

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

**IN RE: ALLERGAN BIOCELL  
TEXTURED BREAST IMPLANT  
PRODUCT LIABILITY LITIGATION**

**THIS DOCUMENT RELATES TO:  
ALL CASES**

**Case No. 2:19-md-02921-BRM-JAD  
MDL No. 2921**

**JUDGE BRIAN R. MARTINOTTI  
JUDGE JOSEPH A. DICKSON**

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO  
DEFENDANTS' MOTION TO STRIKE/MOTION TO DISMISS  
PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT**

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## INTRODUCTION

The Court should deny Allergan's Motion to Strike / Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint (ECF 171-2) as it is a premature attempt to litigate class certification prior to discovery, prior to a motion for class certification, and prior to an answer by Allergan to the Consolidated Class Action Complaint ("CAC"). The Third Circuit and courts in this District have repeatedly held that striking class allegations at the pleading stage with no discovery is a rare and disfavored remedy, and for good reason. Because the question of whether a lawsuit satisfies Fed. R. Civ. P. ("Rule") 23's prerequisites is fact-intensive, the Third Circuit instructs that class certification decisions should be made following discovery on a full factual record. This is not the extraordinary case in which a complaint itself makes clear that class treatment is inappropriate. Allergan's hypotheticals and speculation about how the evidence might reveal difficulties with class treatment are premature. At this stage, the Court must accept Plaintiffs' factual allegations as true. Those allegations are more than sufficient to establish the potential viability of class treatment, and consequently this motion should be denied.

In addition, Allergan's assertion that Plaintiffs cannot satisfy the typicality, predominance, and superiority requirements of Rule 23(a) and (b)(3), or the requirements of Rule 23(b)(2), is wrong. Typicality, a low standard to meet pursuant to Third Circuit law, is easily satisfied because the Plaintiffs and proposed class members were all implanted with Allergan's recalled textured breast implants and assert similar claims.

Allergan's speculation regarding predominance fares no better. Plaintiffs do not assert personal injury claims but rather seek classic class relief such as reimbursement of economic losses resulting from a defective product, damages and penalties from state consumer protection statutes, and the establishment of a medical monitoring program, under traditional tort, consumer

protection, warranty, and medical monitoring causes of action. Courts have repeatedly found such claims not only plausible, but suitable for class treatment, and to the extent there are material differences between the state laws pleaded in the CAC, these can be addressed using ordinary case management tools such as grouping and subclassing. In fact, Allergan's predominance arguments only underscore why it is premature to resolve the issue of class certification at this time, as Allergan effectively asks the Court to draw inferences in *Allergan's* favor, arguing that variation concerning the risks of contracting breast implant associated anaplastic large cell lymphoma ("BIA-ALCL"), and its yet-to-be-asserted and proven affirmative defenses, will defeat predominance. But there is no evidence from which the Court can determine whether any such speculative defense will affect class certification, and under Third Circuit law, affirmative defenses do not preclude class certification.

Likewise, Allergan's challenges to superiority are based on generalized and speculative assertions regarding manageability issues and potential relief, and are unsupported by any evidence. Allergan also ignores the efficiencies associated with resolving central core issues—such as its knowledge and whether the implants increase the risk of cancer—in a single proceeding.

Allergan's Rule 23(b)(2) contentions are similarly unpersuasive, and courts have certified medical monitoring classes under this provision. But without a developed factual record, Plaintiffs and their experts have not yet had an opportunity to develop a medical monitoring plan. Thus, Allergan's criticisms of a yet-to-be-determined plan and whether it satisfies the requirements of Rule 23(b)(2) cannot be evaluated at this early pre-discovery stage.

Finally, in Allergan's Motion to Dismiss Plaintiffs' Master Personal Injury Complaint, Allergan claims that Plaintiffs without a BIA-ALCL diagnosis have no viable legal claims. *See*

ECF No. 171-3 at 5-7.<sup>1</sup> Allergan is wrong. The CAC plausibly alleges that Plaintiffs and the proposed class members are at an increased risk of developing BIA-ALCL and have sustained present, physical injuries requiring medical monitoring. As set forth in detail below, many states recognize medical monitoring as a valid form of relief in these circumstances, and Allergan's arguments otherwise are baseless.

In sum, the CAC is well-pleaded and Plaintiffs should be afforded the opportunity to conduct discovery and demonstrate that class certification is appropriate on a factual record. For these reasons and as set forth below, this motion should be denied.

### **BACKGROUND**

Allergan recalled its textured BIOCELL breast implants and tissue expanders in July 2019 after the FDA found they posed a heightened risk of BIA-ALCL, a type of non-Hodgkin's lymphoma and a cancer of the immune system (the "Recalled BIOCELL Implants"). CAC ¶ 138. BIA-ALCL frequently presents as a late-onset seroma in the breast, which is an accumulation of fluid between the capsule and the implant, resulting in swelling of the breast. *Id.* Left untreated, BIA-ALCL can spread through the body and be fatal. *Id.* Symptoms of BIA-ALCL can arise even after the implant is removed. *Id.* ¶ 139. Diagnostic procedures for detecting BIA-ALCL are invasive and include CT scans, MRIs, and fluid sampling. *Id.* ¶ 140. Treatment and prevention can include removal of the implant and surrounding tissue. *Id.*

For over 20 years, Allergan and its predecessor companies marketed and sold the Recalled BIOCELL Implants. CAC ¶¶ 112-137. To texturize the implant shell, Allergan employed a "salt

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<sup>1</sup> Allergan moved to dismiss the Master Long Form Personal Injury Complaint but did not move to dismiss any causes of action in the CAC. Allergan has therefore waived any argument that any cause of action set forth in the CAC should be dismissed on Rule 12(b)(6) grounds. Nonetheless, Plaintiffs respond in this brief to Allergan's injury-related argument (at ECF 171-3, pp. 5-7), so as to clarify the nature of the Class Plaintiffs' claims.

loss” manufacturing process. CAC ¶¶ 13, 167-70. The salt loss process applies solid particles of cubic salt over the implant shell surface, embedding the particles within. *Id.* The implant is then covered with another silicone layer, which is scrubbed off, and the shell is washed. *Id.* FDA-approved manufacturing specifications required that all solid particles be scrubbed off and dissolved. *Id.* But Allergan performed the final scrubbing process manually, using a highly variable, non-compliant, and uncontrolled method. *Id.* ¶¶ 167-69. These residues and particles, together with the implant’s significantly increased surface area resulting from the texturizing and the chronic friction that inevitably occurs between the body’s tissues and the implant, cause pernicious inflammation, an increase in T-cell activity, malignant T-cell transformation and, ultimately, BIA-ALCL. *Id.* ¶ 170.

Textured implants increase the risk of ALCL up to 3,000 times. *Id.* ¶ 158. The FDA has concluded “that the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately six times the risk of BIA-ALCL with textured implants from other manufacturers.” *Id.* ¶ 193. According to the FDA, the number of Recalled BIOCELL Products in the United States is 246,831. *Id.* ¶ 386.

As early as 1997, women were reported to have developed ALCL after receiving Recalled BIOCELL Implants. *Id.* ¶ 141. Over the course of the next two decades, the number of reported cases of ALCL associated with the Recalled BIOCELL Implants continued to mount. *Id.* ¶ 142-62. Through this period, Allergan concealed the risks of BIA-ALCL by failing to timely, adequately, and appropriately submit adverse event reports or otherwise disclose complete and accurate safety information regarding the Recalled BIOCELL Implants, including by improperly hiding such information in summary adverse event reports. *Id.* ¶ 201-20.



On July 29, 2019, the FDA issued a Class I Recall notice. *Id.* ¶ 2, 191. According to the FDA, the continued distribution of the Recalled BIOCELL Implants “would likely cause serious, adverse health consequences and potentially death from BIA-ALCL.” *Id.* ¶ 193. Allergan, however, has refused to pay for the cost of explant surgeries to remove the implants or for ongoing monitoring and testing for BIA-ALCL. *Id.* ¶ 198.

Plaintiffs and the proposed class members are all women who have or had the Recalled BIOCELL Implants implanted in their bodies and have not been diagnosed with BIA-ALCL. *Id.* ¶ 22-84. Each Plaintiff alleges she is at a significantly heightened risk of developing BIA-ALCL and requires medical monitoring. *Id.* Plaintiffs allege (a) a significantly increased risk of BIA-ALCL; (b) accumulation of foreign and adulterated silicone particles in their bodies, including the resulting inflammation, cellular damage, subcellular damage, and related symptoms; (c) that they have incurred costs of medical treatment such as invasive surgery to explant their defective implants; (d) current physical injuries; and/or (e) economic loss. *Id.* ¶¶ 405-406.

In this case, Plaintiffs and the proposed class members primarily seek economic damages for the costs of medical visits and surgeries to remove the Recalled BIOCELL Implants, and the establishment of a medical monitoring fund that will pay for diagnostic medical services to detect BIA-ALCL. *Id.* Plaintiffs assert the following causes of action: failure to warn (strict liability and negligence), manufacturing defect (strict liability and negligence), design defect (strict liability and negligence), violation of state consumer protection statutes, breach of implied warranty, medical monitoring (in states permitting medical monitoring as a cause of action), and unjust enrichment. The CAC provides proper notice that Plaintiffs may seek to certify a nationwide class and/or various subclasses under Rule 23(a) and (b)(2) and/or (b)(3), and/or under Rule 23(c)(4) (issue certification). *Id.* ¶¶ 269-392. Allergan’s challenges to class certification at this early stage

overlook the flexibility of Rule 23, including the discretion afforded this Court to later modify and shape a class that meets the requirements of Rule 23, and to conform it to the evidence.<sup>2</sup>

Discovery is stayed and Allergan has produced only its Pre-Market Approval (“PMA”) applications to the FDA. Allergan nevertheless asserts that now is the appropriate time for the Court to decide whether Plaintiffs’ claims are suitable for class certification.

