Knoth v. Keith et al Doc. 67

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF MISSISSPPI

WESTERN DIVISION

STEPHANIE S. KNOTH **PLAINTIFF**

V. **CIVIL ACTION NO. 5:18-CV-49 DCB-MTP**

APOLLO ENDOSURGERY US, INC., ET AL. **DEFENDANT**

MEMORANDUM OPINION AND ORDER

This matter is before the Court upon Defendant Apollo Endosurgery US., Inc, ("Apollo")'s Motion to Dismiss (Doc. 46); Plaintiff Stephanie S. Knoth ("Knoth")'s Response (Doc. 51) and Defendant Apollo's Reply (Doc. 55). Having considered the motion, the responses, and applicable statutory and case law, and being otherwise fully informed in the premises, the Court GRANTS in part and DENIES in part Apollo's Motion to Dismiss (Doc. 46).

Background

This is a medical malpractice and products liability dispute, arising from the implant of the Orbera gastric balloon. The Court incorporates in this Order the lengthy description of the background and underlying facts in this action, discussed in its previous Order (Doc. 29).

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On May 4, 2018, Knoth, representing herself pro se, filed this lawsuit against Apollo and other defendants. Doc. 1. As to Apollo, the Complaint makes standard product liability allegations about Knoth's implant, specifically, that the Orbera balloon was unsafe and defective. Id. at ¶ 31-32. Apollo moved to dismiss the case on the basis that Knoth's claims were preempted under 21 U.S.C. § 360k(a), the Medical Device Amendments Act of 1976. "As provided by § 360k(a), Congress expressly preempted any state tort law 'requirement' for a device that differs from its federal requirements." Doc. 47, p. 3.

Express preemption is an indication of Congress's intention to supersede state law. As such, if Apollo's state law claims are preempted by §360k, this court must dismiss the state law claims as being superseded by the Medical Device Amendments Act ("MDA") which establishes a system to regulate medical devices. Preemption in this field is especially onerous, as "there is no private right of action to recover damages or other relief under the MDA." See Blanchard v. Collagen Corp., 909 F.Supp 427, 431 (E.D. La. 1995). Therefore, the only remedy available to plaintiffs is through "traditional state powers, namely, tort compensation and health and safety." Id.

Apollo also relies on the United States Supreme Court's decision in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008)(holding

that the FDA pre-market approval process established federal requirements and the patient's New York common-law claims of negligence, strict liability, and implied warranty against manufacturer were preempted). Apollo cites Riegel as controlling authority because the FDA approved the Orbera balloon as a Class III medical device after the product went through the pre-market approval process. Doc. 47, p. 3.

In October 2018, Knoth retained counsel and sought leave to amend her Complaint to plead state-law claims that "parallel" federal law, agreeing that her original state-law claims were preempted. See Docs. 11, 23. This Court granted her leave to amend the Complaint, and she did so. See Docs. 29, 30. Now, Apollo moves to dismiss Knoth's claims against it, pursuant to FED. R. CIV. P. 12(b)(6). Doc. 46, p. 1.

Standard

Rule 12(b)(6) affords a defendant the opportunity to test the legal sufficiency of the complaint, i.e., whether the plaintiff pleads a legal claim for which relief can be sought. See Electrostim Medical Services, Inc. v. Health Care Service Corp., 614 Fed.Appx. 731, 736 (5th Cir. 2015). To survive a motion to dismiss, the plaintiff's claim for relief must be plausible on its face. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)(quoting Bell Atl. Corp. v. Twombly, 550, U.S. 544, 570

(2007)). The plausibility standard requires that the complaint's factual allegations "be enough to raise a right to relief above the speculative level." Twombly, 550 U.S. at 555. If there is "any evidence in the record from any source from which a reasonable inference in the [nonmoving party's] favor may be drawn, the moving party simply cannot obtain a summary judgment…". Celotex Corp. v. Catrett, 477 U.S. 317, n.2 (1986)(citing In re Japanese Electronic Products Antitrust Litigation, 723 F.2d 238, 258 (3rd Cir. 1983)).

Discussion

1. Pre-Market Approval & Post-Approval Conditions for Class III Devices

The federal Medical Device Amendments of 1976 ("MDA") imposed a "regime of detailed federal oversight," over the market for medical devices. See Riegel v. Medtronic, Inc., 522 U.S. 312, 316 (2008). Congress entered the field of medical device regulation in order to intentionally sweep back state obligations in favor of uniform federal regulation. See id. To do so, the MDA utilized a two-pronged approach: (1) imposing an "intricate regulatory scheme to increase oversight and promote uniformity at the federal level," and (2) eliminating interference by state enforcement agencies through an express

preemption clause, 21 U.S.C. §360k. See Raab v. Smith & Nephew, Inc., 150 F.Supp.3d 671, 682 (S.D. W.Va. 2015).

The degree to which the FDA regulates a medical device depends on the level of classification of the device. The higher the classification the more stringent the regulations. Class III devices are the most highly regulated because the devices are used in supporting or sustaining human life, are substantially important in preventing the impairment of human health, or the devices present an unreasonable risk of illness or injury. See 21 U.S.C. §360(a)(1)(C); Riegel 552 U.S. at 317. Because of this, Class III devices are subjected to extensive regulation before being introduced into the market; specifically, these devices are required to go through a strenuous pre-market approval ("PMA") process to "provide reasonable assurance of their safety and effectiveness." Riegel 552 U.S. at 317. Once a medical device successfully obtains PMA, the MDA "forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing process, labelling, or any other attribute, that would affect safety or effectiveness." Id. at 319(citing 21 U.S.C. §360e(d)(6)(A)(i)).

