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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** **NOTICE OF MOTION TO DISMISS PLAINTIFFS' COMPLAINT** **ORAL ARGUMENT REQUESTED**

THIS DOCUMENT RELATES TO:
ALL CASES

PLEASE TAKE NOTICE that, as counsel may be heard on a date and time to be set by the Court, the undersigned attorneys for Defendants Allergan, Inc. and Allergan USA, Inc., (together, "Allergan") and specially appearing defendants Allergan Limited f/k/a Allergan plc and AbbVie Inc. (collectively, "Defendants") will move before the United States District Court for the District of New Jersey,

Frank R. Lautenberg Post Office and U.S. Courthouse, 1 Federal Square, 50 Walnut Street, Newark, New Jersey 07102 for an Order dismissing (A) Plaintiffs' Consolidated Class Action Complaint [D.E. 118] and every other class action complaint filed in a lawsuit that is part of this MDL, and (B) Plaintiffs' Master Long Form Complaint for Personal Injuries [D.E. 119] and every other complaint filed in a lawsuit that is part of this MDL and alleges personal injury damages, as follows:

(1) Dismissing all of the Plaintiffs' complaints with prejudice, pursuant to Fed. R. Civ. P. 12(b)(6), because all such claims are expressly preempted by federal law as reflected in the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a), and also barred by the FDCA's prohibition on private rights of action, 21 U.S.C. § 337(a), and implied preemption;

(2) Striking Plaintiffs' class allegations and dismissing with prejudice Plaintiffs' Consolidated Class Action Complaint [D.E. 118] and every other class action complaint filed in a lawsuit that is part of this MDL, pursuant to Fed. R. Civ. P. 12(f) and/or 12(b)(6); and

(3) Dismissing Plaintiffs' Master Long Form Complaint for Personal Injuries [D.E. 119] and every other complaint filed in a lawsuit that is part of this MDL and alleges personal injury damages with prejudice, for failure to state a claim, pursuant to Rules 8(a), 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure.

PLEASE TAKE FURTHER NOTICE that in support of this Motion, Defendants will rely upon the accompanying: (1) Memorandum of Law in support of Defendants' Motion to Dismiss on Preemption Grounds; (2) Memorandum of Law in support of Defendants' Motion to Strike/Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint; (3) Memorandum of Law in support of 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), with Appendix A thereto; (4) Declaration of Melissa A. Geist, Esq. in Support of Defendants' Motion to Dismiss, with exhibits thereto; and (5) Request for Judicial Notice, submitted herewith.

PLEASE TAKE FURTHER NOTICE that oral argument is respectfully requested.

Dated: August 7, 2020

Respectfully submitted,
REED SMITH LLP

By: */s/ Melissa A. Geist*
Melissa A. Geist

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	**Case No. 2:19-md-02921(BRM)(JAD)** **MDL No. 2921** **JUDGE BRIAN R. MARTINOTTI** **JUDGE JOSEPH A. DICKSON**

THIS DOCUMENT RELATES TO: ALL CASES

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' MASTER PERSONAL INJURY COMPLAINT AND CONSOLIDATED CLASS ACTION COMPLAINT ON PREEMPTION GROUNDS

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I. INTRODUCTION

In this MDL proceeding, Plaintiffs' Master Complaints allege that Allergan's breast implant devices are defectively designed and manufactured because they either caused them to develop, or placed them at increased risk of developing, anaplastic large cell lymphoma ("ALCL").[1] Plaintiffs also contend that Allergan knew of this risk but failed to adequately warn of it or downplayed the risk in its reporting to FDA. All of this, in turn, allegedly violates FDA regulations and breaches duties of care under state product liability or tort law. Here, however, Plaintiffs' frontal attack on the design, manufacture and labelling of these devices, as well as Allergan's post-marketing reporting, runs squarely into federal preemption principles established by settled law. Dismissal of these claims therefore is called for and respectfully requested.

Allergan's breast implants are Class III Medical devices subject to FDA's highest level of scrutiny under the FDA's Pre-Market Approval ("PMA") process. Before selling any Class III device, manufacturers, like Allergan, must establish that their device is safe and effective for its intended use. This is not a perfunctory exercise. The scrutiny FDA applies is comprehensive, rigorous, and continuous. FDA looks at every aspect of design, manufacture, and labelling before a device is marketed. This same rigorous oversight extends post-approval, including with respect to adverse event reporting on a device's use after sale. Moreover, before,

[1] ALCL is a type of non-Hodgkin lymphoma, classified as a "rare cancer" by the National Institutes of Health. "Anaplastic large cell lymphoma," available at < https://rarediseases.info.nih.gov/diseases/3112/anaplastic-large-cell-lymphoma >.

during and after sale, manufacturers are not permitted to deviate from what FDA's regulations require. If they do, they face corrective measures, including fines and civil penalties as specifically set forth in the controlling regulatory scheme.

To protect the efficacy and vitality of FDA's regulation and oversight over medical devices, Congress enacted an express preemption provision that forecloses state interference with the regulatory process. The provision specifically provides that: "[N]o State may establish or continue in effect" any laws or regulations that are "different from, or in addition to, any requirement" applicable to medical devices under the federal scheme. 21 U.S.C. §360k(a). And to further ensure that no such interference occurs, Congress also prohibits private enforcement of the implementing statutes and regulations and instead required all "proceedings for the enforcement, or to restrain violations" to be brought by the United States. 21 U.S.C. §337(a).

As case after case has held, in their combined effect, these two statutory provisions expressly or impliedly preempt virtually all state law product liability and tort claims, including those that Plaintiffs advance in this MDL. In fact, with respect to breast implant devices specifically, courts have routinely applied these preemptive principles to dismiss claims similar to the ones Plaintiffs are making. The same result should follow here.

In a handful of instances, certain state law claims have survived a preemption defense where there is no demonstrable conflict with the regulatory scheme. For example, if the record shows that a device, as manufactured, deviates from its FDA-approved design, a manufacturing defect claim can be made when permitted under

state law. Other state law claims based on duties imposed by federal regulations are possible, but only if an established state law duty parallels what federal regulations require. Alleged non-compliance with federal regulations alone will not do it—no private plaintiff can bring such a claim, only the federal government. Nor will a breach allegedly founded on an alteration or change in what federal regulations otherwise require—any such allegations impermissibly command something different than what federal law requires.

As these preemptive principles illustrate, the gap left for state law claims over FDA-approved and -cleared medical devices is a narrow one and Plaintiffs' claims, as alleged, do not fit through it. Plaintiffs do not allege that Allegan's devices deviated from their intended design. And there is no established state law that supports the breaches of duty they do allege—whether related to Allergan's devices' design, manufacture, labelling, or its reporting post-sale. On the contrary, Plaintiffs' state law product liability and tort claims improperly challenge the FDA-approved design, manufacture, and labelling and reporting related to Allergan's medical devices. And they just as impermissibly allege breaches of duties founded exclusively on federal regulations with no counterpart duties reflected in state law. Express and implied preemption principles unequivocally bar such claims. There is no relevant case law holding otherwise.

For the reasons set forth more fully below, this Court should grant Allergan's motion and dismiss all claims related to Allergan devices that were subject to the

PMA process.[2] *See, e.g.*, *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) ("*Sprint Fidelis II*") (affirming grant of motion to dismiss disposing of all product liability claims in MDL involving PMA medical device).

II. STANDARD OF REVIEW

For this motion, the Court accepts as true all "well-pleaded factual allegations and matters subject to judicial notice, but it "need not credit a complaint's bald assertions or legal conclusions." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1429 (3d Cir. 1997). Courts also do not accept allegations "contradicted by exhibits attached to the complaint or matters subject to judicial notice." *Gupta v. Wipro Ltd.*, 749 F. App'x 94, 97 (3d Cir. 2018); *see Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 319 (D.N.J. 2014) (on a motion to dismiss, court "may consider … items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case"). Official FDA documents on the FDA's website may be judicially noticed. *See Spizzirri v. Zyla Life Scis.*, 802 F. App'x 738, 739 (3d Cir. 2020); *In re Avandia Mktg. Sales Practices & Prod. Liab. Litig.*, 588 F. App'x 171, 174 n.14 (3d Cir. 2014); *see also Vanderklok v. United States*, 868 F.3d

[2] The order of dismissal should extend to all claims related to devices that received FDA approval through the PMA process, and also devices that (1) FDA reclassified to PMA status, or (2) were the subject of research during the PMA process under the Investigational Device Exception ("IDE"), but never approved. Once the preempted claims are dismissed, the only non-preempted claims alleged concern: (1) non-PMA tissue expanders that were only used for a limited number of indications, and then for only short periods of time, and (2) possibly a few pre-PMA RTV® implants, if any plaintiff was actually implanted with such a device.

189, 205 n.16 (3d Cir. 2017) (the "information is publicly available on government websites and therefore we take judicial notice").

III. STATEMENT OF THE CASE

A. The FDA Comprehensively Regulates All Aspects Of Class III And Class II Medical Devices Before, During, And After Approval

This motion to dismiss rests on the FDA's regulatory process governing Class III and Class II medical devices. That process is reflected in a comprehensive and detailed set of statutes and regulations that are intended, by Congressional mandate, to regulate every aspect of medical device manufacture and marketing in order to maintain the safety and efficacy of the regulated devices, free of state law interference.[3]

For many years, medical devices were designed, manufactured, marketed, and sold without extensive federal regulatory oversight. By 1976, policymakers and the public had become concerned about the lack of federal control because, by that time, "many devices [we]re so intricate that skilled healthcare professionals [we]re unable to ascertain whether they [we]re defective" and "[i]ncreasing numbers of patients [were] exposed to increasingly complex devices which pose serious risk if inadequately tested or improperly designed or used." S. Rep. No. 94-33, at 2 (1975).

In response, Congress enacted the Medical Device Amendments ("MDA") to the existing Food, Drug, and Cosmetic Act ("FDCA"), which gave FDA authority to ensure that all medical devices were safe and effective before entering the

[3] The history and effect of this regulatory effort are chronicled in the many preemption cases cited in this motion.

marketplace. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996) ("*Lohr*") (citing 90 Stat. 539); S. Rep. No. 94-33, at 1. The MDA was, and is, intended to strike a careful balance between "the benefits that medical research and experimentation to develop devices offers to mankind" and "the need for regulation to assure that the public is protected and that health professionals can have more confidence in the performance of devices." S. Rep. No. 94-33, at 6.

To achieve the requisite balance, the MDA established three categories of medical devices, identified respectively as Class I, II, or III, "depending on the risks they present." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Class I devices present the lowest risk and are subject to the least intensive regulation. Class II devices pose intermediate risk (CT scanners, blood tests and prosthetic devices) and are subject to greater general and specific regulatory controls. Before a manufacturer can market Class II medical devices, FDA must clear them through the Section 510(k) process. *See* 21 U.S.C. §360(k). Class II devices cannot be cleared through that process unless they are found to be safe and effective under established regulatory requirements. *See* 21 U.S.C. §360c(a)(1)(B); 21 C.F.R. §807.87.

Class III devices receive the most scrutiny. Because Class III devices are "of substantial importance in preventing impairment to human health," but also pose "unreasonable risk of illness or injury," they are subject to the strictest controls. 21 U.S.C. §360c(a)(1)(C). Before marketing a Class III medical device, the manufacturer must submit a PMA application that FDA can grant "only after it determines that a device offers a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323 (citing 21 U.S.C. §360e(d)).

PMA applications are exhaustive. They must include "full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 109 (2d Cir. 2006) ("*Riegel II*"), *aff'd*, 552 U.S. 312 (2008); *see also* 21 C.F.R. §814.20(b) (specifying PMA application requirements). "Before deciding whether to approve the application, the [FDA] may refer it to a panel of outside experts [citation], and may request additional data from the manufacturer." *Riegel*, 552 U.S. at 318. "FDA spends an average of 1,200 hours reviewing each application" and "must 'weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Id.* (quoting 21 U.S.C. §360c(a)(2)(C)).

As part of its review, FDA can condition approval on adherence to performance standards and impose restrictions on sale or distribution, or compliance with other requirements. It can also impose device-specific requirements by regulation. *Id.* at 319 (citing 21 U.S.C. §§360e(d), 360j(e)(1); 21 C.F.R. §§814.82, 861.1(b)(3)). These conditions are mandatory and exacting. An approved Class III device "may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. §814.80. To that end, manufacturers who wish to change any safety-related aspect of an approved Class

III device (such as its design, warnings, or manufacturing process) must submit a supplemental application to FDA in most instances, unless FDA instructs otherwise. *See* 21 C.F.R. §814.39.

After approval, FDA retains plenary authority to take any additional measures it believes necessary with respect to Class III devices on the market. *See* 21 C.F.R. §360h. These measures include: (1) sending notice to health care professionals, manufacturers, and other affected parties; (2) requiring manufacturers to repair, replace, or refund; or (3) instituting a recall of the device. *See id*. In short, where a medical device "is a PMA device, the FDA continues to monitor and regulate all aspects of the product, including its marketing, labeling and manufacturing." *Cornett v. Johnson & Johnson*, 211 N.J. 362, 378-79, 48 A.3d 1041 (2012) ("*Cornett II*").

As for the continuing regulatory obligations, once a Class III device is on the market, the manufacturer must report about new published or unpublished device-related scientific reports. *See* 21 C.F.R. §814.84(b). It also must report any information that its device "may have caused or contributed to a death or serious injury," or "[h]as malfunctioned and this device or a similar device that [it] market[s] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. §803.50(a). To comply with these adverse event reporting requirements, the manufacturer is "responsible for conducting an investigation of each event and evaluating the cause of the event." *Id*. §803.50(b)(3).

As noted, Congress intended this regulatory process—before and after approval—to operate free from state interference. To help ensure the exclusivity

and effectiveness of federal oversight, the controlling statutes include an express preemption provision, mandating that: "[N]o State may establish or continue in effect" any laws or regulations that are "different from, or in addition to, any requirement" applicable to medical devices under the federal scheme. 21 U.S.C. §360k(a). By enacting this provision, Congress "swept back some state obligations and imposed a regime of detailed federal oversight," enforced by an expert federal agency rather than private plaintiffs and lay juries. *Riegel*, 552 U.S. at 316.

To further preserve the primacy of the FDA's regulatory authority, however, Congress went a step further. That is, the statutory scheme also expressly prohibits private enforcement. Apart from certain lawsuits that states may initiate, "all such proceedings for the enforcement, or to restrain violations … shall be by and in the name of the United States." 21 U.S.C. §337(a). Congress thus has given FDA "a variety of enforcement options that allow it to make a measured response" to any wrongdoing, including "injunctive relief, 21 U.S.C. §332, and civil penalties, 21 U.S.C. §333(f)(1)(A); seizing the device, §334(a)(2)(D); and pursuing criminal prosecutions, §333(a)." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001).

Congress likewise granted FDA "complete discretion" in deciding "how and when [these enforcement tools] should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). Indeed, "[t]his flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Buckman*, 531 U.S. at 349. Accordingly, any attempt by a private plaintiff to sue over a claimed violation of the duties imposed by the federal

regulatory scheme is impliedly preempted by this no private right of action provision. *Id.* at 352-53.

B. FDA Approved Allergan's Class III Breast Implants And Cleared Allergan's Class II Tissue Expanders For Safety And Efficacy, And Continued To Regulate Them After Approval And Clearance

Plaintiffs allege that they developed ALCL, or have a significantly increased risk of developing ALCL, from exposure to Allergan's BIOCELL® breast implants.[4] (Consolidated Class Action Complaint ("CAC") ¶1; Master Long-Form Personal Injury Complaint ("PIC") ¶¶6, 8.) Breast implants generally are used to replace surgically removed breast tissue, to correct developmental defects, or to modify breast size and shape. (CAC ¶99.) They are filled with either saline or silicone gel. (CAC ¶100; PIC ¶5). As designed, Allergan's BIOCELL® breast implants have a textured surface, which is intended to prevent surgical complications after implantation. (CAC ¶1; PIC ¶3.)

FDA oversight of breast implants is decades old. In 1988, FDA reclassified breast implants as Class III devices (PIC ¶48), but required §510(k) clearance, not PMA approval. 53 Fed. Reg. 23856, 23862 (1988). Three years later, in April 1991, FDA declared that all silicone gel-filled breast implants would be subject to PMA approval. Eight years after that, in August 1999, it made the same determination for

[4] Allergan acquired some of the breast implant device lines involved in this litigation from predecessor manufacturers. To avoid confusion, and unless otherwise required, we will use "Allergan" to refer to these manufacturers as well.

saline-filled breast implants. (CAC ¶31; PIC ¶51; *see also* FDA's "Breast Implants—An Information Update—2000"[5].)

In the Master Complaints, Plaintiffs allege exposure to multiple breast implant devices and product lines. The relevant regulatory history is as follows:

- ***Allergan Natrelle® Saline-Filled Breast Implants approved under P990074.*** (CAC ¶2 n.1; PIC ¶41.)

  Allergan submitted a PMA application for this line in November 1999. In May 2000, FDA approved same for use in breast reconstruction procedures in women over 18 years old. (RJN at p. 1; Geist Decl. Exh. 1.) Among its post-approval requirements, FDA required Allergan to conduct and report on certain post-approval studies regarding performance, failure modes, patients' informed decision making, and mechanical testing. (RJN at p. 1; Geist Decl. Exh. 1 (Approval Order).) Allergan submitted forty-four supplemental PMA applications in connection with this device line, with the most recent one approved on July 30, 2020. (RJN at p. 1; Geist Decl. Exh. 2.) This PMA is still in effect.

- ***Allergan Natrelle® Silicone-Filled Textured Breast Implants approved under P020056***. (CAC ¶2 n.1; PIC ¶41.)

  Allergan submitted a PMA application for this line in December 2002. In November 2006, FDA approved same for use in: (1) breast augmentation for women over 22 years old; and (2) breast reconstruction for women of any age. Among its post-approval requirements, FDA required: (1) physicians using the device to complete Allergan's training program; and (2) Allergan to conduct and report on post-approval studies regarding long-term clinical performance, complications and disease, device failure, labeling, and patients' informed decisionmaking (RJN at p. 1; Geist Decl. Exh. 3 (Approval Letter).) Allergan submitted fifty-one supplemental PMA applications in connection with this device line, with the most recent

[5] Available at https://web.archive.org/web/20010915235609/http://www.fda.gov/cdrh/breastimplants/indexbip.PDF (last visited August 6, 2000).

one approved on July 30, 2020. (RJN at p. 1; Geist Decl. Exh. 4.) This PMA is still in effect.

- ***Natrelle®410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants approved under P040046.*** (CAC ¶2 n.1; PIC ¶41.)

  Allergan submitted a PMA application for this line in December 2004. In February 2013, FDA approved same for use in: (1) breast augmentation for women over 22 years old; and (2) breast reconstruction for women of any age. In addition to the standard post-approval requirements, FDA further required Allergan to submit reports from post-approval studies regarding safety and efficacy, long-term clinical performance, rare disease outcomes, labeling, and explant analyses, along with a PMA Core Study that Allergan already had completed. (RJN at p. 2; Geist Decl. Exh. 5 (Approval Letter).) Allergan submitted thirty-two supplemental PMA applications in connection with this device line, with the most recent one approved on July 30, 2020. (RJN at p. 2; Geist Decl. Exh. 6.) This PMA is still in effect.

- ***McGhan BioDIMENSIONAL® Silicone-Filled BIOCELL® Textured Breast Implant, Style 153***. (CAC ¶2 n.1; PIC ¶41.)

  From 1998 to 2006, Allergan's BIOCELL® silicone breast implant line received an Investigative Device Exemption ("IDE"). (CAC ¶115; PIC ¶5 n.3.) An IDE allows a device to be used in strictly regulated clinical trials to collect safety and efficacy data from human test subjects for purposes of obtaining PMA approval or 510(k) clearance. *See* 21 U.S.C. §360j(g). All Style 153 implants were implanted as part of these FDA-regulated clinical trials. (RJN at p. 2; Geist Decl. Exh. 7.) Following the study results, Style 153 implants were discontinued in 2005, FDA approval was not sought, and Style 153 implants were never marketed. (PIC ¶99 n.31; *see* https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer.)

- ***McGhan RTV® Saline-Filled Mammary Implant (implanted before PMA Approval of Allergan Natrelle® Saline-Filled Textured Breast Implant).*** (CAC ¶326.)

In the mid-1980s, these devices were the subject of a Premarket Notification for which FDA granted Section 510(k) clearance. (RJN at p. 2; Geist Decl. Exh. 8; CAC ¶115.) After FDA required saline breast implants to receive PMA approval in 1999, FDA approved the PMA application for these saline implants in May 2000 (RJN at p. 2 n.2; Geist Decl. Exhs. 1-2; CAC ¶118; PIC ¶58).

Plaintiffs also allege exposure to Allergan's BIOCELL® line of tissue expanders. (CAC ¶99; PIC ¶4 n.2.) FDA regulates breast tissue expanders as Class II medical devices. (CAC ¶135.) Tissue expanders are temporary inflatable implants that stretch skin and muscle to create space for breast implants. (CAC ¶99; PIC ¶4.) Allergan's BIOCELL® tissue expanders, like the breast implants in this line, also have a textured surface. (CAC ¶99; PIC ¶4.) Identification of these expanders and their regulatory history is as follows:

- ***Natrelle® 133 Plus Tissue Expander With Suture Tabs***. (CAC ¶¶2 n.1, 326; PIC ¶41.)

  In September 2010, Allergan submitted a Section 510(k) notification for this device, seeking clearance as substantially equivalent to a predicate tissue expander currently on the market. (PIC ¶41 n.19.) In January 2011, FDA cleared it as a Class II device. (PIC ¶52.) FDA reminded Allergan of its ongoing regulatory requirements regarding product registration, labeling, adverse event reporting, good manufacturing practices and quality control systems. (RJN at p. 3; Geist Decl. Exh. 9 (Clearance Letter).)

- ***Natrelle® 133 Plus Tissue Expander***. (CAC ¶¶2 n.1, 326.)

  In July 2015, Allergan submitted a Section 510(k) notification for this device, seeking clearance as substantially equivalent to a predicate tissue expander currently on the market. In August 2015, FDA cleared as a Class II device. (PIC ¶52.) FDA also reminded Allergan of its ongoing regulatory requirements regarding product registration, labeling, adverse event reporting, good manufacturing practices and

quality control systems. (RJN at p. 3; Geist Decl. Exh. 10 (Clearance Letter).)

C. Plaintiffs' Personal Injury And Medical Monitoring Lawsuits Challenge The Design, Manufacture, Labelling, And Post-Sale Reporting For Allergan's Breast Implants And Tissue Expanders

In July 2019, pursuant to an FDA request, Allergan voluntarily recalled various BIOCELL® breast implants and tissue expanders. (CAC ¶191; PIC ¶39.) Litigation followed, resulting in this MDL proceeding. Both Master Complaints allege that Plaintiffs and the putative class were implanted with Allergan's devices and they advance various liability theories that divide into three broad categories:

First, Plaintiffs allege that Allergan concealed the risks of contracting ALCL by failing to comply with various regulatory requirements related to its adverse event reporting, promotional materials, and labelling information. According to Plaintiffs, by 2006, Allergan possessed information and evidence regarding the risks of ALCL, but did not submit timely or adequate adverse event reports to FDA, manipulated data under FDA's "Alternative Summary Report" ("ASR") program, and did not report adverse events risks from the post-approval studies required by FDA. (CAC ¶¶201-220; PIC ¶¶87-95.) Plaintiffs further allege that Allergan downplayed the risk of ALCL in its promotional materials (CAC ¶¶221-26; PIC ¶¶96-105) and failed to revise its product labeling with information regarding ALCL (CAC ¶¶255-265; PIC ¶¶73, 100, 115). These acts purportedly amounted to a "failure to comply" with FDA's "post-approval requirements." (CAC ¶¶262; PIC ¶¶72-73.)

Second, Plaintiffs allege that Allergan's manufacturing process was defective, "result[ing] in an adulterated product." (CAC ¶190; PIC ¶114.) In manufacturing

its breast implants, Allergan utilized a "salt loss" manufacturing process, during which salt particles were embedded into the surface of the implant shell and covered with a layer of silicone. (CAC ¶13; PIC ¶117.) The outer silicone layer was manually scrubbed, and the entire implant shell was washed to remove solid particles. (CAC ¶13; PIC ¶117.) This process allegedly resulted in a textured implant shell intended to prevent growth of excess collagen and fibrous tissue, which in turn kept the implant from hardening and constricting (a condition called capsular contracture). (CAC ¶¶165-68; PIC ¶99.)

Plaintiffs maintain, however, that Allergan's manual scrubbing process—which FDA approved as part of the PMA applications—caused solid particles and residue to remain embedded in the implant shell. (CAC ¶169; PIC ¶¶117-18.) They further assert that the textured surface, combined with the remaining particles and residue, caused an inflammatory response that can ultimately lead to ALCL. (CAC ¶170; PIC ¶¶118-19.) Plaintiffs then allege that this manufacturing process violates various FDA regulations. (CAC ¶¶171-88; PIC ¶119.)

Third, Plaintiffs further claim that Allergan did not satisfy FDA's Current Good Manufacturing Practices ("CGMP"), which require manufacturers to "develop control, and monitor production processes to ensure that a device conforms to its specifications." (CAC ¶176 (citing 21 C.F.R. §820.70).) As described in the Master Complaints, this includes FDA requirements for production process changes, environmental controls, contamination controls, equipment, manufacturing material, automated processes, equipment inspection and testing, manufacturing process

validation, and for implementing corrective action. (CAC ¶¶177-78 (citing 21 C.F.R. §820.70, *et seq.*; CAC ¶180 (citing 21 C.F.R. §820.100).)

Based on these allegations, Plaintiffs advance state law claims for: (1) failure to warn (strict liability and negligence); (2) manufacturing defect (strict liability and negligence); (3) design defect (strict liability and negligence); (4) breach of implied warranty; (5) violations of consumer fraud and deceptive practice statutes; (6) unjust enrichment; (7) declaratory relief; and (8) rescission. A small number of the personal injury Plaintiffs allegedly have developed ALCL. As for the putative class representatives or putative class members who have not, they seek classwide relief in the form of medical monitoring. (CAC ¶269.)

IV. LEGAL ARGUMENT

A. Federal Preemption Principles Foreclose Virtually All State Law Product Liability And Tort Claims Relating To The Design, Manufacture, Labelling And Reporting For FDA Approved And Cleared Medical Devices

Plaintiffs' claims are aimed directly at the FDA's regulatory oversight and, ultimately, at the requirements governing the manufacture, design, distribution, and reporting for Allergan's Class III PMA-approved and Class II cleared breast implants and breast tissue extenders. As a result, Plaintiffs' claims trigger principles of express and implied preemption established by federal law. These preemption principles leave only a narrow gap for state law product liability or tort claims. Plaintiffs' claims, purporting to invoke the law of all 50 states and 6 U.S. territories, do not fit through.

Express preemption. In *Riegel*, the Supreme Court affirmed that federal law expressly preempts state law claims challenging the safety or performance of Class III PMA-approved devices. *See* 552 U.S. at 312. To ensure "innovations in medical device technology are not stifled by unnecessary restrictions," and to prevent "undu[e] burden[]" on device manufacturers from "differing requirements ... imposed by jurisdictions other than the Federal government," Congress adopted §360k(a) as a "general prohibition on non-Federal regulation." *Riegel II*, 451 F.3d at 122 (*quoting* H.R. Rep. No. 94-853, at 12, 45 (1976)). Absent this express prohibition, "additional state duties on top of those imposed by federal law … might check innovation, postpone access to life-saving devices, and impose barriers to entry without sufficient offsetting safety gains." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1346 (10th Cir. 2015) (Gorsuch, J.).

In its reasoning and holding, *Riegel* sets forth a two-step express preemption analysis. In the first step, a court must determine whether "the Federal Government has established requirements applicable to" the medical device. *Riegel*, 552 U.S. at 321-22 (citations and quotation marks omitted). In the second, a court then must determine whether a plaintiff's state-law tort claims would impose "requirements with respect to the device that are different from, or in addition to" the federal requirements. *Id.*

Class III devices, like Allergan's breast implants, satisfy *Riegel*'s first step as a matter of law. *Id.* at 322. As the Third Circuit held: "[B]ecause a manufacturer of a Class III device must receive premarket approval, clear federal safety review ..., and thereby satisfy federal requirements applicable to the device, the manufacturer

of that Class III device receives express preemption protection[].” *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 767 (3d Cir. 2018).

As for *Riegel*’s second step, federal law expressly preempts all state law causes of action that impose safety or effectiveness requirements that are “different from, or in addition to’ the requirements FDA imposed through the PMA process. *Riegel*, 552 U.S. at 322 (quoting §360k(a)). Product liability claims targeting the safety and effectiveness of a PMA medical device necessarily are preempted. *Id*. These include “strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the [PMA device].” *Id.* at 320; *see Shuker*, 885 F.3d at 774 (“negligence, strict liability, and breach of implied warranty claims” preempted; plaintiff allowed to discovery on off-label promotion).

“But state laws are not shut out entirely.” *Shuker*, 885 F.3d at 768. “State requirements are [expressly] pre-empted under the MDA only to the extent that they are ‘different from, or in addition to’ the requirements imposed by federal law.” *Riegel*, 552 U.S. at 330 (quoting §360k(a)(1)). Established state-law “duties [that] parallel federal requirements” avoid express preemption where they “duplicate[] the federal rule” and thus promote “compl[iance] with identical existing ‘requirements’ under federal law.” *Lohr*, 518 U.S. at 495.

Implied preemption. Implied preemption is the other half of the story. The rationale is straightforward. Under the FDCA enforcement of the statute is expressly left (except for certain state proceedings) to the United States. 21 U.S.C. §337(a). By enacting this no-private-right-of-action provision, Congress “le[ft] no doubt that

it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the" FDCA. *Buckman*, 531 U.S. at 349 n.4. Accordingly, any state-law "claim [that] would not exist if the FDCA did not exist," is impliedly preempted because such claims are "in substance (even if not in form) a claim for violating the FDCA." *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1214 (W.D. Okla. 2013), *aff'd*, 784 F.3d 1335 (10th Cir. 2015). And therein lies the conflict that gives rise to implied preemption. A private plaintiff's attempt to sue for a violation of the applicable federal regulations runs squarely into the statutory command that the FDCA is to be "enforced" exclusively by the federal government. *Buckman*, 531 U.S. at 352-53.

Express and implied preemption principles as applied. As this analysis portends, for state law product liability and tort claims to survive, they must fit in the narrow gap left by express preemption on the one hand, and implied preemption on the other. *Sprint Fidelis II*, 623 F.3d at 1204; *e.g.*, *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 492-93 (W.D. Pa. 2012). That is to say, the specific "conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted." *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). Or as one court recently explained, "[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by §360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such claim would be impliedly preempted under *Buckman*)."

Doe v. Bausch & Lomb, Inc., ___ F. Supp. 3d ___, 2020 WL 1164189, at *6 (D. Conn. March 11, 2020) (quoting *Sprint Fidelis II*, 623 F.3d 1200, 1204) (emphasis in *Sprint Fidelis II*, other citations omitted).

Under controlling case law, one thing is clear: it is exceedingly difficult to fit through the gap. Relying on these preemptive principles, federal courts—including the Third Circuit and this Court—have dismissed product liability and tort lawsuits involving Class III PMA-approved devices on preemption grounds in a variety of contexts and over an endless array of state law claims. *See, e.g.*, *Shuker*, 885 F.3d at 770-77 (affirming PMA preemption of all claims against PMA components of medical device system); *D'Addario v. Johnson & Johnson*, 2020 WL 3546750, at *4-5 (D.N.J. June 30, 2020) (dismissing ALCL breast implant claims as preempted); *Chester v. Boston Scientific Corp.*, 2017 WL 751424, at *6-12 (D.N.J. Feb. 27, 2017) (amended complaint dismissed with prejudice in action involving implantable defibrillator).[6]

Class III breast implant devices are no exception. Nor could they be. Since *Riegel*, twenty-two decisions have found actions advancing state law product

[6] *See Williams v. Cyberonics, Inc.*, 388 F. App'x 169, 171 (3d Cir. 2010); *Smith v. Depuy Orthopaedics, Inc.*, 552 F. App'x 192, 196 (3d Cir. 2014), *affirming*, 2013 WL 1108555, at *8-11 (D.N.J. March 18, 2013) ("*Smith II*"); *Horn v. Thoratec Corp.*, 376 F.3d 163, 169, 179-80 (3d Cir. 2004) (recognizing broad PMA preemption pre-*Riegel*); *Hart v. Medtronic, Inc.*, 2017 WL 5951698, at *4-6 (D.N.J. Nov. 30, 2017); *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 598-602 (D.N.J. 2015); *Morton v. Allergan, Inc.*, 2015 WL 12839493, at *4-5 (D.N.J. April 2, 2015); *Millman v. Medtronic, Inc.*, 2015 WL 778779, at *4-6 (D.N.J. Feb. 24, 2015); *Gomez v. Bayer, Corp.*, 2018 WL 10612946, at *2 (N.J. Super. L.D. Aug. 31, 2018) ("*Gomez I*"), *aff'd*, 2020 WL 215897 (N.J. Super. A.D. Jan. 14, 2020).

liability and tort claims involving breast implant devices preempted in their entirety. Creative efforts to plead around express and implied preemption have failed, one after the other. [7]

[7] *Weber v. Allergan, Inc.*, 940 F.3d 1106, 1111-14 (9th Cir. 2019), *affirming*, 2018 WL 9817168, at *2-3 (D. Ariz. Jan. 25, 2018); *Ebrahimi v. Mentor Worldwide LLC*, 804 F. App'x 871 (9th Cir. 2020), *affirming*, 2017 WL 4128976 (C.D. Cal. Sept. 15, 2017), 2018 WL 2448095 (C.D. Cal. May 25, 2018), and 2018 WL 6829122 (C.D. Cal. Dec. 27, 2018); *D'Addario*, 2020 WL 3546750, at *4-5; *Diodato v. Mentor Worldwide LLC*, 2020 WL 3402296, at *2-3 (D. Md. June 19, 2020); *Webb v. Mentor Worldwide LLC*, ___ F. Supp. 3d ___, 2020 WL 1685323, at *4-7 (N.D.N.Y. April 7, 2020); *Jacob v. Mentor Worldwide, LLC*, 393 F. Supp. 3d 912, 923-26 (C.D. Cal. 2019); *Vieira v. Mentor Worldwide, LLC*, 392 F. Supp. 3d 1117, 1128-32 (C.D. Cal. 2019) ("*Jacob Cal.*"); *Jacob v. Mentor Worldwide, LLC*, 389 F. Supp. 3d 1024, 1028-30 (M.D. Fla. 2019), *amended complaint dismissed*, 2019 WL 6766574, at *3 (M.D. Fla. Dec. 10, 2019) ("*Jacob Fla.*"); *Tinkler v. Mentor Worldwide, LLC*, 2019 WL 7291239, at *4-5 (S.D. Fla. Dec. 30, 2019); *Williams v. Mentor Worldwide LLC*, 2019 WL 4750843, at *4-6 (N.D. Ohio Sept. 30, 2019); *Brooks v. Mentor Worldwide, LLC*, 2019 WL 4628264, at *4-7 (D. Kan. Sept. 23, 2019), *appeal docketed*, No. 19-3240 (10th Cir. Oct. 24, 2019); *Sewell v. Mentor Worldwide, LLC*, 2019 WL 4038219, at *7-10 (C.D. Cal. Aug. 27, 2019); *Billetts v. Mentor Worldwide, LLC*, 2019 WL 4038218, at *7-9 (C.D. Cal. Aug. 27, 2019); *Stampley v. Allergan USA, Inc.*, 2019 WL 1604201, at *3 (W.D. La. March 15, 2019), *adopted*, 2019 WL 1601613 (W.D. La. April 15, 2019); *Shelp v. Allergan, Inc.*, 2018 WL 6694287, at *2 (W.D. Wash. Dec. 20, 2018); *Laux v. Mentor Worldwide, LLC*, 2017 WL 5186329, at *2-4 (C.D. Cal. Nov. 8, 2017), *aff'd*, 786 F. App'x 84 (9th Cir. 2019); *Ortiz v. Allergan, Inc.*, 2015 WL 5178402, at *4-5 (S.D.N.Y. Sept. 4, 2015); *Lindler v. Mentor Worldwide LLC*, 2014 WL 6390307, at *2 (D.S.C. Oct. 23, 2014); *Malonzo v. Mentor Worldwide, LLC*, 2014 WL 2212235, at *2-3 (N.D. Cal. May 28, 2014); *Couvillier v. Allergan, Inc.*, 2011 WL 8879258, at *1 (W.D. La. Jan. 20, 2011), *adopted*, 2011 WL 8879259 (W.D. La. Feb. 9, 2011); *Williams v. Allergan USA, Inc.*, 2009 WL 3294873, at *2-5 (D. Ariz. Oct. 14, 2009) (investigational implant); *Dorsey v. Allergan, Inc.*, 2009 WL 703290, at *5-7 (M.D. Tenn. March 11, 2009) (investigational implant); *Cashen v. Johnson & Johnson*, 2018 WL 6809093, at *7-11 (New Jersey Super. L.D. Dec. 24, 2018).

A synthesis of the reasoning and holdings in these cases reveals the working principles that are dispositive in Allergan's motion to dismiss. These principles are founded on *Riegel* and *Buckman*, they are the principles that make the gap so narrow, and they are the principles that spell the end of the state law product liability and tort claims that are the subject of this motion:

First, to survive a motion to dismiss, the complaint must allege the breach of a duty expressly set forth in federal regulations;

Second, to survive a motion to dismiss, the complaint must show that the duty expressly set forth in the federal regulations has a parallel counterpart in an established state law duty of care; and

Third, to survive a motion to dismiss, the complaint must make clear that the breach of duty alleged under state law is not based solely on a federal regulatory duty, without regard to state law.

Application of these three immutable principles dictates the outcome of this motion. When the Master Complaints' allegations are analyzed, their warning and product defect theories, whether in strict liability or negligence, fail under one or more of these principles. The claims either: (i) do not show a violation of federal law; (ii) have no counterpart in established state law; or (iii) are based solely on federal duties of care. Preemption is called for in these circumstances.

B. Plaintiffs' Warning Claims Involving Allergan's Class III Breast Implants Are Expressly And Impliedly Preempted

Plaintiffs advance a litany of warning-based claims couched in various guises in an effort to find a gap in the preemptive principles established by settled federal

law. They purport to attack the adequacy of Allergan's FDA-approved warnings, the content of its FDA-mandated reporting, or the method of reporting itself—all as required by federal regulations and Allergan's PMA approval. To the extent these warning claims attempt to nullify or alter what FDA otherwise has required, they are expressly preempted. Further, to the extent these warning claims are based on duties not found in settled state law, they likewise are expressly preempted. And finally, to the extent these claims are based solely on a purported violation of federal regulations, they are impliedly preempted. From any perspective, therefore, Plaintiffs' warning-based claims must be dismissed.

1. All Warning Claims Based On Allegations That The FDA-Required Warnings Are Inadequate Are Expressly Preempted

Plaintiffs' attacks on the adequacy of Allergan's FDA-approved labels are aimed at the content of the disclosures, the risks disclosed, and the manner in which those risks are disclosed.[8] If these claims took hold, they plainly would require something different from, or in addition to, what the controlling regulations mandate. These claims accordingly cannot survive express preemption and must be dismissed.

The Supreme Court in *Riegel* squarely held that §360k(a) "pre-empt[s] a jury determination that the FDA-approved labeling for a [PMA device] violated a state common-law requirement for additional warnings." 552 U.S. at 329. Claims that "have the effect of establishing a substantive requirement for a specific device, *e.g.*,

[8] The adequacy allegations are found in Plaintiffs' claims aimed at the content of Allergan's FDA-approved labelling, as well as at the promotional materials that are consistent with this labelling. (CAC ¶ 264, PIC ¶ 73.) Plaintiffs therefore are suing over what the FDA chose to require in exercising its regulatory role.

a specific labeling requirement" are preempted as "different from, or in addition to, a federal requirement." *Id.* (citation and quotation marks omitted).

In the wake of *Riegel*, courts uniformly have held that preemption bars product liability claims attacking FDA-approved labeling for Class III devices. That is true whether claims attack the disclosures FDA has approved or whether they would require an addition in some fashion to what the FDA has called for. These kinds of claims "impose different requirements on the [device], as [they] seek to impose liability because defendants did not accompany their product with proper warnings regarding the risks associated with a premarket-approved device." *Shuker*, 885 F.3d at 775. They are, simply put, "a challenge to the adequacy of the information required by FDA during the PMA process and label approved by the agency." *Cornett II*, 211 N.J. at 389, 48 A.3d at 1056; *see also Clements*, 111 F. Supp. 3d at 601 (warning-related claims are "tantamount to a requirement that [defendant] must do something 'different from, or in addition to' what the FDA had already approved"); *Hart*, 2017 WL 5951698, at *5 ("Plaintiff is bringing into question the … warning specifications that the FDA approved and requires for this Class III medical device…. This is precisely what §360k(a) preempts."); *accord*, *Morton*, 2015 WL 12839493, at *3; *Smith*, 2013 WL 1108555, at *8-9; *Gomez I*, 2018 WL 10612946, at *2.

There is no basis to depart from this unanimous case law for the warning claims attacking the adequacy of Allergan's FDA-approved labelling, any other FDA-approved communication or publication, or Allergan's promotional materials that are consistent with the FDA-approved labelling. Plaintiffs' claims are no

different than in the dozens of other lawsuits where express preemption has been applied since *Riegel*, including those involving breast implant devices. Dismissal is required here, too.

2. All Warning Claims Couched As A Failure To Report Adverse Events To FDA Are Expressly Preempted

Plaintiffs also base their failure to warn claims on Allergan's alleged failure to adequately report adverse events to FDA. As Plaintiffs would have it, Allergan's failure to make proper adverse event reports to FDA supposedly breached a state law duty to warn physicians about the potential risks of ALCL.[9] These claims fail under established express preemption principles.

Without conceding that Allergan's reporting failed to comply with FDA requirements in any respect, there is a fundamental problem with all of Plaintiffs' allegations tied to such reporting, no matter how couched or framed. The problem is that there is no parallel state tort duty to report to a federal regulatory agency and no way to construe state law duties to warn implanting physicians as giving rise to such a duty.[10] There is thus nothing parallel on which to base a state law duty in

[9] There are a variety of allegations purporting to support how Allergan fell short in the timing of its disclosures, the content in them and data and content in its reports and in its labelling and promotional materials. (CAC ¶¶ 221, PIC ¶ 96.) Allergan's labelling is FDA-approved and its promotional materials were consistent with that labelling. Plaintiffs' quarrel again is with what FDA required.

[10] Virtually all states recognize the learned intermediary doctrine, which "holds that the manufacturer of a prescription drug or medical device fulfills its duty to warn of the product's risks by informing the prescribing physician of those risks." *In re Zimmer NexGen Knee Implant Prod. Liab. Litig.*, 884 F.3d 746, 751-52 (7th Cir. 2018) (finding appellate authority for learned intermediary doctrine in 48 states). But "FDA is not a health care provider and does not prescribe anything for patients,"

order to avoid express preemption. In that regard, *Riegel* and the cases applying its reasoning make clear that for a state law claim to avoid preemption, it must be grounded in existing state law. The non-preempted parallel state claim cannot be a made-for-litigation invention. But Plaintiff's failure to report allegations are just that. They are invented for this MDL proceeding and they have no grounding in state law. There is no common law "failure to report to a federal agency" tort claim.

Norabuena v. Medtronic, Inc., 86 N.E.3d 1198 (Ill. App. 2017) is typical of cases addressing the "failure to report" duty issue. In *Norabuena*, the court found that a state-law duty to warn a physician "is not synonymous with an affirmative duty to warn a federal regulatory body." *Id.* at 1207. "[A]lthough plaintiffs have identified a federal requirement that their complaint alleges [defendant] violated, there is no [state] requirement that parallels it." *Id.* at 1206. The reason is that "[t]here is no general or background duty under [state] law to report risks to a regulatory body"—that duty typically runs "to the plaintiff herself[.]" *Norman v. Bayer Corp.*, 2016 WL 4007547, at *4 (D. Conn. July 26, 2016).

But *Norabuena* and *Norman* are hardly alone. Federal courts around the country, including the Third Circuit, have held these sorts of failure to report to a federal agency claims to be expressly preempted because they have no counterpart grounding in state law and there is no parallel claim to be made. *See, e.g.*, *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 716-17 (3d Cir. 2018) (failure-to-report theory improperly "attempted to use a federal duty and standard of care as the basis

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so it cannot be a "learned intermediary" entitled to receive product warnings under state law. *Conklin v. Medtronic, Inc.*, 431 P.3d 571, 577 (Ariz. 2018).

for [a] state-law negligence claim"); *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005 (S.D. Ohio 2016) ("the federal duty *to report certain information to the FDA* is not "identical" and thus not parallel, to the state-law duty *to provide warnings to patients or their physicians*") (emphasis original); *Potolicchio v. Medtronic, Inc.*, 2016 WL 3129186, at *4 (E.D. Tenn. June 2, 2016) ("Tennessee law requires manufacturers to warn physicians, but not the FDA"); *English v. Bayer Corp.*, ___ F. Supp. 3d ___, 2020 WL 3454877, at *3 (W.D.N.Y. June 25, 2020) ("[A] standalone claim [for] 'failure to report adverse events to the FDA' is not a cognizable cause of action under New York law."), *appeal docketed*, No. 20-2137 (2d Cir. July 7, 2020); *Chester*, 2017 WL 751424, at *10 (reporting-based claims assert federal requirements and thus "are expressly preempted"); *Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F. Supp. 3d 403, 412 (D. Del. 2014) (claims based on failure to report adverse events to FDA cannot be parallel because "such conduct would not exist apart from the FDCA").[11]

[11] And the list goes on: *McNeil-Williams v. DePuy Orthopaedics, Inc.*, 384 F. Supp. 3d 570, 575 (E.D.N.C. May 292019) ("North Carolina law does not recognize a parallel duty on manufacturers to report to the FDA"); *White v. Medtronic, Inc.*, 2019 WL 1339613, at *6 (E.D. Mich. Feb. 20, 2019) (FDA reporting requirement "has no state law analog, and thus there is no parallel state cause of action"), *adopted*, 2019 WL 1330923 (E.D. Mich. March. 25, 2019), *aff'd*, 808 F. App'x 290 (6th Cir. 2020), *cert. pending*; *Marmol v. St. Jude Med. Ctr.*, 132 F. Supp. 3d 1359, 1370 (M.D. Fla. 2015) ("Florida law lacks a parallel duty to file adverse reports with the FDA"); *Latimer v. Medtronic, Inc.*, 2015 WL 5222644, at *9 (Ga. Super. Sept. 4, 2015) (allegations "cannot support a parallel claim because there is no duty under Georgia law to report adverse events to the FDA"); *Cales v. Medtronic, Inc.*, 2014 WL 6600018, at *10 (Ky. Cir. Nov. 21, 2014) (holding failure-to-report claims expressly preempted as not "parallel" or "genuinely equivalent" to extant state law), *aff'd*, 2017 WL 127731 (Ky. App. June 8, 2017).

And here again, breast implant device cases are no exception. They too hold there is no state law duty to warn FDA. *See D'Addario*, 2020 WL 3546750, at *5 ("Plaintiffs identify no separate state law duty to warn the FDA.") (citation omitted); *Webb*, 2020 WL 1685323, at *5-6; *Jacob Cal.*, 393 F. Supp. 3d at 925; *Vieira*, 392 F. Supp. 3d at 1130-31; *Jacob Fla.*, 389 F. Supp. 3d at 1029; *Tinkler*, 2019 WL 7291239, at *5; *Brooks*, 2019 WL 4628264, at *5-6; *Rowe v. Mentor Worldwide LLC*, 297 F. Supp. 3d 1288, 1295-96 (M.D. Fla. 2018); *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 2448095, at *2-3 (C.D. Cal. May 25, 2018), *aff'd*, 804 F. App'x 871 (9th Cir. 2020); *Malonzo*, 2014 WL 2212235, at *3.

Brooks, 2019 WL 4628264, sets forth the controlling preemption analysis for Allergan's devices. There, the district court ruled that Plaintiffs' "indirect" warning claim arising from an alleged failure to report was expressly preempted. *Id.* at *6. First, the claim was entirely "speculative" because it "assumed" that FDA would have publicized unreported adverse events, which "it is not required to do."[12] *Id.*

[12] Adverse-event reports themselves "are not warnings." *Aaron*, 209 F. Supp. 3d at 1005. Rather, they are inherently unreliable anecdotes. FDA admits that its own regulations require reporting of "incomplete, inaccurate, untimely, unverified, or biased data." *See* FDA, Medical Device Reporting (MDR): How To Report Medical Device Problems (2019), https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems. FDA cautions that these reports are "not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices" and "do[] not necessarily reflect a conclusion by the party submitting the report by FDA ... that the device ... caused or contribute to the reportable event." FDA, Manufacturer & User Facility Device Experience Database – (MAUDE) (2020), https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/manufacturer-and-user-facility-device-experience-database-maude.

But "[e]ven if these allegations were not speculative," they were preempted because "[p]laintiffs have not identified any state law that required [defendant] to report adverse events to the FDA." *Id.* Thus, "like their other claims relating to FDA reporting, plaintiffs are not seeking to enforce state law, but are attempting to enforce federal requirements." *Id.*; *accord*, *e.g.*, *Norabuena*, 86 N.E.3d at 1207; *Marmol*, 132 F. Supp. 3d at 1370.