## **ARGUMENT**

### **I. Striking Class Allegations Is A “Rare” Remedy That Is Not Appropriate Here**

Under Rule 8(a)(2), a complaint requires only “a short and plain statement of the claim showing that the pleader is entitled to relief,” to “give the defendant fair notice of what the ... claim is and the grounds upon which it rests.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). At the pleading stage, “a court must accept as true” all well-pleaded factual allegations, and determine whether those allegations, “accepted as true, ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). By contrast, class certification decisions rest not on *allegations* but on a “rigorous analysis” of the factual evidence. *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011) (“Rule 23 does not set forth a mere pleading standard. A party seeking class certification must affirmatively demonstrate his compliance with the Rule—that is, he must be prepared to prove that there are *in fact* sufficiently numerous parties, common questions of law or fact, etc.”). Relying on allegations in a complaint does not suffice to satisfy the rigorous criteria in Rule 23. Often, the scope of the proposed class or classes sought to be certified will later be refined from those originally alleged based on the evidence learned in discovery.

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<sup>2</sup> See, e.g., *Gwiazdowski v. Cty. Of Chester*, 263 F.R.D. 178, 186 (E.D. Pa. 2009) (exercising discretion to modify class definition at class certification).

The Third Circuit recognizes that class certification decisions should not be made at the pleading stage without a record except in “rare” circumstances “where the complaint itself demonstrates that the requirements for maintaining a class action cannot be met.” *Landsman & Funk PC v. Skinder-Strauss Assocs.*, 640 F.3d 72, 93 n. 30 (3d Cir. 2011), *opinion reinstated in part*, No. 09-3105, 2012 WL 2052685 (3d Cir. Apr. 17, 2012) (rejecting determination of class certification at motion to dismiss stage and noting case was not among “the rare few where the complaint itself demonstrates that the requirements for maintaining a class action cannot be met.”).

Thus, granting a motion to strike class allegations at the pleading stage is a “drastic remedy” and “legion cases have affirmed that motions to strike should be used sparingly, and generally are not favored and usually will be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues.” *Ehrhart v. Synthes (USA)*, No. CIV.A. 07-01237(SDW), 2007 WL 4591276, at \*3 (D.N.J. Dec. 28, 2007) (internal quotations omitted); *McPeak v. S-L Distribution Co.*, No. CIV. 12-348 RBK/KMW, 2014 WL 4388562, at \*3-4 (D.N.J. Sept. 5, 2014) (a motion to strike class allegations should only be granted “when no amount of discovery or time will allow for plaintiffs to resolve deficiencies in class definitions under Rule 23.”) (internal quotations omitted); *In re Paulsboro Derailment Cases*, No. CIV. 12-7586 RBK/KMW, 2014 WL 1371712, at \*3 (D.N.J. Apr. 8, 2014) (denying motion to strike class allegations and acknowledging that “[a] court should grant a motion to strike class allegations only if the inappropriateness of class treatment is evident from the face of the complaint and from incontrovertible facts.”); *see also* 3 Newberg on Class Actions § 7:22 (5th ed.) (“When a defendant moves to defeat certification prior to the end of discovery, many courts simply deny the motion outright on the grounds that the plaintiff is entitled to discovery on class certification issues.”) (citing *Bryant v. Food Lion, Inc.*, 774 F. Supp. 1484, 1495 (D.S.C.

1991) (leading case holding that “to prevail, the defendants have the burden of demonstrating from the face of plaintiffs’ complaint that it will be impossible to certify the classes alleged by the plaintiffs regardless of the facts the plaintiffs may be able to prove.”)). Therefore it is often an abuse of discretion to not allow appropriate discovery before deciding whether to certify a class. *See Damasco v. Clearwire Corp.*, 662 F.3d 891, 897 (7th Cir. 2011) (overruled on other grounds by *Chapman v. All Am. Painting, Inc.*, 796 F.3d 783, 787 (7th Cir. 2015)); *Pitts v. Terrible Herbst, Inc.*, 653 F.3d 1081, 1093 n.5 (9th Cir. 2011) (a court may abuse its discretion by denying discovery crucial to class certification); *Mills v. Foremost Ins. Co.*, 511 F.3d 1300, 1311 (11th Cir. 2008) (“[T]he district court erred in determining that class action treatment was inappropriate as a matter of law from the face of the . . . particular complaint” and in not permitting discovery).

Because federal courts are required to engage in a rigorous analysis to determine whether class certification is proper, “an early motion to strike should be denied so that the court can probe behind the pleadings before coming to rest on the certification question, after discovery has taken place.” *McPeak*, 2014 WL 4388562 at \*4 (internal quotations omitted).<sup>3</sup> As a result, this Court has repeatedly and “emphatically denied requests to strike class allegations at the motion to dismiss stage as procedurally premature.” *Neuss v. Rubi Rose, LLC*, No. CV162339MASLHG, 2017 WL 2367056, at \*10 (D.N.J. May 31, 2017); *Cannon v. Ashburn Corp.*, No. CV 16-1452 (RMB/AMD), 2016 WL 7130913, at \*12 (D.N.J. Dec. 7, 2016) (denying motion to strike class allegations as

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<sup>3</sup> *See also Andrews v. Home Depot U.S.A., Inc.*, No. CIV.A.03CV5200 (DMC), 2005 WL 1490474, at \*3 (D.N.J. June 23, 2005) (“[T]he shape and form of a class action evolves only through the process of discovery.”) (citation omitted); *Horowitz v. AT&T Inc.*, No. 3:17-CV-4827-BRM-LHG, 2018 WL 1942525, at \*17 (D.N.J. Apr. 25, 2018), opinion clarified on denial of reconsideration, No. 3:17-CV-4827-BRM-LHG, 2019 WL 77306 (D.N.J. Jan. 2, 2019).

premature at motion to dismiss stage, following “the majority of courts in this District”).<sup>4</sup> This includes many instances in which courts have rejected defendants’ early challenges to nationwide or multi-state classes, and classes with defendant-perceived individualized fact issues. *See, e.g., Ehrhart*, 2007 WL 4591276, at \*3-4 (in action against radius plate manufacturer, denying motion to strike and rejecting defendants’ arguments that application of laws of multiple states destroys predominance and that resolving class action claims will require “individualized fact specific choice of law inquiries”).<sup>5</sup>

Allergan’s reliance on inapposite case law,<sup>6</sup> strained interpretations of precedent, and the suggestion of an alternative but unsupported standard of review, should be rejected. Indeed, there

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<sup>4</sup> *See also Luppino v. Mercedes-Benz USA, LLC*, No. 09-CV-5582 DMC JBC, 2013 WL 6047556, at \*7 (D.N.J. Nov. 12, 2013) (finding motion to strike premature and stating that “[d]ismissal of class claims prior to discovery and a motion to certify the class by plaintiff is the exception rather than the rule.”); *Durso v. Samsung Elecs. Am., Inc.*, No. 2:12-CV-05352 DMC, 2013 WL 5947005, at \*13 (D.N.J. Nov. 6, 2013) (same); *see also Genova v. IC Sys., Inc.*, No. CV 16-5621, 2017 WL 2289289, at \*9 (D.N.J. May 25, 2017); *Tae In Kim v. Dongbu Tour & Travel, Inc.*, No. 2:12-CV-1136 (WHW), 2012 WL 12903881, at \*3 (D.N.J. June 6, 2012); *Greene v. BMW of N. Am.*, No. CIV. 2:11-04220 WJM, 2013 WL 5287314, at \*7 (D.N.J. Sept. 17, 2013).

<sup>5</sup> *See also Q±Food LLC v. Mitsubishi Fuso Truck of Am., Inc.*, No. CIV.A. 14-6046 MAS, 2015 WL 4603678, at \*7 (D.N.J. July 30, 2015) (denying motion to strike and rejecting as premature defendants’ argument that proposed nationwide class should not be certified); *Fishman v. Gen. Elec. Co.*, No. 2:12-CV-00585 WJM, 2013 WL 1845615, at \*6 (D.N.J. Apr. 30, 2013) (similar); *6803 Blvd. E., LLC v. DIRECTV, Inc.*, No. 12-CV-2657 WHW, 2012 WL 3133680, at \*2 (D.N.J. July 31, 2012) (similar).

<sup>6</sup> Other than *Landsman* (cited *supra*) which sets forth the Third Circuit’s preference to defer class certification determinations until after discovery, defendants cite several cases that are distinguishable from this MDL. *See Mladenov v. Wegmans Food Markets, Inc.*, 124 F. Supp. 3d 360, 372 (D.N.J. 2015) (granting motion to strike where class members, purchasers of defendants’ bread and bakery products, could not be identified in reliable way); *Semeran v. Blackberry Corp.*, No. CV 15-750, 2016 WL 3647966, at \*6 (D.N.J. July 6, 2016), dismissed, No. 16-3318, 2017 WL 3466880 (3d Cir. Jan. 31, 2017) (plaintiff not a member of class of 31 states he sought to represent); *Lafferty v. Sherwin-Williams Co.*, No. CV11706321RBKAMD, 2018 WL 3993448, at \*6 (D.N.J. Aug. 21, 2018) (“potential exposures, if any, [to environmental contamination] are likely drastically different.”); *Advanced Acupuncture Clinic, Inc. v. Allstate Ins. Co.*, No.

is no rule against certifying actions involving allegedly defective products, and such cases are often certified. Indeed, the Third Circuit has noted “a number of mass tort class actions have been certified notwithstanding individual issues of causation, reliance, and damages.” *In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prod. Liab. Litig.*, 55 F.3d 768, 817–18 (3d Cir. 1995). Medical monitoring cases have also been certified as class actions.<sup>7</sup> Consumer fraud<sup>8</sup> and unjust enrichment<sup>9</sup> cases are likewise certified as class actions. And just four years ago, the Third Circuit

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CIV.A.07-4925 (JAP), 2008 WL 4056244, at \*12, 15 (D.N.J. Aug. 26, 2008), *aff’d* on other grounds sub nom. *St. Louis Park Chiropractic, P.A. v. Fed. Ins. Co.*, 342 F. App’x 809 (3d Cir. 2009) (claims of medical provider class were subject to arbitration provision and prone to individualized inquiry to determine whether reimbursements were “reasonable or unreasonable.”).