In addition to device specific regulations, Class III devices are also subject to Current Good Manufacturing Practices ("CGMPs"). See Bass v. Stryker Corp., 669 F.3d 501, 511–512 (5th

Cir. 2012)(citing In re Medtronic, Inc. v. Sprint Fidelis Leads Products Liability Litigation, 623 F.3d 1200, 1206 (8th Cir. 2010)). The FDA has described CGMPs as "an umbrella quality system" providing "general objectives" for all device manufactures. See In re Medtronic, Inc., 623 F.3d at 1206. The requirements are applicable to "any finished device, as defined in this part, intended for human use." Rabb, 150 F.Supp.3d at 684 (citing 21 C.F.R. §820.1(a)(2)). The Seventh Circuit articulated the binding nature of CGMPs in its decision in Bausch v. Stryker Corp.;

> "… federal law is clear: for manufacturers of Class III medical devices, the Quality System Regulations and Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements 'under this chapter.' 21 C.F.R. § 820.1. 'The failure to comply with any applicable provision in this part [of the regulations] renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.' 21 C.F.R. § 820.1(c)."

630 F.3d 546, 555 (7th Cir. 2010); see also, Howard v. Sulzer Orthopedics, 382 Fed.Appx. 436, 440 (6th Cir. 2010)(finding no legal basis to distinguish between general requirements and device-specific requirements). But see, In re Medtronic, 623 F.3d at 1207 (rejecting claims based on violations of Current Good Manufacturing Practices).

It should be noted that in order for a plaintiff to bring a claim against the manufacturer there is no requirement that the FDA instigate an enforcement action or make a "formal" finding that the manufacturer is in violation of federal requirements. See Hughes v. Boston Scientific Corp., 631 F.3d 762, 772–773 (5th Cir. 2011).

After PMA (pre-market approval), manufacturers of Class III devices must comply with a variety of post-approval conditions. See Hughes 631 F.3d at 765(citing 21 U.S.C. §§360c-360j; 21 C.F.R. §§ 814.80, 814.82). If the manufacturer fails to comply with the these conditions, the FDA may withdraw PMA. See id. The FDA can also impose other remedies such as "additional warnings or corrective labeling." Id.

The PMA process and post-approval regulations are one factor in the MDA's coverage of the medical devices field. For a holistic view of this highly regulated area, the Court next looks to the MDA's pre-emption of state law claims.

2. Pre-Emption Under the MDA and Parallel State Law Claims

Section 360k of the MDA contains an express preemption provision that states:

> "no 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).

A two-pronged test determines whether Section 360k expressly preempts a state law claim: (1) whether the federal government has established requirements applicable to the medical device, and (2) if so, whether the state law claim would impose requirements that are "different from or in addition to" the federal requirements. See Riegel, 552 U.S. at 321–322. The first prong is satisfied when a Class III device has undergone the pre-market approval ("PMA") process. See Bass, 669 F.3d at 507.

The second prong permits a State to provide a remedy for damages for claims premised on a violation of FDA regulations or CGMPs, as long as the claim parallels the federal regulations. See Bass, 669 F.3d at 509. The parallel claims doctrine allows plaintiffs to employ state tort law as a "mechanism for enforcing federal requirements." See Raab, 150 F.Supp.3d at 686. In Medtronic, Inc. v. Lohr, the Supreme Court rejected the idea that Congress intended to preclude all common-law causes of action by enacting §360k. 518 U.S. 470, 487 (1996). Such a restriction would effectively remove "all means of judicial recourse for those injured by illegal conduct." Id. As the Supreme Court wrote in Lohr, "Medtronic's construction of §360k

would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation…" Id.

The Fifth Circuit has held that the PMA process "preempts state tort causes of action to the extent that they relate to safety, effectiveness, or other MDA requirements." Gomez v. St. Jude Medical Diag. Div. Inc., 442 F.3d 919, 929 (5th Cir. 2006). To avoid preemption, the general assertions of a state law cause of action cannot "threaten the federal PMA process requirements." See id. at 929–930. However, in cases where a manufacturer is not protected from state tort liability by §360k preemption, the claims are based on violation of applicable federal requirements. See Williams v. Ciba Vision Corp., 100 F.Supp 3d 585, 590 (S.D. Miss. 2015)(citing Hughes, 631 F.3d at 767)).

After the issue of express preemption has been addressed, courts often look to the issue of implied preemption, but inasmuch as the Defendant has not addressed this issue, the Court is not inclined to do so.

Applying Riegel's two-pronged test to Knoth's claim, we first consider whether the FDA has established requirements applicable to the Orbera gastric balloon. Any Class III device

that has received PMA by the FDA satisfies the first prong of the test. See Bass, 669 F.3d at 507. As evidenced by the complaint, the Orbera gastric balloon is a Class III device that has received PMA and therefore the first prong is satisfied. To satisfy the second prong, we must ask whether state law at issue parallels the federal requirement or if it creates a requirement that is "different from or in addition to a federal requirement." 21 U.S.C. §360k. Thus, we consider below the elements of Knoth's state-law claims to determine whether they are parallel to the federal requirements.

