UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

DONALD KODGER Plaintiff, vs. ZIMMER BIOMET HOLDINGS, INC., et al., Defendants.	:	CASE NO. 1:17-cv-1350 OPINION & ORDER [Resolving Docs. 22, 29, 33, 35-1]

JAMES S. GWIN, UNITED STATES DISTRICT JUDGE:

This is a products liability case. Plaintiff Donald Kodger suffered injuries after a bearing in his right knee implant failed. Plaintiff now brings claims of negligence and strict liability against the manufacturers of his knee implant, Zimmer Biomet Holdings, Inc., Biomet Orthopedics LLC, and Zimmer Biomet ("Biomet Defendants").

Defendants move to dismiss Plaintiff's complaint.[1] Plaintiff opposes.[2] For the following reasons, the Court **DENIES** Defendants' motion to dismiss, but **GRANTS** Plaintiff leave to amend the complaint.

I. BACKGROUND

A. Plaintiff's Injuries

On March 31, 2008, Plaintiff Kodger received a right knee Biomet Oxford Meniscal Unicompartmental Knee System ("Biomet knee implant").[3] Three years later, Plaintiff began experiencing severe pain in his right knee.[4] It was not until June 2015 that X-rays revealed that a

[1] Doc. 22.
[2] Doc. 29. Defendants replied. Doc. 33. Plaintiff filed a sur-reply. Doc. 35-1.
[3] Doc. 16-1 at ¶ 8.
[4] Id. at ¶ 10.

component in his Biomet knee implant had collapsed.[5] Plaintiff alleges that the bearing in his Biomet knee implant had collapsed into his knee joint.[6] Plaintiff underwent surgery to obtain a full knee replacement.[7]

According to data in the Manufacturer and User Facility Device Experience ("MAUDE") database, there were 26 total bearing failures for Biomet knee implants manufactured between 2007 and 2008, around the time Plaintiff received his Biomet knee implant.[8] That represents 23% of all bearing failures in Biomet knee implants manufactured between 1999 and 2017.[9]

B. FDA Regulation of the Biomet Knee Implant

Defendants are the developers, manufacturers, and marketers of the Biomet knee implant.[10]

Under the Food, Drug and Cosmetic Act (FDCA),[11] and the Medical Device Amendments of 1976 (MDA),[12] all medical devices, such as the Biomet knee implant, are subject to Food and Drug Administration (FDA)-imposed regulations concerning design, manufacture, labeling, marketing, and sale.

The MDA imposes different levels of federal oversight depending on the medical device's risks.[13] As a Class III device, the Biomet knee implant is subject to the most stringent federal oversight.[14] The Biomet knee implant is a Class III device because "it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness."[15]

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[5] Id. at ¶¶ 12-16.
[6] Id. at ¶¶ 30-33, 47-50.
[7] Id. at ¶¶ 18-19.
[8] Id. at ¶¶ 32, 49.
[9] Id.
[10] Id. at ¶ 24.
[11] 21 U.S.C. § 301 et seq.
[12] 21 U.S.C. § 360c et seq.
[13] § 360c(a)(1)(A)-(C).
[14] Plaintiff does not specifically plead that the Biomet knee implant is a Class III device. See Doc. 16-1. However, the Court can take judicial notice of these facts from the FDA approval letter attached to Defendants' motion, see Doc. 13-1. Plaintiff incorporated it by reference in his complaint (Doc. 16-1 at ¶ 28). See Armengau v. Cline, 7 F. App'x 336, 344 (6th Cir. 2001) ("If referred to in a complaint and central to the claim, documents attached to a motion to dismiss form part of the pleadings.").
[15] Riegel v. Medtronic, Inc., 552 U.S. 312, 317 (2008).