<sup>7</sup> See, e.g., *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, No. CIV.A. 98-20626, 1999 WL 673066, at \*1 (E.D. Pa. Aug. 26, 1999) (conditionally certifying medical monitoring class); *Baker v. Sorin Group Deutschland GMBH*, No. 1:16-cv-260, ECF No. 79 (E.D. Pa. Oct. 23, 2017) (similar); *Donovan v. Philip Morris USA, Inc.*, 268 F.R.D. 1, 27 (D. Mass. 2010) (similar); *Leach v. E.I. Du Pont de Nemours & Co.*, No. 01-C-608, 2002 WL 1270121, at \*18 (W. Va. Cir. Ct. Apr. 10, 2002) (similar); *Josephat v. St. Croix Alumina, LLC*, No. CIV. 1999-0036, 2000 WL 1679502, at \*12 (D.V.I. Aug. 7, 2000) (similar); *O’Connor v. Boeing N. Am., Inc.*, 184 F.R.D. 311, 339 (C.D. Cal. 1998) (similar); *In re Telectronics Pacing Sys., Inc.*, 172 F.R.D. 271, 295 (S.D. Ohio 1997) (similar); *Yslava v. Hughes Aircraft Co.*, 845 F. Supp. 705, 713 (D. Ariz. 1993) (similar).

<sup>8</sup> See, e.g., *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 75 (D.N.J. 2009), opinion clarified, 267 F.R.D. 113 (D.N.J. 2010), opinion modified on reconsideration, No. CIV. 07-2720 DRD, 2010 WL 2976496 (D.N.J. July 22, 2010), abrogated on other grounds (finding class treatment of consumer fraud claims appropriate); *Pro v. Hertz Equip. Rental Corp.*, No. CIV.A.06-3830(DMC), 2009 WL 1010622, at \*2 (D.N.J. Feb. 3, 2009) (ordering that claims asserting violations of the New Jersey Consumer Fraud Act are to receive class treatment); *Elias v. Ungar’s Food Prod., Inc.*, 252 F.R.D. 233, 240 (D.N.J. 2008) (certifying class to pursue claims under the New Jersey Consumer Fraud Act and for breach of express warranty); *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 527 (6th Cir. 2015) (affirming certification of consumer fraud classes).

<sup>9</sup> *Dzielak v. Whirlpool Corp.*, No. CV 2:12-89 (KM) (JBC), 2017 WL 6513347, at \*21 (D.N.J. Dec. 20, 2017) (certifying class on price-premium theory as against Whirlpool, and finding that plaintiffs’ unjust enrichment claims are appropriate for class certification); *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 75 (D.N.J. 2009), opinion clarified, 267 F.R.D. 113 (D.N.J. 2010), opinion modified on reconsideration, No. CIV. 07-2720 DRD, 2010 WL 2976496 (D.N.J. July 22, 2010), abrogated on other grounds (finding class treatment of unjust enrichment

upheld the certification of a class seeking damages against the National Football League (“NFL”) for concussion-related injuries, where the injuries were “unique” and the common questions included “when did the NFL know about the risks of concussion,” “what did it do to protect players,” and “did the League conceal the risks of head injuries?” *In re Nat’l Football League Players Concussion Injury Litig.*, 821 F.3d at 427. Given this clear Third Circuit precedent and the District of New Jersey’s consistent rejection of striking class allegations at the pleadings stage, Allergan’s motion should be denied.

## **II. Plaintiffs Have Plausibly Pleaded The Typicality Requirement of Rule 23(a)(3)**

### **A. Plaintiffs’ Allegations Satisfy The “Low” Threshold Of The Typicality Requirement**

Allergan asserts Plaintiffs cannot satisfy the typicality requirement of Rule 23(a)(3), but fundamentally misunderstands the inquiry. Typicality requires that the “the claims or defenses of the representative parties are typical of the claims or defenses of the class.” Fed. R. Civ. P. 23(a)(3). There is “a low threshold for satisfying” this requirement. *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 183 (3d Cir. 2001). “The typicality requirement is designed to align the interests of the class and the class representatives so that the latter will work to benefit the entire class through the pursuit of their own goals.” *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 141 (3d Cir. 1998). “The typicality criterion is intended to preclude certification of those cases where the legal theories of the named plaintiffs potentially conflict with those of the absentees by requiring that the common claims are comparably central to the claims of the named plaintiffs as to the claims of the absentees.” *Baby Neal for & by Kanter v. Casey*, 43 F.3d 48, 57 (3d Cir. 1994).

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claims appropriate); *Keilholtz v. Lennox Hearth Prod. Inc.*, 268 F.R.D. 330, 343 (N.D. Cal. 2010) (certifying class to pursue unjust enrichment claim).

Typicality does not require complete identity among the facts and legal theories of the class representatives as compared to the absent class members. *See In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prod. Liab. Litig.*, 55 F.3d 768, 817-18 (3d Cir. 1995) (“Rule 23(a) does not require that class members share every factual and legal predicate to meet the commonality and typicality standards.”). “Even relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal theories or where the claim arises from the same practice or course of conduct.” *In re Nat’l Football League Players Concussion Injury Litig.*, 821 F.3d at 428 (internal quotations omitted); *see also Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 141 (3d Cir. 1998) (the typicality “requirement does not mandate that all putative class members share identical claims.”). Indeed, “cases challenging the same unlawful conduct which affects both the named plaintiffs and the putative class usually satisfy the typicality requirement irrespective of the varying fact patterns underlying the individual claims.” *In re Nat’l Football League Players Concussion Injury Litig.*, 821 F.3d at 428 (quoting *Baby Neal for & by Kanter v. Casey*, 43 F.3d 48, 58 (3d Cir. 1994)); *see also* 1 Newberg on Class Actions § 3:29 (5th ed.) (“[T]he plaintiffs’ claims need not be identical to those of the class; typicality will be satisfied so long as “the named representatives’ claims share the same essential characteristics as the claims of the class at large.”).

The CAC pleads that each class representative has claims that are typical of the class’s claims. Each class representative was implanted with one or more Recalled BIOCELL Implants. CAC ¶¶ 22-84. Each class representative alleges that she is at risk of BIA-ALCL and is in need of medical monitoring. *Id.* Each class representative alleges that she would not have used the Recalled BIOCELL Implants had she known of the risk of BIA-ALCL. *Id.* And each class representative alleges that she has suffered, or will suffer, economic injuries in the form of costs



to remove the Recalled BIOCELL Implants and medical monitoring. *Id.* The alleged facts, injuries, and legal theories underlying the class representatives' claims are the same as those underlying the claims of the class members at large.

Allergan argues typicality is lacking and that there is a “failure of representation by jurisdiction” and a “failure of representations by device.” Defs.’ Mem. at 13-14. This argument that there needs to be one named plaintiff from each state with each type of device to satisfy typicality, goes way too far. Typicality is concerned with the interests and claims of the class representatives as compared to the absent class members. Here, the claims all stem from the same *course of conduct by Allergan*, the manufacture and sale of the Recalled BIOCELL Implants. All the Plaintiffs have the same interests as the class members to obtain relief in the form of medical monitoring and repayment of economic losses resulting from the recall. Allergan provides no reason why class members who live in different states or have different styles of the implants have diverging interests, and in fact, they do not.

Allergan also raises that there are differences among devices and implant period, that its knowledge of the risks of BIA-ALCL may have changed over time, that the level of risk may vary among plaintiffs, and so-called “foundational facts” may vary. Defs.’ Mem. at 15-18. Allergan argues these differences are “inherently individual” and defeat typicality. *Id.* at 18. Based upon the case law above, this is not so, and additionally, there has been no discovery, and Allergan’s speculation does not satisfy the rigorous analysis standard that the Supreme Court required in *Dukes*. Nor does Allergan explain how these purported differences affect the interests of the Plaintiffs rather than class members. And the lack of a record makes such an analysis premature and dependent on speculation rather than evidence.

*In re Nat'l Football League Players Concussion Injury Litigation* is instructive. There, the Third Circuit upheld the certification of a class of “[a]ll living NFL football players who retired from playing professional football before July 7, 2014, as well as their representative claimants and derivative claimants” who sought to recover for injuries related to concussions suffered while playing NFL football. 821 F.3d at 425. There were only two class representatives, one former player (Shawn Wooden) who had not yet developed a qualifying diagnosis and one former player (Kevin Turner) who had developed a qualifying condition. *Id.* at 428. Like Allergan, there were those who challenged typicality because “of factual differences between the representatives and other class members, including the number of seasons [played and injuries caused by head trauma.” *Id.* at 428. The Third Circuit quickly dispensed with these objections:

But class members need not ‘share identical claims,’ and ‘cases challenging the same unlawful conduct which affects both the named plaintiffs and the putative class usually satisfy the typicality requirement irrespective of the varying fact patterns underlying the individual claims.’ *Baby Neal*, 43 F.3d at 56, 58. What matters is that Wooden and Turner seek recovery under the same legal theories for the same wrongful conduct as the subclasses they represent. Even if the class representatives’ injuries are unique to their time in football, the NFL’s alleged fraudulent concealment of the risks of head injuries is the same.

