable medical device); *A.F. v. Sorin Grp. USA*, Inc., 346 F. Supp. 3d 534, 544 (S.D.N.Y. 2018) ("[A] manufacturer's duty to take steps that are reasonably necessary to warn the medical community may include warning the FDA as required by the MDA. To the extent Plaintiffs assert a claim for failure to warn the FDA, that claim is not preempted.").

- Pennsylvania. *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016).

- Rhode Island. *Hodges v. Brannon*, 707 A.2d 1225, 1228 (R.I. 1998) (affirming the trial court's limiting the evidentiary use of the defendant's negative event reports filed to the FDA "to the duty-to-warn and notice issues").

- Texas. *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 706 (S.D. Tex. 2014) (allowing the plaintiff's negligence claim "predicated on [the defendant's] failure to submit adverse-event reports to the FDA after the FDA granted the [defendant's] device premarket approval").

- Vermont. *Halsey v. Smith & Nephew*, No. 5:12-cv-171, 2014 U.S. Dist. LEXIS 203484, at *31–32 (D. Vt. Feb. 4, 2014) (citing *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1227 (9th Cir. 2013); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769–70 (5th Cir. 2011)) (allowing a failure to warn claim parallel to federal requirements such as the FDA's medical device reporting regulations).

- Washington. *O'Neil v. St. Jude Med., Inc.*, No. C13-0661RSL, 2013 U.S. Dist. LEXIS 167450, at *11 (W.D. Wash. Nov. 22, 2013) (allowing a failure to warn claim concerning a medical device parallel to the federal obligation to report adverse events to the FDA).

- Wisconsin. *Garross v. Medtronic, Inc.*, 77 F. Supp. 3d 809, 815–16 (E.D. Wis. 2015) (allowing a state common law duty to warn based the defendant's alleged failure to report adverse events concerning a medical device to the FDA).

The following jurisdictions explicitly reject a report-based failure to warn claim:

- Arizona. *Conklin v. Medtronic, Inc.*, 431 P.3d 571, 578 (Ariz. 2018) ("[O]nly federal law, not state law, imposes a duty on [the defendant] to submit adverse event reports to the FDA.").

- Colorado. *Golden v. Brown*, No. 17CV30568, 2017 WL 4239015, at *2 (Colo. Dist. Ct. Sept. 24, 2017) (citations omitted) ("[T]here is no state law duty identical to the federal requirement that a device manufacturer report adverse events to the FDA.").

- Connecticut. *Norman v. Bayer Corp.*, 3:16-cv-00253 (JAM), 2016 U.S. Dist. LEXIS 96993, at *10 (D. Conn. July 26, 2016) (citations omitted) ("There is no general or background duty under Connecticut law to report risks to a regulatory body. . . . The failure-to-warn claim arises solely from the MDA's reporting requirements, and therefore is subject to implied preemption.").

- District of Columbia. *Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 183 (D.D.C. 2018) ("[T]here is no D.C. common law claim that imposes liability for a manufacturer's failure to report to the FDA adverse incidents concerning an approved medical device.").

- Florida. *Romer v. Corin Group, PLC*, No. 2:18-cv-19-FtM-99MRM, 2018 U.S. Dist. LEXIS 152752, at *19 (M.D. Fla. Sept. 7, 2018) (citing *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1200–01 (M.D. Fla. 2013)) ("Since Florida does not provide a duty to file such

[adverse event] reports with the FDA, plaintiffs' claim is merely an 'attempt to recast a claim for violation of the FDCA as a state-law negligence claim' and is impliedly preempted.").

- Georgia. *Cline v. Advanced Neuromodulation Sys.*, 17 F. Supp. 3d 1275, 1285–87 (N.D. Ga. 2014) (dismissing the plaintiff's negligent failure to warn claim based on the defendant's failure to timely file MDRs partly because the FDA's disclosure of MDRs to the public is not guaranteed).

- Kansas. *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1281 (10th Cir. 2021) (affirming dismissal of the plaintiffs' failure to warn claim based on the defendant's failure to conduct post-approval reporting of adverse events to the FDA, because the plaintiffs did not identify a parallel duty under Kansas law).

- Massachusetts. *Phillips v. Medtronic, Inc.*, No. SUCV2009-05286-A, 2012 Mass. Super. LEXIS 3435, at *28 (Mass. Super. July 10, 2012) (citations omitted) ("[A] parallel claim based on failure to report adverse events, corrections and removals, and failure to submit supplemental reports to the FDA is impliedly preempted because it is premised solely on a duty created by the MDA which did not exist in the common law: the duty to provide information to a regulatory agency to enable it to determine whether to take enforcement action with respect to a device approved through the PMA process.").

- Michigan. *Hill v. Bayer Corp.*, No. 19-CV-12198, 2020 U.S. Dist. LEXIS 162917, at *23 (E.D. Mich. Sept. 8, 2020) (concluding the plaintiff's "negligent failure-to-warn-FDA claim[] [is] impliedly preempted," because the plaintiff "has not alleged any Michigan requirement that a manufacturer report adverse events to the FDA"); *White v. Medtronic, Inc.*, No. 18-11590, 2019 U.S. Dist. LEXIS 49259, at *13 (E.D. Mich. Feb. 20, 2019) ("[T]he federal

requirement that manufacturers report adverse events to the FDA has no state law analog, and thus there is no parallel state cause of action.").

- Montana. *Noel v. Bayer Corp.*, No. CV 20-27-BLG-SPW, 2020 U.S. Dist. LEXIS 155133, at *27 (D. Mont. Aug. 26, 2020) ("The claims based on a failure to warn (or report adverse events) to the FDA are impliedly pre-empted because there are no parallel requirements based on Montana law.").

- New Jersey. *D'Addario v. Johnson & Johnson*, No. 19-15627, 2020 U.S. Dist. LEXIS 116760, at *12 (D.N.J. June 30, 2020) (declining to recognize a separate state law duty to warn the FDA).

- North Carolina. *McNeil-Williams v. Depuy Orthopaedics, Inc.*, No. 5:18-CV-220-FL, 2019 U.S. Dist. LEXIS 84339, at *13 (E.D.N.C. May 20, 2019) (finding North Carolina law "does not recognize an independent state law duty to make adverse event reports to the FDA").

- Ohio. *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005–06 (S.D. Ohio 2016) ("[T]here is no state-law duty to report adverse events to the FDA [in Ohio].").

- Oregon. *Alton v. Medtronic, Inc.*, 970 F. Supp. 2d 1069, 1089 (D. Or. 2013) ("[T]o the extent the [plaintiff's] claim was construed as premised on alleged misrepresentations and/or omissions in [the defendant's] mandatory reports to the FDA regarding the risk of adverse outcomes from off-label applications of the [defendant's] device, the claim was clearly impliedly preempted.").

- South Carolina. *Ellis v. Smith & Nephew, Inc.*, No. 6:15-545-TMC, 2016 U.S. Dist. LEXIS 193607, at *19 (D.S.C. Feb. 16, 2016) (declining to recognize a failure to warn claim that is predicated on the defendant's alleged failure to provide required reports to the FDA).

- Tennessee. *Potolicchio v. Medtronic, Inc.*, No. 1:15-cv-122, 2016 U.S. Dist. LEXIS 71723, at *12 (E.D. Tenn. 2016) (citing *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 701 (Tenn. 2011)) ("No Tennessee law requires [the defendant] to warn the FDA about adverse events. Tennessee law requires manufacturers to warn physicians, but not the FDA.").

Finally, the Court is unaware of, and counsel has not provided, any relevant legal authority in the following jurisdictions: Alabama, Alaska, Arkansas, Iowa, Maine, Nebraska, New Hampshire, New Mexico, North Dakota, Oklahoma, South Dakota, Utah, Virginia, West Virginia, and Wyoming. Given the split among the jurisdictions as to the viability of a report-based failure to warn claim, the Court will "opt for the interpretation that restricts liability, rather than expands it, until the Supreme Court of [the State] decides differently." *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 253 (3d Cir. 2010) (citing *Werwinski v. Ford Motor Co.*, 286 F.3d 661, 680 (3d Cir. 2010)). Therefore, the Court assumes a report-based failure to warn claim is not allowed in these states.

Accordingly, Plaintiffs' report-based failure to warn claims are dismissed under the laws of Alabama, Alaska, Arkansas, Arizona, Colorado, Connecticut, District of Columbia, Florida, Georgia, Iowa, Kansas, Maine, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Utah, Virginia, West Virginia, and Wyoming.

### 6. Plaintiffs' Negligent Misrepresentation Claims

#### a. Plaintiffs' Negligent Misrepresentations Claims Are Sufficiently Pleaded

Allergan argues Plaintiffs' negligent misrepresentation claims fail to meet the heightened pleading standard under Rule 9. (ECF No. 171-3 at 21.) Plaintiffs counter their negligent

misrepresentation claims are sufficiently pleaded even under Rule 9, though Rule 9 should not govern Plaintiffs' negligent misrepresentation claims. (ECF No. 220 at 47–48.) The Court agrees.

Determinations regarding Allergan's alleged negligent misrepresentations will involve evaluation of individualized facts, because each individual Plaintiff may have received from Allergan a distinct set of implant-related information. Additionally, the evidence of such alleged misrepresentations is primarily within the control of Allergan. Therefore, at this stage, the Court will not dismiss Plaintiffs' negligent misrepresentation claims based on an insufficiency of facts alleged in the PIC. Moreover, even applying the the heightened pleading standard under Rule 9, the Court finds Plaintiffs have sufficiently pleaded Allergan's alleged negligent misrepresentations.

"Because pleading rules are procedural in nature, 'the transferee court must apply federal law as interpreted by the court of the district where the transferee court sits.'" *In re Asbestos Prods. Liab. Litig. (No. VI)*, 611 F. App'x 86, 89 (3d Cir. 2015) (citing *Various Plaintiffs v. Various Defendants (Oil Field Cases)*, 673 F. Supp. 2d 358, 362 (E.D. Pa. 2009)). Therefore, the Court will apply the federal law in the Third Circuit in determining the pleading standard applicable to Plaintiffs' negligent representation claims.

"[U]nder the Federal Rules, plaintiff's pleading negligent representation without more is sufficient to state a claim." *Manley v. Maran*, No. 02-2504, 2003 U.S. Dist. LEXIS 19696, at *9 (D.N.J. June 20, 2003). "[T]he defendants' objection that plaintiff had to plead specific facts is misplaced," as the plaintiff only need to satisfy "the liberal pleading requirement of Rule 8 and state[] a claim upon which relief can be granted." *Id*. at *9, 11; *see also Argabright v. Rheem Mfg. Co.*, 201 F. Supp. 3d 578, 604 n.12 (D.N.J. 2016) (citations omitted) ("Where the claims are expressly premised on negligence rather than fraud, Fed. R. Civ. P. 9(b) has been held

inapplicable."). However, "where the plaintiff grounds his claims in allegations of fraud—and the claims thus sound in fraud—the heightened pleading requirements of Rule 9(b) apply." *Gray v. Bayer Corp.*, No. 08-4716, 2009 U.S. Dist. LEXIS 48181, at *5 (D.N.J. June 9, 2009) (citing *In re Suprema Specialties, Inc. Securities Litig.*, 438 F.3d 256, 270 (3d Cir. 2006)). But "[a]bsent a determination that plaintiffs' claims sounded in fraud, or some analysis explaining why Rule 9(b) should apply," applying Rule 9(b) to such claims "constitutes legal error." *In re Westinghouse Sec. Litig.*, 90 F.3d 696, 717 n.20 (3d Cir. 1996).

Assuming Plaintiffs' negligent misrepresentation claims sound in fraud, the Court finds they meet the heightened pleading standard under Rule 9. Plaintiffs have alleged the "essential factual background" of Allergan's alleged misrepresentations of its implants that lack any reference to the BIA-ALCL risk, by describing the "who, what, when, where and how of the events at issue." *Suprema Specialties*, 438 F.3d at 276–77 (citation omitted). For example, the PIC describes Allergan's allegedly misleading promotional YouTube video for its Natrelle Breast Implants. (ECF No. 119 at ¶ 97.) This publicly available online video describes (1) the "greatly improved safety" of breast augmentation, and (2) Allergan's textured and smooth implants, but does not make any distinction between the two types of implants as to the significantly increased risks of contracting BIA-ALCL associated with the textured type. (*Id.*) These descriptions may imply Allergan's textured implants, which include the BIOCELL implants, enjoy a greatly improved safety feature comparable to smooth implants, and, therefore, could plausibly be misrepresentations of the implants' safety features. The bottom of the video

displays the following text: "© 2010 Allergan, Inc. ® mark owned by Allergan, Inc."[5] This suggests the video is authored by Allergan and first published in 2010.

**b. Plaintiffs Cannot Assert Negligent Misrepresentation Claims in Some Jurisdictions**

Allergan contends Plaintiffs' negligent misrepresentation claims should be dismissed in the thirteen states that either subsume negligent misrepresentation within the state's product liability statute, or do not recognize negligent misrepresentation as a separate cause of action. (ECF No. 171-3 at 23.) Plaintiffs point out they do not make any negligent misrepresentation claim in two of the thirteen states, i.e., New Jersey and Indiana, and can assert the claim in the other nine states. (ECF No. 220 at 54.) The Court finds Plaintiffs cannot assert negligent misrepresentation claims in some states.

As explained in Part III.B.6.a, *supra*, the Court need not review the factual sufficiency of Plaintiffs' negligent misrepresentation allegations. Moreover, scrutinizing such factual sufficiency under the potentially varying state laws of negligent misrepresentation would be both cumbersome and unrealistic at this stage, especially when individual Plaintiffs may allege separately in their Short Form Complaints Allergan's misrepresentations to which they each have been exposed. Here, the Court will only examine whether Plaintiffs' negligent misrepresentation claims can be viable as a matter of law. The Court will not examine the controlling laws in New Jersey and Indiana, under whose laws Plaintiffs do not assert any negligent misrepresentation claim.

- Alabama:

[5] Dra Panama, *Natrelle Breast Implants - Picking the Right Implants for Your Body and the Surgery Process.*, YouTube (Sept. 23, 2013), https://www.youtube.com/watch?v=vu-0W8vSNrU.