Mississippi Products Liability Act

Knoth brings suit under The Mississippi Products Liability Act ("MPLA") and Mississippi common law. The MPLA applies "in any action for damages caused by a product." Miss. Code. Ann. §11-1-63. The Defendant argues that the MPLA subsumes five of the Plaintiff's claims and that they should be dismissed inasmuch as the MPLA is the exclusive remedy for a products liability claim: (1) Breach of Implied Warranty, (2) Unjust Enrichment, (3) Lack of Informed Consent, (4) violations of the Mississippi Deceptive Trade Practices Act, and (5) Negligent Training and Proctoring & Negligent Certification.

The legislature enacted the MPLA in 1993. At that time, it was unclear as to what extent the MPLA supplanted pre-existing

products liability causes of action. See Mississippi Law of Torts §15:3("MLT"). However, in 2014, the legislature amended the MLPA to include "designers" as entities to whom or to which the MLPA applies. The amendment also added "negligence" as a common law action subsumed by the MLPA. See MLT §15:3. As amended, the MPLA applies to "any action for damages caused by a product, including, but not limited to, any action based on a theory of strict liability in tort, negligence or breach of implied warranty, except for commercial damage to the product itself." Miss. Code Ann. §11-1-63. The MPLA recognizes three traditional categories of product defects: (1) design defects, (2) warnings/instructions defects, and (3) manufacturing defects. See MLT § 15:3.

There have been recent clarifications as to the MPLA's relationship to state common law claims. Prior to 2014, the issue was unsettled, with the Mississippi Supreme Court indicating that the MPLA supplemented rather than supplanted implied warranty actions. See MLT §15:3(citing Bennett v. Madakasira, 821 So.2d 794, 808 (Miss. 2002)(holding that the MPLA does not preclude a plaintiff from proceeding under a breach of implied warranty theory in a products liability case)(emphasis added)). However, the 2014 amendments and the Mississippi Supreme Court's decision in Elliot v. El Paso Corp.

have clarified the state's approach to these issues. 181 So.3d 263 (Miss. 2015). In Elliot the Mississippi Supreme Court wrote,

> "In interpreting and applying the MPLA, we have explained that 'the MPLA provides the exclusive remedy' for products-liability claims, and 'since [the enactment of the MPLA], products-liability claims have been specifically governed by statute, and a claimant, in presenting his case, must pay close attention to the elements of the cause of action and the liability limitations enumerated in the statute.' In other words, the MLPA has abrogated products-liability claims based on strict-liability or negligence theories, and the MPLA now provides the roadmap for such claims."

Id. at 268. The court also noted that a case involving a product defect — even a claim for breach of implied warranty — would be subsumed by the MPLA. Id. at n.24.

Common Law Claims

Defendants argue in their Motion that the MPLA subsumes Knoth's common law claims and those claims must be dismissed. The MPLA, which applies "in any action for damages caused by a product, including, but not limited to, any action based on a theory of strict liability in tort, negligence, or breach of implied warranty, except for commercial damage to the product itself," provides, in relevant part:

> "The manufacturer, designer or seller of the product shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer, designer or seller:
>
> i. (1) The product was defective because it deviated in a material way from the manufacturer's or

designer's specifications or from otherwise identical units manufactured to the same manufacturing specifications, or (2) The product was defective because it failed to contain adequate warnings or instructions, or (3) The product was designed in a defective manner, or (4) The product breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product; and

ii. The defective condition rendered the product unreasonably dangerous to the user or consumer; and

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

Miss. Code Ann §11-1-63(a).

The fact that the MPLA provides the exclusive remedy for suits against a manufacturer, does not mean that common law negligence or breach of implied warranty claims are disallowed. See Young v. Bristol-Myers Squibb Co., No. 4:16-cv-00108-DMB-JMV, 2017 WL 706320, *3 (N.D. Miss. Feb. 22, 2017). Instead, they must be evaluated under the framework of the MPLA. Id. However, as the court in Young wrote:

> "Practically, where a common law claim is subsumed by the MPLA and is brought alongside products liability claims based on the same theory of recovery, the proper course is to dismiss the common law claim to the extent it is duplicative of the parallel products liability counts. To the extent a subsumed common law count is asserted 'as an independent tort claim outside the scope of the MPLA,' the count must be dismissed for failure to state a claim."

Id. at *4. Therefore, within that framework, this court will look to the common law claims that the Defendant argues are subsumed by the MPLA.

Count Five – Implied Warranty

Claims for breach of implied warranty are subsumed by the MPLA. Miss. Code Ann. §11-1-63; see also, Elliot, 181 So.3d 263 at n.24; Arnoult v. CL Medical SARL, No. 1:14-cv-271-KS-MTP, 2015 WL 5554301, *3 (S.D. Miss. Sept. 21, 2015)(writing that the MPLA "specifically provides that it governs claims for breach of an implied warranty arising from damage caused by a product.")

