UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	**Case No.: 2:19-md-2921 (BRM)(JAD)** **MDL NO. 2921** **JUDGE BRIAN R. MARTINOTTI** **JUDGE JOSEPH A. DICKSON**

THIS DOCUMENT RELATES TO: ALL CASES

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' MASTER PERSONAL INJURY COMPLAINT PURSUANT TO FED. R. CIV. P. 8(a), 9(b), and 12(b)(6) (NON-PREEMPTION ISSUES)

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INTRODUCTION

Plaintiffs' Master Long Form Personal Injury Complaint ("PIC") alleges claims for personal injuries arising from Allergan's recalled BIOCELL implants on behalf of three groups of Plaintiffs: (1) women whose implants caused them to be diagnosed with Breast Implant Associated-Anaplastic Large Cell Lymphoma ("BIA-ALCL") and were explanted ("Group 1"); (2) women whose implants caused them injuries and were explanted due to the risk of developing BIA-ALCL ("Group 2"); and (3) women whose implants caused them injuries and who intend to have the implants explanted but due to financial or health constraints currently have not yet done so ("Group 3"). As alleged in detail in the PIC, all Plaintiffs have sustained present personal injuries from the implants and have suffered physical injury, mental anguish, and past and future economic injury.

The PIC painstakingly alleges breaches of state law duties and parallel federal requirements sufficient to withstand Allergan's preemption arguments. *See* Dkt. 216 (Memorandum Of Law In Opposition To Defendants' Motion To Dismiss Plaintiffs' Master Personal Injury Complaint And Consolidated Class Action Complaint) ("Plaintiffs' Preemption Brief"). Moreover, while it is both premature and unnecessary to engage in a state-by-state analysis of each claim at this stage, Plaintiffs have sufficiently pleaded their causes of action and this motion should be denied.

First, Allergan's motion relies on a tortured application of *Erie* principles, while ignoring the widely used judicial tools available to a federal court sitting in diversity when charged with determining state law. Specifically, Allergan states that all claims not recognized by a state's highest court must be dismissed – a position with no support that can be quickly rejected.

Next, Allergan asks the Court to ignore the well-pleaded allegations in the PIC and dismiss the claims of all Plaintiffs who have not already been diagnosed with BIA-ALCL. Allergan attempts to reduce all the other claims of the Group 2 and Group 3 Plaintiffs to a stand-alone "fear of cancer" claim, but ignores the well-pleaded allegations of present injuries sustained by these Plaintiffs in the PIC. Actual harm, although not required in many states, has been alleged on behalf of Plaintiffs in all three groups, and all of the Plaintiffs deserve the chance to prove their claims and damages at trial.

Allergan next invites the Court to dive into a far-reaching state-by-state analysis of each legal claim but relies on inadequate and misleading case citations, while simultaneously pushing the Court to ignore choice of law and other important considerations. While the PIC is a helpful administrative tool in this MDL to navigate common issues and aid discovery, it would be a poor use of the Court's time to engage in a state-by-state analysis of every nuance of state law trying to identify issues that are "uncommon" as opposed to efficiently addressing the common issues.

Allergan's last attack is on the pleading of the causes of action. But Plaintiffs' claims are pleaded sufficiently and Defendants have adequate notice of the asserted claims.

Allergan's motion relies on its Appendix ("Def. Appendix") that purports to survey the laws of certain states as to each issue relating to its motion. Plaintiffs have responded in an abbreviated fashion to inform the Court of countervailing law. Allergan's Appendix is cursory rather than comprehensive, and is an incomplete, often misleading description of state law, giving short shrift to both the law and *Erie* by its limited and hand-picked citations and analysis. Although Allergan's characterization of state law is wrong, even if it were as Allergan represents, every claim would survive in some states. Thus, trimming the case at this early stage of specific state law claims would not limit discovery or gain efficiency, and it also would not

apply to any individual Plaintiff until choice of law and case specific issues are considered in an individual context. Therefore, Plaintiffs urge the Court to defer consideration of specific state law claims or causes of action until a full opportunity is afforded to properly brief the law for a given state in the context of an individual's claim, such as when bellwether trials or summary judgment proceedings are before the Court. In sum, Allergan is asking the Court to prematurely confiscate many Plaintiffs' day in court and the opportunity for redress for serious injuries, including death, and to do so on an incomplete record. Justice requires more. Based upon the following reasons, Allergan's motion to dismiss the PIC should be denied.[1]

LEGAL STANDARDS

Allergan brings this motion under Rule 8(a), 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure. As the moving party, Allergan bears the burden of showing that no claim has been stated. *Thomas v. John A. Youderian, Jr., LLC*, 232 F. Supp. 3d 656, 663-64 (D.N.J. 2017) (citing *Animal Science Products, Inc. v. China Minmetals Corp.*, 654 F.3d 462, n. 9 (3d Cir. 2011)). "'There are no special pleading requirements for product liability claims in general or for Class III medical device claims in particular.'" *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 747 (D. Md. 2015) (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010)). "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544,

[1] Allergan did not move to dismiss *any* causes of action pleaded in the Consolidated Class Action Complaint ("CAC") under Rule 12(b)(6) and therefore has waived the right to do so. The causes of action pleaded in the CAC vary from those in the PIC. For example, the PIC does not seek, as does the CAC, a medical monitoring program (though the PIC seeks compensation for past and future medical expenses that are reasonably related to specific personal injuries, and such expenses may include evaluations for BIA-ALCL). The Class Plaintiffs submitted a separate response to Allergan's arguments relevant to medical monitoring at pages 30-37 of their Memorandum Of Law In Opposition To Defendants' Motion To Strike/Motion To Dismiss Plaintiffs' Consolidated Class Action Complaint, which is incorporated.

546 (2007). In clarifying the pleading requirements applicable to Rule 8, the Supreme Court specifically disavowed any application of *Twombly* that would instruct a district court to impose a new or heightened pleading standard into its Rule 12(b)(6) determinations: "[W]e do not require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 569.

Therefore, the pleading burden imposed by Rule 8 is not especially onerous, *Dudhi v. Temple Health Oaks Lung Ctr.*, No. 18-3514, 2019 WL 426145 (E.D. Pa. Feb. 4, 2019), and is met when the facts as alleged and accepted as true "'give the defendant fair notice of what the ... claim is and the grounds upon which it rests.'" *Erickson v. Pardus*, 551 U.S. 89, 93-94 (2007) (quoting *Twombly*, 550 U.S. at 555). At this stage, the Court does not weigh the evidence, but instead focuses on determining whether the complaint has "facial plausibility." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Twombly*, 550 U.S. at 556).

To the extent Rule 9(b) applies to negligent misrepresentation claims in a limited number of states, it is not proper to zero in on the "particularity" aspect and overlook the flexibility envisioned at the pleading stage. *Allied Medical Assoc. v. State Farm Mut. Auto. Ins. Co.*, No. 08-cv-2434, 2009 WL 1066932, at *3 (E.D. Pa. April 16, 2009). "Plaintiffs may satisfy this requirement by pleading the 'date, place or time' of the fraud, or through 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'" *Lum v. Bank of Am.*, 361 F.3d 217, 224 (3d Cir. 2004) (quoting *Seville Indus. Mach. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984), *abrogated on other grounds by Twombly*, 550 U.S. at 557). The Third Circuit has cautioned against "focusing exclusively on [Rule 9(b)'s]

'particularity' language" because such a focus is "'too narrow an approach [that] fails to take account of the general simplicity and flexibility contemplated by the rules.'" *Seville*, 742 F.2d at 791 (quoting *Christidis v. First Pa. Mortgage Trust*, 717 F.2d 96, 100 (3d Cir. 1983)). Instead, courts must evaluate whether the complaint "adequately describes the nature and subject of the alleged misrepresentation." *Id.*

ARGUMENT

I. ALLERGAN'S *ERIE* ANALYSIS IS INCORRECT AND DOES NOT MANDATE DISMISSAL OF ANY CLAIMS AS THE COURT'S DUTY IS TO APPLY OR PREDICT STATE LAW

Allergan asserts that "where a state's highest court has not recognized a particular cause of action or the relief sought pursuant to it, dismissal is required." MTD at 1. Allergan is wrong. The *Erie* doctrine requires district courts sitting in diversity to determine what the state's highest court would decide. If the state's highest court has not spoken definitively on an issue, federal judges must give careful consideration to sources of state law, including lower state court decisions, to predict how the highest court would rule. *Erie v. Tompkins*, 304 U.S. 64, 78 (1938). Indeed, two years after *Erie*, the Supreme Court rejected the argument Allergan asserts and held that "a federal court is not free to reject [a] state rule merely because it has not received the sanction of the highest state court." *West v. Am. Tel. & Tel. Co.*, 311 U.S. 223, 236–38 (1940). The Court explained:

> A state is not without law save as its highest court has declared it. 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. . . [I]t is the duty of the [federal court] in every case to ascertain from all the available data what the state law is and apply it….

Id. Thus, in the absence of a controlling opinion from a state's highest court, federal courts are "charged with predicting how that court would resolve the issue" by taking into consideration:

"(1) what that court has said in related areas; (2) the decisional law of the state intermediate courts; (3) federal cases interpreting state law; and (4) decisions from other jurisdictions that have discussed the issue." *Canal Ins. Co. v. Underwriters at Lloyd's London*, 435 F.3d 431, 436 (3d Cir. 2006); *see also Koppers Co. v. Aetna Cas. & Sur. Co.*, 98 F.3d 1440, 1445 (3d Cir. 1996) (in predicting state law, a district court should also consider "decisions of … federal courts interpreting that state's law and other state supreme courts that have addressed the issue," as well as "analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand."); *Illinois Nat. Ins. Co. v. Wyndham Worldwide Operations, Inc.*, 653 F.3d 225, 231 (3d Cir. 2011) ("[F]ederal courts must attribute significant weight to [lower state court] decisions in the absence of any indication that the highest state court would rule otherwise.").

This Court just applied these principles in *Curro v. HD Supply, Inc.*, No. 2:19-cv-19198, 2020 WL 3496955 (D.N.J. June 29, 2020) (Martinotti, J.), and analyzed whether the New Jersey Conscientious Employee Protection Act precluded claims asserted by a plaintiff under the New Jersey Law Against Discrimination. *Id*. at *4-6. Finding no controlling decisions from the New Jersey Supreme Court, this Court analyzed decisions from New Jersey's appellate courts and the District of New Jersey and concluded that the New Jersey Supreme Court would permit plaintiff to maintain both causes of action. *Id*. at *5-6.

Allergan's citations to the contrary are misleading. MTD at 3-4. For example, Allergan's quote from *City of Philadelphia v. Lead Indus. Ass'n*, 994 F.2d 112, 123 (3d Cir. 1993), conveys that a federal court can consider how state precedent has "foreshadowed" state law. Similarly, Allergan suggests that *West*, 311 U.S. at 236, holds that a district court sitting in diversity is prevented from predicting state law. Allergan is mistaken. In *West*, the Supreme Court directed

that "an intermediate appellate state court is a datum for ascertaining state law which is not to be disregarded by a federal court unless it is convinced by other persuasive data that the highest court of the state would decide otherwise." *West*, 311 U.S. at 237.

In *Travelers Indem. Co. v. Damman & Co.*, 594 F.3d 238, 244 (3d Cir. 2010), the Third Circuit reiterated these principles and concluded that New Jersey state law would bar the claim at issue. Allergan's quotation from this case (MTD at 4) is incomplete. Following its thorough analysis of "muddled" New Jersey law, the Third Circuit stated:

> Because of the dearth of directly on-point New Jersey case law, this case represents yet another example of how difficult the predictive exercise can be… Given that difficulty, in reaching our conclusion we have exercised restraint in accordance with the well-established principle that where 'two competing yet sensible interpretations' of state law exist, 'we should opt for the interpretations that restrict liability, rather than expands it, until the Supreme Court [of New Jersey] decides differently.'

Id. at 253 (citations omitted).

Allergan's incorrect application of the *Erie* doctrine undercuts significant aspects of its motion. Since Allergan ignores most state law except that issued by a state's highest court, its Appendix is incomplete and misleading, and its analysis is therefore unreliable.[2] This is a

[2] Compounding the matter, when it suits its purpose, Allergan's Appendix occasionally cites to a state's intermediate court or to federal district courts. Thus, Allergan's application of the *Erie* doctrine appears to be that federal courts should ignore intermediate state courts and federal courts unless the decision favors Allergan's position. On this basis, Allergan urges this Court to misapply the *Erie* doctrine and dismiss claims recognized by a state's intermediate courts. In some instances moreover, Allergan is simply wrong. For example, in arguing that the Court should dismiss the "failure to report" portion of Plaintiffs' failure to warn claim, Allergan states: "To date, no state high court has affirmatively adopted a duty to report adverse events to the FDA as an element of a state tort law claim…." MTD at 13. But Allergan fails to inform the Court that in California, the nation's most populous state and one where Allergan has significant facilities and deep ties, at least two appellate courts have determined, and its Supreme Court agrees, that California recognizes a parallel duty to report adverse events to the FDA. *See Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 428-429 (2014) ("Federal law requires manufacturers of class III devices to file adverse event reports…. California law imposes a

separate and independent basis for denial of Allergan's motion. Plaintiffs have not asked the Court to allow "novel" state law personal injury claims, but rather have pleaded standard state law causes of action deeply embedded in our justice system.