Plaintiffs' claims are viable under Alabama law. Allergan suggests Plaintiffs' negligent misrepresentation claims would be considered a product liability action, and may be barred by the learned intermediary doctrine. (ECF No. 236-1 at 240–41.) The Court disagrees. In Alabama, Ala. Code § 6-5-521 "codifies who may bring a 'product liability action,'" including a negligent misrepresentation cause of action, and a plaintiff can assert a negligent misrepresentation claim. *Dalraida Props. v. Elastikote, LLC*, No. 2:14-cv-1213-MHT-PWG, 2015 U.S. Dist. LEXIS 92498, at *16–17 (M.D. Ala. 2015) (citing Ala. Code § 6-5-521). Also, Plaintiffs' negligent misrepresentation claims are not necessarily precluded by the learned intermediary doctrine. "Under the learned intermediary doctrine, a manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product." *Walls v. Alpharma USPD, Inc.*, 887 So. 2d 881, 883 (Ala. 2004). "[I]f the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient." *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 673 (Ala. 2014). "The patient must show that the manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury." *Id.* Here, Plaintiffs allege their physicians were not properly warned of the risks associated with the BIOCELL implants, and the physicians would not have recommended BIOCELL if Allergan provided adequate warnings. (ECF No. 119 at ¶ 204.) Therefore, Plaintiffs' allegations are sufficient under the learned intermediary doctrine.

- Arkansas:

Plaintiffs' claims are not viable under Arkansas law. Allergan argues Arkansas does not recognize negligent misrepresentation as a separate cause of action. (ECF No. 236-1 at 241.) Plaintiffs explain Arkansas recognizes the tort of misrepresentation rather than negligent

misrepresentation. (*Id*. at 242.) The Court disagrees. Arkansas "decline[s] to recognize the tort of negligent misrepresentation." *South County v. First W. Loan Co.*, 871 S.W.2d 325, 326 (Ark. 1994). "Misrepresentation, also commonly referred to as deceit or fraud, has been an intentional tort in Arkansas for well over a century." *Id*. (citations omitted). "Thus, Plaintiffs cannot state a claim of negligent misrepresentation upon which relief may be granted." *Stube v. Pfizer Inc.*, 446 F. Supp. 3d 424, 442 (W.D. Ark. 2020). Plaintiffs claim their factual allegations have sufficiently stated a claim for misrepresentation under Arkansas law. (ECF No. 236-1 at 242.) But this is irrelevant to the viability of Plaintiffs' negligent misrepresentation claims under Arkansas law.

- Florida:

Plaintiffs' claims are viable under Florida law. Florida "recognize[s] a cause of action for negligent misrepresentation." *Moransais v. Heathman*, 744 So. 2d 973, 982 (Fla. 1999) (citing *First Florida Bank, N.A. v. Max Mitchell & Co.*, 558 So. 2d 9 (Fla. 1990)).

- Georgia:

Plaintiffs' claims are viable under Georgia law. Georgia allows a cause of action for negligent misrepresentation, and "adopt[s] the standard for negligent misrepresentation set out in Restatement of Torts 2d, § 552 (1977)." *Neidiger/Tucker/Bruner, Inc. v. Suntrust Bank*, 530 S.E.2d 18, 21 (Ga. Ct. App. 2000) (citing *Robert & Co. Assoc. v. Rhodes-Haverty Partnership*, 300 S.E.2d 503, 504 (Ga. 1983)).

- Louisiana:

Plaintiffs' claims are not viable under Louisiana law. Allergan argues the Louisiana Product Liability Act ("LPLA") is the exclusive theory of liability for manufacturers for damages caused by their products, and Plaintiffs therefore cannot assert negligent misrepresentation claims. (ECF No. 236-1 at 244.) Plaintiffs maintain their negligent

misrepresentation claims could proceed under the LPLA. (*Id*. at 245.) The Court disagrees. "The LPLA establishes the exclusive theory of liability for manufacturers for damages caused by their products." *Baudin v. AstraZeneca Pharms. LP*, 413 F. Supp. 3d 498, 503 (M.D. La. 2019). "The LPLA authorizes four theories of recovery: (1) construction or composition defect; (2) design defect; (3) inadequate warning; or (4) breach of express warranty." *Johnson v. Teva Pharms. USA, Inc.*, No. 2:10 CV 404, 2010 U.S. Dist. LEXIS 84747, at *7 (W.D. La. Aug. 11, 2010) (citing La. Rev. Stat. Ann. § 9:2800.52-54). "A plaintiff may not recover from a manufacturer for damage caused by a product on the basis of any theory not set forth in the LPLA." *Id*. at *7–8 (citing *Jefferson v. Lead Industries, Ass'n., Inc.*, 106 F.3d 1245, 1250–51 (5th Cir. 1997)). A negligent misrepresentation claim is "not cognizable under the LPLA, and must be dismissed." *Lewis v. GE Healthcare, Inc.*, No. 5:19-CV-00490, 2020 U.S. Dist. LEXIS 51999, at *9 (W.D. La. March 25, 2020). Here, Plaintiffs are suing Allergan, a manufacturer, for damages caused by its products. Therefore, the LPLA governs, and does not allow a negligent misrepresentation claim.

- Minnesota:

Plaintiffs' claims are not viable under Minnesota law. Allergan states Plaintiffs fail to plead negligent misrepresentation, because they do not allege pecuniary loss related to a business transaction, and Minnesota limits the negligent misrepresentation claim to damages for pecuniary loss. (ECF No. 236-1 at 245.) Plaintiffs contend Minnesota law does not clearly limit Plaintiffs' claims to pecuniary loss. (*Id*. at 246.) Moreover, Plaintiffs claim to have sustained pecuniary loss related to a business transaction with Allergan: because of Allergan's alleged misrepresentations, Plaintiffs purchased and used implants from Allergan, and incurred pecuniary loss in the form of medical costs and lost wages. (*Id*.) The Court disagrees. In Minnesota,

> One who, in the course of his business, profession or employment, or in a transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

*Bonhiver v. Graff*, 248 N.W.2d 291, 298 (Minn. 1976) (citing Restatement, Torts 2d, Tent. Draft No. 12, § 552). "[T]he scope of a negligent misrepresentation claim" is limited "to a commercial or business setting with consequent pecuniary loss," and does not extend to "medical bills." *Forslund v. Stryker Corp.*, No. 09-2134 (JRT/JJK), 2010 U.S. Dist. LEXIS 104227, at *19–20 (D. Minn. Sept. 30, 2010) (citing *id.*) (dismissing the plaintiff's negligent misrepresentation claim for damages resulting from the defendant's medical implant in the plaintiff's body). Plaintiffs' claims are analogous to that in *Forslund*, and should be dismissed under Minnesota law.

- Mississippi:

Plaintiffs' claims are viable only under the Mississippi Product Liability Act ("MPLA"). Allergan contends Plaintiffs' negligent misrepresentation claims are subsumed by the MPLA and should be dismissed. (ECF No. 236-1 at 247.) The Court finds Plaintiffs' common law negligent misrepresentation claims should be dismissed. "[T]he MPLA applies to 'any action for damages caused by a product.'" *Young v. Bristol-Myers Squibb Co.*, No. 4:16-CV-00108-DMB-JMV, 2017 U.S. Dist. LEXIS 24730, at *8 (N.D. Miss. Feb. 22, 2017) (citing Miss. Code Ann. § 11-1-63(a)). "Accordingly, common law claims based on damages caused by a product are subsumed by the MPLA and must be analyzed under the statute." *Id.* (citing *Elliott v. El Paso Corp.*, 181 So.3d 263, 269 (Miss. 2015)); *see also Arnoult v. CL Med. SARL*, No. 1:14-CV-271-KS-MTP, 2015 U.S. Dist. LEXIS 125843, at *9 (S.D. Miss. Sept. 21, 2015) (citations omitted) ("[T]he

MPLA subsumes negligent misrepresentation claims arising from a defective product."); *Little v. Smith & Nephew, Inc.*, No. 1:15-cv-00028-GHD-DAS, 2015 U.S. Dist. LEXIS 75666, at *34 (N.D. Miss. June 11, 2015) (citations omitted) ("Numerous Mississippi district courts have held that the MPLA subsumes common law negligent misrepresentation claims based on a defective product."). "Common law claims for damages caused by a product which seek to impose liability outside the MPLA's framework must be dismissed for failure to state a claim." *Young*, 2017 U.S. Dist. LEXIS 24730, at *8 (citing *Elliott*, 181 So.3d at 269).

Plaintiffs claim they "may pursue negligent misrepresentation claims outside of the MPLA where, as here, defendant made affirmative misrepresentations in addition to and separate from those made on the product's label," such as Allergan's "affirmative misrepresentations in marketing and other non-PMA materials upon which Plaintiffs and Plaintiffs' physicians relied." (ECF No. 236-1 at 247–48 (citing *R.J. Reynolds Tobacco Co. v. King*, 921 So. 2d 268 (Miss. 2005); *Jowers v. BOC Grp., Inc.*, No. 1:08-CV-0036, 2009 U.S. Dist. LEXIS 53126 (S.D. Miss. Apr. 14, 2009)).) But this argument is contrary to the clear language of the MPLA, which provides:

> The manufacturer, designer or seller of the product shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer, designer or seller:
> (i) 1. The product was defective because it deviated in a material way from the manufacturer's or designer's specifications or from otherwise identical units manufactured to the same manufacturing specifications, or
> 2. The product was defective because it failed to contain adequate warnings or instructions, or
> 3. The product was designed in a defective manner, or
> 4. The product breached an express warranty or *failed to conform to other express factual representations* upon which the claimant justifiably relied in electing to use the product; and
> (ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and

> (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.

Miss. Code Ann § 11-1-63(a). Therefore, in addition to express warranty, the MPLA covers a manufacturer's "other express factual representations," such as Allergan's alleged off-label affirmative misrepresentations.

Plaintiffs' reliance on *Jowers* and *King* does not change the conclusion. The *Jowers* court found an off-label misrepresentation "[went] beyond any failure to warn, and so [wa]s not simply a 'product liability claim,' and, thus, is not automatically abrogated by the MPLA." *Jowers*, 2009 U.S. Dist. LEXIS 53126, at *37. But an off-label misrepresentation, even if not constituting a failure to warn under Miss. Code Ann § 11-1-63(a)(i)2, falls under "other express factual representations" under § 11-1-63(a)(i)4. Therefore, interpreting a manufacturer's off-label misrepresentations as going beyond the MPLA's coverage is contrary to the statute's plain language and multiple Mississippi court decisions after *Jowers*, as cited above. Such an inaccurate interpretation of the MPLA is also not supported by the *King* court, which addressed a "singular issue: Does the inherent characteristic defense of Miss. Code Ann. § 11-1-63(b) . . . bar 'any action for damages caused by' manufactured commercial cigarettes regardless of how the plaintiff labels the causes of action in the complaint?" *King*, 921 So. 2d at 270. "§ 11-1-63(b) is commonly referred to as the 'inherent characteristics defense' and is just that." *Id.* at 272. It provides:

> A product is not defective in design or formulation if the harm for which the claimant seeks to recover compensatory damages was caused by an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability and which is recognized by the ordinary person with the ordinary knowledge common to the community.

Miss. Code Ann § 11-1-63(b). That is to say, the *King* court did not consider the issue of negligent representation, and is therefore inapplicable here. Plaintiffs fail to demonstrate they can pursue negligent misrepresentation claims outside of the MPLA.

Accordingly, the Court dismisses Plaintiffs' common law negligent misrepresentation claims under Mississippi law.

- Ohio:

Plaintiffs' claims are viable under Ohio law. Ohio "recognize[s] the tort of negligent misrepresentation." *Ed Schory & Sons v. Francis*, 662 N.E.2d 1074, 1080 (Ohio 1996) (citations omitted).

- Tennessee:

Plaintiffs' claims are viable under Tennessee law. "Tennessee's courts have also recognized the common-law tort of negligent misrepresentation and have adopted the Restatement (Second) of Torts § 552 (1977) as the guiding principle with regard to these claims." *Hodge v. Craig*, 382 S.W.3d 325, 344 (Tenn. 2012) (citations omitted).

- Texas:

Plaintiffs' claims are viable under Texas law. Allergan maintains Plaintiffs' negligent misrepresentation claim is subsumed by a failure to warn claim. (ECF No. 236-1 at 250 (citing *Phares v. Actavis-Elizabeth LLC*, 892 F. Supp. 2d 835 (S.D. Tex. 2012)).) The Court disagrees. Texas courts "recognize[] a cause of action for negligent misrepresentation where the plaintiff suffered physical harm," even though a plaintiff's negligent misrepresentation claim could be found as "merely a recasting of their failure to warn claim." *Elmazouni v. Mylan, Inc.*, 220 F. Supp. 3d 736, 744 (N.D. Tex. 2016). A negligent misrepresentation may be considered a failure to warn claim when, "[n]o matter how [a plaintiff] casts her claims, [the plaintiff] essentially

alleges that [the defendant] failed to warn her that [the defendant's product] causes [a disease]." *Phares*, 892 F. Supp. 2d at 841. In this situation, if the plaintiff's failure to warn claim is rejected for some reason, then its negligent misrepresentation claim will be rejected for the same reason. *Id*. at 845–46 (dismissing the plaintiff's failure to warn and negligent misrepresentation claims for the same reason, i.e., the defendant owing no legally cognizable duty to the plaintiff); *see also Miles v. Boston Sci. Corp.*, No. H-19-4319, 2020 U.S. Dist. LEXIS 120190, at *26 (S.D. Tex. July 9, 2020) (citations omitted) ("Here, [the plaintiff's] fraud by concealment and negligent misrepresentation claims are premised on her allegation that [the defendant] knowingly omitted material facts about [the defendant's product], or in other words, failed to adequately warn her and her physicians. Since the learned intermediary doctrine applies, her fraud-based and negligent misrepresentation claims fail for the same reasons as her failure to warn claim as discussed above."); *Perez v. Am. Med. Sys.*, 461 F. Supp. 3d 488, 507–08 (W.D. Tex. 2020) ("Plaintiffs' negligent misrepresentation [and] implied warranty . . . claims are all grounded in allegations that Defendant provided inadequate warnings . . . . Therefore, the independent intermediary doctrine applies to these claims. . . . Plaintiffs cannot demonstrate causation as a matter of law [as required under the doctrine for the failure to warn claim]. Therefore, Defendant is entitled to summary judgment on Plaintiffs' negligent misrepresentation . . . as well."). But a plaintiff may still assert a negligent misrepresentation claim independent of a failure to warn claim. *See Hardy v. Zimmer*, No. 2:16-cv-242-JRG, 2017 U.S. Dist. LEXIS 65430, at *4–5 (E.D. Tex. April 28, 2017). In conclusion, Plaintiffs may assert a negligent misrepresentation claim not subsumed by a failure to warn claim under Texas law.

