UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

THIS DOCUMENT RELATES TO: ALL CASES

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

October 7, 2020

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INTRODUCTION

Preemption does not shield Allergan from liability for the harm Plaintiffs suffered because Allergan's BIOCELL breast implants and tissue expanders were implanted into their bodies, including the development of, or the risk of developing, Breast-Implant Associated Anaplastic Large Cell Lymphoma ("BIA-ALCL"). Last year, Allergan recalled these implants at the FDA's urging, after the FDA concluded that continued distribution "would likely cause serious, adverse health consequences, including death, from BIA-ALCL." While federal law preempts tort claims that impose safety and effectiveness requirements that differ from or add to federal requirements specific to a medical device, federal law preserves tort claims for violations of state-law duties that also violate parallel federal requirements. Plaintiffs' claims fall comfortably within that zone of non-preempted tort claims. Plaintiffs assert state law products liability, negligence, misrepresentation, and warranty claims, alleging that Allergan's implants were unreasonably dangerous—and breached Allergan's implied and express warranties and representations—because Allergan failed to warn of the risk of BIA-ALCL and misrepresented the implants' safety, and because the implants had manufacturing defects such as surfaces littered with dangerous debris.

None of Plaintiffs' claims are expressly preempted because none of them challenge the FDA's approval of BIOCELL implants or seek to impose any requirement adding to or differing from federal requirements. Instead, Plaintiffs' claims rest on conduct that violates state-law duties that parallel federal requirements. Allergan violated federal law requiring it to maintain adequate product labeling (including adding warning language when necessitated by new safety information) and to submit adverse event reports to the FDA in a format that the FDA makes available to patients and their physicians. Allergan violated federal requirements to manufacture the implants in accordance with design specifications and to use adequate manufacturing

processes, which resulted in the sale of implants with defects, including unintended and dangerous surface debris. And Allergan violated federal requirements barring misleading marketing and advertising statements when they falsely minimized the risk of BIA-ALCL.

Nor are Plaintiffs' claims impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). *Buckman* holds that "fraud-on-the-FDA" claims are preempted because they are solely efforts to enforce federal requirements, without reference to any state-law duty. All of Plaintiffs' claims rest on violations of traditional state-law duties: to exercise reasonable care to avoid causing physical harm, to manufacture products free of dangerous non-conforming defects, to warn adequately of a product's dangers, and to abide by warranties and representations made in marketing and selling products.

Allergan's brief is an exercise in misdirection. In arguing that "virtually all" state tort claims against device manufacturers are preempted, they ignore the wealth of recent decisions (cited in this brief) holding that state-law claims that parallel federal requirements survive preemption. In arguing that Plaintiffs fail to allege such parallel claims, they ignore Plaintiffs' well-pleaded allegations that do so. And in arguing that Plaintiffs' theories either are not recognized under state law or do not implicate violations of parallel federal requirements, they distort both state law and federal law.

"[A] plaintiff may proceed on her claim so long as she claims the 'breach of a well-recognized duty owed to her under state law' and so 'long as she can show that she was harmed by a violation of applicable federal law.'" *Godelia v. Doe*, 881 F.3d 1309, 1317 (11th Cir. 2018). All of Plaintiffs' claims satisfy this standard.

BACKGROUND

A. Federal Regulation Of Medical Devices Preserves State Law Claims That Parallel Requirements Of Federal Law

The FDA has authority to regulate medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"). The MDA divides medical devices into classes. "Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by 'general controls.'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-77 (1996) (quoting 21 U.S.C. § 360c(a)(1)(A)). "Devices that are potentially more harmful are designated Class II; although they may be marketed without advance approval, manufacturers of such devices must comply with federal performance regulations known as 'special controls.'" *Id.* at 477 (quoting 21 U.S.C. § 360c(a)(1)(B)). "Finally, devices that either 'presen[t] a potential unreasonable risk of illness or injury,' or which are 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' are designated Class III." *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)).

The FDA approves new devices for sale through either of two mechanisms. First, under the premarket approval ("PMA") process, the device undergoes review to provide the FDA "with a 'reasonable assurance' that the device is both safe and effective." *Id.* (quoting 21 U.S.C. § 360e(d)(2)). Second, under the "§ 510(k) process," the FDA can approve a device without review of its safety or effectiveness if the FDA concludes that the device is "substantially equivalent" to a pre-existing device already on the market. *Id.* at 478. Class I and Class II devices do not require PMA review, and the FDA historically has approved many Class III devices using the § 510(k) process rather than the PMA process. *Id.*

The MDA contains the following express preemption provision:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). Subsection (b) authorizes the FDA, acting on authority delegated by the Secretary of Health and Human Services, to "exempt" state requirements from preemption under subsection (a). *Id.* § 360k(b); *Lohr*, 518 U.S. at 482 n.5. Congress thus "authoriz[ed] the FDA to determine the scope of the [MDA's] pre-emption clause." *Wyeth v. Levine*, 555 U.S. 555, 576 (2009).

Exercising this authority, the FDA enacted a regulation construing the preemption clause and exempting certain state requirements from preemption. The regulation provides in part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d). The regulation identifies "examples of State or local requirements that are not regarded as preempted by [21 U.S.C. § 360k]." *Id.* As relevant here, under the regulation, § 360k(a) "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." 21 C.F.R. § 808.1(d).

The Supreme Court has set forth a two-part test for express preemption under 21 U.S.C. § 360k. First, a court "must determine whether the Federal Government has established requirements applicable to" the device. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008). If

not, then state law is not expressly preempted. *Id.* at 322. "If so, [a court] must then determine whether" plaintiffs' claims "are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22 (quoting 21 U.S.C. § 360k(a)). State-law claims based on violations of "parallel" federal requirements are not preempted. *Id.* at 330 (quoting *Lohr*, 518 U.S. at 495).

The Supreme Court has held that the § 510(k) process, which does not include federal safety review, does not "impose device-specific 'requirements'" that preempt state requirements under 21 U.S.C. § 360k and the FDA's implementing regulation. *See Riegel*, 552 U.S. at 322. "Premarket approval, in contrast, imposes 'requirements' under the MDA." *Id.* Plaintiffs' claims are directed to some BIOCELL devices that received PMA approval and others that received § 510(k) approval, and Allergan does not seek preemption of claims relating to the § 510(k) devices. PIC ¶ 43; Allergan Br.[1] 4 n.2.

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court held that federal law impliedly preempts private actions seeking to enforce federal requirements on medical-device manufacturers. In *Buckman*, the plaintiffs did not assert a recognized state-law cause of action. Rather, they brought a "fraud-on-the-FDA" claim. *Id.* at 347. Plaintiffs were injured by the use of orthopedic bone screws in their spines; they sued a medical consulting company that assisted with the manufacturer's application for FDA approval, alleging that the FDA would not have approved the screws but for fraudulent representations the consulting company made to the FDA. *Id.* at 343. The Court held that "plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Id.* at 348.

[1] Mem. of Law in Supp. of Allergan's Mot. to Dismiss Pls.' Master Personal Injury Compl. & Consolidated Class Action Compl. on Preemption Grounds, Dkt. No. 171-1.

The Court reasoned that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. The Court distinguished fraud-on-the-FDA claims from non-preempted claims based "on traditional state tort law principles." *Id.* at 352.

B. Plaintiffs Allege That Allergan Violated State Law And Parallel Federal Law In Distributing Breast Implants That Cause A Risk Of BIA-ALCL[2]

Plaintiffs and class members are patients who had Allergan's BIOCELL textured breast implants and tissue expanders[3] implanted into their bodies. Master Long Form Personal Injury Complaint ("Master Complaint" or "PIC") ¶ 1; Consolidated Class Action Complaint ("Class Complaint" or "CAC") ¶¶ 1, 11. Many Plaintiffs are breast cancer survivors or women who have undergone prophylactic mastectomies, who were implanted with BIOCELL implants in reconstructive surgery. PIC ¶ 8; CAC ¶ 10. Plaintiffs allege that BIOCELL implants cause a form of cancer called Breast-Implant Associated Anaplastic Large Cell Lymphoma, a cancer of the immune system that develops in the area around an implant, often between the implant and the surrounding scar tissue. PIC ¶¶ 1, 27; CAC ¶¶ 1, 138. BIA-ALCL is treated with disfiguring surgery to remove the implant and the surrounding capsule and tissue, and may require other

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[2] This section derives from the allegations in Plaintiffs' complaints. In adjudicating a motion to dismiss based on preemption, this Court "accept[s] all factual allegations as true." *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009) (quoting *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008)).

This brief uses "Allergan" to refer to Allergan USA, Inc., and Allergan, Inc. Plaintiffs asserted claims against many corporate entities affiliated with Allergan. In Case Management Order No. 18, the parties stipulated that the Master Complaint and Class Complaint would proceed only as to Allergan USA, Inc. and Allergan, Inc. Case Management Order No. 18, ¶¶ 2, 9 (Sept. 15, 2020), Dkt. No. 202.

[3] A tissue expander is an empty breast implant gradually filled with saline until the breast tissue expands to the desired size, before a second surgery is performed to remove the tissue expander and insert a permanent breast implant. PIC ¶ 4; CAC ¶ 99. For simplicity, this brief uses "implants" to refer to breast implants and tissue expanders.

treatments such as reconstructive surgery, chemotherapy, and radiation. PIC ¶ 29; CAC ¶ 140. BIA-ALCL causes permanent harm and can be deadly, especially if the cancer is already in an advanced state when detected. PIC ¶¶ 27, 29; CAC ¶¶ 138-139. Some plaintiffs have been diagnosed with BIA-ALCL, others have had their implants removed, and others still have BIOCELL implants in their bodies. PIC ¶ 8.[4]

Last year, at the FDA's urging, Allergan announced a global recall of BIOCELL implants. PIC ¶ 39; CAC ¶ 191. The FDA announced that it had identified 573 known cases of BIA-ALCL worldwide and 33 deaths. PIC ¶ 39; CAC ¶ 192. Allergan was the manufacturer in 481 (or 91%) of the 531 cases in which the implant's manufacturer was known. PIC ¶ 39; CAC ¶ 192. The FDA announced that its "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." PIC ¶ 39; CAC ¶ 193. The FDA concluded: "Continued distribution of Allergan's BIOCELL textured breast implants would likely cause serious, adverse health consequences, including death, from BIA-ALCL." PIC ¶ 39; CAC ¶ 193.

This case involves dozens of recalled models of Allergan's BIOCELL breast implants and tissue expanders. *See* PIC ¶ 41; CAC ¶ 269. Many models were sold pursuant to three PMAs that Allergan received from the FDA on May 20, 2000, on November 17, 2006, and on February 20, 2013. PIC ¶ 53; CAC ¶¶ 118, 123, 126. These PMAs contained Conditions of Approval, requiring Allergan to (among other things) conduct studies of the devices' safety, report adverse events to the FDA, and revise the labeling to add warnings when necessitated by

[4] The Class Complaint, which seeks (among other relief) a medical monitoring program for the benefit of the class, is asserted on behalf of a class of individuals who were implanted with BIOCELL devices and have not yet been diagnosed with BIA-ALCL. CAC ¶ 269.

new safety information. PIC ¶¶ 59-61, 68-71; CAC ¶¶ 119, 124, 127. Other models, including the BIOCELL tissue expanders, were approved through the much less rigorous § 510(k) process. PIC ¶ 52; CAC ¶ 133. Still others were approved for use in investigative studies, or through an exception to the PMA requirement for breast cancer patients requiring reconstruction and revision surgeries. PIC ¶¶ 49-50; CAC ¶ 115.

Plaintiffs allege that Allergan violated many traditional state-law duties, each of which is parallel to federal requirements. These violations relate primarily to Allergan's warnings (or lack thereof), the manufacture of BIOCELL implants, and false or misleading statements by Allergan.

Allergan's failures to warn. Allergan violated state law in failing to warn adequately of the risk of BIA-ALCL, and these violations of state law parallel violations of federal law. *See*, *e.g.*, PIC ¶¶ 184-188; CAC ¶¶ 411-416. Evidence emerged over time that BIOCELL implants cause BIA-ALCL. In 1997, a medical journal published the first reported case of BIA-ALCL, a case associated with a BIOCELL implant. PIC ¶ 31; CAC ¶ 141. Other cases were reported in additional articles in the early 2000s and at conferences and gatherings attended by Allergan representatives. PIC ¶ 31; CAC ¶ 141. In 2016, Allergan conceded that it had received 104 reports of BIA-ALCL between at least 2007 and 2015. PIC ¶ 35; CAC ¶ 142. Even before the FDA urged a recall, accumulating data showing an association between BIOCELL implants and BIA-ALCL led regulators in the European Union, Brazil, and Canada to halt BIOCELL sales. PIC ¶ 40; CAC ¶ 161.

Despite the mounting evidence that BIOCELL causes a serious cancer, Allergan did not strengthen the warnings approved in 2000 and 2006, and did not warn of the risk of BIA-ALCL at all before February 2013. PIC ¶¶ 69, 74, 191; CAC ¶¶ 121, 123. In 2013, Allergan for the

first time added a discussion of ALCL to the labeling of its Natrelle 410 BIOCELL implants. *See* PIC ¶ 74; CAC ¶ 130. But Allergan continued to receive information showing that this warning language was inadequate. It failed to describe the nature, severity, frequency, or causal connection of BIA-ALCL to BIOCELL. PIC ¶ 75; CAC ¶¶ 129, 131. It also tied the cancer risk generally to "breast implants" and to "Allergan's and other manufacturers' breast implants." PIC ¶ 74; CAC ¶ 130. Allergan did not update this warning language even as emerging evidence showed a much higher incidence of BIA-ALCL in BIOCELL implants than in other implants. PIC ¶¶ 75, 192; CAC ¶ 131.

Given those facts and others alleged in the complaints, Allergan violated its state-law duty to warn by failing to maintain adequate labeling of BIOCELL implants. PIC ¶¶ 184-186; CAC ¶ 418. That state-law violation paralleled violations of federal law. PIC ¶ 188. Specifically, the PMAs for BIOCELL included Conditions of Approval requiring Allergan to submit PMA supplements with labeling updates when necessitated by unanticipated adverse events. PIC ¶¶ 60-61. The Conditions of Approval further required Allergan to use the "Changes Being Effected" regulation—which authorized Allergan to add safety information to the label without prior FDA approval—where that procedure was available. PIC ¶ 61. In addition, under the FDCA, a device is "misbranded" if its "labeling is false or misleading in any particular," or if it lacks "such adequate warnings . . . where its use may be dangerous to health," 21 U.S.C. § 352(a)(1), (f)(2), and the FDCA prohibits the sale of misbranded devices, *id.* § 331(a). The state-law duty to warn paralleled the federal requirement in the misbranding provision to maintain adequate warnings. PIC ¶ 67.