II. ALLERGAN'S MOTION IS PREMATURE AND WOULD WASTE JUDICIAL RESOURCES

The Judicial Panel for Multi-District Litigation established this MDL and assigned it to this Honorable Court following Allergan's July 2019 recall of the BIOCELL products. The panel stated that "[a]ll actions share complex factual questions arising from the allegation that Allergan's BIOCELL textured breast implants and tissue expanders significantly increase the risk of developing BIA-ALCL, and that Allergan failed to warn the FDA, patients, and healthcare providers of this risk. The common factual questions include: (1) whether BIOCELL textured breast implants and tissue expanders can cause BIA-ALCL; (2) whether defendants knew or should have known of the risk of BIA-ALCL; (3) whether they provided adequate warnings as to the risk; and (4) the adequacy of defendants' product." *In re Allergan BIOCELL Textured Breast Implant Prod. Liab. Litig.*, 412 F. Supp. 3d 1361, 1362 (J.P.M.L. 2019).

An MDL master complaint is an administrative tool designed to assist with the primary purpose of the centralization itself: discovery. Master complaints are often used in MDL proceedings to allow courts to employ a single uniform complaint upon which decisions can be made on common issues of fact or law, such as the scope of discovery or the existence of

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parallel requirement under the common law strict liability tort of failure to warn."); *Mize v. Mentor Worldwide LLC,* 51 Cal. App. 5th 850, 863 (2020) ("Unlike Arizona, California does recognize a duty to report adverse events to the FDA…."); *Coleman v. Medtronic, Inc.*, 331 P.3d 178, 175 (Cal. 2014) (examining the *Coleman* decision, dismissing the appeal, and ordering that the Court of Appeal decision be published).

personal jurisdiction on a defendant. *See* Manual for Complex Litig., Fourth, § 22.36. Importantly, master complaints do not set forth any plaintiff's specific facts and are not necessarily complete recitations of the factual bases and claims a plaintiff may assert. As such, dismissal of any specific claim alleged in the PIC would be premature.

MDL courts observe generally that a "'master complaint should not be given the same effect as an ordinary complaint. Instead, it should be considered as only an administrative device to aid efficiency and economy.'" *In re Digitek Prods. Liab. Litig.*, MDL No. 08-md-1968, 2009 WL 2433468, at *8 (S.D. W. Va. Aug. 3, 2009) (quoting *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 142 (E.D. La. 2002)); *In re: Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 489 F. Supp. 2d 932, 936 (D. Minn. 2007) ("Consolidation of a master complaint is merely a procedural device designed to promote judicial economy, and, as such, it does not affect the rights of the parties in separate suits."); *In re Rezulin Prods. Liab. Litig.*, 390 F.Supp.2d 319, 330 n. 62 (S.D.N.Y. 2005). The "focus" is on litigation management "as opposed to being a primary operative pleading." *In re Digitek Prods. Liab. Litig.*, 2009 WL 2433468, at *8; *see also In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46 (D.N.J. 2009) ("In the absence of … consent, the majority of courts treat consolidated complaints filed in multi-district litigations as a procedural device rather than a substantive pleading with the power to alter the choice of law rules applicable to the plaintiffs' claims.").

A federal district court reached the same conclusion in denying similar motions to dismiss without prejudice in *In re Nuvaring Prods. Liab. Litig.*, No. 4:08MD1964, 2009 WL 10694306 (E.D. Mo. Dec. 11, 2009), finding "a delay in reaching [defendant's] motions to dismiss will not effect [sic] the discovery process." *Id.* at *3. It also expressed reluctance to get involved with "cumbersome, case-specific legal issues," because the purpose of an MDL is to

deal with "matters common among all cases." *Id.* at *2. Finally, it noted: "While I appreciate [defendant's] desire to clean-up the pleadings in the individual cases this is not the role of an MDL court." *Id.*

The PIC does what a master complaint is supposed to do, setting forth common issues for discovery and allowing for subsequent, plaintiff-specific complaints. It would be both unnecessary and unhelpful to treat the PIC with exacting particularity. State-specific matters can and should be left for later – for bellwether cases, or for the district courts on remand. This is common practice. For example, in one MDL court's practice and procedure order, the court counseled against entangling the MDL in state-law matters: "Many of the legal issues in this MDL arise exclusively under state law, and the Court does not expect to address such issues prior to remand." *In re Ethicon, Inc. Power Morcellator Prods. Liab. Litig.*, No. 2:15-md-2652, Dkt. No 2, at 2 (D. Kan. Oct. 16, 2015). In another example, on the remand of Biomet hip device cases, an MDL court informed remand courts of its work and noted it had "declined to consider state-specific spoliation rules," leaving those to remand courts. *In re Biomet M2a Magnum Hip Implant Prod. Liab. Litig.*, No. 3:12-MD-2391, 2018 WL 7683307, at *5 (N.D. Ind. Sept. 6, 2018); *see also In re Johnson & Johnson Talcum Powder Prods. Litig.*, No. 16-7891, 2017 WL 4570289, at *6, n.11 (D.N.J. Oct. 12, 2017) (federal court would leave state-law issues for state court to resolve on remand).

Master complaints do not "tell the whole story." Personal injury plaintiffs in this MDL will file individual complaints that adopt the PIC and may include additional facts, allegations, and causes of action unique to that plaintiff and her chosen venue. Necessarily, then, any ruling on the PIC would have to take those complaints into account on an individual basis to affirmatively dismiss any individual plaintiff's claim. There is no need for this Court to take this

up now, as opposed to during the bellwether process, and a decision on this motion will gain little efficiency. Allergan will still be subject to discovery regarding its implants, their design, manufacture, approval process, risks and benefits, and other core facts. Discovery would be neither expedited nor streamlined if the Court grants dismissal of some of the state law claims at issue.

III. ALL PLAINTIFFS HAVE ADEQUATELY ALLEGED A PHYSICAL INJURY AND NO CLAIM SHOULD BE DISMISSED

Allergan asserts that to pursue a product liability claim, a woman must leave a carcinogenic medical device to fester in her body until it causes a life-threatening cancer that is diagnosed. If a woman has the cancer-causing device surgically removed to help prevent the cancer from developing after the product is recalled, Allergan claims her case must be dismissed. MTD at 5-7. Thankfully, no state imposes this cruel and barbaric requirement. Furthermore, Group 2 and Group 3 Plaintiffs who have not yet been diagnosed with BIA-ALCL plausibly allege that they have sustained other present physical injuries that entitle them to compensation for past and future medical expenses, pain and suffering, emotional distress, loss of enjoyment of life, lost wages, and death[3] under the law of each jurisdiction.

A. Plaintiffs Without A BIA-ALCL Diagnosis Plausibly Allege Personal Injuries Sufficient To Support Their Claims

[3] *See* PIC ¶¶ 9, 156, 166, 202, 218, 230, 243, 254, and 273 ("As a proximate result of Allergan's wrongful conduct, Plaintiffs have been severely harmed, and have endured pain, suffering, disability, impairment, disfigurement, increased risk of developing cancer, inconvenience, loss of enjoyment of life, aggravation or activation of preexisting conditions, scarring, inconvenience, and incurred costs for medical care and treatment, loss of wages and wage earning capacity, death for certain patients, and other economic and non-economic damages. The losses are permanent and continuing in nature.").

Allergan concedes that a woman in Group 1 whose implant caused her to be diagnosed with full-blown lymphoma has suffered an injury that can support her product liability claims. MTD at 5. But Allergan then argues that every plaintiff without an ALCL diagnosis should have her claims dismissed. In other words, Allergan would have the Court believe that a woman whose doctor surgically removed a recalled BIOCELL implant that caused tissue damage and became, at implantation, a ticking time bomb, has not suffered any injury and cannot assert a product liability claim for her injuries. Allergan's argument is not supported by any state's law and should be rejected.

Even if all states required a showing of a "present physical injury" to support a product liability claim—which Allergan concedes they do not[4]—all Plaintiffs plausibly allege they have suffered a present physical injury.

> **Group 1**: Women who have been diagnosed with BIA-ALCL (a present physical injury) and have endured evaluation, treatment, and one or more surgeries to remove, and in some cases replace, the cancer-causing implant as well as, in some cases, radiation, chemotherapy and death;

[4] Allergan concedes that many jurisdictions do not require a present physical injury to properly state product liability claims. *See* MTD at 1. Indeed, many jurisdictions allow product liability claims based purely on emotional distress caused by a defective and/or malfunctioning product, especially one that causes cancer. *See* Plaintiffs' Appendix, "Mental Distress Damages-"Increased Risk" and "Fear Of", pp. 1-47). In addition to alleging present physical injuries, the PIC alleges that affected women have suffered severe emotional distress as a result of their defective and malfunctioning BIOCELL implant. *See* PIC ¶¶ 9, 156, 166, 202, 218, 230, 243, 254, and 273. Fear of cancer claims are well-grounded in American law. "Modern tort law now recognizes a separate cause of action for serious emotional distress without a contemporaneous physical injury." *In re du Pont C-8 Personal Injury Litig.*, No. 2:13-md-2433, 2016 WL 659112, at *13 (S.D. Ohio Feb. 17, 2016) (citing *Lavelle v. Owens-Corning Fiberglas Corp.*, 30 Ohio Misc. 2d 14, 15 (1987)). Moreover, fear of a future cancer is a compensable element of damages under the law of a majority of States. "[C]ourts having considered cancerphobia . . . almost uniformly have allowed it." *Jackson v. Johns-Manville Sales Corp.*, 781 F.2d 394, 414 (5th Cir. 1986). It is emotional distress, a "form of pain and suffering." *In re du Pont C-8 Litig.*, 379 F. Supp. 3d 669, 674–75 (S.D. Ohio 2019) (quoting from instructions given to jury).

> **Group 2**: Women who have not yet been diagnosed with BIA-ALCL, but whose defective BIOCELL implants have caused them present physical injuries, including dangerous inflammatory reaction, tissue damage, seromas, invasive diagnostic procedures, and one or more surgeries to remove, and in some cases replace, the defective BIOCELL implant; and
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> **Group 3**: Women who have not yet been diagnosed with BIA-ALCL, but whose defective BIOCELL implants have caused them present physical injuries, including dangerous inflammatory reaction, tissue damage, and seromas, and who intend to explant when they are able to afford it or when their health permits.

See PIC ¶¶ 8, 9, and 161. These allegations are taken as true and unquestionably establish physical injury as a matter of law. Every plaintiff alleges their BIOCELL implants are defective and have malfunctioned including by, among other things (1) creating a "'particle laden' environment on the implant surface which exposed patients to particles," (2) exposing patients to "foreign, degraded and loosened fragments of silicone particles and other materials" including "unintended particle residue," (3) causing "shear forces from the excessive number of jagged and sharp particles on the implant surface," and (4) causing "mechanical attachment and detachment of the over-aggressively textured surface to the tissue capsule."[5] *Id*. ¶¶ 118 and 119.

Consequently, all Plaintiff have sustained present physical injuries even if they have not yet been diagnosed with BIA-ALCL, including, without limitation: (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. *See, e.g., id*. ¶¶ 119, 127, and 149.[6] Additionally, the diagnostic tests and medical procedures that Plaintiffs undergo

[5] *See also* PIC ¶ 42 ("each of the BIOCELL products implanted in Plaintiffs . . . (f)ailed to perform in a manner reasonably expected."); *id.* ¶ 154 ("Allergan's textured BIOCELL products did not perform as a physician or an ordinary patient would expect them to perform…").

[6] *See also* PIC ¶ 118 ("Allergan's uncontrolled and un-validated manufacturing processes created a "particle laden" environment on the implant surface which exposed patients to particles that caused chronic inflammation and caused or contributed to the development of ALCL"); *id.* ¶ 127

to detect ALCL further impose physical injuries—such as insertion of a needle into their breasts and for removal of a core of tissue and biopsy (a medical procedure known as a "core biopsy"). *See id.* ¶ 29. These physical injuries are endured by Plaintiffs even before undergoing a surgery to remove the BIOCELL implants. *See* supra at fn. 3. All Plaintiffs have also undergone or will undergo[7] one or more extensive surgeries to remove the BIOCELL implant from their body and, in some cases, replace it with a non-defective implant. This removal surgery involves cutting into the woman's breast, causing extensive and often permanent physical damage, and it is often just the first of several surgeries needed to fully reconstruct the breast after removal. *Id.* ¶ 8. Plaintiffs

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("the particle-laden surface and resulting increased surface area, implant debris shear forces and micro movement shear forces between the capsule and the shell, cause chronic physiologic inflammation and the development of BIA-ALCL in patients."); *id.* ¶¶ 129, 130 ("The adulterated implants created a particle-laden environment and significantly increased the surface area, stimulated shear forces, and caused ongoing micro movement shear forces between the implant surface and tissue capsule, causing chronic inflammation and significantly increased risk of BIA-ALCL."); *id.* ¶ 149 (the defective BIOCELL implant caused "continuous micro movement shear forces between the implant surface and the tissue capsule, and the development of ***chronic inflammation***, ***tissue damage***, seromas and ALCL"); *id.* ¶ 161 (the defective BIOCELL implant caused "continuous micro movement shear forces between the surface of the implants and the tissue capsule, ***proliferation of T-cells***, ***malignant transformation of T-cells, chronic inflammation, tissue damage***, ***seroma formation*** and ALCL, and other harm.) (emphasis added).