- Virginia:

Plaintiffs' claims are not viable under Virginia law. The parties dispute whether Virginia recognizes a negligent misrepresentation claim. (ECF No. 236-1 at 251–52.) Plaintiffs cite *Hansen* to argue negligent misrepresentation is a cognizable claim under Virginia law. (*Id*. at 252 (citing *Hansen v. Stanley Martin Companies, Inc.*, 585 S.E.2d 567, 573 (Va. 2003)).) The Court disagrees. *Hansen* is inapposite here, because the dispute in *Hansen* was governed by Maryland's substantive law. *Hansen*, 585 S.E.2d at 571. Instead, "it is well-established that 'Virginia does not recognize any tort of negligent misrepresentation.'" *A.T. Massey Coal Co. v. Rudimex GmbH*, No. 3:05CV190-JRS, 2006 U.S. Dist. LEXIS 1882, at *16 (E.D. Va. Jan. 9, 2006) (citing *Bentley v. Legent Corp.*, 849 F. Supp. 429, 434 (E.D. Va. 1994)); *see also Zaklit v. Global Linguist Solutions, LLC*, No. 1:14cv314 (JCC/JFA), 2014 U.S. Dist. LEXIS 92623, at *58 (E.D. Va. July 8, 2014) (citations and internal quotations omitted) ("Virginia does not recognize a general cause of action for negligent misrepresentation."); *Johnson v. Capital Area Permanente Group*, 30 Va. Cir. 107, 109 n.2 (Va. Cir. Ct. 1993) (citations omitted) ("Virginia law does recognize negligent misrepresentation.").

Accordingly, the Court dismisses Plaintiffs' negligence misrepresentation claims under the laws of Arkansas, Louisiana, Minnesota, and Virginia, as well as Mississippi's common law.

**7. Plaintiffs Cannot Assert Warranty Claims in Some Jurisdictions**

Allergan states Plaintiffs' warranty claims fail for several reasons: (1) some states do not allow implied warranty claims in prescription medical device litigations; (2) some states require notice as an element of warranty claims, and Plaintiffs do not plead notice in the PIC; and (3) some states require privity to assert warranty claims, and Plaintiffs lack privity with Allergan. (ECF No. 171-3 at 23.) Plaintiffs rebut Allergan's challenges on the following bases: (1) courts frequently permit warranty claims in cases involving prescription medical devices; (2) before the

PIC was filed, Allergan had actual notice of the defects in its BIOCELL implants; (3) to the extent the purpose of a pre-suit notice is to provide an opportunity for the defendant to cure, the notice is not required here, because a cure is impossible for each Plaintiff who is already surgically implanted with Allergan's implant; and (4) Plaintiffs' warranty claims do not require privity because Plaintiffs are alleging personal injury. (ECF No. 220 at 56–60.) The Court finds Plaintiffs' implied warranty claims are not viable in some jurisdictions.

As a threshold matter, the Court will review with substantial leniency the following individualized factual issues, for the reasons explained in Part III.B.1, *supra*. First, a lack of adequate notice by the defendant, even if required for asserting a warranty claim, will not be a ground for dismissal here. This is because whether Allergan has received adequate notice via its own efforts or from a Plaintiff will involve (1) facts specific to each individual Plaintiff and (2) evidence primarily within Allergan's control. Second, the Court will not scrutinize whether Plaintiffs have sufficiently alleged the defects in the BIOCELL implants. This is because the actual implant used by each individual Plaintiff, including its possible defects, is unique. Third, whether Allergan has directed (mis)representations, warranties or other communications towards Plaintiffs involves individualized factual issues, because each Plaintiff may have engaged in a unique set of contacts with Allergan. Fourth, whether Plaintiffs can establish a third party beneficiary status with respect to the agreement between Allergan and its implant distributors involves individualized factual issues, because it may turn on the interactions between each individual Plaintiff and Allergan. As a result, Plaintiffs' potentially insufficient allegations of notice, defects, Allergan's direct contacts with Plaintiffs, and the third party beneficiary status will not be considered in the motion to dismiss inquiry.

However, the Court will examine, under the laws of different jurisdictions: (1) whether warranty claims are allowed in prescription medical device litigations, because this is a purely legal question, and (2) whether privity is required for asserting Plaintiffs' warranty claims, because privity involves a fact common to all Plaintiffs: the BIOCELL implants are prescription medical devices, which suggests Plaintiffs do not purchase the implants directly from Allergan.

In addition, as the following analysis shows, there are often several independent legal theories on which to assert express or implied warranty claims under the law of a given jurisdiction, such as a state's Uniform Commercial Code ("UCC"), product liability statute, common law, and certain exceptions. Plaintiffs, in asserting their warranty claims, do not limit the claims' underlying legal theories. Therefore, as long as Plaintiffs' express or implied claim may be viable under one of the theories recognized in a jurisdiction, the Court will allow that claim to proceed at this stage.

Finally, the viability of an implied warranty of fitness claim is not an issue here, because Plaintiffs do not assert such a claim in the PIC.

- Alabama:

Plaintiffs' claims are viable under Alabama law. The parties dispute whether Alabama law recognizes an implied warranty of merchantability claim for medical devices. (ECF No. 236-1 at 254.) "In general, Alabama law does not recognize a cause of action for breach of implied warranty of merchantability for inherently dangerous products." *Barnhill v. Teva Pharms. USA, Inc.*, 819 F. Supp. 2d 1254, 1263 (S.D. Ala. 2011). "An implantable Class III medical device . . . is an inherently dangerous product." *Grubbs v. Medtronic, Inc.*, No. 2:18-cv-01468-AKK, 2019 U.S. Dist. LEXIS 121216, at *11 (N.D. Ala. July 22, 2019) (citations omitted). However, Alabama allows an implied warranty of merchantability claim based on an alleged failure to

"manufacture the Device in accordance with the FDA's requirements," as opposed to "a general allegation that the product contains inherent dangers." *Id* at *11–12. As discussed in Parts III.A.2 and III.B3, *supra*, Plaintiffs have sufficiently alleged the BIOCELL implants deviate from FDA-approved product specifications, and their implied warranty claims are therefore allowed in Alabama.

- Arizona:

Plaintiffs' claims are viable under Arizona law. The parties dispute whether Arizona law requires privity for an express warranty claim. (ECF No. 236-1 at 255–56.) Plaintiffs cite *Flory* to argue that privity is not required when the defendant's alleged breach of warranty causes physical injury. (*Id*. at 256 (citing *Flory v. Silvercrest Indus.*, 633 P.2d 383 (Ariz. 1981)).) The Court disagrees. *Flory* suggested Arizona Revised Statues ("A.R.S.") § 44-2335 might extend a seller's warranties to "personally injured family members and household members and guests" of its buyer. *Flory*, 633 P.2d at 387–88. But § 44-2335 only "eliminates the necessity of horizontal privity as to certain personally injured plaintiffs, but not the necessity of vertical privity, or privity in the chain of distribution," and "does not create warranties on the part of . . . remote manufacturers." *Id*. Instead, "the Arizona Supreme Court held that the lack of privity between a purchaser and a manufacturer precluded recovery based on express warranty under the U.C.C.," but "the lack of privity did not preclude the purchaser from bringing a cause of action for breach of express warranty outside the U.C.C." *Plagens v. Nat'l RV Holdings, Inc.*, 328 F. Supp. 2d 1068, 1074 (D. Ariz. 2004) (citing *Flory v. Silvercrest Indus. Inc.*, 633 P.2d 383, 387–89 (Ariz. 1981)); *see also In re Horizon Organic Milk Plus DHA Omega-3 Mktg. & Sales Practice Litig.*, 955 F. Supp. 2d 1311, 1339 (S.D. Fla. 2013) (citations and internal quotations omitted) (finding under Arizona law "a plaintiff may not proceed with a breach of warranty action under the

Uniform Commercial Code against a manufacturer not in privity with the plaintiff" but "lack of privity between a manufacturer and retail purchaser does not preclude a claim outside the U.C.C. for breach of express warranty"). Therefore, though privity is required for asserting UCC-based express warranty claims, Plaintiffs may, at minimum, assert non-UCC-based express warranty claims under Arizona law.

Moreover, *Hix* rejected the "argument that a patient of an implantable medical product can never be in privity with the manufacturer." *Hix v. Bos. Sci. Corp.*, No. CV-19-00422-PHX-DJH, 2019 U.S. Dist. LEXIS 197384, at *13 (D. Ariz. Nov. 14, 2019). Instead, privity may "exist between the patient and the manufacturer" and "a breach of express warranty could be brought[,] if the plaintiff was capable of pleading sufficient facts to show that the manufacturer made representations specifically to the plaintiff, rather than just plaintiff's physicians." *Id*. at *14 (citing *Martin v. Medtronic*, Inc., 63 F. Supp. 3d 1050, 1061 (D. Ariz. 2014)). Because the Court will not scrutinze Allergan's representations made to an individual Plaintiff at this stage, Plaintiffs' express warranty claims under Arizona law, whether or not based on UCC, will not be dismissed for a lack of privity.

- California:

Plaintiffs' claims are viable under California law. The parties dispute whether privity of contract is required for Plaintiffs' implied and express warranty claims under California law. (ECF No. 236-1 at 258–60.) "[P]rivity of contract is required in an action for breach of either express or implied warranty." *Blanco v. Baxter Healthcare Corp.*, 70 Cal. Rptr. 3d 566, 582 (Cal. Ct. App. 2008) (citations omitted). However, California courts have not concluded "a patient of an implantable medical product can never be in privity with the manufacturer," and have only held "privity does not exist between the patient and the manufacturer if the patient did not rely

on the manufacturer's judgment but did rely on the physician's skill and judgment." *Zetz v. Bos. Sci. Corp.*, 398 F. Supp. 3d 700, 711 (E.D. Cal. 2019); *see also Fundin v. Chi. Pneumatic Tool Co.*, 199 Cal. Rptr. 789, 793–94 (Cal. Ct. App. 1984) (citing *Burr v. Sherwin Williams Co.*, 268 P.2d 1041, 1049 (Cal. 1954)) ("[W]hen a consumer relies on representations made by a manufacturer in labels or advertising material, recovery is allowable on the theory of express warranty without a showing of privity."); *c.f. Blanco*, 70 Cal. Rptr. 3d at 582 (concluding the plaintiff patient cannot sue the defendant medical device manufacturer for breach of implied warranties, because "there is no evidence [the plaintiff] relied on [the defendant's] judgment that the [device] was appropriate for her"). Because the Court declines to scrutinize whether the PIC contains sufficient allegations of Allergan's misrepresentations made to an individual Plaintiff, the Court will not dismiss Plaintiffs' warranty claims under California law for a lack of privity.

- Florida:

Plaintiffs' claims are viable under Florida law. The parties dispute the privity requirement. (ECF No. 236-1 at 262–63.) "Pursuant to Florida law, the plaintiff must be in privity of contract to recover under theories of breach of express or implied warranties." *Cubbage v. Novartis Pharms. Corp.*, No. 5:16-cv-129-Oc-30PRL, 2016 U.S. Dist. LEXIS 86753, at *20 (M.D. Fla. July 5, 2016) (citations omitted). "Most often, privity does not exist between manufacturers and patients when the medication is only available by prescription." *Dimieri v. Medicis Pharms. Corp.*, No. 2:14-cv-176-FtM-38DNF, 2014 U.S. Dist. LEXIS 95409, at *15 (M.D. Fla. July 14, 2014) (citations omitted). But a plaintiff may meet a "relaxed" privity standard if it "relied on the safety claims in those advertisements" of the defendant manufacturer purposely targeting patients like the plaintiff. *Humleker v. Boston Sci. Corp.*, No. 6:19-cv-121-Orl-31EJK, 2019 U.S. Dist. LEXIS 207077, at *5 (M.D. Fla. Dec. 2, 2019); *c.f. Dimieri*, 2014 U.S. Dist. LEXIS 95409,

at *15–16 (concluding "Plaintiff fails to allege the existence of privity between himself and Defendant" because "Plaintiff does not assert the existence of any direct contact between Defendant and Plaintiff when the physician prescribed" the medicine). Here, the Court will not scrutinize Plaintiffs' direct contacts with Allergan, and therefore will not dismiss Plaintiffs' warranty claims under Florida law for a lack of privity.

- Georgia:

Plaintiffs' claims are viable under Georgia law. The parties dispute the privity requirement. (ECF No. 236-1 at 264–65.) "Georgia law still generally precludes the ultimate consumer from recovering on any express or implied warranty when the manufacturer sells the product to the original consumer, e.g. a retailer." *Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1325–26 (M.D. Ga. 2011) "However, Georgia courts recognize an exception to this general rule." *Id.* at 1326. "If the manufacturer expressly warrants to the ultimate consumer that the product will perform in a certain way or that it meets particular standards, privity with that ultimate consumer is deemed to exist." *Id.* (citations omitted); *see also Hemmings v. Camping Time RV Ctrs., LLC*, No. 1:17-CV-1331-TWT, 2017 U.S. Dist. LEXIS 168417, at *15–16 (N.D. Ga. 2017) ("[W]here the manufacturer extends an express warranty to the end consumer, privity is created that satisfies the requirements of the implied warranty of merchantability."). Here, the Court will not scrutinize whether Plaintiffs have sufficiently alleged an express warranty from Allergan, and therefore will not dismiss Plaintiffs' warranty claims under Georgia law for a lack of privity.

- Idaho:

Plaintiffs' claims are viable under Idaho law. The parties dispute the privity requirement. (ECF No. 236-1 at 265–66.) Plaintiffs argue their warranty claims do not require privity when they are brought under the Idaho Products Liability Reform Act ("IPLRA") rather than UCC. (*Id.*

at 266 (citing *Glenn v. B & R Plastics, Inc.*, 326 F. Supp. 3d 1044, 1063–64 (D. Idaho 2018)).) The Court disagrees. The *Glenn* court ruled "the Idaho Supreme Court had concluded in *Oats* that plaintiffs lacking privity with the manufacturer or seller may pursue their claims for personal injuries based on breach of warranty under the IPLRA rather than the UCC." *Glenn*, 326 F. Supp. 3d at 1064 (citing *Oats v. Nissan Motor Corp.*, 879 P.2d 1095, 1105 (Idaho 1994)). But this is an inaccurate reading of *Oats*, which did not explicitly recognize a non-privity breach of warranty action under the IPLRA; *Oats* only allowed the plaintiff, who initially brought a non-privity breach of warranty action, to proceed under the IPLRA with a strict liability claim. *Oats*, 879 P.2d at 1105 ("[W]hen a plaintiff brings a non-privity breach of warranty action against a manufacturer or seller to recover for personal injuries allegedly sustained as a result of a defective product, that action is one for strict liability in tort, governed by the provisions of the IPLRA."). Instead, "Idaho does not recognize a breach of warranty claim in personal injury products liability actions which do not involve a contractual relationship between the manufacturer and the injured person." *Elliott v. Smith & Nephew*, No. 1:12-CV-0070-EJL-MHW, 2013 U.S. Dist. LEXIS 59072, at *26 (D. Idaho April 15, 2013) (citing *Oats*, 879 P.2d at 1105).

