UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

COLLEEN ROWE,

Plaintiff,

v. Case No: 8:17-cv-2438-T-30CPT

MENTOR WORLDWIDE, LLC and DOES 1-100,

Defendants.

ORDER

In 2015, Plaintiff Colleen Rowe had breast augmentation surgery using Defendant Mentor Worldwide, LLC's MemoryGel Silicone Gel Breast Implants ("MemoryGel Implants"). The left MemoryGel Implant failed, and was replaced seven months later. Now Rowe is suing Mentor for negligence, strict liability, and breach of implied warranty. The Court concludes all but one of the claims must be dismissed because they are preempted or are otherwise unavailable to Rowe.

BACKGROUND

Mentor designs, manufactures, tests, and distributes MemoryGel Implants for use in breast augmentation surgeries. (Doc. 1, ¶ 55). The MemoryGel Implants are a Class III device under the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"), and require premarket approval ("PMA") from the Food & Drug Administration ("FDA"). (Doc. 1, ¶¶ 6–7, 10). Mentor filed a PMA application for the MemoeryGel Implants in December 2003. (Doc. 1, ¶ 56). The FDA provided the PMA in

November 2006, allowing Mentor to market the MemoryGel Implants. (Doc. 1, ¶ 57). A condition of the PMA required Mentor to conduct six post-approval studies regarding the long-term safety and effectiveness of the MemoryGel Implants. (Doc. 1, ¶¶ 58–87).

Plaintiff Rowe had breast augmentation surgery on April 2, 2015, and was implanted with MemoryGel Implants. (Doc. 1, ¶ 125). Nearly seven months later, Rowe began experiencing pain and limited functionality in her left arm. (Doc. 1, ¶ 127). Rowe also experienced "extreme and chronic fatigue, anxiety, depression, muscle pain, muscle weakness, muscle cramps, nausea, bone pain, swelling [in] her joints, stiffness in her joints, irritability, shortness of breath, signs of silicone toxicity, and weight gain." (Doc. 1, ¶ 127). On November 6, 2015, Rowe underwent a second surgery that revealed the left MemoryGel Implant had ruptured. (Doc. 1, ¶ 129). Her surgeon removed the ruptured MemoryGel Implant and replaced it. (Doc. 1, ¶ 129).

Despite replacement of the ruptured MemoryGel Implant, Rowe continued to experience "pain, discomfort, swelling and soreness to her left side at the surgical site…." (Doc. 1, ¶ 131). Rowe also continued to experience "extreme and chronic fatigue, anxiety, depression, joint pain, joint stiffness, irritability, weight gain, shortness of breath, muscle cramps, muscle weakness, nausea and other ailments." (Doc. 1, ¶ 132).

In December 2015, Rowe's surgeon recommended a third surgery conditioned on Rowe signing a release and hold harmless agreement in favor of Defendant Mentor. (Doc. 1, ¶ 133). Rowe has not yet undergone that surgery, but says she intends to have her MemoryGel Implants removed. (Doc. 1, ¶ 139).

Now Rowe is suing Mentor for negligence, strict liability, and breach of implied warranty. (Doc. 1). Rowe alleges generally that Mentor failed to properly conduct the post-approval studies, and failed to warn consumers and physicians about known risks associated with the MemoryGel Implants. Rowe also alleges that her MemoryGel Implant was somehow defective. Finally, Rowe alleges that the MemoryGel Implant was not of merchantable quality, nor reasonably fit for its intended purposes.

MOTION TO DISMISS STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows a complaint to be dismissed for failure to state a claim on which relief can be granted. When reviewing a motion to dismiss, courts must limit their consideration to the well-pleaded allegations, documents central to or referred to in the complaint, and matters judicially noticed. *See La Grasta v. First Union Securities, Inc.*, 358 F.3d 840, 845 (11th Cir. 2004) (internal citations omitted); *Day v. Taylor*, 400 F.3d 1272, 1276 (11th Cir. 2005). Furthermore, they must accept all factual allegations contained in the complaint as true, and view the facts in a light most favorable to the plaintiff. *See Erickson v. Pardus*, 551 U.S. 89, 93–94 (2007).