Knoth claims that "Apollo impliedly warranted the product to be of merchantable quality, safe, and fit for such use. Apollo also impliedly warranted that the product was adequately tested." Amend. Compl. ¶ 126 [ECF No. 30]. Plaintiff alleges that Apollo "withheld and concealed information about the substantial risks of serious injury or death associated with use of the device." Id. at ¶ 127(a). To the extent these common law claims are duplicative of Knoth's product liability claims, the common law claims must be dismissed. The Court grants Apollo's Motion to Dismiss Count Five insofar as it is asserted as an independent tort claim outside the scope of the MPLA.

Count Six – Unjust Enrichment

The common law claim of unjust enrichment is subsumed by the MPLA. Miss. Code Ann. §11-1-63. Knoth alleges that it is unjust for Apollo to retain the payment made by Knoth for the gastric balloon as the plaintiff did not receive a safe and effective product for weight-loss purposes. See Amend. Compl. ¶¶ 135-136 [ECF No. 30]. Accordingly, as this claim is asserted as an "independent tort" outside the scope of the MPLA, it is dismissed for failure to state a claim.

Count Seven – Lack of Informed Consent

Lack of informed consent is subsumed by the MPLA. Miss. Code. Ann. §11-1-63. Knoth alleges that Apollo owed a fiduciary duty to the Plaintiff to "provide and disclose all information material to her care and treatment… all issues with the Orbera gastric balloon system and the substantial risk of serious injury or death associated with the device." Amend. Compl. ¶ 138. [ECF No. 30]. Accordingly, to the extent that the claim is subsumed by the product liability failure to warn claim, Count Seven will be dismissed as duplicative. To the extent Count Seven attempts to impose liability on other grounds, it will be dismissed for failure to state a claim.

Count Ten – Negligent Training and Proctoring & Negligent Certification

In a products liability action, "a negligence claim alleging failure to warn, train, educate, or draft a warning plan… is a claim based upon products liability, and such a claim must be analyzed under the MPLA." Elliot, 181 So.3d at 269. Here, the plaintiff alleges that Apollo did not "proctor and/or properly instruct Plaintiff's surgeons and attending staff as to the safe use of its device nor how to detect complications which its said device causes and is known to cause." Amend. Compl. ¶ 157 [ECF No. 30]. To the extent that Count Ten makes a common-law negligence claim based on the failure to train or certify, it will be dismissed as duplicative. To the extent that Count Ten attempts to impose liability on other grounds, it will be dismissed for failure to state a claim.

Count Eight – Mississippi Deceptive Trade Practice Act

The Plaintiff's allegation that Apollo violated the Mississippi Deceptive Trade Practice Act is not a claim under the MPLA. However, it must be dismissed as the Plaintiff has failed to attempt to resolve the case through an informal dispute settlement program approved by the Mississippi Attorney General, as required under Miss. Code Ann. §75-24-15(2). As the Plaintiff has not made any allegation that she attempted to resolve the claim through any means other than this lawsuit, her

claim must be dismissed as a matter of law. See Wilson v. New Palace Casino, L.L.C., No. 1:11-cv-447-HSO-JMR, 2013 WL 870350, *12 (S.D. Miss. March 7. 2013).

Having considered the claims that are subsumed or dismissed because of the MPLA, or for failure to attempt to resolve the case through an informal dispute settlement, the court turns to the remaining state-law claims to determine whether they are preempted by 21 U.S.C. §360k.

3. Parallel Claims in the Context of Rule 12(b)(6)

Reigel, Lohr, and Buckman provide a framework for preemption analysis. See Waltenburg v. St. Jude Medical, Inc., 33 F.Supp.3d 818, 827 (W.D. Ky. 2014). However, despite the framework, lower courts have struggled to resolve the understandably thorny issue of the degree of particularity required to establish a parallel claim. See id. at 825. The disparity in resolving this issue is apparent when comparing the decisions reached by the Seventh Circuit in Bausch and the Eleventh Circuit in Wolicki-Gables v. Arrow Intern, Inc., 634 F.3d 1296 (11th Cir. 2011). See Raab, 150 F. Supp.3d at 691.

The Seventh Circuit reversed the lower court's decision to dismiss a parallel claim for failing to plead with sufficient particularity. See Bausch, 630 F.3d at 560. The Seventh Circuit held that failure to identify the precise defect or the specific

federal regulatory requirements that the Defendant violated does not support a Rule 12(b)(6) dismissal. See id. The Bausch court highlighted the burden that Class III confidentiality has on plaintiffs, and the bar it would impose on filing successful parallel claims, i.e. plaintiffs not having access to necessary documents and information critical to their claims because the material is deemed confidential. See id. at 560–561.

The Eleventh Circuit requires an enhanced level of pleading. The Wolicki-Gables panel opined, "Plaintiffs cannot simply incant the magic words '[defendants] violated FDA regulations' in order to avoid preemption." See 634 F.3d at 1301. Parallel claims must be specifically stated in the initial pleadings and a plaintiff must allege that the "defendant violated a particular federal specification referring to the device at issue." See id. "To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated." Id.

The Fifth Circuit falls in the middle of these two extremes. In Bass, the court wrote:

> "Although the circuits are not in complete agreement as to what constitutes a sufficient pleading ... [t]he key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is ... the existence of a manufacturing defect caused by a violation of federal regulations *and* allegations connecting

> a defect in the manufacture of the specific device to that plaintiff's specific injury."