Numerous cases demonstrating the non-existence of a state law duty to report to a federal agency dictate the outcome here as well. Plaintiffs allege that the 50 states' laws have such a duty, but plainly they do not. Nor is this litigation a time to invent such a duty. Under *Riegel* and cases applying its reasoning, the parallel state law duty must be established and settled, not something Plaintiffs ask this Court to concoct. Moreover, settled *Erie* principles would stop such a creative effort before it starts.[13] Apart from that, the perils of departing from this parallelism requirement in this context are well-illustrated by the Ninth Circuit's experience in *Stengel v.*

[13] Under *Erie* "it is not the role of a federal court to expand state law in ways not foreshadowed by state precedent." *City of Philadelphia v. Beretta U.S.A. Corp.*, 277 F.3d 415, 421 (3d Cir. 2002); *Erie R.R. Co. v. Thompkins*, 304 U.S. 64, 78 (1938) ("Except in matters governed by the Federal Constitution or by acts of Congress, the law to be applied in any case is the law of the state.") The court's role instead "is to apply the current law of the jurisdiction, and leave it undisturbed." *Leo v. Kerr-McGee Chem. Corp.*, 37 F.3d 96, 101 (3d Cir. 1994). Thus, when confronted with open questions of state-law liability, federal courts in this Circuit must "opt for the interpretation that *restricts* liability, rather than expands it, until the Supreme Court of [the State] decides differently." *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 253 (3d Cir. 2010) (emphasis added; citation omitted); *accord, e.g., Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 254 (3d Cir. 2010); *Werwinski v. Ford Motor Co.*, 286 F.3d 661, 680 (3d Cir. 2002); *Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp.*, 273 F.3d 536, 541-42 (3d Cir. 2001).

Medtronic, Inc., 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc). In *Stengel*, over the defendant's vigorous objection, the Ninth Circuit divined a parallel duty to report state law cause of action from Arizona case law. When the claim was litigated in Arizona, however, the state Supreme Court made it clear that no such duty existed:

> [State] law does not permit a manufacturer to satisfy its duty to warn end-user consumers by submitting adverse event reports to the FDA. And conversely, a manufacturer does not breach its duty to warn end users under [state] law by failing to submit adverse event reports to the FDA. … [The duty to warn] has not been extended to require a manufacturer to submit warnings to a governmental regulatory body. … [E]stablished law does not recognize a claim merely for failing to provide something like adverse event reports … to a government agency that has no obligation to relay the information to the patient.

Conklin, 431 P.3d at 577, 579 (citation omitted).

There is no basis to treat the cases in this MDL any differently than *Conklin* or cases aligned with it, and Plaintiffs' failure to report allegations are expressly preempted and should be dismissed.

3. All Warning Claims Based On The Method For Adverse Event Reporting Are Expressly Preempted

In obvious tension with their failure to adequately report allegations, Plaintiffs acknowledge that Allergan *did report* the vast majority of the supposedly "unreported" events to FDA, through an authorized summary reporting method. (CAC ¶¶212-13; PIC ¶¶28, 91-92, 194.) Moreover, FDA expressly authorized this summary reporting method for "Silicone Gel-filled Internal Inflatable Breast Prosthesis … [and] Saline Internal Inflatable Breast Prosthesis." FDA, Summary Reporting of Medical Device Adverse Events (1997), https://web.archive.org/web/20000914063243/http:/www.fda.gov/cdrh/offerlet.htm

l. Nevertheless, as with their inadequate reporting allegations, Plaintiffs attempt to convert this method of reporting into a state law inadequate warning claim and then litigate over *the method* of reporting despite FDA regulations specifically on point.

But as Plaintiffs again are forced to concede, there is no state law duty to warn grounded in a method of reporting to FDA any more than there is such a duty in reporting to FDA in the first instance. The state law duty to warn still runs to the implanting physician and *not* to FDA. Since these failure to warn allegations once again are not anchored in existing state law, there is no parallel state law requirement, and the "method of reporting" warning claims are expressly preempted.

4. All Warning Claims Relating To Reporting Are Impliedly Preempted

In the absence of any recognized state common-law tort cause of action based on FDA-reporting or on a method of the FDA reporting, Plaintiffs are left to rely on the federal statutory scheme as the sole foundation for their alleged duty of care and its breach. That reliance, however, establishes that their reporting claims, no matter how couched or framed, are impliedly preempted as well.

To start with, *Sikkelee,* 907 F.3d at 701, is on point. There, the Third Circuit explained why the implied preemption principles articulated in *Buckman* foreclose failure to report allegations grounded solely on duties contained in federal statutes. The federal statutory scheme here is enforced by the FDA and does not create a standard of care for personal injury plaintiffs. The same was true under the FAA in *Sikkelee*:

> [Plaintiff] argues the District Court erred in granting [defendant] summary judgment on her failure-to-notify-the-FAA claim. ...

> [Defendant] is entitled to summary judgment on this claim. [Plaintiff] has attempted to use a federal duty and standard of care as the basis for this state-law negligence claim. However, ... Congress has not created a federal standard of care for persons injured by defective airplanes. The District Court therefore properly granted summary judgment to [defendant] on this claim.

Sikkelee, 907 F.3d at 716-17 (citing *Buckman*, 531 U.S. at 348, 353) (quotation marks omitted). Here, as in *Sikkelee*, Plaintiffs cannot base their warning claims on the purported breach of a federal duty because there is no such duty running in favor of private plaintiffs. Further, any attempt to recognize such a duty would impermissibly interfere with what the federal statutory scheme requires.

The New Jersey Supreme Court made this very point in *Cornett II*, 211 N.J. 362, 48 A.3d 1041. In that case, the plaintiffs alleged claims based on the "failure to satisfy federal disclosure requirements" concerning off-label use of a Class II medical device. *Id.* at 372. Grounding a claim on federal requirements related to disclosure was, however, deemed impliedly preempted under *Buckman:*

> [R]egardless of how a plaintiff styles a state claim, if the claim depends on the alleged violation of a federal requirement, it is functionally equivalent to a claim grounded solely on the federal violation, and is impliedly preempted.

Id. at 385 (citing *Buckman*, 531 U.S. at 352-53). The reason for invoking implied preemption in this context, as noted previously, is straightforward enough: "[W]arning" allegations that challenged the "adequacy of the information required by the FDA," would "directly interfere with the acknowledged exclusive authority of the FDA to enforce the FDCA" and were impliedly preempted. *Id.* at 389; *see also Gomez v. Bayer Corp.*, 2020 WL 215897, at *12 (N.J. Super. A.D. Jan. 14,

2020) (affirming dismissal of failure-to-report claims as impliedly preempted as "[o]ur Supreme Court has spoken on the subject of federal preemption … involving PMA devices, and we follow its guidance here").

It should come as no surprise, therefore, that courts routinely bring implied preemption principles to bear when, as here, a complaint's allegations reveal a flawed effort to enforce purported federal duties of care. The *D'Addario* court thus also found the same ALCL-related, failure-to-report claims preempted as "fundamentally alleg[ing] fraud-on-the-FDA." 2020 WL 3546750, at *5. After finding that state law did not allow failure-to-report claims, the *Conklin* court did the same and held that failure-to-report claims are impliedly preempted: "Because only federal law, not state law, imposes a duty … to submit adverse event reports to the FDA, [plaintiff's] failure-to-warn claim is impliedly preempted under 21 U.S.C. §337(a)." 431 P.3d at 578 (citing *Buckman*, 531 U.S. at 352-53).

Other cases align and employ the same reasoning in rejecting failure to report claims on implied preemption grounds. *See Sprint Fidelis II*, 623 F.3d at 1205-06 ("Plaintiffs alleged that [defendant] failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations. … [T]hese claims are simply an attempt by private parties to enforce the MDA, claims foreclosed by §337(a) as construed in *Buckman*.") (applying multiple states' laws); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017) ("Applying *Buckman*, [plaintiff's] failure to report theory is impliedly preempted. … Because this theory of liability is based on a duty to file a report with the FDA, it is very much like the 'fraud-on-the FDA' claim the Supreme Court held was impliedly

preempted in *Buckman*.") (applying Florida law); *Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012) ("[F]ailure to submit reports to the FDA that the FDA requires is arguably a species of fraud on the agency … [and] triggers the same concerns that animated *Buckman*. … [Plaintiff] relies on federal enactments as a critical element in her case. Moreover, this alleged wrong was perpetrated upon the agency, and thus implicates the inherently federal relationship described in *Buckman*.") (applying Michigan law) (quotation marks omitted).

Finally, it should come as no surprise that breast implant device claims are no exception. Thus, in *Brooks*, the court similarly recognized that failure-to-report claims based on federally-created duties of care were impliedly preempted where breast implant devices are involved:

> [T]he MDA would impliedly preempt this theory of recovery. Plaintiffs have not identified any state law that required [defendant] to report adverse events to the FDA. Accordingly, like their other claims relating to FDA reporting, plaintiffs are not seeking to enforce state law, but are attempting to enforce federal requirements. The MDA impliedly preempts this theory of recovery.

2019 WL 4628264, at *6 (citation omitted). *Brooks* also is not alone. *See Vieira*, 392 F. Supp. 3d at 1130-31 (breast implant plaintiff "could not avoid preemption" where the relevant state "does not recognize such claims"); *Jacob Cal.*, 393 F. Supp. 3d at 925 (same).[14]

[14] And, once again, the list goes on. *E.g.* ***Second Circuit*****:** *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 202 (E.D.N.Y. 2015) ("since Plaintiff's failure to warn claim is predicated on Defendant's alleged failure to provide the required reports to the FDA, authority to enforce that claim rests with the FDA"). ***Third Circuit*****:** *Chester*, 2017 WL 751424, at *10 ("claims based upon such violations are impliedly

One cannot read Plaintiffs' complaints—laden with myriad references to the FDCA, FDA, and FDA regulations—and reach any conclusion other than purported FDCA violations are "a critical element" of all their warning claims, thereby mandating that implied preemption be applied.

C. Plaintiffs' Claims Alleging That Allergan Should Have Submitted A "Changes Being Effected" Supplement For Its Warnings Are Expressly Preempted

Plaintiffs also allege that after Allergan learned more about the risk of ALCL, it was required to submit a PMA supplement strengthening its warnings through FDA's "changes being effected" ("CBE") regulation, 21 C.F.R. §814.39(d). (PIC ¶¶64, 189.) Claims based on these allegations are expressly preempted because they purport to impose a mandatory state law duty where federal law does not. A state

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preempted as impermissible attempts to enforce FDA reporting requirements under" *Buckman*). ***Fourth Circuit*:** *Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485, 492 (W.D.N.C. 2017) ("A requirement to report adverse events exists under the FDCA, and plaintiff's cause of action is being brought because ... defendants allegedly failed to meet these reporting requirements. Accordingly, the plaintiff's failure-to-warn claim is preempted.") (citing *Buckman*). ***Tenth Circuit*:** *Littlebear v. Advanced Bionics*, 896 F. Supp. 2d 1085, 1092 (N.D. Okla. 2012) ("[a]ll claims predicated on the failure to comply with adverse event reporting requirements are impliedly pre-empted"). ***Georgia*:** *Latimer*, 2015 WL 5222644, at *9 (quoting and following *Littlebear*). ***Kentucky*:** *Cales*, 2014 WL 6600018, at *10 (claims "predicated on . . . an alleged failure to submit adverse-event reports to the FDA would be impliedly preempted under *Buckman*"). ***Massachusetts*:** *Phillips v. Medtronic, Inc.*, 2012 WL 3641487, at *10 (Mass. Super. July 10, 2012) (a "claim based on failure to report adverse events ... is impliedly preempted because it is premised solely on a duty created by the MDA which did not exist in the common law"). ***New York*:** *Lake v. Kardjian*, 874 N.Y.S.2d 751, 755 (N.Y. Sup. 2008) (failure-to-report claims "are impliedly preempted by federal law, because enforcement of the FDCA, including the MDA, is the sole province of the federal government").

law duty that would require something different from, or in addition to, what federal law requires is expressly preempted, as *Riegel* and its progeny make abundantly clear.

Here, Plaintiffs' proposed mandatory duty to supplement plainly is different. The CBE regulation is permissive, not mandatory. It provides that changes "reflect[ing] newly acquired information that enhances the safety of the device … *may be* placed into effect by the applicant prior to the receipt … of a written FDA order approving the PMA supplement." *Id.* (emphasis added). Further, CBE regulation's use of the permissive "may" stands in sharp contrast to the same regulation's use of the obligatory "shall" for other types of PMA supplements.[15] *See Lopez v. Davis*, 531 U.S. 230, 231 (2001) ("use of the permissive 'may' contrasts with Congress' use of a mandatory 'shall' elsewhere in" same statutory section); *Jahn v. Comm'r, IRS*, 392 F. App'x 949, 950 (3d Cir. 2010) (distinguishing between mandatory "shall" and permissive "may"). Any effort to convert the discretionary duty to supplement into a mandatory one would impermissibly alter the regulation's wording and violate accepted principles of construction as well.

As the Ninth Circuit *en banc* majority also confirmed in *Stengel*, the permissive nature of the CBE regulation is determinative in the preemption analysis. In that case, the court confronted a similar claim that the defendant should have made post-sale warnings that were permitted, but not required, under the applicable

[15] *See* 21 C.F.R. §814.39(a) ("an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device"); 21 C.F.R. §814.39(e)(2) (a "30-day PMA supplement shall follow the instructions" of FDA).

regulations—and held that such a claim was expressly preempted. *Stengel*, 704 F.3d at 1234 ("Regulations issued by [FDA] permitted [defendant] to issue such post-sale warnings, even without receiving prior approval from FDA, but those regulations did not require such warnings. *See* 21 C.F.R. §814.39(d). As a result, any attempt to predicate [plaintiffs'] claim on an alleged state law duty to warn doctors directly would have been expressly preempted ….". *Stengel*, 704 F.3d at 1234 (Watford, J., concurring).

The rationale for this result, as noted, is self-evident: the state-law-breach of duty claim would *require* the manufacturer to have provided a warning where the federal regulation would not. Courts agree that express preemption must take hold in such circumstances. *See Sprint Fidelis II*, 623 F.3d at 1205 ("[e]ven if federal law *allowed* [defendant] to provide additional warnings, as Plaintiffs alleged, any state law *imposing* an additional requirement is preempted by §360k") (emphasis original); *Riley*, 625 F. Supp. 2d at 783 ("[A] failure-to-warn claim cannot parallel §814.39(d) because §814.39(d) merely *permits* a device manufacturer to make a temporary change to a label whereas a successful failure-to-warn claim would *require* such a change.") (emphasis original); *McGookin v. Guidant Corp.*, 942 N.E.2d 831, 838 (Ind. App. 2011) (preempting mandatory CBE claim; "We cannot imagine a plainer example of an attempt to impose a standard of care in addition to the FDA's specific federal requirements."). Permitting such a claim would restrict "[t]he flexibility inherent" in FDA regulations and thus necessarily "impose requirements 'different from, or in addition to' those under federal law." *In re*

Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009) ("*Sprint Fidelis I*").

In sum, Plaintiffs' efforts to fashion a state law duty based on allegations that Allergan was required to supplement its warnings under the CBE regulation are expressly preempted because they are a transparent attempt to change what federal law requires. No state law duty can be employed to accomplish that result in this context and these claims should be dismissed.

D. Plaintiffs' Claims Challenging Allergan's Post-Sale Clinical Studies Are Expressly Preempted

Plaintiffs also assert that Allergan failed to conduct clinical studies after the FDA approved its PMAs. As a result, Plaintiffs further allege that they and their physicians were not warned about the possible risk of ALCL. Plaintiffs allege that Allergan did not comply with FDA's post-approval study requirements regarding long-term performance of the approved devices. (CAC ¶¶227-254; PIC ¶¶6, 53, 77(f), 169, 186, 246.) But there is no state law duty that required Allergan to undertake the studies—that requirement existed solely by virtue of FDA's regulatory oversight and approval of Allergan's PMA. As with failure to report warning claims, therefore, "[w]ithout a freestanding basis in state law," allegations of "failure to 'conduct a study'" also are expressly preempted. *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 747 (D. Md. 2015). Likewise, in *Brooks*, no state-law duty existed to report negative study results about breast implants to the FDA. 2019 WL 4628264, at *6. It was "far too speculative" to "assume that plaintiffs' physicians would have accessed [adverse event] information and relied on it." *Id.*

For these same reasons, "failure to conduct a study" allegations were held preempted in the only other current MDL involving a PMA device. *See In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, 401 F. Supp. 3d 538, 562 (D. Md. 2019) ("[P]laintiffs … pointed to no state-law duty that predated the MDA that would similarly require [defendant] to undertake this research."). And, similar allegations were also preempted in a recent breast implant case. *Ebrahimi*, 2017 WL 4128976, at *5 (preempting allegations that the defendant failed to properly conduct a large post-approval study when the actual number of enrolled patients was fewer than the number prescribed by the FDA, because there is "no parallel state-law duty to conduct post-approval 'follow-through studies.'").

The same result should follow here and the failure to conduct a study claims are expressly preempted and should be dismissed.

E. Plaintiffs' "Manufacturing Defect" Claims Attacking Allergan's PMA-Approved Manufacturing Process Are Expressly Preempted

The Master Complaints contain a variety of allegations styled as "manufacturing defects" that supposedly parallel recognized state law causes of action founded on such defects. Manufacturing defects, when properly alleged, conceivably can fit through the narrow gap between express and implied preemption. Where a device is not manufactured in accordance with approved device specifications, there can be a violation of the federal statute. And, where established state law recognizes product liability claims for products that deviate from the norm, the recognized parallelism exists. Here, however, Plaintiffs efforts to fit their "manufacturing defect" claims in the gap fail for two reasons. First, there are no

allegations that Allergan's breast implants deviated from their FDA-approved design. Second, on analysis, Plaintiffs' allegations are not attacking a deviation from the approved design but rather the design itself. Either way, preemption applies and Plaintiffs' claims fail.

1. Plaintiffs Do Not Allege Any Deviation From FDA Manufacturing Specifications So Express Preemption Applies

Plaintiffs allege that Allergan's devices generally were "adulterated" because of Allergan's use of salt-loss texturing. (*E.g.*, CAC ¶190, PIC ¶114.) Plaintiffs also allege that Allergan did not properly "validate" or otherwise oversee that process, leading to the manufacture of implants that had variable texture. (CAC ¶14; PIC ¶¶118-19, 123 129, 132, 149). But *nowhere* do they allege that any device deviated from an FDA-approved manufacturing process and attendant FDA-approved device specifications. That is fatal to their manufacturing defect claims.

FDA's premarket approval requires the approved device to be manufactured "with almost no deviations from the specifications in its approval application." *Riegel*, 552 U.S. at 323. Thus, as a broad rule, "allegations of strict products liability based on manufacturing defect … are precisely the type of claims the MDA sought to preempt." *Williams v. Cyberonics, Inc.*, 388 F. App'x at 171. "To survive preemption, manufacturing defect claims must allege that the device was not made in accordance with the specifications approved by the FDA." *Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485, 493 (W.D.N.C. 2017). Thus, where plaintiffs fail to plead "how [the device] deviated from the FDA approved manufacturing process" and nowhere "specify a causal connection between the failure of the specific

manufacturing process and the specific defect" their manufacturing defect claims are preempted. *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011).

Judge Shipp's recent decision in a nearly identical breast implant case, *D'Addario*, 2020 WL 3546750, illustrates the proper analysis for manufacturing defect allegations. There, plaintiffs alleged that the defendants' breast implants caused them to develop ALCL. *Id.* at *1. Among other things, they alleged that the implants were "manufactured in a non-conforming manner because they contained a graham-negative biofilm/endotoxin released from the surface of the textured surface which stimulates lymphocytes … and that these bacteria stimulating lymphocytes caused" her disease. *Id.* at *4. Judge Shipp found that the plaintiffs "d[id] not … allege that *the FDA required* the exclusion of this endotoxin." *Id.* (emphasis added). Thus, with no "properly identified" federal requirement supporting the purported manufacturing defect claim, it was preempted. *Id.* Moreover, Judge Shipp continued, "broad[]" allegations that defendants "failed to adhere to numerous federal specifications" could not save the claim, given the plaintiffs' failure to state how any regulatory violation "resulted in the presence of lymphocytes in her implants." *Id.*

Likewise, applying Florida law, the Eleventh Circuit made the same distinction between product liability claims alleging manufacturing as opposed to design defects:

> This distinction between "aberrational" defects and defects occurring throughout an entire line of products is frequently used in tort law to separate defects of manufacture from those of design. ... Stated another way, the distinction is between an unintended configuration, and an

> intended configuration that may produce unintended and unwanted results.

Harduvel v. General Dynamics Corp., 878 F.2d 1311, 1317 (11th Cir. 1989); *see Salinero v. Johnson & Johnson*, 400 F. Supp. 3d 1334, 1344 (S.D. Fla. 2019) (following *Harduvel*), *appeal docketed*, No. 20-10900 (11th Cir. Mar. 9, 2020); *Miller v. United Techs. Corp.*, 660 A.2d 810, 846 (Conn. 1995) (same); *Nicholson v. Pickett*, 2016 WL 854370, at *20 (M.D. Ala. March 4, 2016) (same); *Roll v. Tracor, Inc.*, 102 F. Supp. 2d 1200, 1202 (D. Nev. 2000) (same); *Oliver v. Oshkosh Truck Corp.*, 911 F. Supp. 1161, 1175 (E.D. Wis. 1996) (same), *aff'd*, 96 F.3d 992 (7th Cir. 1996).[16]

In sum, without express allegations showing how Allergan's devices, as manufactured, deviated from their FDA-approved designs, no manufacturing defect allegation can survive preemption. Plaintiffs' manufacturing defect claims must be dismissed for this reason. *See Delaney v. Stryker Orthopaedics*, 2009 WL 564243, at *7 (D.N.J. March 5, 2009) ("As [plaintiff] has not pointed to a defect or a deviation

[16] By way of further example, the same is true in California. *See Hannan v. Boston Sci. Corp.*, 2020 WL 2128841, at *5 (N.D. Cal. May 5, 2020) (granting summary judgment for defendants on manufacturing defect claims when "incorrect manufacturing processes that plaintiffs identify … are indicative of a flaw in the design of an entire line of products rather than one product differing from other ostensibly identical units"); *In re Coordinated Latex Glove Litig.*, 121 Cal. Rptr. 301, 315 (Cal. App. 2002) ("[T]hat simultaneously manufactured [units] were subject to different standards at different production lines, due to the status of the manufacturer's research and development, where scientific knowledge was inconclusive … does not require that some items must be deemed defective under a manufacturing defect approach. Rather, such arguments actually deal with design defect evidence ….").

from the FDA-reviewed … manufacturing specifications regarding the [device] implanted in him, the Court dismisses [his] manufacturing defect claim."); *accord Chester*, 2017 WL 751424, at *8; *Mendez v. Shah*, 94 F. Supp. 3d 633, 638-39 (D.N.J. 2015); *Morton*, 2015 WL 12839493, at *5; *Becker v. Smith & Nephew, Inc.*, 2015 WL 268857, at *3 (D.N.J. Jan. 20, 2015); *Smith*, 2013 WL 1108555, at *9.

2. Plaintiffs' Allegations That All Textured Breast Implants Are Defective As Manufactured Are Expressly Preempted

Plaintiffs' "manufacturing defect" allegations also make clear that they are not really claiming that Allergan's implants deviated from the norm. Far from it, their allegations attack the norm directly and plainly. That is, Plaintiffs' allegations are aimed at the processes by which all of Allergan's devices are manufactured. That is nothing more or less than a design defect allegation disguised in "manufacturing defect" clothing. Case law again supports the application of preemption in this instance.

To begin with, claims that challenge the design and processes by which all of the PMA-market approved medical devices are manufactured, as Plaintiffs' claims do here, are an effort to change what federal regulation commands—the quintessentially preempted claim. *See Walker v. Medtronic, Inc.*, 670 F.3d 569, 580-81 (4th Cir. 2012) ("A common law tort claim that presupposes a Class III device should have been designed in a manner other than that contemplated by its premarket approval is therefore expressly preempted by the MDA as interpreted by *Riegel*.").

In addition, Plaintiffs' attack on the *process* by which all the devices are manufactured is a semantic game that cannot be resorted to avoid preemption. The

Third Circuit's recent decision in *Coba v. Ford Motor Co.*, 932 F.3d 114 (3d Cir. 2019) (applying New Jersey law) recognized as much when the plaintiffs there tried to disguise what was, in effect, a design defect—by calling it a manufacturing defect—in a breach of warranty case. The Court noted that the claims, as alleged, "ha[d] all the trappings of a design defect," since plaintiffs: (1) did not allege "low quality," but rather the defendant's decision to use a particular process in "constructing" the product; and (2) "alleg[ed] that '[a]ll' of the [products] manufactured this way suffer from a 'common' issue." *Id.* at 123.[17] The allegations here align with *Coba* in every material respect. Plaintiffs attack the process by which the devices are made—a charge aimed at the devices' design, not the way a particular device was manufactured.

Here, the devices produced by Allergan's design process have not "deviated from" the FDA approved "specifications, formulae, or performance standards" and are not at variance from "otherwise identical units," N.J.S.A. 2A:58C-2, and Plaintiffs do not claim that is the case. Rather, each device is exactly what the FDA required in its PMA approval. Plaintiffs' "manufacturing defect" allegations therefore must be preempted just as any other effort to impose state law liability over a PMA-approved design would be. Dismissal again is required.

[17] In the *Agent Orange* MDL, the Second Circuit adopted the same reasoning: "plaintiffs allege[d] a defective process, not that the process used was somehow erroneously applied. They therefore allege a design defect." *In re Agent Orange Prod. Liab. Litig.*, 517 F.3d 76, 92 n.15 (2d Cir. 2008) (applying laws of multiple jurisdictions).

F. Plaintiffs' Claims Based In Whole Or In Part On "Adulteration" Are Impliedly Preempted

Plaintiffs have couched their defective device allegations in "adulteration" terminology but that linguistic choice does not avoid preemption. Instead, by relying on "adulteration," they again have made FDCA standards "a critical element" of their claims, in violation of the preemptive principles set forth in *Buckman*, 531 U.S. at 353. Whether a defendant's products are "'adulterated' under … the FDCA" is a "matter[] rest[ing] within the enforcement authority of the FDA, not this Court." *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (quoting district court). "[A] conclusion that a particular ... product is 'adulterated,' in the abstract, means little other than that FDA could choose to initiate enforcement proceedings." *Comty. Nutrition Inst. v. Young*, 818 F.2d 943, 950 (D.C. Cir. 1987). That is why, moreover, that the Third Circuit has mandated preemption in these circumstances:

> [V]iolations of the FDCA do not create private rights of action. Thus, only the government has a right to take action with respect to adulterated products. Additionally, … to the extent [plaintiff's] adulteration claim is derivative of her other claims …, she cannot overcome a finding of preemption merely by claiming that the product was adulterated.

Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir. 1994) (citations omitted); *see also Riegel*, 552 U.S. at 329 ("adulteration and misbranding claims are pre-empted when they have the effect of establishing a substantive requirement for a specific device") (citation and quotation marks omitted).

In this instance, "adulteration" allegations, like Plaintiffs', complaining of "noncompliance with the technical, administrative details of the FDA's complex regulatory scheme" are impliedly preempted because they "would not give rise to

such tort liability if the FDCA or the regulatory regime created pursuant to it had never existed." *Barnes v. Howmedica Osteonics Corp.*, 2010 WL 11565343, at *15 (N.D. Ala. Dec. 14, 2010); *see also Martin v. Medtronic, Inc.*, 2017 WL 825410, at *7 (E.D. Cal. Feb. 24, 2017) (finding "'adulteration'-based claims are incongruous with the common law and thus impliedly preempted because they entirely rest on defendants' purported violations of the FDA's CGMPs"). "Any derivative claim that the [device] was adulterated as a result of" an FDCA violation "is a disguised claim to privately enforce the federal law, prohibited under 21 U.S.C. §337(a)." *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 685 n.20 (W.D. Ky. 2013).[18]

De La Paz v. Bayer Healthcare LLC, 159 F. Supp. 3d 1085 (N.D. Cal. 2016) is on point as well. There, the plaintiff alleged "adulteration" as a "manufacturing" defect based on the defendant's "failing to adequately *document*" a "validation protocol"—"not in the actual manufacture of the product." *Id.* at 1095 (emphasis

[18] *See*, *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 696 (W.D. Tenn. 2011) ("claims premised on Plaintiffs' derivative assertion that the … device … was 'adulterated' or 'misbranded' … are also preempted"); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 660 (S.D. Tex. 2010) (the FDCA "explicitly precludes private enforcement of federal laws regarding 'adulterated' devices"); *Cornwell v. Stryker Corp.*, 2010 WL 4641112, at *4 (D. Idaho Nov. 1, 2010) ("To the extent Plaintiff's parallel claim is based on a theory the medical device implanted in Plaintiff was 'adulterated' such claim must also be dismissed as there is no private right of action"); *Sprint Fidelis I*, 592 F. Supp. 2d at 1162 ("Because Plaintiffs manufacturing-defect claims are preempted, this derivative [adulteration] assertion is also preempted.") (following *Gile*; other citations omitted); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) (plaintiff's claims are "not saved [from preemption] merely by being recast as violations of the federal adulteration and misbranding statutes").

original). That claim was impliedly preempted because it did not resemble a common-law manufacturing defect:

> [Plaintiff] must allege that the irregularities … resulted in a manufacturing defect that caused her injuries. In other words, she cannot state a claim based solely on [defendant's] adulteration of certain … devices, since any such claim would "exist solely by virtue of the [MDA] ... requirements." [Plaintiff] has failed to allege such a manufacturing defect.

Id. at 1094-95 (citing *Buckman*, 531 U.S. at 353). As a result, the claimed FDCA "irregularities" did not create "a breach of any parallel state law duties that could escape implied preemption." *Id.* at 1095.

In this case, Plaintiffs' "adulteration" allegations do not resemble any common law manufacturing defect claim and exist solely by virtue of FDA requirements. All their allegations relying on "adulteration" accordingly are preempted.

G. Plaintiffs' Negligence *Per Se* Claims Are Impliedly Preempted

Plaintiffs' negligence *per se* claims boil down to allegations that Allergan breached duties solely created under the FDCA. These are no different from the kinds of claims that numerous courts around the country have rejected on preemption grounds. The same result should follow here.

By definition, a negligence *per se* claim takes "a legislative enactment or an administrative regulation which is adopted by the court as defining the standard of conduct of a reasonable man." *Ries v. Nat'l R.R. Passenger Corp.*, 960 F.2d 1156, 1158 (3d Cir. 1992) (quoting Restatement (Second) of Torts §288B(1) (1965)). *Accord Sprint Fidelis I*, 592 F. Supp. 2d at 1163. Where negligence *per se* is based

on alleged FDCA violations, the FDCA becomes "a critical element in [Plaintiffs'] case" and the "duty" thereby defined "exist[s] solely by virtue of the [MDA] ... requirements." *Buckman*, 531 U.S. at 353.

In this type of litigation, therefore, negligence *per se* claims are no more than improper attempts at private FDCA enforcement:

> [Plaintiffs'] interpretation of *per se* liability would allow private plaintiffs to recover for violations of a federal statute that creates no private cause of action and, in fact, expressly restricts its enforcement to the federal government. Plaintiffs' theory would undermine section §337(a) by establishing a private, state-law cause of action for violations of the FDCA…. We do not believe the concept of *per se* liability supports such a result.

In re Orthopedic Bone Screw Prod. Liab. Litig., 193 F.3d 781, 791 (3d Cir. 1999) (citation and footnote omitted); *see also Talley v. Danek Med., Inc.*, 179 F.3d 154, 158 (4th Cir. 1999) (holding negligence *per se* claim preempted pre-*Buckman*) (applying Virginia law) ("[T]he negligence *per se* doctrine ... is not a magic transforming formula that automatically creates a private right of action for the civil enforcement, in tort law, of every statute.").

In *Cornett II*, the New Jersey Supreme Court also applied *Buckman* to affirm dismissal of a negligence *per se* claim, holding that the elements of "traditional state law cause[s] of action" exist "with no reference to federal requirements as the measure of the reasonableness or wrongfulness of the manufacturer's conduct." *Cornett II*, 211 N.J. at 385, 48 A.3d at 1054. Since negligence *per se* "depend[ed] on the alleged violation of a federal requirement," it was "functionally equivalent to

a claim grounded solely on the federal violation" and thus impliedly preempted. *Id.* (*Buckman* citations omitted).[19]

In *Brooks*, after looking at similar claims involving breast implants, the court also rejected the plaintiff's "roundabout way of asserting a negligence *per se* claim based on a violation of the FDCA." 2019 WL 4628264, at *7. As the court noted, "negligence *per se* is limited to violations of a statute where the legislature intended to create an individual right of action," and "Congress did not intend a private federal remedy for violations of the FDCA." *Id.* at *5 n.5 (citations and quotation marks omitted). The plaintiff in *Brooks* could not "conjure up a parallel state claim that survives implied preemption" by "argu[ing] that [defendant] violated state law *because* it violated federal law. *Id.* at *7 (emphasis original). In *Rowe*, another breast-implant-related negligence *per se* claim was "impliedly preempted" as "the sort of claim addressed by *Buckman*, in which [the plaintiff] is suing because [the defendant] violated federal regulations." 297 F. Supp. 3d at 1298.

And the MDL court in *In re Bard IVC Filters* considered the same sort of negligence *per se* claims alleged here—"misbranding … false and misleading statements … failing to notify FDA when the [devices] were no longer safe and

[19] *Cornett II* thus affirmed the Appellate Division, which had held that ostensibly state-law claims "had to be preempted [under *Buckman*], because they were in effect no more than *per se* claims for violation of a federal requirement" and were therefore "distinguishable from state-law causes of actions that parallel federal safety requirements." *Cornett v. Johnson & Johnson*, 414 N.J. Super. 365, 394, 998 A.2d 543 (A.D. 2010) ("*Cornett I*"), *aff'd*, 211 N.J. 362, 48 A.3d 1041 (N.J. 2012).

effective, failing to recall the devices, and not maintaining accurate adverse event reports"—and foreclosed those claims on implied preemption grounds:

> While it is true that courts generally have allowed a negligence *per se* claim based on violation of a statute that does not expressly provide for a private right of action, the plain language of §337(a) and the *Buckman* decision indicate that, where the FDCA is concerned, such claim fails.... [A]llowing the claim to go forward would authorize an impermissible action to enforce provisions of the FDCA and its implementing regulations."

2018 WL 1256768, at *8-9 (D. Ariz. March 12, 2018) (applying Georgia law).[20]

Most simply put, FDCA-based negligence *per se* claims are indisputably preempted because they "arise[] directly and wholly derivatively from the violation of federal law." *Norman*, 2016 WL 4007547, at *5; *Green v. Medtronic, Inc.*, 2019 WL 7631397, at *15 (N.D. Ga. Dec. 31, 2019).[21] "[P]laintiffs' claim of negligence

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[20] *See In re Bard IVC Filters Prod. Liab. Litig.*, 2018 WL 4356638, at *2-3 (D. Ariz. Sept. 12, 2018) (same applying Wisconsin law); *In re Bard IVC Filters Prod. Liab. Litig.*, 2017 WL 5625548, at *8-10 (D. Ariz. Nov. 22, 2017) (same applying Georgia law).

[21] *See*, *e.g.*, *Hayes v. Endologix, Inc.*, ___ F. Supp. 3d ___, 2020 WL 1624022, at *4 (E.D. Ky. March 26, 2020) ("negligence *per se* … does not escape preemption"); *Sharp v. St. Jude Med., S.C., Inc.*, 396 F. Supp. 3d 1250, 1261 (N.D. Ga. 2019) ("Plaintiff's negligence *per se* claim is impliedly preempted, as [it] uses Defendants' alleged violation of federal law to substantiate the existence of a state tort claim"); *Mullins v. Ethicon, Inc.*, 2017 WL 275452, at *2 (S.D.W. Va. Jan. 19, 2017) ("plaintiff cannot properly state a negligence *per se* claim under the [FDCA]"); *Perdue v. Wyeth Pharmaceuticals, Inc.*, 209 F. Supp. 3d 847, 851 (E.D.N.C. 2016) ("plaintiff's claim of negligence *per se* based upon a violation of the FDCA is impliedly preempted under *Buckman*"); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 862 (W.D. Tenn. 2015) ("negligence *per se* … claims are impliedly preempted under *Buckman*"); *Thibodeau v. Cochlear Ltd.*, 2014 WL 3700868, at *5 (D. Ariz. July 25, 2014) (negligence *per se* "impliedly preempted because it is based directly on a violation of federal law"); *Zaccarello v. Medtronic, Inc.*, 38 F. Supp. 3d 1061, 1071 (W.D. Mo. 2014) (negligence *per se* "is impliedly preempted because the

per se would not exist prior to the enactment of the FDCA misbranding and adulteration laws because the claim only alleges violation of that law." *Leonard v. Medtronic, Inc.*, 2011 WL 3652311, at *8 (N.D. Ga. Aug. 19, 2011); *Grant v. Corin Group PLC*, 2016 WL 4447523, at *4 (S.D. Cal. Jan. 15, 2016) (same). "While courts have generally allowed a negligence *per se* claim based on violation of a federal statute, the plain language of §337(a) and the *Buckman* decision indicate that, where the FDCA is concerned, such claim fails." *Dunbar v. Medtronic, Inc.*, 2014 WL 3056026, at *5 (C.D. Cal. June 25, 2014).

Plaintiffs' negligence per se claims are no different and deserve the same fate.

H. Plaintiffs' Claims Involving Allergan's Class II Style 153 And McGhan RTV Implants Are Preempted

Plaintiffs further allege that some patients received two specific types of devices, which were cleared by FDA for sale: (1) McGhan Textured Breast Implant, Style 153; and (2) McGhan RTV® Saline-Filled Mammary Implant. (*See* discussion

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applicable standards of care rely on the MDA and, therefore, the existence of this claim exists solely by virtue of the federal requirements"); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 705-06 (S.D. Tex. 2014) (plaintiff "cannot avoid *Buckman*'s implied preemption holding" by asserting negligence *per se*); *Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977, 1000 (D. Ariz. 2013) ("a claim for negligence that is premised solely on a manufacturer's violation of a federal standard—here the FDCA and MDA—is impliedly preempted"); *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1152 (D. Minn. 2011) ("a claim of negligence *per se* cannot be based on a violation of the FDCA … under *Buckman*"); *Franklin v. Medtronic, Inc.*, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) (negligence *per se* claim preempted; "Plaintiff cannot avoid preemption simply by recasting her claims to allege violations of the FDCA"), *adopted*, 2010 WL 2543570 (D. Colo. June 22, 2010); *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002) ("many courts have held plaintiffs cannot seek to enforce [the FDCA] through negligence *per se* tort actions").

supra at 12-13.) But investigational devices (Style 153) cleared as safe and effective by the FDA are fully protected from state tort law claims by PMA preemption. So, too, are reclassified devices (McGhan RTV®) after the date of their reclassification to PMA.[22] Further, the implied preemption arguments above apply equally to all FDA-regulated medical devices, regardless of device classification—*Buckman*, 531 U.S. at 345-46, involved a §510(k) device—and independently require that Plaintiffs' claims be dismissed.

1. PMA Preemption Applies To IDE Medical Devices

"To obtain the data to support an application for premarket approval, a manufacturer may use the device in clinical trials under active FDA supervision pursuant to the FDCA's Investigational Device Exemption ("IDE") provisions and accompanying federal regulations. Premarket approval will be granted only if the IDE investigation proves the device is sufficiently safe and effective." *Orthopedic Bone Screw*, 193 F.3d at 786 (citing 21 U.S.C. §360j(g)). "In granting IDE approval, the FDA imposes detailed requirements on the design, manufacture, and warnings for Class III devices as well as the conduct of the clinical investigation." *Robinson v. Endovascular Techs., Inc.*, 119 Cal. Rptr. 3d 158, 164 (Cal. App. 2010). In fact, FDA's regulatory scheme, "impos[es] over 150 separately numbered regulations on IDE devices." *Burgos v. Satiety, Inc.*, 2010 WL 4907764, at *7-8 (E.D.N.Y. Nov. 30, 2010) (citing 21 C.F.R. §812).

[22] To the extent any Plaintiffs received McGhan RTV® implants before that device's May 2000 PMA, their claims would not be subject to express preemption, unless they seek changes to FDA requirements that could only arise after the PMA date.

Given FDA's close oversight of IDE products, the Third Circuit has recognized that claims involving IDE devices are preempted. *See Gile*, 22 F.3d at 545 ("[S]tate tort law invoked to challenge the safety or effectiveness of a [device] which is part of an FDA investigation is federally preempted."). Preemption is required because "a jury determination that the device is not sufficiently safe and effective would not only be contrary to the experimental purposes of the exemption, but, more important, would directly conflict with FDA's contrasting judgment. *Id.*

Other circuits are in accord. *See, e.g.*, *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1247-48 (7th Cir. 1997) (product liability "claims would defeat the purpose of the investigational device exemption, which is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use") (citation and quotation marks omitted); *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1097 (6th Cir. 1997) ("the application and approval process under the IDE is device specific"); *Becker v. Optical Radiation Corp.*, 66 F.3d 18, 20 (2d Cir. 1995) ("The point of the experiment is to find out *whether* the design is safe and effective. … [S]tate tort claims would impose requirements … that are, certainly, additional to those imposed by the MDA scheme."); *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333-34 (7th Cir. 1992) (affirming dismissal of personal injury action involving an IDE device, on preemption grounds).

Indeed, almost every court since *Riegel* to consider express preemption in the IDE context has recognized the same broad scope of preemption applicable to PMA devices. *See, e.g.*, *Russell*, 2018 WL 5851101, at *4-5 ("state law challenges to

devices granted IDE for clinical testing were preempted by federal law"; "*Riegel* offers the greatest similarity" to IDEs); *Bush v. Goren*, 2014 WL 4160245, at *7 (Mich. App. Aug. 21, 2014) ("Like PMA applications, IDE applications are focused on safety and efficacy and specific to individual devices.") (citation omitted); *accord Parks v. Howmedica Osteonics Corp.*, 2016 WL 7220707, at *6-8 (M.D. Fla. March 11, 2016); *Grant*, 2016 WL 4447523, at *3-5; *Day v. Howmedica Osteonics Corp.*, 2015 WL 13469348, at *4-5 (D. Colo. Dec. 24, 2015); *Killen v. Stryker Spine*, 2012 WL 4498865, at *1 (W.D. Pa. Sept. 28, 2012).

This precedent again includes cases involving Allergan's investigational breast implant devices. *See Dorsey v. Allergan, Inc.*, 2009 WL 703290 (M.D. Tenn. March 11, 2009). ("Unquestionably, state products liability claims with respect to an FDA approved investigational device are preempted" because to hold otherwise "would thwart the goals of safety and innovation.") (citation and quotation marks omitted); *Williams v. Allergan USA, Inc.*, 2009 WL 3294873, at *2-3 (D. Ariz. Oct. 14, 2009) ("FDA has established extensive requirements applicable to" IDE devices).

For these reasons, the preemption analysis for Plaintiffs who received the Style 153 investigational device is no different than it is for Plaintiffs who received PMA devices. In all cases, their claims are preempted.

2. PMA Preemption Applies To Reclassified PMA Medical Devices

The Allergan RTV® breast implant device, while originally approved as "substantially equivalent" under Section 510(k) in the mid-1980s, was required by FDA to be resubmitted as a PMA device in November 1999, and received pre-market

approval in May 2000. Since liability "hinges upon" whether the device was defective "at the time the alleged tort was committed," the PMA in place *at that time* is what matters. *Sprint Fidelis I*, 592 F. Supp. 2d at 556 (internal citation and quotation marks omitted). Thus, the claims of plaintiffs who had post-May 2000 RTV® implants are expressly preempted for all of the reasons previously stated.

PMA preemption thus was applied on similar facts in *Starks v. Coloplast Corp.*, 2014 WL 617130 (E.D. Pa. Feb. 18, 2014), where (as with the RTV®) an implanted device was first cleared under §510(k), but then successfully resubmitted to FDA under the PMA process. *Id.* at *4 n.8. The in-force PMA controlled:

> The §510(k) clearance of a medical device's predicate or its components, however, does not change the preemptive effect of premarket approval of the current device. The ... implant received premarket approval ..., and that premarket approval has preemptive effect.

Id. (citations omitted). As discussed, whether a device enjoys PMA approval when used for a particular patient governs the availability of preemption. Thus, PMA preemption bars all manufacturing defect claims made by plaintiffs receiving RTV® implants after May 2000. To the extent that any claims—such as post-sale duty to warn—would require a modification after the device received PMA, those claims are preempted as well. *See Brooks v. Howmedica, Inc.*, 273 F.3d 785, 789 n.5 (8th Cir. 2001) (PMA preemption applies to device reclassified to §510(k) "after" plaintiff was "exposed") (en banc); *Allen v. Zimmer Holdings, Inc.*, 2015 WL 6637232, at *2 (D. Nev. Oct. 30, 2015) (later reclassification "does not affect the analysis"); *Thompson v. Depuy Orthopaedics, Inc.*, 2015 WL 7888387, at *8 (S.D.

Ohio Dec. 4, 2015) (no preemption where a PMA device had been downclassified to §510(k) prior to plaintiff's use); *Scott v. Pfizer Inc.*, 249 F.R.D. 248, 254 n.8 (E.D. Tex. 2008) (later "reclassification has no bearing on" preemption).

V. CONCLUSION

For the foregoing reasons, this Court should dismiss all claims in the Master Complaints related to devices that received FDA approval through the PMA process and also devices that (1) FDA reclassified to PMA-status, or (2) were the subject of research during the PMA process under the IDE, but never approved.

Dated: August 7, 2020

Respectfully submitted,

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	**Case No. 2:19-md-02921 (BRM)(JAD)** **MDL NO. 2921** **JUDGE BRIAN R. MARTINOTTI** **JUDGE JOSEPH A. DICKSON**

THIS DOCUMENT RELATES TO: ALL CASES

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

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I. INTRODUCTION

Plaintiffs' 1,300-page Consolidated Class Action Complaint ("CAC") would have this Court certify three separate classes purporting to be nationwide in scope:

- ***A "medical monitoring" class*** comprised of all persons who were implanted with Allergan's textured breast implant devices, but have not yet been diagnosed with a cancer of the immune system commonly known as ALCL;[1]
- ***112 separate subclasses***—two for every U.S. State and Territory—consisting of the exact same putative members as the nationwide class; and
- ***A "release subclass***" comprised of persons who signed an optional release of liability as part of their individual warranty claims leading to the explant of their breast implant devices.

As one might expect from the breadth of these descriptions, these alleged classes are extraordinarily diverse. They span a 23-year period, implicate 37 different device lines, and nearly 250,000 implanted devices. There are 63 named Plaintiffs from 39 states; the absent class members come from all 50 states and 6 U.S. Territories, and they bring with them different state laws, different reasons for being implanted, different follow-up treatment, and different risks raised by their implant and treatments.

Given this diversity, the cohesion needed for classwide resolution under Federal Rule of Civil Procedure 23(b)(3) and 23(b)(2) is absent and class certification for these nationwide classes is not possible. Because these problems

[1] Anaplastic Large Cell Lymphoma, or "ALCL" is a type of non-Hodgkin lymphoma, classified as a "rare cancer" by the National Institutes of Health. "Anaplastic large cell lymphoma," available at < https://rarediseases.info.nih.gov/diseases/3112/anaplastic-large-cell-lymphoma >.

are evident from the face of the complaint, this Court can and should act on them *now*, at the pleading stage, before Plaintiffs' overreaching CAC derails this MDL.

That Plaintiffs have failed to plead any potentially certifiable class is hardly a novel conclusion. No federal Court of Appeals has approved nationwide classes of this magnitude for claims involving actual or threatened personal injuries because of the inherently individualized legal and factual inquiries that lie at the heart of the claims as alleged. The same is true for the medical monitoring classes alleged here as case-after-case provides.

Plaintiffs' proposed classes would require the Court to ferret out and apply the substantive laws of the 50 states and 6 U.S. territories governing negligence, strict products liability, breach of warranty, consumer fraud and deceptive practices, unjust enrichment, rescission, and medical monitoring. But the laws of these states and territories are not uniform, making it impossible to fashion a set of classwide legal principles. That barrier to nationwide class certification is only the beginning.

With respect to both the nationwide and statewide classes, any attempt to resolve the liability, causation, and injury issues arising from Plaintiffs' diverse set of claims would engender more individualized factual inquiries involving each class member. These inquires would at a minimum cover the reasons for implantation of their devices, their medical histories before, during, and after implantation, and their alleged risk of injury now. And because the putative classes encompass devices from 37 different product lines implanted across two-plus decades, the risks, benefits, and state of the art with respect to each device will be a moving target for each class member as well. But that would not be the end of it. A jury would then

have to turn to Allergan's available defenses, generating still more individualized issues of law and fact before any resolution could be reached.

In these circumstances, it is apocryphal to say that any class representative is "typical" of another class member—and no one is. The notion that common issues predominate is a fiction as well, given the variations in state law and the need for individualized proof. And no one could describe a classwide trial of all these disparate issues as anything other than an unmanageable nightmare, light years away from the efficient method of resolution Rule 23 envisions. Thus, when the task at hand is considered, it is clear why no Court of Appeals has affirmed or condoned the certification of nationwide medical monitoring classes in circumstances like these.

Class certification is appropriate only where a rigorous analysis reveals that each one of Rule 23's requirements can be met. The claims alleged in the CAC cannot survive that analysis. Failing that, the law is equally clear that courts have no reservoir of discretion to bend Rule 23's requirements to hold to the contrary. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 622 (1997) ("Federal courts, in any case, lack authority to substitute for Rule 23's certification criteria a standard never adopted[.]"). Class litigation is the exception, not the rule, and when, as here, Rule 23's requirements cannot be met class certification must be denied. For more than twenty years, courts have been drawing that conclusion in cases involving personal injury claimants who attempt to form nationwide or statewide classes to adjudicate their disputes and obtain compensation for their injuries because such claims inherently call for individualized inquiries to resolve them. That result should follow here.

Plaintiff's CAC would push this MDL into a thicket of widely divergent state laws, onerous class-based discovery, and an unwieldy class trial. There is no basis in law or logic to go down that path. It is evident from the face of the complaint that the CAC does not satisfy Rule 23. Plaintiffs' class allegations should be stricken.

II. FACTUAL AND PROCEDURAL BACKGROUND

Allergan is a medical device and pharmaceutical company that manufactured the BIOCELL line of breast implant devices. By way of background, breast implants generally are used to replace breast tissue that has been surgically removed, to correct developmental defects, or to modify breast size and shape. (CAC ¶99.) They are filled with either saline or silicone gel. (CAC ¶100.) Allergan's BIOCELL line included a product called a tissue expander, which is a temporary inflatable device used only for some reconstruction patients, to stretch skin and muscle to create space for a permanent breast implant. (CAC ¶99.) Both the breast implants and tissue expanders in Allergan's BIOCELL line had a textured surface, which was intended to prevent surgical complications after implantation. (CAC ¶1.)