*Id.* at 428. The same is true here. Plaintiffs and the proposed class members seek reimbursement of economic losses and medical monitoring related to Allergan’s conduct in developing, manufacturing, and selling the Recalled BIOCELL Implants. Plaintiffs are typical of the class members they seek to represent, and the class allegations should proceed to discovery.

**B. Allergan’s “Standing” Argument Is Misguided**

Allergan claims that Plaintiffs lack “standing” to serve as representatives for class members “from states and territories in which the named Plaintiffs do not live.” Defs.’ Mem. at 15. This argument is premature, misapprehends Plaintiffs’ claims, and misstates the law. “Standing” is a term with many meanings and Allergan is unclear whether it is referring to Article III standing,

statutory standing, or something else. Allergan pays short shrift to this argument and fails to demonstrate why Plaintiffs cannot protect the interests of class members residing in other states.

In recent years, federal courts of appeals have rejected the argument that Article III standing prevents a plaintiff living in one state from serving as a class representative for state law claims of class members in other states. In *Langan v. Johnson & Johnson Consumer Companies, Inc.*, 897 F.3d 88, 5 (2d Cir. 2018), for example, the Second Circuit analyzed “whether there is a standing problem when a plaintiff attempts to sue on behalf of those who may have claims under different states’ laws that generally prohibit the same conduct.” *Id.* The Second Circuit concluded that variations in state laws were “questions of predominance under Rule 23(b)(3), rather than standing under Article III.” *Id.* The court “acknowledge[d] the obvious truth that class actions necessarily involve plaintiffs litigating injuries that they themselves would not have standing to litigate” and stated that “it makes little sense to dismiss the state law claims of unnamed class members for want of standing where there was no requirement that the named plaintiff have individual standing to bring those claims in the first place.” *Id.*

Other Circuits are in accord. See *In re Asacol Antitrust Litig.*, 907 F.3d 42, 51 (1st Cir. 2018) (“[O]nce the named plaintiff establishes injury and membership in the class, the inquiry should shift ‘from the elements of justiciability to the ability of the named representative to fairly and adequately protect the interests of the class.’”) (quoting *Sosna v. Iowa*, 419 U.S. 393, 403 (1975)) (internal citations omitted); *Morrison v. YTB Int’l, Inc.*, 649 F.3d 533, 536 (7th Cir. 2011) (explaining that “application of choice-of-law principles has nothing to do with *standing*, though it may affect whether a class should be certified”); *Fallick v. Nationwide Mut. Ins. Co.*, 162 F.3d 410, 423 (6th Cir. 1998) (“Once his standing has been established, whether a plaintiff will be able to represent the putative class, including absent class members, depends solely on whether he is

able to meet the additional criteria encompassed in Rule 23 of the Federal Rules of Civil Procedure.”); *Melendres v. Arpaio*, 784 F.3d 1254, 1261 (9th Cir. 2015) (adopting similar “class certification approach”).

While the Third Circuit has not addressed the issue, district courts have rejected “standing” challenges to the ability of the named plaintiffs to represent absent class members in other states at the pleading stage. *See Ramirez v. STi Prepaid LLC*, 644 F. Supp. 2d 496, 504-06 (D.N.J. 2009) (“the fact that the named Plaintiffs may not have individual standing to allege violations of consumer protection laws in states other than those in which they purchased Defendants’ calling cards is immaterial”); *In re Generic Pharm. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 831 (E.D. Pa. 2019) (denying motion to dismiss “[b]ecause the state law claims of the named [plaintiffs] largely parallel those of the putative class members, it is both proper and more efficient to consider whether they may pursue their claims on behalf of the unnamed class members in the context of the class certification analysis required under Rule 23 of the Federal Rules of Civil Procedure (*e.g.*, commonality and typicality under 23(a), and predominance under 23(b)”). For these reasons, standing does not implicate typicality and does not justify striking class allegations.

In sum, Allergan’s attacks on typicality rest on misconceptions regarding the applicable legal standard, are premature, and should be rejected, as Plaintiffs’ claims are typical of the claims of the proposed class members.

### **III. Allergan’s Arguments Regarding Predominance Are Misplaced And Premature**

Allergan incorrectly argues that Plaintiffs cannot meet the predominance requirement of Rule 23(b)(3). Many common issues in this case arising out of Allergan’s conduct include: (a) whether the Recalled BIOCELL Implants increase the risk of developing BIA-ALCL; (b) whether Allergan knew or should have known that the Recalled BIOCELL Implants increase the risk of

developing BIA-ALCL; (c) when Allergan obtained such knowledge; (d) whether Allergan failed to warn consumers about the risks of the Recalled BIOCELL Implants; (e) whether the Recalled BIOCELL Implants were manufactured using a defective manufacturing process; (f) whether Allergan breached the implied warranty of merchantability; (g) whether Allergan engaged in acts that violated each of the state consumer fraud and deceptive trade practices acts alleged in the CAC; and (h) whether Allergan was unjustly enriched by its conduct. *All of these questions, and scores of derivative common factual questions under each of these main topic areas, will be subject to the same common discovery and proof*, that will ultimately provide answers applicable to Plaintiffs and the class members. These common questions will predominate over any individualized ones in this class action. Moreover, the remedies sought by the class – a class-wide medical monitoring program and recovery for economic losses – do not present individualized issues that predominate over the common issues.

To be clear, Plaintiffs are not seeking to certify a class for personal injuries such as pain and suffering, as women who wish to file such claims will do so utilizing the Short Form Complaint process. Rather, the CAC is focused on claims that traditionally have been addressed through the class action device. Further, Allergan’s argument was recently rejected on prematurity grounds in *Jones v. Depuy Synthes Products, Inc.*, 330 F.R.D. 298, 308-09 (N.D. Ala. 2018):

Defendants point to several district court decisions that have declined to certify proposed personal injury class actions due to lack of predominance and argue that personal injury classes, such as this one, necessarily fail the predominance inquiry. However, most of these cases were decided at the class certification stage where the courts had the ability to review evidence regarding whether individualized proof was necessary to establish liability. *See, e.g., Haggart v. Endogastric Sols., Inc.*, Civil Action No. 10-346, 2012 WL 2513494, at \*1 (W.D. Pa. June 28, 2012); *In re ConAgra Peanut Butter Prods. Liab. Litig.*, 251 F.R.D. 689, 698 (N.D. Ga. 2008); *Rink v. Cheminova, Inc.*, 203 F.R.D. 648, 652 (M.D. Fla. 2001). While many of the decisions cited by Defendants do note that personal injury claims are often unsuitable for class treatment, the class certification determinations made in those cases were based on the particular factual record developed through discovery. *See, e.g., City of*

*St. Petersburg v. Total Containment, Inc.*, 265 F.R.D. 630, 638 (S.D. Fla. 2010) (looking to evidence that some FlexPipe failures were caused by factors other than plaintiffs' alleged defect to support finding that causation was not susceptible to class-wide proof); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 68 n.45 (S.D.N.Y. 2002) (relying in part on expert testimony to determine that individual questions surrounding causation overwhelmed common issues). Before the Court determines whether this case may proceed as a class action, Plaintiffs should be afforded the same opportunity to develop a factual record as the plaintiffs in those cases.

Likewise, Plaintiffs should be given the same opportunity here to obtain factual evidence through discovery that will confirm the predominance of common issues. At the class certification stage following discovery, Plaintiffs will demonstrate and cite case law supporting that any individual issues that may exist can be addressed using common case management tools and a class action trial plan which may, for example, involve a phased approach, including with respect to damages.

Allergan misleadingly claims that individualized issues including differences in state law, differences in exposure, differences in "reliance," and potential affirmative defenses defeat predominance. As explained next, these speculative concerns are better addressed at the class certification stage and cannot be resolved at the pleading stage.

**A. Allergan's Argument Regarding Variability In State Law Medical Monitoring Remedies Is Premature**

Allergan argues that the "medical monitoring and product liability laws differ widely between the states" and that "in nearly all those states allowing medical monitoring under any circumstances, the liability and causation inquiries are highly individualized." Defs.' Mem. at 20. These arguments should be rejected because Plaintiffs will establish at the class certification stage that any material differences among state laws can be handled through commonly used case management tools, for example, by grouping similar state laws or through subclassing. *See Sullivan v. DB Investments, Inc.*, 667 F.3d 273, 301–02 (3d Cir. 2011) (discussing Third Circuit authority and noting "[w]e have never required the presentation of identical or uniform issues or

claims as a prerequisite to certification of a class. Rather, our jurisprudence evinces a pragmatic response to certifications of common claims arising under varying state laws”); *In re School Asbestos Litig.*, 789 F.2d 996, 1010 (3d Cir. 1986) (“To meet the problem of diversity in applicable state law, class plaintiffs have undertaken an extensive analysis of the variances in products liability among the jurisdictions. That review separates the law into four categories. Even assuming additional permutations and combinations, plaintiffs have made a creditable showing, which apparently satisfied the district court, that class certification does not present insuperable obstacles.”); *In re Welding Fume Prods. Liab. Litig.*, 245 F.R.D. 279 (N.D. Ohio 2007) (“a court could manage the differences in medical monitoring law among the eight states ... by holding separate trials for each state-wide subclass, or perhaps a combined trial for a few statewide subclasses”). The proper time for this analysis is at class certification on a briefed factual record, and not a motion to strike class allegations at the pleading stage.