See 669 F.3d at 511–512. The court in Bass agreed with Bausch's reasoning regarding the confidentiality of medical devices. As the Court wrote, "asking the plaintiff to make more specific allegations than those found in Bass's complaint may make pleading a parallel claim regarding defective manufacturing nearly impossible." Id. at 511.

The Fifth Circuit has held that the pleading standard for a Class III medical device claim alleging a violation of federal law is the same as the plausibility standard of Twombly. See id. at 509. There is no heightened standard to plead a parallel claim for a violation of federal regulations over medical devices, unlike, as an example, the requirements to sustain a plea for fraud.

The Fifth Circuit has determined that a plaintiff who pleads a violation of Current Good Manufacturing Practices — a significantly more general requirement — may succeed. See id. at 512. Other Circuits require a plaintiff to plead violations of PMAs, specific to the device in question. See id. at 512. As previously stated, the issue with this requirement is that a Plaintiff will be unable to access, or have extreme difficulty accessing, confidential PMAs prior to discovery, making a sufficient pleading almost impossible. See id. at 511. It is

with these considerations that the Fifth Circuit determined that a claim which alleges the Defendant violated CGMPs, is sufficient.

Apollo relies on the stringent standard set by Wolicki-Gables to support its argument that Knoth failed to plead with specific particularity. See e.g., 634 F.3d 1296 (11th Cir. 2011). However, the court in Bass clearly rejected that strict line of reasoning when it overturned the District Court's dismissal, which was predicated on the fact that Bass had only alleged violations of CGMPs and not device specific violations. See 669 F.3d at 512. The court in Wolicki-Gables requires devise specific violations. As justification for this Court to dismiss Knoth's claim, Apollo cannot rely upon a standard which the Fifth Circuit has rejected.

Whether Knoth Satisfactorily Plead Parallel Claims

The court in Bass found that the plaintiff pleaded a non-conclusory parallel claim. See Bass, 669 F.3d at 509. Bass asserted that:

> "(1) he received a Shell implant; (2) the FDA had previously warned Stryker of bioburden in excess of FDA regulations in its final rinse of the Shells; (3) after Bass's surgery, Stryker ultimately voluntarily recalled those Shells, including the Shell specifically used in Bass's implant; (4) Bass suffered from a loose Shell due to a lack of bony ingrowth; and (5) the lack of bony ingrowth is a known effect of an

> excess of bioburden and manufacturing residuals on Shells."

Id. at 510. Bass relied on Current Good Manufacturing Practices ("CGMPs") in his pleadings. Plaintiffs often do not have access to specific federal requirements in the PMA prior to filing suit. See id. at 512. Thus, the Fifth Circuit has held that a lack of information specific to the device is not fatal so long as the plaintiff can show a failure by the manufacturer to conform with CGMPs, information in regard thereto is more accessible to plaintiffs. Id. A manufacturer could be "liable even in circumstances where it complied fully with the specific [processes and specifications] approved by the FDA." Howard v. Sulzer Orthopedics, Inc., No. 09-3406, 2010 WL 2545586, at *5 (6th Cir. June 16, 2010).

In Bass, the plaintiff alleged that the device was adulterated due to violations of 21 C.F.R. § 820.20(a), 820.20(b)(2) and 820.70(e). See 669 F.3d at 510. A formal finding or enforcement action by the FDA is not a requisite to a satisfactory parallel claim. Id. at 509. The relevant facts in the Bass pleading were allegations that connected the defect in the manufacture of the specific device to the plaintiff's specific injury. The Defendant was made aware of the defect, that there was bioburden in excess of FDA regulations, and the

Plaintiff's injury is a known effect of that specific defect.

As such, we must then compare Knoth's pleading. Knoth pleaded:

> (1) That she received an Orbera gastric balloon, (2) that the FDA issued three warning letters to providers, one that addressed the potential dangers of the Orbera balloon rupturing because of spontaneous hyperinflation, (3) that Knoth suffered from a ruptured gastric balloon, and (4) that her injury, septic shock etc., is a common effect of a ruptured balloon due to bacterial contamination.

As with Bass, the question is whether Knoth pleaded that Apollo's failure to abide by the CGMPs resulted in the defect that injured Knoth. The complaint makes several allegations of failure to comply with the Federal Food, Drug and Cosmetic Act ("FCDA") — each specifically addressing the issue of spontaneous hyperinflation and the resulting contamination of human blood and tissue.

At this stage of the litigation, "discovery is necessary before the plaintiff can be expected to provide a detailed statement of the specific bases for her claim." Bausch, 630 F.3d at 558. Knoth's complaint has satisfied the plausibility standard of notice pleading as set forth in Twombly, "a claim has facial plausibility when the plaintiff pleads factual

content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Twombly, 550 U.S. at 556.

Apollo relies on Williams v. Ciba Vision Corp., to support its assertion that Knoth has not sufficiently pleaded a parallel claim. 100 F.Supp.3d 585 (S.D. Miss. 2015). In Williams, the Plaintiff alleged that the Defendant "deviated from the manufacturing process that had been pre-approved by the FDA… and utilized a 'modified (buffered tumbling) manufacturing process' which resulted in a 'biofilm formation within the lens….'" Id. at 591. Judge Sul Ozerden dismissed the claim, writing:

> "Plaintiff [Williams] does assert the basic legal elements of a parallel claim, that Defendant deviated from the pre-approved manufacturing process which in turn caused a defect in the lens which in turn caused her injury. However, Plaintiff has not stated any facts to support the conclusory allegation that the alleged 'buffered tumbling process violated the pre-approved manufacturing process or any requirement specific to the MemoryLens IOL."