In July 2019, pursuant to an FDA request, Allergan voluntarily recalled various BIOCELL breast implants and tissue expanders. The CAC alleges that Plaintiffs and the putative class members were implanted with Allergan's recalled products and are now subject to an increased risk of contracting ALCL. (CAC ¶1.)

In the CAC, Plaintiffs assert claims for: (1) failure to warn (strict liability and negligence); (2) manufacturing defect (strict liability and negligence); (3) design defect (strict liability and negligence); (4) breach of implied warranty; (5) violations

of consumer fraud and deceptive practice statutes; (6) unjust enrichment; (7) declaratory relief; and (8) rescission.

Notably, none of the class members are identified in the CAC as having developed ALCL. (CAC ¶269.) Rather, Plaintiffs seek classwide relief in the form of "a Court-supervised, Defendant-funded" medical monitoring program, which will "include a trust fund" to pay for medical monitoring and diagnoses "as frequently and appropriately as necessary." (CAC ¶¶5512, 5528, 5545, 5562, 5579, 5596 5613.) In support of that request, the CAC requests that three classes be certified:

The Nationwide Class. Plaintiffs seek certification of a nationwide class consisting of all patients who were implanted with Allergan's devices, but have not been diagnosed with ALCL. They demand relief in the form of medical monitoring:

> **Nationwide Class**: All individuals in the United States and its territories who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants, FDA-recalled Allergan tissue expanders for the breast that have BIOCELL texturing, and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

(CAC ¶269.)[2]

[2] As written, Plaintiffs' nationwide and subclass definitions purport to include all persons "who, for personal use, implanted" Allergan's products. In other words, the CAC defines the putative classes as persons who implanted Allergan devices *into* patients—i.e., implanting surgeons. Allergan assumes of course that Plaintiffs mean to allege that the putative class consists of persons implanted *with* Allergan's breast implant devices.

The "State" and "Non-PMA Device State" Subclasses. Plaintiffs also allege two broad categories of nearly identical subclasses—112 in all—that divide the nationwide class according to geography and devices implanted. As with the nationwide class, Plaintiffs seek medical monitoring.

Plaintiffs first allege fifty-six (56) "State" subclasses comprised of all persons respectively living in each of the fifty states and six U.S. Territories who received the subject devices. (CAC ¶¶270-325.) The definition for each of these subclasses is identical, except for the particular state or U.S. Territory in which subclass members reside. The New Jersey State Subclass is typical:

> **New Jersey Subclass**: All individuals in New Jersey who, for personal use, implanted FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants, FDA-recalled Allergan Natrelle Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Textured Breast Implants; FDA-recalled Allergan Natrelle 133 Plus Tissue Expanders; FDA-recalled Allergan Natrelle 133 Tissue Expanders with Suture Tabs; and/or McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

(CAC ¶302.)

Plaintiffs also allege fifty-six (56) "Non-PMA Device State" subclasses comprised of all persons respectively living in each of the fifty states and six U.S. Territories who were implanted with certain Allergan devices before May 10, 2000 (the date Allergan first received PMA Approval for one of its device). (CAC ¶¶327-382.) Here, again, New Jersey serves as an example:

> **New Jersey Non-PMA Device Subclass**: All individuals in New Jersey who, for personal use, implanted (i) FDA-recalled Allergan Natrelle Saline-Filled Textured Breast Implants (formerly McGhan RTV Saline-Filled Mammary Implant) prior to PMA approval (i.e., May 10, 2000), (ii) FDA-recalled Allergan Natrelle 133 Plus Tissue Expander, (iii) FDA-recalled Allergan Natrelle 133 Tissue Expander with Suture Tabs, and/or (iv) McGhan BioDIMENSIONAL Silicone-Filled BIOCELL Textured Breast Implants, Style 153 and who have not been diagnosed with breast implant-associated anaplastic large cell lymphoma.

(CAC ¶359.)

The Release Subclass. Lastly, Plaintiffs seek certification of a "Release Subclass" comprised of all individuals who received a subject device and signed a warranty release:

> **Releases [sic] Subclass:** All individuals in the United States who: (i) for personal use, implanted Allergan Natrelle Saline-Filled Textured Breast Implants, Allergan Natrelle Silicone-Filled Textured Breast Implants, Allergan Natrelle 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants, Allergan Natrelle 133 Plus Tissue Expander, or Allergan Natrelle 133 Tissue Expander with Suture Tabs that have been recalled by the FDA; and (ii) signed a *ConfidencePlus* Warranty Release or *ConfidencePlus* Premium Warranty Release.

(CAC ¶383.)

Plaintiffs allege that Allergan provided the *ConfidencePlus*® warranty to patients receiving the devices, but improperly required the putative class members to sign releases of liability in connection with processing warranty claims related to the removal (or "explant") of their devices. (CAC ¶¶7026-29.) They assert three counts on behalf of this subclass: (1) declaratory relief under the Federal Declaratory Judgment Act that the releases are void on public policy grounds; (2) identical relief

under the New Jersey Declaratory Judgment Act; and (3) rescission. (CAC ¶¶ 7050, 7079, 7112.)

Two other procedural developments bear mention. First, Plaintiffs filed their Master Long Form Complaint for Personal Injuries, Damages, and Demand for Jury Trial on May 26, 2020. (MDL No. 2921, Dkt #119.) But the dockets in the MDL, and the individual cases comprising it, reveal that none of the 250-plus individual plaintiffs have adopted the Master Complaint—even though the Plaintiffs' Steering Committee represents almost 75% of those plaintiffs. (*See, e.g.*, Dockets in MDL No. 2921, *Edwards v. Allergan Inc.*, No. 20-cv-09218; *Johnson v. Allergan Inc.*, No. 20-cv-09228; *Vargas v. Allergan Inc.*, No. 20-cv-09057.) Second, Plaintiffs filed an Emergency Motion to Limit Communications with Class Members and Their Physicians, Void Release Signed by Class Members, and Issue Corrective Notice, which this Court recently granted in part and denied in part. (MDL No. 2921, Dkt #144.) In its Order, the Court declined to invalidate the releases, instead directing the parties to meet and confer regarding revisions to the release language, as well as notice to putative class members who already have signed releases. (*Id*. at p.18.) The Court also stated: "Any determination regarding the legal impact of those releases should be made on a case-by-case basis at a later date." (*Id*.)

III. STANDARD OF REVIEW

A court should consider whether an alleged class can be certified "[a]t an early practicable time after a person sues or is sued as a class representative." Fed. R. Civ. P. 23(c)(1)(A). *Mladenov v. Wegmans Food Mkts., Inc.*, 124 F. Supp. 3d 360, 368,

372 (D.N.J. 2015) (striking class allegations *sua sponte* before defendants filed motion to strike). Where the class complaint is fundamentally deficient, courts have discretion to strike or dismiss class allegations *at the pleading stage* before discovery is commenced or a motion for class certification is filed. *See* Fed. R. Civ. Proc. 23(d)(1)(D) ("court may issue orders that … require that the pleadings be amended to eliminate allegations about representation of absent persons and that the action proceed accordingly"); *id.* at 12(f) ("The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter."); *Landsman & Funk PC v. Skinder-Strauss Assocs.*, 640 F.3d 72, 93 n.30 (3d Cir. 2011).

Courts thus can and should strike class allegations "where the complaint itself demonstrates that the requirements for maintaining a class action cannot be met." *Advanced Acupuncture Clinic, Inc. v. Allstate Ins. Co.*, 2008 WL 4056244, at *7 (D.N.J. Aug. 26, 2008); see *Lafferty v. Sherwin-Williams Co.*, 2018 WL 3993448, at *6 (D.N.J. Aug. 21, 2018) (striking class allegations because individual inquiries would be "essential" to the case); *Semeran v. BlackBerry Corp.*, 2016 WL 3647966, at *6 (D.N.J. July 6, 2016) (striking class allegations with prejudice for a "clear lack of standing"). When the face of the CAC is examined here, it is apparent that the claims made in the nationwide classes will not be amenable to classwide resolution

under Rule 23. Allergan's motion to strike or dismiss the class allegations accordingly should be granted.[3]

IV. LEGAL ARGUMENT

"Federal Rules of Civil Procedure 23(a) and (b) set the requirements for class certification. Rule 23(a) requires that (1) the class must be so numerous that joinder of all members is impracticable (numerosity); (2) there must be questions of law or fact common to the class (commonality); (3) the claims or defenses of the representative parties must be typical of the claims or defenses of the class (typicality); and (4) the named plaintiffs must fairly and adequately protect the interests of the class (adequacy of representation, or simply adequacy)." *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184, 190 (3d Cir. 2020) (internal quotations and citation omitted). Each one of Rule 23(a)'s requirements must be met. If not, then the class certification analysis is over. Class certification must be denied. *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 182 (3d Cir. 2001) ("If the class does not satisfy each of the 23(a) criteria, the suit cannot be maintained as a class action.").

If Rule 23(a)'s requirements are met, then the certification analysis turns to Rule 23(b) and its subparts. Here, Plaintiffs seek certification under Rule 23(b)(3) and 23(b)(2). To start with, "[u]nder Rule 23(b)(3), two additional requirements must be met in order for a class to be certified: (1) common questions must

[3] In bringing this motion now, Allergan does not waive its ability to re-assert these arguments, or raise different or additional ones, in any subsequent class certification proceeding.

'predominate over any questions affecting only individual members' (the 'predominance requirement'), and (2) class resolution must be 'superior to other available methods for the fair and efficient adjudication of the controversy' (the 'superiority requirement')." *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 527 (3d Cir. 2004).

As for Rule 23(b)(2), it supports a class action if the requirements of Rule 23(a) are satisfied and "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." Fed. R. Civ. P. 23(b)(2). In other words, classes under Rule 23(b)(2) are "limited to those class actions seeking primarily injunctive or corresponding declaratory relief." *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 142 (3d Cir. 1998); *see also In re Ford Motor Co. E-350 Van Prods. Liab. Litig. (No. II)*, 2012 WL 379944, at *38 (D.N.J. Feb. 6, 2012) (the "primary focus" of a Rule 23(b)(2) class is on injunctive or declaratory relief). "[A]n action for money damages may not be maintained as a Rule 23(b)(2) class action." *In re School Asbestos Litig.*, 789 F.2d 996, 1008 (3d Cir. 1986) (Rule 23(b)(2) "does not extend to cases in which the appropriate final relief relates exclusively or predominantly to money damages").

On balance, Rule 23's requirements are intended to determine whether the joinder of a number of claimants can provide a more efficient path to resolution. Where the adjudication of the representative plaintiffs' claims will serve to resolve the claims of the absent class members, those efficiencies can be achieved. Where the adjudication of the representative plaintiffs' claims will resolve nothing but their

own lawsuits, however, no efficiencies are achieved through classwide joinder. Thus, when the record reveals that numerous individualized legal and factual issues will need to be resolved to decide the class members' claims, Rule 23's provisions for classwide adjudication have no utility.

Here, the CAC reveals that individual inquiries will abound, meaning that Rule 23(a)'s typicality requirement is not met and class certification is not possible under either prong of Rule 23(b). Apart from that, the CAC, on its face, also shows that Rule 23(b)(3)'s predominance requirement cannot be met either. Further, the need for those individualized inquiries means that a classwide trial is not the superior method of resolution. Finally, the lack of cohesion in the class and the nature of the relief sought also establishes that class certification under Rule 23(b)(2) is not possible as well.

A. Plaintiffs Cannot Satisfy The Typicality Requirement Under Rule 23(a)

Rule 23(a)'s requirements are intended to ensure that the class is sufficiently numerous, that it will be properly represented, that the class members share common interest, and that the class representatives' claims are typical of the members of the class. But the reality is that Plaintiffs' nationwide class and subclasses come up short on the representation, commonality, and typicality requirements. This motion will focus on the lack of typicality. The failure to satisfy that requirement alone is sufficient to support a motion to strike all the class allegations.

Under Rule 23(a), typicality means that "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). "[T]he typicality requirement is meant to ensure that class representatives are sufficiently *similar* to the rest of the class—in terms of their legal claims, factual circumstances, and stake in the litigation." *In re Schering Plough Corp. ERISA Litigation*, 589 F.3d 585, 600 (3d Cir. 2009). The necessary similarity is missing in this case.

The CAC identifies 63 named Plaintiffs, who were, during "all relevant times," citizens of 39 different states, except for one who was a citizen of both Illinois and Arizona during the class period [CAC ¶38]. (CAC ¶¶22-84.) None of the named Plaintiffs are citizens of any U.S. Territories. The CAC also alleges that the putative class consists of persons implanted with 246,381 devices spanning 37 different device lines over a 23-year period. But just as with the respective states and territories, the class representatives do not represent all the devices either. For example, the putative class purports to include persons implanted with a Style 153 breast implant, but not a single named Plaintiff alleges being implanted with that particular device. At this most basic level, therefore, the putative class is under-represented and the typicality requirement is not met.

First, there is a failure of representation by jurisdiction. This failure of representation means: (1) 32 subclasses have no representative Plaintiff from their state or territory at all; (2) many of the dual subclasses for each jurisdiction either lack or share a representative; and (3) an unknown number of unidentified named Plaintiffs are purporting to represent the claims of a state or territory of which they are not citizens.

Second, there is a failure of representation by device. The class representatives were not implanted with the entire range of devices over the many years for which relief is sought, and many punitive class members will go unrepresented for this reason as well. But a named plaintiff's claims cannot be typical of any claims brought under the laws of states or territories in which she does not live or was not injured. Nor can they be typical of a device with which she was not implanted.

Because the named representatives do not have claims typical of the entire putative classes, whether nationwide or statewide, the typicality requirement in Rule 23(a) is not met. *See Orr v. Shicker*, 953 F.3d 490, 500 (7th Cir. 2020) ("Typicality requires enough congruence between the named representative's claim and that of the unnamed members of the class to justify allowing the named party to litigate on behalf of the group. As there is no named representative, there is no way to compare anyone's claims with those of the absentees.") (internal quotation marks omitted); *Rapcinsky v. Skinnygirl Cocktails, LLC*, 2013 WL 93636, at *6 (S.D.N.Y. Jan. 9, 2013) ("It is axiomatic that a class representative must be part of the class and possess the same interest and suffer the same injury as the class members. … Here, while the nature of the alleged injury may be the same, [Plaintiff,] having not purchased his products in New York, is an atypical representative of the New York class he purports to represent."); *In re Telectronics Pacing Sys.*, 168 F.R.D. 203, 218 (S.D. Ohio 1996) (finding that the named plaintiff, "an Ohio resident, does not have claims typical of class members who are residents of states that either recognize common law negligence or that do not recognize strict liability").

For the same reason, the named Plaintiffs lack standing to represent the claims of putative classes from states or territories in which the named Plaintiffs do not live. *See In re Insulin Pricing Litig.*, 2019 WL 643709, at *16-17 (D.N.J. Feb. 15, 2019) (Martinotti, J.) (dismissing seventeen state law counts "under the laws of states in which no named plaintiff resides or is alleged to have made any purchases of the subject [medical device]" as the named plaintiffs could not allege any injury in those states and thus lacked Article III standing to represent those state subclasses"); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 157-58 (E.D. Pa. 2009) (dismissing claims under the laws of states "where no named plaintiff is located and where no … named plaintiff purchased" the drug at issue, because the they "provide[d] no facts on which to find a connection between an alleged injury and some wrongful conduct that would implicate the laws of those states in which no plaintiff … resides").

And on further analysis, the lack of typicality between the named representatives in the nationwide and statewide classes and the absent class members runs much deeper than this lack of representation. It is also apparent that the claims of each representative Plaintiff are atypical of each other's, just as they are atypical of the other putative class members'. This atypicality is inherent in the claims being made. The foundational facts that support the underlying liability claims—like negligence, strict liability and consumer fraud—are unique to each class member. The same goes for the medical monitoring relief sought. Atypicality extends to legal issues as well. The laws of the 56 states and territories differ to varying degrees and litigating a claim for an individual from one state will not be typical for litigating a

claim for anyone from another state. In the end, each class members' claims are typical only of their own. For example:

Device And Implant Period. Not every class representative or class member received the same device or has kept her implant for the same length of time. The putative classes consist of persons who received one or more devices from Allergan's 37 breast implant device lines between 1996 and 2019. (CAC, p. 1, fn. 1, ¶¶ 57, 71, 74.) These devices are not limited to breast implants, but include tissue expanders (which are typically intended for short term use to prepare breast tissue for permanent implantation of breast implants), as well as Style 153 devices that were part of a clinical study but ultimately discontinued. Some class members have had their devices since 1997, while others might be more recently implanted, and still others fall somewhere in between. Some putative class members also had their devices explanted at various points during the relevant period.

Device State Of The Art. Additionally, Plaintiffs allege that the information available to Allergan, as well as the scientific and medical communities, has evolved over two-plus decades. For example, Plaintiffs allege that studies or information about the risks of ALCL came to light in 1997, in 2003, 2004, 2011, and then every year from 2014 to 2018. (CAC, ¶ 142-45, 147-50, 153, 161.) They further allege that "[b]eginning at least as early as 2006, Allergan possessed information and evidence demonstrating that its Recalled BIOCELL Implants posed a significant risk of []ALCL." (CAC ¶218.) Every one of those years reflects an evolution in the state of the art and Allergan's attendant knowledge of the risks of ALCL during that period.

Different Outcomes. Moreover, every Plaintiff—named or putative—will face different outcomes over different periods. Even Plaintiffs acknowledge that the risk of contracting ALCL is very small. The CAC alleges that the risk of contracting ALCL "is generally believed to be 1/300,000." (CAC ¶158.) It also alleges that the estimated risk of contracting ALCL for women with textured implants can vary wildly—some estimate the risk to be from 1/3,817 to 1/30,000, while others estimate 1/2,217 to 1/86,029. (CAC ¶158.) Stated another way, some Plaintiffs unfortunately may develop ALCL, but the vast majority likely will not. At the same time, the levels of medical monitoring required will vary depending on what level of risk a given jurisdiction considers "significant" for medical monitoring purposes. The risk inevitably varies among the named Plaintiffs, depending on their length of exposure and other factors, as well as between the named Plaintiffs and members of the putative class.

Foundational Facts. There is more. These individual differences also have consequences as far as the various liability theories are concerned. The circumstances giving rise to Allergan's liability—including issues such as state of the art of the devices at issue—will differ from Plaintiff to Plaintiff, depending on when they were implanted or how long they had their implants. With respect to the foundational facts needed to resolve Allergan's alleged liability, the state of the art will differ, for a plaintiff implanted with a tissue expander for six months in 2004 is not in the same position as a Plaintiff who received a breast implant in 2017 and still has her implant.

Similarly, whether Allergan can be liable for failure to warn depends on what Allergan knew at the time each respective Plaintiff was implanted—a necessarily individualized inquiry given the wide variability in the scientific knowledge throughout the 20-plus year period alleged in the complaint. Also, in the many states adopting the learned intermediary doctrine, Allergan satisfied its duty to warn by informing implanting surgeons rather than the Plaintiffs themselves. Thus, what each implanting surgeon knew or understood about ALCL risks is crucial for establishing liability under these states' laws. That adds another layer of complexity and is, of course, is an inherently individual inquiry.

As this analysis illustrates, resolving each class member's claims will require exploring the facts surrounding implantation, medical history, and post-implant or extended care and treatment. There will be a need to know what device was implanted and when. These foundational facts must then be applied to the underlying legal theories, all of which have elements whose resolution will depend on each class member's foundational facts and the applicable controlling law.

At a bare minimum, the typicality requirement demands a level of similarity in legal and factual circumstances between the class representatives and the class members that provides assurances that their respective claims are enough alike to support classwide resolution. On examination, the opposite is true here and the CAC's class certification allegations should be stricken for this reason alone.

B. Plaintiffs Cannot Satisfy Rule 23(b)(3)

When class certification turns to the predominance and superiority requirements in Rule 23(b)(3), the analysis, as with typicality, looks at the number

of individualized inquiries that will be necessary to resolve each class member's claim. Classwide resolution requires common issues to predominate so that the resolution of the class representative's claims at trial can be applied to the claims of the putative class. Where common issues predominate, resolution in a classwide trial can be viewed as an efficient, and thus superior, method of resolving the putative class members' claims.

But when the various claims made here are subject to the requisite rigorous analysis, a distinct lack of predominance emerges. Unique issues requiring individualized resolution permeate the underlying claims. This extends, in particular, to the medical monitoring relief sought. The pervasive need for individualized resolution, on both law and fact, renders a classwide trial unmanageable in all its particulars. As a result, such a trial is by no means a superior method of resolution.

None of these conclusions, as noted at the outset, are novel. The lack of predominance for nationwide or statewide classes bringing product liability or consumer fraud claims and asking for medical monitoring relief has been recognized in hundreds of cases over more than twenty years. These breast implant cases raise the same unique issues and are just as unsuitable for classwide resolution.

1. Individual Issues Predominate In Plaintiffs' Product Liability And Medical Monitoring Claims

The nationwide medical monitoring classes alleged here cannot meet Rule 23(b)(3)'s predominance requirement for two fundamental reasons: (1) medical monitoring and product liability laws differ widely between the states, so there is no

uniformity in the applicable law; and (2) in nearly all those states allowing medical monitoring under any circumstances, the liability and causation inquiries are highly individualized and not susceptible to classwide proof. The statewide medical monitoring classes, moreover, fail the predominance requirement.

a) Plaintiffs' Nationwide Class Allegations Raise Individualized Legal Questions That Are Not Suitable For Classwide Adjudication

Nationwide class actions require an "extensive analysis" of state law variances so "that class certification does not present insuperable obstacles." *In re School Asbestos Litig.*, 789 F.2d at 1010; *see also Castano v. Am. Tobacco Co.*, 84 F.3d 734, 750 (5th Cir. 1996) (Rule 23 requires courts to "determine whether variations in state law defeat predominance"); *Sanders v. Johnson & Johnson, Inc.*, 2006 WL 1541033, at *4 (D.N.J. June 2, 2006) ("Differences in state law, no matter how slight, are important and must be determined prior to certification."). "In a multi-state class action, variations in state law 'may swamp any common issues and defeat predominance.'" *Grandalski v. Quest Diagnostics, Inc.*, 767 F.3d 175, 180 (3d Cir. 2014) (quoting *Castano*, 84 F.3d at 741).

Here, given the sweeping nature of the CAC—which even Plaintiffs concede requires 63 class representatives and 112 subclasses—this Court will have to apply different and varying substantive laws from numerous states in order to adjudicate Plaintiffs' claims. The need to apply the laws of the various states to resolve the class members' claims shows a lack of predominance. That legal diversity calls for

individualized resolution, undermining the very concept of efficient classwide adjudication.

For example, states vary widely regarding the availability of medical monitoring. At least half do not allow medical monitoring at all. Those states that allow medical monitoring also treat it differently—some require the plaintiff to have a physical injury while others do not, and some treat medical monitoring as a standalone tort while others treat it as an element of damages. *See In re Aredia & Zometa Prods. Liab. Litig.*, 2007 WL 3012972, at *5 (M.D. Tenn. Oct. 10, 2007) ("[T]he laws concerning medical/dental monitoring vary from state to state."); *Foster v. St. Jude Med., Inc.*, 229 F.R.D. 599, 602 (D. Minn. 2005) ("The states are not uniform in their treatment of medical monitoring claims.").[4]

Because of this legal diversity, as case after case has held, a multi-state medical monitoring class is not suitable for classwide resolution under Rule 23. The need to apply the laws of multiple states destroys predominance. *See, e.g.*, *Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1189 (9th Cir. 2001) (affirming denial of medical monitoring class and rejecting plaintiff's contention that "predominance is not destroyed and the case is still manageable as a class action despite the application of the law of multiple jurisdictions."); *In re Nat'l Hockey League Players' Concussion Injury Litig.*, 327 F.R.D. 245 (D. Minn. 2018); *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555, 569 (E.D. Ark. 2005) (denying certification

[4] Allergan has provided a breakdown of the state law variations regarding medical monitoring in pages 20-25 of Appendix A to its 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).

because the class would require application of twenty-four states' medical monitoring laws and those states "differ greatly on their approach to medical monitoring both as a cause of action and as a remedy."); *Foster,* 229 F.R.D. at 605 ("claims for medical monitoring are not treated uniformly among the states, and this divergence creates a 'myriad of individual legal issues that defeat the predominance requirement' and makes certification 'totally unmanageable and inefficient.'" (citation omitted)); *Zehel-Miller v. AstraZenaca Pharm., LP*, 223 F.R.D. 659, 663 (M.D. Fla. 2004) ("The fact that medical monitoring is not treated uniformly throughout the United States creates a myriad of individual legal issues that defeat the predominance requirement of Rule 23(b)(3).").

Not only are the state laws relating to medical monitoring divergent but the substantive law underlying Plaintiffs' claims is balkanized as well. That matters here because in some states permitting medical monitoring, it is a form of relief rather than a substantive claim on its own. Medical monitoring relief thus has to be supported by an underlying substantive claim and there is no uniformity in the various states' laws in that regard.[5] Just last month, the district court in *Adams Pointe I, LP v. Tru-Flex Metal Hose Corp.*, 2020 WL 4199557 (W.D. Pa. July 17, 2020), made this very point in rejecting a nationwide product liability class action:

> As for Plaintiffs' claim for strict products liability, there is no monolithic products liability law in the United States, and each state

[5] As with medical monitoring, Allergan also has provided a breakdown of the myriad differences in state laws controlling the putative class members' substantive claims. (*See* Appendix A to 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))

> varies greatly with regard to the elements of a strict products liability cause of action. The same reasoning applies to Plaintiffs' negligence claims, in which there is no uniform cause of action that applies nationwide. The court would be forced to apply an individualized analysis to each Plaintiffs' claims resulting in a "proliferation of disparate … legal issues" which would compound exponentially.

Id. at *10 (quoting *Georgine v. Amchem Prods.*, 83 F.3d 610, 627 (3d Cir. 1996) (other citations omitted); *see also In re Paxil,* 212 F.R.D. 539, 551 (C.D. Cal. 2003) ("differing standards of liability required by laws of various states preclude a finding that common questions of law predominate"); *Mack v. General Motors Acceptance Corp.,* 169 F.R.D. 671, 678 (M.D. Ala. 1996) (case with varying state law claims is "the antithesis of a class action").

The innumerable differences among states' respective laws regarding negligence and strict product liability[6], state consumer fraud and deceptive trade

[6] *See, e.g.*, *In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1085 (6th Cir. 1996) ("The law of negligence, including subsidiary concepts such as duty of care, foreseeability, and proximate cause, may … differ among the states only in nuance … [b]ut nuance can be important, and its significance is suggested by a comparison of differing state pattern instructions on negligence and differing judicial formulations of the meaning of negligence and the subordinate concepts."); *Matter of Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1300 (7th Cir. 1995) (denying certification of nationwide class because the jury "will receive a kind of *Esperanto* instruction, merging the negligence standards of the 50 states and the District of Columbia"); *Duncan v. Nw. Airlines, Inc.*, 203 F.R.D. 601, 613-14 (W.D. Wash. 2001) ("As described earlier, the laws of negligence and medical monitoring differ from state to state and often remain ambiguous.").

practices[7], unjust enrichment[8], and breach of implied warranty. The diversity in the states' laws compelled rejection of nationwide classes in all of these cases and the same analysis applies here, too. The state-by-state differences in the various substantive elements required to state a claim overwhelm any suggestion of predominance. No amount of pleading or discovery can change that. The CAC's class allegations should be stricken for this independent reason.

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[7] *See In re Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, 194 F.R.D. 484, 489 (D.N.J. 2000) (denying certification because consumer protection statutes vary widely from state to state); *Andren v. Alere, Inc.*, 2017 WL 6509550, at *17 (S.D. Cal. Dec. 20, 2017) (noting "material differences among the states on a fraud cause of action," and "important and meaningful differences between the consumer protection laws of certain states as to the elements of proof of injury, need for proof of actual deception, whether scienter is required, whether reliance is required, whether relief is limited to equitable relief or damages, whether pre-filing notice is required and the varying statute of limitations"); *In re Digitek Prods. Liab. Litig.*, 2010 WL 2102330, at *8 (S.D.W. Va. May 25, 2010) (courts have "overwhelmingly" found "material conflicts among the fifty states' laws on the [consumer fraud] claims plaintiffs bring in this case and have denied class certification, at least in part, on that basis").

[8] *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 591 (9th Cir. 2012) ("The elements necessary to establish a claim for unjust enrichment also vary materially from state to state."); *Colley v. Procter & Gamble Co.*, 2016 WL 5791658, at *7 (S.D. Ohio Oct. 4, 2016) ("Varying state laws preclude Plaintiffs from pursuing an unjust enrichment claim on behalf of a nationwide class."); *Tyler v. Alltel Corp.*, 265 F.R.D. 415 (E.D. Ark. 2010) ("the law of unjust enrichment varies materially from state to state"); *In re Digitek*, 2010 WL 2102330, at *8 (courts have "overwhelmingly" found "material conflicts among the fifty states' laws on the [unjust enrichment] claims plaintiffs bring in this case and have denied class certification, at least in part, on that basis"); *Clay v. Am. Tobacco Co.*, 188 F.R.D. 483, 501 (S.D. Ill. 1999) ("variances exist in state common laws of unjust enrichment" and "the claim of unjust enrichment is packed with individual issues and would be unmanageable").

b) Plaintiffs' Class Allegations Raise Individualized Factual Questions That Are Not Suitable For Classwide Adjudication

As many courts also have held, nationwide or statewide classes seeking medical monitoring relief, as supported by substantive claims of any stripe, also fail to meet the predominance requirement in Rule 23(b)(3) because the class member's claims demand individualized resolution. A class action has no utility in this circumstance either.

1. Multi-Plaintiff Nationwide Medical Monitoring Claims

Over 50 years ago, the drafters of Rule 23's amendments recognized that multi-plaintiff personal injury actions raise highly individualized factual questions that were inimical to class treatment:

> A "mass accident" resulting in injuries to numerous persons is ordinarily not appropriate for a class action because of the likelihood that significant questions, not only of damages but of liability and defenses of liability, would be present, affecting the individuals in different ways. In these circumstances an action conducted nominally as a class action would degenerate in practice into multiple lawsuits separately tried.

Fed. R. Civ. P. 23(b)(3) Advisory Notes to 1966 Amendment.

Echoing the drafters' concerns, the Third Circuit has expressed this same sentiment in the context of products liability claims like those that are part of the CAC in this case. In its seminal *Georgine v. Amchem* opinion, the court explained that "[i]n products liability actions … individual issues may outnumber common issues." 83 F.3d at 628. This is because "[n]o single happening or event occurs to

cause similar types of physical harm or property damage. No one set of operative facts establishes liability. No single proximate cause applies equally to each potential class member and each defendant. Furthermore, the alleged tortfeasor's affirmative defenses (such as failure to follow directions, assumption of the risk, contributory negligence, and the statute of limitations) may depend on facts peculiar to each plaintiff's case." *Id.*

The consequences of this factual diversity for class certification were immediately apparent to the Court: "[e]ven if we were to assume that some issues common to the class beyond the essentially settled question of the harmfulness of asbestos exposure remain, the huge number of important individualized issues overwhelm any common questions. Given the multiplicity of individualized factual and legal issues, magnified by choice of law considerations, we can by no means conclude that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members." *Id*. (quotation marks omitted).

Numerous district courts in this Circuit have rejected class certification in cases like these for similar reasons. In *Sanders*, the district court declined to certify a nationwide medical monitoring class involving a different surgical implant. The district court granted the defendants' motion to strike the class allegations and denied the cross-motion for certification of a nationwide medical monitoring class, in large part because common questions of law and fact did not predominate over individual ones. 2006 WL 1541033, at *2-3, *11 (Brown, C.J.). The court explained:

> Although there would be some common factual issues between members of the Proposed Class, they would not predominate over the individualized ones. In proving their claims, class members would have to provide facts showing the circumstances of how they were injured. Those facts include their reasons for using [the device], whether prior medical conditions caused their alleged injuries, what they understood about the risks of using [the device] when they used the product and the adequacy with which their physicians performed the surgery resulting in the use of the product.

Id. at *6.

Sanders is hardly alone. *See Blain v. Smithkline Beecham Corp.*, 240 F.R.D. 179, 190 (E.D. Pa. 2007) ("Predominance poses a problem for certification in drug product liability cases. Individual issues in such cases invariably overwhelm common ones," such as "medical histories," "the roles of the physician and the physical characteristics in each individual's case …."); *Reilly v. Gould, Inc.*, 965 F. Supp. 588, 598, 603-05 (M.D. Pa. 1997) (granting motion to dismiss personal injury class allegations in medical monitoring case because of individualized issues); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1995 WL 273597, at *10-11 (E.D. Pa. Feb. 22, 1995) (courts routinely "refuse[] to certify classes in actions alleging defective medical products" because the "measure of damages will be dependent almost exclusively on individual factors" such as "causation, liability, and damages," and "there are not enough common questions of law or fact to warrant the use of the class mechanism.")

Barraza v. C. R. Bard, Inc., 322 F.R.D. 369 (D. Ariz. 2017), is particularly instructive on the specific claims in the CAC. The *Barraza* plaintiffs filed a putative class action lawsuit on behalf of patients implanted with an inferior vena cava filter

and sought medical monitoring. *Id.* at 373-74. They asserted a single class consisting of filter recipients who resided in sixteen states that permitted medical monitoring. *Id.* at 374. After realizing that "significant differences" existed between the laws in those sixteen medical monitoring states, the plaintiffs changed course and sought to certify sixteen state specific subclasses instead of a nationwide class. *Id.* at 374-75. But Plaintiffs' maneuvers failed because, no matter how structured, "individual issues will predominate" between the plaintiffs in each subclass. *Id.* at 384.

Barraza further rejected the argument that medical monitoring made all these highly individualized inquiries disappear. While the plaintiffs argued that they face "a common risk and need medical monitoring" that sufficed to certify the class, the court emphasized that the plaintiffs "must also show that Defendants were negligent and caused Plaintiffs' increased risk." *Id.* at 381. "And," in *Barraza*, "it is in proving negligence that individual issues will proliferate." *Id.* The court continued:

> Filter-by-filter inquiries into design and manufacturing defects will be required; at each step, the state of the art must be examined; failures to disclose will vary from year to year and filter to filter; the knowledge possessed by each class member's physician must be established to resolve the learned intermediary defense; and each class member's knowledge of the risk and response to suggestions of removal or medical monitoring will be needed to resolve defenses of assumption of the risk and contributory or comparative negligence.

Id. Moreover, individual inquiries were required regarding "whether the proposed medical monitoring is necessary and distinct from the ordinary course of treatment

the class member is receiving," and "what state's law should apply to each class member's claim." *Id.* at 384.

There is no daylight between *Sanders, Barraza,* and Plaintiffs' case here. Just as each of Plaintiffs' theories of liability arises from disparate state law, each theory also gives rise to an overwhelming number of individualized factual inquiries that preclude use of the class action device. This holds true regardless of whether Plaintiffs want to certify a nationwide class or state subclasses.

Thus, even for states permitting medical monitoring, "each plaintiff's need (or lack of need) for medical monitoring is highly individualized." *In re St. Jude*, 425 F.3d 1116, 1122 (8th Cir. 2005). The plaintiffs ordinarily cannot prove the medical necessity of their "proposed monitoring regime without further individual proceedings to consider class members' individual characteristics and medical histories and to weigh the benefits and safety of a monitoring program." *Gates v. Rohm & Haas Co.*, 655 F.3d 255, 269 (3d Cir. 2011).

Consequently, classwide resolution is incompatible with these circumstances. *See id.*; *accord Barnes*, 161 F.3d at 143 (affirming decertification of class action where too many individual issues existed, including the need for medical monitoring); *In re Fosamax Prods. Liab. Litig.*, 248 F.R.D. 389, 401 (S.D.N.Y. 2008) ("almost every element of a medical monitoring claim … would present case-specific questions that are central to whether class members entitled to recovery in this case. These individualized questions clearly predominate over any common questions in the case."); *Perez v. Metabolife Int'l, Inc.*, 218 F.R.D. 262, 271 (S.D. Fla. 2003) (increased risk of injury is "particularly unsuitable for class treatment");

In re Prempro, 230 F.R.D. at 570 (denying certification of medical monitoring class where "increased risk" could not be proven on a classwide basis); *Rowe v. E.I. DuPont de Nemours and Co.*, 2008 WL 5412912, at *20 (D.N.J. Dec. 23, 2008) ("the necessity for medical monitoring is not a common issue for all class members and, thus, is not subject to common proof."); *Rhodes v. E.I. DuPont de Nemours and Co.*, 253 F.R.D. 365, 380 (S.D.W. Va. Sept. 30, 2008) ("[I]ndividual inquiries into the need for medical monitoring ... would destroy the cohesiveness of the class.").

So it is here as well. Each Plaintiff's alleged increased risk of contracting ALCL may vary according to any number of individual factors. This may include how long the device was implanted, the surgical technique used, and perhaps even each Plaintiff's genetic susceptibility to developing ALCL. Relatedly, each Plaintiff's individual medical history could play a pivotal role in determining the benefits and safety of any medical monitoring regime, as well as how much monitoring each Plaintiff needs.

The cases cited are clear that it is impossible to make a uniform determination that all Allergan device recipients have the same increased risk of harm. The class allegations should be stricken for this reason, too. *See Lafferty v. Sherwin-Williams Co.*, 2018 WL 3993448, at *6 (D.N.J. Aug. 21, 2018) (dismissing medical monitoring claim because "individual fact finding is *essential* to determine whether one of these hazardous substances impacted someone. … Conducting such causative inquiries on a class-wide basis would be problematic and wildly inaccurate—individualized proceedings are necessary."); *O'Connor v. Boeing N. Am., Inc.*, 180 F.R.D. 359, 377 (C.D. Cal. 1997) ("individual issues, such as exposure level, family

history, and other risk factors, will dictate whether class members will qualify for the medical monitoring program Plaintiffs propose, which includes not only examinations, but treatment of diseases as well.").

2. Consumer Fraud And Unjust Enrichment

Plaintiffs allege that Allergan violated consumer fraud/protection statutes and is otherwise liable under unjust enrichment theories. But 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. As the cases routinely recognize, that inquiry is inherently individual. There is no way to adjudicate on a classwide basis whether and to what extent each Plaintiff relied on something Allergan said or didn't say about the risks of ALCL.

Thus, the predominance requirement "is extremely hard to meet when dealing with a case involving fraud and misrepresentation. Common law fraud and misrepresentation claims raise issues that are personal to each individual plaintiff." *Morgan v. Markerdowne Corp.*, 1999 WL 33542938, at *6 (D.N.J. Jan. 27, 1999). "To bring a common law fraud claim on behalf of a class, the representative plaintiff must prove that each member relied on the defendant's alleged misrepresentation and suffered damages because of the reliance … Many courts, however, have held that common law fraud and misrepresentation actions are inappropriate for treatment as a class action suit." *Id.*; *see In re Ford Motor Co.*, 2012 WL 379944, at *13 ("resolution of Plaintiffs' claims will require numerous individualized inquiries into

the alleged misrepresentation, whether it be an affirmative representation or omission."); *See Freedman v. Arista Records, Inc.*, 137 F.R.D. 225, 229 (E.D. Pa. 1991) ("One's [reliance] is personal and as such is not susceptible to a class-based definition.").

Courts routinely reject use of the class action in cases that require proof of reliance because "the very nature of the justified reliance inquiry is highly fact-specific." *Davis v. Bank of Am., N.A.*, 2016 WL 427049, at *5-6 (E.D. Pa. Feb. 3, 2016); *see Burstein v. Ret. Account Plan for Employees of Allegheny Health Educ. & Research Found.*, 2004 WL 2612162, at *5-6 (E.D. Pa. Oct. 21, 2004) ("As it is clear that proving the detrimental reliance element will involve factual disparities among the putative class members and thus present issues that preclude litigation as a class"); *Markocki v. Old Republic Nat'l Title Ins. Co.*, 2015 WL 3421401, at *6 (E.D. Pa. May 27, 2015) (holding that "decertification is necessary on the [consumer fraud] claim because the need to show each class member's justifiable reliance … [which] overwhelms common issues").

Product liability claims, like those made here, are no exception. *See Marcus v. BMW of North Am., LLC.*, 687 F.3d 583 (3rd Cir. 2012) (each plaintiff's knowledge about alleged tire defect was relevant to consumer fraud claim); *In re Prempro*, 230 F.R.D. at 567 (plaintiffs' fraud and unfair competition claims do not satisfy predominance requirement because they require a determination of reliance, which is inherently an individualized factual determination not "suitable for class-wide relief."); *In re St. Jude Med. Inc. Silzone Heart Valves Prods. Liab. Litig.*, 2009 WL 1789376 (D. Minn. June 23, 2009) (granting motion to strike plaintiff's

consumer protection class because it involves an individualized inquiry); *Dhamer v. Bristol-Myers Squibb Co.*, 183 F.R.D. 520, 533 (N.D. Ill. 1998) ("a nationwide class is not a superior method for resolving consumer fraud claims because each prospective plaintiff is going to be involved in extensive individualized proceedings whether a consumer fraud class is certified or not.").

The same holds true for unjust enrichment. *See Grandalski*, 767 F.3d at 184-85 (unjust enrichment claims turn on individualized questions and are inappropriate for class action treatment); *accord Fenwick v. Ranbaxy Pharm., Inc.*, 353 F. Supp. 3d 315 (D.N.J. 2018); *Sergeants Benevolent Ass'n. Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 2011 WL 824607 (E.D.N.Y. Feb. 16, 2011); *Thompson v. Bayer Corp.*, 2009 WL 2424352 (E.D. Ark. Aug. 6, 2009).

In sum, there is no avoiding the lack of predominance for the consumer fraud or unjust enrichment claims. Each theory must be resolved plaintiff-by-plaintiff on its own facts. Classwide resolution will not work for those claims either and the class allegations relating to them should be stricken.

3. Affirmative Defenses

There is yet another layer of individualized resolution involving each class member's claims. Allergan has an array of affirmative defenses that will require individualized findings of fact. For example, 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. Likewise, statute of limitations and statute of

repose defenses necessarily require an assessment of what each Plaintiff knew and when. These issues are not susceptible to common proof, either.

A class action is inappropriate where affirmative defenses would require individualized findings. *See, e.g.*, *Barnes*, 161 F.3d at 149 ("[W]e believe that determining whether each class member's claim is barred by the statute of limitations raises individual issues that prevent class certification."); *In re Fosamax*, 248 F.R.D. at 402 (comparative negligence and assumption of the risk "require assessment of what each class member knew of the risks of ONJ at the time he or she took Fosamax, for example from warnings given by the prescribing physician or through independent research"); *In re Prempro*, 230 F.R.D. at 567 ("assumption of the risk, contributory negligence, comparative negligence, and statutes of limitation all require individual determinations."); *O'Connor v. Boeing N. Am., Inc.*, 197 F.R.D. 404, 409 (C.D. Cal. 2000) (decertifying medical monitoring class in part due to "highly individualistic nature" of statute of limitations); *Arch v. Am. Tobacco Co.*, 175 F.R.D. 469, 491 (E.D. Pa. 1997) ("[a]ssumption of risk is an inherently individual question, turning as it does upon the subjective knowledge and behavior of individual plaintiffs. … Additionally, the class member's knowledge would also be relevant to a determination of comparative fault, which is a defense to the negligence claims. … Defendants also raise a statute of limitations defense, which is not a common issue"); *Guillory v. Am. Tobacco Co.*, 2001 WL 290603 (N.D. Ill. Mar. 20, 2001) ("assumption of risk, contributory negligence, and the statute of limitations raise issues uncommon to the class"); *Lewallen v. Medtronic USA, Inc.*, 2002 WL 31300899, at *4 (N.D. Cal. Aug. 28, 2002) ("In addition, various

affirmative defenses require individualized proof, including the statutes of limitation, consent, assumption of risk, and comparative fault.").

As these authorities show, every class member's claims will trigger the need to examine, on individualized facts, the merits of Allergan's affirmative defenses. Predominance cannot be found for this reason either and the CAC's class allegations thus should be stricken.

c) Individual Issues Of Law And Fact Preclude The Release Subclass

Plaintiffs' allegations regarding the Release Subclass should be stricken for similar reasons. This Court recently addressed issues with respect to the releases in its Order granting in part and denying in part Plaintiffs' Emergency Motion to Limit Communications with Class Members and Their Physicians, Void Release Signed by Class Members, and Issue Corrective Notice. (MDL. No. 2921, Dkt #144.) The Court declined to invalidate the releases, instead directing the parties to meet and confer regarding revisions to the release language, as well as notice to class members who already have signed releases. (*Id.* at 18.) The Court stated: "Any determination regarding the legal impact of those releases should be made on a case-by-case basis at a later date." (*Id.*) Precisely. Adjudication of the Release Subclass claims requires individual, case-by-case adjudication of each putative class member's circumstances.

Specifically, the legal and factual questions surrounding the validity of each class member's Release constitute individualized inquiries, making it impossible for Plaintiffs to meet the predominance requirement. Most jurisdictions measure the

validity of a release agreement by the totality of the circumstances. Applying New Jersey law, *Geraghty v. Ins. Servs. Office, Inc.*, 369 F. App'x 402, 405 (3d Cir. 2010), laid out the following factors to evaluate whether a plaintiff entered into a release knowingly and voluntarily: (1) clarity and specificity of the release language; (2) the plaintiff's education and business experience; (3) the amount of time plaintiff had for deliberation; (4) whether plaintiff knew or should have known her rights upon execution of the release before signing (5) whether plaintiff was encouraged to seek counsel; (6) whether there was opportunity for negotiation; and (7) whether the consideration provided was in line with what the plaintiff was entitled to by law. *Id.*

Here, whether any particular release was "deceptive, misleading, and/or void as against public policy" would necessarily involve individualized factual inquiry as to each Release Subclass plaintiff's circumstances when signing the Release. Each plaintiff's education and business experience, time for deliberation, and whether anyone encouraged her to seek counsel or other advice are impossible to ascertain on a classwide basis. As far as these Plaintiffs and the putative class are concerned, every aspect of the *Geraghty* "totality of circumstances" test is individualized—what she knew, what she was told, who she consulted, how long she waited, and more. There will also be individual questions as to Allergan's representations and alleged omissions—what litigation or regulatory action Allergan received noticed of at any given time, what communications Allergan may have made with surgeons whose patients planned to participate in the Warranty Programs, and more.

As such, as this Court found, it will be impossible to determine whether the Releases were "deceptive, misleading, and/or void" on a classwide basis, because

the inquiry into Release validity is necessarily individual and fact-intensive. *See McFarland v. Yegen*, 1989 U.S. Dist. Lexis 16965, at *30-31 (D.N.J. Oct. 6, 1989) (declining to certify release class when "the inquiry into whether the releases are valid or not will likely turn upon the factual circumstances under which each release was executed," which "mandate[d] the conclusion that the individual issues with respect to the these putative class members predominate over of the common issues); *see also United States v. NYC Dep't of Educ.*, 407 F. Supp. 3d 365, 413-14 (S.D.N.Y. 2018) (totality of the circumstances analysis in determining the validity of liability waiver to be a "peculiarly fact-sensitive inquiry"); *Walker v. Asea Brown Boveri, Inc.*, 214 F.R.D. 58, 65-66 (D. Conn. 2003) (rejecting release class because a "fact-specific inquiry will be necessary to determine whether either of the named plaintiffs knowingly and voluntarily" entered into the release); *Spann v. AOL Time Warner, Inc.*, 219 F.R.D. 307, 319 (S.D.N.Y. 2003) (rejecting release class when "[t]o the extent that the Releases could provide a defense as to recovery under the claims posed in this lawsuit, that defense requires a fact-specific inquiry into the circumstances of the execution of each individual's release.").

* * * * *

In sum, the individual legal and factual questions necessarily predominate over common questions for these nationwide classes. No amount of discovery will change this; if anything, the need for factual discovery will only further expose the impropriety of class treatment. The CAC's class allegations should be stricken.

2. Class Treatment Is Not A Superior Method Of Adjudicating These Claims

Under Rule 23(b)(3), courts also must take a "close look" at whether a class action is "superior to other available methods for the fair and efficient adjudication of the controversy." *Amchem*, 521 U.S. at 615. "The rule asks [the Court] to balance, in terms of fairness and efficiency, the merits of a class action against those of 'alternative available methods' of adjudication." *Georgine*, 83 F.3d at 632-33, *aff'd* 521 U.S. 591; *see Katz v. Carte Blanche Corp.*, 496 F.2d 747, 761 (3d Cir.) (en banc), cert. den., 419 U.S. 885 (1974) (the fairness "criterion for a superiority determination," includes "fairness to the defendant."). Rule 23 identifies four relevant factors courts should consider when making this determination:

- 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). Analysis of these factors only confirms that classwide adjudication would not be "superior" to anything.

Injured Plaintiffs' Control Over Their Own Cases. According to the Third Circuit, a personal injury class action seeking medical monitoring, "suffers from serious problems in the fairness it accords to the plaintiffs [because] [e]ach plaintiff has a significant interest in individually controlling the prosecution of separate

actions. *Georgine*, 83 F.3d at 633. This is because personal injury claims "have a significant impact on the lives of the plaintiffs." *Id*. (quoting Fed. R. Civ. P. 23(b)(3) Advisory Notes to 1966 Amendment); *see also Yandle v. PPG Indus., Inc.*, 65 F.R.D. 566, 572 (E.D. Tex. 1974) ("[T]he court finds that the members of the purported class have a vital interest in controlling their own litigation because it involves serious personal injuries and death in some cases."). Consequently, class treatment is inappropriate for these kinds of cases. *See Georgine*, 83 F.3d at 633; *In re School Asbestos Litig.*, 789 F.2d 996, 1009 (3d Cir.), cert. denied, 479 U.S. 852 (1986) ("Part of the reluctance to apply the class action to mass torts is rooted in the notion that individual plaintiffs have the right to select their own counsel and forum, particularly in personal injury actions.") (citations omitted).