Allergan also violated its state-law duty to warn by failing to report adverse safety information to the FDA, which the FDA would have made publicly available and accessible for

Plaintiffs and their physicians to consider. The FDA maintains the Manufacturer and User Facility Device Experience ("MAUDE") database, a public, searchable, monthly-updated database of all Medical Device Reports ("MDRs") submitted by device manufacturers. PIC ¶ 36; CAC ¶ 206. MDRs are reports of adverse events (such as BIA-ALCL) suffered by users of medical devices, containing a narrative description of the event. PIC ¶ 36; CAC ¶¶ 205, 211. Allergan received many complaints and reports of BIOCELL patients suffering BIA-ALCL, yet Allergan either failed entirely to submit MDRs or delayed several years in doing so. PIC ¶¶ 35-36, 90; CAC ¶ 209. When Allergan submitted MDRs, it often used false and misleading language, such as using an incorrect manufacturer name instead of Allergan, or designating the report as "No Apparent Adverse Event." PIC ¶¶ 87-89; CAC ¶¶ 210-211. Often, when Allergan was notified of an adverse BIA-ALCL event, it did not submit an MDR. Instead, Allergan submitted "Alternative Summary Reports" ("ASRs"), which are merely a series of alphanumeric codes that lack a narrative description of the event and which the FDA did not make publicly available until recently. PIC ¶¶ 91-95; CAC ¶¶ 212-216.

Allergan's reporting practices violated state law and many parallel federal requirements, including regulations requiring Allergan to submit MDRs promptly upon learning of a serious adverse event such as BIA-ALCL. PIC ¶¶ 32-34, 91; CAC ¶¶ 412-13; *see*, *e.g.*, 21 C.F.R. §§ 803.50, 814.84(b)(2), 803.19. Plaintiffs allege that if Allergan had properly reported adverse event information in compliance with state law and parallel federal requirements, the information would have been publicly available through MAUDE, would have reached Plaintiffs and their physicians, and would have caused Plaintiffs either to refrain from using BIOCELL implants or to have existing BIOCELL implants removed. PIC ¶ 199; CAC ¶¶ 422-423.

Allergan's manufacturing defects. Plaintiffs also allege that their BIOCELL implants were defectively manufactured. The implants differed from design specifications and specifications approved by the FDA in ways that rendered them unreasonably dangerous, in violation of state law. PIC ¶¶ 6, 149-150; CAC ¶¶ 14-15, 2148-2153. For example, Plaintiffs allege that the surfaces of the implants were littered with debris, including jagged particles of silicone. PIC ¶¶ 118, 126-127, 129-130, 135, 143, 152, 159, 161; CAC ¶¶ 14, 169, 188. When these foreign particles interact with the body's tissue, they exert forces that cause chronic inflammation, which can lead to BIA-ALCL. PIC ¶¶ 119, 127, 129, 130, 149, 161; CAC ¶¶ 15, 170.

Allergan's manufacturing defects likely are related to the texturing process. BIOCELL implants are textured implants, meaning their surface is textured, rather than smooth. PIC ¶ 3; CAC ¶ 13. Allergan texturized them using a "salt loss" technique. PIC ¶ 5; CAC ¶ 13. This technique called for Allergan placing a tack coat of silicone over the implant, immersing the implant in solid particles of salt, overcoating the implant in a final layer of silicone, curing the implant in an oven, soaking it in warm water, and scrubbing the implant with brushes to remove solid particles and reveal the textured surface. PIC ¶ 117; CAC ¶ 13. Allergan's negligent manufacturing, likely at the texturing stage, which deviated from the approved and intended design, caused its products to have variable roughness, a particle-laden environment, surface debris, and increased surface area, leading to continuous micro-movement shear forces between the surface of the implants and the tissue capsule, proliferation of T-cells, malignant transformation of T-cells, chronic inflammation, tissue damage, seroma formation and ALCL, and other harm. PIC ¶¶ 118, 161; CAC ¶ 14. While Allergan's specifications required gentle agitation, Allergan's workers employed an excessively variable and uncontrolled scrubbing

process, using different brushes and un-validated methods that violated Allergan's manufacturing and design specifications and the FDA's requirements. PIC ¶ 118; CAC ¶ 14.

Allergan's deviations from the approved process resulted in final products that departed from Allergan's specifications, and the specifications approved by the FDA. While the specifications called for removal of particles from the implant's surface, PIC ¶ 117; CAC ¶ 13, the surface instead "included foreign, degraded and loosened fragments of silicone particles and other materials," PIC ¶ 118; *see also* PIC ¶ 119 (the surface of the implants contained an "excessive number of jagged and sharp particles"); CAC ¶¶ 168, 189. "This constituted a defectively manufactured surface, as the manufacturing was in variance from the product specifications and processes." PIC ¶ 118; *see also* CAC ¶ 190.

A report of an inspection of Allergan's manufacturing facilities by France's Agency for the Safety of Health Products ("ANSM") revealed some of the causes of the manufacturing defects. PIC ¶ 121; CAC ¶ 182. ANSM found many "critical" and "major" deficiencies in Allergan's manufacturing processes. PIC ¶ 122; CAC ¶ 184. For example, failures regarding "residue controls" caused a "major risk regarding the . . . safety" of Allergan's implants. PIC ¶¶ 124, 125; CAC ¶¶ 185, 186. Researchers from several U.S. hospitals and universities authored a study reporting that they found "surface debris," such as silicone "white flecks," on the surfaces of new Allergan BIOCELL implants. PIC ¶ 126; CAC ¶ 188.

In their manufacturing-defect claims, Plaintiffs do not challenge Allergan's design of the BIOCELL implants or the specifications approved by the FDA. Instead, Plaintiffs use Allergan's FDA-approved design specifications as a benchmark and allege that Allergan deviated from those specifications in manufacturing Plaintiffs' BIOCELL implants. For example, Plaintiffs allege that "the improper texturing techniques and particle-laden and [debris-

covered] implant surface . . . rendered the manufacture defective, varying from the approved and intended design and manufacturing specifications." PIC ¶ 143; *see also* CAC ¶¶ 168-170.

Plaintiffs' state-law manufacturing defect claims parallel violations of federal law. The PMAs required Allergan to manufacture the implants in compliance with the FDA-approved design specifications and the Current Good Manufacturing Practices ("CGMPs"), a series of FDA regulations regarding manufacturing processes. PIC ¶ 128; CAC ¶ 111. Plaintiffs' complaints identify specific CGMPs that Allergan violated. *See* PIC ¶¶ 132-139; CAC ¶¶ 177-181, 190. Plaintiffs also allege that these manufacturing defects rendered the BIOCELL implants adulterated, in violation of the FDCA. PIC ¶¶ 129-131; CAC ¶¶ 14, 190; 21 U.S.C. § 351(a)(2)(A), (h).

Allergan's deception. Allergan violated multiple state-law duties by making a series of false and misleading non-PMA, and thus unapproved, "voluntary" statements that misrepresented BIOCELL implants' safety or minimized the risk of BIA-ALCL, in a way that diluted and undermined the effectiveness of any warnings. PIC ¶¶ 76, 208, 214; CAC ¶¶ 221-226. For example, as the association between BIOCELL implants and BIA-ALCL began to become public knowledge, physicians expressed concern, but Allergan told them that BIOCELL was safe and that their concerns were unsupported. PIC ¶ 76. Allergan further minimized the risk of BIA-ALCL in public statements. For example, Allergan deceptively stated that BIOCELL patients are more likely to be struck by lightning and twice as likely to be struck by an asteroid than to develop ALCL. PIC ¶ 102; CAC ¶ 224. Allergan also falsely blamed physicians for BIA-ALCL cases, and engaged in a campaign to tell physicians falsely that BIA-ALCL could be prevented through improved cleaning techniques at the time of implantation. PIC ¶ 103; CAC ¶ 225; *see also* PIC ¶¶ 97-99, 101 (additional statements falsely touting the safety and reliability

of BIOCELL implants); CAC ¶¶ 221-223 (same). None of these false statements were required by the FDA's approvals of BIOCELL implants or otherwise approved by the FDA. PIC ¶ 104; CAC ¶ 226. To the contrary, Plaintiffs allege that these false voluntary statements violated not only state law but also the FDCA and FDA regulations, which prohibit false and misleading statements in the marketing and advertising of devices. *See* PIC ¶¶ 106, 222; 21 U.S.C. § 352(q); 21 C.F.R. § 801.6.

C. Procedural Background

Approximately 300 plaintiffs have filed complaints against Allergan, which have been centralized for pretrial administration in this MDL. Pursuant to this Court's case management orders, on May 26, 2020, Liaison Counsel for Plaintiffs and Co-Lead Plaintiffs' Counsel filed the Master Complaint. PIC at 1. While Plaintiffs' individual complaints (including Short Form Complaints filed pursuant to this Court's case management orders) may contain additional and plaintiff-specific allegations, all allegations in the Master Complaint are deemed pleaded in each individual complaint. Case Management Order #17, § III.A, Dkt. No. 201. The Master Complaint asserts claims for manufacturing defect, based on strict liability (Count I) and negligence (Count II). It asserts claims for failure to warn, based on strict liability (Count IV) and negligence (Count V). It asserts claims for general negligence (Count III) and breach of the implied warranty of merchantability (Count VII), primarily based on the aforementioned defects. It asserts claims for negligent misrepresentation (Count VI) and breach of express warranty (Count VIII), based on false representations and warranties Allergan made regarding the safety of its BIOCELL products. Plaintiffs who were implanted with implants or tissue expanders that did not receive PMA approval assert claims of strict liability design defect (Count IX) and negligent design (Count X). The complaint also asserts a claim for survivorship and wrongful death on behalf of representatives of decedents who died after being implanted with BIOCELL

products (Count XI), a loss of consortium claim on behalf of the spouses of those implanted with BIOCELL (Count XII), and a claim for punitive damages (Count XIII).

Certain Plaintiffs also filed the Class Complaint on behalf of a class of all individuals in the United States who were implanted with the recalled BIOCELL implants and tissue expanders, and who have not been diagnosed with BIA-ALCL. CAC ¶ 269.[5] In addition to certain claims also asserted in the Master Complaint (strict liability and negligent failure to warn, strict liability and negligent manufacturing defect, strict liability and negligent design defect (for non-PMA devices), and breach of implied warranty of merchantability), the Class Complaint asserted claims for medical monitoring (Counts 300-305), violations of state consumer fraud and deceptive trade practices acts (Counts 330-382), unjust enrichment (Counts 383-436), declaratory judgment that releases signed by certain class members were unenforceable (Counts 437-438), and rescission of those releases (Count 439). In addition to compensatory and punitive damages, the Class Complaint seeks equitable relief in the form of a court-ordered medical-monitoring program funded by Allergan. CAC at 1313.

Allergan moved to dismiss, asking this Court to dismiss most of Plaintiffs' claims as preempted by federal law.[6]

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[5] Plaintiffs also brought claims on behalf of state-specific subclasses, state-specific subclasses of class members who were implanted with BIOCELL devices that did not receive PMA approval, and a subclass consisting of class members who signed "Warranty Release" forms with Allergan. CAC ¶¶ 270-383.

[6] Allergan does not assert that federal law preempts claims of Plaintiffs who used devices that did not receive approval either through a PMA or through an investigative device exemption. Allergan Br. 56. Allergan has filed separate briefs seeking to dismiss the claims in the Master Complaint on non-preemption grounds and seeking to strike the class allegations in the Class Complaint. Plaintiffs are responding to Allergan's non-preemption arguments in separate opposition briefs.

LEGAL STANDARD

"Preemption is an affirmative defense that the defendant has the burden to prove." *Lupian v. Joseph Cory Holdings LLC*, 905 F.3d 127, 130 (3d Cir. 2018). "Pleadings need not anticipate or attempt to circumvent affirmative defenses" such as "[p]reemption." *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010). In adjudicating a motion to dismiss based on preemption, a court "must 'accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.'" *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 334 (3d Cir. 2009) (quoting *Phillips v. County of Allegheny,* 515 F.3d 224, 231 (3d Cir. 2008)). "[D]ismissal is appropriate under Rule 12(b)(6) only when 'preemption is manifest in the complaint itself.'" *Lupian*, 905 F.3d at 130-31 (quoting *In re Asbestos Prods. Liab. Litig.*, 822 F.3d 125, 133 n.6 (3d Cir. 2016)).

Protecting residents' health and safety from dangerous drugs and medical devices is within the "historic police powers of the States." *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 771 (3d Cir. 2018) (quoting *Lohr*, 518 U.S. at 485). "In products liability actions like this one, the Supreme Court has specified that 'the historic primacy of state regulation of matters of health and safety' requires [courts] to apply the 'presumption against the pre-emption of state police power regulations.'" *Id.* at 770-71 (quoting *Lohr*, 518 U.S. at 485).

ARGUMENT

I. CLAIMS FOR VIOLATIONS OF STATE-LAW DUTIES THAT PARALLEL FEDERAL REQUIREMENTS ARE NOT PREEMPTED

Although the legal regime regarding preemption of medical-device claims evolved from many sources of law—including the Supremacy Clause, the MDA, FDA regulations, several Supreme Court decisions, and countless lower court decisions—the legal rule that requires

denying Allergan's motion is clear: "a plaintiff may proceed on her claim so long as she claims the 'breach of a well-recognized duty owed to her under state law' and so 'long as she can show that she was harmed by a violation of applicable federal law.'" *Godelia v. Doe*, 881 F.3d 1309, 1317 (11th Cir. 2018) (quoting *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017)); *accord Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010) (plaintiff "may" "claim[ ] breach of a well-recognized duty owed to her under state law . . . so as long as she can show that she was harmed by a violation of applicable federal law"). Thus, if a plaintiff alleges that the manufacturer's conduct violated both a state-law duty and a federal requirement, such a claim is not preempted.

That principle follows directly from the MDA and the Supreme Court's decisions interpreting it. The MDA does not purport to preempt the field of state device regulation. Rather, it only preempts state safety and effectiveness requirements that are "different from, or in addition to" federal requirements. 21 U.S.C. § 360k(a). Thus, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (quoting *Lohr*, 518 U.S. at 495). As the Third Circuit has explained, "[e]ven for Class III devices, the Medical Device Amendments' express preemption provision does not reach 'parallel' claims, i.e., claims premised on state requirements that merely incorporate applicable federal requirements and therefore are not 'different from, or in addition to,' federal requirements." *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 768 (3d Cir. 2018).

While *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), held that the MDA impliedly preempts so-called "fraud-on-the-FDA" claims, that implied preemption is limited to "claims [that] exist solely by virtue of the FDCA . . . requirements." *Id.* at 352. By

contrast, claims that, for example, "rely[ ] on traditional state tort law which had predated the federal enactments," such as claims for "the manufacturer's alleged failure to use reasonable care in the production of the product," are not preempted. *Id.* at 352-53 (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984); *Lohr*, 518 U.S. 470).