However, privity is not always necessary for a UCC-based warranty claim under Idaho law. "[A] plaintiff may pursue UCC breach of warranty claims for personal injuries only if: (a) the plaintiff is in contractual privity with the manufacturer or seller, or (b) the plaintiff qualifies as a third party beneficiary of the underlying sales contract." *Corbett v. Remington Arms Co., LLC*, No. 4:15-cv-00279-BLW, 2016 U.S. Dist. LEXIS 58967, at *5 (D. Idaho May 2, 2016) (citing *Oats*, 879 P.2d at 1102). Moreover, for express warranty claims, certain direct contacts between the patient and the manufacturer may meet the privity requirement. *See id.* at *9 ("At best, the existence of a warranty registration card [the plaintiff filled and sent directly to the

defendant] might support an express warranty claim, but [the plaintiff] has not convinced the Court that any such warranty would include implied warranties."). Therefore, Plaintiffs may proceed with UCC-based warranty claims and non-UCC-based express warranty claims, as the Court will not scrutinize whether Plaintiffs have sufficiently alleged a third party beneficiary status or direct contacts with Allergan in the PIC.

- Indiana:

Plaintiffs' claims are viable under Indiana law. The parties dispute the privity requirement. (ECF No. 236-1 at 268.) The Indiana Product Liability Act ("IPLA") "ha[s] codified the entire field of products liability" under Indiana law. *Weigle v. SPX Corp.*, 729 F.3d 724, 737 (7th Cir. 2013); *see also Gardner v. Tristar Sporting Arms*, No. 1:09-cv-0671-TWP-WGH, 2010 U.S. Dist. LEXIS 97188, at *6 (S.D. Ind. Sept. 15, 2010) (citations omitted) ("[T]he IPLA has effectively supplanted products liability common law claims."). "A product can be defective within the meaning of the IPLA because of a manufacturing flaw, a defective design or a failure to warn of the dangers while using the product." *Campbell Hausfeld/Scott Fetzer Co. v. Johnson*, 109 N.E.3d 953, 956 (Ind. 2018). "Thus, the IPLA governs the strict liability and negligence claims." *Ind. Farm Bureau Ins. v. Amazon*, No. 1:19-cv-01568-JRS-TAB, 2020 U.S. Dist. LEXIS 204081, at *4 (S.D. Ind. Oct. 30, 2020) (citations omitted). "[B]reach of implied warranty" and "breach of express warranty" claims are not "recognized under the IPLA." *Bradburn v. Bard, Inc.*, No. 3:19-cv-925-PPS-MGG, 2020 U.S. Dist. LEXIS 101201, at *8 (N.D. Ind. June 9, 2020) (citing Ind. Code § 34-20-1-1). Therefore, Plaintiffs cannot pursue warranty claims under the IPLA.

However, warranty claims can be asserted under Indiana's UCC and independent from the IPLA. *Atkinson v. P & G-Clairol, Inc.*, 813 F. Supp. 2d 1021, 1025 (N.D. Ind. 2011) ("The

fact that the Supreme Court of Indiana has established that different damages are available under tort and contract law for a defective product bolsters the argument that a defective product can give rise to claims under both the IPLA and the UCC."); *Cincinnati Ins. Cos. v. Hamilton Beach/Proctor-Silex, Inc.*, No. 4:05 cv 49, 2006 U.S. Dist. LEXIS 9807, at *8 (N.D. Ind. Feb. 7, 2006) (citations omitted) ("[C]laims under the IPLA are independent from breach of warranty claims alleged under Indiana's adoption of the Uniform Commercial Code."); *Hunt v. Unknown Chem. Mfr. No. One*, No. IP 02-389-C-M/S, 2003 U.S. Dist. LEXIS 20138, at *34 (S.D. Ind. Nov. 5, 2003) (citing *Hitachi Const. Mach. Co., Ltd. v. Amax Coal Co.*, 737 N.E.2d 460 (Ind. App. 2000)) ("[T]he IPLA did not vitiate contract actions under the Uniform Commercial Code"). But the IPLA bars implied warranty claims sounding in tort. *McClellon v. Thermo King Corp.*, No. 1:11-cv-01337-SEB-MJD, 2013 U.S. Dist. LEXIS 174996, at *10–11 (S.D. Ind. Dec. 13, 2013) (citations omitted) ("[A] breach of implied warranty claim duplicates an IPLA strict liability claim and should not be pursued as a separate count."); *1st Call Home Health, LLC v. Porter*, No. 18A05-1110-PL-528, 2012 Ind. App. Unpub. LEXIS 261, at *7 (Ind. Ct. App. March 2, 2012) ("The IPLA effectively supplants the common-law breach of implied warranty in tort claim."). To conclude, "[t]ort-based implied warranty claims are subsumed under the IPLA, but contract-based implied warranty claims are not." *Ind. Farm*, 2020 U.S. Dist. LEXIS 204081, at *7 (citations omitted).

Here, Plaintiffs allege Allergan "impliedly warranted to Plaintiff that the defective implants were of merchantable quality and safe for their ordinary and intended use in the human body as breast implants and tissue expanders." (ECF No. 119 at ¶ 232.) "This is enough for a contract-based claim of breach of implied warranty." *Constructora Mi Casita S De RL De CV v. NIBCO Inc.*, No. 3:16-CV-565-PPS-MGG, 2017 U.S. Dist. LEXIS 126649, at *16 (N.D. Ind.

Aug. 9, 2017) (citations omitted) (noting the plaintiff has pleaded the defendant "impliedly warranted to Plaintiff that [the defendant's products] were of merchantable quality and fit for the use for which they were intended"). As for privity, "Indiana law does not require vertical privity between a consumer and a manufacturer as a condition to a claim by the consumer against the manufacturer for breach of the manufacturer's implied warranty of merchantability." *Hyundai Motor Am., Inc. v. Goodin*, 822 N.E.2d 947, 959 (Ind. 2005). Therefore, Plaintiffs may pursue UCC-based implied warranty claims against Allergan.

In contrast, express warranty claims, even if asserted for the recovery of physical harm, "are not subsumed by the IPLA, particularly in light of the legislative inaction as to the relationship between the UCC and the IPLA." *Bayer Corp. v. Leach*, 153 N.E.3d 1168, 1190 (Ind. Ct. App. 2020) (citing *DePuy, Inc. v. Farmer*, 847 N.E.2d 160, 168 (Ind. 2006)). Also, "vertical privity is not required to pursue a claim based on those alleged express warranties." *Id.* at 1191. "[A] remote purchaser was 'not precluded from suing a manufacturer because of lack of privity of contract, where the manufacturer allegedly made express warranties' directly to the remote purchaser." *Id*. (citing *Prairie Production, Inc. v. Agchem Division-Pennwalt Corp.*, 514 N.E.2d 1299, 1302 (Ind. Ct. App. 1989)). Because the Court declines to scrutinize whether Plaintiffs sufficiently allege direct contacts with Allergan in the PIC, the Court will not dismiss at this stage Plaintiffs' express warranty claims for lack of privity.

In conclusion, under Indiana law, Plaintiffs may assert express warranty claims and UCC-based implied warranty of merchantability claims.

- Kentucky:

Plaintiffs' claims are viable under Kentucky law. The parties dispute the privity requirement. (ECF No. 236-1 at 269.) "Under Kentucky law, privity of contract is an essential

element of a claim for breach of an implied warranty." *Estate of Demoss v. Eli Lilly & Co.*, 234 F. Supp. 3d 873, 822 (W.D. Ky. 2017) (citations omitted). "[P]rivity of contract does not extend beyond the buyer-seller setting, and an intervening purchaser destroys privity." *Id*. (citations omitted). However, "an actual and direct promise for the benefit of a third party will be sufficient to create privity between the promisor and the third party beneficiary." *Louisville Gas & Elec. Co. v. Continental Field Systems, Inc.*, 420 F. Supp. 2d 764, 770 (W.D. Ky. 2005) (citations omitted). Here, whether an individual Plaintiff may establish a third-party beneficiary status will not be scrutinized at this stage, meaning Plaintiffs may proceed with an implied warranty claim. As for asserting an express warranty claim, a contractual privity is not necessary, because privity exists "when the manufacturer made express warranties directly to the intended consumer of the product." *Huff v. Howmedica Osteonics*, No. 5:14-CV-00134-TBR, 2014 U.S. Dist. LEXIS 137735, at *8 (W.D. Ky. Sept. 29, 2014) (citations omitted). Here, whether Allergan extended express warranties to an individual Plaintiff will not be scrutinized at this stage, meaning Plaintiffs may proceed with an express warranty claim. As a result, the Court declines to dismiss Plaintiffs' warranty claims under Kentucky law for a lack of privity.

- Michigan:

Plaintiffs' claims are viable under Michigan law. The parties dispute whether implied warranty claims are barred in prescription medical product litigation. (ECF No. 236-1 at 269–70.) The Court finds Michigan allows an implied warranty claim asserted against medical products, including medical devices. *See Davis v. C.R. Bard, Inc.*, No. 11-12556, 2012 U.S. Dist. LEXIS 172925, at *31 (E.D. Mich. Dec. 6, 2012) (denying the defendant's motion for summary judgement on the plaintiff's implied warranty claim against the defendant's medical device); *Walker v. Johnson & Johnson Vision Prods.*, 552 N.W.2d 679, 682 (Minn. Ct. App. 1996)

(rejecting "the view that § 360k(a) provides blanket preemption of all state law claims against manufacturers of Class III medical devices," including the plaintiff's breach of implied warranty claim); *Smith v. E.R. Squibb & Sons*, Inc., 273 N.W.2d 476, 480 (Mich. 1979) (conceding, in a drug product liability case, implied warranty and negligence may be independent causes of action).

Further, the parties dispute whether privity is required for breach of express warranty claims. (ECF No. 236-1 at 269–71.) Contractual privity is required for a UCC-based express warranty claim. *Tice v. Zimmer Holdings, Inc.*, No. 1:15-cv-134, 2015 U.S. Dist. LEXIS 91738, at *17 (W.D. Mich. July 15, 2015). "[A]n express warranty running from a remote manufacturer to a consumer does not create the requisite contractual privity." *Chiasson v. Winnebago Indus.*, No. 01-CV-74809, 2002 U.S. Dist. LEXIS 27462, at *28 (E.D. Mich. May 16, 2002) (citing *Meridian Mutual Ins. Co. v. Kellman*, 197 F.3d 1178, 1181 (6th Cir. 1999)). "However, an intended third-party beneficiary is in privity of contact with the original parties for purposes of an express warranty." *Montgomery v. Kraft Foods Global, Inc.*, No. 1:12-CV-00149, 2012 U.S. Dist. LEXIS 173035, at *37 (W.D. Mich. Dec. 6, 2012) (citing Mich. Comp. Laws § 600.1405(1)). Here, the Court will not scrutinize whether Plaintiffs may establish an intended third-party beneficiary status, meaning Plaintiffs may proceed with a UCC-based express warranty claim. Moreover, "under Michigan law, the privity requirement of the Michigan UCC is inapplicable to a products liability action based on express warranty." *Bouverette v. Westinghouse Elec. Corp.*, 628 N.W.2d 86, 92 (Mich. Ct. App. 2001) (citing *Reid v. Volkswagen of America, Inc.*, 512 F.2d 1294, 1297 (6th Cir. 1975)). Therefore, Plaintiffs may proceed with express warranty claims, whether or not based on UCC, at this stage under Michigan law.

- Nevada:

Plaintiffs' claims are viable under Nevada law. The parties dispute whether, for an implied warranty of merchantability claim, contractual privity between the buyer and seller is required. (ECF No. 236-1 at 273–74.) The Court finds a split exists among Nevada courts as to whether contractual privity is required for a personally injured user to assert an implied warranty of merchantability claim against the manufactuer of the medical device allegedly causing the injury. While some courts answered in the affirmative, *see Claridge v. I-Flow Corp.*, No. 2:18-cv-01654-GMN-BNW, 2019 U.S. Dist. LEXIS 148935, at *8 (D. Nev. Aug. 30, 2019); *Finnerty v. Howmedica Osteonics Corp.*, No. 2:14-cv-00114-GMN-GWF, 2016 U.S. Dist. LEXIS 123071, *21 (D. Nev. Sept. 12, 2016); *Phillips v. C.R. Bard, Inc.*, No. 3:12-cv-00344-RCJ-WGC, 2014 U.S. Dist. LEXIS 174506, at *24–25 (D. Nev. Dec. 16, 2014), others answered in the negative, *see Reed v. Arthrex, Inc.*, No. 3:17-cv-00337-LRH-WGC, 2017 U.S. Dist. LEXIS 168247, at *10–11 (D. Nev. Oct. 11, 2017); *Forest v. Vitek, Inc.*, 884 F. Supp. 378, 382 (D. Nev. 1993). Even assuming privity is required for an implied warranty of merchantability claim and Plaintiffs lack such privity, Plaintiffs may still pursue this claim under a third party beneficiary theory. *Copper Sands Homeowners Ass'n v. Copper Sands Realty, LLC*, No. 2:10-cv-00510-GMN-GWF, 2012 U.S. Dist. LEXIS 42370, at *11–12 (D. Nev. March 27, 2012) ("[The defendant] argues that [the plaintiffs'] claim for Breach of Implied Warranty fails because there is no privity of contract between the parties. However, because the Court finds that [the plaintiffs] are a third party beneficiary to the contract this argument fails."); *c.f. Neal-Lomax v. Las Vegas Metro. Police Dep't*, No. 2:05-CV-1464-PMP-PAL, 2006 U.S. Dist. LEXIS 49692, at *22 (D. Nev. July 17, 2006) (rejecting the implied warranty claim as a matter of law because the victim, "not a named or intended third party beneficiary of the contract between [the defendant police

department] and [the defendant Taser manufacturer]," "was not in privity with" the defendant Taser manufacturer).

- New York:

Plaintiffs' claims are viable under New York law. The parties dispute whether privity is required for implied warranty claims. (ECF No. 236-1 at 277.) "There is no requirement of privity for [an implied] warranty claim so long as the plaintiff's claim is one for personal injury." *Mahoney v. Endo Health Solutions, Inc.*, No. 15cv9841(DLC), 2016 U.S. Dist. LEXIS 94732, at *12 (S.D.N.Y. July 20, 2016); *see also Bristol Vill., Inc. v. Louisiana-Pacific Corp.*, 916 F. Supp. 2d 357, 363 (W.D.N.Y. 2012) (citations omitted) ("[U]nder New York law, 'a claim based upon a breach of an implied warranty requires a showing of privity between the manufacturer and the plaintiff when there is no claim for personal injuries.'"). Because Plaintiffs are suing Allergan for their personal injuries, they need not allege privity for their implied warranty claims under New York law.