Id. These facts differ from the case at hand because the court in Williams was addressing an actual change in the manufacturing process which the Defendant utilized in making its product. See id. The Plaintiff's failure to allege how this new manufacturing process violated the pre-approval process was fatal to her

claim. However, in this case, the Court is not considering an altered manufacturing process.

This case is more akin to Bass than to Williams. Inasmuch as the FDA sent three warning letters to health care providers regarding the possibility of the Apollo balloon spontaneously hyperinflating, and since Knoth's injury is consistent with hyperinflation set forth in the FDA warning. The core difference between Bass and this claim is that Apollo did not recall the balloon, whereas Bass recalled its Shells because of the manufacturing issue. See Bass, 669 F.3d at 509. However, the manufacturer's decision to recall a product is not a necessary prerequisite to the assertion of a parallel claim.

Therefore, the Court concludes that Plaintiff's claims for relief are sufficiently plausible. See Raab, 150 F.Supp.3d 671 at 694(citing Elmore v. Smith & Nephew, Inc., No. 12 C 8347, 2013 WL 1707956, *5 (N.D. Ill. Apr. 19, 2013)). A plaintiff's pleading burden must "be commensurate with the amount of information available to them." Bausch, 630 F.3d at 561(quoting In re Medtronic, 623 F.3d at 1212 (Melloy, J., dissenting)).

In this case, Knoth identified a specific medical device, the Orbera gastric balloon system, that was manufactured and

produced by the defendant. Knoth sets forth specific allegations that the Orbera gastric balloon was unreasonably dangerous and that the defendant was negligent, citing several violations of the CGMPs. For example, allegations that the defendant "failed to accurately establish the in vivo life expectancy of the Orbera gastric balloon system," "failed to validate the anticipated wear on both healthy tissue and the Orbera gastric balloon prior to their release into commercial distribution," and "failed to appropriately respond to adverse incident reports that strongly indicated the Orbera gastric balloon was Malfunctioning (sic) [as defined in 21 C.F.R. §803.3], or otherwise not responding to their Design Objective Intent," taken as true, suggest a defect in the Orbera balloon as manufactured. Amend. Compl. ¶ 81(a), (b), & (h) [ECF No. 30].

Knoth's allegations about experiencing a balloon rupture and suffering from septic shock due to foreign contaminants in her blood stream, plausibly tie the Defendant's alleged violations of the CGMPs to the defect in the Orbera gastric balloon system. This defect could have made the product unreasonably dangerous, ultimately causing the alleged injuries suffered by Knoth.

The Court recognizes that, prior to discovery, it is often times difficult for a plaintiff to allege specific violations of

Class III devices which have undergone PMA. This court finds that the Plaintiff has met her pleading burden. See Bausch, 630 F.3d at 561 (noting that, in order for a plaintiff to plead a parallel claim with specificity, she would "need access to the confidential materials in the premarket approval application setting forth the medical device's specifications. This is simply not possible without discovery."); Gelber v. Stryker Corp., 788 F.Supp.2d 145, 156 (S.D.N.Y. 2011) ("By pleading the conduct which plaintiffs allege violated the CGMP requirements, describing evidence of the alleged violation, and directing [defendants] to the CGMP requirements generally, plaintiffs have given defendants more than ample notice of the alleged violation of federal law."); Tillman v. Smith & Nephew, No. 12 C 4977, 2013 WL 3776973, *5 (N.D. Ill. July 18, 2013)(allegations of medical complications occurring after implantation, combined with allegations of numerous CGMP violations, sufficient to state claim for negligence and strict products liability).

As to the Defendant's assertion that Knoth has not provided sufficient facts to support her manufacturing defect claim, the Court notes that "the victim of a genuinely defective product… may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem. It is common, for example for injured

plaintiffs to plead both defective manufacture and defective design and to pursue discovery under both theories." Bausch 630 F.3d at 560. With Class III medical devices, an "injured patient cannot gain access to that information without discovery." Id.

Inasmuch as this Court has found that Knoth's allegations satisfy the pleading requirements under Twombly and Iqbal, we must next determine whether any of the Plaintiff's remaining claims are preempted by §360k.

Plaintiff's Remaining Claims

Counts One & Two: Negligence & Strict Liability – Manufacturing and/or Design Defect

Knoth's claim for Manufacturing Defect can proceed because, as discussed above, it is premised on violations of the FDA Regulations and Current Good Manufacturing Practices. As the Fifth Circuit has held, "manufacturing defect claims may proceed, because… to the extent they are premised on violations of FDA regulations, they are parallel claims that are not preempted." Bass v. Stryker Corp., 669 F.3d 501, 515 (5th Cir. 2012). The MPLA claims do not impose different or additional requirements than the FDA regulations. As such, to the extent that Knoth has plausibly tied federal violations to a state law cause of action, the claims are parallel and are not preempted. See Raab, 150 F.Supp.3d at 692–693. Knoth's manufacturing claim

must proceed under the MPLA, as it is the exclusive remedy for products liability actions. Any claims of negligence or strict liability are subsumed by the MPLA. Although Knoth's headings assert that she is pursuing a manufacturing claim under negligence or strict liability, she has pleaded a manufacturing claim as set forth under the MPLA. In her Amended Complaint, Knoth alleges:

> "Specifically, Plaintiff[] allege[s] that at the time the subject components left Defendant's control, (i) one or more were defective because they deviated in a material way from the manufacturer's or designer's specifications, (ii) such defective condition rendered them unreasonably dangerous to the user, and (iii) such condition proximately caused the damages for which recovery is sought herein."