Legal conclusions, though, "are not entitled to the assumption of truth." *Ashcroft v. Iqbal*, 556 U.S. 662, 664 (2009). In fact, "conclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts will not prevent dismissal." *Davila v. Delta Air Lines, Inc.*, 326 F.3d 1183, 1185 (11th Cir. 2003). To survive a motion to dismiss, a complaint must instead contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (internal quotation marks and citations omitted). This plausibility standard is met when the plaintiff

pleads enough factual content to allow the court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (internal citations omitted).

DISCUSSION

Mentor seeks dismissal of the Complaint on multiple grounds, but primarily based on Rowe's claims being expressly and impliedly preempted. (Doc. 11). The Court agrees, except as to Rowe's negligent manufacturing defect claim. So all of Rowe's claims will be dismissed except that one.

But first the Court will address a growing plague on the justice system, which has wreaked havoc in this case and numerous others: poorly drafted pleadings. Federal Rule of Civil Procedure 8 requires claims and defenses to be pleaded in "short and plain" statements. Fed. R. Civ. P. 8(a)(2), (b)(1)(A). Pleading allegations also "must be simple, concise, and direct." Fed. R. Civ. P. 8(d)(1). As the Eighth Circuit explained 50 years ago, "The clear purpose of the rule is to give notice to the other party and not to formulate issues or fully summarize the facts involved." *Clausen & Sons, Inc. v. Theo. Hamm Brewing Co.*, 395 F.2d 388, 390 (8th Cir. 1968).

Courts are also directed to construe pleadings "so as to do justice." Fed. R. Civ. P. 8(e). To that effect, the liberal federal pleading standard "reject[s] the approach that pleading is a game of skill in which one misstep by counsel may be decisive to the outcome and accept[s] the principle that the purpose of pleading is to facilitate a proper decision on the merits." *Beem v. Ferguson*, No. 16-11842, 2018 WL 718609, at *4 (11th Cir. Feb. 6, 2018). So a pleading generally is sufficient if it gives notice of the claims or defense and

the grounds upon which they rest. *Lombard's, Inc. v. Prince Mfg., Inc.,* 753 F.2d 974, 975 (11th Cir. 1985).

There is a point, though, where a pleading becomes deficient not because it lacks sufficient allegations to provide notice of claims, but because it buries those allegations among pages of irrelevant and impertinent material. In other words, it lacks "simple, concise, and direct" allegations that provide "short and plain" statements of the claims. This happens when, to borrow from a familiar analogy, attorneys throw every allegation they can think of into a pleading to see what sticks.

Inevitably, opposing counsel then moves to dismiss. The parties ask the courts to carefully comb through the pleading, determining whether the facts alleged are sufficient to support a claim and whether all of the necessary elements have been pleaded. In doing so, parties skirt their Rule 8 pleading requirements and rely on the Court's obligation to construe the pleading so as to do justice. But this flips Rule 8 on its head and is not required even under the most liberal view of the federal notice-pleading standard.

Rowe's Complaint is such a pleading. The four-count Complaint is a sprawling 60 pages, with an additional 151 pages of exhibits. Count I, for negligence, begins at paragraph 143 on page 41. None of the preceding allegations are incorporated into this count (or any other), indicating that the first 40 pages of the Complaint was unnecessary.

To compound these issues, Rowe's actual claims are far from "short and plain" statements contemplated by Rule 8. The negligence count itself is eight pages long and, as far as the Court can determine, includes six separate negligence theories that are confusingly interwoven among each other. Rowe alleges causation and damages for some

of the theories, but not others. She also repeats the same allegations within and among the various theories, making it unclear to which theory certain allegations pertain.

These problems continue into the other counts as well. For instance, in count II for strict liability for failure to warn, paragraphs 198 and 208 are nearly identical.[1] And while Rowe separated her strict liability claims for failure to warn (count II) and manufacturing defect (count III), both counts contain allegations only relevant to the other claim.