[7] The vast majority of the women in this case have already undergone the surgery to remove their recalled BIOCELL implants, either before or after they have developed full-blown ALCL. Other plaintiffs have not yet been able to undergo the surgery because of medical or financial impediments. Nevertheless, as described above, the BIOCELL implant has ***already*** caused these women to suffer present physical injuries (such as proliferation of their T-cells, malignant mutations of their T-cells, and chronic physiologic inflammation. *See, e.g.*, PIC ¶¶ 119 and 127. These women will suffer additional physical injuries in the future when they are able to undergo the needed removal surgery.

who have not yet been diagnosed with BIA-ALCL have sustained these present, physical injuries,[8] which are compensable under the laws of all relevant jurisdictions.

Finally, Allergan mischaracterizes Plaintiffs' claims as "fear of cancer" or "increased risk" claims. They are not. Plaintiffs allege traditional tort law claims, which, although not required, are accompanied by a present physical injury. As part of the compensation for those injuries, Plaintiffs seek damages for emotional distress, which includes the fear of cancer. *See, e.g.*, PIC ¶¶ 9, 156, 166, 202, 218, 230, 243, 254, and 273. Such damages are routinely permissible. *See* Plaintiffs' Appendix, "Mental Distress Damages-'Increased Risk' and 'Fear Of'" at 1-47.

B. The PIC Does Not Seek A Medical Monitoring Fund

"Medical monitoring relief" is a court-administered fund that provides diagnostic medical care for plaintiffs who, as a result of a defendant's tortious conduct, sustained an increased risk of a particular condition, and require diagnostic care to monitor for and detect that condition. *See Friends for All Children, Inc., Lockheed Aircraft Corp.*, 746 F.2d 816 (D.C. Cir. 1984); *In re Paoli R. Yard PCB Litig.*, 915 F.2d 829, 852 (3d Cir. 1990). To clarify, the PIC does not seek a medical monitoring fund or assert stand-alone causes of action for medical monitoring relief, as

[8] Some plaintiffs have suffered physical injuries in addition to those described in the PIC. For example, approximately 300 personal injury cases are already pending in the MDL, and each describes unique facts and circumstances and descriptions of damages sustained at the time of filing. Case Management Order No. 17 permits plaintiffs to allege additional facts and causes of action that support their individual claims or describe their individual circumstances. While Plaintiffs believe the PIC properly alleges that all plaintiffs have suffered a present physical injury, should the Court consider dismissing any of the Plaintiffs' claims on the basis that they have not sufficiently alleged a present physical injury, Plaintiffs seek leave to amend the PIC to further clarify this issue, and each individual Plaintiff should likewise be given the opportunity to assert or amend their specific pleading to cure any deficiency the Court believes exists, if any.

these are sought in Plaintiffs' Consolidated Class Action Complaint.[9] Rather, the PIC alleges that each plaintiff has sustained a *present* physical injury from their BIOCELL implants and requests, *inter alia,* past and future medical expenses that are reasonably related thereto. All jurisdictions permit recovery of these expenses when a plaintiff proves a personal injury. *See* Plaintiffs' Appendix, "Future Medical Damages" at 48-59. Because Plaintiffs have sufficiently pleaded their product liability claims based on present physical injuries, their claims for past and future medical expenses and emotional distress damages (including the emotional distress caused by the increased risk of cancer) are also properly pleaded. As described in Plaintiffs' Appendix, each state permits plaintiffs to seek past and future medical expenses and emotional distress damages caused by an injury.[10]

Consequently, under every state's laws, all plaintiffs have properly alleged their product liability claims and Allergan's motion to dismiss these claims should be denied.

IV. PLAINTIFFS PLAUSIBLY STATE A CLAIM FOR MANUFACTURING DEFECT BECAUSE THEY ALLEGE THAT ALLERGAN FAILED TO COMPLY WITH FDA APPROVED MANUFACTURING SPECIFICATIONS

Allergan concedes that a manufacturing defect exists when there is "a deviation from the manufacturer's intended specifications that renders the device unreasonably dangerous." MTD at 7-8. Without quoting even one sentence from the PIC, Allergan asserts that the PIC "fails to

[9] Medical monitoring is discussed in greater detail in Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Strike/Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint, filed concurrently herewith. The section of Allergan's Appendix that addresses "medical monitoring" is not applicable to this motion to dismiss the PIC.

[10] As a preliminary matter, Allergan's argument that medical monitoring damages and "fear of cancer" damages are not available—even if it had any merit—would not eliminate any cause of action, or even any claimed element of damages. Allergan's "fear of cancer" argument attacks only the part of the emotional distress damages that relate to a plaintiff's fear of cancer, not the other significant emotional distress claimed by Plaintiffs.

identify a single manufacturing *defect* in any device at issue." *Id.* at 9. Not so. Plaintiffs clearly allege a manufacturing defect: "This action arises from Allergan's wrongful conduct, including its: (a) failure to manufacture the BIOCELL line in accordance with intended and approved design specifications and processes, thereby rendering the product defective…." PIC ¶ 6. Plaintiffs then describe – based on their intensive investigation but without the benefit of discovery – numerous, specific, and detailed ways that Allergan's manufacture of the BIOCELL implants deviated from Allergan's intended design specifications. *See* PIC ¶¶ 108-143 and 146-156. For example, Plaintiffs allege:

- "Allergan used a texturing process in the manufacture of its textured implants that was ***contrary to and inconsistent with the PMAs, the approved design and manufacturing specifications*** and processes for the BIOCELL product line, including the applicable CGMPs, QSRs, other pertinent federal regulations, as well as parallel state law." PIC ¶ 116 (emphasis added).

- "Workers scrubbed the final cured layer of silicone in a scrubbing room using different brushes and un-validated methods that ***violated PMA requirements, Allergan's manufacturing and design specifications***. . . Allergan's uncontrolled and un-validated scrubbing process resulted in final products that ***did not meet the PMA requirements or Allergan's own design and manufacturing specifications***. . . This constituted a defectively manufactured surface, as ***the manufacturing was in variance from the product specifications and processes***, resulting in the presence of unintended particle residue and the production of a product different than the product approved by the FDA, causing severe harm to patients." *Id*. ¶ 118 (emphasis added).

- "The harms described above directly resulted from the ***variations from the approved design and manufacturing specifications***." *Id.* at ¶ 120 (emphasis added).

- "The improper texturing techniques and particle-laden and debris covered implant surface and other out of specification characteristics described above rendered the manufacture defective, ***varying from the approved and intended design and manufacturing specifications***" *Id*. ¶ 143 (emphasis added).

- "[The BIOCELL implants] were adulterated upon manufacture, having been ***defectively manufactured in violation of applicable specifications, the PMA design and manufacturing specifications*** . . . ." *Id.* ¶ 148 (emphasis added).

- "Allergan's defective manufacturing was characterized by the production of unreasonably dangerous materials and surfacing, including ***nonconforming materials and inappropriate unsafe components***, using inconsistent and unsafe techniques and methods which were not reasonably standardized or validated, and which ***deviated from the intended design and manufacturing specifications***, resulting in variable roughness, excessive particle formation, increased surface area, and continuous micro movement shear forces between the implant surface and the tissue capsule, and the development of chronic inflammation, tissue damage, seromas and ALCL." *Id*. ¶ 149 (emphasis added).

- "Allergan's negligent manufacturing, which ***deviated from the approved and intended design***, caused its products to have variable roughness, a particle laden environment, surface debris, increased surface area, continuous micro movement shear forces between the surface of the implants and the tissue capsule, proliferation of T-cells, malignant transformation of T-cells, chronic inflammation, tissue damage, seroma formation and ALCL, and other harm. *Id*. at ¶ 161 (emphasis added).

Contrary to Allergan's assertion, these allegations in the PIC state a manufacturing defect claim. *See, e.g.*, *Bass v. Stryker Corp*., 669 F.3d 501, 510 (5th Cir. 2012) (holding manufacturing defect claim adequately pleaded where the plaintiff alleged that the device caused his injury and that the device "was adulterated due to violations of 21 C.F.R. §§ 820.20(a), 820.20(b)(2), and 820.70(e)"); *Bausch v. Stryker Corp.*, 630 F.3d 546, 549-60 (7th Cir. 2010) (holding claims were adequately pleaded where the plaintiff alleged violations of federal law with respect to manufacturing and inspection processes); *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x. 436, 440-41 (6th Cir. 2010) (holding claim adequately pleaded when the plaintiff identified a deviation from the FDA-approved manufacturing process and a single CGMP that had been violated); *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 105–06 (D. Conn. 2014) (holding manufacturing defect claim adequately pleaded where the plaintiff "specified the defect in the [device] he received and how that defect differed from the federal standards applicable to the device"); *cf. Mendez v. Shaw*, 94 F. Supp. 3d 633 (D.N.J. 2015) (allegations that the product was manufactured in contravention of FDA requirements or CGMPs can be enough to sustain a manufacturing defect claim but the plaintiff's claim was dismissed because she failed to

identify the exact federal requirements at issue). That the defect may be widespread does not change the analysis.

A manufacturing defect is generally defined as a deviation from a manufacturer's intended design or specifications. *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2(a) (1998) ("A product contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product."); David G. Owen, *Manufacturing Defects*, 53 S.C. L. REV. 851, 866 (2002) (discussing development of the departure-from-design test). A plaintiff may establish effectiveness by "either of two alternative methods of proof: comparing the accident-product unit to the manufacturer's formal design specifications *or* to the dimensions and other parameters of some otherwise identical product." *Id*. at 870 (emphasis added).[11] In other words, a plaintiff states a cognizable manufacturing defect claim when she shows a deviation *from intended specifications*; she need not show a deviation *from the norm*.

Allergan misleadingly omits the primarily used definition or "alternative method of proof" when it argues that many states require a "deviation from the norm" for a manufacturing defect. As explained in Plaintiffs' Appendix and Plaintiffs' Preemption Brief, Allergan is wrong. A manufacturing defect can be proven either by showing that the product deviated from design specifications, or that it deviated from other products in the same product line. "As noted previously, a manufacturing defect under the Act occurs when the product comes off the

[11] *See also Notmeyer v. Stryker Corp.*, 502 F. Supp. 2d 1051, 1059 (N.D. Cal. 2007) ("Under California law, a manufacturing defect occurs where the 'product differs from the manufacturer's intended result *or* from other ostensibly identical units from the same product line.'") (quoting *Barker v. Lull Eng'g Co.*, 20 Cal.3d 413, 429 (1978) (emphasis added); N.J.S.A. 2A:58C–2a (defining a manufacturing defect as a deviation "from the design specifications, formulae, or performance standards of the manufacturer *or* from otherwise identical units manufactured to the same manufacturing specifications or formulae") (emphasis added).

production line in a substandard condition based on the manufacturer's own standards or identical units that were made in accordance with the manufacturing specifications." *Myrlak v. Port Auth. Of New York and New Jersey*, 723 A.2d 45, 52 (N.J. 1999) (referencing N.J.S.A. 2A:58C–2a). "Moreover, in reviewing this record for substantial evidence in support of a manufacturing or production defect theory, we must keep in mind the two formulations of the test: A defective product is one that "differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." *In re Coordinated Latex Glove Litig.*, 99 Cal. App. 4th 594, 611 (2002), *as modified on denial of reh'g* (July 15, 2002).

Other cases cited by Allergan also note that a manufacturing defect claim requires a showing of deviation from specifications, which Plaintiffs allege. *See* Def. Appendix at 26-37; *In re Coordinated Latex Glove Litig.*, 99 Cal App. 4th at 607 ("[A manufacturing defect claim] focuses on whether the particular product involved in the accident was manufactured in conformity with the manufacturer's design.") (internal citations and quotations marks omitted); *McConologue*, 8 F. Supp. 3d 93 at 105 (holding a claim was stated where "Plaintiff has sufficiently alleged that the Ceramic Liner implanted in his body was not manufactured in accordance with federal standards and that the failure to meet these standards resulted in the defect observed on the device implanted in his body"); *Piltch v. Ford Motor Co.*, 778 F.3d 628, 632–33 (7th Cir. 2015), *abrogated on other grounds by Kaiser v. Johnson & Johnson*, 947 F.3d 996 (7th Cir. 2020) ("To demonstrate a manufacturing defect, the plaintiff must show that the product . . . deviates from its intended design.") (Indiana law) (internal citations and quotations marks omitted); *Wright v. Brooke Group, Ltd.*, 652 N.W.2d 159, 178 (Iowa 2002) (adopting Restatement definition of manufacturing defect as "*when the product departs from its intended*

design") (emphasis in original).[12] Certainly, it could aid a plaintiff to use the "deviation from the norm" alternative test to prove a manufacturing defect in a single product by comparing and contrasting the defective one to a larger inventory. Nonetheless, the number of products defectively manufactured does not transform the nature of the defect to one of design rather than manufacture. Allergan's argument would lead to the nonsensical result that a manufacturer is insulated from liability when it manufactures all or most products defectively, rather than a few. Thankfully, that is not the law.