- Ohio:

Plaintiffs' claims are viable under Ohio law. The parties dispute whether the Ohio Product Liability Act ("OPLA") abrogates any common law warranty claims, and whether privity is required for Plaintiffs' implied warranty of merchantability claims. (ECF No. 236-1 at 278–79.) "Ohio product liability law was consolidated under the OPLA, Ohio Revised Code section 2307.71 through section 2307.80, and applies to any recovery of compensatory or putative damages based on a product liability claim." *Mitchel v. Proctor & Gamble*, No. 2:09-CV-426, 2010 U.S. Dist. LEXIS 17956, at *5 (S.D. Ohio Mar. 1, 2010) (citing Ohio Rev. Code § 2307.72(A), (B)). An express warranty claim, but not an implied warranty claim, may be asserted under the OPLA. *Everhart v. Tm Claims Serv.*, No. 2:09-cv-267, 2009 U.S. Dist. LEXIS

147751, at *19–20 (S.D. Ohio Oct. 8, 2009). "[A]ll common law claims arising from damages in connection with product liability claims are abrogated by the OPLA." *Stratford v. SmithKline Beecham Corp.*, No. 2:07-CV-639, 2008 U.S. Dist. LEXIS 84826, at *12 (S.D. Ohio June 17, 2008) (citing Ohio Rev. Code § 2307.71(B)). Therefore, Plaintiffs cannot pursue tort-based common law warranty claims and OPLA-based implied warranty claims, though OPLA-based express warranty claims are viable.

However, "Plaintiffs' warranty claims are separately cognizable under contract law and Ohio Revised Code § 1302.26 et seq." (Ohio's UCC), even if the plaintiffs are also "asserting tort claims sounding in product liability." *Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 924 (N.D. Ohio 2009). "[T]o sustain a contract-based breach of implied warranty claim, the parties must be in privity." *Caterpillar Fin. Servs. Corp. v. Harold Tatman & Son's, Enters.*, 50 N.E.3d 955, 962 (Ohio Ct. App. 2015). But "when the manufacturer is so involved in the sales transaction that the distributor merely becomes the agent of the manufacturer, then the manufacturer and the ultimate consumer are in privity of contract." *Bobb Forest Prods., Inc. v. Morbark Indus. Inc.*, 783 N.E.2d 560, 576 (Ohio Ct. App. 2002) (citations omitted). "A consumer may also have privity of contract with the manufacturer if that consumer is an intended third-party beneficiary to a contract." *Id.* at 84 (citations omitted). Whether a Plaintiff can establish an intended third-party beneficiary status or prove the distributor for the BIOCELL implants to be an agent of Allergan will depend on facts specific to that individual Plaintiff, which the Court declines to scrutinize at this stage. As a result, Plaintiffs' UCC-based implied warranty claims are viable under Ohio law.

- Pennsylvania:

Plaintiffs' implied warranty of merchantability claims are not viable under Pennsylvania law. The parties dispute whether implied warranty claims are barred in prescription medical product litigations. (ECF No. 236-1 at 280–81.) In Pennsylvania, there is "a split in authority on the applicability of breach of implied warranty of merchantability claims based on defects in the manufacture of medical devices." *Terrell v. Davol, Inc.*, No. 13-5074, 2014 U.S. Dist. LEXIS 103695, at *22 (E.D. Pa. July 30, 2014). The *Terrell* court refused to recognize "the breach of an implied warranty of merchantability claim [wa]s a viable cause of action under Pennsylvania law" based on defects in prescription medical devices. *Id*. at *23–24. This is in line with some Pennsylvania cases that reject all implied warranty claims in prescription medical device cases. *See Pasqual v. I-Flow Corp.*, No. 13-003571, 2013 Pa. Dist. & Cnty. Dec. LEXIS 15739, at *34 (Allegheny Com. Pl. Oct. 15, 2013) ("Pennsylvania does not recognize implied warranty claims in prescription medical device cases."); *Schiff v. Hurwitz*, No. 12cv0264, 2012 U.S. Dist. LEXIS 70039, at *16 (W.D. Pa. May 18, 2012) ("Breach of implied warranty is inapplicable to prescription medical devices in Pennsylvania."). But other Pennsylvania cases "recognize a claim for breach of the implied warranty of merchantability where it is based on a manufacturing defect" of a prescription medical device. *Doughtery v. C.R. Bard, Inc*, No. 11-6048, 2012 U.S. Dist. LEXIS 100374, 2012 WL 2940727, at *7 (E.D. Pa. July 18, 2012); *see also Smith v. Howmedica Osteonics Corp.*, 251 F. Supp. 3d 844, 855 (E.D. Pa. 2017) (denying the defendant's motion to dismiss "insofar as breach of the implied warranty of merchantability claim asserts a manufacturing defect" in a medical device). With such an unclarity, the Court will "opt for the interpretations that restrict liability," *Travelers Indem. Co. v. Damman & Co.*, 594 F.3d 238, 253 (3d Cir. 2010), and therefore finds Plaintiffs' implied warranty claims not viable in Pennsylvania.

- Tennessee:

Plaintiffs' claims are viable under Tennessee law. The parties dispute the privity requirement. (ECF No. 236-1 at 282–83.) Allergan argues, even if an exception to the privity requirement exists, Plaintiffs not diagnosed with BIA-ALCL cannot assert warranty claims because they do not suffer current injuries. (*Id*. at 283.) The Court disagrees. First, "[t]he Tennessee General Assembly abolished the requirement of privity on April 10, 1972." *Travelers Indem. Co. v. Indus. Paper & Packaging Corp.*, No. 3:02-CV-491, 2006 U.S. Dist. LEXIS 49318, at *29 (E.D. Tenn. July 19, 2006). "The legislation enacted provides that in all cases of action for personal injury or property damage brought on account of . . . breach of warranty, privity shall not be a requirement to maintain said action." *Id.* (citing T.C.A. § 29-34-104). Second, as explained in Part III.B.2, *supra*, the Court declines to determine, at this stage, whether Plaintiffs have alleged any legally cognizable injuries, and therefore, will not dismiss Plaintiffs' claims on that basis.

- Washington:

Plaintiffs' claims are viable under Washington law. The parties dispute the privity requirement for implied warranty claims. (ECF No. 236-1 at 284–85.) Plaintiffs contend privity is met when the buyer is an intended third party beneficiary of the manufacturer's warranties to a third party. (*Id*. at 284.) The Court agrees. Privity is "required for a breach of an implied warranty claim" under Washington law. *Thongchoom v. Graco*, 71 P.3d 214, 219 (Wash. Ct. App. 2005) (citing *Baughn v. Honda Motor Co.*, 727 P.2d 655, 669 (Wash. 1986)). However, there is a third party beneficiary exception to the privity requirement: for a remote purchaser, "implied warranties are enforceable if the manufacturer was involved in the transaction, knew the purchaser's identity and purpose, communicated with the purchaser, or delivered the good." *Johnson v. Metro-Goldwyn-Mayer Studios Inc.*, No. C17-541 RSM, 2017 U.S. Dist. LEXIS

122810, at *15 (W.D. Wash. Aug. 3, 2017) (citing *Touchet Valley Grain Growers, Inc. v. Opp & Seibold Gen. Constr., Inc.*, 831 P.2d 724, 730 (Wash. 1992) (en banc)). At this stage, the Court will not scrutinize whether Plaintiffs may establish a third party beneficiary status. Therefore, Plaintiffs may pursue their implied warranty claims under a third party beneficiary theory.

- Wisconsin:

Plaintiffs' claims are not viable under Wisconsin law. The parties dispute the privity requirement. (ECF No. 236-1 at 285–86.) Notwithstanding the privity requirement, "[t]he Wisconsin Supreme Court has held that 'it is inappropriate to bring an action for breach of warranty where a tort remedy is sought' because 'a breach of warranty theory is encumbered with the ancient baggage of contract actions.'" *Karnes v. C. R. Bard, Inc.*, No. 18-cv-931-wmc, 2019 U.S. Dist. LEXIS 65115, at *20 (W.D. Wis. April 16, 2019) (citing *Austin v. Ford Motor Co.*, 273 N.W.2d 233, 240 (Wis. 1979)). The *Austin* court "established that strict liability in tort actions precludes breach of warranty claims for physically injured users of unreasonably dangerous defective products." *Id*. at *22 (citing *Crosby v. Premier Marine, Inc.*, No. 01 C 50286, 2002 WL 596373, at *1 (N.D. Ill. Apr. 15, 2002)). Here, Plaintiffs have asserted a number of strict liability tort claims. (ECF No. 119 at 73, 89, 116.) Therefore, the Court dismisses Plaintiffs' warranty claims, so that "the interest of justice and the adjudication of claims will be expedited." *Karnes*, 2019 U.S. Dist. LEXIS 65115, at *21 (citing *Austin*, 273 N.W.2d at 240).

In conclusion, the following warranty claims are dismissed: implied warranty of merchantability claims under Pennsylvania law and warranty claims under Wisconsin law.

**8. Summary for Allergan's Motion to Dismiss on Non-Preemption Grounds**

In summary, the Court dismisses: (1) FDCA/CGMP-based negligence *per se* claims

under the laws of Alaska, Arkansas, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Rhode Island, Texas, Utah, Vermont, Washington, West Virginia, and Wyoming; (2) report-based failure to warn claims under the laws of Alabama, Alaska, Arkansas, Arizona, Colorado, Connecticut, District of Columbia, Florida, Georgia, Iowa, Kansas, Maine, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Utah, Virginia, West Virginia, and Wyoming; (3) negligence misrepresentation claims under the laws of Arkansas, Louisiana, Minnesota, and Virginia, as well as common law negligence misrepresentation claims under Mississippi law; and (4) the following warranty claims: implied warranty of merchantability claims under Pennsylvania law and warranty claims under Wisconsin law.

### C. Allergan's Motion to Strike/Dismiss Plaintiffs' Class Allegations (ECF No. 171-2)

Allergan challenges Plaintiffs' class allegations asserted for the following three classes, purportedly nationwide in scope:

> A "medical monitoring" class comprised of all persons who were implanted with Allergan's textured breast implant devices, but have not yet been diagnosed with BIA-ALCL;
> 112 separate subclasses—two for every U.S. State and Territory—consisting of the exact same putative members as the nationwide class; and
> A "release subclass" comprised of persons who signed an optional release of liability as part of their individual warranty claims leading to the explant of their breast implant devices.

(ECF No. 171-2 at 10.)

Plaintiffs argue Allergan's Motion to Strike/Dismiss the CAC is premature and a rare remedy: because the issue of whether Plaintiffs can satisfy Rule 23 is a fact-intensive question, class certification decisions should be made following discovery. (ECF No. 219 at 13.) Allergan contends striking class allegations at the pleadings stage is not rare. (ECF No. 237 at 11 n.1.) Allergan insists courts can strike class allegations whose impropriety is evident from the face of the complaint. (*Id.* at 11.) The Court finds not all the class allegations in the CAC should be stricken/dismissed at this stage.

"Class certification is proper only 'if the trial court is satisfied, after a rigorous analysis, that the prerequisites' of Rule 23 are met.'" *In re Hydrogen Peroxide Antitrust Litigation*, 552 F.3d 305, 309 (3d Cir. 2008) (citations omitted). "The court may 'delve beyond the pleadings to determine whether the requirements for class certification are satisfied.'" *Id.* at 316 (citations omitted). "The majority of courts have found that a Rule 12(b)(6) dismissal of class allegations is appropriate, even when the plaintiff has not yet filed a motion for conditional class certification." *Horowitz v. AT&T Inc.*, No. 3:17-cv-4827, 2018 U.S. Dist. LEXIS 69191, at *51 (D.N.J. April 25, 2018) (citations omitted). But in this District, "dismissal of class allegations at [the pleading] stage should be done rarely and that the better course is to deny such motion because the shape and form of a class action evolves only through the process of discovery." *Id.*; *see also Luppino v. Mercedes-Benz USA, LLC*, No. 09-CV-5582, 2013 U.S. Dist. LEXIS 161689, 2013 WL 6047556, at *3 (D.N.J. Nov. 12, 2013) (citation omitted) ("Generally courts do not consider whether a proposed class meets the Fed. R. Civ. P. 23 class requirements until after plaintiffs move for class certification."). "A defendant may move to strike class action allegations prior to discovery in those rare cases where the complaint itself demonstrates that the requirements for maintaining a class action cannot be met." *Clark v. McDonald's Corp.*, 213 F.R.D. 198, 205 n.3 (D.N.J. 2003)

(citations omitted); *see also McPeak v. S-L Distrib. Co.*, No. 12-348, 2014 U.S. Dist. LEXIS 123728, at *9 (D.N.J. Sept. 5, 2014) (citations omitted) ("It is only when no amount of discovery or time will allow for plaintiffs to resolve deficiencies in class definitions under Rule 23, that a motion to strike class allegations should be granted."). "[T]he usual practice favoring pre-certification discovery derives from the fundamental premise of Fed. R. Civ. P. 12, which is that claims, including class claims, should not be dismissed on the pleadings 'unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *Ehrhart v. Synthes (USA)*, No. 07-01237, 2007 U.S. Dist. LEXIS 94760, at *12 (D.N.J. Dec. 21, 2007) (citing *Conley v. Gibson*, 355 U.S. 41, 45–46, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957)).

Accordingly, the Court will dismiss Plaintiffs' class allegations only if, on its face, the CAC demonstrates the Rule 23 requirements cannot be met even after discovery. In particular, the Court will not consider the potential factual differences among individual Plaintiffs, which could otherwise defeat class certification. For example, in arguing Plaintiffs cannot satisfy the typicality requirement, Allergan refers to a failure of representation by device: the implants used by the class representatives may not be typical of the whole class, because not every type of the BIOCELL Implants has been implanted in the class representatives. (ECF No. 171-2 at 22, 24.) At this stage, the Court will not entertain this alleged failure of representation, which involves factual differences in the actual implant used by individual Plaintiffs, because such "differences among plaintiffs[] may be defeated by common proof developed in discovery." *Landsman & Funk PC v. Skinder-Strauss Assocs.*, 640 F.3d 72, 94 (3d Cir. 2011) (citing *Gene & Gene LLC v. BioPay LLC*, 541 F.3d 318, 327–28 (5th Cir. 2008)); *see also Horowitz*, 2018 U.S. Dist. LEXIS 69191, at *51–52 (declining to dismiss class pleadings under Rule 12(b)(6) in an age

discrimination case, even though the plaintiffs "do not allege that they and all putative collective members were employed by the same [defendant's] entity, worked in the same department, performed similar work, or had similar circumstances of employment," because the plaintiffs "have at least alleged they and the potential opt-ins have been injured by a single policy, the 2020 Scheme, which targeted workers over the age of 40").

**1. Named Plaintiffs Lack Article III Standing in Some Jurisdictions**

Allergan argues the named Plaintiffs lack the standing to serve as class representatives for the subclasses from jurisdictions where the named Plaintiffs are not citizens. (ECF No. 237 at 17.) Plaintiffs contend a plaintiff living in one state can have the standing as a class representative for the state law claims of class members in other states. (ECF No. 219 at 27.) The Court disagrees.