Having painstakingly reviewed the Complaint, the Court can say without doubt that Rowe threw every allegation into the Complaint to see what would stick. And to borrow another saying, the Court is tempted to throw the baby—in this case, one potentially viable claim—out with the bath water. But to do so would not do justice.

So the Court will instead parse through the Complaint and explain why all but one of Rowe's claims fail. But this Order shall serve as notice that this Court will no longer accept pleadings that deviate so drastically from the requirements of Rule 8, and will instead either dismiss the pleading upon proper motion or order a repleader.

A. Law Governing Preemption under the MDA

Rather than re-invent the wheel, the Court relies on the Eleventh Circuit's recent primer on federal preemption law under the MDA:

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[1] Paragraph 198 states: "At all relevant times, Plaintiff's Mentor MemoryGel Silicone Gel Breast Implants were used and implanted into Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants." (Doc. 1).

Paragraph 208 states: "At all relevant times, Plaintiff's Mentor MemoryGel Silicone Gel Breast Implants were used and implanted as intended by Defendants and in a manner reasonably foreseeable to Defendants." (Doc. 1).

> The Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.*, give the FDA regulatory authority over medical devices. [*Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1325 (11th Cir. 2017)]. Class III devices like the LifeVest, which are deemed the highest risk, are required to go through an extensive premarket approval process. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317–18, 128 S.Ct. 999, 1003–04, 169 L.Ed.2d 892 (2008). Once a device has been approved, a manufacturer may not make any change to the device that could affect its safety or effectiveness unless that change gets additional approval from the FDA. *Id.* at 319, 128 S.Ct. at 1005.
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> The MDA provides for two types of preemption of certain state law claims relating to medical devices: express and implied. The express preemption provision bars any claim based on a state law requirement "which is different from, or in addition to, any requirement" under the MDA that "relates to the safety or effectiveness of the device" or any other MDA requirement. 21 U.S.C. § 360k(a). The implied preemption provision of the MDA states that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." *Id.* § 337(a). The Supreme Court has interpreted this implied preemption provision to bar claims that merely attempt to enforce duties owed to the FDA, so-called "fraud-on-the-FDA claims." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348, 121 S.Ct. 1012, 1017, 148 L.Ed.2d 854 (2001).
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> Taken together, these two types of preemption leave a "narrow gap" through which plaintiffs making medical device claims must proceed. *See In re Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010). "To make it through, a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption), but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption)." *Mink*, 860 F.3d at 1327. Put differently, "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.' " *Id.* (quoting *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010)).

Godelia v. Doe 1, 881 F.3d 1309, 1317 (11th Cir. 2018).

To determine whether a complaint alleges a viable claim, the first step is to determine whether the complaint alleges a claim that can stand under state law. *Mink*, 860

F.3d at 1327–28. Only after determining if the claim can stand under state law will a court decide whether the claim is preempted. *Id.*

B. Application of Preemption Law to Rowe's Claims

Rowe alleges four Florida state-law claims against Mentor: (1) negligence, (2) strict liability for failure to warn, (3) strict liability for manufacturing defect, and (4) breach of implied warranty. In a well-written motion, Mentor argues that each of Rowe's claims are preempted, either expressly or impliedly. Mentor also argues that Rowe failed to plausibly plead that the violation of federal requirements caused her injuries, and that she lacks privity with Mentor to sue for breach of implied warranty.

Rather than responding to these arguments, Rowe copied a response to a motion to dismiss that was filed in a California case.[2] *See* Docs. 18 (Rowe's response) and 19-1 (response filed in other case). Rowe's response cites to mostly non-binding law and contains facts that do not apply to her case. So the response, to say the least, is unhelpful.

But even though Rowe's counsel failed to provide the Court with a meaningful response, the Court cannot simply grant Mentor's motion. Instead, the Court will determine whether Rowe pleaded claims that can stand under Florida state law, and then determine if those claims are preempted.

