**UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF FLORIDA**
**TAMPA DIVISION**

**PAUL E. LEDERMAN,**

**Plaintiff,**

**v.** **Case No. 8:13-cv-506-T-30AEP**

**HOWMEDICA OSTEONICS CORP., and STRYKER ORTHOPAEDICS CORP.,**

**Defendants.**
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## ORDER

THIS CAUSE comes before the Court upon Defendant Howmedica Osteonics Corp.'s Motion to Dismiss Amended Complaint (Dkt. 31), Defendant Howmedica Osteonics Corp.'s Notice of Supplemental Authority (Dkt. 32), and Plaintiff Paul E. Lederman's Response in Opposition (Dkt. 33). The Court, having reviewed the motion, response, supplemental authority, and being otherwise advised in the premises, concludes that the motion should be granted without prejudice to Plaintiff to amend his complaint a final time.

## DISCUSSION

This removed case is a medical device product liability action filed on January 15, 2013, in the Twelfth Judicial Circuit, in and for Manatee County, Florida. Plaintiff Paul E. Lederman alleges he sustained injuries from the implantation of a Stryker Trident artificial hip prosthesis designed, manufactured, and sold by Defendant Howmedica Osteonics Corp. ("HOC").

On March 7, 2013, HOC filed a motion to dismiss the complaint on the grounds that the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §360k, to the Federal Food, Drug and Cosmetics Act ("FDCA") preempts all of Plaintiff's claims. On March 19, 2013, Plaintiff filed a motion to remand, which this Court denied because Defendant Dr. Alan L. Valadie was fraudulently joined. The Court accordingly dismissed the claims against Defendant Dr. Alan L. Valadie without prejudice. The Court ordered Plaintiff to file a response to HOC's motion to dismiss on or before April 22, 2013.

Plaintiff did not file a response on April 22, 2013. Accordingly, the Court entered an order to show cause and directed Plaintiff to file his response within fourteen days (by May 8, 2013). On May 7, 2013, Plaintiff filed a motion to amend the complaint, which the Court granted. On May 9, 2013, Plaintiff filed his amended complaint (Dkt. 30). Plaintiff alleges a single claim for negligent manufacturing (Dkt. 30 at ¶ 54). HOC now seeks to dismiss Plaintiff's amended complaint. Like its first motion to dismiss, HOC argues, in relevant part, that Plaintiff's negligent manufacturing claim is expressly preempted by the MDA to the FDCA. For the reasons discussed below, the Court grants HOC's motion without prejudice to Plaintiff to amend his complaint a final time.

## MOTION TO DISMISS STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows a complaint to be dismissed for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). When reviewing a motion to dismiss, a court 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). However, unlike factual allegations, conclusions in a pleading "are not entitled to the assumption of truth." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009). On the contrary, legal conclusions "must be supported by factual allegations." *Id.* Indeed, "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).

## DISCUSSION

Plaintiff alleges a claim for negligent manufacturing. As a result, Plaintiff must plead a manufacturing defect. *See Citizens Prop. Ins. Corp. v. Simkar LLC*, 813 F. Supp. 2d 1356, 1362 (M.D. Fla. 2011).

The parties do not dispute the underlying legal framework. Specifically, the United States Food and Drug Administration ("FDA") approved the medical device implanted in Plaintiff through the Premarket Approval ("PMA") process. As a result of that "rigorous process" for approval, a category of express preemption applies to protect such medical devices from state-law claims seeking to impose liability. *See Riegel v. Medtronic*, 552 U.S. 312, 317 (2008). As summarized in *Riegel*, the MDA contains an express-preemption provision. *See id.* at 316-19 (applying 21 U.S.C. §360c *et seq.*). That provision states as follows:

> [N]o 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.