Indeed here, the MDL Plaintiffs have made clear that they want to control their own fates. Again, Plaintiffs filed the Master Long Form Complaint over two months ago. (*See* MDL No. 2921, Dkt. No. 119) Yet, the docket for this MDL, along with the individual actions comprising it, reveals that the Plaintiffs' Steering Committee to date has refused to adopt that Master Complaint for any of the individual cases in this proceeding—even though the Plaintiffs' Steering Committee is counsel of record in roughly 75% of those individual cases. (*See, e.g.*, Dockets in MDL No. 2921; *Edwards v. Allergan Inc.*, No. 20-cv-09218; *Johnson v. Allergan Inc.*, No. 20-cv-09228; *Vargas v. Allergan Inc.*, No. 20-cv-09057.) In other words, Plaintiffs' lawyers drafted and filed what should have been a "Master" pleading for the entire MDL, but so far have disavowed it for the individual cases comprising that very same MDL. Plaintiffs' apparent intent to forge their own respective litigation

paths is fundamentally at odds with class treatment. Indeed, it confirms that the class members are capable of pursuing their own litigation interests, and thus that class treatment is inferior here. *See Liberty Lincoln Mercury, Inc. v. Ford Mktg. Corp.*, 149 F.R.D. 65, 74 (D.N.J. 1993) (finding "a class action is not appropriate when proposed class members are able to protect and defend their own interests").

Existing Litigation by Class Members. Rule 23(b)(3)(B) "speaks not only of assessing the '*extent* ... of any litigation ... already begun'—presumably meaning the raw number of cases filed relative to the size of the proposed class—but also of the '*nature* of any litigation ... already begun.'" *Abraham v. WPX Prod. Prods., LLC*, 317 F.R.D. 169, 240 (D.N.M. 2016) (emphasis added). To make this assessment, courts "must look at what procedural forms the already-filed cases have taken." *Id.* "For example, if a group of asbestos plaintiffs file for class certification, the court should decline to certify on the ground that asbestos cases [already] are consolidated in [a pending] multidistrict litigation." *Id.* ("[I]f a class has already been certified to pursue certain claims, redundant classes should generally not be certified") (citing 2 *Newberg on Class Actions* §4:70 ("[I]f a *class action* case is already pending, certification of another class suit might not be sensible or superior to the current litigation posture.")).

These redundancy concerns apply with equal force here. Right now, this Court presides over an MDL proceeding intended to coordinate pretrial workup for federal personal injury actions involving Allergan BIOCELL breast implant products. As the JPML recognized, this MDL offers a variety of potential benefits and efficiencies, such as coordinating discovery, streamlining claims and issues for

trial, preventing inconsistent pretrial rulings, and conserving judicial and party resources. (*See* MDL No. 2921, Dkt #96 at p.1 (JPML Transfer Order).) Plaintiffs will be hard-pressed to explain how their alleged class action procedure is superior to, and thus should supplant, the pending MDL proceeding that achieves many of the same efficiencies that Rule 23 is supposed to foster. *Georgine*, 83 F.3d at 634 ("a class action would need significant advantages over alternative means of adjudication before it could become a 'superior' way to resolve this case.")

Manageability of Class Claims. Oftentimes, "[l]ack of manageability is the most compelling reason for denying plaintiffs' motion." *Abbent v. Eastman Kodak Co.*, 1992 WL 1472751, at *10 (D.N.J. Aug. 28, 1992); *see also Georgine*, 83 F.3d at 633-34 (holding that nationwide medical monitoring class "of this magnitude and complexity could not be tried" and "the difficulties likely to be encountered in the management of this action are insurmountable"). That is no less true here.

Consider, first of all, what the class trial will look like. Regardless of whether the Court certifies a nationwide class or 112 subclasses, the Court likely will have to apply the laws of many different jurisdictions for a multitude of claims. Indeed, on its face the CAC purports to assert more than 700 discrete causes of actions—13 claims, each brought under the laws of all U.S. States and Territories. These laws encompass countless different permutations governing Allergan's liability and defenses, which means there is no meaningful way to try the claims from different states together. The end result is that a "class" trial may involve perhaps 56 separate class trials—hardly the kind of efficiency that the class action device is supposed to achieve.

But the alternative—a single trial—is worse. Jury instructions encompassing multiple states' laws will be a nightmare and no juror can reasonably be expected to keep track of which state's laws applies to which Plaintiffs' claims. *See In re Am. Med. Sys.*, 75 F.3d at 1085 ("[i]f more than a few of the laws of the fifty states differ, the district judge would face an impossible task of instructing a jury on the relevant law"); *Harding v. Tambrands Inc.*, 165 F.R.D. 623, 632 (D. Kan. 1996) ("[T]he court believes that instructing the jury in a manner that is both legally sound and understandable to a jury of laypersons would be a herculean task. … The jury would have to be instructed to consider various burdens of proof, and in some cases, contradictory standards of conduct.").

Plaintiffs cannot duck this problem by urging a single jury instruction for each claim because that approach would collide with *Erie*. As Judge Posner explained:

> If one instruction on negligence will serve to instruct the jury on the legal standard of every state of the United States applicable to a novel claim, implying that the claim despite its controversiality would be decided identically in all 50 states and the District of Columbia, one wonders what the Supreme Court thought it was doing in the *Erie* case when it held that it was unconstitutional for federal courts in diversity cases to apply general common law rather than the common law of the state whose law would apply if the case were being tried in state rather than federal court.

Matter of Rhone-Poulenc Rorer Inc., 51 F.3d at 1300-01; *see also Erie R.R. Co. v. Thompkins*, 304 U.S. 64, 78 (1938). Even if the differences among state negligent laws were mere nuances, "nuance can be important, and its significance is suggested by a comparison of differing state pattern instructions on negligence and differing judicial formulations of the meaning of negligence and the subordinate concepts."

Id. "The voices of the quasi-sovereigns that are the states of the United States sing negligence with a different pitch." *Matter of Rhone-Poulenc Rorer Inc.*, 51 F.3d at 1300-01.

This is just the tip of the iceberg. Because state laws differ materially, evidence that might be relevant in one jurisdiction may not be relevant in another. How will the parties and the Court sort through what evidence is admissible and for what purpose—and more importantly, how is the jury supposed to keep it all straight? There is no limiting instruction—regardless of how well-intentioned—that possibly could ameliorate the resulting prejudice and unfairness to Allergan.

In a nationwide or statewide setting, the difficulties undermining a fair or efficient adjudication would only start with the legal diversity. For reasons already discussed, Plaintiff-specific factual inquiries will follow for the resolution of each plaintiff's claims. Each Plaintiff will ultimately have to prove liability and damages on an individual basis. That will involve individualized questions related to state of the art and Allergan's knowledge during the relevant period, individual subjective knowledge regarding Allergan's risks, what each implanting physician told each Plaintiff regarding those risks, the individual increased risk of contracting ALCL, and whether and to what extent each Plaintiff is entitled to medical monitoring. An endless stream of mini-trials of will be required to conclude the classwide claims.[9]

[9] As Judge Jack Weinstein has explained, "[t]he effect of conditional class certification will be for all pending state and federal actions to become part of the mandatory class and to cease to exist as independent cases." *In re Joint E. & S. Dist. Asbestos Litig.*, 134 F.R.D. 32, 36 (E.D.N.Y. 1990). In other words, according to Judge Weinstein, when an MDL court certifies a class action, any individual cases encompassed within that class definition become subsumed by the class, and the

When, as here, the plaintiffs' claims require these kinds of individualized determinations, the superiority requirement is not satisfied. *See Mann v. TD Bank, N.A.*, 2010 WL 4226526, at *18 (D.N.J. Oct. 20, 2010) (class action "presents significant manageability concerns" because the Court would have to conduct fact-intensive mini trials to determine prospective class members, representing an "unmanageable endeavor" and weighing against class certification); *Agostino v. Quest Diagnostics Inc.*, 256 F.R.D. 437, 470 (D.N.J. 2009) (certifying proposed class in light of numerous factual and legal variations "would be the legal equivalent of encountering a sign warning of quicksand, yet rushing headlong forward despite the warning."); *Newton*, 259 F.3d at 192 ("Because injury determinations must be made on an individual basis … plaintiffs fail to satisfy the superiority standard."). The class allegations should be stricken for this reason, too.

C. Plaintiffs Cannot Resort To Rule 23(b)(2)

The CAC also alleges certification under Rule 23(b)(2) of the nationwide class, as well both the state and non-PMA device state subclasses. These allegations fare no better as far as the certification requirements are concerned. As noted at the outset, certification under Rule 23(b)(2) is appropriate only for classes seeking

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MDL court no longer can remand those individual cases to their originating districts for trial. As a result, not only will this Court have to conduct an unwieldy class trial involving medical monitoring of *uninjured* putative class members, but it also must continue to manage the claims of *injured* plaintiffs (i.e., who allege an ALCL diagnosis) who do not fall within the class definition and thus remain part of this MDL. From this perspective too, a class action makes adjudication of these claims less efficient and less manageable—and, ultimately, the inferior method of resolving this litigation.

injunctive or equitable, not monetary, relief and where the class is sufficiently cohesive to facilitate classwide adjudication. *See* discussion *supra* pp. 10-11. These elements cannot be met for the CAC's classes.

In looking at Rule 23(b)(2), regardless of how the plaintiffs frame the medical monitoring request, a court must independently examine the requested relief to determine whether it is truly injunctive in nature. "Relief in the form of medical monitoring may be by a number of means." *Day v. NLO, Inc.*, 144 F.R.D. 330, 335 (S.D. Ohio 1992), *vacated in part on other grounds sub nom. In re NLO, Inc.*, 5 F.3d 154 (6th Cir. 1993). "First, a court may simply order a defendant to pay a plaintiff a certain sum of money." *Id.* "The plaintiff may or may not choose to use that money to have his medical condition monitored." *Id.* "Second, a court may order the defendants to pay the plaintiffs' medical expenses directly so that a plaintiff may be monitored by the physician of his choice." *Id.* Neither of these situations constitutes injunctive relief for purposes of Rule 23(b)(2). *See id.*

"However, a court may also establish an elaborate medical monitoring program of its own, managed by court-appointed court-supervised trustees, pursuant to which a plaintiff is monitored by particular physicians and the medical data produced utilized for group studies. In this situation, a defendant, of course, would finance the program as well as being required by the court to address issues as they develop during program administration." *Id.* at 336.

Based on these principles, courts have found that unless the court or the defendants are substantially involved with overseeing, conducting, managing, and otherwise supervising a medical monitoring relief program, the program is a form of

monetary rather than injunctive relief. *See, e.g.*, *Barnes*, 161 F.3d at 131; *Arch*, 175 F.R.D. at 483; *see also Abbent*, 1992 WL 1472751 at *13. For example, in *Barraza*, the plaintiffs proposed a medical monitoring scheme in which the defendants would pay money into a fund, and the fund would be "used to pay for class members to see their own physicians, receive a scan from a CT provider of their choice, and receive a report on the scan from a designated reviewing radiologist." 322 F.R.D. at 386. The court had "difficulty distinguishing this remedy from a simple claim for money damages that a plaintiff will use to pay for a doctor visit, a CT scan, and review of the scan." *Id.* Even though there were limitations on use of the funds, the court questioned whether "that single distinction—that the funds in this case can be used only for a doctor visit, a scan, and review of the scan—transform this from monetary to injunctive relief? The Court does not think so." *Id*. The court also denied class certification under Rule 23(b)(2). *Id.*

Here, Plaintiffs' seven independent medical monitoring causes of action have attempted to sidestep some of the obvious problems highlighted in the above cases by requesting "a Court-supervised, Defendant-funded" medical monitoring program which will "include a trust fund" to pay for medical monitoring and diagnoses "as frequently and appropriately as necessary." (CAC ¶¶ 5512, 5528, 5545, 5562, 5579, 5596 5613.) But this is virtually the same as what the *Barraza* plaintiffs asked for—"a Court-supervised and Court-administered trust fund, in an amount to be determined, to pay for the medical monitoring protocol for all Class members"—and what the *Barraza* court ultimately refused to certify under Rule 23(b)(2). 322 F.R.D. at 386. The Rule's requirements thus cannot be avoided by mere labels.

In *Barraza*, neither the defendants nor the Court were tasked with assigning or supervising the physicians or monitoring protocols for the plaintiffs; rather, the requested trust fund would exist only to pay for monitoring services conducted by the physicians or facilities of the plaintiffs' own choice. Moreover, any data generated through monitoring would not be used for research purposes or to benefit the class. Similarly here, Plaintiffs have not requested that Allergan do anything beyond paying for a medical monitoring program, and they have not indicated that data generated by such a program will be used for any class benefit. As in *Barraza*, this Court cannot conclude "that a remedy requiring Defendants to do nothing more than write a check can properly be viewed as an injunction." *Id.* at 387.

This rings all the more true given that Plaintiffs consistently reference "medical monitoring" in purely economic terms. *See In re School Asbestos Litig.*, 789 F.2d at 1008 ("[A]n action for money damages may not be maintained as a Rule 23(b)(2) class action."). For example, in each of Plaintiffs' innumerable strict and negligent failure to warn claims, manufacturing defect, and design defect claims, Plaintiffs allege "expenses associated with ongoing medical monitoring" as economic damages they have suffered. (*See, e.g.*, ¶¶ 406, 1263, 2159, 3042, 4125, 4742, 5320.) Similarly, Plaintiffs' state consumer fraud and deceptive trade practices claims, as well as their unjust enrichment claims, allege an "ascertainable loss of money or property, real or personal, as described above, including the present and future costs associated with … the surgical and diagnostic fees and medical monitoring associated with retention of the products," or that Allergan has not compensated them sufficiently for the same. (*See, e.g.*, *id.* ¶¶ 5878, 6484.)

Lastly, as also noted, Rule 23(b)(2) cannot be invoked where the putative class lacks cohesiveness. While Rule 23(b)(2) class actions "have no predominance or superiority requirements, it is well established that the class claims must be cohesive." *Barnes*, 161 F.3d at 143. "This is so because in a (b)(2) action, unnamed members are bound by the action without the opportunity to opt out." *Id.* at 142–43; *accord Gates*, 655 F.3d at 264. "[T]he very nature of the relief available under (b)(2)—injunctive or declaratory relief obtained in a trial of the class representative's claim and applicable to all members of the class—works only when common issues predominate." *Barraza*, 322 F.R.D. at 389. Thus, a district court may "deny certification in Rule 23(b)(2) cases in the presence of disparate factual circumstances." *Barnes*, 161 F.3d at 143 (citation and quotation marks omitted).

In these cases, as discussed above, common issues do not predominate. The putative class is replete with individual legal and factual issues that overwhelm any common questions. Lack of cohesiveness flows *a fortiori* from that discussion. On the whole, Plaintiffs' request for medical monitoring is monetary rather than injunctive in nature and the putative class lacks cohesiveness. Rule 23(b)(2) cannot be used to salvage these invalid allegations and the CAC's class allegations involving this Rule should also be stricken.

V. CONCLUSION

On their face, Plaintiffs' class allegations are unsustainable under Rule 23 and no amount of discovery can change that. The Court has the discretion to strike the class allegations from the CAC and it should do so.

Dated: August 7, 2020

Respectfully submitted,

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	**Case No. 2:19-md-02921 (BRM)(JAD)** **MDL No. 2921** **JUDGE BRIAN R. MARTINOTTI** **JUDGE JOSEPH A. DICKSON**

THIS DOCUMENT RELATES TO: ALL CASES

MEMORANDUM OF LAW IN SUPPORT OF 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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Other Authorities

I. INTRODUCTION

As outlined in Allergan's concurrently-filed Motion to Dismiss on Preemption Grounds, all the claims asserted in Plaintiffs' Master Personal Injury Complaint ("PIC") are preempted by federal law and should be dismissed for that reason. Beyond this insurmountable hurdle lies another: Plaintiffs' personal injury claims cannot survive under state law or the *Erie* principles that bind this Court. Dismissal is required for these reasons also:[1]

Unrecognized Claims Or Requests For Relief. Any adjudication of the various tort claims asserted in this diversity action must be guided by controlling *Erie* principles. Under *Erie*, where a state's highest court has not recognized a particular cause of action or the relief sought pursuant to it, dismissal is required. This Court is not free to create novel state tort law principles so that Plaintiffs' claims can proceed.

No Legally Cognizable Harm. In 41 states, Plaintiffs who have not been diagnosed with ALCL cannot either bring any of the tort claims alleged or obtain medical monitoring relief. The "threat" of future injury will not support an action in tort. Actual harm must be alleged and proven.

Manufacturing Defect. The PIC conflates manufacturing defect claims with design defect claims. As a result, it fails to adequately plead a manufacturing defect claim in strict liability or negligence under any applicable state law.

[1] Although this Memorandum explains why the PIC fails to state valid claims, this Court need not undertake a choice-of-law analysis for any Plaintiff at this stage. Allergan has structured its arguments so that the Court can rule on the counts in the PIC by groups of states, as outlined in the Conclusion and Appendix A to this brief.

Negligence *Per Se*. Plaintiffs' negligence *per se* claims are based on purported violations of federal regulations issued under a statute that bars private enforcement. Most states do not allow that. And, in the few states that might do so, there must be a clear violation of an established regulatory duty. Nothing like that is alleged in this case.

Failure To Warn. Whether in strict liability or negligence, Plaintiffs' warning claims are based on allegations that Allergan failed to report adverse events to the FDA, or used the wrong form in making its reports. No state high court has recognized either version of this theory of liability, and some have expressly rejected in it in the form alleged in the PIC.

Negligent Misrepresentation. The PIC fails to meet the heightened pleading standards required for this claim, and it runs afoul of the laws of those states that do not permit such a claim in product liability actions or that do not recognize it as a separate cause of action at all.

Breach Of Warranty. Many states do not recognize implied warranty claims in actions involving prescription medical products. Those that do typically require notice or privity of contract, neither of which is found in any allegation here.

The PIC impermissibly invents, stretches, or manipulates controlling state law in a fashion that cannot be permitted by this Court in its role under *Erie* or sustained under the standards that control under Federal Rule of Civil Procedure 12(b)(6). The claims made in the PIC as identified in the Conclusion and for the reasons noted in Appendix A, should be dismissed without leave to amend.

II. LEGAL STANDARDS GOVERNING THIS MOTION TO DISMISS

Where a complaint fails to state a claim upon which relief may be granted as a matter of law, Federal Rule of Civil Procedure 12(b)(6) requires its dismissal. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Courts are not compelled to accept "unsupported conclusions and unwarranted inferences." *Trzaska v. L'Oreal USA, Inc.,* 865 F.3d 155, 165 (3d Cir. 2017). Nor must it accept "a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

III. ARGUMENT

A. Claims Not Recognized By The Relevant State's Highest Court Must Be Dismissed

Many of the claims asserted by Plaintiffs in the PIC are not recognized by state high courts and must be dismissed.

In deciding whether a claim exists as a matter of law, it is axiomatic that in diversity actions, the substantive "law to be applied in any case is the law of the State." *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). At the same time, it is the prerogative of each state to "define the nature and extent" of liability under its laws for itself, and that prerogative "would be thwarted if the federal courts were free to choose their own rules of decision whenever the highest court of the state has not spoken." *West v. AT&T Co.,* 311 U.S. 223, 236 (1940).

Erie thus prohibits federal courts from inventing and recognizing novel state law claims in diversity cases to prevent a violation of one of "the most basic principles of federalism." *Pacific Employers Ins. Co. v. Global Reins. Corp.*, 693 F.3d 417, 436 (3d Cir. 2012); *accord Michaels v. New Jersey*, 150 F.3d 257, 259 (3d Cir. 1998) (Alito, J.). As Third Circuit has made plain, "it is not the role of a federal court to expand state law in ways not foreshadowed by state precedent." *City of Philadelphia v. Beretta U.S.A. Corp.*, 277 F.3d 415, 421 (3d Cir. 2002). Instead, district courts must "apply the current law of the jurisdiction, and leave it undisturbed." *Leo v. Kerr-McGee Chem. Corp.*, 37 F.3d 96, 101 (3d Cir. 1994).

Indeed, when confronted with open questions of state-law liability, federal courts in this Circuit must "opt for the interpretation that *restricts* liability, rather than expands it, until the Supreme Court of [the State] decides differently." *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 253 (3d Cir. 2010) (emphasis added; citation omitted).

Plaintiffs in this MDL, however, are asking this Court to do the opposite: allow novel state law personal injury claims—under the laws of all 50 states and the District of Columbia—many of which have not been authorized by statute or adopted by any state's highest court.[2]

[2] For the Court's convenience, and the sake of brevity, Appendix A identifies the governing law of those jurisdictions that preclude each cause of action in the PIC that Allergan contends must be dismissed.

B. Personal Injury Claims Brought By Plaintiffs Without An ALCL Diagnosis Must Be Dismissed

As the Court is aware, Plaintiffs in this MDL fall into either of two groups: (1) the relatively small number of plaintiffs allegedly diagnosed with ALCL; and (2) the overwhelming majority of plaintiffs who merely allege they are in "fear of" developing ALCL at some future time. (PIC ¶8-9.) In other words, most of the personal injury Plaintiffs in this MDL have no injury, and these Plaintiffs cannot state a valid tort cause of action.

In state after state, controlling law requires a tort plaintiff to have suffered legally cognizable injury to bring a lawsuit; tort claims require a plaintiff to have suffered a harm. *See, e.g., Mergenthaler v. Asbestos Corp. of Am.*, 480 A.2d 647, 651 (Del. 1984) ("present physical injury" is an "essential element" of all tort claims). As a result, a large majority of states explicitly reject tort claims for an "increased risk" or "fear of developing a disease due to exposure" without a currently manifest physical injury. *See* App'x A, at 1-19 (listing states that reject "increased risk" and/or "fear of" claims without underlying physical injury).

The Supreme Court of New Jersey, for example, has held that physical injury is a prerequisite to any state law products liability claim, which the PLA defines as "personal physical illness, injury or death." *Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 64-65 (2009); N.J.S.A. 2A:58C-1(b)(2). Similarly, Alabama has long held that a physical injury is required to bring a tort claim under its common law. *See Pfizer, Inc. v. Farsian*, 682 So.2d 405, 407 (Ala. 1996) (holding that a plaintiff's fear that his device was at an increased risk of future failure was not, without more, a

cognizable legal injury). Several states likewise have enacted Product Liability Acts with the same requirements. *E.g.*, Arkansas (Ark. Code §16-116-202(5)); Colorado (Colo. Rev. Stat. §13-21-401(2)); Connecticut (Conn. Gen. Stat. §52-572m(b)); Indiana (Ind. Code §34-20-1-1(3)); Kansas (Kan. Stat. §60-3302(d)); Kentucky (Ky. Rev. Stat. §411.300); and Ohio (Ohio Rev. Code §2307.71). By the same token, a legally cognizable injury is required in every state that follows either the Second or Third Restatements of Torts. *See* Restatement (Second) of Torts §402A(1) (1965) ("liability for physical harm"); Restatement (Third) of Torts, Products Liability §1, comment d (1998) ("The rule stated in this Section applies only to harm to persons or property, commonly referred to as personal injury and property damage.").

In addition, there are a number of states where the states' highest courts have not adopted "increased risk" or "fear of" claims unaccompanied by a physical injury. All of these claims should be dismissed in keeping with *Erie* principles. There is no basis for this Court to address and create such a novel claim for these states. It cannot do so without going beyond the more circumscribed role that *Erie* commands.

The above analysis applies in all its particulars to Plaintiffs' request for a medical monitoring relief and the claims for such relief must be dismissed as well. (PIC at 127, Prayer For Relief.) Most states reject medical monitoring relief as a matter of law. The few states that allow "medical monitoring" (some as a cause of action, which has not been alleged here, and some as a remedy for personal injury), require plaintiffs to first demonstrate a legally cognizable injury. *See*, *e.g.*, *Cure v. Intuitive Surgical Inc.*, 2017 WL 498727 at *6 (N.D. Ga. Jan 30, 2017), *aff'd*, 705 F. App'x 826 (11th Cir. 2017); *Wood v. Wyeth-Ayerst Labs., Div. of Am. Home*

Prods., 82 S.W.3d 849, 859 (Ky. 2002). Mere exposure without some manifestation of physical injury does not suffice. *Cure*, 2017 WL 498727, at *6-7.

The claims supporting Plaintiffs' request for medical monitoring relief must be dismissed as to every plaintiff without ALCL and as to plaintiffs who are residents of all states that do not allow medical monitoring or that do not allow it in litigation involving prescription medical products. *See* App'x A, at 20-25 (listing states that that reject medical monitoring claims without underlying physical injury, and also those states that allow medical monitoring claims without underlying physical injury, in some circumstances, but not in prescription medical product litigation). Finally, dismissal is also required for the medical monitoring claims governed by the law of a jurisdiction where the highest state court has not expressly authorized medical monitoring. *See* App'x A, at 20-25. Recognized *Erie* principles foreclose such a novel expansion of state tort law in these circumstances as well. *See M.G. v. A.I. duPont Hosp. for Children*, 393 F. App'x 884 (3d Cir. 2010).

C. Claims That Are Not Adequately Pled Must Be Dismissed

The PIC's various tort claims also have pleading deficiencies that compel their dismissal. The grounds for dismissal include states that do not allow the claims alleged in the PIC or have not recognized them as pled, or those that would find them inadequately alleged under controlling law.

1. The Manufacturing Defect Claims Are Not Adequately Pled

The concepts underlying claims for manufacturing defects and design defect are different. A manufacturing defect is typically and routinely defined as a *deviation* from the manufacturer's intended specifications that renders the device

unreasonably dangerous. A design defect, by comparison, results when devices are manufactured exactly as intended, but a flaw in the underlying design gives rise to a common defect that exists in every device of that type.

As the Restatement explains, generally, a "manufacturing defect" occurs "when the product departs from its intended design." Restatement (Third) of Torts, Products Liability §2(a) (1998). The Restatement goes on to explain:

> Whereas a manufacturing defect consists of a product unit's failure to meet the manufacturer's design specifications, a product asserted to have a defective design meets the manufacturer's design specifications but raises the question whether the specifications themselves create unreasonable risks.

Id. at cmt d.; *see also Fasolas v. Bobcat of New York, Inc.*, 128 N.E.3d 627, 641 (N.Y. 2019) ("[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") (internal marks omitted); *Evans v. Lorillard Tobacco Co.*, 990 N.E.2d 997, 1010 (Mass. 2013) (manufacturing and design claims held "separate and distinct" for the reasons stated in Restatement §2); *Harrison v. Harrison*, 733 N.W.2d 451, 454 n.2 (Minn. 2007) (noting that a manufacturing defect exists when a product "departs from its intended design" (quoting Restatement §2(a)).

But the "manufacturing defect" claims advanced in the PIC do not allege that *any* of the individual devices deviated from its intended specification. Instead, those allegations attack the manufacturing process itself (*i.e.*, the "salt loss" process), and allege the textured surface of *every* product is defective as a result of that process.

(*See* PIC Counts I and II; PIC ¶117.) In other words, although Plaintiffs purport to assert "manufacturing defect" claims, the PIC fails to identify a single manufacturing *defect* in any device at issue. The devices are manufactured exactly as they should be with a uniformly utilized process that Plaintiffs' claim is deficient. That is a mislabeled design defect, pure and simple, and the PIC's "manufacturing defect" claims are subject to dismissal for that reason.

Specifically, under settled Third Circuit law, a manufacturing defect claim must be dismissed if it omits a required element (an allegation of a *manufacturing* defect) because the problem alleged really is one of design. *Coba v. Ford Motor Co.*, 932 F.3d 114, 123-24 (3d Cir. 2019) (affirming dismissal of "manufacturing" defect claim that "ha[d] all the trappings of a design defect," because the plaintiffs took issue with the use of a particular process in "constructing" the product and "alleg[ed] that '[a]ll' of the [products] manufactured this way suffer from a 'common' issue"). Claims from all states that require a manufacturing defect to involve a deviation from the norm for the device also should be dismissed. *See* App'x A, at 26-37.

2. The Negligence *Per Se* Claims Are Not Adequately Pled

Plaintiffs' negligence *per se* claim alleges that Allergan violated "laws, regulations, and terms of the [FDA's premarket approval]" that "were designed to protect Plaintiff[s] . . . against the risks and hazards that have been suffered as a result of being implanted with BIOCELL products." (PIC ¶176.) This claim fails for multiple independent reasons.

First, at least 12 states do not recognize negligence *per se* at all. *See* App'x A, at 38-59 (including those jurisdictions not recognizing negligence *per se* at all as a cause of action). These states have either abolished, statutorily subsumed, or so severely limited negligence *per se* claims such that virtually all plaintiffs (including Plaintiffs in this MDL) are precluded from asserting claims of this type.

Second, there are 30 states that prohibit plaintiffs from proceeding under a negligence *per se* theory if the underlying statute upon which the plaintiffs' claim is based was never intended to create an independent basis for liability. *See* App'x A, at 38-59 (including those jurisdictions where negligence *per se* is precluded where contrary to legislative intent). Where, as here, a plaintiff complains about an alleged violation of a regulation or statute that does not provide "an independent basis for civil liability or that its violation constitute[s] negligence *per se*," its violation is not actionable. *J.S. v. R.T.H.*, 155 N.J. 330, 349 (1998). Likewise, where a statute "includes … a specific provision making" negligence *per se* inapplicable, "courts should of course honor it." *See* Restatement (Third) of Torts, Physical & Emotional Harm §14, comment c (2010).

The Food, Drug, and Cosmetic Act ("FDCA")—which vests the FDA with its regulatory powers—contains such a provision. Indeed, the FDCA explicitly precludes litigants from private enforcement, and assigns that power exclusively to the federal government. 21 U.S.C. § 337(a).[3] *See*, *e.g.*, *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 355-56 (Ill. 1996). "The FDCA contains clear evidence that

[3] Section 337(a) provides that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."

Congress intended that [it] be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (citing 21 U.S.C. §337(a).). The importance of this prohibition against private enforcement "cannot be overstated." *Merrell Dow Pharms., Inc. v. Thompson*, 478 U.S. 804, 812 (1986). This Court thus should prohibit private enforcement as well.

Third, a negligence *per se* claim can be founded only on a statute or regulation that provides a clear and definite standard of care. Any attempt to base such a claim on a vague or ambiguous enactment therefore is subject to dismissal in those states insisting on clarity. *See* App'x A, at 38-59 (including those jurisdictions where negligence *per se* is inapplicable where the relied-upon law is vague).

As the Fifth Circuit explained:

> Implicit in virtually all discussions of negligence *per se* is the unspoken assumption that the regulation in question establishes a clear minimum standard of care. If the regulation fails to do so, the reason for applying the doctrine fades. An ambiguous or contradictory regulatory standard defeats the certainty on which the rule of *per se* liability rests. Persons affected are deprived of a sure standard upon which they may fashion their affairs.

Dougherty v. Santa Fe Marine, Inc., 698 F.2d 232, 235 (5th Cir. 1983) (citation omitted). Thus, negligence *per se* cannot lie where the defendant allegedly violated a vague enactment that "would allow juries to fix the standard case by case" and under which a defendant "acting in the utmost good faith and diligence could still find itself liable." *In re TMI*, 67 F.3d 1103, 1115 (3d Cir. 1995).

Yet here, the standard Plaintiffs rely on for their negligence *per se* claim is a moving target, untethered to any definitive statutory declaration. For example, the

PIC suggests the "current good manufacturing practices" regulations (or "cGMPs") is the law supplying the relevant standard of care. But cGMPs are not black and white. Instead, these regulations merely direct manufacturers to employ certain practices that they must define for themselves. These cGMPs direct manufacturers to "adopt procedures and controls relating to" design control, quality assurance, manufacturing and processing; or "establish and maintain procedures" to identify and address any product that does not conform; or to formulate and execute a Post-Marketing Surveillance Plan. (PIC ¶56.) Because these cGMPs "do[] not prescribe any particular course of conduct [defendants] must take, or refrain from taking," they cannot support negligence *per se* claims. *Ramirez v. Nelson*, 188 P.3d 659, 666 (Cal. 2008).

Fourth, many states preclude negligence *per se* claims whenever such claims would create novel duties unknown to the common law. That is precisely what Plaintiffs' claims would do here. *See* App'x A, at 38-59 (including those jurisdictions where negligence *per se* may not create novel duties).

In short, just as with their infirm manufacturing defect allegations, the PIC's negligence *per se* claims are an improper attempt to recast state law or displace it entirely. Neither result is legally sustainable, and dismissal is required.

3. The Failure To Warn Claims Are Not Adequately Pled

In their "failure-to-warn" claims, Plaintiffs allege 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 adverse events to the FDA, it did so using an improper "summary" report format. (*See*, *e.g.*,

PIC ¶186 (alleging Allergan "failed to adequately warn health care professionals and the public" by "failing to adequately report post-market adverse events to the FDA" and "misleadingly reporting adverse events via summary reports"). As their theory goes, if Allergan had properly reported adverse events, new warnings "would have been approved by the FDA and disseminated to Plaintiffs and their physicians." (PIC ¶195.)

Although these failure to warn claims are preempted, they are equally defective as pled. 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, and several states have expressly rejected it. *See* App'x A, at 60-79. For these latter states, dismissal of Plaintiffs' failure to warn claims is a given.

But the same is true for those states that have not expressly recognized the duty as well: this Court should not break new ground in doing so. In *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc), for example, the Ninth Circuit hypothesized that Arizona would recognize a state-law "warning" claim predicated on "failure to report" adverse events to the FDA. The Arizona Supreme Court, however, rejected this same hypothesized state law duty. *Conklin v. Medtronic, Inc.*, 431 P.3d 571, 577 (Ariz. 2018) (holding that even if it were to "assume that adverse event reports may constitute relevant warnings" pursuant to Arizona law, "Arizona law does not permit a manufacturer to satisfy its duty to warn end-user consumers by submitting adverse event reports to the FDA").

The same result occurred in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 775 (5th Cir. 2011). The Fifth Circuit purported to find a similar failure to report

adverse event theory in Mississippi's common-law of negligence, and Mississippi responded with a statute precluding common-law negligence entirely. *See Knoth v. Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 694 (S.D. Miss. 2019) (finding the MPLA did not include plaintiff's alleged cause of action and dismissing plaintiff's independent tort claim); *Elliott v. El Paso Corp.*, 181 So. 3d 263, 268-69 (Miss. 2015) (product liability statute's "exclusive remedy" precludes "common-law negligence").

In the same vein, states with reporting statutes of their own do not view them as creating a duty of care that gives rise to a private cause of action. On the contrary, "[t]he vast majority of courts … have held that their reporting statutes do not create a civil cause of action." *Becker v. Mayo Foundation*, 737 N.W.2d 200, 208 (Minn. 2007) (child abuse statute). There is no basis under *Erie* for this Court to break ranks and recognize a cause of action where a state court would not.

Finally, as pled, Plaintiffs' "failure to report" claim goes even further than the claims unwisely recognized in *Stengel* and *Hughes*. Here, Plaintiffs' failure to report claim does not actually allege a failure to report; rather, the allegations criticize the "summary" method by which Allergan made its reports to the FDA. No state, anywhere, has recognized a tort claim premised on the attempted compliance with a federal statute, and it would be a fundamental breach of settled *Erie* limitations for this Court to be the first to do so and then apply it to all 50 states and U.S. territories.

With their failure to report claim, Plaintiffs are asking this Court to create new state law nationwide. That is not permissible in this context or any other.

4. The Negligent Misrepresentation Claims Are Not Adequately Pled

Rule 9 requires a plaintiff to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *Frederico v. Home Depot*, 507 F.3d 188, 200-02 (3d Cir. 2007). Particularity requires sufficient details to put the defendant on notice of the "precise misconduct with which [it is] charged." *Frederico*, 507 F.3d at 200 (citation omitted). At a minimum, Rule 9(b) requires a plaintiff to allege the "essential factual background that would accompany the first paragraph of any newspaper story—that is, the 'who, what, when, where and how' of the events at issue." *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276-77 (3d Cir. 2006) (citation omitted).

This heightened pleading standard applies to Plaintiffs' negligent misrepresentation claims. *In re Westinghouse Sec. Litig.*, 90 F.3d 696, 717 (3d Cir. 1996) ("claims that do sound in fraud must be pled with particularity"); *Cty. of Essex v. Aetna Inc.*, 2018 WL 6584920, at *7 (D.N.J. Dec. 13, 2018) (applying Rule 9(b) to negligent misrepresentation claim sounding in fraud); *Gray v. Bayer Corp.*, 2009 WL 1617930, at *2 (D.N.J. June 9, 2009) (applying Rule 9(b) to negligent misrepresentation claim); *Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538, 550-51 (E.D. Pa. 2014), *aff'd*, 620 F. App'x 82 (3d Cir. 2015) (applying Rule 9(b) to negligent misrepresentation sounding in fraud). The PIC, however, contains none of the necessary particularized detail. Instead, it merely alleges:

- "In the course of marketing the BIOCELL line of products, Allergan made untrue representations of material facts and omitted material information to Plaintiffs, Plaintiffs' physicians, the FDA, and the public at large" (PIC ¶221) through a pre-

consultation video posted on a private YouTube account (PIC ¶97), and implant brochures and product catalogues (PIC ¶¶98-99, 101);

- "Allergan's characterizations of its product, its representations regarding safety and superiority, biocompatibility,…and its simultaneous omission of important safety risks associated with its textured BIOCELL product line, constitute negligent misrepresentation." (PIC ¶221); and

- Allergan's conduct was "active[] and intentional[]" (PIC ¶211), and "undertaken with wanton and willful disregard" (PIC ¶217).

The PIC also alleges that "Allergan made a concerted effort through its agents, employees and medical consultants to pepper the literature with anti-warning messages and to mock the serious and significant ALCL risk to which patients were exposed." (PIC ¶102.) The only examples of such "literature" Plaintiffs cite are: (1) an unattributed statement in an unidentified chapter of an unidentified book authored by a nameless "paid Allergan consultant"; and (2) a statement by yet another unnamed Allergan spokesperson that "a patient is more likely to be struck by lightning than to develop ALCL" made at a date and time unknown to an undisclosed audience. (PIC ¶102.) Anonymity is the antithesis of specificity.

As the recital shows, the PIC's misrepresentation allegations do not come close to meeting Rule 9's requirements. Those allegations fail to set forth any specific facts related to any alleged misrepresentation or omission by any particular Allergan defendant, including: (1) the identity of the employee or agent who made the alleged misrepresentation or omission; (2) the time when the alleged misrepresentation or omission was made; (3) the place where it was made; (4) the content, or lack thereof; (5) the method used to communicate; and (6) whether any

alleged misrepresentation or omission was made to Plaintiff or one of Plaintiffs' prescribing physicians. Any of these omissions is fatal, and the PIC suffers from all of them. That is the end of the line. Plaintiffs' negligent misrepresentation claim must be dismissed. *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d at 276-77; *see also In re Westinghouse Sec. Litig.*, 90 F.3d at 717; *Smajlaj v. Campbell Soup Co.*, 728 F. Supp. 2d 84, 104 (D.N.J. 2011).

While Rule 9 provides sufficient reason to reject Plaintiffs' negligent misrepresentations claims in their entirety, such claims also are subject to dismissal in those states that have either subsumed negligent misrepresentation within the state's product liability statute, or otherwise have concluded that it is not recognized as a separate cause of action. *See* App'x A, at 80-82. In either case, the claims cannot survive for this reason as well.

5. The Warranty Claims Are Not Adequately Pled

The PIC's breach of warranty claims fail for many of the same reasons analyzed above. To start with, many states do not allow implied warranty claims at all in prescription medical device litigation. Several states also require notice as an element of warranty claims. And still others require privity to assert implied warranty claims, express warranty claims, or both. *See* App'x A, at 83-92.

For those states that do not allow such claims for these prescription medical devices or require allegations of notice or privity—which are unpled in the PIC—dismissal is called for. Plaintiffs from these states cannot pursue warranty claims in conflict with these states' laws or the elements that their states' laws require.

IV. CONCLUSION

For the foregoing reasons, this Court should grant Allergan's motion, and issue an order dismissing:

- ***Claims for Strict Liability Defective Manufacturing (Count I); Negligent Manufacturing (Count II); General Negligence (Count III); Strict Liability Failure to Warn (Count IV); Negligent Failure to Warn (Count VI); Strict Liability Design Defect (Count IX); and Negligent Design (Count X)*** as to all Plaintiffs who do not have an ALCL diagnosis and for whom the following jurisdictions provide the controlling law: Alabama; Alaska; Arizona; Arkansas; Colorado; Delaware; District of Columbia; Florida; Georgia; Idaho; Illinois; Indiana; Kentucky; Louisiana; Maine; Massachusetts; Minnesota; Mississippi; Montana; Nebraska; Nevada; New Hampshire; New Jersey; New York; North Carolina; North Dakota; Ohio; Oregon; Pennsylvania; Rhode Island; South Carolina; South Dakota; Tennessee; Texas; Utah; Vermont; Virginia; Washington; West Virginia; Wisconsin; and Wyoming.

- ***Prayer for Relief for Medical Monitoring (PIC, p. 127)*** as to all Plaintiffs who do not have an ALCL diagnosis and for whom the following jurisdictions provide the controlling law should be precluded from pursuing medical monitoring as a remedy: Alabama; Alaska; Arizona; Arkansas; Connecticut; Delaware; District of Columbia; Georgia; Hawaii; Illinois; Indiana; Iowa; Kansas; Kentucky; Maine; Michigan; Minnesota; Mississippi; Missouri; Nebraska; New Jersey; North Carolina; North Dakota; Oklahoma; Oregon; Pennsylvania; Puerto Rico; Rhode Island; South Carolina; South Dakota; Tennessee; Texas; Virginia; Washington; Wisconsin; and Wyoming.

- ***Claims for Strict Liability Defective Manufacturing (Count I) or Negligent Manufacturing (Count II)*** as to all Plaintiffs for whom the following jurisdictions provide the controlling law: Alabama; Arizona; Arkansas; California; Colorado; Connecticut; Delaware; District of Columbia; Florida; Georgia; Hawaii; Illinois; Indiana; Iowa; Kansas; Kentucky; Louisiana; Maine; Maryland; Massachusetts; Michigan; Minnesota; Mississippi; Missouri; Montana; Nebraska; Nevada; New Hampshire; New Jersey; New Mexico; New York; North Carolina; North Dakota; Ohio; Oklahoma; Oregon; Pennsylvania; Puerto Rico; Rhode

Island; South Carolina; South Dakota; Tennessee; Texas; Utah; Vermont; Virginia; Washington; West Virginia; Wisconsin; and Wyoming.

- ***Claims for Negligence Per Se (Count III)*** as to all Plaintiffs for whom the following jurisdictions provide the controlling law: Alabama; Alaska; Arizona; Arkansas; California; Colorado; Connecticut; Delaware; District of Columbia; Florida; Georgia; Hawaii; Idaho; Illinois; Indiana; Iowa; Kansas; Kentucky; Louisiana; Maine; Maryland; Massachusetts; Michigan; Minnesota; Mississippi; Missouri; Montana; Nebraska; Nevada; New Hampshire; New Jersey; New Mexico; New York; North Carolina; North Dakota; Ohio; Oklahoma; Oregon; Pennsylvania; South Carolina; Tennessee; Texas; Utah; Vermont; Virginia; Washington; West Virginia; Wisconsin; and Wyoming.

- ***Claims for Strict Liability Failure to Warn (Count IV) and Negligent Failure to Warn (Count V)*** ***Premised on an Alleged Failure to Report Adverse Events to the FDA*** as to all Plaintiffs for whom the following jurisdictions provide the controlling law: Alabama; Alaska; Arizona; Arkansas; Colorado; Connecticut; Delaware; District of Columbia; Florida; Georgia; Hawaii; Illinois; Indiana; Iowa; Kansas; Louisiana; Maine; Maryland; Massachusetts; Michigan; Minnesota; Mississippi; Missouri; Montana; Nebraska; Nevada; New Hampshire; New Jersey; New Mexico; New York; North Carolina; North Dakota; Ohio; Oklahoma; Puerto Rico; Rhode Island; South Carolina; South Dakota; Tennessee; Texas; Vermont; Virginia; Washington; West Virginia; Wisconsin; and Wyoming.

- ***Claims for Negligent Misrepresentation (Count VI)*** as to all Plaintiffs, for failure to satisfy Rule 9's heightened pleading standard, and for additional state law reasons, as to all Plaintiffs for whom the following jurisdictions provide the controlling law: Alabama; Arkansas; Florida; Georgia; Indiana; Louisiana; Minnesota; Mississippi; New Jersey; Ohio; Tennessee; Texas; and Virginia.

- ***Claims for Breach of the Implied Warranty of Merchantability (Count VII)*** as to all Plaintiffs for whom the following jurisdictions provide the controlling law: 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.

- ***Claims for breach of express warranty (Count VIII)*** as to all plaintiffs for whom the following jurisdictions provide the controlling law: 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.

Dated: August 7, 2020

Respectfully submitted,

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UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

IN RE ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	**Case No. 2:19-md-02921(BRM)(JAD)** **MDL No. 2921** **JUDGE BRIAN R. MARTINOTTI** **JUDGE JOSEPH A. DICKSON**

THIS DOCUMENT RELATES TO: ALL CASES

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TO DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF 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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Alabama	"Under current Alabama case law, mere exposure to a hazardous substance resulting in no present manifestation of physical injury is not actionable under the AMLA where the exposure has increased only minimally the exposed person's chance of developing a serious physical disease and that person has suffered only mental anguish." *Houston Cty. Health Care Auth. v. Williams*, 961 So. 2d 795, 810-11 (Ala. 2006) (citing *Thomas v. BSE Indus. Contractors, Inc.*, 624 So. 2d 1041 (Ala. 1993); *Hinton v. Monsanto Co.*, 813 So. 2d 827, 829 (Ala. 2001); and *Southern Bakeries, Inc. v. Knipp*, 852 So. 2d 712 (Ala. 2002)). "A person exposed to a known hazardous substance but not claiming a present physical injury or illness as a result may not recover as damages the costs of medical monitoring." *Houston Cty. Health Care*, 961 So. 2d at 811 (vacating class-certification order as to uninjured plaintiffs because " this subset of patients, and [] their representative, have suffered no actual injury and thus lack standing to maintain this action"). "Opening the courts generally for compensation for fear of future disease would be a dramatic change in the law and could engender significant unforeseen and unforeseeable consequences; awarding such compensation is better left to the Legislature." *Southern Bakeries*, 852 So. 2d at 718. "Alabama courts have never allowed a recovery based on a product that, like Farsian's valve, is and has been working properly." *Pfizer, Inc. v. Farsian*, 682 So. 2d 405, 407 (Ala. 1996) ("The question certified to this Court concerns whether Farsian may maintain a fraud claim under Alabama law. We conclude that he may not. … Under Alabama law, [a plaintiff]'s fear that his [heart] valve could fail in the future is not, without more, a legal injury sufficient to support his claim."); *Id.* (explaining that "[r]egardless of how Farsian pleads his claim, his claim is in substance a product liability/personal-injury claim—Farsian seeks damages because of the risk

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	that his heart valve may one day fail. … Other courts have refused to recognize a cause of action in similar cases when the heart valve has not failed.") (citing *Angus v. Shiley Inc.*, 989 F.2d 142 (3d Cir. 1993)). "An alleged 'increased risk of harm' is not sufficient to survive summary judgment under Alabama law, which requires proof that the alleged negligence *probably* caused the injury. So strict is Alabama law on this point that Alabama courts have even rejected 'medical monitoring' claims, in which plaintiffs allege that because prior medical procedures increased their risk of *future* harm, they were 'injured' by the need, going forward, to self-monitor in order to detect future medical ailments." *Looney v. Moore*, 886 F.3d 1058, 1063-64 (11th Cir. 2018) ("Plaintiffs' negligence, negligence per se, breach of fiduciary duty, and products liability claims are not viable under Alabama law, and the district court correctly granted summary judgment to Defendants.") (emphases in original; internal cites omitted).
Alaska	Alaska has not affirmatively addressed "increased risk" and/or "fear of" claims without underlying physical injury.
Arizona	"Permitting an action for damages and recovery after exposure but prior to manifestation of a bodily injury could result in windfalls to healthy plaintiffs who never manifest injury and insufficient compensation for those who do." *Transamerica Ins. Co. v. Doe*, 840 P.2d 288, 291 (Ariz. App. 1992). "There can be no claim for damages for the fear of contracting asbestos-related diseases in the future without the manifestation of a bodily injury." *Burns v. Jaquays Mining Corp.*, 752 P.2d 28, 31 (Ariz. App. 1987).

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	"Plaintiffs' claim for fear of future product failure cannot stand because such a claim is not recognized by Arizona courts." *In re Minnesota Breast Implant Litig.*, 36 F. Supp. 2d 863, 876 (D. Minn. 1998).
Arkansas	Arkansas has not affirmatively addressed "increased risk" and/or "fear of" claims without underlying physical injury.
Colorado	Colorado has not affirmatively addressed "increased risk" and/or "fear of" claims without underlying physical injury.
Delaware	"In any claim for mental anguish, whether it arises from witnessing the ailments of another or from the claimant's own apprehension, an essential element of the claim is that the claimant have a present physical injury." *Mergenthaler v. Asbestos Corp. of Am.*, 480 A.2d 647, 651 (Del. 1984) (affirming dismissal and rejecting "plaintiffs' argument that 'a claim for the expenses of medically required surveillance and related mental anguish caused thereby is maintainable under Delaware law even if there is no present physical disease.'").
District of Columbia	"Actual, not speculative, damage is required to succeed on a [tort] claim." *In re Estate of Curseen*, 890 A.2d 191, 194 n.3 (D.C. 2006). "The mere breach of a[n owed] duty, causing only nominal damages, speculative harm, or the threat of future harm—not yet realized—does not suffice to create a cause of action for negligence." *Knight v. Furlow*, 553 A.2d 1232, 1235 (D.C. 1989) (internal marks and cites omitted).