1. Negligence

Rowe alleges six different theories as to why Mentor is liable for negligence: (a) failure to warn, (b) failure to report, (c) failure to comply with federal requirements, (d)

[2] That case is *Mize v. Mentor Worldwide, LLC,* No. 2:17-cv-1747-DMG-KS (C.D. Cal.).

negligent misrepresentation, (e) negligence *per se*, and (f) manufacturing defect. Under Florida law, "[t]o maintain an action for negligence, a plaintiff must establish that the defendant owed a duty, that the defendant breached that duty, and that this breach caused the plaintiff damages." *Chang v. JPMorgan Chase Bank, N.A.*, 845 F.3d 1087, 1094 (11th Cir. 2017) (*Fla. Dep't of Corr. v. Abril*, 969 So.2d 201, 204 (Fla. 2007)). The Court, in looking at each theory separately, will determine whether Rowe sufficiently pleaded a claim for negligence that is recognized under Florida law, and then determine if that theory is preempted.

a. Failure to warn

Negligent failure to warn is a recognized action under Florida law. *Mink*, 860 F.3d at 1329. And Rowe alleges in the Complaint all of the necessary elements to state a claim for negligent failure to warn: she alleges Mentor had a duty to provide adequate warnings about the risks of the MemoryGel Implants (Doc. 1, ¶ 145), that Mentor breached the duty by failing to warn of the risks associated with MemoryGel Implants (Doc. 1, ¶ 148), and that the failure to warn caused her damages (Doc. 1, ¶ 154). So Rowe adequately pleaded a claim that can stand under Florida law.

But this claim is expressly preempted. Rowe does not allege that Mentor failed to give the warning required by the FDA and federal requirements. So Rowe is attempting to hold Mentor to a state-law requirement that is different or in addition to what federal law requires. *Mink*, 860 F.3d at 1325 (quoting 21 U.S.C. § 360k(a)). So Rowe cannot pursue negligence based on this theory of liability.

b. Failure to report

Similar to the prior theory, Rowe states a viable Florida state-law claim for negligent failure to report. In fact, the Eleventh Circuit has equated failure to report with failure to warn under Florida law. *Id.* at 1329 ("Florida law recognizes this [failure to report adverse events] theory as 'negligent failure to warn.' "). Rowe alleges in the Complaint that Mentor had a duty to disclose its knowledge of adverse events (Doc. 1, ¶ 151), that Mentor failed to report adverse events (Doc. 1, ¶¶ 146–147), and that the failure caused Rowe's damages. (Doc. 1, ¶ 154).[3]

But like its sister theory above, Rowe's failure to report theory of liability is also preempted, albeit impliedly instead of expressly. Rowe alleges that Mentor should have reported adverse events, presumably to the FDA as required by federal regulations. As the Eleventh Circuit explained in *Mink*, a failure to report claim like this is "very much like the 'fraud-on-the FDA' claim the Supreme Court held was impliedly preempted in *Buckman*" because Rowe is alleging Mentor "failed to tell the FDA those things required by federal law." 860 F.3d at 1330. So Rowe cannot pursue negligence based on this theory of liability.

c. Failure to comply with federal laws

Rowe alleges that Mentor's MemoryGel Implants PMA required them to conduct six studies (Doc. 1, ¶ 149), and that Mentor negligently failed to comply with these

[3] Admittedly, it is unclear if Rowe intended to allege this theory of liability given that the allegations are out of order. But the Court addresses it in an abundance of caution.

requirements (Doc. 1, ¶ 150). Rowe also alleges that Mentor breached a general duty of care to Rowe by Mentor's "failure to comply with its PMA and FDA post-marketing regulations," which caused Plaintiff's damages. (Doc. 1, ¶ 154).

Rowe's claim is for breach of the federal requirements and regulations. But Rowe never identifies a parallel state duty to comply with the requirements and regulations. And this Court is unaware of any duty imposed under Florida law imposing such a duty. So the Court concludes that Rowe has failed to state a viable negligence claim under Florida law.