*Id.* at 316 (quoting 21 U.S.C. § 360k(a)). Thus, state-law claims against PMA medical devices are preempted when they seek to impose requirements that are "different from, or in addition to" the "detailed federal oversight" involved in PMA. *Id.*

The Eleventh Circuit has applied this form of express preemption to a Florida law manufacturing defect claim. *See Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011). In *Wolicki-Gables*, the Eleventh Circuit held that a claim that the manufacturer "fail[ed] to reasonably manufacture the [PMA medical device] in a reasonable manner" was preempted under *Riegel* and section 360k(a). *Id.* The Eleventh Circuit noted that such a claim "could [impose] liability even if the manufacturer had completely complied with the" federal requirements for the medical device. *Id.* Thus, like any claim that would require the medical device to be manufactured other than in the manner approved and required by the PMA, the claim imposed a requirement "different from, or in addition to" the PMA requirements. *Id.*; *see Stokes v. I-Flow Corp.*, 2013 WL 1715427, at *6 (M.D. Fla. Apr. 8, 2013) ("Florida laws . . . for negligent [] manufacture . . . imposed requirements that were 'different from, or in addition to' the federal requirements established for the premarket approval of the device at issue").

A limited exception to the rule of express preemption may apply for "parallel claims" in which the state-law requirement matches the federal requirement. *See Riegel*, 552 U.S. at 330; *Wolicki-Gables*, 634 F.3d at 1300-01. The parties dispute whether Plaintiff alleges

a parallel claim. Although Plaintiff argues standards set forth by other Circuits, the Court will not ignore the binding and specific requirements for alleging a parallel claim set forth in *Wolicki-Gables. See* 634 F. 3d at 1300-01.

Under *Wolicki-Gables*, "for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are '*genuinely* equivalent.'" *Id.* at 1300 (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)) (emphasis in original). To allege a "genuinely equivalent" parallel claim:

> Plaintiffs cannot simply incant the magic words "[Appellees] violated FDA regulations" in order to avoid preemption. 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. To properly allege parallel claims, the complaint must set forth facts pointing to specific PMA requirements that have been violated.
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> . . .
>
> The[] allegations [must] set forth [a] specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged.

*Id.* at 1301-02 (internal citations and quotation omitted). In other words, a plaintiff must "identify [a] particular specification or specific PMA requirement or FDA regulation that [d]efendant violated" regarding the plaintiff's medical device and that caused the plaintiff's injury. *Kaiser v. DePuy Spine, Inc.*, 2013 WL 2006122, at *4 (M.D. Fla. May 14, 2013) (dismissing claims under PMA preemption).

Plaintiff attempts to allege a parallel claim by asserting that HOC violated several federal regulations. Plaintiff alleges that the FDA sent a warning letter to HOC in March

2007 regarding an inspection of HOC's manufacturing plant in Ireland, and sent another warning letter to HOC in November 2007 regarding an inspection of HOC's manufacturing plant in New Jersey. Plaintiff alleges that the warning letters addressed violations of Current Good Manufacturing Practice ("CGMP") requirements at both plants. Plaintiff further alleges that the medical device implanted in his hip was manufactured at one of those two plants.

Under certain circumstances, an FDA warning letter may support a parallel claim, including under the *Wolicki-Gables* standard. *See Cline v. Advanced Neuromodulation Sys., Inc.*, 2012 WL 7009687, at *6 (N.D. Ga. Nov. 7, 2012) (plaintiff used warning letter to "allege[] specific facts about when and how these violations occurred in the manufacture of the specific device at issue"); *see also Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 156 (S.D.N.Y. 2011) (plaintiff used warning letter to support allegations that her medical device "was adulterated because some of the components, as a result of the manufacturing process, contained excess levels of manufacturing residue"). The violations stated in the warning letter must, however, relate to the plaintiff's medical device and alleged injury. *See Anthony v. Stryker Corp.*, 2010 WL 1387790, at *4 (N.D. Ohio Mar. 31, 2010) (plaintiff did not allege "that his injuries were caused by any act of noncompliance specified in the [] warning letters"); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 283 (E.D.N.Y. 2009) ("Plaintiff has failed to demonstrate that the injuries she sustained resulted from the federal violations spelled out in the warning letters."). This requirement is consistent with the specific

requirements for alleging "genuine equivalence" from *Wolicki-Gables*. *See* 634 F.3d at 1300-01.