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Florida	"[A]ny recovery for cancer damages must await the actuality of cancer …" *Eagle-Picher Indus., Inc. v. Cox*, 481 So. 2d 517, 520-21 (Fla. Dist. Ct. App. 1985) (holding "that the plaintiff cannot recover damages in the present case for his enhanced risk of contracting cancer in the future."). "There is no cognizable cause of action for a mere wrong without damage." *Colville v. Pharmacia & Upjohn Co.*, 565 F. Supp. 2d 1314, 1322-23 (N.D. Fla. 2008) ("[A] diagnosis, [is] not a disease. Therefore, Plaintiff has been unable to establish any current or future injury as a result of her … diagnosis.").
Georgia	"If the damage incurred by the plaintiff is only the imaginary or possible result of a tortious act or if other and contingent circumstances preponderate in causing the injury, such damage is too remote to be the basis of recovery against the wrongdoer." OCGA § 51-12-8. "A fear of future damages is too speculative to form the basis for recovery." *Finnerty v. State Bank & Tr. Co.*, 687 S.E.2d 842, 845 (Ga. App. 2009), *disapproved of on other grounds by Cumberland Contractors, Inc. v. State Bank & Tr. Co.*, 755 S.E.2d 511 (Ga. App. 2014). "The plaintiffs contend that they stated a claim for relief … because the amended complaint also alleged that they 'suffered and will continue to suffer physical, neurological, and mental effects.' The problem is that the amended complaint did not contain any allegations more specific than those vague, conclusory statements. It did not contain, for example, an allegation that the plaintiffs had or will experience any particular symptom as a result of the defendants' purported negligence. As the Supreme Court has explained, such 'naked assertion[s] devoid of further factual enhancement' do not 'suffice.'" *Cure v. Intuitive Surgical Inc.*, 705 F. App'x 826, 828-29 (11th Cir. 2017) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678, (2009)).
Idaho	"'Where the basis for awarding damages is the potential risk of susceptibility to future disease, the predicted future disease must be medically reasonably certain to follow from the existing

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	present injury. While it is unnecessary that the medical evidence conclusively establish with absolute certainty that the future disease or condition will occur, mere conjecture or even possibility does not justify the court awarding damages for a future disability which may never materialize.'" *Mansfield v. United States*, 2019 WL 6868965, at *4 (D. Idaho Dec. 16, 2019) (quoting *Hepburn v. Boston Sci. Corp.*, 2018 WL 2275219, at *1 (D. Idaho May 17, 2018)) ("In this case there is only 'mere conjecture' that future harm might occur. At most there might be a 'possibility' of future harm, but that is not sufficient under the law. Thus, the claim for damages for fear of future harm must be dismissed."). "It is not necessary for [a plaintiff] to prove the existence of an actual injury in order to overcome a motion to dismiss. At this stage, [plaintiffs] need only allege facts sufficient to show a plausible claim for a recoverable injury. [A] Complaint does not do so" if "the allegations raise only a fear of 'potential exposure' and an injury stemming from [plaintiff's] fear of actual exposure." *Stanton v. Battelle Energy Alliance, LLC.*, 83 F. Supp. 3d 937, 946-47 (D. Idaho 2015).
Illinois	The Supreme Court of Illinois "has repeatedly 'observe[d] that, because a plaintiff can sustain a cause of action only where he or she has suffered some injury to a legal right, harm caused by the defendant's conduct is an essential element of every cause of action.' Indeed, courts generally recognize that there must be an actual loss to the interest of the plaintiff before a cause of action accrues. The wrongful or negligent act of the defendant, by itself, gives no right of action to anyone. Until the defendant's wrongful or negligent act produces injury to the plaintiff's interest by way of loss or damage, no cause of action accrues." *Lewis v. Lead Indus. Ass'n*, ___ N.E.3d ___, 2020 IL 124107, ¶¶ 29-30 (Ill. May 21, 2020) (collecting cases); *Rozenfeld v. Medical Protective Co.*, 73 F.3d 154, 155 (7th Cir. 1996) (applying Illinois law) ("A tort does not occur when the tortfeasor violates his duty of care to the victim, but when the tortfeasor injures the victim.").

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	"[A]s a matter of law, an increased risk of future harm is an *element of damages* that can be recovered for a present injury—it is *not* the injury itself." *Williams v. Manchester*, 888 N.E.2d 1, 13 (Ill. 2008) (emphases in original). "There was a split of authority in the appellate court over whether the increased risk of future injury was compensable as an element of damages. Further, those appellate court decisions that allowed recovery did not discuss the form of the instruction. We have now definitively spoken to this issue. ... the increased risk of future injury [i]s an element of damages." *Dillon v. Evanston Hosp.*, 771 N.E.2d 357, 372 (Ill. 2002) (reversing plaintiff's damages award for the increased risk of future injury). "The federal cases ... are consistent with the Illinois Supreme Court's cases involving increased risk of future harm. ... [T]he Illinois Supreme Court explained that the increased risk of future harm is an element of damages that can be recovered for a present injury, noting that the increased risk is not the injury itself." *Greenlee v. United States*, 2010 WL 11688472, at *6, *10 (S.D. Ill. Oct. 14, 2010) ("Even if the [plaintiffs] offer proof of the proper standard of care ... and negligent failure to comply with the applicable standard, they must also show *a resulting injury* proximately caused by the" breach) (emphasis in original).
Indiana	"[A] cause of action accrues at that point at which a physician who is reasonably experienced at making such diagnoses could have diagnosed the individual with a [product]-related illness or disease." *AlliedSignal, Inc. v. Ott*, 785 N.E.2d 1068, 1075 (Ind. 2003); *id*. at n.8 (collecting cases to hold that "[t]he actionable harm is the manifestation of disease in the body" and "[t]o the extent that [prior case law] holds to the contrary, it is overruled.").
Kentucky	"In recent decades, the issue of present physical injury has intersected with an emerging family of tort cases based on exposure to toxic or otherwise harmful substances. The most significant of

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	these cases, *Capital Holding v. Bailey, Ky.*, 873 S.W.2d 187 (Ky. 1994), analyzed a series of earlier decisions by this Court dealing with the question of whether a tort claim could stand without an injury to support it. Addressing specifically the question of whether mere contact with toxic or harmful substances gives rise to a cause of action in tort, the *Capital Holding* decision remained true to traditional tort law requirements, holding essentially that even where exposure and negligent conduct could be proven, a case must be dismissed if the plaintiff can prove no present physical injury. ... [W]e join with the trial court and Court of Appeals in concluding that it is the governing precedent as to the issue at hand." *Wood v. Wyeth-Ayerst Labs., Div. of Am. Home Prod.*, 82 S.W.3d 849, 852 (Ky. 2002).
Louisiana	"Instead of determining whether plaintiffs proved a particular likelihood of genuine and serious mental distress arising from special circumstances, the trial court evaluated the evidence to determine whether plaintiffs' fears of developing cancer were reasonable. Such an evaluation constituted legal error." *Bonnette v. Conoco, Inc.*, 837 So. 2d 1219, 1234-35 (La. 2003) ("due to their inherently speculative nature, in order for plaintiffs to recover emotional distress damages in the absence of a manifest physical injury, they must prove their claim is not spurious by showing a particular likelihood of genuine and serious mental distress arising from special circumstances."). "Louisiana law does not permit a party to maintain an action for mental anguish based on an alleged 'fear' of contracting a disease in the future absent a showing that the party was actually exposed to a contaminated agent." *Nesom v. Tri Hawk Int'l*, 985 F.2d 208, 209-10 (5th Cir. 1993) ("plaintiff was not entitled to maintain a cause of action for his alleged 'fear of contracting a disease in the future, absent an accompanying physical injury *and* absent any proof that he was actually exposed to the disease which is the source of his fear.'").

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	"While we recognize that the fear of an unknowable, but potentially fatal, defect in a heart valve is perfectly rational, and almost certainly sincere, we have serious concerns about permitting recovery for such fear absent actual failure of the valve." *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1099-1000 (5th Cir. 1991).
Maine	Under Maine law, "a plaintiff may recover damages for emotional distress resulting from the tortious conduct of a defendant in three distinct situations. First, as traditionally provided, mental distress or 'pain and suffering' accompanying physical injury caused by tortious conduct is compensable. Second, … a plaintiff may recover damages for emotional distress resulting from negligent conduct (even though that conduct caused no direct physical injury) if the distress is 'substantial and manifested by objective symptomatology,' that is, results in illness or bodily harm. And, third, … a defendant is subject to liability if he engages in extreme or outrageous conduct that intentionally or recklessly inflicts severe emotional distress upon another." *Vicnire v. Ford Motor Credit Co.*, 401 A.2d 148, 154-55 (Me. 1979) ("We now adopt the rule of liability stated in the Restatement of Torts.").
Massachusetts	"'Does Massachusetts recognize a right of action for emotional distress and anxiety caused by the negligence of a defendant, in the absence of any evidence of physical harm, where such emotional stress and anxiety are the result of an increased statistical likelihood [that] the plaintiff will suffer serious disease in the future?' We answer, No." *Payton v. Abbott Labs*, 437 N.E.2d 171, 174-75 (Mass. 1982) ("No Massachusetts case has yet concluded that a plaintiff who alleges that she was a direct victim of a defendant's negligent conduct, but who does not allege that she has suffered resulting physical harm, can recover for emotional distress. ... Jurisdictions allowing recovery for emotional distress without proof of physical harm in negligence cases are clearly in the minority.").

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	"Apprehension of a heightened risk stemming from an allegedly defective product that has not failed or caused harm is insufficient as a matter of law to support a claim." *Watkins v. Omni Life Science Inc.*, 692 F. Supp. 2d 170, 176 (D. Mass. 2010) (citing *Anderson v. W.R. Grace & Co.*, 628 F. Supp. 1219, 1231 n.6 (D. Mass. 1986) ("The weight of authority would deny plaintiffs a cause of action solely for increased risk because no 'injury' has occurred.")).
Minnesota	Under Minnesota law, a defendant is "not negligent as a matter of law until his acts or omissions resulted in damage to [the plaintiff]. Indeed, damage is an essential element of a negligence cause of action. Moreover, the threat of future harm, not yet realized, will not satisfy the damage requirement." *Reliance Ins. Co. v. Arneson*, 322 N.W.2d 604, 607 (Minn. 1982) (citing W. Prosser, *The Law of Torts* 143 (4th ed. 1971) and *Johnson v. Rouchleau-Ray Iron Land Co.*, 168 N.W. 1 (Minn. 1918)).
Mississippi	"As to the law, it is clear that Mississippi does not recognize a cause of action for fear of possibly contracting a disease at some point in the future." *Brewton v. Reichhold Chems., Inc.*, 707 So. 2d 618, 620 (Miss. 1998). "Mississippi has not recognized a cause of action for fear of future disease." *Beech v. Leaf River Forest Prod., Inc.*, 691 So. 2d 446, 451 (Miss. 1997) (citing *Leaf River Forest Prods., Inc. v. Ferguson*, 662 So. 2d 648, 658 (Miss. 1995)).
Montana	Montana has not affirmatively addressed "increased risk" and/or "fear of" claims without underlying physical injury.
Nebraska	"[Plaintiff] contends that we have recognized a cause of action for fear of future product failure based on her interpretation of our opinion in *Hartwig v. Oregon Trail Eye Clinic*, 580 N.W.2d 86 (Neb. 1998) ... We did not establish in *Hartwig* a separate cause of action or theory of recovery for fear of future product failure. A search of case law in other jurisdictions has also not revealed

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	support for adopting such a cause of action. Accordingly, [Plaintiff]'s assignment of error on this issue is without merit." *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 845 (Neb. 2000).
Nevada	"The Nevada Supreme Court has not yet recognized a fear of cancer, absent proof of physical injury or illness, as sufficient to sustain a cause of action in tort. We therefore conclude that plaintiff's failure to allege a legally cognizable injury is sufficient to uphold the district court's dismissal of plaintiff's negligence, nuisance, fraud, and strict liability claims against all defendants." *Galaz v. United States*, 175 F. App'x 831, 832 (9th Cir. 2006).
New Hampshire	New Hampshire has not affirmatively addressed "increased risk" and/or "fear of" claims without underlying physical injury.
New Jersey	As used in the New Jersey Products Liability Act, "'Harm' means (a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph." N.J.S.A. 2A:58C–1(b)(2). "We read our PLA to require a physical injury. Prior to the enactment of the PLA, we adopted generally the view of *Restatement (Second) of Torts* § 402A (1965), in which strict liability in tort for defective products spoke only in terms of physical harm. Nothing in the legislative history of the PLA suggests that the Legislature intended to eliminate that physical component." *Sinclair v. Merck & Co.*, 195 N.J. 51, 64, 948 A.2d 587, 595 (2008) (internal citations omitted). "Plaintiff alleges that, 'as a result of Defendants failure to warn, she is at *risk of* suffering from serious health complications,' including 'tilt, fracture, or breakage of the filter, perforation of the vena cava or other soft tissue, and other serious problems,' without alleging that these adverse health effects have, in fact, occurred after the implantation of her device. … And, more

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	importantly, Plaintiff also alleges that no medical provider has recommended 'revision or removal of [her] device,' notwithstanding her alleged increased risk of experiencing adverse health complications. Therefore, because Plaintiff's warning defect claim is asserted on the basis of 'serious problems' that she has not experienced, [it] is dismissed." *Hindermyer v. B. Braun Med. Inc.*, 419 F. Supp. 3d 809, 829 (D.N.J. 2019) (Wolfson, J.).
New York	"Of course, to the extent that plaintiffs alleged independent causes of action for medical monitoring or fear of cancer, the district court was correct to dismiss these claims. … In other words, a fear of cancer without some physical manifestation of contamination is not an independent basis for a cause of action." *In re World Trade Ctr. Lower Manhattan Disaster Site Litig.*, 758 F.3d 202, 213 (2d Cir. 2014). *Aberbach v. Biomedical Tissue Services, Ltd.*, 854 N.Y.S.2d 143, 145 (N.Y. App. Div. 2008) (affirming motion to dismiss negligence claims in a products liability action because "the complaint fail[ed] to allege a cognizable injury suffered as a result of the appellants' alleged negligence.").
North Carolina	"We are sympathetic to Plaintiffs' situation. Although none of the Plaintiffs is presently diagnosed with an illness ... there is evidence that their exposure to these chemicals increased their future risk of serious illnesses, including certain cancers. These claims are not totally novel; Plaintiffs in many jurisdictions have raised similar claims. However, for several reasons, we elect not to create these new causes of action." *Curl v. Am. Multimedia, Inc.*, 187 N.C. App. 649, 655-56, 654 S.E.2d 76, 81 (2007) (internal citations omitted). "If a North Carolina court were faced with the question of whether to create a tort based upon alleged increased risk of disease or for medical monitoring costs, the undersigned has concluded that it would decline to create such a tort." *Carroll v. Litton Sys.*, 1990 WL 312969, at *51-56

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	(W.D.N.C. Oct. 29, 1990), *aff'd in part & rev'd in part on other grounds*, 47 F.3d 1164 (4th Cir. 1995) (table).
North Dakota	North Dakota, like "[a]majority of jurisdictions[,] follows the Restatement 2d Torts § 436A (1965) and requires bodily harm to recover for negligent infliction of emotional distress." *Muchow v. Lindblad*, 435 N.W.2d 918, 921-22 (N.D. 1989).
Ohio	As used in the Ohio Products Liability Act, "'Harm' means death, physical injury to person, serious emotional distress, or physical damage to property other than the product in question. Economic loss is not 'harm.'" Ohio Rev. Code Ann. § 2307.71(A)(7). *Lorenzi v. Pfizer, Inc.*, 519 F. Supp. 2d 742, 751 (N.D. Ohio 2007) (granting summary judgment in favor of manufacturer of prescription contraceptive because the "Plaintiff [wa]s unable to show a current or future injury").
Oregon	"Following our precedents, we hold that negligent conduct that results only in a significantly increased risk of future injury that requires medical monitoring does not give rise to a claim for negligence. The trial court correctly dismissed plaintiff's complaint for failure to state a negligence claim, and the Court of Appeals correctly affirmed the trial court's judgment." *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181, 187 (Or. 2008).
Pennsylvania	"[W]e hold that awarding damages for the increased risk and fear of cancer is contrary to the established jurisprudence of this Commonwealth ..." *Simmons v. Pacor, Inc.*, 543 Pa. 664, 679, 674 A.2d 232, 239-40 (1996); *id.* at 237 ("After examining the issue at great length, we agree that asymptomatic [conditions are] not a compensable injury which gives rise to a cause of action."). "Pennsylvania courts have recognized causes of action for intentional infliction of emotional distress even though the plaintiff has not suffered a direct physical injury, but these cases have

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	been in narrow situations involving particular plaintiffs in which defendants were accused of wrongful conduct either aimed specifically at the plaintiffs or likely to have a special impact on them as distinguished from a large group of persons. We find these cases of limited precedential value here for we are convinced that the Pennsylvania Supreme Court would not apply their principles in a situation in which the alleged wrongdoing was directed at a class of consumers rather than a particular plaintiff. If the Supreme Court of Pennsylvania recognized a cause of action for intentional infliction of emotional distress on the allegations of [Plaintiff]'s complaint, it effectively would sanction a large, if not vast, number of lawsuits by consumers who obtained properly functioning [heart] valves. We do not believe that it would do any such thing." *Angus v. Shiley Inc.*, 989 F.2d 142, 147-48 (3d Cir. 1993) (internal citations omitted).
Rhode Island	"Exposure to a carcinogenic agent does not automatically result in the development of cancer. If mere exposure to a potential carcinogenic was actionable, the courts would be inundated with actions arising merely from an individual's daily activities such as consuming a soft drink. Therefore, ... we conclude that in the absence of any physical manifestation of asbestos-related illness or disease, plaintiff could not establish a *prima facie* case of negligence as a matter of law, and therefore, summary judgment was proper. Further, we hold that the possibility of contracting cancer resulting from mere exposure to a carcinogen, although potentially increasing one's risk of developing cancer, is too tenuous to be a viable cause of action." *Kelley v. Cowesett Hills Assocs.*, 768 A.2d 425, 430 (R.I. 2001) (internal citations omitted). "[T]his Court has specifically stated that in Rhode Island no difference exists between negligent and intentional infliction of emotional distress claims in respect to the need for physical symptomatology. We have recognized the right to recover damages by one who has been subjected to the intentional *or* the negligent infliction of mental distress as long as the distress is *accompanied by physical ills.*" *Clift v. Narragansett Television L.P.*, 688 A.2d 805, 813 (R.I. 1996) (internal marks and cites omitted); *cf. Marchetti v. Parsons*, 638 A.2d 1047, 1052 (R.I.

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	1994) (recovery for negligent infliction of emotional distress requires a showing of accompanied physical symptomatology).
South Carolina	"It is well settled in South Carolina that in a personal injury action, the verdict may include only such future damages as 'reasonably certain will of necessity' result in the future from the injury. The 'reasonably certain' rule has been described as one 'which manifestly and logically will reasonably come to pass, and not a mere possibility or probability.' It is a consequence 'which follows the original act complained of in the usual, ordinary, and experienced course of events.'" *Rabb v. Orkin Exterminating Co.*, 677 F. Supp. 424, 426-28 (D.S.C. 1987) (holding further that "evidence of the Plaintiffs' fear of increased risk of disease was properly excluded at trial") (internal citations omitted).
South Dakota	South Dakota has not affirmatively addressed "increased risk" and/or "fear of" claims without underlying physical injury.
Tennessee	"Tennessee law also requires that, to recover for future effects of an injury, the future effects must be shown to be reasonably certain and not a mere likelihood or possibility and that, before a plaintiff may recover for potential injuries, there must be a reasonable degree of medical certainty that the plaintiff will develop a disease in the future as a result of an injury." *Potts v. Celotex Corp.*, 796 S.W.2d 678, 681 (Tenn. 1990) (citations omitted).
Texas	Plaintiffs "argue that they are entitled to recover mental anguish damages even if they sustained no physical injury, as long as their fear of developing some [product]-related disease is reasonable. This argument conflicts with our decision in *Boyles v. Kerr*, [855 S.W.2d 593 (Tex. 1993)], where we held that 'there is no general duty not to negligently inflict emotional distress.'" *Temple-Inland Forest Prod. Corp. v. Carter*, 993 S.W.2d 88, 91 (Tex. 1999).

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	The "tortious breach of [a] duty ... is not a wrong for which mental anguish is compensable absent physical injury. This is true whether the [] duty arises from the common law or from the federal regulation invoked by [Plaintiffs] in their pleadings. Accordingly, [Plaintiffs] cannot recover mental anguish damages absent physical injury." *Id*. *Tedford v. Warner-Lambert Co.*, 327 F.3d 423, 428 n.11 (5th Cir. 2003) (noting one of the two plaintiffs who had taken the drug at issue "could not assert a cognizable claim because she had not yet suffered any injury"). "The wrongs [Plaintiffs] allege—failure to warn and sale of a defective product—are products liability claims. Yet, the damages they assert—benefit of the bargain, out of pocket expenditures—are contract law damages. The plaintiffs apparently believe that if they keep oscillating between tort and contract law claims, they can obscure the fact that they have asserted no concrete injury. Such artful pleading, however, is not enough to create an injury in fact. ... By definition, [Plaintiff]'s no-injury 'damages' will not vary with Wyeth's degree of negligence or the drug's propensity for harm. [Plaintiff] has not even indicated what additional warnings Wyeth should have included or which of [the drug]'s defects Wyeth should have cured—perhaps because as one not injured by the drugs, she does not know." *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 321 (5th Cir. 2002) (noting that the learned intermediary doctrine "provide[s] plaintiffs an additional hurdle in demonstrating causation. ... To find causation, we would have to infer the absurd—for example, that an extra warning, though inapplicable to [plaintiff], might have scared her and her doctor from [the drug]. Such reasoning is too speculative to establish Article III standing."). "There is no cause of action under Texas law where a plaintiff's product is and has been functioning without incident. Texas law does not recognize a claim seeking to recover for alleged concern or anxiety that a functioning product might fail at some future unknown time."

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	Lauterbach v. Shiley, Inc., 1991 WL 148137, at *9 (S.D. Tex. Mar. 29, 1991) (citing *Gideon v. Johns-Manville Sales Corp.*, 761 F.2d 1129, 1131-37 (5th Cir. 1985)). "Since the state courts have not ruled that future anticipated injuries in products liability cases would amount to an injury, the federal court should not advance such a theory. Federal Courts exercising diversity jurisdiction may not create theories of recovery which are unprecedented in state law, but must simply apply the state law as it exists. In the instant action, state law dictates that the product must be defective and cause an injury to recover in a products liability case. *Id.* (citing *Harmon v. Grande Tire Co.*, 821 F.2d 252, 259 (5th Cir. 1987); and *Dean v. Dean*, 837 F.2d 1267 (5th Cir. 1988)).
Utah	Under Utah law, "even though there exists a possibility, even a probability, of future harm, it is not enough to sustain a claim, and a plaintiff must wait until some harm manifests itself." *Riggs v. Asbestos Corp.*, 304 P.3d 61, 67 (Utah App. 2013); *see Seale v. Gowans*, 923 P.2d 1361, 1364-65 (Utah 1996) (holding "that damages in the form of an enhanced risk" are insufficient to sustain a cause of action); *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 978-79 (Utah 1993) ("[m]ere exposure to an allegedly harmful substance ... is not enough for recovery" because "the plaintiff is not harmed until the onset of the actual illness").
Vermont	Vermont has not affirmatively addressed "increased risk" and/or "fear of" claims without underlying physical injury.
Virginia	"Except for the intentional infliction of emotional distress, damages for emotional distress may not be recovered under West Virginia or Virginia law absent a finding of physical injury." *Ball v. Joy Techs., Inc.*, 958 F.2d 36, 38 (4th Cir. 1991) (citations omitted). "Plaintiff urges this court to expand the law of torts in West Virginia and Virginia and recognize exposure to toxic substances as a physical injury. The *Erie* doctrine permits federal courts to rule

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	upon state law as it presently exists and not to surmise or suggest its expansion. Because the law of West Virginia and Virginia requires physical injury before a plaintiff may recover damages for emotional distress, the district court was correct in concluding that the exposure of the plaintiffs to toxic chemicals did not constitute an injury that would entitle them to recover damages for emotional distress." *Id.* at 39 (internal marks and citation omitted). *Contreras v. Thor Norfolk Hotel, LLC*, 292 F. Supp. 2d 798, 801 (E.D. Va. 2003) ("[B]ecause Plaintiff does not suffer from an[y current] disease, he may not recover ... for the psychological injuries he has alleged, including 'emotional distress' and 'fear of developing' asbestosis and cancer. The United States Court of Appeals for the Fourth Circuit has held that 'Virginia requires physical injury before a plaintiff may recover damages for emotional distress.'").
Washington	"Lacking controlling precedent on which to rely, the court makes several observations based on Washington precedent that applies only obliquely to Plaintiffs' claims. First, Washington does not provide a contract or negligence remedy for every conceivable injury. ... Second, no Washington court has recognized a cause of action or remedy in which the sole injury is an increased risk of a future harm (whether or not accompanied by monitoring costs). ... Third, if the Washington Supreme Court were to recognize a common law cause of action to recover for an increased risk of identity theft, it would apparently be the only court to do so. So far as the court is aware, every court that has considered a similar claim has found that it is not cognizable under applicable state law." *Krottner v. Starbucks Corp.*, 2009 WL 7382290, at *7 (W.D. Wash. Aug. 14, 2009) (collecting cases) (internal citations omitted).
West Virginia	"Except for the intentional infliction of emotional distress, damages for emotional distress may not be recovered under West Virginia or Virginia law absent a finding of physical injury." *Ball*

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	v. Joy Techs., Inc., 958 F.2d 36, 38-39 (4th Cir. 1991) (“The law of West Virginia and Virginia requires physical injury before a plaintiff may recover damages.”).
Wisconsin	“[W]e have generally held that a tort claim is not capable of present enforcement ... unless the plaintiff has suffered actual damage. Actual damage is harm that has already occurred or is ‘reasonably certain’ to occur in the future. Actual damage is not the mere possibility of future harm.” *Tietsworth v. Harley-Davidson, Inc.*, 677 N.W.2d 233, 239 (Wis. 2004) (internal citations omitted). Under Wisconsin law, a “complaint must adequately plead an actual injury—a loss or damage that has already occurred or is reasonably certain to occur—in order to state an actionable fraud claim.” *Id*. at 240. “Wisconsin law holds that the ‘mere possibility of future harm’ does not constitute actual injury or damage.” *Alsteen v. Wauleco, Inc.*, 802 N.W.2d 212, 215 (Wis. App. 2011). “[T]he mere fact that the model’s failure rate was unusually high, as Medtronic admitted in its advisories, does not automatically create liability. Under the circumstances, the real cause of the [plaintiff’s] injuries was [his] personal belief that his pacemaker was likely to fail unless the lead was replaced, that such a failure would be life-threatening, and that the risk of failure outweighed the risks of replacement surgery.” *O’Brien v. Medtronic, Inc.*, 439 N.W.2d 151, 154 (Wis. App. 1989) (noting “the adverse consequences of permitting recovery under the facts presented. ... If we are going to do so based only on a higher-than-average failure rate, it would present difficult line-drawing problems. Additionally, were we to allow recovery here, liability would be based on the recipient's subjective state of mind no matter how unreasonable that might be. The undesirability of that result is apparent.”).

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Wyoming	“In Wyoming, our decisions have restricted recovery for emotional distress damages without accompanying physical injury.” *Long-Russell v. Hampe*, 39 P.3d 1015, 1017 (Wyo. 2002) (collecting cases).

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Alabama	Alabama does not recognize a cause of action for medical monitoring absent physical injury. *Hinton v. Monsanto Co.*, 813 So. 2d 827, 832 (Ala. 2001); *Houston Cty. Health Care Auth. v. Williams,* 961 So. 2d 795, 811 (Ala. 2006) (same).
Alaska	The Alaskan Supreme Court has not definitively ruled on whether a cause of action arises from medical injury absent physical injury. *West v. Williams Alaska Petroleum, Inc.*, 2011 WL 12548809, at *3 (Alaska Super. March 16, 2011), *reconsideration denied*, 2011 WL 12548813 (Alaska Super. April 6, 2011) (same).
Arizona	Medical monitoring damages are not available where plaintiffs fail to show value of increased testing over "what would normally have been prudent for them based on their individual circumstances." *DeStories v. City of Phoenix*, 744 P.2d 705, 711 (Ariz. App. 1987).
Arkansas	Arkansas has rejected medical monitoring as a cause of action, and questions its availability as a remedy. *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555, 569 (E.D. Ark. 2005).
Connecticut	The Connecticut Supreme Court has not addressed whether medical monitoring can be the basis for a cause of action; however, for a plaintiff to recover damages for future medical monitoring one must have sustained an actionable injury. *McCullough v. World Wrestling Ent., Inc.*, 172 F. Supp. 3d 528, 567 (D. Conn. 2016); *Poce v. O & G Indus., Inc.*, 2017 WL 6803084, at *4 (Conn. Super. Dec. 5, 2017) (same); *Dougan v. Sikorsky Aircraft Corp.*, 2017 WL 7806431, at *4-7 (Conn. Super. March 28, 2017) (same).
Delaware	Delaware has refused to recognize a medical monitoring claim absent present injury. *Mergenthaler v. Asbestos Corp. of Am.*, 480 A.2d 647, 651 (Del. 1984); *M.G. v. A.I. duPont Hospital For Children*, 393 F. App'x 884, 892-93 (3d Cir. 2010) (same).

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District of Columbia	Whether a cause of action or a part of damages requested, medical monitoring requires that the plaintiff have a present injury and a reasonable fear that the present injury could lead to the future occurrence of disease. *Witherspoon v. Philip Morris, Inc.*, 964 F. Supp. 455, 467 (D.D.C. 1997).
Georgia	Georgia does not recognize medical monitoring claims absent a cognizable injury. *Cure v. Intuitive Surgical, Inc.*, 2017 WL 498727, at *6 (N.D. Ga. Jan 30, 2017), *aff'd*, 705 F. App'x 826 (11th Cir. 2017); *Parker v. Wellman Brush, Inc.*, 377 F. Supp. 2d 1290, 1302 (N.D. Ga. 2005) (same).
Hawaii	Hawaii has not affirmatively addressed medical monitoring claims without underlying physical injury.
Illinois	The Illinois Supreme Court doubts whether medical monitoring can be a form of recovery absent present injury. *Lewis v. Lead Indus. Ass'n*, ___ N.E.3d ___, 2020 WL 2562929, at *6 (Ill. May 21, 2010); *Jensen v. Bayer AG*, 862 N.E.2d 1091, 1101 (Ill. 2007) (same); *Lewis v. Lead Indus. Ass'n, Inc.*, 793 N.E.2d 869, 877 (Ill. 2003) (same).
Indiana	Indiana finds that medical monitoring claims involving class actions engender too many individual issues to be suitable. *Adams v. Clean Air Systems, Inc.*, 586 N.E.2d 940, 942 (Ind. App. 1992); *Pisciotta v. Old Nat'l Bancorp*, 499 F.3d 629, 639 & n.10 (7th Cir. 2007) (same); *Johnson v. Abbott Labs.*, 2004 WL 3245947, at *4 (Ind. Cir. Dec. 31, 2004) (same).
Iowa	Iowa does not recognize a claim for medical monitoring as an independent cause of action nor does it recognize medical monitoring as a form of damages when there is no cognizable injury. *Pickerell v. Sorin Group USA, Inc.*, 293 F. Supp. 3d 865, 868 (S.D. Iowa 2018).

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Kansas	Kansas does not recognize medical monitoring as a free-standing cause of action, but as a component of damages. *Burton v. R.J. Reynolds Tobacco Co.*, 884 F. Supp. 1515, 1522 (D. Kan. 1995).
Kentucky	Kentucky does not recognize medical monitoring as an independent cause of action, expressing an unwillingness to upend traditional notions of tort law and step into the role of the legislature. *Wood v. Wyeth-Ayerst Labs.*, 82 S.W.3d 849, 859 (Ky. 2002); *Modern Holdings, LLC v. Corning, Inc.*, 2015 WL 1481457, at *16 (E.D. Ky. March 31, 2015) (same).
Maine	Maine has not affirmatively addressed medical monitoring claims without underlying physical injury.
Michigan	Michigan does not recognize a cause of action for medical monitoring as a cognizable claim. *Henry v. Dow Chem. Co.*, 701 N.W.2d 684, 686 (Mich. 2005).
Minnesota	Minnesota recognizes medical monitoring as an element of monetary damages only when a plaintiff can establish an injury in fact. *Thompson v. Am. Tobacco Co.*, 189 F.R.D. 544, 552 (D. Minn. 1999); *Palmer v. 3M Co.*, 2007 WL 1879844 (Minn. Dist. June 19, 2007) (same); *Palmer v. 3M Co.*, 2005 WL 5891911 (Minn. Dist. April 26, 2005) (same).
Mississippi	Mississippi does not recognize a medical monitoring cause of action without a showing of physical injury. *Paz v. Brush Engineered Materials, Inc.*, 949 So. 2d 1, 9 (Miss. 2007).
Missouri	Missouri does not recognize medical monitoring as an independent cause of action nor does it recognize medical monitoring as a remedy outside of actual exposure in toxic tort cases. *Ratliff v. Mentor Corp.*, 569 F. Supp. 2d 926, 929 (W.D. Mo. 2008).

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Nebraska	Nebraska does not recognize a claim for medical monitoring when no present physical injury is alleged. *Trimble v. Asarco, Inc.*, 232 F.3d 946, 952 (8th Cir. 2000); *Schwan. v. Cargill Inc.*, 2007 WL 457042, at *1 (D. Neb. Dec. 21, 2007) (same).
New Jersey	In product liability cases, New Jersey does not recognize medical monitoring as a cause of action nor does New Jersey recognize medical monitoring as a form of damages absent a physical injury. N.J. Stat. Ann. § 2A:58C-1b(2); *Sinclair v. Merck & Co.*, 195 N.J. 51, 65-66, 948 A.2d 587, 595-96 (2008) (same); *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 2011 WL 4007878, at *2 (E.D. Pa. Sept. 7, 2011) (applying New Jersey law) (same).
North Carolina	North Carolina does not recognize medical monitoring as an independent cause of action. *Curl v. American Multimedia, Inc.*, 654 S.E.2d 76, 81 (N.C. App. 2007).
North Dakota	The North Dakota Supreme Court has not affirmatively addressed the issue of whether North Dakota law recognizes a claim for medical monitoring, however, it is well-established that North Dakota requires "proof of actual damages" for "torts of negligence, fraud and deceit." *Mehl v. Canadian Pac. Ry. Ltd.*, 227 F.R.D. 505, 518 (D.N.D. 2005).
Oklahoma	Oklahoma does not recognize medical monitoring as a remedy except for those who have suffered a present injury. *McCormick v. Halliburton Co.*, 895 F. Supp. 2d 1152, 1158-59 (W.D. Okla. 2012); *Cole v. ASARCO Inc.*, 256 F.R.D. 690, 695-96 (N.D. Okla. 2009) (same).
Oregon	Oregon does not recognize a claim for medical monitoring absent physical injury. *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181, 187 (Or. 2008).
Pennsylvania	"Medical monitoring is a suitable form of relief in toxic substance exposure types of cases because doctors can often diagnose warning signs of diseases and other medical problems associated with toxic substance exposure through medical monitoring. The same argument,

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	however, cannot be made for medical monitoring relief in products liability cases, where diseases caused by exposure to toxic substances are not the type of injury at issue." *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1995 WL 273597, at *9 (E.D. Pa. Feb. 22, 1995) (citation omitted).
Puerto Rico	Puerto Rico does not permit claims for medical monitoring. *Ruiz v. Am. Tobacco Co.*, 180 F.R.D. 194, 199 (D.P.R. 1998).
Rhode Island	Rhode Island only permits a plaintiff to recover for medical monitoring damages where such future apprehended consequences are reasonably certain to ensue. *Miranda v. Dacruz*, 2009 WL 3515196, at *7 (R.I. Super. Oct. 26, 2009).
South Carolina	The South Carolina Supreme Court has not affirmatively addressed whether medical monitoring can be the basis for an independent cause of action; however, South Carolina courts predict that the Supreme Court would not recognize medical monitoring. *Easler v. Hoechst Celanese Corp.*, 2014 WL 3868022, at *10 n.5 (D.S.C. Aug. 5, 2014); *Rosmer v. Pfizer, Inc.*, 2001 WL 34010613, at *5 (D.S.C. March 30, 2001) (same).
South Dakota	South Dakota does not allow medical monitoring claims without underlying physical injury. *Peterson v. Safway Steel Scaffolds Co.*, 400 N.W.2d 909, 912 (S.D. 1987); *Rynders v. E.I. Du Pont De Nemours & Co.*, 21 F.3d 835, 842 (8th Cir. 1994).
Tennessee	Tennessee does not permit claims for medical monitoring absent physical injury. *Bostick v. St. Jude Med., Inc.*, 2004 WL 3313614, at *14 (W.D. Tenn. Aug. 17, 2004).
Texas	The Texas Supreme Court has not affirmatively addressed whether medical monitoring can be the basis for an independent cause of action; however, Texas courts predict that the Supreme Court would not recognize medical monitoring. *Norwood v. Raytheon Co.*, 414 F. Supp. 2d 659,

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	667 (W.D. Tex. 2006); *Downer v. Simon Prop. Group Texas L.P.*, 2009 WL 2199352 ¶16 (Tex. Dist. May 28, 2009) (same).
Virginia	The Virginia Supreme Court has not affirmatively addressed whether medical monitoring can be the basis for an independent cause of action; however, Virginia courts predict that the Supreme Court would not recognize medical monitoring.. *In re All Pending Chinese Drywall Cases*, 2010 WL 7378659, at *9-10 (Va. Cir. March 29, 2010).
Washington	Washington does not recognize a standalone claim for medical monitoring. *Krottner v. Starbucks Corp.*, 2009 WL 7382290, at *7 (W.D. Wash. Aug. 14, 2009); *Duncan v. Nw. Airlines*, 203 F.R.D. 601, 605 (W.D. Wash. 2001) (same); *Durocher v. Riddell, Inc.*, 97 F. Supp. 3d 1006 (S.D. Ind. 2015) (same).
Wisconsin	Wisconsin recognizes medical monitoring as a form of damages only when there is an actual injury. *Alsteen v. Wauleco, Inc.*, 802 N.W.2d 212, 219 (Wis. 2011). "[D]efining the need for medical monitoring as an 'injury' does nothing more than attach a specific item of damages to what is actually a claim for increased risk of future harm. Yet, Wisconsin tort law does not compensate for increased risk of future harm; actual, present injury is required. That [Plaintiff] seeks medical monitoring damages, as opposed to some other measure of compensation, does not change this result." *Id*. at 218-19 (internal citations omitted). *Alsteen v. Wauleco, Inc.*, 802 N.W.2d 212, 215 (Wis. App. 2011).
Wyoming	Wyoming has not affirmatively addressed medical monitoring claims without underlying physical injury.

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Alabama	Distinguishing a manufacturing defect from a design defect insofar as a manufacturing defect presents itself when "one, or a few of the products of a line are defective such as the occasional exploding soft drink bottle" whereas a design defect has "occurred when every product of a line is defective due to a faulty blueprint." *Schwartz v. Volvo N. Am. Corp.*, 554 So. 2d 927, 941 n.5 (Ala. 1989); *Nicholson v. Pickett*, 2016 WL 854370, at *20 (M.D. Ala. March 4, 2016) (same).
Arizona	Distinguishing a manufacturing defect from a design defect insofar as the former is flawed as a result of something that went wrong during the manufacturing process whereas the latter concerns a product manufactured as designed but is unreasonably dangerous. *Gomulka v. Yavapai Mach. & Auto Parts, Inc.*, 745 P.2d 986, 988-89 (Ariz. App. 1987); *Hedding v. Broan-NuTone, Inc.*, 2010 WL 11627611, at *2 n.1 (D. Ariz. Jan. 13, 2010) (same).
Arkansas	Distinguishing a manufacturing defect from a design defect insofar as the former involves "a configuration of a product that deviates from the intended design," and the latter "is executed according to plan but produces unintended and unwanted results." *McLelland v. Ridge Tool Co.*, 342 F. Supp. 3d 851, 857 (W.D. Ark. 2018) (distinguishing between manufacturing defect and design defect); *Simpson v. Wright Med. Grp., Inc.*, 2018 WL 1570795, at *9 (E.D. Ark. March 30, 2020) (same, in medical device case).
California	Defining a design defect analysis as one that "focuses upon whether the product was designed to perform as safely as an ordinary consumer would expect or whether the risk of danger inherent in the design outweighed the benefits of the design." *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 454 (Cal. 1978). Defining a manufacturing defect as one that is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from some other ostensibly identical units of the same product line. *In re Coordinated Latex Glove Litig.*, 99 Cal. App. 4th 594, 605, (Cal. App. 2014) (medical device case). Numerous California cases have dismissed design defect claims masquerading as manufacturing defects in medical device cases.

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	E.g., *Hannan v. Boston Sci. Corp.*, 2020 WL 2128841, at *5-6 (N.D. Cal. May 5, 2020); *Sivilli v. Wright Med. Tech., Inc.*, 2019 WL 3803808, at *2-3 (S.D. Cal. Aug. 13, 2019); *Patton v. Forest Labs., LLC*, 2017 WL 10439658, at *7 (C.D. Cal. Nov. 1, 2017); *Jager v. Davol, Inc.*, 2017 WL 696081, at *5 (C.D. Cal. Feb. 9, 2017).
Colorado	Distinguishing between manufacturing defect from a design defect insofar as the former is caused by the "product fail[ing] to conform to the manufacturer's specifications" whereas the latter is rendered unreasonably dangerous "despite the fact that it was manufactured exactly as intended." *Walker v. Ford Motor Co.*, 406 P.3d 845, 849 (Colo. 2017).
Connecticut	Distinguishing a manufacturing defect from a design defect insofar as the former is an instance of "shoddy workmanship" and the latter is one "inherent in the product or system." *Miller v. United Techs. Corp.*, 660 A.2d 810, 846 (Conn. 1995); *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 110 (D. Conn. 2014) (allegations that the FDA's design of a product is defective are insufficient to support a design defect claim); *Johannsen v. Zimmer, Inc.*, 2005 WL 756509, at *8 (D. Conn. March 31, 2005) (distinguishing between a design defect and a manufacturing defect in medical device case).
Delaware	Distinguishing a manufacturing defect from a design defect insofar as the former arises when a manufacturer fails to take reasonable care in the making of a product and the latter arises when the product line is designed improperly. *Di Ienno v. Libbey Glass Div., Owens-Illinois, Inc.*, 668 F. Supp. 373, 377 (D. Del. 1987); *McLaughlin v. Dover Downs, Inc.*, 2008 WL 2943392, at *15 (Del. Super. July 17, 2008) (same).
District of Columbia	Defining a design defect and a manufacturing defect. *Cormier v. D.C WASA*, 2011 WL 4543680, at *27 (D.C. Super. Sept. 30, 2011); *Brandt v. Uniroyal, Inc.*, 425 A.2d 162, 163 (D.C. App. 1980) (same).

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Florida	"The distinction between 'aberrational' defects and defects occurring throughout an entire line of products is frequently used in tort law to separate defects of manufacture from those of design. Stated another way the distinction is between an unintended configuration, and an intended configuration that may produce unintended and unwanted results." *Harduvel v. Gen. Dynamics Corp.*, 878 F.2d 1311, 1317 (11th Cir. 1989) (internal citation omitted); *Salinero v. Johnson & Johnson*, 400 F. Supp. 3d 1334 (S.D. Fla. 2019) (defining the elements of a manufacturing defect in medical device case insofar as a plaintiff must prove (1) that the product was defective, (2) the defect existed at the time the product left the defendant-manufacturer's control, and (3) the defect proximately caused the plaintiff's injuries); *Hall v. Sunjoy Indus. Grp., Inc.*, 764 F. Supp. 2d 1297, 1302-03 (M.D. Fla. 2011) (same).
Georgia	Distinguishing a manufacturing defect from a design defect insofar as the former is a defect that is "measurable against a built-in objective standard or norm or proper manufacture" and the latter is defective because "all products have the defect." *Lloyd's Syndicate No. 5820 v. AGCO Corp.*, 756 S.E.2d 520, 522-23 (Ga. 2014); *May v. Ethicon, Inc.*, 2020 WL 674357, at *3 (N.D. Ga. Feb. 11, 2020) (same, in medical device case); *In re C.R. Bard, Inc.*, 2013 WL 2431975, at *4 (S.D.W. Va. June 4, 2013) (applying Georgia law) (dismissing a design defect claim masquerading as a manufacturing defect in medical device case).
Hawaii	Distinguishing a manufacturing defect from a design defect insofar as the former does not "conform to the quality of other products of its kind" and the latter cannot be "measured against a standard set by the manufacturer." *Wagatsuma v. Patch*, 879 P.2d 572, 583 & n.6 (Haw. App. 1994).
Illinois	Distinguishing a manufacturing defect from a design defect insofar as the former "departs from its intended design" and the latter arises when "the specific units conform to the intended design, but the intended design itself." *Blue v. Envtl. Eng'g, Inc.*, 828 N.E.2d 1128, 1138 (Ill. 2005);

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	Gravitt v. Mentor Worldwide, LLC, 2018 WL 2933609, at *9 (N.D. Ill. June 12, 2018) (same with respect to breast implants).
Indiana	Distinguishing a design defect from a manufacturing defect insofar as the former "deviates from its intended design" and the latter has an "alternative design." *Piltch v. Ford Motor Co.*, 778 F.3d 628, 632 (7th Cir. 2015), *abrogated on other grounds*, *Kaiser v. Johnson & Johnson*, 947 F.3d 996 (7th Cir. 2020); *United States Specialty Ins. Co. v. Daimler Trucks N. Am., LLC*, 2018 WL 4680231, at *6 (S.D. Ind. Sept. 28, 2018) (defining a design defect as one that arises when a manufacturer failed to exercise reasonable care in designing the product).
Iowa	Defining a manufacturing defect as one that departs from its intended design and a design defect is one where the entire design of a product line is defective. *Wright v. Brooke Group, Ltd.*, 652 N.W.2d 159, 178 (Iowa 2002); *Linden v. CNH Am., LLC*, 673 F.3d 829, 835 (8th Cir. 2012) (distinguishing between design defect and a manufacturing defect); *Depositors Ins. Co. v. Wal-Mart Stores, Inc.*, 506 F.3d 1092, 1095 (8th Cir. 2007) (same).
Kansas	Distinguishing a manufacturing defect from a design defect insofar as the former must show that the product was different from others produced and the latter must show that a design defect encompasses all products of that type. *Jenkins v. Amchem Prods.*, 886 P.2d 869, 887 (Kan. 1994); *Davison v. C.R. Bard, Inc.*, 2020 WL 2513069, at *4 (D. Kan. May 15, 2020) (same in medical device case); *Reed v. Keating, Inc.*, 1989 WL 159343, at *1-2 (D. Kan. Dec. 13, 1989), *on reconsideration*, 1990 WL 11113 (D. Kan. Jan. 9, 1990) (same).
Kentucky	Distinguishing a manufacturing defect from a design defect insofar as the former is a deviation from the product line and the latter concerns itself with the feasibility of a safer alternative design (and the other does not). *Nichols v. Union Underwear Co., Inc.*, 602 S.W.2d 429, 433 (Ky. 1980); *Wright v. Gen. Elec. Co.*, 242 S.W.3d 674, 682 (Ky. App. 2007) (a component part manufactured

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	as designed is a design defect and not a manufacturing defect); *Edwards v. Hop Sin, Inc.*, 140 S.W.3d 13, 15 (Ky. App. 2003) (defining a manufacturing defect).
Louisiana	Defining a manufacturing defect and a design defect. La. Rev. Stat. §§ 9:2800.52, 9:2800.55; *Weams v. FCA US L.L.C.*, 2019 WL 960159, at *20 (M.D. La. Feb. 27, 2019), *cert. denied*, 2019 WL 3812222 (M.D. La. July 9, 2019), *appeal dismissed*, 2019 WL 4673560 (5th Cir. Aug. 9, 2019) (distinguishing a manufacturing defect from a design defect insofar as the former is a deviation from the product line and the latter is a problem of the entire product line); *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 263 (5th Cir. 2002) (defining a manufacturing defect).
Maine	Distinguishing a manufacturing defect from a design defect insofar as the former involves "fail[ure] to comply with product specifications" and the latter whether "the risks of the drug's design outweigh its therapeutic benefits *Doe v. Solvay Pharm., Inc.,* 350 F. Supp. 2d 257, 263, 268 (D. Me. 2004) (following Restatement (Third) of Torts), *aff'd,* 153 F. App'x 1 (1st Cir. 2005).
Maryland	Defining a manufacturing defect as one in which "the defect is a result of an error in the manufacturing process, that is where the product is in a condition not intended by the seller". *Phipps v. Gen. Motors Corp.*, 363 A.2d 955, 959 (Md. 1976); *Klein v. Sears, Roebuck & Co.*, 608 A.2d 1276, 1280 (Md. App. 1992); *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 411 (D. Md. 2001) (defining a design defect analysis as one that focuses "upon the specifications for the construction of the product and the risks and benefits associated with that design").
Massachusetts	Distinguishing a manufacturing defect from a design defect insofar as the former is a deviation from the intended design and the latter is complaint with the design, but the design itself is defective. *Evans v. Lorillard Tobacco Co.*, 990 N.E.2d 997, 1010 (Mass. 2013); *Acevedo v. Johnson & Johnson*, 2018 WL 4693958, at *5 (D. Mass. Sept. 30, 2018) (same, in medical device case).