In recent years, drug and device manufacturers have tried to expand *Buckman*'s reach to bar claims for violating recognized state common law duties that parallel requirements under the FDCA, but courts have repeatedly rejected such attempts. For example, failure-to-warn claims alleging that the manufacturer violated the state-law duty to warn adequately (including by failing to report information to the FDA), while also violating federal labeling or reporting requirements, are not preempted under *Buckman*. As the Fifth Circuit reasoned in rejecting preemption for such a claim, the claims in *Buckman* were preempted because those plaintiffs "were attempting to assert a freestanding federal cause of action based on violation of the FDA's regulations" but "did not assert violation of a state tort duty." *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 775 (5th Cir. 2011). By contrast, a claim for violating "the underlying state duty to warn about the dangers or risks of [a] product" is not preempted, even where the plaintiff "seeks to prove [a defendant's] breach of the state duty by showing that [the defendant] violated the FDA's [medical device reporting] regulations." *Id.*; *see also McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040-41 (9th Cir. 2015) ("McClellan's claims were not fraud-on-the-FDA claims. The failure-to-warn claims McClellan alleged did not arise solely by virtue of the MDA.").

Allergan appears to acknowledge (at 22) that claims for violating state-law duties that parallel federal requirements are not preempted. Allergan errs, however, in asserting (at 2) that "case after case has held" that the MDA "expressly or impliedly preempt[s] virtually all state law product liability and tort claims." No court has ever held such a thing. To the contrary,

Plaintiffs cite dozens of cases holding that tort claims against manufacturers of PMA-approved Class III devices are not preempted. *See*, *e.g.*, *infra*, pp. 21, 27-30, 43-44, 54-55, 58 & nn.7, 8, 12, 27, 32, 33, 35. As explained herein, under the principles set forth in those decisions, Plaintiffs have pleaded valid, non-preempted claims for violations of state-law duties that parallel federal requirements.

II. PLAINTIFFS' FAILURE-TO-WARN CLAIMS ARE NOT PREEMPTED

Plaintiffs' failure-to-warn claims are not preempted because Plaintiffs allege that Allergan violated the state-law duty to warn adequately of dangers caused by its products, and Allergan's violations of state law parallel violations of federal law. Plaintiffs allege three separate failures by Allergan, each of which is independently sufficient to support a failure-to-warn claim. First, Allergan failed to add adequate warnings of BIA-ALCL to the labeling of BIOCELL implants. Second, Allergan failed to report adverse-event information about BIA-ALCL to the FDA, which would have made the information publicly available, including to Plaintiffs and their physicians. Third, Allergan engaged in a campaign of false and misleading non-PMA statements that minimized the risk of BIA-ALCL, thus diluting the effect of any warnings and rendering Allergan's warnings inadequate as a whole (Plaintiffs show that their misrepresentation-based claims are not preempted in a separate section, *see infra* Section IV.A). For each of these three failures, Plaintiffs allege violations both of a recognized state-law duty and parallel federal requirements. Thus, Plaintiffs' failure-to-warn claims are neither expressly nor impliedly preempted.

A. Plaintiffs' Claims Based On Failure To Update BIOCELL Labeling Are Not Preempted

Allergan violated state law by failing to warn adequately with regard to BIA-ALCL. State law imposed on Allergan a duty to warn of the risk that patients with BIOCELL implants

would develop BIA-ALCL. *See* PIC ¶¶ 200, 215; Dan B. Dobbs et al., *The Law of Torts* § 464 (2d ed. June 2020 update) ("a product is defective . . . when its manufacturer or distributor fails to provide a reasonable warning for reasonably foreseeable harm"). Allergan breached that state-law duty: during the relevant period, Allergan either did not mention BIA-ALCL at all on BIOCELL labeling, or did not maintain adequate warnings in light of emerging knowledge of BIA-ALCL risks. *See* PIC ¶¶ 69, 74-75, 185, 191-196, 205, 212; CAC ¶¶ 121, 123, 129-131.

This claim is not expressly preempted because Allergan's state-law duty parallels, and does not add to or differ from, federal law. Two sources of federal law independently required Allergan to add warning language to BIOCELL's labeling when new information about the risk of BIA-ALCL rendered the existing labeling inadequate.

1. The BIOCELL PMAs required Allergan to warn of BIA-ALCL

The PMAs for BIOCELL implants required Allergan to update the labeling. Specifically, these PMAs included the following Conditions of Approval:

a. "Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval unless the change is of a type for which a 'Special PMA Supplement-Changes Being Effected' is permitted under 21 C.F.R. 814.39(d). . . . 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.'

b. 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."

PIC ¶ 61.

The PMAs thus required Allergan to submit a PMA supplement "when unanticipated adverse effects" or "increases in the incidence of anticipated adverse effects . . . necessitate a labeling . . . modification." The PMAs further directed that, when permitted, the proper regulatory mechanism is to "implement[ ]" the changes "before FDA approval" by submitting a

"Special PMA Supplement-Changes Being Effected" under 21 C.F.R. § 814.39(d). This regulation, known as the "CBE" regulation, authorizes device manufacturers to make "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association," *id.* § 814.39(d)(2)(i), and to do so without prior FDA approval. *Cf. Wyeth v. Levine*, 555 U.S. 555, 568 (2009) (under analogous CBE regulation for prescription drugs, a manufacturer "may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval"). Here, reasonable evidence of a causal relationship between BIOCELL implants and BIA-ALCL existed. *See* PIC ¶¶ 31-36, 64; CAC ¶¶ 141-162; *supra* pp. 7-8. Thus, "[t]he Conditions of Approval directed Allergan to disseminate strengthened labeling pending FDA approval, pursuant to the CBE regulations." PIC ¶ 63. The state-law duty—to update product labeling to add adequate warnings of a dangerous risk when new evidence arises to connect the product to that risk—parallels the federal requirement in the PMA Conditions of Approval.

Many courts have held that the MDA does not preempt claims, such as Plaintiffs' here, based on violations of state-law duties that parallel federal requirements imposed in a PMA order or as conditions of approval in a PMA. *See Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015) (rejecting preemption for failure-to-warn claims "parallel to several federal duties imposed by the PMA"); *Gavin v. Medtronic, Inc.*, 2013 WL 3791612, at *12 (E.D. La. July 19, 2013) (rejecting preemption for failure-to-warn claims based on violations of the "Conditions of Approval of the PMA," which "included the obligation under 21 C.F.R. § 803.50 to report incidents in which the device may have caused or contributed to serious injury and the

obligation under 21 C.F.R. § 814.39 to submit a PMA supplement when unanticipated adverse effects or increases in incidences of anticipated adverse effects occur").[7]

2. The federal misbranding provisions required Allergan to warn of BIA-ALCL

The misbranding provisions of the FDCA also required Allergan to update its labeling. Under federal law, a device is misbranded (and thus may not be sold) "[i]f its labeling is false or misleading in any particular," and "[u]nless its labeling bears . . . such adequate warnings against use in those pathological conditions . . . where its use may be dangerous to health." 21 U.S.C. § 352(a)(1), (f)(2). Thus, like state law, the misbranding provisions placed on Allergan "the requirement to maintain adequate warnings." PIC ¶ 67. Allergan violated that requirement because BIOCELL's labeling lacked adequate warnings about BIA-ALCL, and the 2013 warning language (which equated the BIA-ALCL risk caused by BIOCELL with risk caused by other

[7] *See also Cline v. Advanced Neuromodulation Sys., Inc.*, 17 F. Supp. 3d 1275, 1285 (N.D. Ga. 2014) (rejecting preemption where plaintiff alleged that defendant breached "a duty under federal law . . . incorporated into [a] PMA Supplement"); *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 181 (N.D.N.Y. 2014) ("Plaintiff has sufficiently pled a parallel state claim . . . by . . . alleging that Defendant violated the applicable PMAs."); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 697 (W.D. Tenn. 2011) (claims "not preempted" "[t]o the extent that Plaintiffs' claims are premised on the allegation that Advanced Bionics' deviated from the manufacturing and design requirements set forth in PMA Supplement 30"); *Warren v. Howmedica Osteonics Corp.*, 2011 WL 1226975, at *4 (E.D. Mo. Mar. 29, 2011) (claims "survive preemption" where they "allege that defendants failed to manufacture the Trident System in conformity with the FDA's PMA specifications"); *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 685 (W.D. Ky. 2013) (rejecting preemption for claim that defendant "failed to manufacture the Vendor B HiRes 90k in conformity with its PMA Supplement"); *McAfee v. Medtronic, Inc.*, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015) (rejecting preemption where plaintiff alleged defendant "violated the PMA and conditions of approval by failing to file timely adverse event reports"); *Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 835 (W.D. Ky. 2014) (claim not preempted where plaintiff "alleges that Defendants' manufacture of the Riata leads deviated from the PMA and PMA Supplements"); *Eggerling v. Advanced Bionics, L.L.C.*, 958 F. Supp. 2d 1029, 1038 (N.D. Iowa 2013) (rejecting preemption where device "was not manufactured in compliance with AB's PMA Supplement"); *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 838 (S.D. Ind. 2009) (rejecting preemption for "claims premised on Howmedica's alleged failure to manufacture the Trident in accordance with the PMA issued by the FDA").

implants) was rendered misleading by emerging evidence that BIOCELL implants carried a much greater risk than other implants. *See* PIC ¶¶ 31-36, 64, 75, 191-92; CAC ¶¶ 129-131.

State-law claims based on conduct that renders a device misbranded in violation of federal law are not preempted. That conclusion follows from the principle that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" because "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (quoting *Lohr*, 518 U.S. at 495). One of the cases prominently relied on by Allergan (at 26, 29), *Norabuena v. Medtronic, Inc.*, 2017 IL App (1st) 162928, 86 N.E.3d 1198, applied that principle to hold that failure-to-warn claims were "neither expressly nor impliedly preempted insofar as they parallel the federal prohibition against misbranding." *Id.* ¶ 31. Other cases are in accord.[8]

3. Allergan fails to acknowledge those parallel federal requirements

Allergan's argument for preemption of Plaintiffs' labeling-based claims fails because Allergan ignores the sources of federal law that impose parallel requirements. Allergan argues

[8] *See Wildman v. Medtronic, Inc.*, 874 F.3d 862, 868 (5th Cir. 2017) (express warranty claim based on false advertising statements was not preempted because it was "parallel" to the federal provision that "[a] device is misbranded if it is sold using 'false or misleading advertising' ") (quoting 21 U.S.C. § 352(q)(1)); *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977, 991 (D. Ariz. 2013) ("when Medtronic allegedly violated federal law by engaging in off-label promotion that damaged the Plaintiff and thereby misbranded the Infuse device, it departed the realm of federal regulation and returned to the area of traditional state law remedies") (footnotes omitted); *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, 401 F. Supp. 3d 538, 560 (D. Md. 2019) ("*Smith & Nephew Birmingham*") (claims premised on manufacturer's "alleged false or misleading statements about the [device] . . . are not preempted" because "[t]he FDCA expressly prohibits misbranded or adulterated devices from entering the market"); *Bayer Corp. v. Leach*, 2020 WL 4811506, at *8 (Ind. Ct. App. Aug. 19, 2020) (agreeing with Seventh Circuit's conclusion that "[t]he evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient," and finding "the Seventh Circuit's reasoning equally applicable to the condition of being 'misbranded' ") (quoting *Bausch*, 630 F.3d at 557); *cf. Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 487 n.4 (2013) (suggesting that claims "that parallel the federal misbranding statute" would escape preemption).

(at 35-38) that Plaintiffs cannot assert a claim for failure to change the label through a CBE supplement because the CBE regulation permits, but does not require, such a change. Allergan reasons that a state-law requirement to update the label would impose an additional requirement beyond the CBE regulation. Allergan's argument fails because it ignores that two other sources of federal law—the PMAs applicable to BIOCELL implants and the FDCA's misbranding provisions—required Allergan to update its labeling under the circumstances alleged by Plaintiffs. None of the cases cited by Allergan involved a claim (like Plaintiffs' claims here) that federal law required a label change. *See*, *e.g.*, *McGookin v. Guidant Corp.*, 942 N.E.2d 831, 838 (Ind. App. Ct. 2011) ("The Appellants herein do not allege that Guidant violated federal requirements. Instead, they contend that Guidant should be liable for its failure to add warnings that are permitted, but not required, by federal law.").

Allergan does not contend that a claim based on Allergan's failure to update BIOCELL's labeling to warn of BIA-ALCL would be impliedly preempted under *Buckman*. Any such argument on reply would be not only waived but also meritless. Plaintiffs' failure-to-warn claim based on product labeling is undoubtedly a recognized state-law tort claim.[9] Thus, "[b]ecause Plaintiffs are asserting breach of recognized state law duties which are *parallel* to federal regulations (as opposed to an independent implied right action under the MDA to directly *enforce* those regulations), their claims are not impliedly preempted under *Buckman*." *Kubicki ex rel. Kubicki v. Medtronic*, 2013 WL 1739580, at *11 (D.D.C. Mar. 21, 2013).

[9] *See*, *e.g.*, Restatement (Second) of Torts § 402A cmt. j (1965) ("In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use."); Restatement (Third) of Torts: Products Liability § 2(c) (1998) ("A product . . . is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller . . . and the omission of the instructions or warnings renders the product not reasonably safe.").

B. Plaintiffs' Failure-To-Warn Claims Based On Inadequate Reporting To The FDA Are Not Preempted

Plaintiffs assert valid state-law failure-to-warn claims based on inadequate reporting of safety information to the FDA. The MDA does not preempt those traditional state-law claims because Plaintiffs allege that Allergan violated parallel FDA regulations regarding reporting of adverse safety information. *See*, *e.g.*, PIC ¶¶ 33-37, 88-95, 186-190, 204, 213 (citing, *e.g.*, 21 C.F.R. §§ 814.84, 803.50, 803.10, 803.17, 803.18, 803.20, 803.3, 803.52, 803.53, 803.56, 820.198, 803.19).

Allergan does not argue, nor could it, that Plaintiffs' reporting-based claims seek to impose any requirement that differs from or adds to federal requirements. Rather, Allergan argues (at 25-30) that such claims lack a basis in any state-law duty, and (at 31-35) that such claims are impliedly preempted under the rationale of *Buckman*'s preemption of "fraud-on-the-FDA" claims. Both of Allergan's arguments are incorrect.

1. The claims are not expressly preempted

a. Allergan erroneously frames its argument (at 25-30) in terms of express preemption. Its theory (at 26) is that "[t]here is no common law 'failure to report to a federal agency' tort claim." That is an argument that Plaintiffs' allegations fail to state a valid claim under governing state tort law. It is not an express-preemption argument because it does not contend that Plaintiffs' state-law claim stems from any duty that adds to or differs from federal requirements. As Allergan does not dispute, Plaintiffs allege that Allergan violated parallel federal requirements in the PMAs and FDA regulations regarding reporting of adverse events.