Here, Plaintiff fails to plead the necessary nexus between the warning letters, his device, and his injuries. For example, Plaintiff fails to allege how warning letters issued in 2007, regarding inspections in 2006 and 2007, and referencing complaints dating back to 2005, could relate to his medical device implanted in 2004. Plaintiff alleges generally that his medical device was defectively manufactured because it "contained dimensional mismatches . . . [that] resulted in altered articulating surface geometries," which "led to unanticipated backside wear of the device and the introduction of an unreasonable amount of wear particles into [his] body." (Dkt. 30 at ¶ 54). Plaintiff fails to allege, though, which "particular federal specification" or "specific PMA requirements" that HOC violated for his medical device and how those violations caused the alleged defect and injuries. Instead, Plaintiff misapplies the standard and alleges that, due to a defect, HOC violated conditions set forth in the PMA.

In sum, in order to state a parallel claim based on the warning letters, Plaintiff must allege the specific federal requirements applicable to his medical device that are identified in the warning letters, along with the violations of those requirements set forth in the warning letters, and how those violations caused his claimed defect and injury. *See Wolicki-Gables*, 634 F.3d at 1301-02 (plaintiff must allege the "specific problem, or failure to comply with any FDA regulation that can be linked in the injury alleged"); *Llado-Carreno v. Guidant Corp.*, 2011 WL 6223409, at *5-*6 (S.D. Fla. May 16, 2011) (granting motion to dismiss

because "general allegations are insufficient to satisfy the requisite elements of a parallel claim").

Notably, although HOC deems the warning letters "irrelevant," HOC fails to show that the warning letters are inapplicable to Plaintiff's claims. Neither Plaintiff nor HOC provided the warning letters to the Court, even though the Court may take judicial notice of them at the pleadings stage. *See Rounds v. Genzyme Corp.*, 440 Fed. Appx. 753, 754-56 (11th Cir. 2011) (relying upon FDA-related documents filed in support of a motion to dismiss); *Kaiser*, 2013 WL 2006122, at *5 n.2 ("tak[ing] judicial notice of public records of the FDA relating to the medical device involved in this case" on a motion to dismiss).

Accordingly, although HOC's motion should be granted, the dismissal is without prejudice. The Court will provide Plaintiff a *final* opportunity to plead a parallel claim based upon the warning letters, provided that Plaintiff can do so consistent with his Rule 11 obligations.

The Court also concludes that the other issues raised by the parties are premature given that Plaintiff has not pled a parallel claim.[1]

[1] HOC's argument that Plaintiff's amended complaint must be dismissed even if he can plead a parallel claim because Florida law does not recognize a claim to enforce violations of FDA regulations is well-taken. *See Kaiser*, 2013 WL 2006122, at *5 (noting that "district courts in this Circuit have consistently held that [parallel claims] that seek to enforce violations of FDA regulations are barred because Florida does not recognize such causes of action"). However, the Court declines to reach this issue until it becomes relevant, that is, until the Court concludes that Plaintiff has pled a parallel claim.

It is therefore **ORDERED AND ADJUDGED** that:

1. Defendant Howmedica Osteonics Corp.'s Motion to Dismiss Amended Complaint (Dkt. 31) is granted without prejudice to Plaintiff to amend his complaint.

2. Plaintiff shall file his second amended complaint within fourteen (14) days of this Order. Failure to file a second amended complaint by this time shall result in the closure of this case without further notice.

**DONE** and **ORDERED** in Tampa, Florida on June 19, 2013.

**JAMES S. MOODY, JR.**
**UNITED STATES DISTRICT JUDGE**

**Copies furnished to:**
Counsel/Parties of Record

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