Allergan’s concerns regarding factual issues among class members, such as differing risks of contracting ALCL, are pure speculation and have no place here. Defs.’ Mem at 30. Allergan itself recognizes the speculative nature of its arguments. *Id.* (“Each Plaintiff’s alleged increased risk of contracting ALCL **may vary**”; “This **may** include how long the device was implanted;” “Plaintiff’s individual medical history *could* play a pivotal role in determining the benefits and safety of any medical monitoring regime”) (emphasis added). Whether the issues on which Allergan speculates will ultimately present individualized issues depends on the facts adduced in discovery and the proposed medical monitoring program that will be the subject of expert testimony, and the scope of the classes that Plaintiffs seek to certify following discovery, which are not presently before the Court.

Importantly, Allergan’s citations of cases in which medical monitoring claims were not certified were made after a record was developed through discovery and in most cases, the presentation of expert testimony. *See, e.g., Gates v. Rohm & Haas Co.*, 655 F.3d 255, 261 (3d Cir. 2011) (interlocutory appeal of class certification decision after fact and expert discovery where parties’ experts modeled emissions and exposure from pollutants); *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 133 (3d Cir. 1998) (appeal of decision to decertify class and grant summary judgment after fact and expert discovery ); *In re Fosamax Prod. Liab. Litig.*, 248 F.R.D. 389, 391, n.1, 394 (S.D.N.Y. 2008) (denying class certification after “the parties have established an extensive evidentiary record,” which included expert reports, deposition transcripts, interrogatory responses, plaintiff fact sheets, FDA reports concerning adverse event reports and post-marketing safety reviews, and 40 articles and chapters regarding disease cause, diagnosis, and treatment); *Rowe v. E.I. duPont de Nemours & Co.*, No. CIV. 06-1810 (RMB), 2008 WL 5412912, at \*3 (D.N.J. Dec. 23, 2008) (denying class certification after “a lengthy discovery period,” which included fact and expert discovery); *Rhodes v. E.I. du Pont de Nemours & Co.*, 253 F.R.D. 365, 369 (S.D.W. Va. 2008) (denying class certification “after extensive discovery”).

Other cases cited by Allergan involve environmental harms where the exposure to the hazardous material was in question. *See, e.g., Lafferty v. Sherwin-Williams Co.*, No. CV-11-706321-RBK/AMD, 2018 WL 3993448, at \*6 (D.N.J. Aug. 21, 2018). Here, exposure concerns do not exist as every Plaintiff and proposed class member had the textured implants put into their body. Allergan’s challenges to predominance are speculative and meritless.

**B. Allergan’s Challenges To Plaintiffs’ Consumer Protection And Unjust Enrichment Claims Are Misguided**

With respect to Plaintiffs’ statutory consumer protection and unjust enrichment claims, Allergan asserts that “each of these claims is premised upon what Allergan told each Plaintiff or



her implanting physician, and more importantly, each Plaintiff's subjective state of mind regarding whether they relied on any misrepresentations in deciding to proceed with an implant." Defs.' Mem. at 31. Allergan, however, relies on inapposite cases involving common law fraud, which Plaintiffs have not alleged. *Id.*

To the contrary, Plaintiffs allege claims under state consumer fraud statutes, many of which relax or reject the requirements for proving common law fraud such as reliance. *See, e.g., Int'l Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co.*, 192 N.J. 372, 389, 929 A.2d 1076, 1086 (2007) ("Our statute essentially replaces reliance, an element of proof traditional to any fraud claim, with the requirement that plaintiff prove ascertainable loss."); *State by Humphrey v. Alpine Air Prod., Inc.*, 500 N.W.2d 788, 790 (Minn. 1993) ("In passing consumer fraud statutes, the legislature clearly intended to make it easier to sue for consumer fraud than it had been to sue for fraud at common law. The legislature's intent is evidenced by the *elimination* of elements of common law fraud, such as proof of damages or reliance on misrepresentations.").

Further, material omissions are also actionable under consumer fraud statutes and proof of reliance is generally relaxed with respect to omissions. *See In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 74 (D.N.J. 2009), *opinion modified on reconsideration*, No. CIV. 07-2720 DRD, 2010 WL 2976496 (D.N.J. July 22, 2010), *abrogated on other grounds* (finding class treatment of consumer fraud claims appropriate) ("It is well-established that plaintiffs asserting fraud claims involving primarily failure to disclose material information need not demonstrate positive proof of reliance in order to recover.") (internal quotation marks omitted); *see In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 103 Cal. Rptr. 3d 83, 95 (Cal. Ct. App. 2009) ("[c]ausation, on a classwide basis, may be established by materiality," and "if . . . material misrepresentations have been made to the entire class, an inference of reliance arises as to the class.").

Each Plaintiff alleges that she would not have had the Recalled BIOCELL Implants implanted in her body had she known the implants “would subject her to a significantly increased risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other costs and procedures to detect and treat BIA-ALCL.” CAC ¶¶ 22-84. Indeed, it is implausible that any woman would have chosen the Recalled BIOCELL Implants as opposed to the many other implants available, once sufficiently warned regarding the risks of BIA-ALCL.

Allergan also includes in its brief citations to cases in which unjust enrichment claims were not certified, but cannot link the facts of those cases to the claims asserted here because there has been no discovery in this case. Defs.’ Mem. at 33. Once again, unjust enrichment claims have been certified, *see supra*, footnote 10, and such determinations are better evaluated after discovery and at the motion for class certification stage on a full record.

**C. Allergan’s Affirmative Defenses Have Not Yet Been Asserted And Do Not Provide A Basis To Strike The Class Allegations**

Allergan’s argument regarding affirmative defenses is equally infirm. Allergan boldly argues that “the assumption of risk and comparative negligence defenses will require inquiries into what each Plaintiff knew about the risks associated with their devices and whether they chose to proceed with their devices in light of that knowledge.” Defs.’ Mem. at 33. Allergan then argues the same inquiries will be needed to adjudicate statutes of limitations and statutes of repose.

Allergan is wrong both in terms of the timing of its motion and its assertion that affirmative defenses will preclude class certification. Regarding the timing, *every* case that Allergan cites in support of its argument was decided at the class certification stage, not on a motion to strike. *See Barnes v. Am. Tobacco Co.*, 161 F.3d 127 (3d Cir. 1998); *In re Fosamax Prods. Liab. Litig.* 248 F.R.D. 389 (S.D.N.Y. 2008); *O’Connor v. Boeing N. Am., Inc.*, 180 F.R.D. 359 (C.D. Cal. 1997), *Guillory v. Am. Tobacco Co.*, 2001 WL 290603 (N.D. Ill. Mar. 20, 2001); *Lewallen v. Medtronic*

*USA, Inc.*, 2002 WL 31300899 (N.D. Cal. Aug. 28, 2002); *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555 (E.D. Ark. 2005). The reason is simple. Discovery is necessary to establish the evidentiary record that is required to determine whether and how the affirmative defenses affect class treatment. As a district court explained, “[b]ecause discovery is essential to determining whether a case can be maintained as a class action, a motion to strike that is filed before a plaintiff has moved to certify a class is premature.” *Austin v. Submission Invention Corp.*, No. 19-1396, 2020 WL 2771076, at \*10 (W.D. Pa. 2010); *DiFlavis v. Choice Hotel Int’l, Inc.*, 2019 WL 1505860, at \*7 (E.D. Pa. Apr. 5, 2019). This is because “the shape and form of a class action evolves only through the process of discovery.” *Lightbourne v. Printroom Inc.*, No. No. 13-876-JLS (RNBx), 2014 WL 12597108, at \*8 (C.D. Cal. Sept. 8, 2014) (citation omitted). “Therefore, the Court finds the better course in this case, as in most, is ‘to analyze the elements of the parties’ substantive claims and review facts revealed in discovery in order to evaluate whether the requirements of Rule 23 have been satisfied.’” *Id.* (quoting *In re Ford Motor Ignition Switch Prods. Liab. Litig.*, 174 F.R.D. 332, 338 (D.N.J. 1997)); see also *Bishop v. Delaval, Inc.*, 2020 WL 4669185, \*2 (Jan. 28, 2020) (W.D. Mo.) (denying motion to strike class allegations on the basis of defendant’s affirmative defenses, as “at this early stage in litigation, prior to any class discovery or a motion for class certification, the Court cannot determine whether individualized matters will predominate over common issues.”).

Allergan is also substantively wrong. The Third Circuit and other Circuits have concluded that affirmative defenses do not preclude class certification. See, e.g., *In re Community Bank of Northern Virginia*, 622 F.3d 275, 293, n.13 (3d Cir. 2010); *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 138 (2d Cir. 2001) (noting the presence of affirmative defenses does not automatically render class certification inappropriate); *Int’l Woodworkers of Am. v. Chesapeake Bay Plywood Corp.*, 659 F.2d 1259, 1270 (4th Cir.1981) (“Courts passing upon motions for class

certification have generally refused to consider the impact of such affirmative defenses as the statute of limitations on the potential representative's case.”); *see also* 2 NEWBERG ON CLASS ACTIONS § 4:57 (5<sup>th</sup> ed.) (“Statute of limitations defenses – like damage calculations, affirmative defenses, and counterclaims – rarely defeat class certification.”).<sup>10</sup> Indeed, affirmative defenses themselves often involve common proof. *See, e.g., In re Checking Account Overdraft Litig.*, 307 F.R.D. 630, 650 (S.D. Fla. 2015) (certifying class despite assertion of affirmative defenses and noting “Wells Fargo’s affirmative defenses do not defeat certification for the additional reason that they raise common questions of proof that predominate over individualized issues.”). The same is anticipated here in that many of Allergan’s affirmative defenses will present common issues of fact and law that, among the other issues, will predominate in this litigation and will be able to be answered for all class members at the same time in one class action trial.