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[12] *See also Ex rel. Harrison v. Harrison*, 733 N.W.2d 451, 455 (Minn. 2007) ("A manufacturing defect in the products liability context means the product departs from its intended design.") (internal citations and quotations marks omitted); *In re C.R. Bard, Inc.*, No. 2:11-CV-00114, 2013 WL 5591948, at *3 (S.D. W. Va. June 4, 2013) ("Mississippi law on manufacturing defects requires a showing that the product deviated in a material way from the manufacturer's specifications or from otherwise identical units manufactured to the same manufacturing specifications.") (internal citations and quotations marks omitted); *Richcreek v. Gen. Motors Corp.*, 908 S.W.2d 772, 776 (Mo. Ct. App. 1995) ("(A) manufacturing defect occurs when something goes wrong in the manufacturing process and the product is not in its intended condition. The product is evaluated against the producers' own standards, and compared to like products.") (internal citations and quotation marks omitted); *Freeman v. Hoffman-La Roche, Inc.*, 260 Neb. 552, 556 (2000) ("[A] manufacturing defect[] is one in which the product differs from the specifications and plan of the manufacturer.") (citation omitted); *Delaney v. Stryker Orthopaedics*, No. CIV.A. 08-03210DMC, 2009 WL 564243, at *7 (D.N.J. Mar. 5, 2009) (dismissing manufacturing defect claim where plaintiff had "not pointed to a defect or a deviation from the FDA-reviewed Trident™ manufacturing specifications"); *Yanovich v. Zimmer Austin, Inc.*, 255 F. Appx. 957, 962 (6th Cir. 2007) ("[plaintiff] could have identified a manufacturing defect by demonstrating that the extracted patellas deviated in a material way from *either* (1) Zimmer's design specifications/standards; *or* (2) otherwise identical units made by Zimmer") (Ohio law) (emphasis in original); *Kious v. Teva Pharm. USA, Inc.*, No. CIV-16-990-R, 2016 WL 9559038, at *2 (W.D. Okla. Dec. 8, 2016) ("Under Oklahoma law, [a] product is defective in manufacture if it deviates in some material way from its design or performance standards. The issue is whether the product was rendered unsafe by an error in the manufacturing process, which is "often established by showing that a product, as produced, failed to conform with the manufacturer's specifications.") (internal citations and quotations marks omitted)); *Zuzel v. SEPTA*, No. CV 19-268, 2019 WL 3252936, at *4 (E.D. Pa. July 18, 2019) ("(A) manufacturing defect only exists where the product that injured the plaintiff deviated somehow from the intended design of the manufacturer.") (internal citations and quotations marks omitted); *Ford Motor Co. v. Ledesma*, 242 S.W.3d 32, 41–42 (Tex. 2007) ("[A] manufacturing defect must deviate from its specifications or planned output in a manner that renders the product unreasonably dangerous.").

Allergan does not point to a single case that dismissed a manufacturing defect claim similar to the one Plaintiffs allege here, *i.e.*, that the product deviated from the intended specifications and caused the plaintiff's injuries. Instead, Allergan attempts to confuse the issue by citing cases involving very different facts and causes of action. For example:

- *Fasolas v. Bobcat of New York, Inc.*, 128 N.E.3d 627, 641 (N.Y. 2019) involved a design defect claim and not a manufacturing defect claim at all. Allergan relies on a ***dissenting opinion*** (without so informing this Court) and an observation offered in dicta of the dissent which states: "[u]nlike manufacturing defects, in design defect cases, the alleged product flaw arises from an intentional decision by the manufacturer to configure the product in a particular way."

- *Evans v. Lorillard Tobacco Co.*, 990 N.E.2d 997, 1010 (Mass. 2013) involved a tobacco smoker's death in which there was no claim of manufacturing defect nor even a discussion of a pleading requirement of deviation from intended design.

- *Harrison v. Harrison*, 733 N.W.2d 451, 454 n.2 (Minn. 2007) is a negligence case by a minor child against his parents for negligently installing a car seat, not involving a manufacturing defect claim or a failure to plead deviation from intended design.

- *Coba v. Ford Motor Co.*, 932 F.3d 114, 123-24 (3d Cir. 2019) is a ruling on summary judgment (not a motion to dismiss) in a putative class action case for *breach of warranty* in connection with Ford fuel tanks in which the plaintiff did not allege any deviation from specifications. The case had nothing to do with pleading requirements for a product liability manufacturing defect case. Ford's warranty covered manufacturing defects but not design defects. Throughout the case, the plaintiff there, unlike Plaintiffs here, never alleged that the product deviated in any way from the manufacturer's intended specifications and argued only that the design of the product was the cause of the failure. *Coba v. Ford Motor Co.*, No. 12-cv-1622, 2016 WL 5746361, at *10 (D.N.J. Sept. 30, 2016). Moreover, even though the plaintiff in *Coba* never specifically alleged a manufacturing defect, the court still denied the defendant's motion to dismiss when the complaint was challenged at the pleading stage, holding that "it is unclear whether the Fuel Tank Defect is design defect or a defect in materials or workmanship, and the Court need not resolve the issue at the pleading stage. . . . [T]he defendant's characterization of the nature of the claim pre-discovery should not control whether the complaint survives." *Coba v. Ford Motor Co.*, 2013 WL 244687, at *7 (D.N.J. Jan. 22, 2013) (internal citations omitted).[13]

[13] Courts have recognized that practical hurdles exist at the pleading stage for plaintiffs, as confidential information such as PMA files are unavailable to Plaintiffs, and discovery is often important to manufacturing defect claims and should be permitted. *See Bausch.*, 630 F.3d at 558

Allergan's subpar workmanship in the manufacture of BIOCELL products caused extensive manufacturing defects, but Plaintiffs have not alleged that the defects were identical or equal. In fact, Plaintiffs describe the "excessively variable and uncontrolled" scrubbing of the implant surfaces, resulting in "inconsistent texturing" and "variable roughness." PIC ¶¶ 118, 129, 130, 149, and 151. Thus, whether using the "deviation from intended and approved design specifications" test or the "deviation from the norm" alternative, Plaintiffs have sufficiently pleaded their manufacturing defect claim and the motion to dismiss this claim should be denied.

V. PLAINTIFFS' NEGLIGENCE P*ER SE* CLAIM IS ADEQUATELY PLEADED

Allergan limits its challenge of Count III of the Master Complaint ("General Negligence, Negligence Per Se") to the allegations pertaining to negligence *per se* for violations of duties set forth under federal law, including the Medical Devices Act, 21 U.S.C. § 360k ("MDA") and FDA regulations. Contrary to Allergan's statements, Plaintiffs are not suing for violations of federal law to enforce federal duties, as that is the FDA's responsibility. Rather, Plaintiffs are suing for damages for breaches of state law duties that mirror the federal requirements. States

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("[D]istrict courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim."); *Coleman v. Medtronic, Inc.*, 223 Cal.App.4th 413, 436 (2014) (recognizing the need for discovery before determining whether claim had been stated); *Money v. Johnson & Johnson*, No. 15-cv-03213-LB, 2016 U.S. Dist. LEXIS 70808, at *13 (N.D. Cal. May 31, 2016) ("Even though he does not currently cite to precise provisions of the PMA — which the defendants may prefer — his allegations tied to the PMA are sufficiently specific to proceed to discovery. To hold otherwise would impose on Mr. Money an impossible pleading standard because he has not yet received the PMA (a confidential document)."); *Warren v. Howmedica Osteonics Corp.*, No. 4:10 CV 1346 DDN, 2011 WL 1226975, at *5 (E.D. Mo. March 29, 2011) ("[P]laintiffs are permitted to proceed to discovery to determine which particular PMA specifications defendants may have violated in manufacturing [the device].") Plaintiffs also seek discovery here to further support their claims.

permit such claims, with few expressly rejecting them. Therefore, the negligence *per se* claim should stand.

A. Violations Of The FDCA Can Constitute A Legitimate Basis For A Negligence *Per Se* Claim Pursuant to the RESTATEMENT (SECOND) OF TORTS

The almost universal application of the negligence *per se* doctrine stems from the RESTATEMENT (SECOND) OF TORTS § 286, that lists only four "purposes" that a law must have for a violation to constitute negligence *per se*.[14] Over forty years ago, the Second Circuit held that the federal Food, Drug, and Cosmetic Act ("FDCA") could be used as a basis for a negligence *per se* claim because it satisfied the four purposes set forth in the Restatement. *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727, 733 (2d Cir. 1979). The Second Circuit's reasoning has been widely applied since that decision and is applicable here.[15]

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[14] These purposes are: (1) to protect a class of persons which includes the one whose interest is invaded; (2) to protect the particular interest which is invaded; (3) to protect that interest against the kind of harm which has resulted; and (4) to protect that interest against the particular hazard from which the harm results. RESTATEMENT (SECOND) OF TORTS §286 (1965).

[15] *See, e.g., Stanton by Brooks v. Astra Pharmaceutical Products, Inc.*, 718 F.2d 553, 565 (3d Cir. 1983) (holding that failure to comply with FDA regulations constituted negligence *per se* under Pennsylvania law); *Green v. Dolsky*, 685 A.2d 110, 117–18 (Pa. 1996) (holding state law claims alleging FDA requirements were not followed not preempted); *Allen v. Delchamps, Inc.*, 624 So.2d 1065 (Ala. 1993) (permitting FDCA-based negligence *per se* claim because the plaintiffs relied on the regulations to establish a duty or standard care, and not to sue directly under the FDCA); *Mize v. Mentor Worldwide LLC*, 265 Cal. Rptr. 3d 468, 481 (Ct. App. 2020); *Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422 (W.D.N.Y. 2001) (misbranding or otherwise illegally omitting product warnings required by FDCA can support a claim for negligence *per se*); *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198, 214 (E.D.N.Y. 2004) (misbranding or otherwise illegally omitting product warnings required by FDCA can support a claim for negligence *per se*); *Howard v. Zimmer, Inc.*, 299 P.3d 463, 473 (Okla. 2013) (permitting FDCA-based negligence *per se* claim where the plaintiffs relied on regulations to establish a standard of care); *Fry v. Allergan Medical Optics*, 695 A.2d 511, 516 (R.I. 1997) (finding state law claims alleging a departure from FDA-imposed standards are not preempted because "they would not impose different or additional requirements but would instead merely enforce the exact requirements imposed by federal law."); *Valente v. Sofamor*, 48 F. Supp. 2d 862, 875-76 (E.D. Wis. 1999) (noting the FDCA creates no private right of action but

For example, in *Stanton by Brooks v. Astra Pharm. Prods., Inc*., 718 F.2d 553 (3d Cir. 1983), infant Harrikah Stanton suffered irreversible brain damage after being administered Xylocaine, a local anesthetic. Among other things, her guardian sued for Astra's failure to file adverse event reports concerning the drug with the FDA, as the FDCA required. *Id*. at 557. The jury determined that Astra's failure to comply with the FDA's regulations supported a finding of liability based on negligence as well as strict liability under RESTATEMENT (SECOND) OF TORTS § 402A (1965). *Id.* at 558. Astra appealed and challenged the application of federal law to its conduct as a basis for liability. *Id*. In upholding the verdict, the Third Circuit held that "Astra's conduct was negligent *per se* and that such conduct proximately caused Harrikah's injuries; we further conclude that the jury could find that Xylocaine was a defective product within the meaning of section 402A and that the defective product was a proximate cause of the harm." *Id.* at 559-60. Thus, the defendant was obligated to comply with the federal statutes and regulations and the violation of the federal safety regulations constituted negligence *per se* because the infant was in the class of those intended to be protected from the type of harm that she suffered. *Id.* at 564.

Allergan argues that the FDCA lacks the requisite demonstration of legislative intent to become the basis for the imposition for civil liability in certain jurisdictions. MTD at 10-11. To

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nonetheless found that Congress intended to allow state common law claims for violations of the FDCA for medical devices, namely a violation related to pre-market approval of a system for inserting screws into individual's spine); *Marvin v. Zydus Pharm. (USA) Inc*., 203 F. Supp. 3d 985 (W.D. Wis. 2016); *Kurer v. Parke, Davis & Co*., 679 N.W.2d 867, 868 (Wis. Ct. App. 2004) (finding drug manufacturer could be found negligent *per se* for failing to warn a patient about possible side effects of an oral contraceptive and court held "violations of FDA regulations may constitute negligence per se" and noted that "compliance with FDA standards will foreclose negligence per se").

the contrary, in *Medtronic, Inc. v. Lohr*, the Supreme Court noted that the MDA was enacted "to provide for the safety and effectiveness of medical devices intended for human use" and that the primary issue motivating the MDA's enactment was "the safety of those who use medical devices." 518 U.S. 470, 490-91 (1996). Such clear recognition that the statute's primary motivation is to protect the safety of those who use medical devices is sufficient to infer the intent of Congress that the statute can be used as a basis for civil liability under state common law. *See also In re Orthopedic Bone Screw Products Liability Litig.*, 193 F.3d 781, 791 (3d Cir. 1999) (recognizing liability *per se* is available when FDA regulations are used merely to establish the standard or duty that the defendants allegedly failed to meet).