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Michigan	Distinguishing between a manufacturing defect and a design defect insofar as the former is a malfunction with the manufacturing process and the latter is a deliberate and documentable decision on the part of manufacturers. *Gregory v. Cincinnati Inc.*, 538 N.W.2d 325, 329 & n.10 (Mich. 1995); *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 183, 185 (Mich. 1984) (same).
Minnesota	Distinguishing a manufacturing defect from a design defect insofar as the former exists when the product "departs from its intended design" and the latter is a defect in a consciously chosen design. *Harrison v. Harrison*, 733 N.W.2d 451, 454 n.2 (Minn. 2007); *Bilotta v. Kelley Co.*, 346 N.W.2d 61, 623 n.3 (Minn. 1984) (same); *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1147 (D. Minn. 2011) (same, in medical device case).
Mississippi	Distinguishing between a manufacturing defect and a design defect insofar as the former is a deviation from the design and the latter's design is inherently dangerous. Miss. Code § 11-1-63(a)(i); *In re C.R. Bard, Inc.*, 2013 WL 5591948, at *4 (S.D.W. Va. June 4, 2013) (applying Mississippi law) (medical device case).
Missouri	Distinguishing between a manufacturing defect and a design defect insofar as the former exists when "something goes wrong in the manufacturing process" and the latter exists when the "defect lies in a consciously chosen design." *Richcreek v. Gen. Motors Corp.*, 908 S.W.2d 772, 776 (Mo. App. 1995); *Duke v. Gulf & W. Mfg. Co.*, 660 S.W.2d 404, 411 (Mo. App. 1983) (same); *In re NuvaRing Prods. Liab. Litig.*, 2013 WL 3716389, at *8 (E.D. Mo. July 12, 2013) (same in medical device case); *Bruce Martin Const., Inc. v. CTB, Inc.*, 2012 WL 6203112 (E.D. Mo. Dec. 12, 2012), *aff'd*, 735 F.3d 750 (8th Cir. 2013) (same).
Montana	Distinguishing a manufacturing defect from a design defect insofar as the former exists when the product is not constructed correctly and the latter exists when the specifications were defective. *Wood v. Old Trapper Taxi*, 952 P.2d 1375, 1380 (Mont. 1997); *Rix v. Gen. Motors Corp.*, 723

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	P.2d 195, 200 (Mont. 1986) (same); *Johnson v. Am. Honda Motor Co.*, 2012 WL 1027588, at *8 (D. Mont. Mar. 26, 2012) (same).
Nebraska	Distinguishing a manufacturing defect from a design defect insofar as the former exists when the product differs from the specifications of the manufacturer and the latter exists when the product meets the specification of the manufacturer, but nonetheless poses an unreasonable risk of danger. *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 833 (Neb. 2000); *Kudlack v. Fiat S.p.A.*, 509 N.W.2d 603, 610 (1994) (same); *Nerud v. Haybuster Mfg.*, 340 N.W.2d 369, 374 (1983), *overruled on other grounds*; *Rahmig v. Mosley Match. Co.*, 412 N.W.2d 56, 68 (1987) (same).
Nevada	Noting that evidence of an "unexpected, dangerous malfunction gives rise to an inference of a manufacturing defect." *Krause Inc. v. Little*, 34 P.3d 566, 571-72 (Nev. 2001); *Roll v. Tracor, Inc.*, 102 F. Supp. 2d 1200, 1202 (D. Nev. 2000) (distinguishing between a manufacturing defect and a design defect).
New Hampshire	Distinguishing between a manufacturing defect and a design defect insofar as the former is an "accidental variation caused by a mistake in the manufacturing process" and the latter exists when "the product is manufactured in conformity with the intended design but the design itself poses unreasonable dangers to consumers." *Thibault v. Sears, Roebuck & Co.*, 118 N.H. 802, 807 (1978).
New Jersey	Defining a manufacturing defect and a design defect. N.J.S.A. 2A:58C-2; *Coba v. Ford Motor Co.*, 932 F.3d 114, 123-24 (3d Cir. 2019) (finding that Plaintiff's claim while alleged as a manufacturing defect is disguised as a design defect since allegations that a product line suffered from a common issue is more akin to a design defect claim); *Hindermyer v. B. Braun Med., Inc.*, 419 F. Supp. 3d 809, 827 (D.N.J. 2019) (defining a manufacturing defect in medical device case);

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	Delaney v. Stryker Orthopaedics, 2009 WL 564243, at *6 (D.N.J. March 5, 2009) (describing the deficiencies in Plaintiff's manufacturing defect claim in medical device case).
New Mexico	Defining an improper design and improper manufacture of a product. *Perfetti v. McGhan Med.*, 662 P.2d 646, 649-50 (N.M. App. 1983) (breast implant case); *Nowell v. Medtronic, Inc.*, 372 F. Supp. 3d 1166, 1228 (D.N.M. 2019) (same in medical device case).
New York	Distinguishing a manufacturing defect from a design defect insofar as the former is a deviation from the product line and the latter exists when the alleged product flaw arises from an intentional decision by the manufacturer. *Fasolas v. Bobcat of New York, Inc.*, 128 N.E.3d 627, 641 (N.Y. 2019); *Caprara v. Chrysler Corp.*, 417 N.E.2d 545, 552 (N.Y. 1981) (same); *Tears v. Boston Sci. Corp.*, 344 F. Supp. 3d 500, 511 (S.D.N.Y. 2018), *reconsideration denied*, 2019 WL 2866847 (S.D.N.Y. July 3, 2019) (same in medical device case).
North Carolina	Distinguishing a manufacturing defect from a design defect insofar as the former exists when there is a "miscarriage in the manufacturing process that produces an unintended result" and the latter exists when "an injury-producing hazard accompanying normal use of a product" came about through compliance with a design. *Boudreau v. Baughman*, 368 S.E.2d 849, 860 (N.C. 1988).
North Dakota	Distinguishing a manufacturing defect from a design defect insofar as the former exists when a product deviates from its intended design and the later exists when the design itself is defective. *Oanes v. Westgo, Inc.*, 476 N.W.2d 248, 253 (N.D. 1991); *Herman v. Gen. Irrigation Co.*, 247 N.W.2d 472, 478 (N.D. 1976) (delineating when a manufacturing defect can be inferred).
Ohio	Defining a manufacturing defect and a design defect. Ohio Rev. C. § 2307.74(A); *Yanovich v. Zimmer Austin, Inc.*, 255 F. App'x 957, 962 (6th Cir. 2007) (distinguishing between a design

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	defect and a manufacturing defect in medical device case insofar as the former exists when the design causes the product to be dangerous and the latter exists when a product deviates from design specifications); *Biehl v. B.E.T., Ltd.*, 2018 WL 684646, at *6 (S.D. Ohio Feb. 2, 2018), *aff'd*, 2018 WL 7502930 (6th Cir. Oct. 17, 2018) (same).
Oklahoma	Distinguishing a manufacturing defect from a design defect claim insofar as the former exists when there are deviations from device specifications and the latter exists when the design is inherently dangerous. *Wheeler v. HO Sports Inc.*, 232 F.3d 754, 757-58 (10th Cir. 2000); *Kious v. Teva Pharm. USA, Inc.*, 2016 WL 9559038, at *2 (W.D. Okla. Dec. 8, 2016) (same).
Oregon	Distinguishing a manufacturing defect from a design defect claim insofar as the latter is dependent "on a finding that the product was unreasonably dangerous for its intended use, and in turn, the unreasonableness of the danger must necessarily be derived from the state of the art at the time of design." *Roach v. Kononen*, 525 P.2d 125, 127 (Or. 1974); *Lakin v. Senco Prod., Inc.*, 925 P.2d 107, 118 (Or. App. 1996), *aff'd*, 987 P.2d 463 (Or. 1999), *clarified*, 987 P.2d 476 (Or. 1999) (distinguishing between a manufacturing defect and a design defect claim); *Ramirez v. ITW Food Equip. Grp.*, LLC, 686 F. App'x 435, 437 (9th Cir. 2017) (same).
Pennsylvania	Distinguishing a manufacturing defect from a design defect claim insofar as the former exists when there is a deviation of the product from design specification and the latter exists when there is a breakdown in the design of the product leading to an unreasonably dangerous product. *Schindler v. Sofamor, Inc.*, 774 A.2d 765, 771 (Pa. Super. 2001) (medical device case); *Chandler v. L'Oreal USA, Inc.*, 774 F. App'x 752, 754 (3d Cir. 2019) (same); *Zuzel v. SEPTA*, 2019 WL 3252936, at *4 (E.D. Pa. July 18, 2019) (same).
Puerto Rico	Distinguishing between a manufacturing defect and a design defect insofar as the former exists when a product "differs from the manufacturer's intended result" and the latter exists when a

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	product fails to "perform as safely as an ordinary consumer would expect when used in an intended and foreseeable manner." *Rivera v. Superior Packaging, Inc.*, 132 D.P.R. 115, 127-28 (P.R. 1992); *Carballo Rodriguez v. Clark Equip. Co.*, 147 F. Supp. 2d 66, 71 (D.P.R. Jun. 6, 2001) (same).
Rhode Island	Distinguishing a manufacturing defect from a design defect insofar as the former is caused by a "mistake or accident in the manufacturing process" and the latter is a defect in the design of the product thereby rendering it "unreasonably dangerous." *Guilbeault v. R.J. Reynolds Tobacco Co.*, 84 F. Supp. 2d 263, 276 (D.R.I. 2000).
South Carolina	Defining a manufacturing defect and a design defect. *Watson v. Ford Motor Co.*, 699 S.E.2d 169, 174 (S.C. 2010) (adopting *Third Restatement*).
South Dakota	Defining a manufacturing defect and a design defect. *Peterson v. Safway Steel Scaffolds Co.*, 400 N.W.2d 909, 912 (S.D. 1987); *Rynders v. E.I. Du Pont De Nemours & Co.*, 21 F.3d 835, 842 (8th Cir. 1994) (same).
Tennessee	Distinguishing between a manufacturing defect and a design defect insofar as the former exists when a product is "defectively manufactured" and the latter arises when a "product was defectively designed" thereby rendering the entire product line "unreasonably dangerous." *Taylor v. Square D Co.*, 2003 WL 23093835, at *5 (Tenn. App. Dec. 30, 2003).
Texas	Distinguishing a manufacturing defect from a design defect insofar as the former exists when a finished product deviates from its construction or quality and the latter requires proof and a jury finding of a safer alternative design. *Ford Motor Co. v. Ledesma*, 242 S.W.3d 32, 42 (Tex. 2007); *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 432-34 (Tex. 1997) (same); *De Los Santos v. Ford Motor Co.*, 2015 WL 3776389, at *4 (Tex. App. June 17, 2015) (same).

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Utah	Distinguishing a manufacturing defect from a design defect insofar as the former involves "a deviation from the product's design specifications" and the latter involves a defective execution of the design. *Wankier v. Crown Equip. Corp.*, 353 F.3d 862, 867 (10th Cir. 2003).
Vermont	Distinguishing between a manufacturing defect and a design defect insofar as a design defect arises when a design flaw affects the entire product line and a manufacturing defect affects a single or individual product. *Manning v. Goodyear Tire & Rubber Co.*, 2005 WL 5895181, at *2 (Vt. Super July 20, 2005).
Virginia	Distinguishing a manufacturing defect from a design defect insofar as the former exists when one compares the alleged defective product to the entire product line. *Morgen Indus., Inc. v. Vaughan*, 471 S.E.2d 489, 492 (1996); *Sykes v. Bayer Pharms.*, 548 F. Supp. 2d 208, 215 (E.D. Va. 2008).
Washington	Distinguishing a manufacturing defect from a design defect insofar as the former involves an "aberration" of one product over and against the entire product line and the latter exists when the entire product line's design is defective. *Cavner v. Cont'l Motors, Inc.*, 2019 WL 1254015, at *4 (Wash. Ct. App. March 18, 2019).
West Virginia	Distinguishing a manufacturing defect from a design defect insofar as the former exists when a product deviates from the manufacturer's intended design and the latter exists when the entire design renders the product unreasonably dangerous. *Bennett v. Asco Servs., Inc.*, 621 S.E.2d 710, 717 (W. Va. 2005); *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 682 (1979) (same).
Wisconsin	Defining a design defect and a manufacturing defect. Wis. Stat. § 895.047(1)(a); *Nationwide Agribusiness Ins. Co. v. Meller Poultry Equip., Inc.*, 2015 WL 998331, at *2 (E.D. Wis. March 5, 2015) (distinguishing between a design defect and a manufacturing defect insofar as the former

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	exists when the entire product line's design renders all products unreasonable dangerous and the latter exists when a single product suffers from a construction defect as compared to the entire product line).
Wyoming	Distinguishing between a manufacturing defect and a design defect insofar as the former are "imperfections that inevitable occur in a typically small percentage of products" and the latter exists when the design renders all products unusually dangerous. *Loredo v. Solvay Am., Inc.*, 212 P.3d 614, 630 (Wyo. 2009); *McLaughlin v. Michelin Tire Corp.*, 778 P.2d 59, 64 (Wyo. 1989) (same).

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Alabama	Statutory negligence is inapplicable to violations of vague enactments. *Thetford v. City of Clanton*, 605 So. 2d 835, 842 (Ala. 1992).
Alaska	Negligence *per se* claims under Alaska's Food, Drug, and Cosmetics Act are inapplicable because the statute is too vague to be used as a reasonable standard of care, and amounts to little more than a duplication of the common law tort duty to act reasonably under the circumstances. *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200-01 (Alaska 1992). Statutory provision is not a proper basis for a negligence *per se* instruction because it amounts to little more than a duplication of the common law tort duty to act reasonably under the circumstances. *Dahle v. Atlantic Richfield Co.*, 725 P.2d 1069, 1073-74 (Alaska 1986).
Arizona	Negligence *per se* is limited to situations involving a violation of a specific legal requirement, not a general standard of care. To provide the basis for a negligence *per se* claim, a statute must proscribe certain or specific acts. Therefore, if a statute defines only a general standard of care, negligence *per se* is inappropriate. *Ibarra v. Gastelum*, ___ P.3d ___, 2020 WL 4218020, at *3 (Ariz. App. July 23, 2020); *Reyes v. Frank's Service & Trucking, LLC*, 334 P.3d 1264, 1272 (Ariz. App. 2014) (same). Negligence *per se* may not create novel duties. Negligence *per se* claims cannot create new liabilities which would conflict with state public policy. *Waldon v. Ariz. Pub. Serv. Co.*, 642 F. App'x. 667, 669 (9th Cir. 2016). Negligence *per se* may not create a duty unknown in Arizona common law. *RTC v. Dean*, 854 F. Supp. 626, 643 (D. Ariz. 1994).
Arkansas	Under Arkansas law, the violation of a statute is only evidence of negligence and does not constitute negligence *per se*. *Central Okla. Pipeline, Inc. v. Hawk Field Services, LLC*, 400 S.W.3d 701, 712 (Ark. 2012).

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	The FDCA does not provide a private right of action under which plaintiffs may bring suit. *In re Aredia & Zometa Prods. Liab. Litig.*, 2010 WL 5136142, at *4 (M.D. Tenn. Dec. 7, 2010) (applying Arkansas law).
California	Generally, the doctrine of negligence *per se* is not a separate cause of action, but creates an evidentiary presumption that affects the standard of care in a cause of action for negligence. The doctrine of negligence *per se* does not provide a private right of action for violation of a statute. *Das v. Bank of Am., N.A.*, 112 Cal. Rptr. 3d 439, 448 (Cal. App. 2010); *Johnson v. Honeywell Int'l Inc.*, 101 Cal. Rptr. 3d 726, 731 (Cal. App. 2009) (same). There is no private right of action to enforce compliance with FDA regulations and any assertion of failure to comply is preempted. *Scott v. CIBA Vision Corp.*, 44 Cal. Rptr. 2d 902, 912 (Cal. App. 1995). A negligence *per se* claim alleging violation of the FDCA is nothing more than a private right of action under the FDCA for damages, which is not available under the plain language of 21 U.S.C. § 337(a). *Dunbar v. Medtronic, Inc.*, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014). Negligence *per se* inapplicable to violations of vague enactments. A statute cannot create a separate duty or standard of care when it does not prescribe a particular course of conduct one must take or refrain from taking. *Ramirez v. Nelson*, 188 P.3d 659, 666-67 (2008). An administrative agency cannot by its own regulations create a remedy that the Legislature has withheld. *Centinela Freeman Emergency Med. Assocs. v. Health Net of Cal., Inc.*, 1 Cal. 5th 994, 1012, 382 P.3d 1116, 1127 (2016). Negligence *per se* may not be based on regulatory, as opposed to statutory, violations. *California Serv. Station & Auto. Repair Ass'n v. Am. Home Assur. Co.*, 73 Cal. Rptr. 2d 182, 188 (Cal. App. 1998).

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Colorado	Negligence *per se* is precluded where it is contrary to legislative intent. *Gerrity Oil & Gas Corp. v. Magness*, 946 P.2d 913, 924 (Colo. 1997); *Gammill v. United States*, 727 F.2d 950, 953 n.3 (10th Cir. 1984) (same). Negligence *per se* claims cannot stand as there is no private cause of action under the FDCA. *Franklin v. Medtronic, Inc.*, 2010 WL 2543579, at *8 (Mag. D. Colo. May 12, 2010), *adopted*, 2010 WL 2543570 (D. Colo. June 22, 2010). A central element of negligence *per se* is that there be a violation of a statute, which prescribes, or proscribes, specific and detailed conduct on the part of the alleged tortfeasor. *Hilberg v. F.W. Woolworth Co.*, 761 P.2d 236, 238 (Colo. App. 1988). A claim for negligence *per se* requires a statute, the violation of which can be clearly established. In other words, the relevant statute needs to prescribe or proscribe some relatively discrete action. *Brigance v. Vail Summit Resorts, Inc.*, 2016 WL 931261, at *2 (D. Colo. March 11, 2016), *aff'd* 883 F.3d 1243 (10th Cir. 2018). Negligence *per se* may not create novel duties. *Reich v. Genzyme Corp.*, 2015 WL 13236347, at *9 (D. Colo. Aug. 14, 2015), *adopted*, 2015 WL 5842418 (D. Colo. Oct. 7, 2015).
Connecticut	Negligence *per se* actions are precluded where they would contravene the clear legislative intent of the statute. *Coastline Terminals of Conn., Inc. v. USX Corp.*, 156 F. Supp. 2d 203, 210-11 (D. Conn. 2001). Negligence *per se* inapplicable to violations of vague enactments. *Pelletier v. Sordoni/Skanska Constr. Co.*, 945 A.2d 388, 404 (Conn. 2008).
Delaware	Private enforcement of the FDCA through negligence *per se* claims is contrary to the legislative intent. *Guinan v. A.I. DuPont Hosp. for Children*, 597 F. Supp. 2d 485, 513 & n.14 (E.D. Pa. 2009), *rev'd on other grounds*, 393 F. App'x 884 (3d Cir. 2010).

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	Negligence *per se* is inapplicable to violations of vague enactments. *Joseph v. Monroe*, 419 A.2d 927, 931 (Del. 1980).
District of Columbia	Negligence *per se* is inapplicable to violations of vague enactments. *Night & Day Mgmt., LLC v. Butler*, 101 A.3d 1033, 1040 (D.C. 2014); *McNeil Pharmaceutical v. Hawkins*, 686 A.2d 567, 582 (D.C. App. 1996) (same as to FDCA-based allegations); *Sibert-Dean v. Washington Metro. Area Transit Auth.*, 721 F.3d 699, 704 (D.C. Cir. 2013) (same). Negligence *per se* may not create novel duties. *Ginsberg v. Granados*, 963 A.2d 1134, 1141 (D.C. 2009); *Art Metal-U.S.A., Inc. v. United States*, 753 F.2d 1151, 1158-59 (D.C. Cir. 1985) (same).
Florida	Under Florida law, a statutory violation does not give rise to a private cause of action absent a clear legislative intent to do so. *Murthy v. N. Sinha Corp.*, 644 So. 2d 983, 985 (Fla. 1994); *Wolicki-Gables v. Doctors Same Day Surgery Ctr., Ltd.*, 216 So. 3d 665, 673 (Fla. App. 2017) (same). Florida law bars plaintiffs from using state negligence actions to seek recovery for FDCA violations. *Markland v. Insys Therapeutics, Inc.*, 270 F. Supp. 3d 1318, 1331 (M.D. Fla. 2017). Any regulation that purports to establish a duty of reasonable care must be specific; one that sets out only a general or abstract standard of care cannot establish negligence. *Murray v. Briggs*, 569 So. 2d 476, 481 (Fla. App. 1990); *Liese v. Indian River County Hosp. Dist.*, 701 F.3d 334, 353-354 (11th Cir. 2012) (same). Negligence *per se* may not create novel duties. *Levine v. Wyeth, Inc.*, 684 F. Supp. 2d 1338, 1344-45 & n.5 (M.D. Fla. 2010). Negligence *per se* may not be based on regulatory, as opposed to statutory, violations. *Murray v. Briggs*, 569 So. 2d 476, 480 (Fla. App. 1990).

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Georgia	No private right of action or negligence *per se* exists for FDCA enforcement. *Friedlander v. HMS-PEP Prods., Inc.*, 485 S.E.2d 240, 242 (Ga. App. 1997); *In re Bard IVC Filters Prod. Liab. Litig.*, 2017 WL 6523833, at *6 n.4 (D. Ariz. Dec. 21, 2017) (same); *Leonard v. Medtronic, Inc.*, 2011 WL 3652311, at *7-8 (N.D. Ga. Aug. 19, 2011) (same). Vague regulations that do not require specific conduct are too broad to establish standard of care in negligence *per se* actions. *Allen v. Lefkoff*, 453 S.E.2d 719, 722 (Ga. 1995); *King v. Avtech Aviation, Inc.*, 655 F.2d 77, 79 (5th Cir. 1981). Negligence *per se* may not create novel duties. *Walton v. UCC X, Inc.*, 640 S.E.2d 325, 327-28 (Ga. App. 2006).
Hawaii	Hawaii law does not recognize a negligence *per se* cause of action for violation of a statutory standard. *Camara v. Agsalud*, 685 P.2d 794, 798 (Haw. 1984); *Sailola v. Mun. Servs. Bureau*, 2014 WL 3389395, at *9 (D. Haw. July 9, 2014) (same); *Aana v. Pioneer Hi-Bred Int'l, Inc.*, 965 F. Supp. 2d 1157, 1175 (D. Haw. 2013) (same). Negligence *per se* may not create novel duties. *Hulsman v. Hemmeter Dev. Corp.*, 647 P.2d 713, 719-20 (Haw. 1982).
Idaho	Negligence *per se* is precluded where it is contrary to legislative intent. *Steed v. Grand Teton Council, Inc.*, 172 P.3d 1123, 1128 (Idaho 2007); *Nation v. State of Idaho, Dep't of Correction*, 158 P.3d 953, 966 (Idaho 2007) (same). The doctrine of negligence *per se* mandates that the statute or ordinance must clearly define the required standard of conduct. *Stem v. Prouty*, 272 P.3d 562, 568 (Idaho 2012).

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Illinois	Illinois does not recognize negligence *per se* as an independent cause of action. *Kalata v. Anheuser-Busch Cos.*, 581 N.E.2d 656, 661 (Ill. 1991). Private enforcement of the FDCA through negligence *per se* claims is contrary to the legislative intent. *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 356-357 (Ill. 1996); *Anthony v. Country Life Mfg., L.L.C.*, 2002 WL 31269621, at *3 (N.D. Ill. Oct. 9, 2002). Negligence *per se* may not create novel duties. *Cuyler v. United States*, 362 F.3d 949, 952 (7th Cir. 2004).
Indiana	Like general negligence, negligence *per se* is not a cognizable independent claim and is subsumed by the Indiana Product Liability Act. Ind. Code § 34-20-1-1; *Cavender v. Medtronic, Inc.*, 2017 WL 1365354, at *5 (N.D. Ind. April 14, 2017). Not every statute creates an implied right of action, and a claim of negligence *per se* depends on a determination of legislative intent. *Neal v. Cure*, 937 N.E.2d 1227, 1238 (Ind. App. 2010). *N.G. Hatton Tr. v. Young*, 97 N.E.3d 282, 287 (Ind. App. 2018) (same). Regulations cannot be used to expand or otherwise affect a defendant's common law duties or liabilities under a negligence per se theory, or as evidence of an expanded standard of care. *Jeffords v. BP Prod. N. Am. Inc.*, 963 F.3d 658, 664 (7th Cir. 2020). Negligence *per se* is inapplicable where alleged duties are undefined, or defined only in abstract or general terms, leaving the jury to ascertain reasonableness. *Board of Comm'rs v. Briggs*, 337 N.E.2d 852, 865 (Ind. App. 1975). Negligence *per se* may not create novel duties. *Lockett v. Planned Parenthood, Inc.*, 42 N.E.3d 119, 131 (Ind. App. 2015).

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	Negligence *per se* may not be based on regulatory, as opposed to statutory, violations. *Vandenbosch v. Daily*, 785 N.E.2d 666, 670 (Ind. App. 2003).
Iowa	In order for the violation of rules of conduct to constitute negligence *per se*, those rules must establish specific standards that are to be followed unwaveringly in all instances. *Griglione v. Martin*, 525 N.W.2d 810, 812 (Iowa 1994), *overruled on other grounds by Winger v. CM Holdings, L.L.C.*, 881 N.W.2d 433 (Iowa 2016).
Kansas	Negligence *per se* claims as an independent cause of action were abolished by the Kansas Product Liability Act, K.S.A. § 60-3301 *et seq. Mattos v. Eli Lilly & Co.*, 2012 WL 1893551, at *3 (D. Kan. May 23, 2012) (abolished by product liability statute). To prevail on a negligence *per se* claim, plaintiff must establish that an individual right of action for injury arising out of the violation was intended by the legislature. *Short v. Ultramar Diamond Shamrock*, 46 F. Supp. 2d 1199, 1200-01 (D. Kan. 1999). Negligence *per se* is inapplicable to violations of vague enactments. *Watkins v. Hartsock*, 783 P.2d 1293, 1297 (Kan. 1989).
Kentucky	Where the statute both declares the unlawful act and specifies the civil remedy available to the aggrieved party, the aggrieved party is limited to the remedy provided by the statute. *Grzyb v. Evans*, 700 S.W.2d 399, 401 (Ky. 1985). Negligence *per se* is unavailable where "[p]laintiff refers to a broad category of federal regulations and fails to allege how the device violated those regulations or how that deviation caused her injuries. This lack of specificity is fatal to her claim." *Kitchen v. Biomet, Inc.*, 2014 WL 694226, at *5 (E.D. Ky. Feb. 21, 2014).

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	Under Kentucky law, violations of federal laws and regulations and the laws of other states do not create a cause of action based on negligence *per se*. *St. Luke Hospit.al, Inc. v. Straub*, 354 S.W.3d 529, 534 & n.14 (Ky. 2011); *T & M Jewelry, Inc. v. Hicks*, 189 S.W.3d 526, 530 (Ky. 2006) (same); *Moore v. Zydus Pharms. (USA), Inc.*, 277 F. Supp. 3d 873, 883 (E.D. Ky. 2017) (same).
Louisiana	Louisiana has rejected the doctrine of negligence *per se*. *Galloway v. State*, 654 So. 2d 1345, 1347 (La. 1995); *BellSouth Telecomms., Inc. v. Bennett Motor Express, L.L.C.*, 131 So. 3d 236, 244 (La. App. 2013) (same). The FDCA does not provide a private right of action under which plaintiffs may bring suit. *McNeely v. Danek Med., Inc.*, 1999 WL 1117108, at *2 (W.D. La. July 8, 1999). "To establish negligence *per se* there must be a specific federal statute, regulation, or regulation mandated by treaty, which establishes specific safety requirements, the violation of which may be evaluated objectively within the language of the regulation." *Duzon v. Stallworth*, 866 So. 2d 837, 849 (La. App. 2002) (applying maritime law). "Implicit in virtually all discussions of negligence *per se* is the unspoken assumption that the regulation in question establishes a clear minimum standard of care. If the regulation fails to do so, the reason for applying the doctrine fades. An ambiguous or contradictory regulatory standard defeats the certainty on which the rule of *per se* liability rests. Persons affected are deprived of a sure standard upon which they may fashion their affairs." *Dougherty v. Santa Fe Marine, Inc.*, 698 F.2d 232, 235 (5th Cir. 1983).
Maine	Maine does not recognize the doctrine of negligence *per se*. *Binette v. Dyer Library Ass'n*, 688 A.2d 898, 904 (Me. 1996); *Miller v. Zimmer Biomet, Inc.*, 2017 WL 5914695, at *7 (D. Me. Nov. 30, 2017), *adopted*, 2017 WL 6540030 (D. Me. Dec. 20, 2017) (same).

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Maryland	There is no cause of action for negligence *per se* under Maryland law. *Kiriakos v. Phillips*, 139 A.3d 1006, 1016 (Md. 2016); *Bray v. Marriott Int'l*, 158 F. Supp. 3d 441, 444 (D. Md. 2016) (same). The Federal Food, Drug, and Cosmetics Act fails to provide a statutory basis to impose a duty on a manufacturer to an individual. *Gourdine v. Crews*, 955 A.2d 769, 790-91 (Md. 2008).
Massachusetts	The Commonwealth of Massachusetts does not follow the doctrine of negligence *per se*. *Juliano v. Simpson*, 962 N.E.2d 175, 179-80 (Mass. 2012). Negligence *per se* cannot create novel duties. "Where, as here, a statute makes no express provision for a private right of action, legislative intent determines whether a private right may be inferred." *Juliano v. Simpson*, 962 N.E.2d 175, 179 (Mass. 2012). "In addition to citing no cases in which a court has found such a duty, Plaintiffs fail to identify indicia that the highest court of any of the relevant states would expand the state's tort law in such a way as to include the proposed new duty of care. A federal court sitting in diversity cannot be expected to create new doctrines expanding state law. It is not appropriate for this court to create the proposed duty as a new component of the common law, especially given that it is such a radical departure from the law as it exists." *Hochendoner v. Genzyme Corp.*, 95 F. Supp. 3d 15, 31 (D. Mass. 2015*), aff'd in part & vacated in part on other grounds*, 823 F.3d 724 (1st Cir. 2016) (internal citation omitted).
Michigan	Michigan does not adhere to the doctrine of negligence *per se*. *Zeni v. Anderson*, 243 N.W.2d 270, 280-82 (Mich. 1976); *Campbell v. Nationstar Mortgage*, 611 F. App'x 288, 299 (6th Cir. 2015) (same). Negligence *per se* is precluded where it is contrary to legislative intent. *Epps v. 4 Quarters Restoration LLC*, 872 N.W.2d 412, 420-21 (Mich. 2015).

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Minnesota	Negligence *per se* is precluded where it is contrary to legislative intent. *In re Shigellosis Litig.*, 647 N.W.2d 1, 10 (Minn. App. 2002); *Olson v. Moorhead Country Club*, 568 N.W.2d 871, 873 (Minn. App. 1997) (same). "[A] claim of negligence per se cannot be based on a violation of the FDCA." *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1152 (D. Minn. 2011). Negligence *per se* is inapplicable to violations of vague enactments. *Pacific Indemnity Co. v. Thompson-Yaeger, Inc.*, 260 N.W.2d 548, 559 (Minn. 1977). For the violation of a statute to constitute negligence *per se* the statute must define a fixed standard of care. *Shigellosis*, 647 N.W.2d at 10-11. "The inherent flexibility of the CGMPS and QSRs also dooms Plaintiffs' claims that alleged violations of this regulatory scheme can form the basis of a valid claim for negligence per se because no mandatory statutory or regulatory duty was breached." *In re Medtronic Sprint Fidelis Lead Prods. Liab. State Court Litig.*, 2009 WL 3417867, at *18 n.24 (Minn. Dist. Oct. 20, 2009).
Mississippi	Negligence *per se* is precluded where it is contrary to legislative intent. *Hollingsworth v. Hercules, Inc.*, 2016 WL 7409130, at *5 (S.D. Miss. Dec. 22, 2016). The FDCA does not provide a private right of action under which plaintiffs may bring suit. *Coleman v. Danek Medical, Inc.*, 43 F. Supp. 2d 629, 633 n.2 (S.D. Miss. 1998). Negligence *per se* may not be based on regulatory, as opposed to statutory, violations. *Union Carbide Corp. v. Nix*, 142 So. 3d 374, 387 (Miss. 2014); *Sumrall v. Miss. Power Co.*, 693 So. 2d 359, 367 (Miss. 1997) (same).

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Missouri	Missouri does not allow private causes of action for damages based solely on the violations of a statute unless the legislature intended the violations to be privately actionable. *Vilcek v. Uber USA, LLC*, 902 F.3d 815, 819 (8th Cir. 2018). Negligence *per se* is inapplicable to violations of vague enactments. *Cisco v. Mullikin*, 2012 WL 549504, at *2-3 (E.D. Mo. Feb. 21, 2012). The performance standards cited by plaintiff were insufficient to state a cause of action for negligence *per se* because the regulations at issue were not sufficiently precise about what a person must do to comply. *In re Genetically Modified Rice Litig.*, 666 F. Supp. 2d 1004, 1022-23 (E.D. Mo. 2009). Negligence *per se* cannot create novel duties. *Mediq PRN Life Support Servs., Inc. v. Abrams*, 899 S.W.2d 101, 110 (Mo. App. 1994).
Montana	Negligence *per se* is precluded where it is contrary to legislative intent. *Doyle v. Clark*, 254 P.3d 570, 577 (Mont. 2011). In order to impute liability to a defendant as a matter of negligence per se, this Court has repeatedly stated that the defendant must have violated a statute, as opposed to merely an administrative regulation, safety code, or professional standard. *Harwood v. Glacier Elec. Coop., Inc.*, 949 P.2d 651, 656 (Mont. 1997); *Thayer v. Hicks*, 793 P.2d 784, 792 (Mont. 1990) (same).
Nebraska	There is no cause of action for negligence *per se* under Nebraska law. *Scheele v. Rains*, 874 N.W.2d 867, 872 (Neb. 2016); *In re Derailment Cases*, 416 F.3d 787, 795 (8th Cir. 2005) (same).

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Nevada	The FDCA does not provide a private right of action under which plaintiffs may bring suit as negligence *per se*. *Miller v. DePuy Spine, Inc.*, 638 F. Supp. 2d 1226, 1231 (D. Nev. 2009). Violation of an administrative regulation does not constitute negligence *per se*, since it lacks the force and effect of a substantive legislative enactment. *Price v. Sinnott*, 460 P.2d 837, 839-40 (Nev. 1969); *Fernandez v. Mollet*, 2018 WL 324816, at *4 (D. Nev. Jan. 8, 2018) (negligence per se may not be based on regulatory, as opposed to statutory violations).
New Hampshire	Where a regulation "does nothing more than proscribe negligence, and does not identify any particular standard of care appropriate to the circumstances of this case, plaintiffs have failed to state a claim for negligence *per se* based on that regulation." *Yost v. US Airways, Inc.*, 2011 WL 1655714, at *3-4 (D.N.H. May 2, 2011). In the absence of a common law duty, a plaintiff cannot maintain a negligence action, even though the defendant has violated a statutory duty. *Town of Londonderry v. Mesiti Dev., Inc.*, 129 A.3d 1012, 1019 (N.H. 2015) (internal citation omitted). Negligence *per se* may establish the nature of a duty, but cannot establish the existence of a duty. *Pruden v. CitiMortgage, Inc.*, 2014 WL 2142155, at *19 (D.N.H. May 23, 2014).
New Jersey	Negligence *per se* is precluded where it is contrary to legislative intent. Unless "the Legislature intended that … [a] statute constitute an independent basis for civil liability or that its violation constitute negligence per se, its violation is not actionable." *J.S. v. R.T.H.*, 714 A.2d 924, 934 (N.J. 1998). Under New Jersey law, violations of administrative regulations are not proof of negligence *per se*. *Bedford v. Riello*, 920 A.2d 693, 700 (N.J. Super. App. Div. 2007); *Senisch v. Tractor Supply Co.*,

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	2018 WL 324717, at *12 (D.N.J. Jan. 8, 2018) (same); *Cruz v. ATCO Raceway, Inc.*, 2015 WL 4040619, at *5 n.6 (D.N.J. July 1, 2015) (same).
New Mexico	Because the FDCA expressly prohibits the bringing of a private cause of action under the Act, to allow a state negligence *per se* action based upon alleged violations of the FDCA would defeat the purpose of that prohibition. *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1240-41 (D.N.M. 2008). Negligence *per se* is inapplicable to violations of vague enactments. *Heath v. La Mariana Apartments*, 180 P.3d 664, 669 (N.M. 2008); *Parra v. Atchison, Topeka & Santa Fe Ry. Co.*, 787 F.2d 507, 509 (10th Cir. 1986) (same). Negligence *per se* cannot create novel duties. *F.D.I.C. v. Schuchmann*, 235 F.3d 1217, 1226 (10th Cir. 2000).
New York	Negligence *per se* is inapplicable to violations of vague enactments. *Nicholson v. South Oaks Hosp.*, 811 N.Y.S.2d 770, 771 (N.Y. App. Div. 2006). Alleged violations of "vague and open-ended" Current Good Manufacturing Practices that do not impose specific duties are insufficient to state a claim for negligence *per se*. *Babayev v. Medtronic, Inc.*, 228 F. Supp. 3d 192, 219 (E.D.N.Y. 2017). Negligence *per se* cannot create novel duties. *Cheeseboro v. Little Richie Bus Service, Inc.*, 254 F. Supp. 3d 485, 493 (E.D.N.Y. 2017). The "Court may not announce a duty of care where the New York courts have declined to do so; nor may this Court impose a duty of care based upon a statute that does not permit a private right of action." *Aiken v. Interglobal Mergers & Acquisitions*, 2006 WL 1878323, at *2 (S.D.N.Y. July 5, 2006). Negligence *per se* may not be based on regulatory, as opposed to statutory violations. *Yenem Corp. v. 281 Broadway Holdings*, 964 N.E.2d 391, 394 (N.Y. 2012); *Elliott v. City of New York*, 747

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	N.E.2d 760, 763-64 (N.Y. 2001); *McGowan v. United States*, 825 F.3d 118, 128 (2d Cir. 2016) (same).
North Carolina	"Plaintiffs are precluded by 21 U.S.C. § 337(a) from bringing a state claim to redress alleged violations of the FCDA." *Osburn v. Danek Med., Inc.*, 520 S.E.2d 88, 93 (N.C. App. 1999), *aff'd*, 542 S.E.2d 215 (N.C. 2000). "[T]he negligence *per se* doctrine does not create new causes of action. In addition, the Federal Food, Drug and Cosmetic Act ('FDCA') does not provide a private right of action under which plaintiffs may bring suit. The statute itself provides that all such proceedings for the enforcement or to restrain violations of the Act shall be by and in the name of the United States (with one exception not applicable here). 21 U.S.C. § 337(a). The Supreme Court has stated that the FDCA leaves no doubt that it is the federal government rather than private litigants who are authorized to file suit for noncompliance with the Act." *In re Aredia & Zometa Prods. Liab. Litig.*, 2010 WL 5092784, at *2-3 (M.D. Tenn. Dec. 7, 2010) (applying North Carolina law).

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	Negligence *per se* is inapplicable to violations of vague enactments. *Goodman v. Wenco Foods, Inc.*, 423 S.E.2d 444, 452 (N.C. 1992) (adulteration claim under state "Little FDCA" statute); *Jones v. GMRI, Inc.*, 551 S.E.2d 867, 873 (N.C. App. 2001) (same).
North Dakota	"The separation-of-powers doctrine and principles of federalism militate against the adoption of the federal statute as the standard of care in a state negligence action when no private cause of action, either explicit or implicit, exists in the federal statute." *R.B.J. Apartments, Inc. v. Gate City Savings & Loan Ass'n*, 315 N.W.2d 284, 290 (N.D. 1982).
Ohio	The Ohio Product Liability Act, codified at Ohio Revised Code §§ 2307.71 to 2307.80, "explicitly eliminate[s] 'all common law product liability claims or causes of action.'" The common law claim of negligence *per* se has been abrogated by the Ohio Product Liability Act. *Hendricks v. Pharmacia Corp.*, 2014 WL 2515478, at *4 (S.D. Ohio June 4, 2014), *adopted*, 2014 WL 4961550 (S.D. Ohio Oct. 2, 2014). There can be no cause of action for negligence *per se* in the absence of legislative intent. *Wyatt v. Roses Run Country Club*, 119 N.E.3d 1006, 1010 (Ohio App. 2018). It is well-settled that there is no private right of action under the FDCA. *Edwards v. Warner-Lambert*, 2012 WL 2156246, at *4 (S.D. Ohio June 13, 2012). "In other words, if a positive and definite standard of care has been established by legislative enactment whereby a jury may determine whether there has been a violation thereof by finding a single issue of fact, a violation is negligence per se; but where the jury must determine the negligence or lack of negligence of a party charged with the violation of a rule of conduct fixed by legislative enactment from a consideration and evaluation of multiple facts and circumstances by the process of applying, as the standard of care, the conduct of a reasonably prudent person, negligence per se is not involved." *Chambers v. St. Mary's School*, 697 N.E.2d 198, 201 (Ohio

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	1998). "A finding of negligence per se requires a violation of a statute which sets out a specific standard of conduct." *Rimer v. Rockwell Int'l Corp.*, 641 F.2d 450, 455 n.2 (6th Cir. 1981). Negligence *per se* may not be based on regulatory, as opposed to statutory violations. *Lang v. Holly Hill Motel, Inc.*, 909 N.E.2d 120, 124 (Ohio 2009); *Chambers*, 697 N.E.2d at 202-03.
Oklahoma	Negligence *per se* is inapplicable to violations of vague enactments. *Athey v. Bingham*, 823 P.2d 347, 349 (Okla. 1991). There can be no cause of action for negligence *per se* where the statute at issue "lacks the specificity necessary to provide any meaningful 'substitute' for common law duties of reasonable care." *Ross v. Univ. of Tulsa*, 2015 WL 4064754, at *3 (N.D. Okla. July 2, 2015). Dismissal of plaintiff's negligence *per* se claim was appropriate because one, the Food, Drug and Cosmetic Act ("FDCA") does not create a private right of action, 21 U.S.C. § 337(a), and two, the administrative requirement at issue lacks any independent substantive content and "does not impose a standard of care, the breach of which could form the basis of a negligence per se claim." *Johnson v. Smith & Nephew Richards, Inc.*, 1999 WL 1117105, at *2 (N.D. Okla. Sept. 30, 1999).
Oregon	Negligence *per se* is precluded where it is contrary to legislative intent. *Bob Godfrey Pontiac, Inc. v. Roloff*, 630 P.2d 840, 845-46 (Or. 1981). The phrase "negligence *per se*" can apply only to cases brought on a theory of liability for negligence rather than liability grounded in obligations created by statute. ... When a plaintiff invokes a governmental rule in support of that theory, the question is whether the rule, ... so fixes the legal standard of conduct that there is no question of due care left for a factfinder to determine; in other words, that noncompliance with the rule is negligence as a matter of law. *Shahtout v. Emco Garbage Co.*, 695 P.2d 897, 899 (Or. 1985); *Frank v. Cascade Healthcare Cmty., Inc.*, 2013 WL 867387, at *10 (D. Or. March 6, 2013) (finding the policies and guidelines at issue insufficient

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	to fix the legal standard of conduct and create a civil cause of action for a negligence per se or statutory tort claim.). "Strictly speaking, the doctrine of 'negligence *per se*' does not create a cause of action. Rather, it refers to a standard of care that a law imposes within a cause of action for negligence." *Gattman v. Favro*, 757 P.2d 402, 404 n.3 (Or. 1988); *Braun-Salinas v. American Family Ins. Group*, 665 F. App'x. 576, 578 (9th Cir. 2016) (same).
Pennsylvania	For "a *per se* negligence holding [to be] warranted in an appropriate case, logically, the statute at issue would have to be so specific as to leave little question that a person or entity found in violation of it deviated from a reasonable standard of care." A "statute [that] essentially expresses the familiar and flexible reasonable man standard ... does not support a *per se* negligence shortcut." *Shamnoski v. PG Energy, Div. of S. Union Co.*, 858 A.2d 589, 601-02 (Pa. 2004). Negligence *per se* cannot lie where the defendant allegedly violated a vague enactment that "would allow juries to fix the standard case by case" and under which a defendant "acting in the utmost good faith and diligence could still find itself liable." *In re TMI*, 67 F.3d 1103, 1115 (3d Cir. 1995).
South Carolina	Negligence *per se* is precluded where it is contrary to legislative intent. *Doe v. Marion*, 645 S.E.2d 245, 248-49 (S.C. 2007).

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Tennessee	Negligence *per se* is precluded where it is contrary to legislative intent. *Brown v. Tenn. Title Loans, Inc.*, 328 S.W.3d 850, 857 (Tenn. 2010). The FDCA, which is administrative in nature, lacks sufficient substantive content to support a claim for negligence *per se*. *Bish v. Smith & Nephew Richards, Inc.*, 2000 WL 1294324, at *3 (Tenn. App. Aug. 23, 2000). "There is no private cause of action for violation of the [federal] FDCA and therefore no basis for a negligence *per se* claim linked to an alleged violation of its provisions. The rationale behind such a holding is that the language of the Act and its legislative history evidences Congress' intent that the FFDCA should only be enforced by the government. Similarly, the [Tennessee] FDCA, which is modeled after the FFDCA, places authority in the Commissioner to police violations, T.C.A. §§ 53–1–201– § 53–1–210, and places the duty on the district attorney general or city attorney to whom the Commissioner reports violations to bring appropriate proceedings in the proper court." *Gentry v. Hershey Co.*, 687 F. Supp. 2d 711, 723 (M.D. Tenn. 2010) (internal citations omitted). A statute cannot trigger the negligence *per se* doctrine where it contains only "general guidance" and is "posed in non-specific terms." *Shaw v. Metro. Gov't of Nashville & Davidson County*, 596 S.W.3d 726, 734 (Tenn. App. 2019). FDCA statutes lack sufficient substantive content to support a negligence *per se* claim. *King v. Danek Med., Inc.*, 37 S.W.3d 429, 458 (Tenn. App. 2000). Negligence *per se* may not create novel duties. The negligence *per se* doctrine "does *not* permit a court to recognize new common-law duties that could not support an ordinary negligence claim." *Faber v. Ciox Health, LLC*, 944 F.3d 593, 599 (6th Cir. 2019). "[T]he Court, sitting in diversity, is not inclined to impose a new legal duty, which might create a burden on the Tennessee judiciary, and result in a significant change in Tennessee tort law." *Blasingame v. Church Joint Venture, L.P.*, 2015 WL 4758933, at *8 (W.D. Tenn. Aug. 12, 2015).

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Texas	Negligence *per se* is precluded where it is contrary to legislative intent. *House, Inc. v. Williams*, 313 S.W.3d 796, 810-11 (Tex. 2010). "Texas law likely does not recognize a cause of action for negligence per se based solely on the violation of the FDCA and FDA regulations." *Monk v. Wyeth Pharms., Inc.*, 2017 WL 2063008, at *8 (W.D. Tex. May 11, 2017). "Although the Fifth Circuit and the Texas Supreme Court have not ruled on this issue, one Texas court has held the FDCA and FDA regulations do not give rise to a negligence per se cause of action under the standard the Texas Supreme Court established in *Perry v. S.N.*, 973 S.W.2d 301 (Tex. 1998). The Court finds the [] Court's application of the *Perry* factors persuasive and declines to create a new cause of action." *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 594 (W.D. Tex. 2002). Negligence *per se* is available only where the statute clearly defines the prohibited or required conduct. *Perry*, 973 S.W.2d at 307-08. Negligence *per se* is inappropriate where the regulations at issue do not prescribe a particular standard of conduct but instead require the exercise of judgment as a prudent person. *Claybrook v. Time Definite Services Transportation, LLC*, 2016 WL 3963025, at *3 (N.D. Tex. July 21, 2016). Negligence *per se* may not create novel duties. *Perry*, 973 S.W.2d at 306. "As there is currently no Texas law creating a common law cause of action for a statutory violation for which violation there is an express and comprehensive statutory cause of action, we will not undertake to ourselves create such a Texas common law cause of action." *Johnson v. Sawyer*, 47 F.3d 716, 729 (5th Cir. 1995). Negligence *per se* may not be based on regulatory, as opposed to statutory, violations. *Ridgecrest Retirement & Healthcare v. Urban*, 135 S.W.3d 757, 763 (Tex. App. 2004).

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Utah	Negligence *per se* is precluded where it is contrary to legislative intent. Absent plain language, an enactment will not support legislative intent sufficient to establish negligence *per se* or prima facie negligence. *Colosimo v. Gateway Cmty. Church*, 424 P.3d 866, 884 (Utah App. 2018). Negligence *per se* is inapplicable to violations of vague enactments. "[A]n alleged violation of a specific, objective safety rule could warrant an instruction on negligence *per se*;" however, negligence *per se* does not apply where the "rule at issue [is] not specific enough to supply a standard the jury could apply." *Green v. Denver & Rio Grande Western R.R. Co.*, 59 F.3d 1029, 1034 (10th Cir. 1995).
Vermont	Negligence *per se* may not create novel duties. "Safety statutes in the above line of authority do not themselves create a privately enforceable legal duty; they merely supply the standard of care in the face of an established common-law duty. Where a plaintiff seeks to use a safety statute as the standard of care under the prima facie negligence rule, there must be an existing duty recognized by the common law." *Sheldon v. Ruggiero*, 202 A.3d 241, 249 (Vt. 2018).
Virginia	Negligence *per se* is inapplicable to violations of vague enactments. A FDCA violation cannot form the basis of a negligence *per se* claim where it lacks any independent substantive content and does not impose a standard of care. *Talley v. Danek Medical, Inc.*, 179 F.3d 154, 161 (4th Cir. 1999). Negligence *per se* may not create novel duties. "A statute may define the standard of care to be exercised where there is an *underlying common-law duty*, but the doctrine of negligence per se does not create a cause of action where none otherwise exists." *Parker v. Carilion Clinic*, 819 S.E.2d 809, 824 (Va. 2018). "[T]o proceed with a negligence *per se* action, a plaintiff must first establish a duty based in tort. … If the duty was not created, it cannot supply the duty of care

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	required for a negligence per se cause of action." *Steward v. Holland Family Pros., LLC*, 726 S.E.2d 251, 256 (Va. 2012).
Washington	"A breach of a duty imposed by statute, ordinance, or administrative rule shall not be considered negligence per se…" Wash. Rev. Code § 5.40.050. The concept of negligence *per se*, however, does not constitute a separate cause of action. *Atherton Condo. Apartment-Owners Ass'n. v. Blume Dev. Co.*, 799 P.2d 250, 262 & n.13 (Wash. 1990). The FDCA does not create a private right of action. *Chester v. Deep Roots Alderwood, LLC*, 371 P.3d 113, 117 (Wash. App. 2016).
West Virginia	A negligence *per se* claim is not available under the Food, Drug, and Cosmetics Act, 21 U.S.C. § 321 *et seq.* The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions. The violation of a statute is *prima facie* negligence and not negligence *per se*. *Mullins v. Ethicon, Inc.*, 2017 WL 275452, at *2 (S.D. W. Va. Jan. 19, 2017) (citations omitted).
Wisconsin	Negligence *per se* is precluded where it is contrary to legislative intent. "This court has repeatedly indicated that a statute will not be interpreted to impose a greater duty than that imposed by the common law unless it clearly and beyond any reasonable doubt expresses such purpose by language that is clear, unambiguous, and peremptory. A court may also look to the legislative history of a statute to discern whether the legislature intended a violation to impose negligence *per se*." *Antwaun A. v. Heritage Mut. Ins. Co.*, 596 N.W.2d 456, 466 (Wis. 1999) (citations omitted). Negligence *per se* cannot be found to exist where there is no expression of legislative intent that the statute become the basis for imposition of civil liability. *Lynch v. Flowers Foods Specialty Group*, 2011 WL 3876951, at *5-6 (E.D. Wis. Aug. 31, 2011).