[ECF No. 30] at p. 21. This is a manufacturing claim as set forth under the MPLA. See Miss. Code Ann. § 11-1-63.

To the extent, however, that Knoth is pursuing a claim that the Orbera system design, as approved by the FDA in the PMA, is defective, such claim is preempted. See Gomez v. St. Jude Medical Daig. Div. Inc., 442 F.3d 919, 930 (5th Cir. 2006)("to permit a jury to second-guess the [defendant's] design by applying the Louisiana statutory standard for unreasonably dangerous design would risk interference with the federally

approved design standards and criteria."); see also, Carlson v. Medtronic Inc., No. 3:13-cv-687-WHB-RHW, 2014 WL 11514911, at *4 (S.D. Miss. Aug. 28, 2014)("[D]esign-related defect claims whether sounding in strict liability or negligence, are preempted because the FDA has already assessed and approved the risks and utility of the existing design of the [medical device]").

The Supreme Court in Medtronic, Inc. v. Lohr, found that state law negligent design claims are not preempted. See 518 U.S. at 487. However, in Lohr, the medical device at issue did not go through a strenuous pre-market approval process but entered the market without further regulatory analysis as a §510(k) device that is "substantially equivalent" to a pre-existing device. Id. at 478. Section 510(k)'s process is not comparable to the pre-market approval process, as it takes an average of 20 hours to complete the § 510(k) review as compared to the 1,200 hours to complete pre-market approval. Id. at 478–479.

Because Lohr addressed a medical device that was exempt from pre-market approval, the Court proceeded with the Plaintiff's design claim. As the Court wrote, "[t]he 510(k) process is focused on equivalence, not safety." Id. at 493. Multiple Circuits have distinguished this decision, finding that

claims of design defects cannot proceed for devices that undergo pre-market approval. See Caplinger v. Medtronic, Inc., 784 F.3d 1335, 1345 (10th Cir. 2015); Walker v. Medtronic, Inc., 670 F.3d 569, 581 (4th Cir. 2012); Bausch v. Stryker Corp., 630 F.3d 546, 560 (7th Cir. 2010)("If the problem turns out to be a design feature that the FDA approved, section 360k will protect the manufacturer."); Horn v. Thoratec Corp., 476 F.3d 163, 177–178 (3rd Cir. 2004); Mendes v. Medtronic, Inc., 18 F.3d 13, 18 (1st Cir. 1994)(writing that design defect claims are preempted if the device received premarket approval).

Count Three – Negligence – Failure to Warn

Knoth alleges that Apollo violated the following federal regulations for her failure to warn claim:

> "Pursuant to 21 C.F.R. § 814.80, Defendant had a duty and was required to manufacture, package, store, label, distribute, and advertise it in a manner consistent with the conditions for approval specified by the FDA in the device's PMA approval order. Defendant violated this duty.
>
> Pursuant to 21 C.F.R. § 814.82 and 814.84, Defendant also had a duty and was required to provide all of the post-approval reports and information identified by the FDA in the device's approval order including, but not limited to, timely submission of informative adverse reaction and device defect reports. Defendant violated this duty.
>
> Defendant failed to submit a PMA supplement for review and approval by the FDA, in violation of 21 C.F.R. § 814.39.

> Defendant sold, distributed and permitted use of its devices in violation of the regulations prescribed under 21 U.S.C. § 360j(e), 21 U.S.C. § 352(r).
>
> Defendant violated its duty under 21 U.S.C. § 360i to collect data and maintain records of Orbera® gastric balloons that had failed, and report issues concerning the safety and effectiveness of such devices."

Amend. Compl. ¶¶ 91, 92, 93, 94, & 95 [ECF No. 30]. Knoth relies on Hughes v. Boston Scientific Corp., for her assertion that the failure to warn claim can proceed. See e.g., 631 F.3d 762 (5th Cir. 2011).

The court in Hughes made clear that the plaintiff's state law products liability claims were expressly preempted. See 631 F.3d at 768–769. "To permit a jury to decide [plaintiff's] claims that the information, warnings, and training material the FDA required and approved through PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [the defendant]." Gomez, 442 F.3d at 931. However, the court in Hughes permitted the plaintiff's failure to warn claim to proceed under a theory of negligence. As the court wrote:

> "… the Mississippi duty to provide 'adequate warnings or instructions,' which is imposed on manufacturers pursuant to the products liability code, Miss. Code Ann. §§ 11-1-63(a)(i)(2), (c)(i), has been construed by Mississippi courts as a duty to provide 'reasonable warnings' of risks."