Allergan suggests that "at least" a dozen states have abolished or restricted the negligence *per se* doctrine so as to preclude its application here. MTD at 10. While some states have disavowed a negligence *per se* claim based upon federal violations, as seen above in footnote 15, many states do indeed recognize such claims.[16] And, contrary to Allergan's assertion, such claims are not novel. Again, the shortcomings of Allergan's Appendix are apparent here too. For example, nowhere in its Appendix does Allergan mention the two California decisions that mirror Plaintiffs' claims, *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 433 (2014) ("California recognizes the applicability of negligence *per se* in a broad range of scenarios, including violation of federal law…. Because Coleman's negligence claim based on Medtronic's failure to file adverse event reports is cognizable under California law and is parallel to federal

[16] Some states have adopted negligence *per se* based upon violations of federal standards that have been adopted as state requirements, others have rejected it, and some have not yet spoken. A state by state analysis must be done to meaningfully categorize them, and must also consider choice of law rules, *Erie* principles, and individual state laws. Allergan did not perform that analysis.

requirements, he may proceed on this theory."); and *Mize v. Mentor Worldwide LLC*, 51 Cal. App. 5th 850, 865-866 (2020) ("[Plaintiff] also alleged that Mentor's manufacturing defects and its failure to properly report adverse events to the FDA caused her injuries. These injuries are clearly those the MDA and FDA regulations sought to prevent, and Mize is in the class the FDA sought to protect. She may therefore pursue her negligence per se claim."). The same should apply here.

B. Plaintiffs' Claims Are for Damages Under State Law, Not To Enforce A Private Cause of Action For Violations Of Federal Law

While it is true that only the federal government can sue for enforcement of FDA regulations, Plaintiffs are not suing to enforce federal regulations but are instead suing for damages under parallel state law caused by Allergan's common law negligence. *See* 21 U.S.C. § 337(a); *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, 300 F. Supp. 3d 732, 747 (D. Md. 2018). Indeed, Plaintiffs assert no federal claims but merely are relying on federal requirements to establish the standard of care for their state law claim that Allergan negligently caused them harm.[17] Plaintiffs have identified independent duties that Allergan owed under their respective states' laws, PIC ¶¶ 171-180, that are informed by—and, per *Lohr*, mirror—federal statutes, regulations, and actions. *Id.* ¶¶ 168-70. These traditional duties of care, when read in conjunction with the federal safety statutes and administrative regulations governing the device, and the various duties imposed thereunder, form the basis of a claim of negligence *per se*. Violations of these duties often substitute for key elements of a state law negligence claim (*i.e.*, duty and breach). *See* Plaintiffs' Appendix, "Negligence *Per Se*" at

[17] *See generally* Plaintiffs' Preemption Brief, Dkt. 216 (explaining why Plaintiffs' claims are grounded on longstanding state tort law for post-market misconduct, rather than fraud on a federal agency, and therefore are not subject to implied preemption under *Buckman*).

88-132. Therefore, Plaintiffs have stated a claim under the laws of a number of states and Allergan's motion should be denied.

VI. ALLERGAN CHALLENGES ONLY ONE ASPECT OF PLAINTIFFS' FAILURE TO WARN CLAIMS, RENDERING DISMISSAL INAPPROPRIATE

Plaintiffs allege that Allergan had a duty to warn Plaintiffs, the medical community, Plaintiffs' treating physicians, and the public. *See, e.g.*, PIC ¶¶ 200, 215. Allergan moves to dismiss Plaintiffs' failure to warn claims (Counts IV and V) only to the extent that they depend on an alleged failure to report adverse events to the FDA. MTD at 12-14. As explained in Plaintiffs' Preemption Brief which is incorporated here by reference, Plaintiffs have alleged numerous factual bases for their failure to warn claims, including, without limitation, (1) the failure to add adequate warnings of BIA-ALCL to the labeling of BIOCELL implants; (2) the failure to report adverse event information about BIA-ALCL to the FDA, which would have made the information publicly available (including to Plaintiffs and their physicians); (3) Allergan's engagement in a campaign of false and misleading statements that minimized the risk of BIA-ALCL; and (4) Allergan's flouting of post-approval study requirements imposed by the FDA. *See, e.g.*, PIC ¶¶ 33-38, 60-61, 67, 87-95, and 181-219.

Allergan challenges only the second allegation in the preceding paragraph.[18] MTD at 13 (arguing only that "no state court has affirmatively adopted a duty to report adverse events to the

[18] Allergan incorrectly claims that Plaintiffs assert "two contradictory theories: (1) that Allergan failed to warn of the risks of their devices by failing to report adverse events to the FDA; or (2) that while Allergan actually did report events to the FDA, it did so using an improper "summary" report format." MTD at 12. In fact, Plaintiffs allege that Allergan violated FDA reporting regulations and parallel state law duty to warn by ***both*** never reporting numerous failures of the implants to the FDA as required, and in addition, for reporting some failures improperly, through the subterfuge of "summary reports" that Allergan was not permitted to use for such failures and which hid the failures from consumers, healthcare professionals and the FDA. *See e.g.*, PIC ¶¶ 90, 186, and 190. Both are deficiencies in reporting and constitute a failure to report.

FDA as an element of a state law claim and several states have expressly rejected it."). In fact, Allergan does not dispute that it had a legal duty to warn Plaintiffs, medical professionals, and the FDA. MTD at 12-14. Nor does Allergan claim that Plaintiffs failed to plead *any* cognizable claim for failure to warn. Thus, even if Allergan were correct on the law – and it is not – the wholesale dismissal of Plaintiffs' failure to warn claims would still be inappropriate.

But dismissal is also inappropriate to the extent that Plaintiffs' failure to warn claims are based upon Allergan's failure to report adverse events. Failure to warn is a traditional state law claim based on the universally accepted notion that a manufacturer must use reasonable care to warn of product defects and dangers. RESTATEMENT (SECOND) TORTS § 388 (1965) (imposing on manufacturers a duty to "exercise reasonable care" to warn of product dangers, including via third parties); *see also Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 991 (8th Cir. 1969) (referring to the "undisputed duty to make *reasonable efforts* to warn the medical profession"; "the manufacturer may be held liable… (for) the failure to give a warning *reasonable under the circumstances*") (emphasis added); *In re Smith & Nephew BHR & R3 Hip Implant Prods. Liab. Litig.*, 300 F. Supp. 3d 732, 747 (D. Md. 2018) (denying motion to dismiss failure to warn claims in 42 jurisdictions and characterizing the claims as "traditional state law causes of action that owe their existence to health and safety concerns); *Pliva, Inc. v. Mensing*, 564 U.S. 604, 643 (2011) (characterizing "failure to warn" actions as "longstanding") (Sotomayor, J., dissenting).

Accordingly, courts rely on common law principles when concluding that a manufacturer's failure to report adverse events to the FDA constitutes a plausible failure to warn claim. For example, in *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343 (D. Del. 2019), the

court analyzed Delaware law—specifically, its adoption of the RESTATEMENT (SECOND) OF TORTS § 388 ("Section 388")—and characterized St. Jude's duty to warn as a duty "to warn a third party of a product's dangerous propensities, where there is a reasonable assurance that the information will reach those whose safety depends on such information." *Id.* at 359. Encompassed in the reasonableness standard articulated in Section 388 is the duty to report adverse events to the FDA, and thus the plaintiff plausibly alleged a failure to warn via adverse event reporting. The courts in *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016), and *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 899-900 (M.D. Pa. 2017), held similarly.

Likewise, in *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762 (5th Cir. 2011), the Fifth Circuit characterized the plaintiffs' failure to warn claim, which was supported with evidence that Boston Scientific had not adequately reported adverse events to the FDA, as "a Mississippi tort claim based on the underlying state duty to warn about the dangers or risks of product. ***She seeks to prove Boston Scientific's breach of the state duty by showing that Boston Scientific violated the FDA's MDR regulations***." *Id.* at 359-360 (emphasis added). The court in *A.F. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 544 (S.D.N.Y. 2018) held that "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***" and added: "plaintiffs' claim is based on the underlying state duty to warn about the dangers or risks of the product." (quotations omitted) (emphasis added). *See also Bull v. St. Jude Med., Inc.*, No. 17-1141, 2018 U.S. Dist. LEXIS 115730, at *28 (E.D. Pa. July 12, 2018) ("Plaintiff has alleged that St. Jude violated a state tort law, namely by failing to warn physicians about the risks of the Riata ST Lead *based on* the failure to fully comply with its federal duty to report all adverse events to the FDA via MDRs in a timely manner.")

(emphasis in original); *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015) ("Maryland tort law recognizes that a duty to warn can undergird a negligence case in product liability actions. 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***.") (quotations omitted) (emphasis added); *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 185 (N.D.N.Y. 2014) ("Plaintiff argues that Defendants' failure to timely report to the FDA led to a violation of state law, ***in that Defendants also did not exercise reasonable care in informing the medical community of known risks***"; denying motion to dismiss) (emphasis added); *Bradburn v. CR Bard, Inc.*, No. 19-cv-925, 2020 WL 3065024, at *2 (N.D. Ind. June 9, 2020) (allowing negligence claims to proceed where the plaintiff alleged that Bard concealed adverse event reports from medical professionals in a reporting system used by the FDA known as the Alternative Summary Reporting Program).

Because the doctrine is rooted in widely-accepted, traditional tort law principles, courts in at least 15 states explicitly recognize a state law duty to warn via adverse event reporting: *see Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 360 (D. Del. 2019) (Delaware); *Rowe v. Mentor Worldwide, LLC*, 297 F. Supp. 3d 1288, 1295-1296 (M.D. Fla. 2018) (Florida); *Beavers-Gabriel v. Medtronic, Inc.*, No. CIV 13-00686, 2015 Wl 143944 at *12 (D. Haw. Jan. 9, 2015) (Hawaii); *Gravitt v. Mentor Worldwide, LLC*, No. 17-C-5428, 2018 WL 2933609, at *9 (N.D. Ill. June 12, 2018); *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026, 1034 (N.D. Ill. 2016) (Illinois); *Fisk v. Medtronic, Inc.*, No. 3:17-cv-032, 2017 WL 4247983, at *6 (N.D. Ind. Sept. 25, 2017) (Indiana); *Gavin v. Medtronic*, No. CIV.A. 12-0851, 2013 WL 3791612, at *14 (E.D. La. July 19, 2013) (Louisiana); *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md.

2015) (Maryland); *Angeles v. Medtronic, Inc.*, 863 N.W.2d 404, 419 (Minn. Ct. App. 2015) (Minnesota); *Williams v. Bayer Corp.*, 541 S.W.3d 594, 605-606 (Mo. Ct. App. 2017) (Missouri); *Scovil v. Medtronic Inc.*, No. 2:14-cv-00213, 2015 WL 880614, at *7 (D. Nev. Mar. 2, 2015) (Nevada); *A.F. by & Through Fogel v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 543-544 (S.D.N.Y. 2018); *Rose v. Bayer Corp.*, No. MRS-L-265-20, at 14 (N.J. Super. Ct. July 31, 2020), motion for leave to appeal granted and pending (New Jersey); *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170 (N.D.N.Y. 2014) (New York); *Hill v. Abbott Labs.*, No. 6:19-cv-01011, 2020 WL 4820243, at *6 (D.S.C. Aug. 19, 2020) (South Carolina); *O'Neil v. St. Jude Med., Inc.*, No. C13-00661, 2013 WL 6173803, at *3 (W.D. Wash. Nov. 22, 2013) (Washington); *Marvin Zydus Pharm. (USA) Inc.*, 203 F. Supp. 3d 985, 989 (W.D. Wis. 2016) (Wisconsin). Moreover, most of the remaining states are also likely to recognize that Allergan's failure to report adverse events provides a sufficient basis for Plaintiffs' failure to warn claim.[19]

[19] *See, e.g.*, *Robles v. Shoreside Petroleum*, 29 P.3d 838 (Alaska 2001) (favorably applying Section 388 and citing analogous cases from Iowa and New York); *Jones v. Bowie Indus.*, 282 P.3d 316, 336 (Alaska 2012) (recognizing a manufacturer's post-sale duty to warn when danger is potentially life threatening) (Alaska); *Dildine v. Clark Equip. Co.*, 282 Ark. 130 (1984) (*citing* Section 388) (Arkansas); Colo. Pattern Jury Instr. Civ. 14.19 (a manufacturer "must use reasonable care to warn") (Colorado); *Vitanza v. Upjohn Co.*, 257 Conn. 365 (Conn. 2001) (product seller has a duty "to provide suitable warnings to the person best able to take or recommend precautions against the potential harm of the product"); *Lafountain v. Smith & Nephew, Inc.*, No. 14CV1598, 2016 U.S. Dist. LEXIS 92680, at *13-14 (D. Conn. 2016) (plaintiffs' failure to warn claim, based in part on its violation of "FDA standards for approval, testing, and reporting," were plausible, motion to dismiss on this ground denied); *cf. Norman v. Bayer Corp.*, No. 3:16-cv-00253, 2016 U.S. Dist. LEXIS 96993 (D. Conn. July 26, 2016) (plaintiff failed to plead sufficient facts; finding no duty but misapplying Section 388 in the drug context as imposing a duty to warn a distributor, not via other third parties like the FDA) (Connecticut); *Dine v. Western Exterminating Co.*, No. 86-1857, 1988 U.S. Dist. LEXIS 4745, at *17-18 (D.D.C. March 9, 1988) (favorably citing Section 388 and comment n); *Payne v. Soft Sheen Prods.*, 486 A.2d 712, 721-722 (D.C. 1985) (same) (District of Columbia); *Cline v. Advanced Neuromodulation Sys.*, 17 F. Supp. 3d 1275, 1286-86 (N.D. Ga. 2014) (implicitly recognizing the duty to warn via adverse events, but granting dismissal on other grounds); *Carter v. E.I. Dupont Nemours & Co.*, 217 Ga. App. 139, 140 (1995) (adopting Section 388) (Georgia);

Allergan failed to disclose this case law to the Court and instead tries to graft mandatory reporting statutes—pertaining to child abuse and banking—to unrelated common law claims.