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	Negligence *per se* may not create novel duties. *Logarta v. Gustafson*, 998 F. Supp. 998, 1006 (E.D. Wis. 1998).
Wyoming	Negligence *per se* is inapplicable to violations of vague enactments. *Short v. Spring Creek Ranch, Inc.*, 731 P.2d 1195, 1199 (Wyo. 1987). Negligence *per se* may not create novel duties. "Before a statute can be said to establish a standard of care, there must be a legal duty to which the statutory standard of care can be applied." *Sorensen v. State Farm Auto. Ins. Co.*, 234 P.3d 1233, 1240 (Wyo. 2010).

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Alabama	"[T]he legislature did not intend to confer a private right of action for any breach of the duty to report imposed by the statute. ... While the Act imposes a duty on an individual to make such a report, there is no indication of any legislative intent to impose civil liability for failure to report." *C.B. v. Bobo*, 659 So. 2d 98, 102 (Ala. 1995) ("The [reporting statute] creates a duty owed to the general public, not to specific individuals, and, consequently, it does not create a private cause of action in favor of individuals. Therefore, to the extent that the plaintiffs rely on that statute, they fail to state a cause of action."). "The Alabama Supreme Court has held that the mandatory reporting statute does not create a private right of action and that a plaintiff may not bring negligence or wantonness claims based on violations of this statute. Thus, to the extent that [plaintiff] brings negligence and wantonness claims ..., those claims fail as a matter of law." *Weissenbach v. Tuscaloosa City Sch. Sys.*, 2018 WL 5848047, at *8 (N.D. Ala. Nov. 8, 2018) (internal citation omitted).
Alaska	Non-compliance with and/or lack of enforcement of a reporting statute designed to "ensur[e] that reports of harm are properly investigated and followed up by the state ... does not create a private cause of action." *Hymes v. DeRamus*, 222 P.3d 874, 889 (Alaska 2010); *see Christoffersen v. State*, 242 P.3d 1032 (Alaska 2010) (affirming summary judgment in favor of defendants, notwithstanding their failure to comply with a mandatory reporting statute, because they "had no actionable tort duty to warn").
Arizona	"[E]ven if we assume that adverse event reports may constitute relevant warnings, Arizona law does not permit a manufacturer to satisfy its duty to warn end-user consumers by submitting adverse event reports to the FDA. And conversely, a manufacturer does not breach its duty to warn end users under Arizona law by failing to submit adverse event reports to the FDA. [Plaintiff] cites no authority, and we are aware of none, for the proposition that Arizona law requires a

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	manufacturer to warn a federal agency." *Conklin v. Medtronic, Inc.*, 431 P.3d 571, 577 (Ariz. 2018).
Arkansas	Following the "longstanding rule that this court construes statutes ... imposing burdens and liabilities that do not exist at common law, in favor of the party sought to be penalized" and finding no liability when one "who has a statutorily-imposed individual duty to report ... fails to report." *Cooper Clinic, P.A. v. Barnes*, 237 S.W.3d 87, 91 (Ark. 2006).
Colorado	"Regarding Plaintiff's Failure to Warn claim, Defendant asks the court to reconsider the viability of the case law cited by the court, specifically *Stengel* and *Hughes.* The court has reconsidered and agrees that these cases cannot be reconciled with 21 U.S.C. § 360k(a) as interpreted in *Riegel* or 21 U.S.C. § 337(a) as interpreted in *Buckman.* There is no state law duty identical to the federal requirement that a device manufacturer report adverse events to the FDA, as required to state a parallel claim. Thus, allegations that Defendant failed to report adverse events to the FDA do not state a parallel claim." *Golden, v. Brown,* 2017 WL 4239015, at *2 (Colo. Dist. Sept. 24, 2017) (internal citations omitted); *see Jacob v. Mentor Worldwide, LLC,* 393 F. Supp. 3d 912, 925 (C.D. Cal. 2019) ("Plaintiff Nunn is preempted from making a failure to warn claim, because her home state of Colorado does not recognize such claims.") (applying Colorado law).
Connecticut	"In an action for neglect of duty it is not enough for the plaintiff to show that the defendant neglected a duty imposed by statute, and that he would not have been injured if the duty had been performed, but to entitle him to recover, he must further show that such duty was imposed for his benefit, or was one which the defendant owed to him for his protection and security, from the particular loss or injury of which he complains." *Ward v. Greene*, 839 A.2d 1259, 1267-68 (Conn. 2004) (explaining that, if "a reporting statute's broad policy statement does not, by itself, define

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	the class of persons protected by the statute," the court should not infer an expansive private right of action for the statute's violation). "[W]e note that [plaintiff]'s injuries were, in the abstract, a foreseeable consequence of the defendant's failure to report ... [t]he conclusion that a particular injury to a particular plaintiff or class of plaintiffs possibly is foreseeable does not, in itself, create a duty of care. ... Many harms are quite literally foreseeable, yet for pragmatic reasons, no recovery is allowed. ... A further inquiry must be made, for we recognize that duty is not sacrosanct in itself, but is only an expression of the sum total of those considerations of policy which lead the law to say that the plaintiff is entitled to protection. ... While it may seem that there should be a remedy for every wrong, this is an ideal limited perforce by the realities of this world. Every injury has ramifying consequences, like the ripplings of the waters, without end. The problem for the law is to limit the legal consequences of wrongs to a controllable degree." *Ward v. Greene*, 839 A.2d 1259, 1271 (Conn. 2004). *Norman v. Bayer Corp.*, 2016 WL 4007547, at *4-5 (D. Conn. July 26, 2016) (dismissing with prejudice plaintiffs' products liability claims relating to a Class III medical device, rejecting the allegation "that defendants were negligent *per se* insofar as defendants violated several FDA statutes and regulations" because, although "[a] defendant may be negligent *per se*—that is, presumed negligent—when she violates certain laws related to the harm the plaintiff suffered[, t]he only laws plaintiff identifies here are federal and part of the FDA regulatory scheme. This claim plainly is not parallel to the federal scheme, but arises directly and wholly derivatively from the violation of federal law. The claim is therefore subject to implied preemption.").
Delaware	The Supreme Court of Delaware "not only held that [mandatory reporting] statutes such as the one at bar could not be used as a basis for *per se* liability, but that such statutes could not be used as a standard of care whatsoever." *Harden v. Allstate Ins. Co.*, 883 F. Supp. 963, 971-72 (D. Del.

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	1995). Delaware "law is clear that it is inappropriate to utilize a [mandatory reporting] statute such as the one at issue in this litigation, either for establishing negligence *per se*, or for any indication of negligence." *Id*. at 972. "Plaintiff's negligence cause of action would impose requirements on Medtronic—to perform and report additional studies—which are different from and in addition to those imposed by the FDA. Plaintiff's failure to warn cause of action would require that Medtronic provide warnings in addition to or different from those required by the FDA. To the extent plaintiff's cause of action for negligent misrepresentation alleges that Medtronic failed to disclose material facts, plaintiff has not alleged that Medtronic's warning label for the infuse device did not comply with the FDA. Therefore, any 'material facts' which plaintiff asserts are missing would require a change in those warnings or disclosures required by the FDA. Each of these causes of action is expressly preempted." *Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F. Supp. 3d 403, 411-12 (D. Del. 2014).
District of Columbia	"Plaintiffs struggle mightily to avoid the implications of the undisputed fact that there is no D.C. common law claim that imposes liability for a manufacturer's failure to report to the FDA adverse incidents concerning an approved medical device." *Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 183 (D.D.C. 2018). "Plaintiffs insist that Medtronic's violation of the federal reporting requirements effectively amounted to a failure to warn consumers for the purpose of D.C.'s common law tort. This creative effort to craft a D.C. common law claim that is substantially equivalent to the federal law's adverse-event reporting requirements fails for at least two reasons. First of all, it ignores the overarching mandate that the state claim and the federal claim must be *genuinely*—as opposed to effectively—equivalent. That is, if Plaintiffs' core contention is that the state common law was violated because Medtronic failed to warn consumers of device-related risks upon learning new

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	adverse information, then the federal requirement that such a claim actually parallels is a duty to warn *consumers* of device-related risks in light of new adverse events (i.e., the duty to update product labels post-approval), *not* the C.F.R.'s requirement that manufacturers report such events *to the FDA*. Put another way, the common law failure to warn claim is not, in fact, the functional equivalent of a manufacturer's failure to report adverse incidents to the FDA in violation of federal law, and Plaintiffs have not identified a federal regulation that imposes upon manufacturers the specific obligation to warn consumers of adverse post-approval events. Second, Plaintiffs' parallel state law claim argument ultimately relies on sheer speculation: Plaintiffs contend that, *if* Medtronic had complied with the federal requirement to report adverse events to the FDA, and *if* the FDA had directed Medtronic to update the label of the [PMA-approved medical device] based on these reported events, then Medtronic would have had the duty to provide adequate warnings to consumers, as D.C. common law requires. But it is by no means certain that the FDA would have directed Medtronic to give consumers different or additional information about the [PMA-approved medical device] if the agency had been made aware of other incidents that predated [Plaintiff's] injury. And unless such label changes would *necessarily* have occurred as a result of Medtronic's failure to notify the FDA, Plaintiffs' contention that Medtronic's failure to notify the agency is the functional equivalent of failing to warn consumers in violation of state law cannot be sustained." *Id.* at 183-84. "[T]his Court does not accept Plaintiffs' argument that Medtronic's established reporting failures are truly parallel to the complaint's claims that Medtronic is liable for failing to provide adequate warnings to [Plaintiff] and her physicians regarding risks associated with the pump under District of Columbia law." *Id.* at 184. Plaintiffs' "failure to warn claims are fundamentally based on the contention that Medtronic breached a duty to provide additional warnings, and to recall the pump for label changes, in light of the deficiencies in the device that the post-approval events revealed. But the MDA's express

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	preemption clause prohibits the Court (or a jury) from making any such liability determination." *Id.* at 185. "[T]his Court is confident that the one claimed violation of federal law that is sufficiently specific to support a parallel state law claim concerning the [PMA-approved device at issue]—i.e., Medtronic's established failure to report subsequent adverse events to the FDA in a timely manner, as the adverse reporting regulations require—does not actually equate with the D.C. common law failure to warn claims that the [Plaintiffs] allege, and as a result, the MDA's express preemption provision bar these state law claims." *Id.*
Florida	There is no cause of action for an alleged violation of a statutory duty to report. *Welker v. S. Baptist Hospital, Inc.*, 864 So. 2d 1178, 1182 (Fla. App. 2004); *see Mora v. S. Broward Hospital Dist.*, 710 So. 2d 633, 634 (Fla. App. 1998) (holding that statutory violations of a reporting requirement did not result in a civil cause of action). "[T]he Eleventh Circuit made clear that *Buckman*'s holding—i.e., that fraud-on-the-FDA claims are impliedly preempted—extends to failure-to-warn claims where the plaintiff alleges that the device's warnings were inadequate because the defendant-manufacturer failed to provide sufficient information to the FDA." *Tinkler v. Mentor Worldwide, LLC*, 2019 WL 7291239, at *4 (S.D. Fla. Dec. 30, 2019). "[S]ignificantly, a survey of the case law shows that Plaintiff's failure-to-warn theory has been consistently held to be preempted. To the extent Plaintiff's theory is that Mentor failed to report or underreported to the FDA information about Breast Implant Illness, such that the FDA could not ensure that the Breast Implants came with warnings that adequately disclosed the risk of Breast Implant Illness, this theory cannot support a state-law failure-to-warn claim due to implied

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	preemption. Indeed, two of the three regulations cited in Plaintiff's briefing on the Motion reflect duties owed to the FDA, not to Plaintiff." *Id.* at *5. "Because Plaintiff's theory of failure-to-warn liability would clearly be preempted even if the pleading deficiencies were cured, granting leave to amend would be futile." *Id.*, at *6. "Negligent failure to warn is a recognized action under Florida law. ... But this claim is expressly preempted. [Plaintiff] does not allege that Mentor failed to give the warning required by the FDA and federal requirements. So [Plaintiff] is attempting to hold Mentor to a state-law requirement that is different or in addition to what federal law requires. So [Plaintiff] cannot pursue negligence based on this theory of liability. Similar to the prior theory, Rowe states a viable Florida state-law claim for negligent failure to report. In fact, the Eleventh Circuit has equated failure to report with failure to warn under Florida law. ... But like its sister theory above, [Plaintiff]'s failure to report theory of liability is also preempted, albeit impliedly instead of expressly. [Plaintiff] alleges that Mentor should have reported adverse events, presumably to the FDA as required by federal regulations. As the Eleventh Circuit explained in *Mink*, a failure to report claim like this is 'very much like the "fraud-on-the FDA" claim the Supreme Court held was impliedly preempted in *Buckman*' because [Plaintiff] is alleging Mentor 'failed to tell the FDA those things required by federal law.' So Rowe cannot pursue negligence based on this theory of liability." *Rowe v. Mentor Worldwide, LLC*, 297 F. Supp. 3d 1288, 1296 (M.D. Fla. 2018) (internal citations omitted). "[Plaintiff] alleges that Mentor's MemoryGel [Breast] Implants PMA required them to conduct six studies, and that Mentor negligently failed to comply with these requirements. [Plaintiff] also alleges that Mentor breached a general duty of care to [her] by Mentor's 'failure to comply with its PMA and FDA post-marketing regulations,' which caused Plaintiff's damages. [Plaintiff]'s claim is for breach of the federal requirements and regulations. But [Plaintiff] never identifies a

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	parallel state duty to comply with the requirements and regulations. And this Court is unaware of any duty imposed under Florida law imposing such a duty. So the Court concludes that [Plaintiff] has failed to state a viable negligence claim under Florida law. Even if she had, though, this theory of liability would be impliedly preempted." *Id.* at 1296 (internal citations omitted).
Georgia	"The *legal* duty to report, however, is imposed in Georgia by statute, and as stated above, this statute does not give rise to a private cause of action for damages." *McGarrah v. Posig*, 280 Ga. App. 808, 810, 635 S.E.2d 219, 222 (2006) (emphasis in original); *see id.* (noting that "any change in the law in these matters lies in the realm of the legislature" and cautioning that "[t]he ramifications of creating a tort liability must be weighed against the consequences of resultant potential over-reporting."). *Vance v. T.R.C.*, 494 S.E.2d 714, 716 (Ga. App. 1997) (holding that failure to report in violation of a statute "does not create a civil cause of action"); *id*. at 717 ("The purpose of the statute is ... 'to protect and enhance the welfare of" the public. It is not, therefore, to provide monetary damages to the injured."). "Plaintiff's theory of liability is based on a duty to file a report with the FDA, which is very much like a fraud-on-the FDA claim and is preempted. Contrary to Plaintiff's arguments, the fact that the device at issue was subject to a recall does not change the Court's conclusion." *Sharp v. St. Jude Med., S.C., Inc.*, 396 F. Supp. 3d 1250, 1260 (N.D. Ga. 2019) (internal marks and cites omitted); *id*. at 1261 (holding that "if Plaintiff's theory is that St. Jude had a duty to provide adverse events reports directly to patients and physicians, the claims is expressly preempted because it seeks to impose a duty to warn onto defendants that is broader and in addition to those required by federal law.") (internal marks and cites omitted).

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	"Plaintiff alleges that the SJM Defendants failed to report to the FDA information required by federal law. Such a claim is impliedly preempted. ... [E]ven if Plaintiff's failure to report to the FDA claim was not impliedly preempted, it would still be subject to dismissal because Plaintiff has not alleged that the SJM Defendants' alleged reporting failure to the FDA was the proximate cause of the decedent's injuries." *Williams v. St. Jude Med., S.C., Inc.*, 2017 WL 11113322, at *9 (N.D. Ga. Oct. 19, 2017) (noting that "the FDA's disclosure of reports to the public is not mandatory"; "Plaintiff does not explain if or how the FDA would disclose the SJM Defendants' reportable information to the decedent," and "made no allegation that the decedent ever consulted FDA disclosures in making his decision about implantation.").
Hawaii	"Having undertaken an analysis of the factors the [Supreme Court of Hawai'i] considered relevant in determining whether there is a private right of action under a Hawai'i statute, the Court concludes that based upon the legislative purpose and history of Chapter 350, the level of detail provided for by Chapter 350, and authority from other jurisdictions, the Hawai'i legislature did not intend to create a duty that would subject a private party (and analogously the Government) to tort liability based upon a failure to report ..." *Williams v. United States*, 711 F. Supp. 2d 1195, 1206-07 (D. Haw. 2010).
Illinois	Plaintiffs "allege Medtronic failed to report adverse events to the FDA as required as a condition to the Infuse's premarket approval. However, although plaintiffs have identified a federal requirement that their complaint alleges Medtronic violated, there is no Illinois requirement that parallels it. Plaintiffs asserted claims for failure to warn. Although Illinois recognizes that a manufacturer may satisfy its duty to warn by conveying information to third-party learned intermediaries, this is not synonymous with an affirmative duty to warn a federal regulatory body." *Norabuena v. Medtronic, Inc.*, 86 N.E.3d 1198, 1206-07 (Ill. App. 2017) (citing *Kirk v.*

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	Michael Reese Hospital & Medical Center, 117 Ill. 2d 507, 519, 111 Ill. Dec. 944, 513 N.E.2d 387 (1987)). "In order to establish a strict liability failure to warn claim under Illinois law, a plaintiff must prove that the manufacturer did not disclose an unreasonably dangerous condition or instruct on the proper use of the product as to which the average consumer would not be aware. Similarly, in order to prove a negligent failure to warn claim, a plaintiff must show that the manufacturer negligently failed to instruct or warn of a danger of the product and that failure proximately caused the plaintiff's injuries." *Id*. at 1207 (internal citations omitted). "A conventional principle of tort law, in Illinois as elsewhere, is that if a statute defines what is due care in some activity, the violation of the statute either conclusively or (in Illinois) presumptively establishes that the violator failed to exercise due care." The federal court stressed, however, "[b]ut the statutory definition does not come into play unless the tort plaintiff establishes that the defendant owes a [common law] duty of care to the person he injured because tort liability depends on the violation of a duty of care to the person injured by the defendant's wrongful conduct." Ordinarily the scope of a tort duty of care is stated in a jurisdiction's case law, and "although the legislature can and sometimes does create a duty of care to a new class of injured persons, the mere fact that a statute *defines* due care does not in and of itself create a duty enforceable by tort law." *Varela v. St. Elizabeth's Hosp. of Chicago, Inc.*, 867 N.E.2d 1, 10-11 (Ill. App. 2006) (quoting *Cuyler v. United States*, 362 F.3d 949 (7th Cir. 2004)) (internal marks and citations omitted). "*Cuyler* [*v. United States*, 362 F.3d 949 (7th Cir. 2004)] stands for the propositions that (1) there is no duty under the Illinois common law of torts or the Reporting Act (325 ILCS 5/1 *et seq.* (West 2002)) to rescue others from being injured by third parties, and (2) a plaintiff proceeding under the common law must first establish that the defendant owed a common law duty of care to the

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	person he injured before a court will look to a statute to define the specific level of care that was owed. Therefore, the case that is at the center of the plaintiffs' duty of care argument actually supports summary judgment for Dr. Gomez and the other defendants." *Varela v. St. Elizabeth's Hosp. of Chicago, Inc.*, 867 N.E.2d 1, 11 (Ill. App. 2006) (quoting *Cuyler v. United States*, 362 F.3d 949 (7th Cir. 2004)). "[A]n implied private cause of action is not necessary to provide an adequate remedy for violations of the statute. A cause of action should only be implied in a statute 'in cases where the statute would be ineffective, as a practical matter, unless such an action were implied.'" *Doe 1 ex rel. Tanya S. v. N. Cent. Behavioral Health Sys., Inc.*, 816 N.E.2d 4, 7-8 (Ill. App. 2004) ("[A]lthough the plaintiffs are members of the class of individuals who are to be protected by the Reporting Act, and even though the harm suffered by the children was of the type the statute was designed to prevent, the plaintiffs have not shown that a private cause of action may be implied in the statute. There is no evidence that the statute was designed to provide monetary remedies for victims of abuse or to impose civil liability on those who fail to report. Furthermore, there is nothing to show that the statute suffers from inadequate enforcement absent a private remedy.").
Indiana	"Because there can be no private right of action for a violation of the [Bank Secrecy Act] and its [Suspicious Activity Reports] reporting requirements, [Defendants'] failure, if any, to file such reports would not support the [Plaintiffs'] cause of action." *EngineAir, Inc. v. Centra Credit Union*, 107 N.E.3d 1061, 1073 (Ind. App. 2018). "Like the majority of states, Indiana does not recognize a private right of action for failure to report ... Our reporting statutes do not explicitly provide a private right of action, and we have previously held that the legislature did not intend that a private right of action be implied."

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	Sprunger v. Egli, 44 N.E.3d 690, 693 (Ind. App. 2015) (citing *C.T. v. Gammon*, 928 N.E.2d 847, 853-54 (Ind. App. 2010)).
Iowa	Plaintiffs "argue for the court to recognize a duty of care based upon the monitoring and reporting requirements ... Plaintiffs cite no decision by an Iowa court, or any other court, recognizing such a duty arising from that Act. Rather, courts have uniformly rejected such an argument." *Armstrong v. Am. Pallet Leasing, Inc.*, 678 F. Supp. 2d 827, 874-75 (N.D. Iowa 2009) (granting motion to dismiss breach of fiduciary duty case predicated on violations of the Bank Secrecy Act).
Kansas	"The purpose of the reporting statute is to provide for the protection of children who have been abused by encouraging the reporting of suspected child abuse and by insuring the thorough and prompt investigation of such reports. There is no express indication of legislative intent to impose any liability for failure to report. The decision to report suspected abuse should be based on something more than suspicion…. If the legislature had intended to grant a private right of action … it would have specifically done so…. The legislature has not utilized the amendment opportunities to add a private cause of action. No private cause of action exists…. The child abuse reporting portion of instruction No. 9 should not have been given." *Kansas State Bank & Tr. Co. v. Specialized Transp. Servs., Inc.*, 819 P.2d 587, 604 (Kan. 1991). "Although there is no dispute that Kansas law does not hold healthcare professionals liable for failing to report ... our final task is to predict whether the Supreme Court of Kansas would recognize such a duty as part of the overall duty [of care]. We conclude that it would not." *Portenier v. United States*, 520 F. App'x 707, 716 (10th Cir. 2013). In a breast implant litigation, filed by counsel on the PSC in this MDL, "Plaintiffs argue[d] that [the manufacturer]'s duty to warn extended to three different parties: (1) patients, (2) the FDA and (3) physicians." *Brooks v. Mentor Worldwide, LLC*, 2019 WL 4628264, at *5 (D. Kan. Sept.

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	23, 2019). The Court "easily dispose[d]" of the first claim, holding that "[n]either plaintiff can sue for failure to warn patients because Kansas and Missouri have adopted the learned intermediary doctrine, which holds that a manufacturer's duty to warn extends only to prescribing physicians, and not to patients. Even if state law permitted plaintiffs to bring a claim for failure to warn patients, the MDA would expressly preempt that claim because plaintiffs have not identified any such requirement under federal law." *Id*. As for their argument that [defendant] had a duty to warn the FDA, "Plaintiffs have not identified a state law that required Mentor to conduct follow-up studies in accordance with FDA regulations, nor have plaintiffs identified a state law that required Mentor to report findings to the FDA. Therefore, plaintiffs are not enforcing state law, but attempting to enforce FDA regulations. The MDA impliedly preempts this type of action." *Id*. Finally, the Court rejected Plaintiffs' argument that the defendant-manufacturer "had a duty to warn physicians about health risks associated with its implants, both *directly* (by updating its labels) and *indirectly* (by reporting to the FDA)" because "[e]ven if these allegations were not speculative, the MDA would impliedly preempt this theory of recovery. Plaintiffs have not identified any state law that required [defendant] to report adverse events to the FDA. Accordingly, like their other claims relating to FDA reporting, plaintiffs are not seeking to enforce state law, but are attempting to enforce federal requirements. The MDA impliedly preempts this theory of recovery. Therefore, the Court dismisses plaintiffs' claims of failure to warn." *Id*. at *6 (internal citations omitted). *Pontious v. Medtronic, Inc.*, 2011 WL 6091749, at *2 (D. Kan. Dec. 7, 2011) (holding the MDA impliedly preempts KCPA claim based on failure to report information to FDA as required by federal regulations, not under state law).
Louisiana	*Morris v. Wyeth, Inc.*, 2012 WL 601455, at *4-5 (W.D. La. 2012), *aff'd*, 713 F.3d 774 (5th Cir. 2013) (dismissing plaintiffs' failure to warn claims without leave to amend where they were based on an allegedly inadequate FDA-approved warning label, and further dismissing "their failure to

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	test and report claim because Plaintiffs do not allege a colorable claim under the LPLA and the FDCA does not grant a private right of action.").
Maine	Maine has not recognized the failure to report adverse events as a basis for a failure to warn claim.
Maryland	*Lemon v. Stewart*, 682 A.2d 1177, 1185 (Md. 1996) (holding that, although health care providers had duty to inform patients of certain information, their alleged breach of that duty could not be basis for negligence and negligent misrepresentation claims asserted by non-patient plaintiffs). *Sheridan v. United States*, 969 F.2d 72, 74-75 (4th Cir. 1992) (affirming summary judgment in favor of defendants, "finding plaintiffs failed to state a claim for relief under Maryland law" insofar as plaintiffs alleged their injuries were the result of a serviceman's failure to comply with Navy regulations and the Navy's failure to report the serviceman's non-compliance as statutorily required).
Massachusetts	Massachusetts law "does not provide a private right of action against mandatory reporters who fail to report ..." *Doe v. D'Agostino*, 367 F. Supp. 2d 157, 176 (D. Mass. 2005).
Michigan	Mandatory "reporting statute creates a private right of action *only* in an identified" class and *not* the general public. *Murdock v. Higgins*, 559 N.W.2d 639, 646-47 (Mich. 1997); *see Boman v. Catholic Diocese of Grand Rapids*, 2018 WL 3129703, at *5 (Mich. App. June 26, 2018) (same). *Marcelletti v. Bathani*, 500 N.W.2d 124, 128-29 (Mich. App. 1993) ("The statute names twelve agencies or groups of individuals to whom reports may be released. The plaintiffs do not fall into any of these categories. ... Plaintiffs' statutory claim was properly dismissed.") *El Camino Res., Ltd. v. Huntington Nat. Bank*, 722 F. Supp. 2d 875, 923 (W.D. Mich. 2010), *aff'd*, 712 F.3d 917 (6th Cir. 2013) ("it is now well settled that the anti-money-laundering obligations

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	of banks, as established by the Bank Secrecy Act, obligate banks to report certain customer activity to the government but do not create a private cause of action permitting third parties to sue for violations of the statute. ... If the [defendant] did violate its obligations under the Bank Secrecy Act, it may be accountable to the United States government for its failures, but no duty arises to plaintiffs for any such failure.").
Minnesota	Minnesota does not recognize a common law cause of action for failure to report to a government agency. *Becker v. Mayo Found.*, 737 N.W.2d 200, 207 (Minn. 2007); *Valtakis v. Putnam*, 504 N.W.2d 264, 266-67 (Minn. App. 1993); *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010).
Mississippi	The Mississippi Products Liability Act ("MPLA") as amended by the Mississippi Supreme Court is the exclusive remedy for products liability actions, therefore, as Plaintiff's cannot bring a negligence-based failure to warn claim under the MPLA, a failure-to-report claim must be dismissed. *Knoth v. Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 694-95 (S.D. Miss. 2019).
Missouri	"[N]o private cause of action can be implied under the Child Abuse Reporting Act ... the alleged breach of the Act also does not amount to negligence per se." *E.M. v. Gateway Region Young Men's Christian Ass'n*, ___ S.W.3d ___, 2020 WL 1921035, at *5-6 (Mo. App. April 21, 2020); *Bradley v. Ray*, 904 S.W.2d 302, 312-15 (Mo. App. 1995) (observing that without a specific duty to particular individuals, there is no private cause of action); *Brooks v. Mentor Worldwide, LLC*, 2019 WL 4628264, at *5 (D. Kan. Sept. 23, 2019) (applying Missouri law) (finding that "Plaintiffs have not identified a state law that required [defendant] to conduct follow-up studies in accordance with FDA regulations, nor have plaintiffs identified a state law that required [defendant] to report findings to the FDA. Therefore, plaintiffs are not enforcing state law, but attempting to enforce FDA regulations. The MDA impliedly preempts this type of action.").

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Montana	Montana has not recognized the failure to report adverse events as a basis for a failure to warn claim.
Nebraska	If there is no duty to report, Plaintiff cannot be held liable for failing to report to a government agency. *Bell v. Grow With Me Childcare & Preschool LLC*, 907 N.W.2d 705, 720 (Neb. 2018).
Nevada	Nevada has not recognized the failure to report adverse events as a basis for a failure to warn claim.
New Hampshire	Without specific legislation creating a duty, New Hampshire is unwilling to create a duty for failure to make reports. *Gauthier v. Manchester School Dist.*, 123 A.3d 1016, 1021 (N.H. 2015); *Marquay v. Eno*, 662 A.2d 272, 278 (N.H. 1995) ("declin[ing] … to create a duty to report bullying").
New Jersey	Regulation requiring emergency medical technicians and others to report any instance where a crewmember acted outside of his or her approved scope of practice did not impose on an EMT a duty to report his co-worker's alleged sexual abuse of a minor victim; the regulation was limited to conduct by the child's parent, guardian, or other person having custody and control of the child. *G.A.-H. v. K.G.G.*, 210 A.3d 907, 916 (N.J. 2019); *Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1057 (N.J. 2012), *abrogated on other grounds by McCarrell v. Hoffmann-LaRoche, Inc.*, 227 N.J. 569 (2017) (no duty to make adverse event reports to FDA); *J.S. v. R.T.H.*, 714 A.2d 924, 934 (N.J. 1998) "we do not conclude that the Legislature intended that the child-abuse reporting statute constitute an independent basis for civil liability or that its violation constitute negligence per se.").
New Mexico	New Mexico will not imply a duty to report unless provided for by the legislature. *Johnson v. Holmes*, 377 F. Supp. 3d 1084, 1098 (D.N.M. 2004).

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New York	A standalone claim for failure to report adverse events to the FDA is not a cognizable cause of action under New York law. *Heidt v. Rome Mem. Hosp.*, 724 N.Y.S.2d 139, 787 (N.Y. App. Div. 2007); *English v. Bayer Corp.*, ___ F. Supp. 3d ___, 2020 WL 3454877, at *3 (W.D.N.Y. June 25, 2020) (same); *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 201-02 (E.D.N.Y. 2015); *In re Agape Litig.*, 681 F. Supp. 2d 352, 360-61 (E.D.N.Y. 2010) (same).
North Carolina	*McNeil-Williams v. DePuy Orthopaedics, Inc.*, 384 F. Supp. 3d 570, 575-76 (E.D.N.C. 2019); *Taylor & Co. v. Bank of Am. Corp.*, 2014 WL 3557672, at *3 (.W.D.N.C. June 5, 2014), *adopted*, 2014 WL 3557679 (W.D.N.C. July 18, 2014).
North Dakota	North Dakota has not recognized the failure to report adverse events as a basis for a failure to warn claim.
Ohio	State requirements are pre-empted under the MDA only to the extent that they are different from, or in addition to the requirements impose by federal law. *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1005 (S.D. Ohio 2016); *Towne Auto Sales, LLC v. Tobsal Corp.*, 2017 WL 5467012, at *2 (N.D. Ohio Nov. 14, 2017) (no private cause of action exists unless the statute specifically provides for one); *Spitzer Mgmt., Inc. v. Interactive Brokers, LLC*, 2013 WL 6827945, at *2 (N.D. Ohio Dec. 20, 2013) (same).
Oklahoma	The child abuse reporting statutes do not create a private right of action, if there is no provision for civil liability. *Paulson v. Sternlof*, 15 P.3d 981, 984 (Okla. App. 2000).
Puerto Rico	Puerto Rico does not recognize a state-tort cause of action for failure to report or warn a third party. *Martinez Colon v. Santander Nat'l Bank*, 4 F. Supp. 2d 53, 57 (D.P.R. March 31, 1998).

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Rhode Island	Rhode Island has not recognized the failure to report adverse events as a basis for a failure to warn claim.
South Carolina	Retail store was not civilly liable due to store employees' failure to report suspected child abuse, as required by the South Carolina Reporter's Statute, because it did not create a private cause of action for negligence based on failure to report suspected or known child abuse. *Doe v. Wal-Mart Stores, Inc.*, 711 S.E.2d 908, 910-11 (S.C. 2011); *Bean v. Upsher-Smith Pharms., Inc.*, 2017 WL 4348330, at *2 (D.S.C. Sept. 29, 2017) (same); *Ellis v. Smith & Nephew Inc.*, 2016 WL 7319397, at *18 (D.S.C. Feb. 16, 2016) (same).
South Dakota	South Dakota has not recognized the failure to report adverse events as a basis for a failure to warn claim.
Tennessee	The common law of Tennessee does not impose a duty on a treating physician to either report suspected child abuse or to prevent any such child abuse. *Belle Meade Title & Escrow Corp. v. Fifth Third Bank*, 282 F. Supp. 3d 1033, 1038 (M.D. Tenn. 2017); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 860-61 (W.D. Tenn. 2015) (finding that "to the extent that Plaintiffs seek recourse for Defendants' failure to file adverse event reports with the FDA, the Court finds such claims impliedly preempted [since a] duty to disclose lack of FDA approval for [an] off-label procedure [is] not required by [the] FDA and [is] therefore preempted); *Ham v. Hosp. of Morristown, Inc.*, 917 F. Supp. 531, 534 (E.D. Tenn. 1995) (same).
Texas	Texas will not create a duty to make reports to a government agency, if the statute does not provide for one. *Perry v. S.N.*, 973 S.W.2d 301, 304-06 (Tex. 1998); *Doe v. Apostolic Assembly of Faith in Christ Jesus*, 2020 WL 1684227, at *13-14 (W.D. Tex. April 6, 2020) (same); *S.N.B. v. Pearland Indep. Sch. Dist.*, 120 F. Supp. 3d 620, 632 (S.D. Tex. 2014) (same); *Doe v. S & S*

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	Consol. Indep. Sch. Dist., 149 F. Supp. 2d 274, 299 (E.D. Tex. 2001), *aff'd mem.*, 309 F.3d 307 (5th Cir. 2002) (same).
Vermont	Vermont rejected non-FDCA failure to warn tort claims based on a mandated-reporter statute since Defendant did make the report as required under the statute and did not owe any common law duty to the child. *Sheldon v. Ruggiero*, 202 A.3d 241, 248-49 (Vt. 2018); *Lyman v. Pfizer*, 2012 WL 368675 at *15 (D. Vt. Feb. 3, 2012).
Virginia	Virginia rejects the common-law duty to report. Virginia declined to create a legal duty on Defendant since the amended complaint did not assert any specifics about preacher's sexual abuse allegations and how, if at all, any social services or law enforcement authorities resolved it: "We do not believe that his prior allegation, given its vague description in the amended complaint and the absence of any assertion that the responsible authorities had verified it, was enough, standing alone, to trigger a legal duty to terminate [preacher] from any employment or agency relationship that he had with the church defendants." *A.H. v. Church of God in Christ, Inc.*, 831 S.E.2d 460, 475 (Va. 2019).
Washington	Washington has not recognized the failure to report adverse events as a basis for a failure to warn claim.
West Virginia	The West Virginia Supreme Court of Appeals rejected a civil claim based on a failure to warn the West Virginia Department of Health and Human Resources of suspected child abuse since no private civil cause of action existed under the relevant statute. *Barbina v. Curry*, 650 S.E.2d 140, 145 (W. Va. 2007); *Arbaugh v. Bd. of Educ., County of Pendleton*, 591 S.E.2d 235, 241 (W. Va. 2003) (same).

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Wisconsin	Wisconsin declined to create a private cause of action where none existed. *Grad v. Assoc. Bank*, 2011 WL 2184335, at *5 (Wis. App. June 7, 2011); *Isely v. Capuchin Province*, 880 F. Supp. 1138, 1148 (D. Mich. 1995) (declining to step into the role of the legislature and create a private cause action under Wisconsin's child abuse reporting law).
Wyoming	Wyoming has not recognized the failure to report adverse events as a basis for a failure to warn claim.

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NEGLIGENT MISREPRESENTATION	
Alabama	Personal injury actions based on "innocent or negligent misrepresentation" in the "marketing" of a product would be considered a "product liability action under Alabama law." *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prods. Liab. Litig.*, 2015 WL 7076012, at *6 (E.D. Pa. Nov. 13, 2015) (applying Alabama law); *Tutwiler v. Sandoz Inc.*, 2017 WL 3315381, at *2 (N.D. Ala. Aug. 3, 2017) (Plaintiff failed to overcome the learned-intermediary doctrine since she failed to show but for the false representation made in a warning, the prescribing physician would not have prescribed the medication to the patient).
Arkansas	Arkansas does not recognize negligent misrepresentation as a separate cause of action. *Forester v. Ethicon, Inc.*, 2017 WL 525853, at *3 (S.D.W. Va. Feb. 8, 2017) (applying Arkansas law).
Florida	Plaintiff has not sufficiently pled misrepresentation since plaintiff did not adhere to the particularity requirements under Federal Rule of Civil Procedure 9(b). *Dimieri v. Medicis Pharms. Corp.*, 2015 WL 1523909, at *4 (M.D. Fla. April 3, 2015).
Georgia	Plaintiff failed to meet the pleading requirements of Rule 9(b) since Plaintiff does not "identify any statements that were misrepresentations. Plaintiff does not indicate which Defendant made any particular statement. In other words, Plaintiff does not state the who, what, when, where and how of the facts supporting the fraud claims." *Brazil v. Janssen Research & Dev. LLC*, 249 F. Supp. 3d 1321, 1340 (N.D. Ga. 2016).
Indiana	Indiana law only permits a claim for negligent misrepresentation in certain contexts wherein the defendant supplies false information for the guidance of others in their business transactions. Plaintiff failed to plead negligent misrepresentation since she conceded that there was no business transaction with Defendant. *Wortman v. C.R. Bard, Inc.*, 2019 WL 6329651, at *6 (S.D. Ind. Nov. 26, 2019); *Short v. Eli Lilly & Co.*, 2009 WL 9867531, at *8 (Ind. Super. March 25, 2009); *Short v. Eli Lilly & Co.*, 2009 WL 9867531, at *8 (Ind. Super. March 25, 2009) (finding as a

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NEGLIGENT MISREPRESENTATION	
	matter of law, Plaintiff's misrepresentation claim fails since Plaintiff did not receive or rely on any statements from Defendant).
Louisiana	The Louisiana Product Liability Act ("LPLA") is the exclusive theory of liability for manufacturers for damages caused by their products, therefore, plaintiff did not recover from the manufacturer on a negligent misrepresentation claim since it is a theory of liability that falls outside what is contemplated by the LPLA. *Baudin v. AstraZeneca Pharm. LP*, 413 F. Supp. 3d 498, 503 (M.D. La. 2019); *Thomas v. Bracco Diagnostics Inc.*, 2019 WL 4254015, at *2 (Mag. W.D. La. July 23, 2019), *adopted*, 2019 WL 4254137 (W.D. La. Sept. 6, 2019) (same).
Minnesota	Plaintiff failed to plead negligent misrepresentation since they did not allege pecuniary loss related to a business transaction. *Smith v. Brutger Cos.*, 569 N.W.2d 408, 414 (Minn. 1977); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 351 (Minn. Ct. App. 2001) (even if plaintiff's negligent misrepresentation claim was not preempted, plaintiff still failed to plead negligent misrepresentation since the Minnesota Supreme Court has expressly limited this claim to damages for pecuniary loss and not negligent misrepresentation involving the risk of physical harm; *Grozdanich v. Leisure Hills Health Ctr., Inc.*, 25 F.Supp.2d 953, 987 (D. Minn. 1998) (same).
Mississippi	Where a common law claim is subsumed by the Mississippi Product Liability Act ("MPLA") and is brought alongside products liability claims based on the same theory of recovery, the proper course is to dismiss the common law claim to the extent it is duplicative of the parallel products liability counts. *Young v. Bristol-Myers Squibb Co.*, 2017 WL 706320, at *4 (N.D. Miss. Feb. 22, 2017); *Estes v. Lanx, Inc.*, 2015 WL 9462964, at *9 (N.D. Miss. Dec. 23, 2015), *aff'd*, 660 F. App'x 260 (5th Cir. 2016) ("Because Plaintiff in the case *sub judice* alleges that Defendant made representations with respect to the screw that mirror his allegations concerning the alleged

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NEGLIGENT MISREPRESENTATION	
	representations in his failure-to-warn claim, the Court finds that his negligent misrepresentation claim is subsumed by the MPLA and must be dismissed.").
New Jersey	Plaintiffs' fraud-based claims must be dismissed because such claims are "subsumed by the NJPLA where the core issue is harm allegedly caused by a defendant's products." *Indian Brand Farms v. Novartis Crop Prot., Inc.*, 890 F. Supp. 2d 534, 539-40 (D.N.J. 2012).
Ohio	Plaintiff failed to sufficiently allege negligent misrepresentation since "there is no evidence that the representations were made to [Plaintiff] either directly or through a physician." *Thompson v. DePuy Orthopaedics, Inc.*, 2015 WL 7888387, at *16 (S.D. Ohio Dec. 4, 2015).
Tennessee	Plaintiff did not state a sufficient product defect claim under the Tennessee Product Liability Act ("TPLA"), therefore, Plaintiff's false misrepresentation claims must also be dismissed. *Fleming v. Janssen Pharms., Inc.*, 186 F. Supp. 3d 826, 836 (W.D. Tenn. 2016); *Ross v. Sofamor, S.N.C.*, 1999 WL 613357, at *7 (W.D. Tenn. March 10, 1999) (Plaintiff failed to state a claim for negligent misrepresentation because Plaintiff did not demonstrate actual reliance).
Texas	The Court treated Plaintiff's negligent misrepresentation claim as a failure-to-warn claim. *Phares v. Actavis-Elizabeth LLC*, 892 F. Supp. 2d 835, 841-42 (S.D. Tex. 2012).
Virginia	A plaintiff must show a false representation by a defendant of a material fact made intentionally and knowingly with intent to mislead, reliance by misled party, and resulting injury to party misled. Failing to demonstrate evidence that Defendant misled Plaintiff is insufficient to state a claim for false representation. *Bentley v. Legent Corp.*, 849 F. Supp. 429, 434 (E.D.Va. 1994), *aff'd sub nom. Herman v. Legent Corp.*, 50 F.3d 6 (4th Cir. 1995).

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Alabama	"In general, Alabama law does not recognize a cause of action for breach of implied warranty of merchantability for inherently dangerous products." *Barnhill v. Teva Pharms. USA, Inc.*, 819 F. Supp. 2d 1254, 1263-64 (S.D. Ala. 2011); *In re Trasylol Prods. Liab. Litig.*, 2011 WL 2117257, at *6 (S.D. Fla. May 23, 2011) ("Alabama law does not provide for a general breach of implied warranty cause of action for alleged injuries from a pharmaceutical."). *McClain v. Metabolife Int'l, Inc.*, 193 F.Supp.2d 1252, 1258 (N.D. Ala. 2002) (noting that "the U.C.C. is concerned with product *quality*, while products liability law ... is concerned with product *safety*") (emphasis in original).
Arizona	Arizona law requires that a plaintiff give notice before bringing a claim for breach of warranty. "Where a tender has been accepted, [t]he buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." Ariz. Rev. Stat. § 47-2607; *Pace v. Sagebrush Sales Co.*, 560 P.2d 789, 792 (Ariz. 1977) (implied and express). Arizona law requires privity between the parties as an element of an express warranty claim. "Under Arizona law, any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. Any affirmation that forms the basis of an express warranty must be between the seller and the buyer." *Martin v. Medtronic, Inc.*, 63 F. Supp. 3d 1050, 1061 (D. Ariz. 2014) (internal citations omitted); *Arvizu v Medtronic, Inc.*, 41 F. Supp. 3d 783, 793-94 (D. Ariz. 2014) (same).
Arkansas	Arkansas law requires that a plaintiff give notice before bringing a claim for breach of warranty. "Where a tender has been accepted, the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." Ark. Code Ann. § 4-2-607(3)(a); *Forester v. Ethicon, Inc.*, 2017 WL 525853, at *3 (S.D.W. Va. Feb. 8, 2017) (applying Arkansas law). *See also Statler v. Coca-Cola Bottling*

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	Co., 669 S.W.2d 460, 464 (Ark. 1984) ("In order to state a cause of action for breach of implied warranty, an allegation of notice of the defect to the seller must be pleaded.").
California	Under California Civil Code § 1793.02(e)(3), there is no implied warranty of fitness for an "assistive device" if that assistive device is a "surgical implant performed by a physician or surgeon." Cal. Civ. Code § 1793.02(e)(3). *Hammarlund v. C.R. Bard, Inc.*, 2015 WL 5826780, at *6 (C.D. Cal. Oct. 2, 2015); *Markowitz v. Davol Inc.*, 2015 WL 12696031, at *4-5 (C.D. Cal. June 19, 2015) (same); *Coleman v. Boston Scientific Corp.*, 2011 WL 3813173, at *6 (E.D. Cal. Aug. 29, 2011) (same). California law requires that a plaintiff give notice before bringing a claim for breach of warranty. "Where a tender has been accepted, the buyer must, within a reasonable time after he or she discovers or should have discovered any breach, notify the seller of breach or be barred from any remedy" Cal. Com. Code § 2607(3)(A) (implied); Under California law, to state a claim for breach of express warranty, a buyer must plead that notice of the alleged breach was provided to the seller within a reasonable time after discovery of the breach. *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1181 (C.D. Cal. 2013) (express). Under California law, privity of contract is required for both implied and express warranty action. While there exceptions to the rule, privity of contract remains a requirement in express warranty actions. However, in the context of implantable medical devices, courts have generally concluded that these exceptions do not apply, since "the transaction is between the manufacturer and the physician, not the patient." As a result, various courts have dismissed breach of warranty claims for a lack of privity or reasonable reliance where the product at issue is an implantable medical device. *Jager v. Davol Inc.*, 2016 WL 6157942, at *4 (C.D. Cal. Oct. 20, 2016) (express). Under California law, claims of implied warranty may be brought only by those in privity with the named defendant. *Elkind v. Revlon Consumer Prods. Corp.*,

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	2015 WL 2344134, at *14 (E.D.N.Y. May 14, 2015). "California courts have painstakingly established the scope of the privity requirement under California Commercial Code section 2314, and a federal court sitting in diversity is not free to create new exceptions to it." *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1024 (9th Cir. 2008).
Colorado	To recover for personal injuries due to a breach of warranty, a person to whom the warranty extends must within a reasonable time after he discovers or should have discovered any breach, notify the seller of breach or be barred from that remedy. Colo. Rev. Stat. § 4-2-607(3)(a). *Palmer v. A.H. Robins Co.*, 684 P.2d 187, 205-207 (Colo. 1984); *Hawkinson v. A.H. Robins Co.*, 595 F. Supp. 1290, 1312-13 (D. Colo. 1984) (same).
Florida	Pursuant to Fla. Stat. § 672.607(3)(a), breach of warranty claim must allege notice to seller of breach. *Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1325 (M.D. Fla. 2013). "Privity is required in order to recover damages from the seller of a product for breach of express or implied warranties." "[U]nder Florida law: A plaintiff who purchases a product but does not buy it directly from the defendant, is not in privity with the defendant." *Ripple v. Davol, Inc.*, 2017 WL 2363697, at *4 (S.D. Fla. May 31, 2017); *see also Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1325 (M.D. Fla. 2013) (same).
Georgia	Breach of implied warranty is not available in prescription medical device litigation absent some showing that the product itself was somehow defective and not of its usual or expected quality. Ga. Code §§ 11-2-314, 11-2-315. *Presto v. Sandoz Pharms. Corp.*, 487 S.E.2d 70, 75 (Ga. App. 1997). "Under Georgia law, to recover for a breach of warranty, a plaintiff must show privity between himself and the defendant. Georgia law still generally precludes the ultimate consumer from recovering on any express or implied warranty when the manufacturer sells the product to the

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	original consumer. Privity with a consumer is deemed to exist if the manufacturer expressly warrants to the ultimate consumer that the product will perform in a certain way or that it meets particular standards." *Benefield v. Pfizer Inc.*, 103 F. Supp. 3d 449, 463-64 (S.D.N.Y. 2015) (applying Georgia law) (internal citations omitted); *Wheeler v. Novartis Pharms. Corp.*, 944 F. Supp. 2d 1344, 1354 (S.D. Ga. 2013) ("[I]f a defendant is not the seller to the plaintiff-purchaser, the plaintiff as the ultimate purchaser cannot recover on the implied or express warranty, if any, arising out of the prior sale by the defendant to the original purchaser, such as the distributor or retailer from whom plaintiff purchased the product.").
Idaho	Under Idaho law, privity of contract is required to bring claims for breach of implied or express warranty. Idaho does not recognize a breach of warranty claim in personal injury products liability actions which do not involve a contractual relationship between the manufacturer and the injured person. *Wilson v. Amneal Pharms., L.L.C.*, 2013 WL 6909930, at *15-16 (D. Idaho Dec. 31, 2013); *Elliott v. Smith & Nephew, Inc.*, 2013 WL 1622659 at *8 (D. Idaho April 15, 2013) (same).
Illinois	In a claim for breach of implied warranty, under section 2-607 of the Uniform Commercial Code, a "buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of [the] breach or be barred from any remedy ..." 810 ILCS 5/2–607(3)(A). "The content of the notification need merely be sufficient to let the seller know that the transaction is still troublesome and must be watched." 810 ILCS 5/2-607 cmt. 4. Notice must be given directly. A plaintiff seeking economic damages for breach of implied warranty must also allege privity of contract with the defendant. *Prescott v. Argen Corp.*, 2014 WL 4638607, at *3 (N.D. Ill. Sept. 17, 2014) (implied).