In any event, Allergan's state-law argument is wrong, at least in the vast majority of states. Plaintiffs' reporting-based failure-to-warn claims rest on a well-recognized aspect of the

traditional state-law duty to warn patients or their physicians adequately of a product's risks.[10] If Allergan had properly reported information about BIOCELL patients suffering BIA-ALCL to the FDA, then that information would have been accessible to Plaintiffs and their physicians in the publicly available, searchable, monthly-updated MAUDE database. PIC ¶ 36; CAC ¶ 206. Plaintiffs or their physicians would then have received the information, and would not have chosen to use BIOCELL devices. PIC ¶ 199; CAC ¶ 423. Allergan's characterization of this claim (at 25) as a "duty to report to a federal regulatory agency" claim ignores that the state-law obligation to report information to the FDA flows directly from the duty to warn patients or their physicians. Plaintiffs' claim is a traditional failure-to-warn claim: Allergan had a state-law duty to warn Plaintiffs or their physicians of the dangers of BIA-ALCL, and one way in which Allergan breached that duty was its failure to report information to the FDA that would have been made available to Plaintiffs and their physicians through a public database.

The relevance of disclosures to third parties, such as regulators, to failure-to-warn claims has a longstanding basis in tort law. Comment n to Section 388 of the Restatement (Second) of Torts states that information given by a manufacturer of a product to a "third person" who will relay that information to the product's user is relevant to whether the manufacturer has satisfied its duty to warn. Restatement (Second) of Torts § 388 cmt. n (1965). In recent years, several district courts within this Circuit have recognized that comment n supports holding that a device manufacturer can violate its traditional state-law duty to warn by failing to report adverse safety

[10] While manufacturers generally owe a duty to warn users of products, in the prescription drug and device context, some states apply the learned intermediary doctrine, which holds that in some circumstances, the manufacturer's duty is to warn the patient's physician. *See*, *e.g.*, *Perez v. Wyeth Labs Inc.*, 734 A.2d 1245, 1257 (N.J. 1999) (recognizing general applicability of learned intermediary doctrine but holding that the shift in burden does not apply where the warning is not adequate, or where the manufacturer engages in direct-to-consumer advertising). Allergan warned neither physicians nor patients.

information to the FDA. For example, in *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Pa. 2016), the court held that Pennsylvania law allowed a failure-to-warn claim against a device manufacturer based on "failure to report adverse events to the FDA." The court grounded this state-law obligation in a decades-old Pennsylvania appellate decision adopting comment n and interpreting it to signify that "a supplier's duty to warn is discharged by providing information about the product's dangerous propensities to a third person upon whom it can reasonably rely to communicate the information to the ultimate users of the product or those who may be exposed to its hazardous effects." *Id.* (quoting *Phillips v. A.P. Green Refractories Co.*, 630 A.2d 874, 882 (Pa. Super. Ct. 1993), *aff'd*, 665 A.2d 1167 (Pa. 1995)); *see also Silver v. Medtronic, Inc.*, 236 F. Supp. 3d 889, 900 (M.D. Pa. 2017) (agreeing with *McLaughlin* that comment n supports "liability for the failure to report to the FDA" because "the FDA may be reasonably relied upon to disclose information regarding medical device failures through the publicly accessible database when provided with that information"); *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 359 (D. Del. 2019) (affirming the viability under Delaware law of "state law failure to warn claims premised on Section 388, which focus on a manufacturer's failure to report adverse events to the FDA," and holding that such claims are "not preempted"). An Idaho federal court likewise relied on a decades-old Idaho Supreme Court decision adopting comment n to hold: "under Idaho law a manufacturer of a product may have a duty to forewarn a user of the product, regardless whether the user is the direct purchaser of the product or not. In the context of Class III medical devices, that should be construed to include warnings and reports to the FDA." *Richardson v. Bayer Healthcare Pharm. Inc.*, 2016 WL 4546369, at *8 (D. Idaho Aug. 30, 2016) (citation omitted).

Dozens of cases applying the law of nearly every state[11] have held that state law recognizes failure-to-warn claims against device manufacturers based on inadequate reporting to the FDA and that such claims are not preempted when they are based on parallel violations of federal reporting requirements. *See*, *e.g.*, *Hughes*, 631 F.3d at 769, 775 (rejecting preemption for claim "predicated on Boston Scientific's failure to report 'serious injuries' and 'malfunctions' of the device as required by the applicable FDA regulations," and holding that this claim is "based on the underlying state duty to warn about the dangers or risks of [a] product"); *Coleman v. Medtronic, Inc.*, 167 Cal. Rptr. 3d 300, 311 (Cal. Ct. App. 2014) ("Federal law requires manufacturers of class III devices to file adverse event reports whenever the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred. . . . California law imposes a parallel requirement under the common law strict liability tort of failure to warn."); *Angeles v. Medtronic, Inc.*, 863 N.W.2d 404, 419 (Minn. Ct. App. 2015) ("Because appellants' claim that Medtronic failed to warn the FDA of adverse events is based in traditional state tort law, we conclude that this claim is not expressly or impliedly preempted by federal law to the extent that appellants allege that Medtronic failed to report adverse events to the FDA."); *Williams v. Bayer Corp.*, 541 S.W.3d 594, 605-06 (Mo. Ct. App. 2017) ("[plaintiff's] claim is not analogous to the 'fraud-on-the-FDA' theory that was rejected in *Buckman* and is instead grounded on a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product, which Williams argues Bayer breached by failing to meet the post-premarket approval reporting requirements listed in the MDA and the Essure PMA"); Decision

[11] In another medical device MDL, a federal court held that all plaintiffs, from 41 states and the District of Columbia, asserted valid, non-preempted claims for inadequate reporting to the FDA. *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, 300 F. Supp. 3d 732, 735, 747-48 (D. Md. 2018).

at 14, *Rose v. Bayer Corp.*, No. MRS-L-265-20 (N.J. Super. Ct. July 31, 2020), *motion for leave to appeal granted and pending* (attached as Ex. A) (holding that allegations that defendant "failed to report [adverse] events in a reasonably prompt manner on an ongoing basis to the FDA, to update the FDA, and to enable the FDA to inform and educate the product's current and future consumers" stated claims for breach of obligations that "exist under federal law and regulation," and "[t]hese duties and obligations also parallel state law duties"); *Williams*, 123 F. Supp. 3d at 742-43 (Maryland tort law imposes "duty to warn" that "extends beyond the time of sale, and requires the manufacturer to make 'reasonable efforts' to convey an effective warning. And reasonable efforts would, in some circumstances, entail a warning to a third party such as the FDA.") (citation omitted); *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026, 1035 (N.D. Ill. 2016) (Illinois's duty to warn imposes obligation "to engage in 'reasonable conduct for the benefit' of the end user. Here, that reasonable conduct includes fully and correctly complying with FDA disclosure requirements. The Lavertys' claims are not impliedly preempted."); *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 185 (N.D.N.Y. 2014) (rejecting preemption for plaintiff's claim that "that Defendants' failure to timely report to the FDA led to a violation of state law, in that Defendants also did not exercise reasonable care in informing the medical community of known risks," and holding that "New York imposes" a duty to report to the FDA); *Gavin*, 2013 WL 3791612, at *12-14 ("the [Louisiana Products Liability Act] recognizes that the manufacturer has a duty to use reasonable care to provide an adequate warning to users and handlers of the device if it knows or should have known that the device presents a serious risk of harm even after the device has left the manufacturer's control, and Plaintiff has alleged that Medtronic violated the analogous duties owed under the federal regulations to report adverse events") (footnote omitted); *Marion v. Smith & Nephew, Inc.*, 2016

WL 4098608, at *5 (D. Utah July 28, 2016) (by alleging violations of FDA reporting requirements, plaintiff "adequately pled a parallel state law negligence claim that is not preempted by § 360k"); *Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 839 (W.D. Ky. 2014) (rejecting dismissal of state-law claim "based on Defendants' violation of the applicable federal reporting requirements"); *McAfee v. Medtronic, Inc.*, 2015 WL 3617755, at *5 (N.D. Ind. June 4, 2015) (denying motion to dismiss because plaintiff "has stated plausible claims for relief under state law based on an alleged failure to warn the FDA"); *Beavers-Gabriel v. Medtronic, Inc.*, 2015 WL 143944, at *12 (D. Haw. Jan. 9, 2015) (under Hawaii law, the "duty of care supplies a basis for Plaintiff's strict liability and negligence claims that arises independently of Plaintiff's duty to warn the FDA under federal law"); *Scovil v. Medtronic Inc.*, 2015 WL 880614, at *7 (D. Nev. Mar. 2, 2015) (recognizing duty under Nevada law "to report adverse events to the FDA"); *McLaughlin*, 172 F. Supp. 3d at 838; *Freed*, 364 F. Supp. 3d at 359; *Richardson*, 2016 WL 4546369, at *8.[12]

[12] *See also Jones for Jones v. Medtronic, Inc.*, 2018 WL 1462169, at *4-5 (Minn. Ct. App. Mar. 26, 2018) ("Jones argues that her complaint sufficiently alleged that these federal reporting failures hid issues from the FDA that would otherwise have been conveyed to medical professionals when Kaitlyn was admitted at the hospital, and therefore, Medtronic's failure to report these issues resulted in Kaitlyn's death. Again, we believe this failure-to-warn claim survives preemption."); *Houston v. Medtronic, Inc.*, 2014 WL 1364455, at *7 (C.D. Cal. Apr. 2, 2014) (rejecting dismissal of "claim of failure to warn the FDA," holding that California law duty to warn "can be satisfied by conveying warnings to a third party [w]hen a manufacturer or distributor has no effective way to convey a product warning to the ultimate consumer"); *Fisk v. Medtronic, Inc.*, 2017 WL 4247983, at *6 (N.D. Ind. Sept. 25, 2017) ("Indiana law . . . duty to warn . . . will sometimes require the manufacture to provide the information to third parties rather than the end users themselves."); *A.F. by & Through Fogel v. Sorin Grp. USA, Inc.*, 346 F. Supp. 3d 534, 544 (S.D.N.Y. 2018) ("[A] manufacturer's duty to take steps that are reasonably necessary to warn the medical community may include warning the FDA as required by the MDA. To the extent Plaintiffs assert a claim for failure to warn the FDA, that claim is not preempted."); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 251 (S.D.N.Y. 2013) (rejecting preemption for claim that plaintiff "was injured based on S & N's failure to comply with the premarket approval's monitoring and reporting requirements"); *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 887-88 (N.D. Cal. 2013) (accepting plaintiff's argument that his

b. The extensive case law recognizing state-law failure-to-warn claims based on failure to report information to the FDA belies Allergan's assertion (at 25) 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." Allergan's total disregard of the contrary decisions is reason enough to reject its argument. To be sure, Allergan cites some cases (at 25-29) purportedly holding that a particular state's law does not recognize a duty to report to the FDA (mostly federal district court cases). But some of these cases hold that there *is* a state-law duty to report information to the FDA, the exact opposite of Allergan's

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"failure to warn claim is a parallel claim that is not expressly preempted because it is based on Defendants' failure to report to the FDA adverse events regarding the dangers of off-label use, as required by federal law"); *Caton v. Stryker Sustainability Sols., Inc.*, 2014 WL 12599850, at *2 (C.D. Cal. Sept. 12, 2014) (rejecting preemption for claims based on "Defendants' alleged failure to make disclosures to the FDA"); *Funke v. Sorin Grp. USA, Inc.*, 147 F. Supp. 3d 1017, 1024 (C.D. Cal. 2015) ("The California duty to warn does not solely run to doctors, but to the FDA as well."); *Frere v. Medtronic, Inc.*, 2016 WL 9455137, at *5 (C.D. Cal. June 1, 2016) ("Plaintiff claims that Defendants failed to adhere to the FDA's requirements in manufacturing the Device and did not warn the FDA about these failures—conduct that also violates California law."); *Mize v. Mentor Worldwide LLC*, 265 Cal. Rptr. 3d 468, 479 (Cal. Ct. App. 2020) ("A claim based on the failure to warn the FDA of adverse events is not preempted to the extent state tort law recognizes a parallel duty. California law recognizes a manufacturer's duty to warn the FDA of adverse events."); *Gravitt v. Mentor Worldwide, LLC*, 289 F. Supp. 3d 877, 889-90 (N.D. Ill. 2018) (recognizing "state law duty of a manufacturer to inform regulators and the public when it has reason to know that a product is riskier than initially believed"); *Comella v. Smith & Nephew, Inc.*, 2013 WL 6504427, at *2 (N.D. Ill. Dec. 11, 2013) (finding claim for "failure to advise the FDA" about dangers of a device were "based on the common law duty to warn" and "sufficiently parallel to the requirement to make disclosures under the federal regulations so as not to be preempted"); *Lance v. Bayer Essure Inc.*, 2016 WL 4417248, at *6 (Cal. Super. Ct. Aug. 02, 2016) (rejecting preemption for claims "based on the allegations of Defendants' failures to comply with its reporting obligation to the FDA"); *Smith & Nephew Birmingham*, 401 F. Supp. 3d at 557-58 ("state law may give rise to a coextensive duty to warn a federal regulatory body such as the FDA about adverse events"); *Bull v. St. Jude Med., Inc.*, 2018 WL 3397544, at *8-9 (E.D. Pa. July 12, 2018) ("Plaintiff's state law failure to warn claim identifies a state duty to warn physicians of risks inherent in medical devices that is parallel to St. Jude's duty to comply with MDR reporting requirements.").

mischaracterization.[13] Moreover, many of Allergan's cases are from jurisdictions where other cases have recognized that the traditional duty to warn can encompass an obligation to report information to the FDA, including New Jersey,[14] Delaware,[15] New York,[16] California,[17] Missouri,[18] Illinois,[19] and Kentucky.[20]

Underscoring the weakness of Allergan's argument, in support of Allergan's non-preemption brief, Allergan presented an appendix of cases that purported to include a state-by-

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[13] *See*, *e.g.*, *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 2448095, at *2 (C.D. Cal. May 25, 2018) ("California law imposes a parallel requirement" to the federal requirement "that manufacturers of Class III devices report to the FDA" information about serious adverse events); *Jacob v. Mentor Worldwide, LLC*, 393 F. Supp. 3d 912, 925 (C.D. Cal. 2019) ("California law recognizes such a duty to warn" the FDA), *appeal filed*, No. 19-56391 (9th Cir. Nov. 27, 2019); *Vieira v. Mentor Worldwide, LLC*, 392 F. Supp. 3d 1117, 1131 (C.D. Cal. 2019) (same), *appeal filed*, No. 19-56394 (9th Cir. Nov. 27, 2019). Another case cited by Allergan, *Webb v. Mentor Worldwide LLC*, 453 F. Supp. 3d 550, 559-60 (N.D.N.Y 2020), did not involve a claim based on failure to report information to the FDA.

[14] *Compare Chester v. Boston Sci. Corp.*, 2017 WL 751424 (D.N.J. Feb. 27, 2017); *D'Addario v. Johnson & Johnson*, 2020 WL 3546750 (D.N.J. June 30, 2020), *with Rose*, No. MRS-L-265-20.

[15] *Compare Scanlon v. Medtronic Sofamor Danek USA Inc.*, 61 F. Supp. 3d 403 (D. Del. 2014), *with Freed*, 364 F. Supp. 3d 343.

[16] *Compare English v. Bayer Corp.*, 2020 WL 3454877 (W.D.N.Y. June 25, 2020), *appeal filed*, No. 20-2137 (2d Cir. July 7, 2020), *with Rosen*, 41 F. Supp. 3d 170.