Id. at 769. "Riegel, Lohr, and Gomez are consistent in holding that claims for negligent failure to warn or negligent manufacturing of a device are not preempted, provided that such claims are premised entirely on violation of the applicable federal requirements." Id. at 770.

As such, Knoth asserts that she is able to bring a similar failure to warn claim under a theory of negligence. However, the Fifth Circuit's decision in Hughes occurred prior the 2014 MPLA amendments and the Mississippi Supreme Court's decision in Elliot. The Fifth Circuit premised its holding in Hughes on the assumption "that a failure to warn claim may be pursued under Mississippi law…." Id. at 769. As this court has previously mentioned, the 2014 amendments and Elliot clarified the scope and exclusivity of the MPLA. Significantly for this particular claim, the 2014 amendments included "negligence" as a cause of action for which the MPLA applies. A "negligence claim alleging failure to warn… is a claim based upon products liability, and such a claim must be analyzed under the MPLA." Elliot, 181 So.3d at 269.

Under the MPLA, the defendant can bring a products liability claim for failure to warn if the "product was defective because it failed to contain adequate warnings or instructions." Miss. Code Ann. §11-1-63(a)(i)(2). Any other

claim must be dismissed for asserting an independent tort claim outside of the MPLA's purview. Here, Knoth does not allege that the Orbera gastric balloon failed to contain adequate warnings or instructions – which would be expressly preempted by §360k(a). Therefore, the MPLA does not include Knoth's alleged cause of action for failure to warn, so it must be dismissed for stating an independent tort claim.

Count Four – Breach of Express Warranty

Knoth's breach of express warranty claim is solely based on Apollo's false or misleading marketing. Knoth claims that the marketing materials are false or misleading in violation of 21 U.S.C. §352(q). The Plaintiff alleges the following, resulting in a breach of express warranty:

> 1) The ORBERA® website claims a patient will lose "3 Times the Weight";
>
> 2) That the ORBERA® is the #1 Gastric Balloon;
>
> 3) That the procedure is a simple and safe non-surgical procedure usually done in 20 minutes;
>
> 4) That Apollo selects only the most qualified specialists to perform the ORBERA® weight loss procedure;
>
> 5) That ORBERA® press releases compared the risk as the same as a colonoscopy;
>
> 6) That the ORBERA® gastric balloon system is the most studied intragastric balloon globally with impressive weight loss and safety results; and

> 7) That the balloon inserted into the stomach is the size of a grapefruit.

EFC 52 at p. 19. Knoth claims that these statements are false and misleading because the "FDA did not approve" them. EFC 52 at p. 19–20. An express warranty claim must fail as a matter of law if it is contrary to the FDA's approval of the medical device. See In re Medtronic Inc., 623 F.3d at 1208. However, Knoth does not allege that Apollo violated an express warranty for any marketing materials that the FDA approved. Therefore, the express warranty claim does not obstruct the FDA's regulation of the Class III devise, and the claim is not preempted.

Apollo argues in the alternative, that if the express warranty claim is not preempted, it should be dismissed for failure to plead specific facts "regarding the warranty and the alleged false and/or misleading nature of it." According to Apollo, the Plaintiff has not alleged that the marketing materials are false or misleading for any reason other than the fact that they were not approved by the FDA. This Court finds that it is premature to address the breach of express warranty, an issue which will be considered after discovery or at trial.

Count Nine – Punitive Damages.

A claim for punitive damages is not a separate cause of action but is based on the underlying cause of action. See Lewis

v. Intermedics Intraocular, Inc., No. 93-0007, 1993 WL 533976, *9 (E.D. La. Dec. 10, 1993). Therefore, the claim for punitive damages survives this motion for summary judgment only insofar as it relates to the plaintiff's claims that were not preempted by 21 U.S.C. § 360k(a) or subsumed by the MPLA. See id.

CONCLUSION

The following claims are subsumed by the MPLA and are dismissed as being duplicative or because they assert an independent cause of action: Count Three – Negligence – Failure to Warn, Count Five – Implied Warranty, Count Six – Unjust Enrichment, Count Seven – Lack of Informed Consent, and Count Ten – Negligent Training and Proctoring & Negligent Certification. Count Eight, asserting that Apollo violated the Mississippi Deceptive Trade Practice Act, is dismissed inasmuch as there was no attempt to pursue resolution through an informal dispute settlement program as required by statute.

The following claims are not preempted by the federal Medical Device Amendments of 1976, 21 U.S.C. §360k, and therefore, shall not be dismissed at this stage of the litigation: Count Four – Breach of Express Warranty, and Count Nine – Punitive Damages.

Count One – Negligence – Manufacturing and/or Design Defect and Count Two – Strict Liability – Manufacturing and/or Design Defect are dismissed in part. The Plaintiff's design defect claims are dismissed. The Plaintiff's manufacturing defect claims are dismissed to the extent that the claims allege a duplicative or independent tort under the MPLA. However, Knoth may proceed with a manufacturing claim to the extent that it is brought as a violation of the MPLA.

Accordingly,

IT IS HEREBY ORDERED AND ADJUDGED that Defendant Apollo's Motion to Dismiss is GRANTED in part and DENIED in part.

SO ORDERED this the 8th day of November, 2019.

_/s/ David Bramlette_____
UNITED STATES DISTRICT JUDGE