"[A] class representative must be part of the class and 'possess the same interest and suffer the same injury' as the class members." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348–49 (2011) (citations omitted). "[C]lass representatives must meet Article III standing requirements the moment a complaint is filed." *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 367 (3d Cir. 2015) (citing *Lewis v. Casey*, 518 U.S. 343, 358 (1996)). "[N]amed plaintiffs lack standing to assert claims under the laws of the states in which they do not reside or in which they suffered no injury." *In re Ductile Iron Pipe Fittings ("DIPF") Indirect Purchaser Antitrust Litig.*, No. 12-169, 2013 U.S. Dist. LEXIS 142466, at *35 (D.N.J. Oct. 2, 2013); *see also Cooper v. Medimetriks Pharms., Inc.*, No. 18-11987, 2019 U.S. Dist. LEXIS 50265, at *11–12 (D.N.J. March 25, 2019) (citing *McGuire v. BMW of N. LLC*, No. 13-7356, 2014 U.S. Dist. LEXIS 77009, 2014 WL 2566132, at *6 (D.N.J. June 6, 2014)) ("Cooper is the only named plaintiff in this Action. Cooper is not a New Jersey resident (she is a resident of Ohio) and Cooper did not suffer any alleged injuries in New Jersey (she was allegedly injured in Ohio), and thus Cooper is

barred from proceeding as a class representative for the [New Jersey state] claims."); *Lauren v. PNC Bank, N.A.*, 296 F.R.D. 389, 391 (E.D. Pa. 2014) ("[The plaintiff] suffered an alleged injury exclusively under Ohio law. Therefore, she does not have standing to assert unjust enrichment claims under the law(s) of any other state."); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 157–58 (E.D. Pa. 2009) (finding the named plaintiffs have no standing to bring claims under the laws of states where no named plaintiff is located and where no member of a named plaintiff purchased the defendant's accused product).

However, prior to the class certification stage, it is premature to examine the named plaintiffs' "standing to pursue claims on behalf of absent class members of the nationwide class . . . in states other than those in which they were injured," because such an inquiry "is one of predominance" and "only arises if the Court certifies the nationwide class." *In re FieldTurf Artificial Turf Mktg. & Sales Practices Litig.*, No. 3:17-md-2779, 2018 U.S. Dist. LEXIS 149379, at *28 (D.N.J. Aug. 31, 2018) (citations omitted). After all, "class discovery will unveil the various members of the currently unknown class," which will enable the court to determine whether all the state law claims have "a proper representative who resides in the subject states and if those claims may proceed, even if the named [plaintiffs'] claims become moot." *In re Liquid Aluminum Sulfate Antitrust Litig.*, No. 16-md-2687, 2017 U.S. Dist. LEXIS 115294, at *84 (D.N.J. July 20, 2017) (citing *U.S. Parole Comm'n v. Geraghty*, 445 U.S. 388, 413 (1980)). In contrast, when it comes to state-specific (sub)classes, the court may "dismiss the state subclasses of which no Plaintiff is a member" at the pleading stage. *FieldTurf*, 2018 U.S. Dist. LEXIS 149379, at *29; *see also In re: Niaspan Antitrust Litig.*, No. 13-MD-2460, 2015 U.S. Dist. LEXIS 164021, at *8–9 (E.D. Pa. Dec. 8, 2015) (citations and internal quotations omitted) (concluding at the pleading stage that the named plaintiffs "lack standing to bring claims on

behalf of" the state-specific classes when the named "plaintiffs have not alleged that any one named plaintiff either resides in or made purchases and/or reimbursements of [the accused product] in those states").

Plaintiffs cite *Ramirez* to argue the named Plaintiffs can represent absent class members in other states. (ECF No. 219 at 28 (citing *Ramirez v. STi Prepaid LLC*, 644 F. Supp. 2d 496, 504–06 (D.N.J. 2009)).) Indeed, the *Ramirez* court held "once threshold individual standing by the class representative is met, a proper party to raise a particular issue is before the court, and there remains no further separate class standing requirement in the constitutional sense." *Ramirez*, 644 F. Supp. 2d at 504–05 (citing *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 306–07 (3d Cir. 1998)). However, both *Ramirez* and *Prudential* involved a nationwide class. *Id*. at 498; *Prudential*, 148 F.3d at 289. Therefore, the two cases are inapplicable, because the issue here is the named Plaintiffs' standing as representatives for certain state-specific subclasses.

Accordingly, the Court finds the named Plaintiffs do not have the standing as class representatives to assert claims for the state-specific subclasses of which they are not members. The named Plaintiffs are citizens of 39 different states. (*See* ECF No. 118 at ¶¶ 22–84.) Therefore, the Court dismisses the claims of the following subclasses of which no named Plaintiff is a member: Alaska, American Samoa, Arkansas, District of Columbia, Guam, Hawaii, Indiana, Kansas, Maryland, Mississippi, Nebraska, New Hampshire, North Dakota, Northern Mariana Islands, Puerto Rico, U.S. Virgin Islands, and Vermont. Plaintiffs may later reappoint class representatives or reformulate (sub)classes to cure the above deficiencies.

**2. The Class Allegations Meet the Typicality Requirement**

Allergan argues Plaintiffs cannot satisfy the typicality requirement under Rule 23(a). (ECF No. 171-2 at 21.) Allergan points out the 63 named Plaintiffs are citizens of 39 different states, which leads to a failure of representation by jurisdiction: (1) 32 subclasses are not represented by any named Plaintiff; (2) some dual subclasses for each jurisdiction lack or share a representative; (3) an unknown number of unidentified named Plaintiffs purport to represent the claims of a jurisdiction of which they are not citizens. (*Id*.) Plaintiffs insist they meet the typicality requirement: even though they live in different states, their claims all stem from the same course of conduct by Allergan, i.e., the manufacture and sale of the BIOCELL Implants, and all Plaintiffs share the same interests in obtaining reliefs in the form of medical monitoring and repayment of economic losses resulting from Allergan's recall. (ECF No. 219 at 25.) The Court agrees.

A defendant's challenge of typicality may be "premature" and "not appropriate" at the pleading stage, because "[d]ismissal of class claims prior to discovery and a motion to certify the class by plaintiff is the exception rather than the rule." *Durso v. Samsung Elecs. Am., Inc.*, No. 2:12-cv-05352, 2013 U.S. Dist. LEXIS 160596, at *35 (D.N.J. Nov. 6, 2013) (citations omitted). Further, the following analysis shows Plaintiffs meet the typicality requirement.

"The Third Circuit has 'set a low threshold for satisfying' the typicality requirement holding that 'if the claims of the named plaintiffs and class members involve the same conduct by the defendant, typicality is established.'" *In re Remeron End-Payor Antitrust Litig.*, No. 04-5126, 2005 U.S. Dist. LEXIS 27011, at *24 (D.N.J. Sept. 13, 2005) (citing *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 183–84 (3d Cir. 2001)). "[C]lass members need not 'share identical claims'" to satisfy the typicality requirement. *In re NFL Players*

*Concussion Injury Litig.*, 821 F.3d 410, 428 (3d Cir. 2016) (citing *Baby Neal v. Casey*, 43 F.3d 48, 56 (3d Cir. 1994)). "The typicality requirement is designed to align the interests of the class and the class representatives so that the latter will work to benefit the entire class through the pursuit of their own goals." *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 141 (3d Cir. 1998) (citing *Baby Neal v. Casey*, 43 F.3d 48, 57 (3d Cir. 1994)). The court need not "consider the variations among the laws of the 50 states" in the typicality inquiry. *Prudential*, 148 F.3d at 311 (affirming the district court's finding of typicality, despite the defendant's challenge that the district court's typicality analysis was inadequate for not having considered the variations among the laws of the 50 states); *see also In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 529, 531–32 (3d Cir. 2004) (affirming the district court's finding of typicality based on the same alleged wrongful conduct of the defendant and the same general legal theories underlying the plaintiffs' claims, while addressing variance of the substantive laws of the fifty states only in the commonality and predominance analysis); *In re Sch. Asbestos Litig.*, 789 F.2d 996, 1010 (3d Cir. 1986) (considering the variances in products liability law among different states only in the Rule 23(b)(3) analysis).

Here, the claims asserted by the named Plaintiffs and putative class members stem from the same course of conducts of Allergan. The named Plaintiffs and putative class members share an aligned interest in seeking damages from Allergan. The Court need not consider the variances among controlling state laws for the typicality inquiry. Therefore, Plaintiffs meet the typicality requirement.

### 3. The Rule 23(b)(3) Inquiry Is Premature

#### a. The Court Declines to Dismiss Plaintiffs' Class Allegations on Predominance Grounds

Allergan argues the nationwide medical monitoring classes cannot meet Rule 23(b)(3)'s predominance requirement, because: (1) medical monitoring and product liability laws differ widely between the states; and (2) the liability and causation inquiries are highly individualized and not susceptible to class-wide proof. (ECF No. 171-2 at 28–29.) Allergan contends Plaintiffs' claims for consumer fraud and unjust enrichment cannot meet the predominance requirement, because (1) the relevant factual inquiry is inherently individual, such as Plaintiffs' reliance on Allergan's representation or omission (*id*. at 40), and (2) consumer protection statutes and unjust enrichment claims vary widely between states (ECF No. 237 at 39). Allergan also claims to have an array of affirmative defenses that will require individualized findings of fact, and are not susceptible to common proof. (ECF No. 171-2 at 42–43.) Finally, Allergan maintains the legal and factual questions surrounding the validity of each class member's Release constitute individualized inquiries, making it impossible for Plaintiffs to meet the predominance requirement. (*Id*. at 44.)

Plaintiffs claim they will establish at the class certification stage that any material differences among state laws can be handled through commonly used case management tools, for example, by grouping similar state laws or through subclassing. (ECF No. 219 at 30.) Plaintiffs argue Allergan's concerns regarding any factual issues among class members are speculative before discovery. (*Id*. at 31.) As for the consumer fraud and unjust enrichment claims, Plaintiffs point out the reliance requirement has been relaxed under most state laws. (*Id*. at 33.) Plaintiffs contend Allergan's potential affirmative defenses do not provide a basis to strike the class allegations, because (1) discovery is necessary to determine whether and how the affirmative

defenses affect class treatment, and (2) affirmative defenses in themselves do not preclude class certification. (*Id*. at 34–36.) Finally, Plaintiffs allege the Court need not decide prior to discovery whether challenging the releases through the mechanism of a class action would be impermissible, because (1) the release is a form document, so that the challenges likely do not entail consumer-specific evidence, and (2) relevant extrinsic evidence unlikely involves meaningful variation among the vast majority of class members. (*Id*. at 37–38.) The Court agrees.

"[A]t the motion to strike stage, the burden on plaintiffs is less than at the certification stage." *In re Ry. Indus. Emple. No-Poach Antitrust Litig.*, 395 F. Supp. 3d 464, 514 (W.D. Pa. 2019). "The court must determine only whether plaintiffs satisfied their burden to set forth factual allegations to advance a prima facie showing of predominance or that at least it is likely that discovery will reveal evidence" so that critical elements of Plaintiffs' claims "may be proven on a class-wide basis." *Id*. Courts in this Circuit have declined to conduct a predominance inquiry upon a defendant's motion to strike/dismiss a plaintiff's class allegations, recognizing the dismissal of class claims before discovery and a class certification motion "is the exception rather than the rule." *Luppino v. Mercedes-Benz USA, LLC*, No. 09-CV-5582, 2013 U.S. Dist. LEXIS 161689, at *20 (D.N.J. Nov. 12, 2013); *Durso v. Samsung Elecs. Am., Inc.*, No. 2:12-cv-05352, 2013 U.S. Dist. LEXIS 160596, at *35 (D.N.J. Nov. 6, 2013); *see also Derrick v. Glen Mills Sch.*, No. 19-1541, 2019 U.S. Dist. LEXIS 220610, *25–26 (E.D. Pa. Dec. 19, 2019) ("Without the benefit of at least some limited discovery, . . . any determination regarding predominance would be premature."); *Goldman v. RadioShack Corp.*, No. 2:03-CV-0032, 2003 U.S. Dist. LEXIS 7611, at *2 (E.D. Pa. April 16, 2003) (postponing "class certification because further discovery is needed regarding the predominance test of FED. R. CIV. P. 23(b)(3)"); *Seiffert v. Green*, No. 81-1956, 1988 U.S. Dist. LEXIS 1375, at *3 (E.D. Pa. Jan. 13, 1988)

(granting a motion for class certification while noting "[i]f discovery reveals such extensive individualized proof that common issues of law or fact no longer predominate, class action treatment may no longer be appropriate"); *c.f. Sanders v. Johnson & Johnson, Inc.*, No. 03-2663, 2006 U.S. Dist. LEXIS 35881, at *33–34 (D.N.J. May 31, 2006) (striking class allegations at the pleading stage, based on variances in the applicable state laws and individual factual circumstances, when the plaintiff also filed a cross-motion for partial class certification, so that "the Court does not need to address whether [the defendants'] motion [to strike] was timely or premature"). After all, "[i]t is not this Court's place to predict what evidence may be found and which theory (or theories) Plaintiffs may pursue." *Buck v. Am. Gen. Life Ins. Co.*, No. 17-13278, 2018 U.S. Dist. LEXIS 186890, at *25 (D.N.J. Oct. 31, 2018) (dismissing the defendant's motion to strike class allegations on predominance grounds). Courts in other circuits have also suggested a pre-discovery predominance inquiry is premature. *See Amaraut v. Sprint/United Mgmt. Co.*, No. 3:19-cv-411-WQH-AHG, 2020 U.S. Dist. LEXIS 7558, at *28–29 (S.D. Cal. Jan. 14, 2020) (holding the plaintiffs seeking pre-certification discovery need not "make a prima facie showing that Rule 23 class action requirements are satisfied or to show that discovery is likely to produce substantiation of the class allegations"); *Choi v. Kimberly-Clark Worldwide, Inc.*, No. SA CV 19-0468-DOC (ADSx), 2019 U.S. Dist. LEXIS 175623, at *16 (C.D. Cal. Aug. 28, 2019) (concluding the defendant's argument that variances in state law will defeat the predominance of a nationwide class is premature and "Plaintiff should be afforded the opportunity to conduct discovery and determine whether a narrower class than the definition proposed in the Complaint is appropriate"); *Smith v. Pizza Hut, Inc.*, No. 09-cv-01632-CMA-BNB, 2011 U.S. Dist. LEXIS 76793, at *16 (D. Colo. July 14, 2011) (citations omitted) ("[T]he predominance of individual questions is only relevant at the post-discovery stage of the collective action certification.");

*Chenensky v. New York Life Ins. Co.*, No. 07 Civ. 11504, 2011 U.S. Dist. LEXIS 48199, at *10–11 (S.D.N.Y. April 27, 2011) (declining to consider the predominance requirement before class discovery, because any conclusion will be "based on assumptions of fact rather than on findings of fact" and the plaintiffs may redraw "class boundaries that obviate the need for individual proof" after discovery).