It also received this classification because the Biomet knee implant is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "presents a potential unreasonable risk of illness or injury."[16]

As a result, before the Biomet knee implant could enter the market, it had to go through the FDA's Premarket Approval (PMA) process.[17] To receive FDA approval, Defendants were required to submit information about their device's proposed design, manufacture, and labeling.[18] Based on these submissions and a comprehensive review, the FDA had to determine whether the Biomet knee implant was suitable for the market. The FDA grants PMA only if there is "reasonable assurance" of the device's "safety and effectiveness."[19]

On April 21, 2004, the FDA approved the Biomet knee implant for commercial distribution.[20]

Even though PMA was granted, as manufacturers of the Biomet knee implant, Defendants remain subject to FDA regulations. Among other requirements, manufacturers must follow FDA's Current Good Manufacturing Practice (CGMP) requirements.[21] "To comply with CGMP requirements, a device manufacturer must adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action."[22]

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[16] § 360c(a)(1)(C)(ii).
[17] 21 U.S.C. § 360e.
[18] Id.
[19] § 360e(d). This "safety and effectiveness" determination involves a risk-benefit analysis; the FDA "weig[hs] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." § 360c(a)(2)(C).
[20] Doc. 16-1 at ¶¶ 26-28.
[21] Gelber v. Stryker Corp., 788 F.Supp.2d 145, 152 (S.D.N.Y. 2011) (citing 21 U.S.C. § 360j(f) and 21 C.F.R. §§ 820 et seq.); id. § 820.1(c).
[22] Gelber, 788 F.Supp.2d at 152 (citing 21 C.F.R. §§ 820.1-.250).

II. LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'"[23] The plausibility requirement is not a "probability requirement."[24] Plaintiff need not try to prove his case in the complaint. But there must be "more than a sheer possibility that the defendant has acted unlawfully."[25]

Federal Rule of Civil Procedure 8 provides the general pleading standard and only requires that a complaint "contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief."[26] "Rule 8 marks a notable and generous departure from the hypertechnical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions."[27] In deciding a motion to dismiss under Rule 12(b)(6), "a court should assume the[] veracity" of "well-pleaded factual allegations," but need not accept a plaintiff's conclusory allegations as true.[28]

In resolving a motion to dismiss, the Court must confine its review to the matters in the pleadings.[29] If the Court reviews matters outside the pleadings, "the motion must be treated as one for summary judgment under Rule 56."[30]

In their reply to Plaintiff's opposition, Defendants asked this Court to convert their motion to dismiss into a motion for summary judgment.[31] Defendants submitted a declaration and two

[23] Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic v. Twombly, 550 U.S. 544, 570 (2007)).
[24] Id. (quoting Bell Atlantic, 550 U.S. at 556).
[25] Id.
[26] Fed. R. Civ. P. 8(a)(2).
[27] Iqbal, 556 U.S. at 678-79 (citations omitted).
[28] Id. at 679.
[29] Fed. R. Civ. P. 12(d).
[30] Id.
[31] See Doc. 33 at 3 n.5.

exhibits that are extrinsic to the pleadings.[32] Because the Court has not given the parties prior notice of its decision to do this conversion, the Court declines Defendants' request.[33] Accordingly, in deciding this motion, this Court excludes Defendants' materials extrinsic to the pleadings.[34]

III. ANALYSIS

In this products liability case, Plaintiff brings claims of negligence and strict liability for manufacturing defects associated with his Biomet knee implant.[35]

In seeking dismissal, Defendants argue that Plaintiff Kodger's claims must be dismissed because they are (1) federally preempted and (2) abrogated by the Ohio Product Liability Act (OPLA).[36] Defendants also argue that Plaintiff fails to plead how Defendants' alleged federal regulation violations caused his injuries.[37]

The Court finds that the claims are not federally preempted or abrogated by the OPLA. Plaintiff also sufficiently pleads causation.

The Court, however, directs Plaintiff to file an amended complaint to identify the specific OPLA provisions that form his product liability claims. The Court therefore will allow Plaintiff to amend his complaint to address the deficiency that this Court here describes.

A. Federal Preemption

The Court finds that Plaintiff's claims are neither expressly nor impliedly preempted by federal law.

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[32] See Docs. 33-2; 34-1. These documents state that Plaintiff's Biomet knee implant was not manufactured in 2007 or 2008, as Plaintiff alleges in his Complaint. See Doc. 34-1.
[33] See Armengau, 7 F. App'x at 343 ("Because of the risk of prejudicial surprise arising from the court's treating a motion to dismiss as a motion for summary judgment, Rule 12(b) further requires notice and an opportunity to supplement the record before the court enters summary judgment.").
[34] The Court will also not take judicial notice of Defendants' extrinsic materials because they concern adjudicative facts. See id. at 344-45 (finding that taking judicial notice of "adjudicative facts" would "run afoul of Rule 12(b)'s admonition against considering matters outside the pleadings").
[35] Plaintiff says he does not allege any failure to warn claim. Doc. 29 at 2. We therefore do not consider the claim.
[36] Doc. 22; Doc. 33.
[37] Doc. 33 at 2-3.