[17] *Compare Jacob*, 393 F. Supp. 3d 912; *Ebrahimi v. Mentor Worldwide LLC*, 2018 WL 6829122 (C.D. Cal. Dec. 27, 2018); *Vieira*, 392 F. Supp. 3d 1117; *Malonzo v. Mentor Worldwide, LLC*, 2014 WL 2212235 (N.D. Cal. May 28, 2014), *with Coleman*, 167 Cal. Rptr. 3d 300; *Mize*, 265 Cal. Rptr. 3d 468; *Houston*, 2014 WL 1364455; *Eidson*, 981 F. Supp. 2d 868; *Caton*, 2014 WL 12599850; *Frere*, 2016 WL 9455137; *Lance*, 2016 WL 4417248.

[18] *Compare Brooks v. Mentor Worldwide, LLC*, 2019 WL 4628264 (D. Kan. Sept. 23, 2019) (applying Missouri law), *appeal filed*, No. 19-3240 (10th Cir. Oct. 24, 2019), *with Williams v. Bayer Corp.*, 541 S.W.3d 594.

[19] *Compare Norabuena*, 86 N.E.3d 1198, *with Laverty*, 197 F. Supp. 3d 1026; *Gravitt*, 289 F. Supp. 3d 877; *Comella*, 2013 WL 6504427.

[20] *Compare Cales v. Medtronic, Inc.*, 2014 WL 6600018 (Ky. Cir. Ct. Nov. 21, 2014), *with Waltenburg*, 33 F. Supp. 3d 818.

state survey of decisions rejecting a "duty to report adverse events to the FDA as an element of a state tort law claim." Allergan Non-Preemption Br.[21] 13; App. A to Allergan Non-Preemption Br. 60-79, Dkt. No. 171-4. But most of the authorities included in the appendix are inapposite cases holding that statutes obligating certain teachers, caregivers, and officials to report child abuse, sexual abuse, elder abuse, or financial misconduct do not create a private right of action. *See generally* App. A to Pls.' Non-Preemption Br. ("Pls.' App. A") ("Failure To Warn" section).[22]

Allergan's cases rejecting failure-to-warn claims based on inadequate reporting to the FDA are mostly federal district court cases misconstruing state-law concepts of tort liability. Such cases fail to recognize that reporting-based claims flow from the traditional duty to warn patients or their physicians. Typical of such cases is *Potolicchio v. Medtronic, Inc.*, 2016 WL 3129186 (E.D. Tenn. June 2, 2016), which reasoned: "No Tennessee law requires Medtronic to warn the FDA about adverse events. Tennessee law requires manufacturers to warn physicians, but not the FDA." *Id.* at *4. That reasoning ignores that a tort claim imposing liability for inadequate reporting to the FDA is based on the traditional state-law duty to warn patients or their physicians. In this case, Plaintiffs contend that Allergan had a duty to warn Plaintiffs or

[21] Mem. of Law in Supp. of Allergan's Mot. to Dismiss Pls.' Master Compl. (Non-Preemption Issues), Dkt. No. 171-3.

[22] *See*, *e.g.*, *C.B. v. Bobo*, 659 So. 2d 98, 102 (Ala. 1995); *Hymes v. DeRamus*, 222 P.3d 874, 889 (Alaska 2010); *Cooper Clinic, P.A. v. Barnes*, 237 S.W.3d 87, 91 (Ark. 2006); *Williams v. United States*, 711 F. Supp. 2d 1195, 1206-07 (D. Haw. 2010); *Armstrong v. American Pallet Leasing, Inc.*, 678 F. Supp. 2d 827, 874-75 (N.D. Iowa 2009); *Doe v. D'Agostino*, 367 F. Supp. 2d 157, 176 (D. Mass. 2005); *Murdock v. Higgins*, 559 N.W.2d 639, 646-47 (Mich. 1997); *Becker v. Mayo Found.*, 737 N.W.2d 200, 207 (Minn. 2007); *Bell v. Grow With Me Childcare & Preschool LLC*, 907 N.W.2d 705, 720 (Neb. 2018); *Marquay v. Eno*, 662 A.2d 272, 278 (N.H. 1995); *Paulson v. Sternlof*, 15 P.3d 981, 984 (Okla. Civ. App. 2000); *Doe v. Wal-Mart Stores, Inc.*, 711 S.E.2d 908, 910-11 (S.C. 2011); *Perry v. S.N.*, 973 S.W.2d 301, 304-06 (Tex. 1998); *Sheldon v. Ruggiero*, 202 A.3d 241, 248-49 (Vt. 2018); *A.H. v. Church of God in Christ, Inc.*, 831 S.E.2d 460, 475 (Va. 2019); *Barbina v. Curry*, 650 S.E.2d 140, 145 (W. Va. 2007).

their physicians, and Allergan breached that duty by failing to communicate information to the FDA that would have then been made available to Plaintiffs and their physicians through the MAUDE database. *See* PIC ¶ 199; CAC ¶¶ 206, 423. Such a claim "is actually derived from the independent duty to actively warn potential . . . users, even through disclosure to regulatory bodies." *Richardson*, 2016 WL 4546369, at *8. Accordingly, the Court should not follow cases such as *Potolicchio*, which misconstrue the relevant state-law obligation as a "duty to warn the FDA" distinct from the traditional state-law duty to warn patients or their physicians.[23]

Plaintiffs acknowledge that the Arizona Supreme Court recently held that inadequate reporting to the FDA cannot form the basis of a failure-to-warn claim under Arizona law. *Conklin v. Medtronic, Inc.*, 431 P.3d 571 (Ariz. 2018). Therefore, Plaintiffs for whom Arizona law applies cannot assert a failure-to-warn claim based on a theory of inadequate reporting, though they can pursue failure-to-warn claims based on inadequate labeling and misleading marketing statements. However, as shown by the extensive case law recognizing such a theory, the Arizona Supreme Court's view is against the weight of authority nationwide. Indeed, the Arizona Supreme Court acknowledged that it its holding stemmed from a recent change in Arizona law to repudiate longstanding common-law principles set forth in Section 388 of the Restatement (Second) of Torts. *Id.* at 577-78.[24] No other state high court has followed the

[23] Allergan cites a case reasoning that a reporting-based claim is "entirely 'speculative' because it 'assumed' that FDA would have publicized unreported adverse events." Allergan Br. 28 (quoting *Brooks*, 2019 WL 4628264, at *6). But here, Plaintiffs allege that the FDA's practice is to "publish[] adverse events and MDRs in a public, searchable database called MAUDE and update[] the report monthly with 'all reports received prior to the update.'" PIC ¶ 36. This allegation quotes the FDA's language on the web page for MAUDE. *See* FDA, *MAUDE – Manufacturer and User Facility Device Experience* (Aug. 31, 2020), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

[24] The Arizona Supreme Court further stated in dicta that Section 388 would not support liability for inadequate reporting because a device manufacturer does not have "reasonable

Arizona Supreme Court, and there is no reason to think that any state high court will do so. *See generally* Pls.' Non-Preemption Br., § III.F; Pls.' App. A ("Failure To Warn" section).

Because state-law claims for failure to warn plaintiffs and physicians arising out of inadequate reporting to the FDA have been widely recognized based on established principles of tort law, Allergan's argument (at 29) that *Erie* principles prevent this Court from "invent[ing]" or "concoct[ing]" a new duty falls flat. Allergan cites cases in which the Third Circuit has declined to make "unprecedented" state law holdings that were "not foreshadowed by state precedent." *City of Phila. v. Beretta U.S.A. Corp.*, 277 F.3d 415, 421 (3d Cir. 2002); *Leo v. Kerr-McGee Chem. Corp.*, 37 F.3d 96, 101 (3d Cir. 1994) (refusing to "stretch" governing state law "far beyond its original scope"). By contrast, this case involves the traditional state-law duty to warn plaintiffs and physicians, which as dozens of courts have held, can be violated by failing to report information to the FDA. *Freed*, *Silver*, and *McLaughlin* confirm that recognizing liability for inadequate reporting to the FDA is not precluded in this Circuit. *See generally* Pls.' Non-Preemption Br. § III.A.

If anything, the caution inherent in the *Erie* doctrine counsels against granting Allergan's motion. Allergan urges this Court to make *Erie* guesses that all 50 states would reject failure-to-warn claims based on inadequate reporting to the FDA, even in states where appellate courts have recognized such liability. *See*, *e.g.*, *Coleman*, 167 Cal. Rptr. 3d at 311; *Angeles*, 863 N.W.2d at 419; *Williams v. Bayer Corp.*, 541 S.W.3d at 605-06. Allergan makes this audacious

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assurance" that the FDA will publish adverse event reports such as MDRs. *Conklin*, 431 P.3d at 578. But the court ignored that the FDA has a longstanding practice of publishing MDRs on a monthly basis. *See* PIC ¶ 36; CAC ¶ 206; *supra* note 22; *see also Silver*, 236 F. Supp. 3d at 900 ("We easily conclude that the FDA may be reasonably relied upon to disclose information regarding medical device failures through the publicly accessible database when provided with that information.").

request based on a few pages of briefing in support of a motion to dismiss on an affirmative defense, where Allergan bears the burden of proof.

Should the Court wish to engage in such an exercise in *Erie* guessing, it should follow the dozens of cases cited by Plaintiffs and the Second Restatement. But the Court need not engage in any *Erie* guessing to resolve the preemption motion. Because Allergan does not contend that this theory adds to or differs from federal law, the Court can deny Allergan's preemption motion on the basis that Plaintiffs' reporting-based failure-to-warn claims are not preempted to the extent they are valid under state law. The Court could then defer resolving the case-specific state-law questions until each state's law can be properly briefed on a full record. *See In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, 401 F. Supp. 3d 538, 558 (D. Md. 2019) (rejecting dismissal based on preemption because, "[a]t this stage of the litigation, the plaintiffs have at least plausibly alleged that state law may, in some cases, impose a duty on medical device manufacturers to report adverse events to the FDA").

c. Allergan erroneously argues (at 31) that the Court should disregard allegations that Allergan improperly submitted ASRs regarding BIA-ALCL events rather than MDRs. According to Allergan, "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." But, characterizations aside, Allergan indisputably owes a duty under state law to warn patients or their physicians of product risks. Because the duty runs to Plaintiffs or their physicians, the difference between MDRs and ASRs is crucial. MDRs contain a full narrative description of the event and are published in MAUDE every month. PIC ¶ 36; CAC ¶ 213. ASRs, however, contain only a series of alphanumeric codes (not a narrative description) and were not made publicly available for years. PIC ¶¶ 94-95; CAC ¶¶ 213, 215. Thus, a manufacturer's improper

submission of ASRs rather than MDRs violates both the state law duty to warn patients or their physicians and parallel federal requirements.

2. The claims are not impliedly preempted

Allergan also argues (at 31) that Plaintiffs' claims based on failures to report information to the FDA are impliedly preempted because, according to Allergan, Plaintiffs "rely on the federal statutory scheme as the sole foundation for their alleged duty of care and its breach," "[i]n the absence of any recognized state common-law tort cause of action based on FDA-reporting." That argument fails for the same reason as Allergan's express-preemption argument: Plaintiffs sue not for violating FDA regulations but for violating traditional state-law duties that parallel federal requirements.

As shown above, a wealth of authority confirms that a manufacturer can violate the traditional state-law duty to warn patients and physicians of dangers in its products by failing to report adverse safety information to the FDA, which makes the information publicly available. Because such a claim is "based . . . on traditional state tort law principles," *Buckman*, 531 U.S. at 352, it is not preempted. Plaintiffs are "not . . . suing *because* [Allergan's] conduct violates the FDCA." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010). They are suing because Allergan violated its state-law duty to warn Plaintiffs and their physicians by failing to report adverse safety information to the FDA, which would have included that information in a public database.

In *Hughes*, the Fifth Circuit explained that such claims are "not analogous to the 'fraud-on-the-FDA' theory in *Buckman*." 631 F.3d at 775. "The plaintiffs in *Buckman* were attempting to assert a freestanding federal cause of action based on violation of the FDA's regulations; the plaintiffs did not assert violation of a state tort duty." *Id.* The plaintiff in *Hughes*, like Plaintiffs here, asserted a "tort claim based on the underlying state duty to warn about the dangers or risks

of product" and sought "to prove [the manufacturer's] breach of the state duty by showing that [the manufacturer] violated the FDA's MDR regulations." *Id.* That kind of claim "surviv[es] implied preemption." *Id.*; *accord Waltenburg*, 33 F. Supp. 3d at 840 ("Plaintiffs are alleging a recognized state tort claim based on the underlying state-law duty to warn about the dangers or risks of a product. They seek to prove Defendants' breach of that duty by showing that Defendants violated the applicable federal reporting requirements. As such, . . . Plaintiffs' claim is not impliedly preempted by . . . *Buckman*."). Each of the cases cited by Plaintiffs recognizing a state-law claim based on inadequate reporting to the FDA similarly held that such claims were not impliedly preempted. *See generally supra* pp. 27-30 & n.12.

In the decisions Allergan cites (at 32-35) holding that reporting-based claims are impliedly preempted, the courts based their conclusions on the premise that state law does not recognize such a claim. For example, one case prominently relied on by Allergan reasons: "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." *Brooks v. Mentor Worldwide, LLC*, 2019 WL 4628264, at *6 (D. Kan. Sept. 23, 2019), *appeal filed*, No. 19-3240 (10th Cir. Oct. 24, 2019) (citation omitted). As shown above, ample authority demonstrates the state-law foundation of Plaintiffs' failure-to-warn claims based on inadequate reporting to the FDA.[25] The cases

[25] For example, in applying Missouri law, *Brooks* ignored that the Missouri Court of Appeals has held that there is "a well-established duty imposed on manufacturers by Missouri state law to warn consumers about the risks of using their product," which a device manufacturer may "breach[ ] by failing to meet the post-premarket approval reporting requirements listed in the MDA." *Williams*, 541 S.W.3d at 606.

Allergan cites are unpersuasive and do not support the extraordinary *Erie* guess Allergan asks this Court to make in the context of an omnibus motion to dismiss based on preemption.

C. The FDA's Interpretation Of The MDA Offers An Alternative Basis To Reject Preemption Here

The FDA's interpretation of the MDA provides an additional, independent reason to reject preemption. The FDA has explained that, "[t]o have preemptive force under Section 360k(a), a federal requirement ordinarily must be not only device-specific, but also relevant to the asserted state claim." U.S. Amicus Br. at *10, *Medtronic, Inc. v. Stengel*, No. 12-1351, 2014 WL 2111719 (U.S. May 20, 2014).[26] Thus, PMA approval only has preemptive effect with respect to "any claim alleging in substance that FDA should have conditioned its approval on adopting some other design, manufacturing specification, or labeling." *Id.* at *12. That PMA does not preempt claims that "attack [a manufacturer's] conduct *after* its device received premarket approval." *Id.* For example, a claim for "failure to make a CBE revision to the device's labeling" based on information that arose after approval is not preempted. *Id.*

Under the FDA's analysis, Plaintiffs' claims are not preempted. None of Plaintiffs' claims as to premarket-approved implants attack the PMA itself. Rather, all such claims stem from Allergan's failures after PMA—specifically, the failure to warn adequately as information emerged connecting BIOCELL implants to BIA-ALCL, and the failure to manufacture the implants in line with the PMA's specifications and requirements.