Even if she had, though, this theory of liability would be impliedly preempted. This is the quintessential claim that the Supreme Court held was impliedly preempted in *Buckman* because Rowe is suing under this theory "because the conduct violated" the federal requirements. *Godelia*, 881 F.3d at 1317. So Rowe cannot pursue a negligence claim based on this theory of liability.

d. Negligent misrepresentation

Florida law recognizes an action for negligent misrepresentation. *Id.* at 1321. A negligent misrepresentation action is subject to the heightened Federal Rule of Civil Procedure 9(b) pleading standard. *Lamm v. State St. Bank & Tr.*, 749 F.3d 938, 951 (11th Cir. 2014). This standard requires "a plaintiff [to] plead 'facts as to time, place, and substance of the defendant's alleged fraud,' specifically 'the details of the defendant['s] allegedly fraudulent acts, when they occurred, and who engaged in them.'" *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006). "In other words, the plaintiff must identify: (1) the allegedly fraudulent statement, document, representation, or omission made; (2) the time, place, and person responsible for each misrepresentation; (3)

the manner in which each misrepresentation misled the plaintiff; and (4) what the defendant gained from the alleged fraud." *MidAmerica C2L, Inc. v. Siemens Energy, Inc.*, No. 617CV171ORL40KRS, 2017 WL 1322327, at *4 (M.D. Fla. Apr. 7, 2017) (citing *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1291 (11th Cir. 2010)).

Here, Rowe alleges that Mentor had a duty to truthfully and accurately communicate about the risks associated with the MemoryGel Implants. (Doc. 1, ¶¶ 155, 161). Rowe then alleges that Mentor breached this duty when it did the following:

- "negligently disseminated inaccurate and misleading information to physicians" (Doc. 1, ¶ 156);
- "disseminated false information, in that they engaged in false and misleading sales and marketing tactics, touting the aesthetic beauty of breast augmentation and minimizing the risks" (Doc. 1, ¶ 158);
- "produced false and misleading sales and marketing tactics and concealed adverse information" (Doc. 1, ¶ 159);
- "disseminated the false information, as referenced above, to physicians, the medical community, and the public" (Doc. 1, ¶ 162);
- "negligently failed to exercise reasonable care to ensure that the information disseminated to physicians and patients concerning the properties and effects of Mentor MemoryGel Silicone Gel Breast Implants was accurate and not misleading" (Doc. 1, ¶ 163); and
- "failing to ensure representations regarding Mentor MemoryGel Silicone Gel Breast Implants were truthful, accurate, and not misleading" (Doc. 1, ¶ 164).

Rowe then alleges she relied on the negligent misrepresentations to her detriment. (Doc. 1, ¶¶ 166–67).

A brief review of the allegations shows that they are wholly inadequate to meet the Rule 9(B) pleading standard. Rowe never identifies what the misrepresentations were, when they were made, how they were made, where they were made, or who made them.

As best this Court can tell, the misrepresentations about which Rowe complains have to do with Mentor's reports to the FDA since she does not allege any other communications were made by Mentor. She also fails to allege that the misrepresentations were made to her or to her physician. So Rowe fails to plead a plausible claim for negligent misrepresentation under Florida law.

To the extent Rowe is alleging Mentor made misrepresentations in its reports to the FDA, the Court concludes those claims are impliedly preempted. This would be the same sort of "fraud-on-the-FDA" claims the Eleventh Circuit has concluded are impliedly preempted in failure to report claims. *Mink*, 860 F.3d at 1330. So the Court concludes that Rowe's negligent misrepresentation claim—if properly pleaded—would be impliedly preempted, and Rowe cannot pursue negligence based on this theory of liability.[4]

e. Negligence *per se*

Rowe's negligence *per se* theory fails for nearly the same reasons her failure to comply with federal laws theory failed. While Florida recognizes a cause of action for negligence *per se* in some instances, "violation of a federal regulation does not create civil liability based upon a theory of negligence *per se* in the absence of evidence 'of a legislative intent to create a private cause of action.' " *Pantages v. Cardinal Health 200, Inc.*, No. 5:08CV116OC-10GRJ, 2009 WL 2244539, at *2 (M.D. Fla. July 27, 2009). Rowe alleges violations of numerous federal regulations[5] but never identifies any private right of

[4] If Rowe intended to plead this claim based on other, unalleged misrepresentations, she may seek leave of Court to reassert this claim with the specificity required by Rule 9(b).