Lamb v. Manitowoc Co., 570 N.W.2d 65 (Iowa 1997) (adopting Section 388) (Iowa); *Long v. Deere & Co.*, 238 Kan. 766 (1986) (recognizing adoption of Section 388) (Kansas); *Koken v. Black & Veatch Const., Inc.*, 426 F.3d 39, 48 (1st Cir. 2005) (recognizing Maine's reliance on Section 388) (Maine); *Carrel v. Nat'l Cord & Braid Corp.*, 447 Mass. 431, 440-41 (2006) (recognizing Section 388) (Massachusetts); *Glittenberg v. Doughboy Recreational Indus.*, 441 Mich. 379, 389-390 (1992) (citing Section 388 favorably) (Michigan); *Jackson v. Coast Paint & Lacquer Co.*, 499 F.2d 809, 813-814 (9th Cir. 1974) (applying Section 388 under Montana law) (Montana); *Erickson v. U-Haul, Inc.*, 274 Neb. 236, 242-246 (2007) (applying Section 388) (Nebraska); *Buckingham v. R.J. Reynolds Tobacco Co.*, 142 N.H. 822, 829 (1998) (recognizing adoption of Section 388); *State v. Purdue Pharma, LP*, No. 217-2017-cv-00402, 2018 WL 4566129, at *6 (N.H. Super. Sept. 18, 2018) (a manufacturer's duty is "only fulfilled once it *adequately* warns the physician," which "given the fact intensive nature," cannot be decided on a motion to dismiss) (N.H. Super. Ct. Sept. 18, 2018) (emphasis in original); *Jenksy v. Textron, Inc.*, No. 09-CV-205, 2012 WL 2871686, at *2 (D.N.H. July 10, 2012) (recognizing post-sale duty to warn) (New Hampshire); *Couch v. Astec Indus., Inc.*, 132 N.M. 631, 641 (2002) (recognizing post-sale duty to warn, which must be executed using "ordinary care to avoid the risk") (New Mexico); *Stegall v. Catawba Oil Co.*, 260 N.C. 459 (1963) (recognizing Section 388); N.C. Gen. Stat. § 99B-5(a)(2) (post-sale duty to warn) (North Carolina); *Crowston v. Goodyear Tire & Rubber Co.*, 521 N.W.2d 401, 409 (N.D. 1994) (post-sale duty to warn, requiring manufacturers to take "reasonable steps to warn foreseeable users"); *Collette v. Clausen*, 667 N.W.2d 617, 624 (N.D. 2003) (applying Section 388) (North Dakota); *Jacobs v. E.I. du Pont de Nemours & Co.*, 67 F.3d 1219, 1238-1240 (6th Cir. 1995) (applying Section 388 and comment n under Ohio law) (Ohio); *Duane v. Oklahoma Gas & Elec. Co.*, 833 P.2d 284, 286 (Okla. 1992) (adopting Section 388) (Oklahoma); *Guevara v. Dorsey Lab., Div. of Sandoz, Inc.*, 845 F.2d 364 (1st Cir. 1988) (applying Section 388 under Puerto Rico law) (Puerto Rico); *Maggi v. DeFusco*, 107 R.I. 278 (1970) (applying Section 388); *Gray v. Derderian*, 365 F. Supp. 2d 218, 228 (D.R.I. 2005) (recognizing duty to warn) (Rhode Island); *Kendall v. Bausch & Lomb, Inc.*, No. CIV. 05-5066, 2009 WL 1740002, at *9 (D.S.D. June 17, 2009) (recognizing South Dakota's adoption of Section 388) (South Dakota); *Whitehead v. Dycho Co.*, 775 S.W.2d 593 (Tenn. 1989) (applying Section 388) (Tennessee); *Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 186-191 (Tex. 2004) (applying Section 388); *Wilson v. Glenro, Inc.*, No. 5:10-cv-185, 2012 U.S. Dist. LEXIS 40068, at *22-23 (D. Vermont March 23, 2012) (Vermont law requires a manufacturer to "take the precautions that a reasonable person would take in presenting the product to the public") (Vermont); *Featherall v. Firestone Tire & Rubber Co.*, 219 Va. 949, *962 (1979) (adopting Section 388) (Virginia); *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 307 S.E.2d 603, 609 (1983) (citing Section 388 with approval) (West Virginia); *Continental Ins. v. Page Eng'g Co.*, 783 P.2d 641, 661-662 (Wyo. 1989) (manufacturer has "duty to take reasonable steps" to warn; recognizing post-sale duty; applying Section 388) (Wyoming).

Def. Appendix at 60-79 (citing cases from Delaware, Florida, Hawaii, Illinois, Indiana, Minnesota, Missouri, New Jersey, New York, South Carolina, and Wisconsin for the proposition that state mandatory reporting statutes relating to child abuse or banking do not create a private cause of action for failure to report). Plaintiffs are not seeking to create a private right of action under state child abuse or banking statutes. The rest of Allergan's citations are similarly misleading. *See* Plaintiffs' Appendix, "Failure to Warn" at 133-179.

Allergan's cited case law to the contrary is irrelevant, non-existent, or distinguishable. For 18 states—Alaska, Connecticut, Georgia, Iowa, Kansas, Massachusetts, Michigan, Nebraska, New Hampshire, New Mexico, North Carolina, Oklahoma, Puerto Rico, Tennessee, Texas, Vermont, Virginia, and West Virginia—Allergan again relies on cases about child abuse reporting statutes or financial misconduct, that are irrelevant to this analysis. In fact, that is the only law Allergan cites for Alaska, Iowa, Massachusetts, Michigan, Nebraska, New Hampshire, New Mexico, Oklahoma, Puerto Rico, Texas, Virginia, and West Virginia. Allergan provides no authority for Maine, Montana, North Dakota, Rhode Island, or South Dakota. And to the extent that Allergan cites *any* relevant law, those cases are distinguishable. *See* Plaintiffs' Appendix, "Failure to Warn" at 133-179. Finally, while outlier states Arizona and Mississippi may not recognize a duty to warn via adverse event reporting, Plaintiffs still state plausible failure to warn claims in those states, albeit on different factual bases. *See* Plaintiffs' Appendix, "Failure to Warn," at 133-179.

In sum, Allergan misleads on this issue. Whether a state's highest court "has affirmatively adopted a duty to report adverse events to the FDA as an element of a state tort law claim" is not the question. MTD at 13. Rather, the Court must analyze, consistent with *Erie* principles, whether a state would find that a manufacturer's common law duty to exercise

reasonable care to warn includes a duty to report adverse events to the FDA or the additional bases on which Plaintiffs bring their failure to warn claim (which Allergan has not even contested). As detailed above and in the PIC, Plaintiffs have stated plausible claims and Allergan's motion should be denied.

VII. PLAINTIFFS' NEGLIGENT MISREPRESENTATION CLAIMS ARE SUFFICIENTLY PLEADED

Allergan attacks the entirety of Count VI, the Negligent Misrepresentation claims, contending that Rule 9(b) pleading standards apply and Plaintiffs have fallen short. Allergan also challenges the claims under thirteen states' laws on other bases set forth in its Appendix.[20] Although Plaintiffs need not meet Rule 9(b)'s heightened pleading requirements to adequately allege negligent misrepresentation, Plaintiffs have met that standard in the PIC. Moreover, given that more detailed information and evidence is exclusively in Allergan's hands, the pleading requirements should not be rigidly enforced at this pre-discovery stage. Further, Allergan has overstated and mischaracterized the law in its non-Rule (9)(b) challenges as to the eleven states for which Plaintiffs asserted claims.

Allergan omits discussion of pertinent state law in its brief and dedicates most of its effort to discussion of New Jersey cases[21] when Plaintiffs did not even allege negligent misrepresentation claims under New Jersey law. Allergan also cites multiple Third Circuit cases originating from New Jersey and Pennsylvania district courts in support of its position that Rule

[20] Allergan challenges Negligent Representation claims in Alabama, Arkansas, Florida, Georgia, Indiana, Louisiana, Minnesota, Mississippi, New Jersey, Ohio, Tennessee, Texas and Virginia. Plaintiffs did not allege claims under New Jersey or Indiana law.

[21] Allergan cites seven cases in its brief; five are New Jersey cases and two are Pennsylvania cases.

9(b) applies and neither explains why Third Circuit law would govern the complete matter nor acknowledges that there is a split within the Third Circuit and among the states about application of Rule 9(b).[22]

To be clear, Plaintiffs' allegations regarding Allergan's negligent misrepresentation satisfy the requirements of Rule 8 as well as Rule 9(b), even though Rule 9(b) should not be applied to Plaintiffs' negligent misrepresentation claims. A blanket application of the Rule 9(b) standard would effectively disregard contrary law from other courts and overlook that Plaintiffs pleaded a cause of action for negligent misrepresentation and *not* fraud.[23] While there are some

[22] For example, in *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d at 829, the court stated:

> There is currently a disagreement among district courts in the Third Circuit regarding whether Rule 9(b) applies to claims based on negligent misrepresentation." *See also Schmidt v. Ford Motor Co.*, 972 F.Supp.2d 712, 720 n. 3 (E.D. Pa. 2013) (comparing *Hanover Ins. Co. v. Ryan*, 619 F.Supp.2d 127, 142 (E.D. Pa. 2007), with *Brandow Chrysler Jeep Co. v. DataScan Techs.*, 511 F.Supp.2d 529, 537 (E.D. Pa. 2007)). Some courts have held that the "particularity requirement of Rule 9(b) applies to claims of negligent misrepresentation." *Hanover Ins. Co.*, 619 F.Supp.2d at 142. Other courts have stated that "Rule 9(b) does not govern claims of negligent misrepresentation." *Brandow Chrysler*, 511 F.Supp.2d at 537. Still "[o]ther courts, although declining to apply Rule 9(b), have held that a plaintiff must nonetheless plead negligent misrepresentation with a degree of specificity." *Scott v. Bimbo Bakeries, USA, Inc.*, Civ. A. No. 10–3154, 2012 WL 645905, at *5 (E.D. Pa. Feb. 29, 2012) (citations and internal quotation marks omitted). Given this lack of consensus, we will not apply the pleading standards in Rule 9(b) to the negligent misrepresentation claim but, instead, only hold Plaintiffs' negligent misrepresentation claim to the pleadings standard of Rule 12(b)(6) as we have done with negligent misrepresentation claims in the past. See, e.g., *HCB Contractors v. Rouse & Assocs.*, Civ. A. No. 91–5350, 1992 WL 176142, at *6 (E.D. Pa. July 13, 1992) (stating that, "because a claim of negligent misrepresentation is distinct from a claim of fraud under Pennsylvania law, Rule 9(b) does not apply to the former according to its terms").

[23] Defendants cite *Frederico v. Home Depot*, 507 F.3d 188 (3d Cir. 2007) and *In re Supreme Specialties, Inc. Sec. Litig.*, 438 F.3d 256 (3d Cir. 2006), both New Jersey cases, to inform the

courts that treat negligent misrepresentation claims as tantamount, or nearly tantamount, to fraud claims, others treat them as sounding in negligence, to which Rule 9(b) does not apply. *See Williams v. Equity Holding* Corp., 498 F. Supp. 2d 831, 842 (E.D. Va. 2007); *Clifton v. I-Flow Corp.*, No. 11-cv-627, 2011 WL 5077615, at *3 (N.D. Ill. Oct. 26, 2011); *Proctor v. Metro. Money Store Corp.*, 645 F. Supp. 2d 464, 476 (D. Md. 2009); *McLaughlin*, 172 F. Supp. 3d at 838.