Courts have not gone as far as the FDA in concluding that post-PMA claims are not subject to preemption. *Cf.*, *e.g.*, *Shuker*, 885 F.3d at 767-68. Even so, Plaintiffs submit that the

[26] The Solicitor General (joined by the General Counsel of the FDA's parent agency, the Department of Health and Human Services) filed this brief on behalf of the United States and at the Supreme Court's invitation. The brief "represents the views of the FDA." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 n.3 (2011).

FDA correctly construed the relevant statutes, regulations, and governing Supreme Court precedent. Although this Court need not adopt the FDA's analysis to deny Allergan's motion, that analysis provides an independent basis to reject preemption.

III. PLAINTIFFS' MANUFACTURING-DEFECT CLAIMS ARE NOT PREEMPTED

A. Plaintiffs Assert Valid Manufacturing-Defect Claims That Parallel Violations Of Federal Law

Plaintiffs allege that their BIOCELL implants were rendered defective and unreasonably dangerous because they deviated from Allergan's design specifications and the specifications and processes incorporated into the PMAs and the FDA's regulations. PIC ¶¶ 148-151; CAC ¶¶ 168-181. For example, Plaintiffs allege that the surface of their implants contained debris, including silicone particles, which when implanted into Plaintiffs' bodies exerted forces on the surrounding tissue that caused chronic inflammation and created a risk of BIA-ALCL. PIC ¶¶ 118-119, 126-127, 129-130, 135, 143, 149 152, 159, 161; CAC ¶¶ 14-15, 169-170, 188, 2154. This debris was not an intended part of the design for BIOCELL implants; rather, the debris constituted one example of the deviations from Allergan's FDA-approved specifications, which called for the surface of the implants to be scrubbed clean of solid particles. PIC ¶¶ 117, 118, 143, 149; CAC ¶¶ 13-14, 168-169.

Plaintiffs' manufacturing-defect claims are not expressly preempted because the state-law duties that Allergan violated parallel federal requirements. The manufacturing defects alleged in Plaintiffs' complaints deviated from the PMA specifications, and violated many federal CGMPs applicable to the BIOCELL devices. Most notably, Allergan violated a CGMP that requires "removal of . . . manufacturing material" that can have an adverse effect on quality, such as the debris that Allergan failed to remove from Plaintiffs' implants. 21 C.F.R. § 820.70(h); PIC ¶ 135; CAC ¶ 177; *see also Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 441 (6th Cir.

2010) (21 C.F.R. § 820.70(h) requires "actual removal" of manufacturing material). Plaintiffs also allege violations of CGMPs requiring Allergan to test its products, PIC ¶ 132 (citing 21 C.F.R. § 820.30); CAC ¶ 175, monitor production processes to ensure that products conform to specifications, PIC ¶ 134 (citing 21 C.F.R. § 820.70); CAC ¶¶ 176-177, maintain procedures to identify and dispose of products that fail to conform to specifications, PIC ¶ 136 (citing 21 C.F.R. § 820.90); CAC ¶ 179, implement preventive and corrective actions in response to recurring quality problems, PIC ¶ 137 (citing 21 C.F.R. § 820.100(a)); CAC ¶ 180, establish procedures for quality audits, PIC ¶ 138 (citing 21 C.F.R. § 820.22); CAC ¶ 174, and adequately inspect, test, and validate products, PIC ¶ 139 (citing 21 C.F.R. § 820.160).

In addition, Plaintiffs allege that these manufacturing defects rendered the BIOCELL implants adulterated, in violation of the FDCA. PIC ¶¶ 129-31; CAC ¶¶ 14, 190; 21 U.S.C. § 351(a)(2)(A) (device is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health"); 21 U.S.C. § 351(h) (violations of CGMPs render a device adulterated); 21 U.S.C. § 331(a) (FDCA prohibits sale of adulterated devices).

Plaintiffs also allege that "[t]he precise provisions of the PMAs, and the design and manufacturing specifications, and specified processes, are in the exclusive control of Allergan and regulatory bodies and have not been provided to Plaintiffs." PIC ¶ 143. Plaintiffs therefore "reserve the right to amend" their manufacturing-defect allegations "with additional facts and allegations once Allergan produces all of its PMA files and specifications and manufacturing records for the BIOCELL line of products." PIC ¶ 143. As the Seventh Circuit held, it would be unreasonable to demand greater specificity at the pleading stage because "[t]he specifications of the FDA's premarket approval documents, for example, are confidential, and there is no public

access to complete versions of these documents. An injured patient cannot gain access to that information without discovery." *Bausch*, 630 F.3d at 560.

Even so, Plaintiffs supported their manufacturing-defect claims with detailed factual allegations. For example, Plaintiffs alleged that a French government inspection of Allergan's manufacturing facilities found extensive deviations from proper manufacturing processes, *see* PIC ¶¶ 121-125; CAC ¶¶ 182-187, and that U.S. researchers found surface debris in a study of new BIOCELL implants, *see* PIC ¶ 126; CAC ¶ 188.

The Eleventh Circuit recently concluded that the MDA did not preempt an analogous manufacturing-defect claim. In *Mink*, the plaintiff "allege[d] that [the manufacturer] violated the Florida common law duty to use due care in manufacturing a medical device. This duty is parallel to the federal requirement that the [device] be manufactured according to the approved specifications for the medical device. . . . So Florida law does not impose any different or additional requirement on the device." 860 F.3d at 1330. Quoting *Lohr*, the court explained that "Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* (quoting *Lohr*, 518 U.S. at 495). "In sum, this claim is precisely the type the Supreme Court has told us survives express preemption." *Id.* at 1331; *accord Godelia*, 881 F.3d at 1319 ("Mr. Godelia reiterates that his claims 'are premised only on Zoll's violations of federal regulations, which also caused a violation of Florida's common law duty to use due care in manufacturing the LifeVest.' This Court recognized in *Mink* that both Florida negligence and strict liability claims based on manufacturing defects can survive express preemption.") (emphasis omitted). The same conclusion applies here.

Furthermore, because Plaintiffs' manufacturing-defect claims rest on traditional state-law duties (to manufacture with reasonable care and free of defect), they are not impliedly preempted. As the Seventh Circuit reasoned, such claims, "like those in *Lohr*, and unlike those in *Buckman*, are tort law claims based on manufacturing defects, not fraud on a federal agency." *Bausch*, 630 F.3d at 557. There is "no way in which" manufacturing-defect claims "conflict with the federal regulations," and thus there is "no reason for them to be impliedly preempted." *Id.*; *see also Silver*, 236 F. Supp. 3d at 898 ("easily reject[ing]" argument that manufacturing-defect claims were impliedly preempted "because the common law tort claims arise from the manufacturer's alleged failure to use reasonable care in the production of a product, not solely FDA violations").

The Sixth Circuit has accordingly rejected preemption for a claim much like Plaintiffs' claims here, for failure to remove manufacturing residue from a medical device. As in this case, the *Howard* plaintiff alleged that the manufacturer "failed to remove the . . . residue that the . . . manufacturing process left behind," which rendered the devices dangerous. 382 F. App'x at 438. As in this case, the *Howard* plaintiff alleged that the manufacturer violated 21 C.F.R. § 820.70(h) by failing to remove the residue. 382 F. App'x at 440. The court held that this regulation required "actual removal" of manufacturing material. *Id.* at 441. Thus, the plaintiff's claims were not preempted because "a state may provide a damages remedy for violations of an identical state requirement." *Id.* If anything, Plaintiffs' arguments against preemption are stronger than the argument that prevailed in *Howard* because Plaintiffs allege not only violations of 21 C.F.R. § 820.70(h), but also violations of numerous other federal requirements.

Reported decisions are virtually unanimous in concluding that federal law does not preempt claims that a device was defectively manufactured in violation of federal requirements.

See, *e.g.*, *Bass v. Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012) ("Bass has sufficiently pleaded parallel claims in his first amended complaint, to the extent that the claims are based upon manufacturing defects resulting from violations of federal regulations."); *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1248 (7th Cir. 1997) ("The heart of Chambers' negligent manufacturing claim is that Osteonics did not follow the FDA requirements or agreed-upon procedures . . . Such a claim should not be preempted because there is no reason to protect a manufacturer who fails to follow the proscribed requirements and procedures for producing a device[.]"); *Mize v. Mentor Worldwide LLC*, 265 Cal. Rptr. 3d 468, 476-77 (Cal. Ct. App. 2020) ("Mize's manufacturing defect claims are premised, at least in part, on Mentor's alleged failure to comply with manufacturing requirements imposed by the FDA. . . . Mize does not seek to enforce any exclusively federal requirement; her claims are predicated on violations of state tort law. . . . There is thus no conflict with section 337(a), and no implied preemption under *Buckman*."); *Jones for Jones v. Medtronic, Inc.*, 2018 WL 1462169, at *4 (Minn. Ct. App. Mar. 26, 2018) ("Jones's manufacturing-defect claim is parallel to the requirements of the FDCA and the claim survives express preemption. Additionally, the claim survives implied preemption because it is rooted in traditional Minnesota tort law that would entitle Jones to recovery even in the absence of the FDCA."); *Allo v. Allergan USA, Inc.*, 2020 WL 814855, at *3 (E.D. La. Feb. 19, 2020) ("She says that Allergan's implant product was defective in construction or composition because it did not meet FDA regulations governing shell thickness. Because this claim is premised on Allergan's alleged violation of FDA regulations, it is a permissible parallel claim that is not preempted by 21 U.S.C. § 360k(a)."); *Bledsoe v. Medtronic, Inc.*, 2020 WL 43107, at *7 (N.D. Ind. Jan. 3, 2020) ("to the extent the Plaintiff's Complaint alleges that his injuries were caused by a manufacturing defect in the production of his medical device *and* that

the defect was caused by a violation of the federal requirements, his claim is properly pled and not preempted"); *Frere v. Medtronic, Inc.*, 2016 WL 9455137, at *6 (C.D. Cal. June 1, 2016) ("Plaintiff's manufacturing defect claims are 'not preempted insofar as [they] allege[] that the manufacturing of the device both fell short of the FDA's requirements for manufacturing and—based on the same deficiency—was defectively manufactured under California law.'").[27]

[27] *See also Caton v. Stryker Sustainability Sols., Inc.*, 2015 WL 12426110, at *4 (C.D. Cal. May 12, 2015) (rejecting preemption for claim that device "deviated from the product the FDA approved in the PMA because the cup and cap of the [device] were not adequately coated, causing the device to 'shed debris and cause[] cobalt and chromium poisoning'"); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 156 (S.D.N.Y. 2011) (rejecting preemption for claim that device "was adulterated because some of the components, as a result of the manufacturing process, contained excess levels of manufacturing residue"); *Rowe v. Mentor Worldwide, LLC*, 297 F. Supp. 3d 1288, 1299 (M.D. Fla. 2018) (manufacturing defect claim "not . . . preempted" because "the Florida common law duty to use due care in manufacturing is parallel to the federal requirement that a device be manufactured according to federal specifications"); *Grant v. Corin Grp. PLC*, 2016 WL 4447523, at *4 (S.D. Cal. Jan. 15, 2016) ("This manufacturing defect negligence claim is not preempted because the state law duty of care in the manufacture of the Cormet System is 'parallel' to the FDA-Imposed manufacturing requirements."); *Eggerling*, 958 F. Supp. 2d at 1038 ("The Eggerlings *have* made the appropriate allegations that the cochlear implant that their daughter received was not manufactured in compliance with AB's PMA Supplement, and they have alleged and generated genuine issues of material fact that such manufacturing defects caused their harm. Thus, they have alleged a manufacturing defect within the meaning of Iowa law, and their manufacturing defect claims are, to this extent, non-preempted 'parallel' state-law claims."); *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 106 (D. Conn. 2014) ("McConologue has pleaded sufficient facts to find that his injury plausibly resulted from a violation of FDA manufacturing standards, resulting in a fractured Liner, in connection with his manufacturing defect claims. He has thus successfully pleaded a parallel manufacturing defect claim that is not preempted by § 360k."); *Bausch*, 630 F.3d at 555-57; *Mink*, 860 F.3d at 1330-31; *Godelia*, 881 F.3d at 1319; *Silver*, 236 F. Supp. 3d at 898; *Littlebear v. Advanced Bionics, LLC*, 896 F. Supp. 2d 1085, 1092 (N.D. Okla. 2012); *Warren v. Howmedica Osteonics Corp.*, 2010 WL 5093097, at *5-6 (E.D. Mo. Dec. 8, 2010); *Sadler*, 929 F. Supp. 2d at 685-86; *Purchase*, 896 F. Supp. 2d at 697; *Green v. Medtronic, Inc.*, 2020 WL 4577713, at *3 (N.D. Ga. May 1, 2020); *Cline*, 17 F. Supp. 3d at 1285; *Purcel v. Advanced Bionics Corp.*, 2008 WL 3874713, at *3 (N.D. Tex. Aug. 13, 2008); *Rosen*, 41 F. Supp. 3d at 181-82; *Williams*, 123 F. Supp. 3d at 743; *Fisk*, 2017 WL 4247983, at *6; *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901, 908 (S.D. Ohio 2012); *Simoneau v. Stryker Corp.*, 2014 WL 1289426, at *6 (D. Conn. Mar. 31, 2014); *Gray v. Stryker Corp.*, 2013 WL 633120, at *4 (S.D. Ind. Feb. 20, 2013); *Sumpter v. Allergan Inc.*, 2018 WL 4335519, at *2 (E.D. Mo. Sept. 11, 2018); *Elmore v. Smith & Nephew, Inc.*, 2013 WL 1707956, at *3 (N.D. Ill. Apr. 19, 2013); *Raab v. Smith & Nephew, Inc.*, 150 F. Supp. 3d 671, 692-93 (S.D. W. Va. 2015); *Waltenburg*, 33 F. Supp. 3d at

B. Allergan's Preemption Arguments Rest On Mischaracterizations Of Plaintiffs' Claims

In light of the numerous decisions rejecting preemption for manufacturing-defect claims, Allergan concedes, as it must (at 39), that manufacturing-defect claims "can fit through the . . . gap between express and implied preemption" where plaintiffs assert a state-law manufacturing-defect claim based on conduct that violates a federal requirement. That is what Plaintiffs did here. To avoid the fatal import of its concession, Allergan resorts to mischaracterizing Plaintiffs' claims and allegations.