Especially *where Allergan has not yet even filed an answer setting forth affirmative defenses*, it would be an error to conclude that “no amount of discovery” would assist Plaintiffs in meeting their class certification burden. *Goode v. LexisNexis Risk & Info. Analytics Group, Inc.*, 284 F.R.D. 238, 244 (E.D. Pa. 2012) (*citing Thompson v. Merck & Co., Inc.*, 2004 WL 62710 (E.D. Pa. 2004)). Allergan’s motion should be denied.

#### **D. The Court Should Not Strike The Release Subclass Allegations**

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<sup>10</sup> *In re Myford Touch Consumer Litigation*, No. 13-cv-03072, 2018 WL 3646895, at \*2 (N.D. Cal. Aug. 1, 2018) (“Adjudication of individualized affirmative defenses typically does not defeat predominance under Rule 23(b)(3) because “[t]he Court has various tools at its disposal to manage resolution of those issues to the extent that they arise.”) (citation omitted); *Roy v. Cnty. of Los Angeles*, No. CV 12-09012-AB, 2018 WL 3436887, at \*4 (C.D. Cal. July 11, 2018) (denying decertification based on the defendant’s argument that individualized inquiries will be required to adjudicate affirmative defenses); *In re TD Bank, N.A. Debit Card Overdraft Fee Litig.*, 325 F.R.D. 136 (D. S.C. 2018) (defenses of ratification, waiver, estoppel, and voluntary payment will not defeat certification); *Tait v. BSH Home Appliances Corp.*, 289 F.R.D. 466, 486 (C.D. Cal. 2012) (similar).

Allergan requests that the Court strike the class allegations as to the “Release Subclass.” Defs.’ Mem. at 35-38. This request is also premature and should be denied. Plaintiffs filed the CAC before the Court’s July 14, 2020 ruling that “patients who signed [the] release must be provided information about their opportunity to challenge them.” ECF No. 144 at 18. The Court declined to invalidate the releases now but noted that “[a]ny determination regarding the legal impact of those releases should be made on a case-by-case basis at a later date.” *Id.*

Allergan claims that extrinsic evidence about the circumstances under which the releases were procured would be necessary thus making class certification inappropriate, but this is not necessarily so. Defs.’ Mem. at 35. There is no need for the Court to decide now, prior to discovery, that challenging the releases through the mechanism of a class action would be impermissible, as that would be based upon speculation.

First, the release is a form document. Cases involving form contracts with identical language are frequently certified. *Gillis v. Respond Power, LLC*, 677 F. App’x 752, 756 (3d Cir. 2017) (“[F]ederal courts have recognized that claims involving the interpretation of standard form contracts are particularly well-suited for class treatment” and collecting authority). Because the release is a form document, challenges to it that do not entail consumer-specific evidence are well-suited for class treatment. For example, any challenges to the release on public policy grounds should be a common legal question that can be answered by common proof.

To the extent extrinsic evidence is considered in deciding the validity of the release, it is unlikely there will be meaningful variation among the vast majority of class members regarding how the release was presented. As Allergan pointed out, the release was part of Allergan’s Confidence Plus Warranty program, which long predated the recall and this litigation. The release was presented by Plaintiffs’ doctors and thus it is unlikely that many class members will have consulted with a

lawyer prior to signing the release. And Allergan admitted during the hearings on this issue that there is no other evidence regarding instructions or training provided to doctors for presentation of the release. As a result, discovery should confirm that the information Allergan directed patients to receive was common.

Courts have found that where extrinsic evidence is common, class certification is appropriate. In *Red Barn Motors, Inc. v. NextGear Capital, Inc.*, 915 F.3d 1098, 1102 (7th Cir. 2019), for example, the Seventh Circuit reversed the district court's order to decertify a class that was based on the court's concerns regarding the need to consider extrinsic evidence to certify a class involving interpretation of a form contract. *Id.* at 1101-1102. The Seventh Circuit reasoned that, "[e]ven if the determination that the language is ambiguous as to when interest could accrue opens the door to extrinsic evidence to ascertain the intended meaning of that provision, the determination of its meaning would apply to all signatories and therefore would be capable of class-wide resolution." *Id.* at 1101. The court reached this holding despite evidence that certain party representatives had conversations about the defendant's practices after the contracts were executed. *Id.* The court explained that when a form contract is "almost universally signed without negotiation or modification, there is no reason to think that the interpretation of the provision will vary from one signatory to another, and therefore the issue is one that is capable of a common answer." *Id.* at 1102.

As one potential mechanism for challenging the validity and enforceability of the release is through class proceedings, there is no justification at this stage for striking the class allegations.

#### **IV. A Class Action Is A Superior Method Of Adjudicating Plaintiffs' Claims And It Would Be Premature To Rule Otherwise At This Early Stage**

In evaluating the superiority prong of Rule 23(b)(3), as Allergan admits, the Court must take a "close look" at whether a class action is "superior to other available methods for the fair and efficient adjudication of the controversy." Defs.' Mem. at 38 (quoting *Amchem Prods., Inc. Windsor*,

521 U.S. 591, 615 (1997)). Such a “close look” requires the Court to consider *evidence* of the superiority factors: the class members’ interests in individually controlling the prosecution or defense of separate actions; the extent and nature of any litigation concerning the controversy already begun by or against class members; the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and the likely difficulties in managing a class action. Fed. R. Civ. P. 23(b)(3); see *In re Domestic Drywall Antitrust Litig.*, 2017 WL 3700999 (E.D. Pa. Aug. 24, 2017) (analyzing evidence at class certification stage to determine if class issues predominated).

Allergan makes no effort to address Rule 23(b)(3)’s superiority factors (including how these factors apply to each specific cause of action alleged in the CAC), but instead draws sweeping conclusions about certification of personal injury claims (a non-sequitur), the class trial and alleged manageability issues, the supposed difficulties with the relief, and other speculative problems for which it offers no evidence, or for issues that are not even applicable anymore. Allergan also fails to consider the realistic alternatives to class treatment, the administrative feasibility of tens of thousands of trials all focused on the same common issues, the potential that no woman would pursue her economic harm, statutory consumer protection, or medical monitoring case individually given the time and expense, or any other superiority factors.

Allergan next speculates that Plaintiffs “will be hard-pressed to explain how their alleged class action procedure is superior to, and thus should supplant, the pending MDL proceedings that achieves many of the same efficiencies that Rule 23 is supposed to foster.” Defs.’ Mem. at 41. Allergan speculates regarding what a class trial “may involve perhaps” and about how a class trial might be difficult to manage. *Id.* at 41. Here, over 246,000 women were implanted with the Recalled BIOCELL Implants. It cannot seriously be disputed that a single class action trial adjudicated with common proof (or perhaps even several trials as ultimately managed), would be far more efficient

than *thousands* of individual trials based on the same common evidence, to adjudicate Plaintiffs' claims for economic losses, violation of state consumer protection statutes, and for a medical monitoring program.<sup>11</sup> Allergan's superiority argument therefore boils down to another premature challenge to a motion for class certification that should be denied.<sup>12</sup>

**V. Class Certification Under Rule 23(b)(2) Is Plausible But Is Premature To Decide At This Stage**

Plaintiffs have properly pled the prerequisites for a Rule 23(b)(2) medical monitoring class. As set forth above, Plaintiffs have alleged that Allergan "has acted or refused to act on grounds that apply generally to the class," Fed. R. Civ. P. 23(b)(2), by manufacturing, marketing, and selling the defective Recalled BIOCELL Implants that caused class members to suffer a risk of BIA-ALCL. Furthermore, Plaintiffs allege "that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole," Fed. R. Civ. P. 23(b)(2), specifically, that Allergan should be ordered to implement and fund a medical monitoring program for the benefit of the class. *See* CAC ¶ 391. While Plaintiffs will need to present evidence to support certification of a Rule 23(b)(2) class at the class certification stage, at the pleading stage, its allegations are sufficient.

Allergan contends that Plaintiffs cannot certify a Rule 23(b)(2) medical monitoring class unless the Court or Defendants are involved with "overseeing, conducting, managing, or otherwise supervising" the relief. Defs.' Mem. at 45-46. Allergan further speculates and cites out-of-context

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<sup>11</sup> The precise common issues to be tried and the way to do so should be decided on a robust factual record following the class certification decision, and not in the factual void that exists now.

<sup>12</sup> Allergan asserts that Plaintiffs' refusal to adopt the allegations in the Master Complaint shows an "apparent intent to forge their own respective litigation paths [and] is fundamentally at odds with class treatment." Defs.' Mem. at 39-40. But Plaintiffs were filing their own complaints because no Short-Form Complaint had been agreed upon – a problem contributed to by Allergan. That is not the case anymore as by agreement of the parties, the Court has ordered all individual plaintiffs to file short-form complaints in Case Management Order No. 17.



snippets of the CAC to suggest that Plaintiffs' desired medical monitoring remedy is monetary in nature. *Id.* at 47. Finally, Allergan blurs the line between Rule 23(b)(3) and (b)(2) classes, arguing that Rule 23(b)(2) certification is improper because the classes lack "cohesiveness" because "common issues do not predominate." *Id.* at 48.