Therefore, the Court finds a predominance inquiry is premature at this stage. First, as previously explained, the Court will not scrutinize the factual differences among individual class members at this stage, and will not dismiss class allegations because of such potential differences. Second, the variances of controlling state laws do not necessarily defeat predominance. Without discovery, the Court is unable to examine how these state laws will apply to the facts of Plaintiffs, so as to determine whether "questions of law or fact common to the members of the class predominate over any questions affecting only individual members." Fed. R. Civ. P. 23(b)(3). Discovery may also help Plaintiffs reformulate their (sub)classes, and group the varying state laws, if feasible, into a few categories in light of the facts revealed in discovery. Third, Plaintiffs have made a prima facie showing of predominance. Plaintiffs refer to a series of common factual and legal issues arising out of Allergan's conducts, which, after discovery, may provide answers applicable to all named Plaintiffs and other class members. (ECF No. 219 at 28–29.) Plaintiffs also point out the remedies sought by the class, i.e., a class-wide medical monitoring program and recovery for economic losses, will not present individualized issues that predominate over common ones. (*Id*. at 29.) These showings cut against striking/dismissing Plaintiffs' class allegations. *C.f. Lafferty v. Sherwin-Williams Co.*, No. 1:17-06321, 2018 U.S. Dist. LEXIS 141549, at *13–14 (D.N.J. Aug. 21, 2018) (finding individualized factual issues predominate common issues at the pleading stage in a toxic exposure tort case, where "individual fact finding

is essential to determine whether one of these hazardous substances impacted" the plaintiffs, some of whom "have never been exposed to hazardous substances").

Finally, Allergan relies on *Almond* to argue that the variations in state law could be a basis to strike class allegations. (ECF No. 246 at 3.) Indeed, the *Almond* court, at the pleading stage of a prescription drug product liability litigation, concluded a nationwide class that sought the medical monitoring relief could not meet Rule 23(b)(3)'s predominance requirement, because "a fault line divides class members whom state law permits to seek relief through a no-injury medical monitoring claim, and those whom state law prohibits" asserting no-injury medical monitoring claims. *Almond v. Janssen Pharms., Inc.*, No. 20-2183, 2020 U.S. Dist. LEXIS 207900, at *22 (E.D. Pa. Nov. 6, 2020). However, the Court notes the nationwide class in *Almond* could be divided into two subclasses: one subclass for the jurisdictions that permit a no-injury medical monitoring claim, and the other subclass for those that prohibit such a claim. It is within a district court's sound discretion, after performing a balancing analysis of costs and benefits, to allow or refuse the creation of subclasses under Rule 23(c). *In re Ins. Brokerage Antitrust Litig.*, 579 F.3d 241, 271 (3d Cir. 2009); *In re Cendant Corp. Sec. Litig.*, 404 F.3d 173, 202 (3d Cir. 2005). A district court may formulate subclasses "independently of any proposals made by the parties." *Reyes v. Netdeposit, LLC*, 802 F.3d 469, 494 (3d Cir. 2015) (citing Tobias Barrington Wolff, *Discretion in Class Certification*, 162 U. Pa. L. Rev. 1897, 1898 (2014)). Here, the Court is not in a position to question whether it was within the *Almond* court's discretion not to consider the above possible subclasses. But the Court could exercise its discretion here to grant Plaintiffs the opportunity of discovery, so that they may reformulate subclasses, if necessary, in light of the facts revealed in the discovery. The Court will then examine whether Plaintiffs' proposed subclasses or other arrangements meet the predominance requirement.

Accordingly, at this stage, the Court declines to dismiss Plaintiffs' class allegations on predominance grounds.

**b. The Court Declines to Dismiss Plaintiffs' Class Allegations on Superiority Grounds**

Allergan argues the analysis of the four superiority factors under Rule 23(b)(3) shows a class action would not be superior to other available methods. (ECF No. 171-2 at 47.) First, Allergan states Plaintiffs have indicated a clear intent to control their own individual cases, as the Plaintiffs' Steering Committee to date has refused to adopt the PIC for any of the individual cases in this MDL, even though the Committee is the counsel of record in roughly 75% of those individual cases. (*Id.* at 48.) Second, Allergan claims it is hard to prove Plaintiffs' proposed class action is superior to, and therefore should supplant, the pending MDL that achieves many of the same efficiencies that Rule 23 is supposed to foster. (*Id.* at 50.) Third, Allergan points out the great multitude of claims under the varying laws of 56 jurisdictions make the proposed class action unmanageable: the difficulty of formulating jury instructions and conducting individualized factual inquires under these different state laws will be substantial. (*Id.* at 50–52.) Plaintiffs counter a single class action trial adjudicated with common proof is more efficient than multiple individual trials based on the same common evidence. (ECF No. 219 at 39–40.) Plaintiffs explain individual Plaintiffs have agreed to file Short Form Complaints according to the Case Management Order No. 17, which should not suggest an intent to control their own individual cases. (*Id.* at 40 n.12.) Plaintiffs state Allergan's superiority argument is a premature factual argument that will hinge on the full discovery record. (ECF No. 263 at 19.) Plaintiffs point out individual and class action cases frequently proceed together in product liability MDLs, and do not conflict with each other, because class members are always free to opt out of a class action or file individual actions. (*Id.*) The Court agrees.

Under Rule 23(b)(3), courts must take a "close look" at whether a class action is "superior to other available methods for the fair and efficient adjudication of the controversy." *Amchem Prods. v. Windsor*, 521 U.S. 591, 615 (1997) (citing Fed. R. Civ P. 23(b)(3)). Rule 23(b)(3) provides a list of factors pertinent to a court's the predominance and superiority analysis:

> (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions;
> (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class;
> (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum;
> (D) the difficulties likely to be encountered in the management of a class action.

Fed. R. Civ P. 23(b)(3). "The superiority requirement asks the court to balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication." *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 316 (3d Cir. 1998) (citations and internal quotations omitted). Before discovery, however, "there is insufficient information to conduct an informed balancing assessment." *Kantor v. Hiko Energy, LLC*, 100 F. Supp. 3d 421, 431 (E.D. Pa. 2015). "Erring in favor of the class action proceeding in this instance," a court may "decline to strike the class allegations" on superiority grounds. *Id.* (citing *Kahan v. Rosenstiel*, 424 F.2d 161, 169 (3d Cir. 1970)) "Many courts have determined that discovery is helpful and relevant in determining whether to certify a class and especially in evaluating the class certification factor of superiority." *Santiago v. Apothaker Scian, P.C.*, No. 2:16-CV-1432, 2017 U.S. Dist. LEXIS 64760, at *5 (D.N.J. April 27, 2017) (citations omitted).

The Court finds a superiority inquiry is premature at this stage. First, without discovery, the Court is unable to examine whether applying the varying state laws to the facts here will render a class action unmanageable and undesirable. The discovery will also help Plaintiffs

formulate subclasses or group the controlling state laws into limited categories that may make their proposed class action more manageable and desirable. Second, the failure of the Plaintiffs' Steering Committee to adopt the PIC is irrelevant here. After all, individual Plaintiffs, when filing their Short Form Complaints, will adopt the PIC. The Court discerns no reason why the Plaintiffs' Steering Committee should adopt the PIC. Third, "[t]he superior nature of the class action is closely related to the predominance requirement because 'only where predominance exists do the economies of scale justify aggregating claims in a class action.'" *In re Microcrystalline Cellulose Antitrust Litig.*, 218 F.R.D. 79, 93 (E.D. Pa. 2003) (citing *In re Mercedes-Benz Antitrust Litig.*, 213 F.R.D. 180, 186 (D.N.J. 2003)). Since the Court finds a predominance inquiry is premature, the superiority determination should also be postponed. Accordingly, the Court declines to dismiss Plaintiffs' class allegations on superiority grounds.

**4. A Rule 23(b)(2) Medical Monitoring Class Is Inapplicable**

Allergan argues Plaintiffs cannot invoke Rule 23(b)(2) for their proposed class action, because (1) all the reliefs they request, including those for medical monitoring, consumer fraud, and unjust enrichment, are in essence economic damages, and (2) their proposed classes lack cohesiveness. (ECF No. 171-2 at 55–57.) Plaintiffs counter it is premature at this stage to decide whether they can establish a Rule 23(b)(2) medical monitoring class, because discovery will help them formulate a medical monitoring program for Allergan to fund and implement. (ECF No. 219 at 40–41.) Plaintiffs contend Allergan blurs the line between Rule 23(b)(3) and (b)(2) classes by arguing the Rule 23(b)(2) certification is improper for lacking cohesiveness. (*Id.* at 41.) The Court finds a Rule 23(b)(2) class is inapplicable here.

Rule 23(b)(2) class actions are limited to those seeking "injunctive relief or corresponding declaratory relief [that] is appropriate respecting the class as a whole." Fed. R.

Civ. P. 23(b)(2). "Rule 23(b)(2) applies only when a single injunction or declaratory judgment would provide relief to each member of the class." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 360 (2011). Apart from the medical monitoring program, Plaintiffs do not request other injunctive or declaratory reliefs in the CAC. Therefore, as for the Rule 23(b)(2) inquiry, the Court will only consider the appropriateness of a Rule 23(b)(2) medical monitoring class.

As the following analysis shows, Plaintiffs not diagnosed with BIA-ALCL may not recover the medical monitoring relief under the laws of some jurisdictions. Though Plaintiffs not diagnosed with BIA-ALCL claim to have sustained physical injuries in the form of certain subclinical changes (ECF No. 220 at 25), these subclinical changes are not legally recognizable injuries in some jurisdictions. If such jurisdictions require a present injury in requesting the medical monitoring relief, then Plaintiffs not diagnosed with BIA-ALCL may not request the medical monitoring relief in these jurisdictions.

The following jurisdictions explicitly refuse to consider subclinical changes as legally recognizable physical injuries:

- Alabama. *Lindsey v. 3M Co.*, No. 5:15-cv-01750-AKK, 2020 U.S. Dist. LEXIS 52159, at *5 (N.D. Ala. March 26, 2020) ("Alabama law requires that plaintiffs currently have a disease as a result of exposure in order to recover in tort.").

- Arizona. *Burns v. Jaquays Mining Corp.*, 752 P.2d 28, 30 (Ariz. Ct. App. 1987) ("[S]ubclinical injury resulting from exposure to asbestos is insufficient to constitute the actual loss or damage to a plaintiff's interest required to sustain a cause of action under generally applicable principles of tort law.").

- Delaware. *In re Asbestos Litig.*, No. 87C-09-24, 1994 Del. Super. LEXIS 693, at *9 (Del. Super. June 14, 1994) ("[A]symptomatic pleural thickening, which results only in

scarring of the lungs without any physical impairment or illness, is not an actual loss and therefore should not be considered a compensable injury.").

- Georgia. *Parker v. Brush Wellman, Inc.*, 230 F. App'x 878, 882 (11th Cir. 2007) (citing *Boyd v. Orkin Exterminating Co., Inc.*, 191 Ga. App. 38, 381 S.E.2d 295, 298 (Ga. Ct. App. 1989), *overruled on other grounds*, *Hanna v. McWilliams*, 213 Ga. App. 648, 446 S.E.2d 741 (Ga. Ct. App. 1994)) (In the leading Georgia case dealing with exposure to a toxic substance, the Court of Appeals indicated that a personal injury plaintiff must present evidence of 'actual disease, pain or impairment of some kind.'").

- Hawaii. *In re Hawaii Fed. Asbestos Cases*, 734 F. Supp. 1563, 1567 (D. Haw. 1990) ("[T]he mere presence of asbestos fibers, pleural thickening or pleural plaques in the lung unaccompanied by an objectively verifiable functional impairment is not enough" to "show a compensable harm by adducing objective testimony of a functional impairment due to asbestos exposure.").

- Indiana. *Ott v. AlliedSignal, Inc.*, 827 N.E.2d 1144, 1156 (Ind. Ct. App. 2005) ("[S]ubclinical injuries or other physiological changes resulting from exposure to asbestos are insufficient to support a cause of action until symptoms emerge or until the disease can be diagnosed without resort to extraordinary procedures.").

- Iowa. *Pickrell v. Sorin Grp. USA*, Inc., 293 F. Supp. 3d 865, 868 (S.D. Iowa 2018) (finding the plaintiff suffered no injury because she was asymptomatic).

- Kentucky. *Luttrell v. Cooper Indus.*, 60 F. Supp. 2d 629, 630–32 (E.D. Ky. 1998) (stating the plaintiff's "personal injury claim for cancer had not accrued at the time of the earlier lawsuit" where "the plaintiffs offered evidence that they suffered cellular damage that had yet to be manifested as physical injuries").

- Maine. *Bernier v. Raymark Industries, Inc.*, 516 A.2d 534, 543 (Me. 1986) (citations omitted) ("[S]ubclinical injury . . . is 'insufficient to constitute the actual loss or damage to a plaintiff's interest required to sustain a cause of action under generally applicable principles of tort law.'").

- Maryland. *Exxon Mobil Corp. v. Albright*, 433 Md. 303, 386 (Md. 2013) (citations omitted) ("In the context of physical injuries sustained as a result of exposure to toxic substances, subcellular change produced by exposure to toxic chemicals—without manifested symptoms of a disease or actual impairment—is not a compensable 'injury' under Maryland law.").

- Mississippi. *Harris v. Brush Wellman, Inc.*, No. 1:04cv598HSO-RHW, 2007 U.S. Dist. LEXIS 81970, at *38–39 n.16 (S.D. Miss. Oct. 30, 2007) (citing *Paz v. Brush Engineered Materials, Inc.*, 949 So. 2d 1 (Miss. 2007)) ("[T]he Mississippi Supreme Court determined that plaintiffs did not demonstrate an actionable injury despite allegations of subclinical, subcellular, and cellular injury.").

- Missouri. *Laswell v. Brown*, 683 F.2d 261, 269 (8th Cir. 1982) (declining to recognize the exposure "to an unusually high risk of disease in genetically passed cellular damage" as a cognizable injury under Missouri law).

- New Jersey. *Caterinicchio v. Pittsburgh Corning Corp.*, 605 A.2d 1092, 1096 (N.J. 1992) ("[T]he presence of pleural thickening may not, alone, mandate a jury finding of compensable injury for an otherwise healthy plaintiff."); *Schweitzer v. Consolidated Rail Corp. (Conrail)*, 758 F.2d 936, 942 (3d Cir. 1985) ("[S]ubclinical injury resulting from exposure to asbestos is insufficient to constitute the actual loss or damage to a plaintiff's interest required to sustain a cause of action under generally applicable principles of tort law.").