Although Allergan also cites two Pennsylvania cases, it failed to cite relevant Pennsylvania law distinguishing between fraud and negligent misrepresentation claims and the different pleading standards applicable to them. For example, the plaintiffs in *McLaughlin* brought both a negligent misrepresentation claim and a fraudulent misrepresentation claim that were virtually identical. 172 F. Supp. 3d at 829. The court held the fraud claim was not pleaded with sufficient specificity under Rule 9(b); however, the negligent misrepresentation claim was held to be adequately pleaded pursuant to Rule 12(b)(6) and was permitted to proceed. *Id*. at 830. The misrepresentations at issue in *McLaughlin*, similar to the negligent misrepresentations alleged in the PIC, appeared primarily on Bayer's website and in Essure brochures. The plaintiffs there alleged that Bayer intentionally made statements to induce the plaintiffs to have its Essure device implanted, that plaintiffs justifiably relied upon those misrepresentations prior to implantation, and that plaintiffs never would have had Essure implanted had they been aware that the representations were false." *Id*.; *compare* PIC ¶¶ 96-107; ¶¶ 219-230.

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requirements of Rule 9. These cases both deal with causes of action for fraud and *not* negligent misrepresentation.

Even if the Court engages in a Rule 9(b) analysis here, Plaintiffs meet the pleading standard because they "accompany their allegations with facts indicating why the charges against defendants are not baseless and why additional information lies exclusively within defendants' control." *FDIC v. Bathgate*, 27 F.3d 850, 876 (3d Cir. 1994). The fact that there may be details not yet in plaintiffs' possession does not warrant dismissal, as "[t]he Third Circuit has recognized . . . [] most purveyors of fraud, and especially those who engage in fraudulent activities within the corporate sphere, are consciously and vigilantly engaged in an effort to disguise the nature of their endeavors." *U.S. ex rel. Budike v. PECO Energy*, 897 F. Supp. 2d 300, 316 (E.D. Pa. 2012) (citing *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989) (explicitly noting that "sophisticated defrauders" can be expected to attempt to "conceal the details of their fraud")). "In order to account for this reality, Rule 9(b)'s particularity requirement is properly relaxed 'when factual information [regarding the defendant's conduct] is peculiarly within the defendant's knowledge or control.'" *Id.* at 316.

The PIC additionally states with specificity facts sufficient to support Plaintiffs' misrepresentation claims under any analysis. For example, Plaintiffs allege that despite FDA regulations prohibiting such conduct, Allergan "continuously undermined the warning (and subsequent warnings) and misrepresented the risk of BIA-ALCL in its non-PMA communications." Specifically, Allergan paid consultants to falsely report that "the cause of late-onset seroma remained idiopathic, suggesting that the condition arises without any identifiable cause. Allergan had reason well before this date to suspect an association between ALCL and its textured implants." PIC ¶ 28 n.8. If Allergan requires the "who, what, when and where" of these false statements, it need look no further than precise citations to publications in the PIC. *Id*.

Allergan also "concealed and disguised the risks, including submission of adverse event reports with incorrect manufacturer names, including 'Santa Barbara' and 'Costa Rica, instead of using the name Allergan. As a result, consumers, healthcare professionals, and the FDA were unable to detect signals and trends in Allergan's products, depriving the FDA, physicians and consumers of the necessary information to make an informed decision about whether Allergan's products were safe and effective." *Id.* ¶ 87. Further, Allergan, again in violation of federal regulations, falsely promoted its breast implants without including the FDA mandated warnings. *Id.* ¶¶ 96-97.

The misrepresentations include false claims that the products were superior, safe and well-studied, but failed to include any reference to the ALCL risk. *Id.* ¶¶ 96-107. For example, in its Natrelle Gel-filled implant brochure, Allergan represented that the implants were of "premium" and "proven" quality, and they "have been shown to be biocompatible and reliable, making it an appropriate choice." *Id.* ¶ 98. Likewise, in a September 2004 brochure, Allergan touted the benefits of its BIOCELL textured surface implants, representing that the implants were of "innovative, premium quality….to meet our customer needs…," that the implants were "at the forefront of technology," and that the implants' "textured surface…allow[ed] for mild tissue adherence which has been associated with a reduced risk of capsular contracture." *Id.* ¶¶ 99-100 (referencing statements made in response to the FDA's May 14, 2020 letter); ¶ 101 (referencing statements made in a 2002 brochure); ¶ 103 (referencing statements made in a 2019 clinical presentation). Had Allergan been forthcoming regarding the true nature of its BIOCELL implants, Plaintiffs and their physicians would have been more fully informed of the risks of ALCL, and Plaintiffs would not have had the BIOCELL implants or expanders placed inside their bodies. *Id.* ¶ 107.

Plaintiffs provide a specific example of Allergan's misleading promotional material:

> For example, referring to its Natrelle Breast Implants in a YouTube video posted on the internet, Allergan noted that the "Pre-Consultation Kit" is available to help a patient prepare for a consultation with her physician. In this direct to patient appeal, Allergan noted that their implants are "FDA approved, tested, durable" and "Breast augmentation is the most common and uncomplicated plastic surgery procedure…Decades of experience with the science of breast augmentation have greatly approved safety…enhanced technology for safer and more beautiful options than ever before."[24] The publicly available video describes textured and smooth implants without making any distinction in the significantly increased risks associated with the textured version of Allergan implants. Instead, the two types of implants were marketed as having the same benefits and potential complications, without any reference to BIA-ALCL."

PIC ¶ 97.

As alleged in the PIC, Allergan manufactured the BIOCELL implants in violation of the PMA, federal regulations, and established specifications and manufacturing processes, thus resulting in "adulterated" and "misbranded" devices. *See, e.g.*, PIC ¶¶ 54-57, 108-143. All the while, Allergan improperly told consumers, physicians, and the medical community at large that the implants were safe and compliant, but omitted mention of the risks associated with ALCL. *See, e.g.*, PIC ¶¶ 87-107. These statements and omissions were made in Allergan's promotional and marketing materials, including brochures, websites, and communications, through its agents, sales representatives and paid consultants.[25] *Id.* ¶¶ 87, 96.

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[24] *See* https://www.youtube.com/watch?v=vu-0W8vSNrU.

[25] Allergan erroneously contends that Plaintiffs are required to identify every consultant and representative. MTD at 16. But as this Court has noted, "Rule 9(b) does not require such precision. Rather, where it can be shown that the requisite factual information is particularly within the defendant's knowledge or control, the rigid requirement of [Rule] 9(b) may be relaxed." *U.S. ex rel. Rahimi v Zydus Pharm. (USA), Inc.*, No. CV 15-6536 (BRM) (DEA), 2017 WL 1503986, at *12 (D.N.J. Apr. 26, 2017), *on reconsideration in part, on other grounds, sub nom. Rahimi v Zydus Pharm. (USA) Inc.*, No. CV 15-6536-BRM-DEA, 2018 WL 515943 (D.N.J. Jan. 23, 2018) (rejecting defense argument that plaintiff was required to "identify the pharmacies involved" in an alleged scheme of fraudulently inflating drug prices). The names and

These allegations are more than sufficient to apprise Allergan of the precise misconduct with which it is charged, *i.e.*, that in the course of marketing the BIOCELL implants, Allergan made untrue representations of material facts regarding the true nature and quality of the product, and omitted material information regarding the risks of ALCL, to Plaintiffs, Plaintiffs' physicians, the medical community, and the public at large. Any argument for further specificity, at the pleading stage, is contrary to Third Circuit law and without merit. *See, e.g.*, *Blue Line Coal Co. v. Equibank*, 683 F. Supp. 493, 497 (E.D. Pa. 1988) (noting that "the standard for 9(b) is a generous one in this Circuit" and the Third Circuit "has cautioned that focusing exclusively on Rule 9(b)'s particularity language is too narrow an approach and fails to take account of the general simplicity and flexibility contemplated by the rules.'") (internal quotation marks and brackets omitted) (citing *Christidis v. First Pa. Mortgage Trust*, 717 F.2d 96, 100 (3d Cir. 1983)).

Allergan acknowledges that negligent misrepresentation claims are viable, separate causes of action in nearly every state, but then argues it is not recognized in others and misstates applicable law in support of its position.[26] *See* Plaintiffs' Appendix, "Negligent Misrepresentation," at 180-190. For example, Allergan contends that Texas law fails to recognize both negligent misrepresentation and failure to warn. MTD at p. 19. Allergan is wrong. *See, e.g.*, *In re: DePuy Orthopaedics, Inc.*, No. 3:11-MD-2244-K, 2016 WL 6268090, at

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identities of Allergan's representatives and consultants are within its knowledge and control and, the allegations, as pleaded, inject sufficient precision and measure of substantiation into Plaintiffs' allegations. No more is required at this stage.

[26] Allergan does not dispute that negligent misrepresentation claims exist under the laws of all states but Alabama, Arkansas, Indiana, Louisiana, Mississippi, New Jersey, Tennessee, and Texas.

*6 (N.D. Tex. Jan. 5, 2016) (denying motion for summary judgment on plaintiffs' negligent misrepresentation and failure to warn claims asserted under Texas law); *Lea v. Wyeth LLC*, No. 1:03-CV-1339, 2011 WL 13192701, at *11, 17 (E.D. Tex. Oct. 28, 2011) (same); *In re Testosterone Replacement Therapy Prod. Liab. Litig.*, No. 14 C 1748, 2014 WL 7365872, at *14 (N.D. Ill. Dec. 23, 2014) (denying motion to dismiss plaintiffs' negligent misrepresentation and failure to warn claims in several states including Texas). *See* Plaintiffs' Appendix at 188-189.

Allergan also contends that thirteen states[27] have either subsumed negligent misrepresentation within their product liability laws or have otherwise concluded that negligent misrepresentation is not recognized as a separate cause of action. MTD at 23. This argument, however, ignores that Plaintiffs' negligent misrepresentation claims are asserted under applicable product liability laws where appropriate. *See, e.g.*, PIC at ¶ 229 (asserting negligent misrepresentation pursuant to product liability laws in Alabama and Mississippi).[28] In addition, Plaintiffs meet the requirements of the nine other states challenged by Allergan in which Plaintiffs have asserted claims. *See* Plaintiffs' Appendix, "Negligent Misrepresentation," at 180-190. As previously noted, Plaintiff made no claims under two of thirteen states, New Jersey and Indiana.

Given that there are choice of law and case specific issues, and a lack of a universal standard and consistent approach under state law, an across-the-board application of Rule 9(b) would be erroneous. Even so, Plaintiffs have met the elevated pleading burden of Rule 9(b),

[27] Alabama, Arkansas, Florida, Georgia, Indiana, Louisiana, Minnesota, Mississippi, New Jersey, Ohio, Tennessee, Texas and Virginia.

[28] Allergan needlessly attacks negligent misrepresentation claims asserted in states where Plaintiffs have not asserted negligent misrepresentations claims. *See, e.g.*, Plaintiffs' Appendix "Negligent Misrepresentation" at 180-90.

making dismissal of Plaintiffs' negligent misrepresentation claims inappropriate. The claims asserted are not baseless and are sufficiently detailed to apprise Allergan of the allegations, including much of the who, what, when, and where behind the misrepresentations. Moreover, the full details are uniquely and exclusively within Allergan's control. For these reasons and as detailed above and in Plaintiffs' Appendix, Allergan's motion to dismiss the negligent misrepresentation claims should be denied.

VIII. PLAINTIFFS' BREACH OF WARRANTY CLAIMS ARE SUFFICIENTLY PLEADED

Allergan's cursory and generalized assault on Plaintiffs' express and implied warranty claims (Counts VIII and VII)—only a subset of which it seeks to dismiss—asserts in six sentences that (a) some states require notice, (b) some states require privity, and (c) some states do not permit implied warranty claims in prescription medical device litigation. MTD at 17. Allergan, however, glosses over the details that, when considered, require denial of Allergan's motion.[29]

Count VIII of the PIC alleges the extensive non-PMA actions by Allergan that serve as the factual bases for Plaintiffs' express warranty claims. Count VII alleges the violations of the implied warranties made by Allergan. To the extent the Court finds any technical deficiency in the pleading of the claims (or to any claims), Plaintiffs respectfully request the opportunity to cure them.

[29] Allergan challenges the express warranty claims as to twenty-one states including Arizona, Arkansas, California, Colorado, Florida, Georgia, Idaho, Illinois, Indiana, Kentucky, Michigan, Minnesota, Missouri, New Hampshire, New Mexico, New York, Oregon, Pennsylvania, Tennessee, Texas, and Wisconsin. Allergan challenges the implied warranty claims as to twenty-six states including Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Idaho, Illinois, Indiana, Kentucky, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New Mexico, New York, Ohio, Oregon, Pennsylvania, Tennessee, Texas, Washington, and Wisconsin.

A. To The Extent Required Allergan Had Pre-suit Notice of Plaintiffs' Claims

Allergan appears to assert that notice is required for any warranty claim and, presumably, that Plaintiffs failed to provide it. Many states have adopted the Uniform Commercial Code's ("UCC") formulation of express warranty, as well as the implied warranties of merchantability and fitness for a particular purpose. *See* U.C.C. §§ 2-313 to -315. Section 2-607(3)(a)—the origin of the "notice" requirement—provides that a buyer must, within a reasonable time after she discovers or should have discovered any breach, notify the seller of the alleged breach. But this provision only applies to merchant buyers: it is not essential when, as here, plaintiff consumers bring personal injury or property damage claims (as opposed to claims for pure commercial loss). *See Wright Bachman, Inc. v. Hodnett*, 133 N.E.2d 713 (Ind. 1956); *Kennedy v. F. W. Woolworth Co.*, 200 N.Y.S. 121 (N.Y. App. Div. 1923); *Silverstein v. R. H. Macy & Co.*, 40 N.Y.S.2d 916 (N.Y. App. Div. 1943).[30]

Moreover, notice is governed by a reasonableness standard that must be analyzed under the circumstances. The Official Comments to Section 2-607 provide:

> The time of notification is to be determined by applying commercial standards to a merchant buyer. "A reasonable time" for notification from a retail consumer is to be judged by different standards so that in his case it will be extended, for the rule of requiring notification is designed to defeat commercial bad faith, not to deprive a good faith consumer of his remedy.