Plaintiffs and their experts have not had the opportunity for discovery at this stage and therefore have not yet formulated a plan for medical monitoring. Discovery and expert recommendations are needed to develop and set forth such a plan. Any attacks on such a plan or its propriety under Rule 23(b)(2) are purely speculative at this point. *See, e.g., Latard v. Union Carbide Corp.*, 2020 WL 2949781 (S.D. W. Va. 2020) (motion to strike medical monitoring class allegations was premature as "Defendant's arguments on the issues of commonality and cohesiveness of the putative Class's claims are merely speculation at this point in the proceedings."); *Chenensky v. N.Y. Life. Ins. Co.*, No. 07 Civ. 11504, 2011 WL 1795305, at \*1 (S.D.N.Y. Apr. 27, 2011) ("Motions to strike are generally looked upon with disfavor [and] a motion to strike class allegations ... is even more disfavored because it requires a reviewing court to preemptively terminate the class aspects of ... litigation ... before plaintiffs are permitted to complete the discovery to which they would otherwise be entitled on questions relevant to class certification."); *Ehrhart v. Synthes*, 2007 WL 4591276 (D.N.J. 2007) (denying motion to strike class allegations relating to a request to certify a medical monitoring claim).

Allergan misconstrues the Rule 23(b)(2) standard and controlling case law. The Third Circuit has explicitly declined to address whether a medical monitoring class can be certified under Rule 23(b)(2). *See Gates v. Rohm & Haas Co.*, 655 F.3d 255, 264 (3d Cir. 2011). Further, a recent Third Circuit decision described the plaintiffs' proposed medical monitoring claims as "requests for injunctive relief." *Giovanni v. United States Dep't of Navy*, 906 F.3d 94, 119-21 (3d Cir. 2018).

And at least one court within the Third Circuit has certified a medical monitoring class under Rule 23(b)(2). *See Baker v. Sorin Group Deutschland GMBH*, No. 1:16-cv260, ECF No. 79. (W.D. Pa. Oct. 23, 2017). Regardless of whether certification of a medical monitoring class may be difficult, Allergan has not shown it is impermissible under any set of facts. The fact that Allergan speculates as to possibilities instead of presenting evidence, again shows why this argument is premature. Discovery will illuminate the appropriateness of a medical monitoring class, and any determination should await class certification and be decided on a factual record rather than upon speculation.

#### **VI. Allergan’s Arguments Regarding Medical Monitoring Relief Should Be Rejected**

In its Motion to Dismiss Plaintiffs’ Master Personal Injury Complaint Pursuant to Fed. R. Civ. P. 8(a), 9(b), and 12(b)(6), Allergan argues that “personal injury claims brought by Plaintiffs without an ALCL diagnosis must be dismissed.” ECF No. 171-3 at 5. Allergan mischaracterizes the plaintiffs’ claims as “‘increased risk’ or ‘fear of’ claims unaccompanied by physical injury” and argues that requests for “medical monitoring relief” should be dismissed. *Id.* at 6. Allergan attached an Appendix of case law to support its position. Defs.’ Appendix, ECF No. 171-4.

Plaintiffs respond here to Allergan’s contention that women without a BIA-ALCL diagnosis have no viable legal claims, because Allergan is just wrong. To be clear, however, Allergan did not move to dismiss *any* causes of action pleaded in the CAC under Rule 12, and thus waived the right to do so, and this section should not be construed such that any challenge to such claims is ripe or appropriate given the lack of a pending motion. As described below, however, in all instances, Allergan’s challenges to the availability of medical monitoring relief fail.<sup>13</sup> All of the

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<sup>13</sup> The Personal Injury Plaintiffs responded to Allergan’s motion including by clarifying that they do not seek “medical monitoring” as a cause of action, but simply seek run-of-the-mill future medical expenses associated with their personal injury claims, which is different than the medical monitoring program sought in the CAC on a classwide basis.

Class Plaintiffs allege an increased risk of BIA-ALCL *and* physical harm sufficient to support their request for medical monitoring relief and their standalone medical monitoring causes of action.

**A. Courts Have Long Recognized Claims For Medical Monitoring Due To Exposure Even Without Manifestation Of The Ultimate Harm Sought To Be Avoided**

In 1984, the D.C. Circuit held that a plaintiff may recover for diagnostic medical examinations when a defendant’s tortious conduct has exposed a plaintiff to an increased risk of harm that proximately causes the need for comprehensive diagnostic examinations even without manifestation of the ultimate harm. *Friends for All Children, Inc., Lockheed Aircraft Corp.*, 746 F.2d 816 (D.C. Cir. 1984). This is “medical monitoring” as meant in the CAC. In its well-reasoned opinion, the court observed that the Restatement (Second) Torts, § 7, defines an “injury” as an “invasion of a legally protected interest,” noting:

[i]t is difficult to dispute that an individual has an interest in avoiding expensive diagnostic examinations just as he or she has an interest in avoiding physical injury. When a defendant negligently invades this interest, the injury to which is neither speculative nor resistant to proof, it is elementary that the defendant should make the plaintiff whole by paying for the examinations.

*Id.* at 826. In 1990, the Third Circuit recognized a medical monitoring cause of action under Pennsylvania law. *In re Paoli R. Yard PCB Litig.*, 915 F.2d 829 (3d Cir. 1990). As the Third Circuit explained, “medical monitoring claims acknowledge that, in a toxic age, significant harm can be done to an individual tortfeasor, notwithstanding latent manifestation of that harm.” *Id.* at 852. And the nature of the claim itself—which requires a plaintiff to provide sufficient evidence of both exposure and the need for monitoring—prevents courts from speculating about the “probability of future injury.” *Id.*

Many states now explicitly recognize tort claims for medical monitoring relief when a plaintiff states a significantly increased risk of harm. A few states require those plaintiffs to also

plead a physical manifestation of some sort, such as subcellular injury. And another collection of states recognizes medical monitoring as a stand-alone cause of action. Plaintiffs have plausibly stated requests for medical monitoring relief and/or causes of action for medical monitoring in each of these jurisdictions, as set forth in detail in the CAC.

Medical monitoring is different from an “enhanced risk” or “fear of cancer” claim, neither of which Plaintiffs allege here. As the Third Circuit explained, “an action for medical monitoring seeks to recover only the quantifiable costs of periodic medical examinations necessary to detect the onset of physical harm, whereas an enhanced risk claim seeks compensation for the anticipated harm itself, proportionately reduced to reflect the chance that it will not occur.” *In re Paoli R. Yard PCB Litig.*, 916 F.2d 829, 850 (3d Cir. 1990). In “fear of” cases, plaintiffs seek damages for emotional distress caused by their fear of contracting cancer (or any other disease). *See, e.g., Mauro v. Ryamark Indus. Inc.*, 116 N.J. 126 (1989); *Simmons v. Pacor, Inc.*, 543 Pa. 664 (1996). That is not this case. The Class Plaintiffs do not seek damages on a class basis in proportion to the relative risk of contracting BIA-ALCL or for emotional distress. Rather, the Class Plaintiffs are seeking, on a classwide basis, the costs of ongoing diagnostic monitoring and testing and the costs associated with removing the Recalled BIOCELL Implants.

Plaintiffs allege that Allergan’s defective Recalled BIOCELL Implants have caused a substantially increased risk of BIA-ALCL that requires diagnostic examination; subcellular and cellular injury; inflammation; and other physical manifestations. *See, e.g., CAC ¶¶ 405-406.* As reflected below, these allegations are sufficient to support Plaintiffs’ medical monitoring claims.

**B. Plaintiffs’ CAC Includes Plausible Claims For Medical Monitoring Relief**

- 1. Plaintiffs plead stand-alone causes of action for medical monitoring in the seven states that recognize medical monitoring as a cause of action.**

Some states have recognized medical monitoring as a stand-alone cause of action, and thus Plaintiffs properly plead causes of action for medical monitoring in Colorado, Florida, Massachusetts, Montana, Pennsylvania, Utah, and West Virginia. CAC, Counts 300-305. Allergan asserts that Plaintiffs have not alleged an injury under the relevant negligence-based state laws. *See* ECF 151-3 at 5-7; Defs.' Appendix at 20-25 (ECF 171-4). Yet in Colorado, Florida, Montana, Pennsylvania, Utah, and West Virginia, a plaintiff's increased risk of harm due to a defendant's tortious conduct, absent manifestation of the ultimate harm, is enough to support a stand-alone claim for medical monitoring. *See Bell v. 3M Co.*, 344 F. Supp. 3d 1207 (D. Colo. 2018); *Petito v. A.H. Robins Co., Inc.*, 750 So. 2d 103, 106-107 (Fla. Dist. Ct. App. 1999); *Lamping v. Am. Home Prod.*, 2000 Mont. Dist. LEXIS 2580, at \*1 (Mont. Dist. Ct. 2000); *Redland Soccer v. Dep't of Army*, 696 A. 2d 137, 195 (Pa. 1997); *Hansen v. Mountain Fuel Supply Co.*, 858 P. 2d 970 (Utah 1993); *Bower v. Westinghouse Elec. Corp.*, 206 W. Va. 133 (1999). In Massachusetts, a significantly increased risk of harm coupled with subcellular damage is sufficient to state a stand-alone medical monitoring claim. *Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215 (2009). Thus, Plaintiffs' allegations are sufficient.