[5] The specific regulations are "21 C.F.R. § 803.10; 21 C.F.R. § 803.50; 21 C.F.R. § 803.52;

action applicable to them. So negligence *per se* for violation of these specific regulations is not a viable theory of negligence that can stand under Florida law.

But even if negligence *per se* as pleaded was a viable theory under Florida law, Rowe's claim would be impliedly preempted. This is the sort of claim addressed by *Buckman*, in which Rowe is suing *because* Mentor violated federal regulations. *Godelia*, 881 F.3d at 1317. Because this is not a parallel claim, it is preempted, and Rowe cannot pursue negligence based on this theory.

f. Manufacturing defect

Florida recognizes negligence actions based on a theory of manufacturing defect. *Mink*, 860 F.3d at 1329 (citing *Ford Motor Co. v. Evancho*, 327 So.2d 201, 202 (Fla. 1976)). "In Florida, 'a manufacturer's duty to inspect and test ....[sic] is a subpart of a manufacturer's duty to design a product with reasonable care.' " *Godelia*, 881 F.3d at 1318 (quoting *Adams v. G.D. Searle & Co.*, 576 So.2d 728, 730–31 (Fla. 2d DCA 1991)). And the Florida common law duty to use due care in manufacturing a medical device "is parallel to the federal requirement that the [device] be manufactured according to the approved specifications for the medical device." *Mink*, 860 F.3d at 1330.

Here, Rowe alleged that Mentor negligently manufactured the MemoryGel Implant in the following ways:

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21 C.F.R. §803.53; 21 C.F.R. § 803.56; 21, C.F.R. § 806; 21 C.F.R. § 814.1; 21 C.F.R. § 814.3; 21 C.F.R. § 814.9; 21 C.F.R. § 814.20; 21 C.F.R. § 814.37; 21 C.F.R. § 814.39; 21 C.F.R. § 814.80; 21 C.F.R. § 814.82; 21 C.F.R. § 814.84; 21 C.F.R. § 820.1; 21 C.F.R. § 820.5; 21 C.F.R. § 820.20; 21 C.F.R. § 820.22; 21 C.F.R. § 820.25; 21 C.F.R. § 820.30; 21 § C.F.R. 820.70; 21 § 820.90; and 21 C.F.R. § 820.160." (Doc. 1, ¶ 169). The Court notes that some of these so-called regulations are scope and definition sections that cannot be violated, negligently or otherwise.

- manufacturing actual Mentor MemoryGel Silicone Gel Breast Implants that differ from the specifications set forth in the PMA, its Supplements, the Conditions of Approval, and/or other federal regulations;
- manufacturing actual Mentor MemoryGel Silicone Gel Breast Implants with nonconforming materials and uncertified components, inconsistent with the specifications set forth in the PMA, its Supplements, the Conditions of Approval and/or other federal regulations;
- failing to conduct regular risk analysis of Mentor MemoryGel Silicone Gel Breast Implant;
- failing to properly meet the applicable standard of care by not complying with applicable federal regulations;
- carelessly and negligently selling and distributing Mentor MemoryGel Silicone Gel Breast Implants in violation of the PMA and federal law;
- negligently incorporating components into Mentor MemoryGel Silicone Gel Breast Implants that could not stand up to normal usage;
- failing to exercise reasonable care in its inspecting and testing of the product; and
- failing to exercise reasonable care in its manufacturing and quality control processes.

(Doc. 1, ¶ 174(a)–(h). Rowe also separately alleges that the "manufacturing process did not conform to the FDA's current good manufacturing practices ("cGMP") design controls enumerated in 21 C.F.R. § 820.30." (Doc. 1, ¶ 178). Rowe then alleges that she was implanted with a MemoryGel Implant that was defectively manufactured (Doc. 1, ¶ 186), and that the defective MemoryGel Implant caused her damages (Doc. 1, ¶ 187).