Allergan erroneously asserts that "there are no allegations that Allergan's breast implants deviated from their FDA-approved design" and that "Plaintiffs' allegations are not attacking a deviation from the approved design but rather the design itself." Allergan Br. 39-40; *see also id* at 40 ("*nowhere* do [Plaintiffs] allege that any device deviated from an FDA-approved manufacturing process and attendant FDA-approved device specifications"). In fact, Plaintiffs allege that Allergan's and the FDA's specifications called for implants scrubbed clean of foreign residue, but Allergan produced implants that deviated from those specifications because the surfaces of the implants contained debris. For example, Plaintiffs alleged in the Master Complaint:

- Allergan's approved salt loss technique required "manually scrubbing the implant with brushes in an effort to remove all solid particles and reveal the textured surface," but instead, Allergan used a scrubbing technique that "was inherently and excessively variable and uncontrolled." PIC ¶¶ 117-118.

835-36; *Tillman v. Smith & Nephew, Inc.*, 2013 WL 3776973, at *3 (N.D. Ill. July 18, 2013); *Freed*, 364 F. Supp. 3d at 362-63; *Bailey v. Medtronic, Inc.*, 2017 WL 6035329, at *7 (S.D. Ind. Dec. 6, 2017); *Womack v. Nevro Corp.*, 2019 WL 5722569, at *2 (M.D. Fla. Sept. 23, 2019); *Williams v. St. Jude Med., S.C., Inc.*, 2017 WL 11113322, at *8 (N.D. Ga. Oct. 19, 2017); *Hofts*, 597 F. Supp. 2d at 836-37; *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 799 (W.D. La. 2008); *Knoth v. Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 692-93 (S.D. Miss. 2019); *Halsey v. Smith & Nephew, Inc.*, 2014 WL 12717702, at *8 (D. Vt. Feb. 4, 2014); *Burgos v. Satiety, Inc.*, 2011 WL 1327684, at *4 (E.D.N.Y. Apr. 5, 2011).

- "Allergan's uncontrolled and un-validated scrubbing process resulted in final products that did not meet the PMA requirements or Allergan's own design and manufacturing specifications. For example, Allergan's uncontrolled and un-validated manufacturing processes created a 'particle laden' environment on the implant surface which exposed patients to particles that caused chronic inflammation and caused or contributed to the development of ALCL." PIC ¶ 118.

- Because defectively manufactured BIOCELL implants contained "unintended particle residue," they were "different than the product approved by the FDA, causing severe harm to patients." PIC ¶ 118.

- In violation of federal regulations, Allergan failed to establish validation procedures, establish quality procedures for contractors, monitor production processes, remove manufacturing materials and debris, establish procedures for removing defective and nonconforming products, establish procedures for correcting recurring quality problems, establish procedures for quality audits, and conduct adequate testing and inspection of its products. PIC ¶¶ 132-139. A French government inspection of Allergan's facilities revealed many "critical" and "major" "deviations" from standards and legal requirements. PIC ¶¶ 121-125.

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

- BIOCELL implants were "defectively manufactured in violation of applicable specifications, the PMA design and manufacturing specifications, QSRs and CGMPs, and other state and federal requirements as discussed supra, including 21 C.F.R. § 820." PIC ¶ 148.

The Class Complaint contains similar allegations. *See*, *e.g.*, CAC ¶¶ 168-181, 2188-2195.

When Plaintiffs' allegations are properly understood, the cases cited by Allergan compel rejection of its preemption defense. For example, in *Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485 (W.D.N.C. 2017), the court acknowledged that manufacturing-defect claims "survive preemption" where the plaintiff "allege[s] that the device was not made in accordance with the specifications approved by the FDA," but the court dismissed the claim because the "plaintiff ha[d] not linked any manufacturing deficiency to the device that the plaintiff received and how it caused the alleged injuries." *Id.* at 493. Similarly, in *Funk v. Stryker Corp.*, 631 F.3d 777 (5th Cir. 2011), the court dismissed a "conclusory and vague" claim that "d[id] not specify the

manufacturing defect" or explain "how it deviated from the FDA approved manufacturing process," but the court indicated that a claim would survive if it specified "what went wrong in the manufacturing process and cite[d] the relevant FDA manufacturing standards Stryker allegedly violated." *Id.* at 782. In *Morton v. Allergan, Inc*., the court recognized that manufacturing-defect claims based on violations of federal regulations "at least potentially set forth a state-law claim based on a violation of federal law that would fall within the 'parallel claim' exception to preemption." *See* 2015 WL 12839493, at *5 (D.N.J. Apr. 2, 2015). The court dismissed the claim only because it "offer[ed] little more than labels and conclusions." *Id.* And in *D'Addario v. Johnson & Johnson*, 2020 WL 3546750 (D.N.J. June 30, 2020), the court dismissed a manufacturing-defect claim for failure to allege a violation of an FDA requirement, but granted plaintiffs leave to amend to "flush out th[e] theory" that the defendant violated the FDA's CGMP regulations. *Id.* at *4.

Here, Plaintiffs have alleged a manufacturing defect violating FDA requirements that those courts indicated would be sufficient to avoid preemption. Further detail would require access to Allergan's confidential PMA documents, which Plaintiffs have thus far not received. As the Seventh Circuit held in *Bausch*, Plaintiffs "pled sufficiently given the amount of information to which [they] had access." 630 F.3d at 561. Allergan's other cases similarly do not support preemption.[28]

[28] *See Delaney v. Stryker Orthopaedics*, 2009 WL 564243, at *6 (D.N.J. Mar. 5, 2009) (holding claim preempted where "[n]o facts have been asserted to support the bald allegation that the [medical device malfunctioned] because of a manufacturing defect"); *Chester v. Bos. Sci. Corp.*, 2017 WL 751424, at *9 (D.N.J. Feb. 27, 2017) (claims dismissed because plaintiffs failed to make "plausible pleading of if, how, or when Defendants violated any of the listed regulations"); *Mendez v. Shah*, 94 F. Supp. 3d 633, 638-39 (D.N.J. 2015) (observing that "citing to the FDA's [CGMP] . . . could present a parallel federal claim" but dismissing for failure to identify which regulations were violated); *Becker v. Smith & Nephew, Inc*., 2015 WL 268857, at *3 (D.N.J. Jan. 20, 2015) (dismissing for failure to allege elements of claim; no mention of

Allergan also argues that Plaintiffs' claims are not really manufacturing-defect claims, but are instead "disguised" design-defect claims, because Plaintiffs purportedly do not allege "that Allergan's implants deviated from the norm." Allergan Br. 43; *see also id.* at 41 (suggesting that manufacturing defects must be " 'aberrational' defects" that do not "occur[ ] throughout an entire line of products"). But tort law does not require "deviation from the norm" as an element of a manufacturing-defect claim. Rather, "[a] product contains a manufacturing defect when the product departs from its intended design." Restatement (Third) of Torts: Product Liability § 2(a) (1998) ("Restatement (Third)"). Most states "explicitly provide a *two-pronged definition of manufacturing defect* which allows a plaintiff to establish defectiveness by *either of two alternative methods of proof*: comparing the accident-product unit to the manufacturer's formal design specifications or to the dimensions and other parameters of some otherwise identical product." David G. Owen, *Manufacturing Defects*, 53 S.C. L. Rev. 851, 870 (2002) (emphases added). A manufacturing defect need not be "aberrational," as Allergan suggests (at 41): "One can certainly conceive of situations in which a manufacturer's shoddy workmanship . . . produces a defect that occurs throughout an entire line of products." *Mitchell v. Lone Star Ammunition, Inc.*, 913 F.2d 242, 247 n.10 (5th Cir. 1990).[29] Thus, a manufacturer does not inoculate itself against liability by repeating a manufacturing defect en masse. Plaintiffs further respond to this argument in their non-preemption response brief and accompanying

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preemption); *Smith v. Depuy Orthopaedics, Inc*., 2013 WL 1108555, at *13 (D.N.J. Mar. 18, 2013) (dismissing claim for failure to adequately plead violation of federal requirements), *aff'd in part*, 552 F. App'x 192 (3d Cir. 2014).

[29] *Harduvel v. General Dynamics Corp.*, 878 F.2d 1311 (11th Cir. 1989), cited by Allergan (at 41-42), is not to the contrary. *Harduvel* recognized that "[t]o say that a product failed to conform to specifications is just another way of saying that it was defectively manufactured." *Id.* at 1321. In other words, where, as here, plaintiffs allege that products were defective because of deviations from specifications, the claim is for a manufacturing defect.

appendix, and incorporate that discussion here. *See* Pls.' Non-Preemption Br. § III.D; Pls.' App. A ("Manufacturing Defect" section).

Even if "deviation from the norm" were required, Plaintiffs alleged such deviations. Allergan's scrubbing of the implant surfaces was "excessively variable and uncontrolled," PIC ¶ 118, resulting in "inconsistent texturing," PIC ¶¶ 129, 130, and implants with "variable roughness," PIC ¶¶ 149, 161; *see also* CAC ¶¶ 14, 163, 169, 171, 2151, 2153. While each of the implants may have suffered from the same general types of defect (e.g., unintended surface debris), Plaintiffs allege that each implant deviated from the norm in its own way.

Allergan's workmanship was so shoddy that it caused widespread manufacturing defects. Plaintiffs alleged that their implants were defective because of deviations from Allergan's specifications and the FDA's requirements, and that suffices to state a non-preempted manufacturing-defect claim.

C. Plaintiffs Properly Asserted Manufacturing-Defect Claims Parallel To The FDCA's Adulteration Provisions

Plaintiffs' manufacturing-defect claims also parallel the FDCA's prohibition on marketing an adulterated device. *See* 21 U.S.C. § 331(a) (prohibiting sale of adulterated devices); § 351 (defining adulteration). Allergan argues (at 45-47) that Plaintiffs' claims are impliedly preempted to the extent that they include allegations that BIOCELL devices are adulterated in violation of the FDCA. According to Allergan, "Plaintiffs' 'adulteration' allegations do not resemble any common law manufacturing defect claim and exist solely by virtue of FDA requirements." Allergan Br. 47. Allergan is incorrect.

Plaintiffs allege that the BIOCELL implants were adulterated because of the same conduct that forms the core of Plaintiffs' state-law manufacturing-defect claims. Specifically, the devices were adulterated because they contained unintended surface debris, thereby departing

from Allergan's specifications, and because Allergan violated several federal CGMPs, causing the deviations from specifications. *See* PIC ¶¶ 129, 130, 135; CAC ¶¶ 14, 172, 190; 21 U.S.C. § 351(a)(2)(A) (device is adulterated if it has been "prepared . . . under insanitary conditions whereby it may have been contaminated with filth"); 21 U.S.C. § 351(h) (violation of CGMPs renders device adulterated). Thus, the implants were adulterated because of the same facts that support liability under the state-law principle imposing liability on a seller of a defectively manufactured product. *See* Restatement (Third) §§ 1, 2(a).

There is no "adulteration exception" to the general rule that a state-law tort claim that parallels federal requirements is not preempted. The Seventh Circuit rejected a similar preemption argument in *Bausch*. There, the defendants argued that "Bausch's claim that the medical device was 'adulterated' must be impliedly preempted because there is simply no state tort duty to manufacture a product that is not adulterated." 630 F.3d at 557. The Court "disagree[d]," explaining that "the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law. The evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient." *Id.* Many other cases recognize that *Buckman* does not bar manufacturing-defect claims that parallel the federal adulteration provision. *See*, *e.g.*, *Bass*, 669 F.3d at 510, 514 (claim for manufacturing defect caused by violations of FDA regulations that rendered device adulterated not impliedly preempted because "[t]his case is premised on state-law tort claims rather than any duties independently created by FDA regulations"); *Jones*, 2018 WL 1462169, at *4; *Silver*, 236 F. Supp. 3d at 898-99; *Gelber*, 788 F. Supp. 2d at 156; *Purcel*, 2008 WL 3874713, at *3-5.

Allergan's cases do not hold otherwise. Rather, Allergan cites cases holding that plaintiffs cannot state a non-preempted claim merely by showing that a device is adulterated, without showing that the manufacturer also violated a state-law duty. For example, in *Perez v. Nidek Co.*, the Court held that a failure to disclose that the FDA had not approved a device for a particular kind of surgery was impliedly preempted because it "exist[s] solely by virtue of the FDCA . . . requirements," unlike non-preempted claims that "ar[i]se from the manufacturer's alleged failure to use reasonable care in the production of the product." 711 F.3d 1109, 1119 (9th Cir. 2013) (alterations in original).[30] The Third Circuit's decision in *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir. 1994), is even further afield. There, the court held that a claim was expressly preempted because it sought to impose disclosure requirements on the manufacturer that went beyond federal requirements. *Id.* at 543-44. While the plaintiff argued that the device was adulterated, the court noted that the "record does not contain any facts to support such a claim" of adulteration, and concluded that a plaintiff "cannot overcome a finding of preemption merely by *claiming* that the product was adulterated." *Id.* at 544 (emphasis added). *Gile*, which was decided before the Supreme Court recognized the validity of parallel claims in *Lohr* and *Riegel*, does not support preemption for traditional state-law manufacturing-defect claims that parallel the FDCA's adulteration provisions.

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[30] *See also*, *e.g.*, *Barnes v. Howmedica Osteonics Corp.*, 2010 WL 11565343, at *15 (N.D. Ala. Dec. 14, 2010) (rejecting claim that a device was adulterated due to violations of "technical, administrative" regulations, where such violations "would not give rise to such tort liability if the FDCA or the regulatory regime created pursuant to it had never existed"); *Martin v. Medtronic, Inc.*, 2017 WL 825410, at *7 (E.D. Cal. Feb. 24, 2017) (claims "rest[ed] entirely on defendants' alleged violation of federal requirements" regarding adulteration, but only made "conclusory" allegations of violation of parallel state law); *Sadler*, 929 F. Supp. 2d at 685 n.20 (claim that device was adulterated because of "violation of an administrative obligation" to file paperwork with the FDA was impliedly preempted, because this was "a disguised claim to privately enforce the federal law" that was not based in violation of any state law duty).

IV. PLAINTIFFS' REMAINING CLAIMS ARE NOT PREEMPTED

A. Plaintiffs' Misrepresentation-Based Claims Are Not Preempted

Plaintiffs assert several claims based on Allergan's misrepresentations, including negligent misrepresentation, breach of express warranty, and breach of state consumer-fraud and deceptive-trade-practice statutes. Plaintiffs' failure-to-warn claims likewise encompass the theory that Allergan's false and misleading statements rendered Allergan's warnings of BIA-ALCL inadequate. Allergan's brief contains no argument that Plaintiffs' misrepresentation-based claims are preempted. Therefore, Allergan has waived any preemption argument as to those claims. *See Cobra Enters., LLC v. All Phase Servs., Inc.*, 2020 WL 2849892, at *1 (D.N.J. June 1, 2020) ("this Court will not accept arguments offered for the first time in the reply brief, as they were not properly asserted in the opening brief and Plaintiffs have not had the opportunity to respond to them").

In any event, the claims are not preempted. They are traditional state-law claims resting on two forms of misconduct that parallel violations of federal law: Allergan wrongly concealed or omitted information about the dangers of BIA-ALCL, *see*, *e.g.*, PIC ¶¶ 221, 224; CAC ¶¶ 5858-5859, 5864, and Allergan affirmatively misrepresented the safety of BIOCELL implants in advertising statements outside of the labeling, *see*, *e.g.*, PIC ¶¶ 76, 97-104, 208, 214, 221, 224, 246, 247; CAC ¶¶ 5858-5859.