U.C.C. § 2-607, cmt. 4. Here, prior to filing the PIC, Allergan (a) had actual notice that its recalled BIOCELL implants were defective and unfit for their intended purpose, (b) knew the

[30] This is particularly true when the injured party is in a consumer-type relationship with the seller. *See, e.g.*, *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897 (Cal. 1962); *Ruderman v. Warner-Lambert Pharmaceutical Co.*, 184 A.2d 63 (Conn. Super. Ct. 1962); *Deveny v. Rheem Mfg. Co.*, 319 F.2d 124 (2d Cir. 1963); *LaHue v. Coca-Cola Bottling Co.*, 314 P.2d 421 (Wash. 1957); *Di Pangrazio v. Salamonsen*, 393 P.2d 936 (Wash. 1964).

manufacturing process was defective and non-compliant, (c) knew its BIOCELL implants cause BIA-ALCL, (d) was directed by the FDA to institute a recall, and (e) had been subjected to other consumer lawsuits and class actions. In these circumstances, notice is plainly sufficient even without the individual consumer providing Allergan with an individual written notice. *See Wallman v. Kelley*, 976 P.2d 330, 333 (Colo. Ct. App. 1998) (whether notice is sufficient or reasonable is a factual determination; litigation can constitute notice; denying summary judgment when the plaintiff did not give pre-suit notice before litigation but claimed that the FDA's pre-suit efforts to ban the product at issue were sufficient)[31]; *Stuhlmacher v. Home Depot U.S.A., Inc.*, No. 2:10-cv-467, 2011 U.S. Dist. LEXIS 50887 (N.D. Ind. May 11, 2011) (allegation that manufacturer was generally on notice of product defect before suit sufficient to plead notice); *Collins v. Pfizer, Inc.*, No. 1:08-cv-0888, 2009 U.S. Dist. LEXIS 3719, at * 6-12 (S.D. Ind. Jan. 20, 2009) (motion to dismiss denied where plaintiff alleged notice by commencement of litigation); *Cincinnati Ins. Cos. v. Hamilton Beach/Proctor-Silex, Inc.*, No. 4:05-cv-49, 2006 U.S. Dist. LEXIS 9807, at *11 (N.D. Ind. Feb. 7, 2006 ("a plaintiff need only allege generally that all conditions precedent have occurred"); *City of Wyoming v. Procter & Gamble Co.*, 210 F. Supp. 3d 1137, 1157 (D. Minn. 2016) ("bar for sufficiency [of notice] is low"; declining to dismiss claim where plaintiffs failed to provide notice before initiation of lawsuit and no showing of prejudice was made); *Badilla v. Wal-Mart Stores E., Inc*., No. 2017-NMCA-021, ¶ 21, 389 P.3d 1050, 1057 (N.M. Ct. App. 2016) (commencement of litigation can constitute notice where other factors, such as "the obviousness of the defect, the perishable

[31] Allergan's cited cases do not state otherwise. *See* Def. Appendix at 85; *Hawkinson v. A.H. Robins CO.*, 595 F. Supp. 1290, 1312-13 (D. Colo. 1984) ("the timeliness and adequacy of notice are fact questions to be determined in the context of the circumstances of the case); *Palmer v. A.H. Robins Co.*, 684 P2d 187, 205-207 (Colo. 1984) (there is no proscribed form of notice required).

nature of the goods, and possible prejudice to the seller from the delay," suggest it is reasonable) (*citing* 18 Williston on Contracts, § 52:44 (4th ed. 2015)); *Indem. Ins. Co. of N. Am. v. Deer & Co.*, No. 2:11-cv-00260, 2012 U.S. Dist. LEXIS 135980 (N.D. Miss. Sept. 24, 2012) ("whether the notice requirement has been complied with is a question which is particularly within the province of the jury," denying defendant's motion to dismiss where the goods were destroyed before plaintiff could give notice and thus an opportunity to cure was not presented); *Cone v. Vortens, Inc.*, No. 4:17-cv-00001, 2019 U.S. Dist. LEXIS 54329, at *15-16 (E.D. Tex. March 13, 2019) ("ordinarily, notice is a question of fact which is to be determined by the trier of fact"; denying summary judgment where plaintiff did not give seller notice but evidence indicated seller was already on notice of the defect) (citations and quotations omitted).

Moreover, to the extent the purpose of pre-suit notice is to provide an opportunity to cure, *see Watson Quality Ford, Inc. v. Casanova,* 999 So. 2d 830, 834-835 (Miss. 2008), here there could be no such opportunity. The products were already surgically implanted in each plaintiff before she became aware they were unfit for their intended use. Thus, even if Plaintiffs failed to give pre-suit notice, Allergan was not deprived of an opportunity to cure. Allergan cites no authority for the notion that notice is required when cure is impossible.

B. Plaintiffs' Warranty Claims Do Not Require Privity When Plaintiffs Allege Personal Injury

State warranty duties parallel those imposed by the FDA and thus have repeatedly been recognized in the medical device context.[32] *See, e.g.*, Plaintiffs' Appendix, "Warranty Claims,"

[32] *See, e.g., Bass v. Stryker Corp.*, 669 F.3d 501, 516-17 (5th Cir. 2012); *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 839-40 (S.D. Ind. 2009); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 2011 U.S. Dist. LEXIS 41758, at *22 (S.D.N.Y. 2011); *Purcel v. Advanced Bionics Corp.*, No. 3:07-cv-1777, 2010 U.S. Dist. LEXIS 67109, at *38-39 (N.D. Tex. June 30,

at 191-213. Under the UCC, the language describing the goods becomes part of the basis of the bargain, creating an express warranty that the goods will conform to the description. *See* U.C.C. § 2-313. Allergan incorrectly contends that privity between plaintiff and defendant is often required to state such a claim. MTD at 17. While U.C.C. § 2-313(1)(a) refers to an affirmation of fact or promise "made by the seller to the buyer," Official Comment 2 makes clear that this is not limited to the seller's immediate buyer. Rather, "the warranty sections of this Article are not designed in any way to disturb those lines of case law growth which have recognized that warranties need not be confined either to sales contracts or to the direct parties to such a contract." U.C.C. § 2-313, cmt. 2. The provisions of Section 2-318 regarding third party beneficiaries explicitly recognize this case law development. *See* U.C.C. § 2-318.

The same holds true for implied warranties. *See Henningsen v. Bloomfield Motors, Inc.*, 32 N.J. 358, 384 (1960) ("The obligation of the manufacturer should not be based alone on privity of contract. It should rest . . . upon the demands of social justice."). Moreover, non-privity actions are widely allowed in instances of personal injury and property damage. *See, e.g., H. Hirschmann, LTD. v. Green Mt. Glass, LLC*, 2016 WL 3683518 (D. Vt. July 6, 2016). The Official Comment to Section 2-318 of the UCC confirms "certain beneficiaries [receive] the benefit of the same warranty which the buyer received in the contract of sale, thereby freeing any such beneficiaries from any technical rules as to 'privity.'" *See* U.C.C. § 2-318, cmt. 2.

Allergan incorrectly claims certain state laws require privity, including Tennessee and Indiana. They do not. T.C.A. § 29–34–104 ("Privity not required. - In all causes of action for

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2010); *Kallal v. Ciba Vision Corp.*, No. 09-CV-3346, 2010 U.S. Dist. LEXIS 56838, at *8 (N.D. Ill. June 9, 2010).

personal injury or property damage brought on account of negligence, strict liability or breach of warranty, including actions brought under the provisions of the Uniform Commercial Code, privity shall not be a requirement to maintain said action."); *Sullivan v. Panther Petroleum, LLC,* No. 119CV01259STAJAY, 2020 WL 1550230, at *5 (W.D. Tenn. Mar. 31, 2020) (noting the statute "eliminate[d] the requirement of vertical privity in lawsuits covered by the act."); *Hyundai Motor Am., Inc. v. Goodin,* 822 N.E.2d 947, 959 (Ind. 2005) (Indiana does not require privity).

C. Courts Frequently Permit Warranty Claims in Cases Involving Prescription Medical Devices or Pharmaceuticals

Finally, Allergan contends that states do not allow warranty claims for prescription medical devices. MTD at 17. Allergan is wrong. Courts have recognized that claims can be stated based upon warranty claims. For example, plaintiffs have been permitted to pursue express warranty claims for statements made outside the premarket approval process, as described in the PIC, Count VIII. *See Michael v. Shiley*, 46 F.3d 1316, 1325-28 (3d Cir. 1995); *Delaney v. Stryker Orthopaedics*, No. 08-03210, 2009 WL 564243, at *5-6, (D.N.J. March 5, 2009); *Richman v. W.L. Gore & Assocs., Inc.,* 881 F. Supp. 895, 904-05 (S.D.N.Y. 1995); *Holbrook v. Boston Scientific Corp.*, -- F. Supp. 3d--, 2020 WL 5540544, at *6-7 (D. Mass. Sept. 16, 2020);

In arguing otherwise, Allergan misstates and oversimplifies relevant law. For example, Alabama recognizes a breach of implied warranty claim when a medical device is not fit for its intended use and when it adversely affects "at least some significant number of persons." For example, the plaintiff in *Grubbs v. Medtronic, Inc.*, No. 2:18-cv-01468, 2019 U.S. Dist. LEXIS 121216 (N.D. Ala. July 22, 2019), alleged that defendant Medtronic breached its implied warranty of merchantability when it sold plaintiff an implantable Class III medical device that was not manufactured in accordance with FDA requirements and was not fit for its intended use.

Id. at *11. The court held that these facts were sufficient to state a claim for breach of implied warranty under Alabama law. *Id.*; *see also Griggs v. Combe*, 456 So.2d 790, 793 (Ala. 1984) (regarding a drug to which plaintiff had an uncommon allergic reaction: "a product must adversely affect at least some significant number of persons before a question of 'merchantability' arises.").[33]

Plaintiffs' warranty claims are plausibly stated and the motion to dismiss should be denied.

IX. PLAINTIFFS REQUEST LEAVE TO AMEND THE PIC TO ADDRESS ANY DEFICIENCIES

If the Court determines the PIC is deficient in any way, Plaintiffs respectfully request leave to amend under Rule 15(a). The Third Circuit has held that a request for leave to amend "must be granted if the deficiency could be cured by amendment." *Nix v. Welch & White, P.A.*, 55 Fed. Appx. 71, 73 (3d Cir. 2003); *see also* Fed. R. Civ. P. 15(a)(2) (a party's request for leave to amend a pleading "shall be freely given when justice so requires."). Any potential deficiencies in the PIC are curable, and therefore providing Plaintiffs leave to amend is appropriate.

CONCLUSION

The PIC sets forth well-pleaded allegations that are sufficient to survive Allergan's preemption and non-preemption challenges. With respect to this motion, Allergan incorrectly

[33] Allergan's cited cases when read closely actually state similarly. *See* Def. Appendix at 83; *In re Trasylol Prods. Liab. Litig.*, No. 08-MD-01928, 2011 WL 2117252, at *6 (S.D. Fla. May 20, 2011) (Alabama does not recognize a breach of implied warranty claim for a pharmaceutical *when there is no evidence that the medication is not fit for its intended use*); *Barnhill v. Teva Pharms. USA, Inc.*, 819 F. Supp. 2d 1254, 1263-64 (S.D. Ala. 2011) (Alabama recognizes the "possibility of a breach-of-implied-warranty claim against a drug manufacturer, if the product adversely affected a 'significant number of persons'" and was non-merchantable); *McClain v. Metabolife Int'l, Inc.*, 193 F. Supp. 2d 1252, 1258 (N.D. Ala. 2002) (plaintiffs did not contend that the product was unfit for its intended purpose or that it was not manufactured in accordance with required specifications: they simply claimed the product caused cancer).

applies *Erie*, ignores that all Plaintiffs have alleged present personal injuries, and mischaracterizes Plaintiffs' claims. Allergan further asks the Court to prematurely and improperly discard claims without consideration of each individual state's law, *Erie* principles, choice of law implications, and matters unique and specific to each plaintiff. Based upon the foregoing, Plaintiffs have met their pleading burden and this motion should be denied.

The PIC is a helpful administrative tool for the management of common issues in the personal injury claims in this MDL, and, until such time as bellwether selections or remand, state-by-state and plaintiff-specific analysis should be deferred. Finally, should the Court find any inadequacies in the allegations as pleaded, Plaintiffs request discovery and leave to amend to address any pleading deficits.

Dated: October 9, 2020

Respectfully submitted,

/s/ James E. Cecchi

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing on October 9, 2020, by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by CM/ECF system.

By: /s/ *James E. Cecchi*
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