Mentor argues that these allegations are insufficient because Rowe does not allege how the MemoryGel Implant she received deviated from the cGMPs. (Doc. 11, pp. 15–18). Mentor also argues that Rowe has not pointed to any device-specific requirements with which the MemoryGel Implant did not comply (Doc. 11, pp. 17–18). In making these

arguments, Mentor relies on *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011), in which the Eleventh Circuit explained,

> "Plaintiffs cannot simply incant the magic words '[Appellees] violated FDA regulations' in order to avoid preemption." *In re Medtronic Inc.,* 592 F.Supp.2d 1147, 1158 (D.Minn.2009). Parallel claims must be specifically stated **in the initial pleadings**. A plaintiff must allege that "[the] defendant violated **a particular federal specification referring to the device at issue.**"*Ilarraza v. Medtronic, Inc.,* 677 F.Supp.2d 582, 589 (E.D.N.Y.2009). "To properly allege parallel claims, **the complaint must set forth facts" pointing to specific PMA requirements that have been violated**. *Parker v. Stryker Corp.*, 584 F.Supp.2d 1298, 1301 (D.Colo.2008). The trial court stated in *Parker* that an allegation that "the manufacturing processes for the device and certain of their ... components did not satisfy the Food and Drug Administrations's Pre–Market Approval standards for the devices" is insufficient to satisfy the requisite elements of a parallel claim as set forth in *Riegel* if the complaint fails to "provide any factual detail to substantiate that crucial allegation." *Id.* at 1302.

634 F.3d at 1301 (bold added for emphasis). While *Wolicki-Gables* was an appeal of an order granting summary judgment as opposed to a motion to dismiss, the above excerpt clearly discusses what is required at the initial pleading stage. Applying the standard in *Wolicki-Gables*, the Court concludes Rowe's Complaint would be deficient.

But the Eleventh Circuit has recently readdressed this pleading requirement in *Mink* and *Godelia* and appears to have stepped back from *Wolicki-Gable*'s requirements. In *Mink* and *Godelia*, the Eleventh Circuit ruled that a claim for manufacturing defect passes muster even if a plaintiff fails to identify device-specific regulations that were violated. *Mink*, 860 F.3d at 1331 n.3 ("To the extent [the defendant] argues that some of the federal regulations cited by [the plaintiff] are not sufficiently device-specific, we reject its argument."); and *Godelia*, 881 F.3d at 1320 ("The fact that the regulations identified are not device-specific is of no moment."). The holdings in *Mink* and *Godelia* are directly at odds with *Wolicki-*

Gables,[6] and appear to announce a new standard the Eleventh Circuit is directing courts to apply. Applying that new standard, the Court concludes that Rowe pleaded enough to state a claim for negligence based on a theory of manufacturing defect.

And the Court concludes such a claim would not be preempted. As explained above, 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. *Mink*, 860 F.3d at 1330. So Rowe has stated a parallel claim and will be able to pursue negligence based on this theory of liability.

That said, the negligence count is nearly eviscerated by the Court's ruling on the other theories. Rather than forcing Mentor to determine which allegations in the negligence count pertain to Rowe's manufacturing defect theory, the Court will order Rowe to replead her claim in an amended complaint.

2. Strict liability – failure to warn

In this count, Rowe alleges that Mentor is strictly liable for both failure to warn and for failure to comply with its reporting obligations. As noted above, both causes of action are recognized under Florida law as a failure to warn claim. *Mink*, 860 F.3d at 1329. And, for the same reasons noted in the previous section, both of these theories are preempted.

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[6] The Eleventh Circuit unconvincingly attempts to distinguish *Godelia* from *Wolicki-Gables* by stating the plaintiff in Godelia identified specific federal regulations that the subject devices violated. *Godelia*, 881 F.3d at 1320. But the *Godelia* Court went on to say that the regulations did not have to be device specific, *id.*, just like the *Mink* Court. 860 F.3d at 1331 n.3. But the *Wolicki-Gables* Court was clear that a plaintiff had to allege violation of "a particular federal specification referring to the device at issue." 634 F.3d at 1301.