Insofar as these claims rest on concealment or omission, they are not preempted for the same reasons Plaintiffs' failure-to-warn claims are not preempted. *See supra* Part II. Like the failure-to-warn claims, these claims hinge on Allergan's failure to disclose adequately the risks of BIA-ALCL, which violated parallel federal requirements. Moreover, Plaintiffs' claims are not impliedly preempted because the duty to disclose arises under state law, independently of federal requirements. *See*, *e.g.*, PIC ¶ 229; CAC ¶ 5864.

Plaintiffs' claims based on affirmative misrepresentations likewise are not preempted. These claims are based solely on voluntary statements that were not required by the FDA's PMA orders or otherwise approved by the FDA. *See* PIC ¶¶ 96, 102, 103, 246, 248, 250; CAC ¶¶ 221, 224, 225. For example, Allergan falsely represented that a patient is more likely to be struck by lightning and twice as likely to be struck by an asteroid as to develop ALCL. PIC ¶ 102; CAC ¶ 224. State-law requirements prohibiting such misrepresentations are not expressly preempted because they parallel the federal misbranding statute—which prohibits "advertising" that "is false or misleading in any particular," 21 U.S.C. § 352(q).[31] Plaintiffs' misrepresentation claims are not impliedly preempted because they rest on state-law duties that exist independently of federal requirements: duties to warn adequately of a product's dangers, PIC ¶ 204, to exercise reasonable care to avoid making negligent misrepresentations, *see* PIC ¶¶ 221, 229, to honor express warranties, *see* PIC ¶¶ 247-248, 251, and to abide by state statutes prohibiting consumer fraud and deceptive trade practices, *see*, *e.g.*, CAC ¶¶ 5857, 5881-5882.

Binding precedent from the Third Circuit holds that state-law tort claims based on misleading advertising or marketing statements are not preempted. In *Shuker*, plaintiffs alleged that the manufacturer engaged in "misleading" marketing statements about the safety and capabilities of the device. 885 F.3d at 777. The court held that such a claim was not preempted because the manufacturer allegedly "breached its duty under federal law [21 U.S.C. § 352(q)] not to advertise its medical device in that misleading manner." 885 F.3d at 777. The allegations were thus sufficient to "escape express preemption as a parallel claim." *Id.* at 776.

Many other courts have similarly recognized that claims based on false or misleading advertising or marketing statements outside of approved labeling are not preempted. "[W]hen a

[31] This provision applies to "any restricted device." 21 U.S.C. § 352(q). The FDA's PMAs for BIOCELL implants stated that the implants were restricted devices. PIC ¶ 55.

claim challenges a warranty that goes above and beyond any guarantee the FDA expressly or implicitly approved, it is a parallel one." *Wildman v. Medtronic, Inc.*, 874 F.3d 862, 868 (5th Cir. 2017). Such a claim "is parallel because . . . federal law requires that representations about medical devices be truthful." *Id.* (citing prohibition on "false or misleading advertising" in § 352(q)(1)). Another case prominently cited by Allergan held that failure-to-warn claims based on non-labeling misrepresentations "are neither expressly nor impliedly preempted" because they "parallel the federal requirements regarding misbranding: both prohibit the omission of material risks of the device when marketing a product." *Norabuena*, 86 N.E.3d at 1207-08.[32]

Furthermore, several courts (including one in this District) have held that express warranty claims are not preempted because "a breach of express warranty does not implicate a state action (but is rather a voluntary commitment between two contracting parties) and does not seek to enforce a requirement different from, or in addition to, federal requirements." *Huber v.*

[32] *See also Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1058 (N.J. 2012) ("to the extent the breach of express warranty claim is based on voluntary statements, i.e., statements not approved by the FDA or mandated by the FDA about the use or effectiveness of the product for on-label or off-label uses, a breach of express warranty claim may proceed because federal law requires any warranty statement to be truthful and accurate"), *abrogated on other grounds by McCarrell v. Hoffmann-La Roche, Inc.*, 153 A.3d 207 (N.J. 2017); *Rose*, No. MRS-L-265-20, at 15 ("to the extent that breach of express warranty claims are based on voluntary statements (not app[r]oved or mandated by the FDA) a breach of express warranty claim may proceed because federal law requires any warranty statements to be truthful and accurate"); *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 743 (D. Md. 2015) (breach of warranty claim not preempted "to the extent that it is based on those statements made in voluntary communications with the medical profession or the public . . . because federal law already requires [Smith & Nephew] to ensure that any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law"); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 704 (S.D. Tex. 2014) ("[M]aking false or misleading statements about medical devices is prohibited by federal law. This means that Schouest's state law fraud claims based on false off-label promotion would, if proven, also amount to a violation of federal law, and thus such claims could survive preemption."); *Bayer*, 2020 WL 4811506, at *7-8; *Ramirez*, 961 F. Supp. 2d at 991-92; *Westmoreland v. Medtronic, Inc.*, 2017 WL 5132669, at *3 (E.D. Mo. Nov. 6, 2017); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1042 (D. Haw. 2014); *Smith & Nephew Birmingham*, 401 F. Supp. 3d at 560; *Knoth v. Apollo Endosurgery US, Inc.*, 425 F. Supp. 3d 678, 695 (S.D. Miss. 2019).

Howmedica Osteonics Corp., 2008 WL 5451072, at *4 (D.N.J. Dec. 31, 2008).[33] Allergan cannot avoid liability for its voluntary, non-PMA misrepresentations about the safety of BIOCELL implants, which violated both state and federal law.

B. Plaintiffs' Claims For Breach Of The Implied Warranty Of Merchantability Are Not Preempted

Allergan does not argue that Plaintiffs' claims based on the implied warranty of merchantability are preempted, and accordingly has waived any such argument. *See Cobra Enters.*, 2020 WL 2849892, at *1. In any event, these claims are not preempted because they parallel violations of federal law. "[A]n implied warranty claim is not preempted if the plaintiff alleges that the defendant violated federal requirements *and* can ultimately show a causal link between the violation and the breach of the implied warranty." *Bass*, 669 F.3d at 517; *see also id.* at 516-17 (collecting cases). Plaintiffs allege that the BIOCELL implants were not merchantable because of the violations of federal requirements regarding manufacturing and labeling discussed above. *See* PIC ¶¶ 240; CAC ¶¶ 5620-23. Thus, their implied warranty claims are not preempted.

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[33] *See also Godelia*, 881 F.3d at 1322 ("Because Mr. Godelia's claims for fraudulent misrepresentation, negligent misrepresentation, fraudulent marketing and promotion, and breach of express warranty are traditional state-law claims and address promises made by ZOLL rather than imposed by the state, we conclude that these claims are not impliedly or expressly preempted"); *Cline v. Advanced Neuromodulation Sys., Inc.*, 914 F. Supp. 2d 1290, 1299 (N.D. Ga. 2012) ("Moreover, this claim for breach of express warranty is not based on a coercive or regulatory state law 'requirement' under the language of § 360k(a). Rather, it is based on an obligation that Defendant has freely imposed on itself. The 'requirement[s] imposed by an express warranty claim are not imposed under State law, but rather imposed *by the warrantor*.' ") (quoting *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 525 (1992)) (brackets in original); *Lafountain v. Smith & Nephew, Inc.*, 2016 WL 3919796, at *6 (D. Conn. July 18, 2016) ("Breach of express warranty is not 'categorically preempted' even in cases of Class III medical devices because the MDA do not prohibit a manufacturer from imposing upon itself contractual standards that differ from federal requirements.").

C. Plaintiffs' Claim for General Negligence and Negligence Per Se Is Not Preempted

Allergan argues (at 47-51) that Plaintiffs' "negligence per se claims" are impliedly preempted. But Plaintiffs assert no freestanding negligence per se cause of action. Rather, in a claim denominated as "General Negligence, Negligence Per Se," PIC Count III, Plaintiffs argue that Allergan breached its common law "duty to exercise reasonable care" to avoid causing harm to Plaintiffs. PIC ¶ 168. Plaintiffs seek to establish Allergan's breach of its common law negligence duty in either of two ways. First, Plaintiffs allege that Allergan's conduct fell below the common law standard of "reasonable care," while also violating parallel federal requirements. PIC ¶ 169. This traditional negligence claim does not depend on the negligence per se doctrine, and Allergan does not argue that it is preempted. Second, Plaintiffs invoke the doctrine of negligence per se, under which "Allergan's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of negligence." PIC ¶ 174.

Insofar as Count III relies on the doctrine of negligence per se, the claim is not impliedly preempted because it remains a traditional state-created cause of action, not an attempt to assert an implied private right of action under the FDCA. The primary case relied on by Allergan, *In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 781 (3d Cir. 1999) ("*Bone Screw*"), shows that state-created causes of action that invoke negligence per se based on FDCA violations are *not* preempted. In *Bone Screw*, the Third Circuit favorably cited cases holding "that violations of a federal statute or regulations constituted negligence per se under state law." *Id.* at 790. Those cases "make clear the doctrine of per se liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort." *Id.* The court contrasted a valid negligence per se claim with the "quite different" "theory of per se liability advanced by the plaintiffs" in

that case: there, the plaintiffs did "not invoke the statutory violations to prove defendants' liability for a separate underlying tort, but instead contend the violations themselves form a cause of action." *Id.* at 791. Specifically, plaintiffs sued for "conspiracy to violate the FDCA," *id.* at 788, but did not connect the statutory violation to an underlying state-law tort, such as negligence. *Bone Screw* thus establishes that violations of federal law can be used to support liability on an underlying tort, including negligence through the doctrine of negligence per se.[34]

Moreover, several appellate courts have applied the framework set forth by the Supreme Court in *Buckman* and *Riegel* to hold that negligence per se claims based on violations of the FDCA or FDA regulations are non-preempted parallel claims. For example, the Oklahoma Supreme Court "allow[ed] a negligence per se claim to proceed" because it "acknowledge[d] the distinction between attempting to enforce a federal regulation and allowing a parallel claim for negligence per se bottomed on violation of the regulation." *Howard v. Zimmer, Inc.*, 299 P.3d 463, 472-73 (Okla. 2013) (footnotes omitted). The court recognized that parallel negligence per se claims "have been blessed by the United States Supreme Court in [*Riegel*] and [*Lohr*] distinguishing between attempts to enforce a federal regulation and reliance on the violation of such rules to bring a parallel claim." *Id.* Similarly, the Fifth Circuit "conclude[d] that invoking

[34] *Talley v. Danek Medical, Inc.*, 179 F.3d 154 (4th Cir. 1999), did not, as Allergan asserts (at 48), "hold[]" that a "negligence *per se* claim" was "preempted." Rather, *Talley* held that violation of an FDA regulation did not establish negligence per se under Virginia law because that regulation did not set a standard of care. 179 F.3d at 161. *Cornett*, cited by Allergan (at 48-49), did not even mention a negligence per se claim, let alone hold that such a claim was preempted. Rather, *Cornett* held that plaintiffs' claims were not preempted to the extent they rested on violation of federal requirements. 48 A.3d at 1058-59.

the negligence per se doctrine to support a negligence claim that is otherwise parallel to federal requirements is not expressly preempted." *Hughes*, 631 F.3d at 772.[35]

The district court cases Allergan cites (at 49-51) holding that negligence per se claims are impliedly preempted are unpersuasive for several reasons. First, they ignore the substantial appellate authority to the contrary. Second, they are based on the reasoning that "a negligence per se claim alleging violation of the FDCA is nothing more than a private right of action under the FDCA for damages," *Dunbar v. Medtronic, Inc.*, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014), and that a "negligence per se claim exists solely because of alleged violations of the FDCA and its implementing regulations," *In re Bard IVC Filters Prods. Liab. Litig.*, 2017 WL 5625548, at *8 (D. Ariz. Nov. 22, 2017). That reasoning misunderstands the nature of the negligence per se doctrine. The duty at issue in a "negligence per se claim" is the traditional state-law negligence duty: to exercise reasonable care to avoid causing physical harm to others. Thus, "negligence per se is a theory or 'doctrine' that assists a party in proving negligence" under state law. *Hughes*, 631 F.3d at 771. Finally, none of Allergan's cases rejecting negligence per se claims are within the Third Circuit, which has recognized the distinction between a negligence per se claim (such as Plaintiffs' claim here) that "invoke[s] the statutory violations to prove defendants' liability for a separate underlying tort," and a preempted claim that FDCA violations "themselves form a cause of action." *Bone Screw*, 193 F.3d at 790-91.

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[35] *See also Coleman*, 167 Cal. Rptr. 3d at 314 (finding "no preemption of state law claims based on negligence per se"); *Mize*, 265 Cal. Rptr. 3d at 481 (rejecting preemption of negligence per se claim because "[s]tate-law tort claims that attempt to enforce [federal] standards are not expressly preempted since the state requirements are identical to federal requirements"); *Bausch*, 630 F.3d at 553 (rejecting preemption for negligence claim under state law that "treats a violation of a statute or ordinance designed to protect human life or property as prima facie evidence of negligence"); *Howard*, 382 F. App'x at 442 ("Howard's negligence per se claim for GMP violations is not preempted.").

In short, Plaintiffs' reliance on the negligence per se doctrine does not trigger preemption. Even if it did, Count III of the Master Complaint would not be preempted insofar as it relies on a theory of general negligence.

D. Plaintiffs' Allegations Regarding Allergan's Failure To Conduct Post-Approval Studies Do Not Implicate Preemption

Preemption doctrine erects no bar to Plaintiffs' allegations regarding the inadequacies of Allergan's investigation of the safety of BIOCELL implants. Plaintiffs allege that Allergan violated federal requirements in FDA regulations and the PMA orders to conduct post-approval studies regarding the safety of BIOCELL implants, and that the FDA sent Allergan a warning letter concluding that Allergan had failed to meet its obligations. PIC ¶¶ 78-86; CAC ¶¶ 227-248. Those allegations support Plaintiffs' claims for general negligence, PIC ¶¶ 167-180, and negligent failure to warn, PIC ¶¶ 203-218; CAC (Counts 49-101), which are traditional state-law claims. Allergan mischaracterizes (at 39) Plaintiffs' complaints as asserting "failure to conduct a study claims" and asserts that such claims lack a "freestanding basis in state law" and therefore "are expressly preempted." But Plaintiffs assert no "failure to conduct a study claim." Allergan's failures to study BIOCELL implants' safety are relevant to whether Allergan met its state-law duties to exercise reasonable care to avoid causing physical harm to Plaintiffs, and to warn Plaintiffs of the dangers of BIOCELL implants. *See* PIC ¶¶ 175, 204; CAC ¶ 1268. Because these allegations support Allergan's state-law claims and do not add to or differ from the requirements of federal law, they do not implicate preemption.

CONCLUSION

The Court should deny Allergan's Motion to Dismiss and hold that federal law does not preempt Plaintiffs' claims.

Respectfully submitted,

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October 7, 2020

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing on October 7, 2020, by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ James E. Cecchi
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