- New York. *Caronia v. Philip Morris USA, Inc.*, 5 N.E.3d 11, 18 (N.Y. 2013) ("[I]t is speculative, at best, whether asymptomatic plaintiffs will ever contract a disease; allowing them to recover medical monitoring costs without first establishing physical injury would lead to the inequitable diversion of money away from those who have actually sustained an injury as a result of the exposure.").

- North Carolina. *Dennis v. Bayer Healthcare Pharms. Inc.*, No. 3:18-CV-00491-KDB-DCK, 2020 U.S. Dist. LEXIS 18180, at *18–19 (W.D.N.C. Feb. 3, 2020) (citations omitted) ("In cases involving disease, North Carolina courts have held that a cause of action does not accrue until the disease is diagnosed.").

- Ohio. *Ackison v. Anchor Packing Co.*, 897 N.E.2d 1118, 1125–26 (Ohio. 2018) (declining to find asymptomatic pleural thickening sufficient to establish a compensable injury for asbestos exposure).

- Pennsylvania. *Zieber v. Bogert*, 565 Pa. 376, 382 (E.D. Pa. 2001) (finding asymptomatic asbestos-related pleural thickening is not a compensable injury); *Schweitzer v. Consolidated Rail Corp. (Conrail)*, 758 F.2d 936, 942 (3d Cir. 1985) ("[S]ubclinical injury resulting from exposure to asbestos is insufficient to constitute the actual loss or damage to a plaintiff's interest required to sustain a cause of action under generally applicable principles of tort law.").

- Virginia. *Contreras v. Thor Norfolk Hotel, L.L.C.*, 292 F. Supp. 2d 798, 802 (E.D. Va. 2003) ("[U]ntil Plaintiff is diagnosed with an asbestos-related disease, he has no cause of action stemming from a physical injury.").

- Texas. *McManaway v. KBR, Inc.*, No. H-10-1044, 2015 U.S. Dist. LEXIS 190297, at *56 (S.D. Tex. Jan. 23, 2015) (ruling the plaintiffs cannot recover for their asymptomatic

genetic transformation injuries); *Ford Motor Co. v. Miller*, 260 S.W.3d 515, 518 (Tex. App. 2008) (citing RESTATEMENT (SECOND) OF TORTS § 7 cmt. b (1965)) ("[A] mere physical change that is not detrimental does not constitute a harm.").

- West Virginia. *Ball v. Joy Mfg. Co.*, 755 F. Supp. 1344, 1371 (S.D.W. Va. 1990) (concluding the plaintiffs, who were exposed to toxic chemicals but not yet diagnosed with a related disease, "may not recover such [medical monitoring] costs here because they have not suffered an actionable injury under the law of West Virginia").

- Wisconsin. *Peter v. Sprinkmann Sons Corp.*, 860 N.W.2d 308, 313 (Wis. Ct. App. 2015) ("[The plaintiff] did not have any legally cognizable claim for injuries before April 29, 1994, because [the plaintiff] was not diagnosed with mesothelioma until 2012."); *Alsteen v. Wauleco, Inc.*, 802 N.W.2d 212, 217–18 (Wis. Ct. App. 2011) ("[A]symptomatic plaintiffs who are merely exposed to toxic chemicals do not suffer a corresponding physical injury.").

The following jurisdictions do not allow a medical monitoring relief without a present physical injury:

- Alabama. *Hinton v. Monsanto Co.*, 813 So. 2d 827, 829 (Ala. 2001) (rejecting the plaintiff's contention that he could recover for "medical monitoring" without a "manifest, present injury").

- Delaware. *In re Asbestos Litig.*, No. 87C-09-24, 1994 Del. Super. LEXIS 685, at *4 (Del. Super. Ct. Aug. 5, 1994) (citing *Mergenthaler v. Asbestos Corp. of America*, 480 A.2d 647, 651 (Del. 1984)) ("Because the Court has determined that plaintiffs do not have a compensable physical injury, plaintiffs may not recover for the expenses of medical surveillance.").

- District of Columbia. *Witherspoon v. Philip Morris, Inc.*, 964 F. Supp. 455, 467 (D.D.C. 1997) (citing *R.J. Reynolds v. Burton*, 884 F. Supp. 1515, 1523 (D. Kan. 1995)) ("Whether a cause of action or a part of damages requested, medical monitoring requires that the plaintiff have a present injury and a reasonable fear that the present injury could lead to the future occurrence of disease.").

- Georgia. *Parker v. Brush Wellman, Inc.*, 377 F. Supp. 2d 1290, 1302 (N.D. Ga. 2005) ("This Court does not read Georgia law as permitting the establishment of a medical monitoring fund with respect to persons who have not endured a cognizable tort injury.").

- Iowa. *Pickrell v. Sorin Grp. USA*, Inc., 293 F. Supp. 3d 865, 868 (S.D. Iowa 2018) ("[T]he Iowa Supreme Court, if confronted with the opportunity to recognize a medical monitoring cause of action, would either decline to do so or would require an actual injury.").

- Kentucky. *Wood v. Wyeth-Ayerst Labs.*, 82 S.W.3d 849, 857 (Ky. 2002) ("rejecting prospective medical monitoring claims (in the absence of present injury)").

- Louisiana. *Burmaster v. Plaquemines Parish Gov't*, 982 So. 2d 795, 806 (La. 2008) (citing *Bourgeois v. A.P. Green Indus., Inc.*, 783 So. 2d 1251, 1255 (La. 2001)) ("[T]he Louisiana Legislature amended La. Civ. Code art. 2315 to eliminate medical monitoring as a compensable item of damage, unless the plaintiff has manifested physical or mental injury or disease.").

- Michigan. *Henry v. Dow Chem. Co.*, 701 N.W.2d 684, 692–93 (Mich. 2005) (holding a medical monitoring claim "does not exist in Michigan" and "our common law requires a present injury in addition to economic loss incurred as a result of that injury").

- Minnesota. *Palmer v. 3M Co.*, No. C2-04-6309, 2007 Minn. Dist. LEXIS 162, at *46 (Minn. Dist. Ct. June 19, 2007) ("Minnesota law does not recognize an independent tort of

medical monitoring."); *Thompson v. Am. Tobacco Co.*, 189 F.R.D. 544, 555 (D. Minn. 1999) (citations omitted) ("[E]ach Plaintiff seeking participation in a medical monitoring program must establish injury;" "an increased risk of disease due to 'mere exposure to a toxic substance' by itself is not a sufficient injury under Minnesota law.").

- Mississippi. *Paz v. Brush Engineered Materials, Inc.*, 949 So. 2d 1, 9 (Miss. 2007) (declining to recognize "a medical monitoring cause of action without a showing of physical injury").

- New York. *Caronia v. Philip Morris USA, Inc.*, 5 N.E.3d 11, 18 (N.Y. 2013) ("[P]olicy reasons set forth above militate against a judicially-created independent cause of action for medical monitoring. Allowance of such a claim, absent any evidence of present physical injury or damage to property, would constitute a significant deviation from our tort jurisprudence.").

- North Carolina. *Curl v. Am. Multimedia, Inc.*, 654 S.E.2d 76, 81 (N.C. Ct. App. 2007) (electing not to create a new cause of action of medical monitoring for the plaintiffs that are not diagnosed with an illness).

- North Dakota. *Mehl v. Canadian Pac. Ry.*, 227 F.R.D. 505, 518 (D.N.D. 2005) ("Given these basic principles of North Dakota tort law, a plaintiff would be required to demonstrate a legally cognizable injury to recover any type of damages in a newly recognized tort, including a medical monitoring claim.").

- Oklahoma. *Taylor v. Michelin N. Am., Inc.*, No. 14-CV-293-JED-FHM, 2018 U.S. Dist. LEXIS 54405, at *23 (N.D. Okla. March 30, 2018) (dismissing the plaintiffs' medical monitoring class allegations because "the plaintiffs have not yet presented evidence of physical injuries attributable to contaminants from the plant"); *Reece v. AES Corp.*, No. CIV-12-0457-JH,

2014 U.S. Dist. LEXIS 2236, at *31 (E.D. Okla. Jan. 8, 2014) ("Plaintiffs concede that Oklahoma law does not allow a remedy for medical monitoring in the absence of an existing disease or physical injury.").

- Oregon. *Hamilton v. Silven, Schmeits & Vaughan*, No. 2:09-cv-1094-SI, 2013 U.S. Dist. LEXIS 74352, at *27 (D. Or. May 28, 2013) (citing *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181, 186 (Or. 2008)) ("Medical monitoring damages are not recoverable in Oregon without some present symptoms."); *Lowe*, 183 P.3d at 187 ("[N]egligent conduct that results only in a significantly increased risk of future injury that requires medical monitoring does not give rise to a claim for negligence.").

- Tennessee. *Bostick v. St. Jude Med., Inc.*, No. 03-2636 BV, 2004 U.S. Dist. LEXIS 29997, at *45 (W.D. Tenn. Aug. 17, 2004) (citations omitted) ("Tennessee requires present injury for medical monitoring claims.").

- Texas. *Norwood v. Raytheon Co.*, 414 F. Supp. 2d 659, 665 (W.D. Tex. 2006) ("[T]he Texas Supreme Court appears likely to reject medical monitoring claims . . . in the absence of a present physical injury.").

- Washington. *Duncan v. Northwest Airlines, Inc.*, 203 F.R.D. 601, 606–07 (W.D. Wash. 2001) (concluding a stand-alone medical monitoring cause of action "is contrary to Washington law, which is grounded in actual present injury and limits recovery for enhanced risk").

- West Virginia. *Ball v. Joy Mfg. Co.*, 755 F. Supp. 1344, 1371 (S.D.W. Va. 1990) (concluding the plaintiffs, who were exposed to toxic chemicals but not yet diagnosed with a related disease, "may not recover such [medical monitoring] costs here because they have not suffered an actionable injury under the law of West Virginia").

- Wisconsin. *Alsteen v. Wauleco, Inc.*, 802 N.W.2d 212, 218–19 (Wis. Ct. App. 2011) (citations omitted) ("[D]efining the need for medical monitoring as an 'injury' does nothing more than attach a specific item of damages to what is actually a claim for increased risk of future harm. Yet, Wisconsin tort law does not compensate for increased risk of future harm; actual, present injury is required.").

As a result, in the jurisdictions that (1) reject subclinical changes as physical injuries and (2) require physical injuries be shown for recovering the medical monitoring relief, the Plaintiffs not diagnosed with BIA-ALCL cannot request the medical monitoring relief. Whether Plaintiffs' other alleged injuries, such as those relating to diagnostic procedures and removal surgeries, are legally cognizable is irrelevant, because they are not the types of injuries that give rise to the need of medical monitoring. As a result, the Plaintiffs not diagnosed with BIA-ALCL cannot obtain a medical monitoring relief, at least, under the laws of Alabama, Delaware, Georgia, Iowa, Kentucky, Mississippi, New York, North Carolina, Texas, West Virginia, and Wisconsin.

In other words, a nationwide Rule 23(b)(2) class action for medical monitoring will not provide any relief to some Plaintiffs. The Court needs no individualized factual inquiries or discovery to reach this conclusion, because Plaintiffs concede only 16.7% of Plaintiffs are diagnosed with BIA-ALCL (ECF No. 263-1 at 1), and refer to class members not diagnosed with BIA-ALCL in every state-specific subclass (ECF No. 118 at ¶¶ 270–382). Because the proposed medical monitoring class "includes class members from states that expressly prohibit no-injury medical monitoring claims, the declaratory relief Plaintiff[s] seek[] could never be 'appropriate respecting the class as whole.'" *Almond v. Janssen Pharms., Inc.*, No. 20-2183, 2020 U.S. Dist. LEXIS 207900, at *21 (E.D. Pa. Nov. 6, 2020). "Accordingly, the nationwide class cannot

satisfy Rule 23(b)(2)." *Id.* (citations omitted). Plaintiffs may later reformulate medical monitoring (sub)classes to cure the above deficiencies.

In sum, the Court dismisses Plaintiffs' class allegations asserted for (1) the following subclasses: Alaska, American Samoa, Arkansas, District of Columbia, Guam, Hawaii, Indiana, Kansas, Maryland, Mississippi, Nebraska, New Hampshire, North Dakota, Northern Mariana Islands, Puerto Rico, U.S. Virgin Islands, and Vermont; and (2) a nationwide Rule 23(b)(2) medical monitoring class.

## IV. CONCLUSION

For the reasons set forth above, Allergan's Motion to Strike/Dismiss CAC (ECF No. 171-2), Motion to Dismiss Plaintiffs' complaints on preemption grounds (ECF No. 171-1), and Motion to Dismiss PIC (ECF No. 171-3) are **GRANTED IN PART and DENIED IN PART** as follows: The Court dismisses with prejudice all Plaintiffs' claims to the extent they are based on the alleged defects in Allergan's investigational devices used in an approved clinical trial, other than Allergan's tissue expanders and implants sold before the 2000 PMA. In addition, the Court dismisses with prejudice Plaintiffs' claims for: negligence *per se* (Count III) to the extent the claims are asserted under the laws of Alaska, Arkansas, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Rhode Island, Texas, Utah, Vermont, Washington, West Virginia, and Wyoming; strict liability (Count IV) and negligent failure to warn (Count V) to the extent they are based on Allergan's alleged failure to (1) warn on its label the risk of developing BIA-ALCL and (2) conduct post-PMA clinical studies, for the BIOCELL implants, other than Allergan's tissue expanders and implants sold before the 2000 PMA; strict liability

(Count IV) and negligent failure to warn (Count V) to the extent they are based on Allergan's alleged failure to adequately report safety information to the FDA under the laws of Alabama, Alaska, Arkansas, Arizona, Colorado, Connecticut, District of Columbia, Florida, Georgia, Iowa, Kansas, Maine, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Utah, Virginia, West Virginia, and Wyoming; negligent representation (Count VI) the extent they are asserted under the laws of Arkansas, Louisiana, Minnesota, and Virginia, as well as Mississippi common law; implied warranty of merchantability (Count VII) to the extent they are asserted under Pennsylvania law and Wisconsin law; and express warranty (Count VIII) to the extent they are asserted under Wisconsin law. Also, the Court strikes/dismisses without prejudice Plaintiffs' class allegations for (1) the a nationwide Rule 23(b)(2) medical monitoring class; and (2) the PMA and non-PMA Device State Subclasses the extent of the subclasses for Alaska, American Samoa, Arkansas, District of Columbia, Guam, Hawaii, Indiana, Kansas, Maryland, Mississippi, Nebraska, New Hampshire, North Dakota, Northern Mariana Islands, Puerto Rico, U.S. Virgin Islands, and Vermont. The motions to dismiss are denied as to the remaining claims.

**Date: March 19, 2021**

***/s/ Brian R. Martinotti***
**HON. BRIAN R. MARTINOTTI**
**UNITED STATES DISTRICT JUDGE**