Rowe's claim that Mentor failed to warn consumers and physicians is expressly preempted because it requires Mentor to comply with a Florida requirements that is different from or in addition to the federal requirements. *Id.* at 1325 (quoting 21 U.S.C. § 360k(a)). And the failure to report claim is impliedly preempted because it is based solely on Mentor violating a federal requirement without identifying a parallel state requirement. *Id.* at 1330. Accordingly, this count is preempted.

3. Strict liability – manufacturing defect

In this count, Rowe alleges that Mentor is strictly liable for a manufacturing defect. But unlike in the negligent manufacturing defect claim, Rowe here never identifies any specific regulations that were violated.[7] Instead, Rowe generically refers to all of "the FDA's Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. § 820.1, et seq." (Doc. 1, ¶ 228). This is akin to the "violated FDA regulations" allegations rejected in *Wolicki-Gables*, 634 F.3d at 1301, and would also be insufficient under *Mink* and *Godelia*. Because these allegations fail to identify a federal regulation that was violated, the Complaint fails to state a parallel claim, and the Court concludes this claim is expressly preempted. *See id.* at 1302 (concluding the court did not err in concluding claims were preempted when the plaintiff failed to "set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged.").

[7] The Court again notes that Rowe never incorporated her prior allegations into this count. So although she alleged specific regulations in the negligence count, the Court will not consider those allegations in analyzing this strict liability count.

4. Breach of implied warranty

In the final count, Rowe alleges that Mentor breached its implied warranty that the MemoryGel Implant was of merchantable quality and reasonably fit for its intended purposes. "Under Florida law, a plaintiff cannot recover economic losses for breach of implied warranty in the absence of privity." *Mesa v. BMW of N. Am., LLC*, 904 So. 2d 450, 458 (Fla. Dist. Ct. App. 2005). As Mentor argues, Rowe never alleges she has privity with Mentor, nor can she since the MemoryGel Implant is a prescription medical device unavailable for purchase directly by consumers. (Doc. 11, p. 24). Rowe apparently concedes this point since she did not respond to it. *Stewart v. Sotolongo*, No. 8:07-CV-54-T-24 MAP, 2007 WL 1796545, at *12 (M.D. Fla. June 21, 2007) (presuming arguments are conceded with not addressed in response); *William Kramer & Assocs., LLC v. United States*, No. 8:08CV640T24MAP, 2008 WL 5051429, at *2 (M.D. Fla. Sept. 10, 2008) (same). The Court concludes Rowe's breach of implied warranty claim must be dismissed because she lacks privity with Mentor, as she has conceded.

CONCLUSION

Rowe's claims against Mentor—except her claim for negligence based on a manufacturing defect theory—must be dismissed. Her remaining negligence theories are either unable to stand under Florida law, or are preempted by federal law. Rowe's strict liability claims for failure to warn and failure to report are also expressly and impliedly preempted. Rowe's strict liability manufacturing defect claim is preempted because she fails to identify any specific regulation the MemoryGel Implant did not satisfy. And

Rowe's claim for breach of implied warranty fails because she lacks privity with Mentor. The Court directs Rowe to replead her remaining claim for negligent manufacturing defect.

Accordingly, it is ORDERED AND ADJUDGED that:

1. Defendant's Rule 12(b)(6) Motion to Dismiss Plaintiff's Complaint (Doc. 11) is GRANTED IN PART.
2. The Complaint (Doc. 1) is DISMISSED as follows:
   a. Count I is dismissed with prejudice as to all theories of liability except manufacturing defect; and
   b. Counts II, III, and IV are dismissed with prejudice in their entirety.
3. Plaintiff Colleen Rowe is directed to replead the sole remaining count for negligent manufacturing defect within fourteen (14) days from the date of this Order in accordance with the requirements of Federal Rule of Civil Procedure 8. Failure to do so could result in this case being dismissed.

DONE and **ORDERED** in Tampa, Florida, this 2nd day of March, 2018.

JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies furnished to:
Counsel/Parties of Record