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	To enforce an express warranty under Illinois law, a party without a warranty assignment alleging purely economic loss must be in privity of contract. *Keith v. Ferring Pharms.*, 2016 WL 5391224, at *7-8 (N.D. Ill. Sept. 27, 2016) (express).
Indiana	In breach of implied warranty of merchantability cases, one of those preconditions is that the seller be given notice of the product defect prior to the plaintiff filing suit. *Lautzenhiser v. Coloplast A/S*, 2012 WL 4530804, at *5 (S.D. Ind. Sept. 29, 2012); *Ganahl v. Stryker Corp.*, 2011 WL 693331, at *3-4 (S.D. Ind. Feb. 15, 2011) (finding notice required for breach of express and implied warranty). Privity of contract is a requirement for breach of express warranty claims. *Stewart v. Sanofi-Aventis U.S. LLC*, 2013 WL 1834562, at *6-7 (N.D. Ala. April 30, 2013) (applying Indiana law).
Kentucky	Privity of contract is required for breach of implied and express warranty claims. A breach of warranty claim is rooted in contract, not tort law. Under Kentucky law, a plaintiff-buyer must establish that it enjoyed privity of contract with the defendant-seller against whom the warranty claim is asserted. In other words, in order to proceed on a breach of warranty claim, a plaintiff alleging injury from a product must establish a buyer-seller relationship. *Cales v. Medtronic, Inc.*, 2015 WL 4081908, at *8 (Ky. Cir. July 1, 2015).
Michigan	Implied warranty claims are barred in prescription medical product litigation. *Smith v. E.R. Squibb & Sons, Inc.*, 273 N.W.2d 476, 480 (Mich. 1979). Privity is required for breach of express warranty claims. *Keith v. Ferring Pharm., Inc.*, 2016 WL 5391224, at *7 (N.D. Ill. Sept. 27, 2016).
Minnesota	Notice must generally precede a successful warranty-breach claim: Minnesota law requires that a buyer who discovers a breach of warranty "must within a reasonable time after the buyer

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	discovers or should have discovered any breach notify the seller of [the] breach or be barred from any remedy." Minn. Stat. § 336.2-607(3)(a); *Yarrington v. Solvay Pharms., Inc.*, 2006 WL 2729463, at *5-6 (Minn. App. Sept. 26, 2006).
Mississippi	To recover on a claim for breach of an implied warranty of merchantability, a plaintiff must demonstrate the following: (1) That a "merchant" sold "goods," and he was a merchant with respect to "goods of the kind" involved in the transaction, (2) which were not merchantable at the time of sale, and (3) injuries and damages to the plaintiff or his property, (4) caused proximately and in fact by the defective nature of the goods, and (5) notice to the seller of the injury. With respect to the last element, the Mississippi Supreme Court has noted that "though there may have been a breach of the warranty of merchantability, the seller has a right to attempt cure. An opportunity for the seller to cure is a reasonable requisite of a buyer's right of recovery." To survive a Rule 12(b)(6) motion, a plaintiff is required to plead specific facts that he provided such notice. *Little v. Smith & Nephew*, 2015 WL 3651769, at *12 (N.D. Miss. June 11, 2015); *Austin v. Bayer Pharms. Corp.*, 2013 WL 5406589, at *9 (S.D. Miss. Sept. 25, 2013) (dismissing plaintiff's claim for implied warranty of merchantability where she failed to plead notice).
Missouri	Section 2-607 of the Uniform Commercial Code, as adopted by Missouri, provides that "the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." Mo. Rev. Stat. § 400.2-607(3). *Budach v. NIBCO, Inc.*, 2015 WL 6870145, at *3-5 (W.D. Mo. Nov. 6, 2015) (requiring notice for implied and express warranty claims).
Nevada	For a claim of implied warranty of merchantability, Nevada case law requires contractual privity between the buyer and seller. *Finnerty v. Howmedica Osteonics Corp.*, 2016 WL

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	4744130, at *7 (D. Nev. Sept. 12, 2016); *Phillips v. C.R. Bard, Inc.*, 2014 WL 7177256, at *10 (D. Nev. Dec. 16, 2014) (same).
New Hampshire	Under New Hampshire's commercial code, a "buyer" who accepts tender of goods, "must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." N.H. Rev. Stat. 382-A:2-607(3)(a). "[A]bsent even an allegation of compliance with the Code's warranty notice provisions, Plaintiff's claim—on that premise—must fail." *Sawyer v. Purdue Pharm. Corp.*, 2013 WL 6840145, at *6 (M.D. Pa. Dec. 27, 2013) (applying New Hampshire law).
New Mexico	Notice is a required element of a breach of warranty claim. "Where a tender has been accepted, the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." N.M. Stat. § 55-2-607. *Aguirre v. Atrium Medical Corp.*, 2019 WL 2210801, at *6-7 (D.N.M. May 22, 2019).
New York	To assert a breach of warranty claim under New York law, "the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy[.]" N.Y. U.C.C. § 2-607(3)(a). *Tomasino v. Estee Lauder Cos.*, 44 F. Supp. 3d 251, 260-62 (E.D.N.Y. 2014). Under New York law, claims of implied warranty may be brought only by those in privity with the named defendant. *Elkind v. Revlon Consumer Prods. Corp.*, 2015 WL 2344134, at *14 (E.D.N.Y. May 14, 2015) (implied).

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Ohio	All common law claims arising from damages in connection with product liability claims are abrogated by the Ohio Products Liability Act. *Williams v. Bausch & Lomb Co.*, 2009 WL 2983080, at *4 (S.D. Ohio Sept. 14, 2009); *Stratford v. SmithKline Beecham Corp.*, 2008 WL 2491965, at *7 (S.D. Ohio June 17, 2008) (same). Under Ohio law, privity of contract is generally a prerequisite to a claim for breach of the implied warranty of merchantability. *Curl v. Volkswagen of Am., Inc.*, 871 N.E.2d 1141, 1147-48 (2007) ("In Ohio, damages are recoverable for breach of implied warranties only if there is privity of contract between the parties.").
Oregon	Oregon Revised Statute § 72.6070(3) provides when a tender of goods has been accepted, "[t]he buyer must within a reasonable time after the buyer discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." This district has interpreted the notice requirement of § 72.6070(3) to apply in warranty actions "for personal injuries resulting from the purchase of a consumer product," including an action against a drug maker. *Parkinson v. Novartis Pharm. Corp.*, 5 F. Supp. 3d 1265, 1276 (D. Or. 2014); *Allen v. G. D. Searle & Co.*, 708 F. Supp. 1142, 1160 (D. Or. 1989) (requiring notice for implied and express warranty claims).
Pennsylvania	Implied warranty of merchantability is unavailable for claims involving a prescription medical product. *Makripodis v. Merrell-Dow Pharm., Inc.*, 523 A.2d 374, 376-77 (Pa. Super. 1987); *Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 901 (M.D. Pa. 2017) (same); *Kee v. Zimmer, Inc.*, 871 F. Supp.2d 405 (E.D. Pa. 2012) (same). Notice is required for breach of warranty claims. Where tender is accepted, a buyer must "within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." 13 Pa. Cons. Stat. § 2607(c)(1). "[T]he purpose of notification under § 2607(c) is to allow the seller an opportunity to resolve the

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	dispute regarding an alleged breach before the buyer initiates a lawsuit." Plaintiff bears the burden to prove compliance with § 2607 before recovering for breach of warranty. In context of a motion to dismiss, Plaintiff must "plead, at a minimum, ... that [she] provided reasonable notification ... to state a viable claim for recovery ... or be barred from any remedy." *Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405, 411 (E.D. Pa. 2012); *AFSCME Dist. Counsel 47 Health & Welfare Fund v. Ortho-McNeil-Janssen Pharms., Inc.*, 2010 WL 891150, at *7 (E.D. Pa. March 11, 2010) (same).
Tennessee	Tennessee law requires privity for breach of warranty claims. *Brown v. Janssen Pharms.*, 2014 WL 1654051, at *4 (N.D. Ohio April 24, 2014).
Texas	Pre-suit notice is required for breach of warranty claims under Texas law. Section 2.607(c)(1) of the Texas Business and Commerce Code provides that "[w]here a tender has been accepted ... the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy[.]" Tex. Bus. & Comm. Code § 2.701(c)(1). The purpose of this requirement is to give the seller an opportunity to inspect the product to determine whether it was defective and to allow the seller an opportunity to cure the breach, if any. A buyer's failure to notify a seller, including a remote seller such as the manufacturer, of a product's alleged defect within a reasonable time of discovering the defect bars the buyer from recovering for a breach of warranty under Section 2.314. *Elmazouni v. Mylan, Inc.*, 220 F. Supp. 3d 736, 746 (N.D. Tex. 2016); *Morgan v. Medtronic, Inc.*, 172 F. Supp. 3d 959, 970 (S.D. Tex. 2016) (applying Texas law).
Washington	Privity is required for breach of implied warranty claims. *McFarland v. APP Pharms., LLC*, 2011 WL 5507209, at *3 (W.D. Wash. Nov. 8, 2011); *McFarland v. APP Pharms. Inc.*, 2011 WL 2413797, at *3 (W.D. Wash. June 13, 2011) (same).

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Wisconsin	Under Wisconsin's version of the Uniform Commercial Code ("UCC"), a buyer "must within a reasonable time after the buyer discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." Importantly, Wisconsin law does not appear to recognize any exceptions to the notice requirement. Wisconsin courts have held that "[s]uch notice is a condition precedent to a right of recovery." *Blitz v. Monsanto Co.*, 317 F. Supp. 3d 1042, 1054-55 (W.D. Wis. 2018); *Kessler v. Samsung Elecs. Am. Inc.*, 2018 WL 7502913, at *4-6 (E.D. Wis. Feb. 16, 2018) (same). "Wisconsin law requires privity of contract between the parties before liability can be founded on breach of express or implied warranty." *Twin Disc. Inc. v. Big Bud Tractor, Inc.*, 582 F. Supp. 208, 215 (E.D. Wis. 1984). *See also Staudt v. Artifex Ltd.*, 16 F. Supp. 2d 1023, 1030 (E.D. Wis. 1998) (privity rule applied to personal injury action).

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	**Case No. 2:19-md-02921(BRM)(JAD)** **MDL No. 2921** **JUDGE BRIAN R. MARTINOTTI** **JUDGE JOSEPH A. DICKSON**

THIS DOCUMENT RELATES TO: ALL CASES

DECLARATION OF MELISSA A. GEIST, ESQ.
IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS
PLAINTIFFS' MASTER COMPLAINTS

Pursuant to 28 U.S.C. § 1746, I, Melissa A. Geist, Esq., declare as follows:

1. I am an attorney at law of the State of New Jersey and a partner of the law firm Reed Smith LLP, counsel for defendants Allergan, Inc. and Allergan USA, Inc. (together, "Allergan") in the above-captioned matter. I submit this declaration based on personal knowledge and in support of Defendants' Motion to Dismiss

Plaintiffs' Consolidated Class Action Complaint [ECF No. 118] and Master Long-Form Personal Injury Complaint [ECF No. 119].

2. Attached hereto as **Exhibit 1** is a true and correct copy of P990074 Approval Order, dated May 10, 2000, for Allergan's Natrelle® Saline-Filled Breast Implants.

3. Attached hereto as **Exhibit 2** is a true and correct copy of P990074 Supplement 44 Approval, dated July 30, 2020, for Allergan's Natrelle® Saline-Filled Breast Implants, which is publicly maintained on the FDA website and at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P990074S044 (last accessed Aug. 7, 2020).

4. Attached hereto as **Exhibit 3** P020056 Approval Order, dated November 17, 2006, for Allergan's Allergan Natrelle® Silicone-Filled Textured Breast Implants.

5. Attached hereto as **Exhibit 4** P020056 Supplement 51 Approval, dated July 30, 2020, for Allergan's Allergan Natrelle® Silicone-Filled Textured Breast Implants, which is publicly maintained on the FDA website at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020056S051 (last accessed Aug. 7, 2020).

6. Attached hereto as **Exhibit 5** P040046 Approval Order, dated February 20, 2013, for Allergan's Natrelle®410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants.

7. Attached hereto as **Exhibit 6** P040046 Supplement 32 Approval, dated July 30, 2020, for Allergan's Natrelle®410 Highly Cohesive Anatomically Shaped

Silicone Filled Breast Implants, which is publicly maintained on the FDA website at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040046S032 (last accessed Aug. 7, 2020).

8. Attached hereto as **Exhibit 7** is a true and correct copy of the FDA Safety Communication, dated July 24, 2019, a copy of which is also maintained on the FDA website at: https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer (last accessed Aug. 7, 2020).

9. Attached hereto as **Exhibit 8** is a true and correct copy of the 510(k) K854948 Clearance Letter for the McGhan RTV® Saline-Filled Mammary Implant.

10. Attached hereto as **Exhibit 9** is a true and correct copy of the 510(k) K102806 Clearance Letter, dated January 5, 2011, for Allergan's Natrelle® 133 Plus Tissue Expander With Suture Tabs.

11. Attached hereto as **Exhibit 10** 510(k) K143354 Clearance Letter, dated August 10, 2015, for Allergan's Natrelle® 133 Plus Tissue Expander.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 7th day of August, 2020.

By: */s/ Melissa A. Geist*
Melissa A. Geist

EXHIBIT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Mr. Raymond C. Duhamel, Ph.D.
Vice President, Regulatory and Clinical Affairs
McGhan Medical Corporation
700 Ward Drive
Santa Barbara, California 93111

Re: P990074
McGhan Medical RTV Saline-Filled Breast Implant
Filed: November 16, 1999
Amended: A1 - December 9, 1999; A2 – December 16, 1999; A3 – December 20, 1999; A4 - January 7, 2000; A5 - January 27, 2000; A6 - February 22, 2000; A7 - March 22, 2000; A8 – March 30, 2000; and A9 – May 8, 2000.

Dear Dr. Duhamel:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the McGhan RTV Saline-Filled Breast Implant. This device is indicated for: (1) breast augmentation for women 18 years or older and (2) breast reconstruction.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may continue commercial distribution of the device upon receipt of this letter.

The sale and distribution of this device is restricted to prescription use in accordance with 21 CFR 801.109, under the authority of section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). As a restricted device, the device is subject to sections 502(q) and (r) of the act.

In addition to the post-approval requirements in the enclosure, "Conditions of Approval," the following are specific conditions of approval for this PMA to which you have agreed and must be included in the post-approval reports:

1. 10-year post-approval study to assess the long-term clinical performance of the device. All patients enrolled in the 1995 Studies will be asked to enroll in this post-approval study. Safety data such as reoperations, deflation, capsular contracture, and pain will be collected annually out to 10 years for each patient;

2. retrieval study to collect visual examination, physical, and histological data on explanted implants to determine the mode of failure of implants;

3. focus-group study to obtain immediate feedback on the patient informed decision brochure from both augmentation and reconstruction patients. This will involve obtaining responses from patients on the patient labeling format and content, generating a report of the findings, and incorporating all appropriate revisions immediately; and

4. mechanical testing (i.e., fatigue rupture and shelf-life).

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible, you must submit an amendment to this PMA submission with copies of the approved patient labeling (i.e., patient informed decision brochure) and package labeling in final printed form. Beginning June 21, 2000, all distributed package inserts and patient informed decision brochures must be the current PMA-approved labeling. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment. Please see the CDRH Pilot for Review of Final Printed Labeling document at http://www.fda.gov/cdrh/pmat/pilotpmat.html for further details.

FDA also reminds you that all advertisements and promotional labeling materials (including educational brochures, ads for newspapers, television, radio, etc.) must be modified to comply with 502(r) of the act and 21 CFR 801.109(d). As you were informed, the advertisements and promotional labeling materials submitted thus far do not meet these requirements and are not to be used in their current form. There will be no transition period for these materials. As of the date of approval, all advertisements and promotional labeling materials must be in conformance

with section 502(r) of the act for advertising and 21 CFR 801.109(d) for promotional labeling. Information contained on your Internet site must also include this information. Questions concerning these materials may be directed to the Promotion and Advertising Policy Staff, Office of Compliance, CDRH at (301) 594-4639.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Sam Arepalli, Ph.D at (301) 594-3090.

Sincerely yours,

David W. Feigal, Jr. M.D., M.P.H.
Acting Office Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Issued: 3-4-98

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It

allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1)Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a)unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b)reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each

identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1)A mix-up of the device or its labeling with another article.

(2)Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a)has not been addressed by the device's labeling or

(b)has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3)Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of

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information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1)May have caused or contributed to a death or serious injury; or

(2)Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

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EXHIBIT 2

FDA U.S. FOOD & DRUG ADMINISTRATION

Premarket Approval (PMA)

New Search[22] Back to Search Results

Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the original PMA[23] record for more information.

Device	NATRELLE Saline-Filled Breast Implants
Generic Name	Prosthesis, Breast, Inflatable, Internal, Saline
Regulation Number	878.3530[24]
Applicant	Allergan 2525 Dupont Dr. Irvine, CA 92612
PMA Number	P990074
Supplement Number	S044
Date Received	06/30/2020
Decision Date	07/30/2020
Product Code	FWM[25]
Advisory Committee	General & Plastic Surgery
Supplement Type	30-Day Notice
Supplement Reason	Process Change - Manufacturer/Sterilizer/Packager/Supplier
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

the addition of an alternative detection method for the Quality Control bacterial endotoxin testing of the finished devices

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24. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=878.3530
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=1&ProductCode=FWM

Page Last Updated: 08/03/2020

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24. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?FR=878.3530
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=1&ProductCode=FWM

EXHIBIT 3

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Patricia S. Walker, M.D., Ph.D.
Executive Vice President, Chief Scientific Officer
Allergan
5540 Ekwill Street
Santa Barbara, California 93111

NOV 17 2006

Re: P020056
Inamed® Silicone-Filled Breast Implants (Styles 10, 15, 20, 40, 45, 110, 115, and 120)
Filed: December 30, 2002
Amended: January 10, March 24, June 16, and July 2, 2003; June 17 and 24, and August 20, 2004; March 31, April 8, May 27, June 20, July 1, November 1, and December 28, 2005; June 28, October 2, and October 3, 2006.
Procode: FTR

Dear Dr. Walker:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Inamed® Silicone-Filled Breast Implants. This device is indicated for breast augmentation for women at least 22 years old and for breast reconstruction for women of any age. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act. More specifically, completion of your physician training

program is required as a condition of access to your product. FDA will, however, allow a 90-day transition period for all current Core Study and Adjunct Study investigators, after which these physicians must also have completed the training program in order to have access to the Allergan product.

In addition to the postapproval requirements outlined in the enclosure, you have agreed to the conditions of approval described in items 1 through 6 below.

1. Core Postapproval Study

   You must continue your Core Study until all patients have completed their 10-year evaluation in order to assess the long-term clinical performance of your product. Data are to be collected via annual physician follow-up evaluations. The primary changes to the protocol from premarket to postapproval are that all non-MRI patients will have a MRI at years 7 and 9 and that all patients who were explanted without replacement will be evaluated through 10 years, as per the protocol. You must also update your patient and physician labeling to reflect 5 and 10-year Core Study findings, as soon as these data are available, as well as any other timepoint deemed necessary by FDA if significantly new information from this study becomes available.

2. Large Postapproval Study

   You must conduct the 10-year large postapproval study, as per the protocol that was submitted to FDA on October 16, 2006. This study, which will begin patient enrollment within 90 days after PMA approval, will be a separate study from the Core Study and will include 39,390 Allergan silicone gel patients and 19,605 saline-filled breast implant patients as the control group. The purpose of this study is to address specific issues for which the Core Study was not designed to fully answer, as well as to provide a real-world assessment of some endpoints. The endpoints in the large postapproval study include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and rupture results. Data are to be collected via annual patient questionnaires, either completed via the web, mail, or telephone. There will also be physician evaluations at years 1, 4, and 10 to collect local complication data. You must update your patient and physician labeling to reflect 5 and 10-year large postapproval study findings, as soon as these data are available, as well as any other timepoint deemed necessary by FDA if significantly new information from this study becomes available.

   On a quarterly basis, you must submit a report to FDA that includes: (1) the number enrolled by implant group (silicone versus saline); (2) the number enrolled by indication (primary augmentation, revision-augmentation, primary reconstruction, revision-reconstruction) and implant group; (3) the number enrolled by race/ethnicity and implant

group; (4) the enrollment rate versus the stated goals; and (5) the follow-up rates versus the stated goals. FDA will inform you when quarterly reports are no longer necessary.

Every 6 months for the first 2 years and then annually, thereafter, you are to submit a progress report that includes: (1) the status of patient enrollment as it compares to the stated goals; (2) the status of the race/ethnicity distribution as it compares to the stated goals; (3) detailed patient and device accounting; (4) a summary of findings for all study endpoints; and (5) the reasons why a patient was ineligible or chose not to enroll.

3. Device Failure Studies

You must continue preclinical studies to further characterize the long-term modes and causes of failure of explanted retrieved devices for the 10-year duration of the large postapproval study. In addition, you must perform additional studies to address the following specific issues:

- further evaluation of iatrogenic failures to address issues raised by the April 2005 Panel
- the characterization of when surgical instrument damage occurs
- further evaluation and characterization of failures due to surgical impact
- characterization of the cause of sharp edge openings
- any correlation between surgical factors (e.g., incision size) and device rupture.

You must also update your patient and physician labeling to reflect any relevant findings.

4. Focus Group Study

You must complete a focus group study of the augmentation and reconstruction patient labeling. This will involve an independent group obtaining responses from patients on the format and content of the approved labeling. Upon completion of the focus group study, you must provide a supplement with a report of the focus group study findings and revised patient and physician proposed labeling changes based on those study findings.

5. Informed Decision Process

As part of your formal informed decision process, you must distribute your approved Patient Planner, which will serve as a collective source of information (including the patient labeling) for the patient. Both the physician and the patient are intended to sign designated sections in order to best assure that a patient has obtained the labeling in an adequate enough time prior to surgery to read it and has understood the risks and other information associated with the Allergan device. You must administer your approved survey to a random selection of 50 physicians on an annual basis to determine the success of this

process and provide a summary of the survey findings to FDA. FDA will inform you when a survey summary is no longer necessary. In addition, you are to provide training on this process as part of your physician training program.

6. Allergan Adjunct Study

You must cease new enrollment into the Allergan Adjunct Study (P910044) and continue follow-up of all currently-enrolled Allergan Adjunct Study patients through their 5-year evaluations. You are to report these data as part of annual reports for P020056.

Expiration dating for this device has been established and approved at 5 years.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Stephen Rhodes at (240) 276-3638.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

EXHIBIT 4

FDA U.S. FOOD & DRUG ADMINISTRATION

Premarket Approval (PMA)

Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the original PMA[23] record for more information.

Device	NATRELLE Silicon-Filled Breast Implants
Generic Name	Prosthesis, Breast, Noninflatable, Internal, Silicone Gel-Filled
Regulation Number	878.3540[24]
Applicant	Allergan 2525 Dupont Dr. Irvine, CA 92612
PMA Number	P020056
Supplement Number	S051
Date Received	06/30/2020
Decision Date	07/30/2020
Product Code	FTR[25]
Advisory Committee	General & Plastic Surgery
Supplement Type	30-Day Notice
Supplement Reason	Process Change - Manufacturer/Sterilizer/Packager/Supplier
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

the addition of an alternative detection method for the Quality Control bacterial endotoxin testing of the finished devices

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7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm

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EXHIBIT 5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FEB 20 2013

Allergan
% Amy Tezel, Ph.D
Director, Regulatory Affairs
71 S. Los Carneros Road
Goleta, California 93117

Re: P040046
Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants (Styles 410FM, 410FF, 410MM and 410MF)
Filed: December 6, 2004
Amended: June 20, September 14, and November 16, 2005; February 16, March 20, May 10, October 2, and December 6, 2006; January 5, February 23, March 26, and August 29, 2007; January 22, February 11 and 27, March 12 and 14, April 18, and July 25, 2008; November 17, 2009; June 10, October 28, and November 5, 2010; February 2 and 23, October 13, and November 30, 2011; and February 27, March 2, May 9, and November 29, 2012
Procode: FTR

Dear Dr. Tezel:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants. This device is indicated for women for the following uses (procedures):

- Breast Augmentation for women at least 22 years old. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.

- Breast Reconstruction. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to

provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices. More specifically, completion of your physician training program is required as a condition of access to your product. FDA will, however, allow a 90-day transition period for all current Core and Continued Access Studies investigators, after which these physicians must also have completed the training program in order to have access to the Allergan product.

Expiration dating for this device has been established and approved at 5 years.

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" (please use this title even if the specified interval is more frequent than one year) and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the conditions outlined above, you must conduct the following post-approval studies that will evaluate the long-term safety and effectiveness of your approved device.

1. PMA Core Study

At the time of approval, all patients in the PMA Core study have completed their 10 year follow-up, i.e. the last patient was enrolled to the study on February 28, 2002. Therefore, you must submit a final study report for the Premarket Core Study within 90 days of your receipt of this letter. Please submit the final report as a PAS study report to the PMA and in addition please submit a supplement to the IDE referencing the final report is being submitted for P040046.

2. Natrelle 410 Full and Moderate height/projection Breast Implant Continued Access Study (Natrelle 410 CAS)

Per Natrelle 410 Full and Moderate height/projection Breast Implant Continued Access Study_ protocol version dated August 17, 2012 (e-mail), the Natrelle 410 CAS will consist of the continued follow-up, for 5-years post-implantation, of approximately 3,500 subjects who were enrolled before the date of approval in the 410 Continued Access and 410 Continued Access Revision/Reconstruction Expansion clinical studies. All safety and effectiveness endpoints evaluated premarket will continue to be studied through 5-years of follow-up. Descriptive statistics will be provided. Additional analyses will be performed as per protocol version dated August 17, 2012. You are also required to conduct Device Explant Analyses for all devices retrieved from women enrolled in the Natrelle 410 CAS as outlined in the protocol version dated June 8, 2012.

On an annual basis and until the completion of 5 year follow-up, you must submit, a PAS progress report to FDA that includes: patient compliance, a summary of findings for all study endpoints, and results of the device explant analyses for devices explanted within this study.

3. Natrelle 410 Breast Implant US Post-Approval Study (Natrelle 410 US-PAS)

Per Natrelle 410 US Post-approval Study protocol version dated August 16, 2012 (e-mail), this study is a newly enrolled cohort study in the US. The purpose of this study is to evaluate the long-term clinical performance of Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants under general conditions of use in the postmarket environment. The study will enroll 2,287 women receiving Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants and 300 women receiving Natrelle Saline implants as the comparison group. Study subjects will be followed annually for 10 years. Data will be collected on the following safety endpoints: connective tissue diseases (CTDs), rheumatologic and neurologic signs and symptoms, cancer (lung and breast, including the potential of breast implant interference with mammography and delay of breast cancer detection), suicide/attempted suicide, local complications (including infection, rupture; including rupture rate following mammography), reoperation and implant removal, reproductive complications in women who attempt to have children, lactation complications, and congenital deformities. The effectiveness will be assessed by participants' responses to questions addressing their satisfaction with the breast implants and psychosocial well-being.

Data are to be collected via annual patient questionnaires. For the patients who receive Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants, there will also be physician evaluations at years 1, 5, and 10. Descriptive statistics will be provided for the studied endpoints. In addition, the association between the studied endpoints and the approved device

will be assessed as per protocol version dated August 16, 2012. You are also required to conduct Device Explant Analyses for all devices retrieved from women enrolled in the Natrelle 410 US-PAS per protocol version dated June 8, 2012. You must report results of these explant analyses in the post-approval study Annual Report.

You also agree to participate as a stakeholder in developing the National Breast Implants Registry and to contribute data from your Natrelle 410 US Post-Approval Study to the Registry upon its implementation. Please be advised that because the establishment of the National Breast Implants Registry is currently in progress, this condition of approval will be labeled as "Study Pending" upon further notification from the FDA. Under this agreement, you must submit interim reports every 6 months that include: (1) activities that you undertake for the development of the National Breast Implant Registry; (2) US sales data for the Natrelle 410 breast implants; and (3) US implant data for the Natrelle 410 breast implants.

Otherwise, your reporting requirements for the Natrelle 410 US-PAS are as follows:
On a quarterly basis, you must submit a report to FDA that includes: (1) the number enrolled by subjects receiving studied device versus enrolled in comparison group; (2) the number enrolled by indication (primary augmentation, revision-augmentation, primary reconstruction, revision-reconstruction) for subjects receiving studied device; (3) the number enrolled by race/ethnicity; (4) the enrollment rates versus the stated goals; (5) the reason why eligible patients were not enrolled into the study; and (6) the follow-up rates versus the stated goals. FDA will inform you when quarterly reports are no longer necessary.

In addition, every 6 months for the first 2 years and then annually, thereafter, you are to submit a progress report that includes: (1) the status of patient enrollment as it compares to the stated goals; (2) the status of the race/ethnicity distribution as it compares to the stated goals; (3) detailed patient and device accounting; (4) the reasons why eligible patients were not enrolled into the study; (5) the follow-up rates versus the stated goals; and (6) a summary of findings for all study endpoints.

You must update your patient and physician labeling to reflect 5 and 10-year Natrelle 410 US-PAS study findings, as soon as these data are available, as well as any other time point deemed necessary by FDA, if significantly new information from this study becomes available.

4. Allergan Silicone Breast Implants and Case-control Studies

In order to evaluate the rare endpoints, we approve your proposal to conduct case-controlled studies using data that is already collected in countries where the device has been on the market for years. Per Allergan Silicone Breast Implants and Case-control Study protocols version dated August 3, 2012 (e-mail), the purpose of the Allergan Silicone Breast Implants and Case-control Studies is to evaluate the association between Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants and five rare disease outcomes (rare connective tissue

diseases, rare neurological diseases, brain cancer, cervical/vulvar cancer and lymphoma). These studies will be conducted in the United Kingdom and will enroll a total of 7,500 cases and 4,000 controls. For each of the five rare disease outcomes, 1,500 cases will be enrolled and compared to the controls on the history of the implantation of Natrelle silicone gel-filled breast implants.

Every 6 months for the first 2 years and then annually, you must submit a report to FDA that includes: (1) the number enrolled by cases and controls; (2) the enrollment rate versus the stated goal. FDA will inform you when quarterly reports are no longer necessary. In addition, within 3 months of the completion of subject enrollment and data collection, you must submit a final Allergan Silicone Breast Implants and Case-control study report that includes the results and conclusions of the Allergan Silicone Breast Implants and Case-control studies.

5. Focus Group Study

Per the Focus Group Study protocol version dated September 7, 2012, the purpose of the Focus Group Study is to evaluate the augmentation and reconstruction patient labeling. This will involve an independent group obtaining responses from patients on the format and content of the approved labeling. Upon completion of the focus group study, you must submit a Final Report of the Focus Group Study findings and suggested revision of patient and physician labeling based on those findings.

6. In addition to the studies listed above, you must conduct non-PAS Device Explant Analyses for all Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants that are retrieved in the commercial setting outside the post-approval studies, as per explant analysis protocol version dated June 8, 2012. On an annual basis, you must report the results of these Device Explant Analyses in the PMA Annual Reports.

Please be advised that the Post-Approval Study Reports should be submitted separately for each study. Two copies for each study, identified as "PMA Post-Approval Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm#2).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any

interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Tajanay Ki at (301) 796-6970.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

EXHIBIT 6

FDA U.S. FOOD & DRUG ADMINISTRATION

Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the original PMA[23] record for more information.

Device	NATRELLE Style 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants
Generic Name	Prosthesis, Breast, Noninflatable, Internal, Silicone Gel-Filled
Regulation Number	878.3540[24]
Applicant	Allergan 2525 Dupont Dr. Irvine, CA 92612
PMA Number	P040046
Supplement Number	S032
Date Received	06/30/2020
Decision Date	07/30/2020
Product Code	FTR[25]
Advisory Committee	General & Plastic Surgery
Supplement Type	30-Day Notice
Supplement Reason	Process Change - Manufacturer/Sterilizer/Packager/Supplier
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

the addition of an alternative detection method for the Quality Control bacterial endotoxin testing of the finished devices

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EXHIBIT 7

Allergan Recalls Natrelle Biocell Textured Breast Implants Due to Risk of BIA-ALCL Cancer

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

The recall described in this notice is the same one that was announced in the FDA Safety Communication (/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue) from July 2019.

Recalled Product

- Allergan Natrelle BIOCELL Textured Products:
  - Allergan Natrelle Saline-Filled Textured Breast Implants
  - Allergan Natrelle Silicone-Filled Textured Breast Implants
  - Allergan Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone- Filled Textured Breast Implants
  - Allergan Natrelle 133 Plus Tissue Expander
  - Allergan Natrelle 133 Tissue Expander with Suture Tabs
- Lot numbers: All lots (for complete listing of all styles (/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue), see the FDA Safety Communication)
- Manufacturing Dates: July 25, 2014 - June 21, 2019
- Distribution Dates: September 14, 2014- July 24, 2019
- Devices Recalled in the U.S.: 246,381
- Date Initiated by Firm: July 24, 2019

Device Use

Breast implants are used in both breast augmentation surgery (to increase the breast size) and in breast reconstruction (to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality). Breast implants may also be used in revision surgery to correct or improve the result of a primary breast implant surgery. Tissue expanders are used in breast reconstruction following mastectomy, treatment of underdeveloped breasts, and treatment of soft tissue deformities. The expander is intended for temporary (less than six months implantation under the skin (subcutaneous) or under the muscle (submuscular).

Reason for Recall

The FDA requested that Allergan recall all BIOCELL textured breast implants and tissue expanders marketed in the U.S. due to risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), a cancer of the immune system. Based on the currently available information, the FDA's analysis demonstrated that the risk of BIA-ALCL with Allergan BIOCELL textured implants is approximately 6 times the risk of BIA-ALCL with textured implants from other manufacturers marketing in the U.S. and continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences, including death, from BIA-ALCL.

Of the 573 worldwide reported total cases of BIA-ALCL, 481 patients are reported to have Allergan breast implants at the time of diagnosis. Of those cases, 12 deaths occurred in patients implanted with an Allergan breast implant at the time of their BIA-ALCL diagnosis.

Although Allergan Natrelle 133 and 133 Plus tissue expanders have not been associated with BIA-ALCL to date, both devices have the same Biocell texture. While tissue expanders are only indicated to be used for 6 months, to date there is no information on what duration of exposure to the Biocell texture may induce BIA-ALCL.

Who May be Affected

- Any patient undergoing cosmetic or reconstructive surgery using Allergan Natrelle BIOCELL textured products is exposed to the problem device
- Surgeons who have implanted Allergan Natrelle BIOCELL textured products
- Health care providers who treat patients with breast implants

What to Do

For patients who have no symptoms, removal of these or other types of breast implants is not recommended, due to the low risk of developing BIA-ALCL. However, if you have any questions, talk to your health care provider.

Medical interventions to reduce the risk of BIA-ALCL due to the use of Allergan textured implants include foregoing breast reconstruction or augmentation or using alternative breast implants or autologous tissue.

Allergan sent Urgent Medical Device Recall (Removal) letters to U.S. customers, including surgeons, instructing them to return all unused product to a third-party recall provider, Inmar RX Solutions, as described in the letter.

Allergan also mailed notification letters to patients in three separate campaigns.

Contact Information

For specific questions about the recalled products, contact the manufacturer, Allergan, at IR-Medcom@allergan.com (mailto:IR-Medcom@allergan.com) or call 1-800-678-1605 option #2.

Full List of Affected Devices

The complete list of devices (/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue) is included in the FDA Safety Communication from July 2019.

Note: McGhan BioDIMENSIONAL Silicone-Filled Biocell Textured Breast Implants Style 153 were evaluated in clinical studies, but never marketed. Therefore, they are **not** included as part of the withdrawn product. However, patients who participated in the clinical study may have them implanted.

Additional Resources

- Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=&productdescriptiontxt=&productcode=&IVDProducts=&rootCauseText=&recallstatus=&centerclassificationtypetext=&rec
- Allergan Press Release: Allergan Voluntarily Recalls BIOCELL® Textured Breast Implants and Tissue Expanders (https://www.allergan.com/news/news/thomson-reuters/allergan-voluntarily-recalls-biocell-textured-brea) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- FDA Press Release: FDA takes action to protect patients from risk of certain textured breast implants; requests Allergan voluntarily recall certain breast implants and tissue expanders from market (/news-events/press-announcements/fda-takes-action-protect-patients-risk-certain-textured-breast-implants-requests-allergan)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online, by regular mail or by FAX.

EXHIBIT 8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

MAR 7

Ms. Julie D. Bell
Senior Engineer
Product Development
McGhan Medical Corporation
700 Ward Drive
Santa Barbara, California 93111

Re: K854948
McGhan Saline Filled
Mammary Implant

Dated: February 3, 1986
Received: February 5, 1986

Dear Ms. Bell:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

Kshitij Mohan

Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

EXHIBIT 9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Allergan Medical
% Mr. Micah Schloss
Associate Regulatory Analyst
71 S. Los Carneros Road
Goleta, California 93117-5506

JAN 5 2011

Re: K102806
Trade/Device Name: NATRELLE® Tissue Expanders
Regulation Number: 21 CFR 878.3600
Regulation Name: Tissue expander
Regulatory Class: II
Product Code: LCJ
Dated: December 3, 2010
Received: December 8, 2010

Dear Mr. Schloss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102806

Device Name: NATRELLE® Tissue Expanders

Indications for Use: The NATRELLE® Tissue Expanders are used in breast reconstruction following mastectomy, treatment of underdeveloped breasts, and treatment of soft tissue deformities. The expanders are intended for temporary subcutaneous implantation and are not intended for use beyond six months.

Prescription Use __X_____ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102806

EXHIBIT 10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 20, 2015

Allergan Incorporated
Mr. Bruce Krattenmaker
Vice President, Regulatory Affairs
2525 Dupont Drive
Irvine, California 92612

Re: K143354
Trade/Device Name: Natrelle® 133 Plus Tissue Expander
Regulatory Class: Unclassified
Product Code: LCJ
Dated: July 16, 2015
Received: July 20, 2015

Dear Mr. Krattenmaker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, sMisbranding by reference to premarket notificationS (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143354

Device Name
Natrelle® 133 Plus Tissue Expander

Indications for Use *(Describe)*
The Natrelle® 133 Plus Tissue Expanders can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Date Prepared:

November 20, 2014

510(k) Owner's Name and Contact Information:

Allergan
Contact Person: Bruce Krattenmaker
2525 Dupont Drive
Irvine, CA 92612
Phone: (714) 246-6182
Fax: (714) 796-9724

Device Information:

Proprietary Name:	Natrelle® 133 Plus Tissue Expander
Common Name:	Tissue Expander
Classification Name:	Expander, Skin, Inflatable
Product Code:	LCJ

Predicate Device:

Mentor CPX 4 Breast Tissue Expanders and Mentor CPX 4 with Suture Tabs Breast Tissue Expanders (K130813)

Device Description:

The Natrelle® 133 Plus Tissue Expanders are designed to develop tissue flaps as part of 2-stage reconstruction mammoplasty. The devices are constructed from silicone elastomer and consist of an expansion envelope with a BIOCELL® textured surface, an orientation line, three suture tabs (optional), a MAGNA-SITE® integrated injection site, and a stable base to enable outward expansion. The tissue expanders are available in multiple styles and sizes to meet diverse surgical needs.

The MAGNA-SITE® injection site and MAGNA-FINDER® Xact external locating device contain rare-earth, permanent magnets for an accurate injection system. When the MAGNA-FINDER® Xact external locating device is passed over the surface of the tissue being expanded, its rare-earth, permanent magnet indicates the location of the MAGNA-SITE® injection site. The injection site is self-sealing and includes a titanium needle guard to prevent inadvertent puncture through the base of the injection site.

Intended Use/Indications for Use:

The Natrelle® 133 Plus Tissue Expanders can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

Technological Characteristics:

The Natrelle® 133 Plus Tissue Expander has the same fundamental technological characteristics as the predicate device. Like the predicate, the Natrelle® 133 Plus Tissue Expander is composed of a silicone expansion envelope with a textured surface, which expands with sequential injections of sterile saline. Both the predicate and the Natrelle® 133 Plus Tissue Expander utilize an integrated, self-sealing magnetic injection site that can be located using a magnetic locating device.

Performance Data:

Non-clinical performance data were submitted to support the substantial equivalence of the Natrelle® 133 Plus Tissue Expander to the predicate device. These data included biocompatibility data and mechanical testing data. Where appropriate, testing was conducted according to methods prescribed by relevant ASTM and/or ISO standards. All pre-established acceptance criteria were met.

Conclusions:

The Natrelle® 133 Plus Tissue Expander has the same intended use and indications for use as the predicate device. The results of non-clinical testing demonstrate that the design features of the Natrelle® 133 Plus Tissue Expander do not raise different questions of safety and effectiveness or negatively impact safety and effectiveness (relative to the predicate device). Therefore, the Natrelle® 133 Plus Tissue Expander is substantially equivalent to the tissue expanders marketed by Mentor (K130813).

REED SMITH LLP
506 Carnegie Center, Suite 300
Princeton, New Jersey 08540
Princeton, New Jersey 08540
Telephone: (609) 987-0050
Facsimile: (609) 951-0824

Attorneys for Defendants
Allergan, Inc. and Allergan USA, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE ALLERGAN BIOCELL TEXTURED BREAST IMPLANT PRODUCTS LIABILITY LITIGATION	**Case No. 2:19-md-02921(BRM)(JAD)** **MDL No. 2921** **JUDGE BRIAN R. MARTINOTTI** **JUDGE JOSEPH A. DICKSON**

THIS DOCUMENT RELATES TO: ALL CASES

DEFENDANTS' REQUEST FOR JUDICIAL NOTICE

PLEASE TAKE NOTICE that Defendants Allergan, Inc. and Allergan USA, Inc. (collectively, "Allergan" or "Defendants"), by and through their undersigned counsel, respectfully request the Court take judicial notice of the following documents, true and correct copies of which are attached as Exhibits 1 to 10 to the accompanying Declaration of Melissa A. Geist, Esq. in support of Defendants' Motion to Dismiss Plaintiffs' Complaint.

I. INTRODUCTION

"All actions [in this MDL] arise out of Allergan's announcement on July 24, 2019, of a voluntary worldwide recall of its BIOCELL textured breast implants and tissue expanders." JPML Transfer Order, dated Dec. 18, 2019 at 1. Plaintiffs' Consolidated Class Action Complaint ("CAC") [ECF No. 118] and Master Long-Form Personal Injury Complaint ("PIC") [ECF No. 119] (together, "Plaintiffs' Master Complaints") allege exposure to five lines of breast implant devices. The FDA has granted approval for these Class III medical devices through the Premarket Approval process, as set forth in the following exhibits:

1. **Allergan Natrelle® Saline-Filled Breast Implants approved under P990074 (CAC ¶2 n.1; PIC ¶41)**

   - Exhibit 1: P990074 Approval Order, dated May 10, 2000.
   - Exhibit 2: P990074 Supplement 44 Approval, dated July 30, 2020, a copy of which is also maintained on the FDA website at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P990074S044 (last accessed: Aug. 7, 2020).

2. **Allergan Natrelle® Silicone-Filled Textured Breast Implants approved under P020056 (CAC ¶2 n.1; PIC ¶41)**

   - Exhibit 3: P020056 Approval Order, dated November 17, 2006.

- Exhibit 4: P020056 Supplement 51 Approval, dated July 30, 2020, a copy of which is also maintained on the FDA website at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P020056S051 (last accessed: Aug. 7, 2020).

3. Natrelle®410 Highly Cohesive Anatomically Shaped Silicone Filled Breast Implants approved under P040046 (CAC ¶2 n.1; PIC ¶41)

- Exhibit 5: P040046 Approval Order, dated February 20, 2013.

- Exhibit 6: P040046 Supplement 32 Approval, dated July 30, 2020, a copy of which is also maintained on the FDA website at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040046S032 (last accessed: Aug. 7, 2020).

4. McGhan BioDIMENSIONAL® Silicone-Filled BIOCELL® Textured Breast Implant, Style 153 (CAC ¶2 n.1; PIC ¶41)[1]

- Exhibit 7: FDA Safety Communication, dated July 24, 2019, a copy of which is also maintained on the FDA website at: https://www.fda.gov/medical-devices/medical-device-recalls/allergan-recalls-natrelle-biocell-textured-breast-implants-due-risk-bia-alcl-cancer (last accessed: Aug. 7, 2020).

5. McGhan RTV® Saline-Filled Mammary Implant (implanted before PMA Approval of Allergan Natrelle® Saline-Filled Textured Breast Implant) (CAC ¶326)[2]

- Exhibit 8: 510(k) K854948 Clearance Letter.[3]

---

[1] All Style 153 implants were implanted as part of FDA-regulated clinical trials. (*see* Ex. 7.) FDA approval was not sought, and the Style 153 implants were discontinued in 2005 and never marketed. (*Id.*; PIC ¶99 n.31.)

[2] In the mid-1980s, these devices were the subject of a Premarket Notification for which FDA granted Section 510(k) clearance. (*See* Ex. 8; CAC ¶115.) After FDA required saline breast implants to receive PMA approval in 1999, FDA approved the PMA application for these saline implants in May 2000. (*See* Exs. 1-2; CAC ¶118; PIC ¶58).

[3] Due to the passage of time, the original ink-stamped date is no longer legible.

In addition to the PMA-approved Class III breast implants listed above, Plaintiffs also allege exposure to Allergan's BIOCELL® line of tissue expanders. (CAC ¶99; PIC ¶4 n.2.) FDA granted Section 510(k) clearance to these Class II medical devices, as set forth in the following Exhibits:

1. ***Natrelle® 133 Plus Tissue Expander With Suture Tabs*** **(CAC ¶¶2 n.1, 326; PIC ¶41)**

   - Exhibit 9: 510(k) K102806 Clearance Letter, dated January 5, 2011.

2. ***Natrelle® 133 Plus Tissue Expander*** **(CAC ¶¶2 n.1, 326)**

   - Exhibit 10: 510(k) K143354 Clearance Letter, dated August 10, 2015.

II. ARGUMENT

Under the Federal Rules of Evidence, a Court may "judicially notice a fact that is not subject to reasonable dispute" when such facts are "(1) generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). Pursuant to Rule 201, courts—including those within the Third Circuit—routinely take judicial notice of FDA materials in connection with product liability cases such as this one. *See, e.g.*, *Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F. Supp. 3d 403, 413, n.6 (D. Del. 2014) (taking judicial notice of veracity of "FDA document titled InFUSE Bone Graft/LT–CAGE Lumbar Tapered Fusion Device Important Medical Information ('Important Medical Information'), available on the FDA's public website"); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 481 n.26 (W.D. Pa. 2012) (taking judicial notice of the Summary of Safety and

Effectiveness Data for Class III device in ruling on motion to dismiss); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice of FDA Report published on the FDA's website).

More specifically, in finding claims preempted under *Riegel v. Medtronic*, 552 U.S. 312 (2008), district courts have routinely taken judicial notice of a Class III device's status as a premarket-approved device. *See, e.g.*, *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 592, n.2 (D.N.J. 2015) ("facts about the FDA approvals of Sculptra are also matters of public record, appropriate for judicial notice under Federal Rule of Evidence 201").

Here, the BIOCELL devices identified in Plaintiffs' Master Complaints are all either PMA-approved Class III medical devices or 510(k)-cleared Class II medical devices, as established by the official FDA documents attached as Exhibits 1-11. District Courts in this Circuit routinely take judicial notice of these types of FDA documents when considering a motion to dismiss. *See, e.g., Freed v. St. Jude Med., Inc.*, 2017 WL 4102583, *2 (D. Del. Sept. 15, 2017). *See also Gupta v. Wipro Ltd.*, 749 F. App'x 94, 97 (3d Cir. 2018) (explaining that, when ruling on a motion to dismiss, a district court must not accept allegations "contradicted by exhibits attached to the complaint or matters subject to judicial notice"); *see Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 319 (D.N.J. 2014) (on a motion to dismiss, court "may consider . . . items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case").

The FDA posted information on its website about the PMA-approvals and 510(k) clearances FDA granted to these medical devices and, ultimately, information

about Allergan's voluntary recall of these medical devices, copies of which are attached as Exhibits 1 through 10. Official FDA documents maintained on the FDA's website may be judicially noticed. *See Spizzirri v. Zyla Life Scis.*, 802 F. App'x 738, 739 (3d Cir. 2020); *In re Avandia Mktg. Sales Practices & Prod. Liab. Litig.*, 588 F. App'x 171, 174 n.14 (3d Cir. 2014); *see also Vanderklok v. United States*, 868 F.3d 189, 205 n.16 (3d Cir. 2017) (the "information is publicly available on government websites and therefore we take judicial notice").

These exhibits are not subject to dispute, and are equally available to the public and the Court. These official FDA documents reflect actions taken or information disseminated by the FDA, specifically relating to the medical devices at issue in this case. Defendants therefore respectfully requests the Court take judicial notice of the attached exhibits.

III. CONCLUSION

WHEREFORE, Defendants respectfully request the Court take judicial notice of Exhibits 1 through 10, attached to the accompanying Declaration of Melissa A. Geist, Esq. in support of Defendants' Motion to Dismiss Plaintiffs' Complaint.

Dated: August 7, 2020

Respectfully submitted,
REED SMITH LLP

By: */s/ Melissa A. Geist*
Melissa A. Geist

Attorneys for Defendants
Allergan Inc. and Allergan USA, Inc.

REED SMITH LLP
506 Carnegie Center, Suite 300
Princeton, New Jersey 08540
Princeton, New Jersey 08540
Telephone: (609) 987-0050
Facsimile: (609) 951-0824

Attorneys for Defendants
Allergan Inc. and Allergan USA, Inc.

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** **CERTIFICATE OF SERVICE**

THIS DOCUMENT RELATES TO:
ALL CASES

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the following documents were filed via the Court's CM/ECF system on this 7th day of August, 2020:

(1) Notice of Motion to Dismiss Plaintiffs' Complaint;

(2) Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiffs' Master Personal Injury Complaint and Consolidated Class Action Complaint on Preemption Grounds;

(3) Memorandum of Law in support of Defendants' Motion to Strike/Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint;

(4) Memorandum of Law in support of 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), with Appendix A thereto;

(5) Declaration of Melissa A. Geist, Esq. in Support of Defendants' Motion to Dismiss Plaintiffs' Master Complaint, with exhibits thereto; and

(6) Defendants' Request for Judicial Notice.

By: /s/ *Melissa A. Geist*
Melissa A. Geist