**2. Plaintiffs plead plausible requests for tort-based medical monitoring relief in other specific jurisdictions because they allege an increased risk of harm that necessitates diagnostic examination.**

In Arizona, District of Columbia, Indiana, Missouri, Nevada, New Hampshire, and Ohio, courts have concluded that a plaintiff's increased risk of harm because of a defendant's tortious conduct and the concomitant need for diagnostic examination can support medical monitoring as a form of relief for an underlying tort claim. *See Burns v. Jaquays Mining Corp.*, 752 P.2d 28 (Ariz. Ct. App. 1987); *Cook v. Rockwell Int'l Corp.*, 755 F. Supp. 1468 (D. Colo. 1991); *Friends for All Children, Inc., v. Lockheed Aircraft Corp.*, 746 F.2d 816 (D.C. Cir. 1984); *Allgood v. GMC*,

No. 02-cv-1077, 2005 WL 2218371, at \*7-8 (S.D. Ind. Sept. 12, 2005); *Meyer v. Flyor Corp.*, 220 S.W. 3d 712 (Mo. 2007); *Sadler v. PacifiCare of Nev., Inc.*, 340 P. 3d 1264 (Nev. 2014); *Hermens v. Textiles Coated Inc.*, No. 216-2017-cv-524, slip. Op. at 9-12 (N.H. Super. Ct., Hillsborough Cnty. N. March 16, 2018) (discussed in *Brown v. St. Gobain Performance Plastics Corp.*, No. 16-cv-242, 2018 WL 10517306, at \*2-3 (D.N.H. Oct. 10, 2018)); *Elmer v. S.H. Bell Co.*, 127 F. Supp. 3d 812 (N.D. Ohio 2015); *Day v. NLO*, 851 F. Supp. 869 (S.D. Ohio 1994); *Wilson v. Brush Wellman, Inc.*, 103 Ohio St. 3d 538 (2004).

In its Motion to Dismiss (ECF 171-3) and Appendix, Allergan omits controlling case law or cites no relevant law at all for these states. As for Arizona, it cites *DeStories v. City of Phoenix*, 744 P. 2d 705, 711 (Ariz. App. 1987), solely for the proposition that to receive medical monitoring, Plaintiffs must show “the value of increased testing” over what would normally “have been prudent,” but overlooks that both *DeStories* and *Burns*, 752 P.2d 28—which it does not cite—recognize medical monitoring absent manifestation of the ultimate harm. *See* Defs.’ Appendix at 20. Allergan’s District of Columbia case, *Witherspoon v. Philip Morris, Inc.*, 964 F. Supp. 455, 467 (D.D.C. 1997), recognizes medical monitoring as a component of damages, and Allergan wholly disregards *Friends for All Children*, which recognized medical monitoring as a valid form of relief for an underlying tort. Defs.’ Appendix at 21. The Indiana cases cited by Allergan in its Appendix at 21, are similarly inapt. *See Adams v. Clean Air Sys., Inc.*, 586 N.E. 2d 940 (Ind. Ct. App. 1992) (granting summary judgment on plaintiffs’ request for medical monitoring and emotional distress damages because they merely alleged a “possibility” of asbestos exposure); *Pisciotta v. Old Nat’l Bancorp*, 499 F.3d 629 (7th Cir. 2007) (a data breach case in which the court notes that under Indiana law, “exposure [of data] alone does not give rise to a legally cognizable injury”; medical monitoring is not even addressed); *Johnson v. Abbott Labs.*, No. 06C01-0203-

PL-89, 2004 WL 3245947 (Ind. Cir. Dec. 31, 2004) (an Indiana trial court decision denying class certification to a class of Oxycontin users, failing to meaningfully analyze medical monitoring, and citing a case that predated and was addressed in the reasoned analysis of *Allgood*).

Allergan also omits controlling case law from the highest courts of Missouri, Nevada, and Ohio, all of which recognize medical monitoring as a remedy, absent present physical injury. *See supra; compare* Defs.’ Appendix at 22, 23. Instead, Allergan cites *Ratliff v. Mentor Corp.*, 596 F. Supp. 2d 926 (W.D. Mo. 2008), for the notion that Missouri’s medical monitoring remedy is limited to injuries that develop “as a result of exposure to toxic substances.” Defs.’ Appendix at 22. Even if this were an accurate statement of Missouri law – which is it not – Plaintiffs sufficiently allege that the Recalled BIOCELL Implants contain toxic and adulterated substances which cause their increased risk of BIA-ALCL. *See, e.g.*, CAC ¶ 453. Allergan provides no Nevada-related or Ohio-related medical monitoring law in its Appendix, and the law it does cite in the “increased risk” section of Appendix A is irrelevant. *See* Def. Appendix at 10, 12, 23. Finally, Allergan cites no New Hampshire law. *See* Appendix at 10, 23. For these reasons, Allergan’s challenges fail.

**3. Plaintiffs adequately plead requests for tort-based medical monitoring relief in five states because they allege subcellular damage, cellular damage, and physical accumulation of toxins.**

Courts in five states including Connecticut, Minnesota, New York, Rhode Island, and Vermont, allow a remedy for medical monitoring where there is subcellular damage, cellular damage, “bodily change,” or an accumulation of toxins, coupled with an increased risk of harm. In other words, these five states have concluded that the “actual injury” component of their state law tort actions is satisfied through evidence of physical effect, permitting recovery for medical monitoring. *See, e.g.*, *Goodall v. United Illuminating*, No. X04CV 950115437S, 1998 WL 914274, at \*4 (Conn. Super. Ct. Dec. 15, 1998) (detrimental conditions); *Martin v. Shell*, 180 F. Supp. 2d

313 (D. Conn. 2002) (“various health problems” and symptoms); *Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215 (2009) (physiological changes); *In re NHL Players’ Concussion Injury Litig.*, 327 F.R.D. 245, 264 (D. Minn. 2018) (cell damage); *Benoit v. Saint-Gobain Performances Plastics Corp.*, 959 F.3d 491 (2d Cir. 2020) (accumulation of toxins); *Miranda v. DaCruz*, No. 04-2210, 2009 R.I. Super LEXIS 129 (Super. Ct. R.I. Oct. 26, 2009) (subcellular change); *Sullivan v. Saint-Gobain Performance Plastics Corp.*, 431 F. Supp. 3d 448 (D. Vt. 2019) (presence or accumulation of toxin).

Plaintiffs sufficiently allege that the Recalled BIOCELL Implants have caused subcellular and cellular changes, inflammation, and the accumulation of toxic and adulterated materials within Plaintiffs’ bodies. *See, e.g.*, CAC ¶¶ 5319-5320; 767-768; 799-780; 925-926; 1069-1070; 1194-1195. Thus, Plaintiffs have plausibly stated requests for tort-based medical monitoring relief in Connecticut, Minnesota, New York, Rhode Island, and Vermont.

Allergan’s cited authority stands for the unremarkable proposition that, for these states, an increased risk of harm, without more, cannot support a request for medical monitoring. But Plaintiffs have pleaded an increased risk of harm *coupled with physical manifestations and effects* such as subcellular damage, inflammation, and malignant T-cell transformation. *See, e.g., McCullough v. World Wrestling Ent., Inc.*, 172 F. Supp. 3d. 528 (D. Conn. 2016) (an increased risk of harm may be an actionable injury for negligence, but plaintiffs’ claim failed for other reasons; plaintiffs cited no authority supporting the adoption of an independent medical monitoring cause of action); *Poce v. O & G Indus., Inc.*, No. HHDCV176074254S, 2017 Conn. Super. LEXIS 5019 (Conn. Super. Ct. Dec. 5, 2017) (“some physical component of injury” may be enough to constitute “actionable injury,” but plaintiffs did not allege *any* physical manifestation of injury); *Dougan v. Sikorsky Aircraft Corp.*, No. X03-HHD-CV12-6033069, 2017 Conn. Super. LEXIS



5207, at \*18 (Conn. Super. March 28, 2017) (plaintiffs’ allegation of an increased risk of harm and undetectable, pre-clinical disease is not sufficient to state an injury, but symptoms related to exposure would be); *In re NHL Players’ Concussion Injury Litig.*, 327 F.R.D. 245 (D. Minn. 2018) (post-dating Allergan’s cited cases and concluding that “cell damage” constitutes an injury sufficient to support a medical monitoring request)<sup>14</sup>; *Kelley v. Cowesett Hills Assocs.*, 768 A.2d 425, 430, n. 9 (R.I. 2001) (a “cancer phobia” case in which the plaintiff alleged the *potential* for cancer but pleaded no symptoms or other physical manifestation, and thus did not state an actionable injury). Compare Defs.’ Appendix at 20, 22, 24. Allergan cites no relevant law for New York or Vermont. See Defs.’ Appendix at 23, 25.

In sum, Allergan’s challenges to Plaintiffs’ medical monitoring claims are without merit.

### **CONCLUSION**

Allergan’s motion to strike the class allegations is scattershot, speculative, and premature. Plaintiffs should be afforded the opportunity to conduct discovery before class certification is briefed and decided on a full record. Based upon the foregoing, Allergan’s motion to strike should be denied. Further, any challenge at this stage to Plaintiffs’ well-pleaded claims for a medical monitoring program are without merit.

Dated: October 9, 2020

Respectfully Submitted,

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<sup>14</sup> *In re NHL Players’ Concussion Injury Litig.* further analyzes *Thompson v. Am. Tobacco Co.*, 189 F.R.D. 544 (D. Minn. 1999), one of Allergan’s cited cases, concluding it does not hold differently. Allergan also cites *Palmer*, in which the court recognized that subcellular injury and/or accumulation of toxins could state an injury. *Palmer v. 3M Co.*, No. C2-04-6309, 2009 Minn. Dist. LEXIS 362 (Minn. Dist. Ct. March 13, 2009).

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