1. Express Preemption

The MDA does not expressly preempt Plaintiff's product liability claims.

In support for their motion to dismiss, Defendants argue that Plaintiff's negligence and strict liability claims are expressly preempted because Plaintiff's claims suggest that Defendants should have "done something differently than what was approved by the FDA."[38] Defendants also argue that Plaintiff's claims are expressly preempted because they do not identify specific CGMP manufacturing requirements that the Defendants violated.[39] Plaintiff asserts that his claims are not expressly preempted since they are based solely on federal regulation violations that he specifically identified.[40]

The MDA's express preemption clause, in relevant part, states that:

> [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.[41]

The Supreme Court in Riegel v. Medtronic, Inc. described a two-part test for determining whether a plaintiff's products liability claims are expressly federally preempted.[42] First, the Court asks whether the federal government has established any requirements applicable to the medical device in question.[43] If so, the Court next asks whether the state requirement at issue is related to safety and effectiveness and "different from, or in addition to," any federal requirements.[44] If the answer is yes, the state law claim is federally preempted.[45]

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[38] Doc. 22 at 9.
[39] Doc. 33 at 4-5.
[40] Doc. 29 at 5.
[41] 21 U.S.C. § 360k(a).
[42] 552 U.S. at 321-22.
[43] Id.
[44] Id.
[45] Id.

Under this test, most state common-law tort duties are expressly preempted. Nevertheless, the MDA provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations."[46] In such a case, the state claims are not preempted because the state duties run "'parallel,' rather than add to, federal requirements."[47]

The first Riegel prong is satisfied here. As a Class III device, the Biomet knee implant underwent a required PMA process and is thus subject to FDA regulations.[48]

The second prong, however, is not satisfied.

In Howard v. Sulzer Orthopedics, Inc., the Sixth Circuit found that a plaintiff's negligence per se claim was not "different from, or in addition to" federal requirements, and was thus a parallel state law claim.[49] There, the plaintiff alleged a breach of duty based on the violation of an FDA regulation that generally required manufacturers to keep medical devices oil-free.[50] Without identifying the applicable state law, the court held that "a state may provide a damages remedy for violations of an identical [requirement as the FDA regulation]."[51] The court also held that the plaintiff need not allege violations of device-specific federal regulations, in order to allege a parallel state law claim.[52]

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[46] Id. at 330.
[47] Id.
[48] See id. at 321-22.
[49] 382 F. App'x 436, 441 (6th Cir. 2010).
[50] Id.
[51] Id.; see also Bausch v. Stryker Corp., 630 F.3d 546, 555-58 (7th Cir. 2010) (citing to Howard, 382 F. App'x at 440) (finding that plaintiff's negligence and strict liability claims based on a manufacturing defect in her hip replacement system were parallel state law claims).
[52] Howard, 382 F. App'x at 440 (reversing summary judgment on preemption grounds, as CGMP requirements relating generally to medical devices are "not so vague as to be incapable of enforcement"); see also Bausch, 630 F.3d at 555 ("Like the Sixth Circuit in Howard, we do not see a sound legal basis for defendants' proposal to distinguish between general requirements and 'concrete, device-specific' requirements."). Defendants' case citations do not persuasively demonstrate that allegations of general CGMP violations are insufficient to survive preemption. See Doc. 33 at 4-5. Unlike Plaintiff Kodger, plaintiffs in those cases did not identify specific CGMPs violated by the defendants. See, e.g., Warstler v. Medtronic, Inc., 238 F. Supp. 3d 978, 987-88 (N.D. Ohio 2017), reconsideration denied, No. 3:16CV00385, 2017 WL 3088037 (N.D. Ohio July 20, 2017); Anthony v. Stryker Corp., No. 1:09-CV-2343, 2010 WL 1387790, at *3-5 (N.D. Ohio Mar. 31, 2010).

Here, safety and effectiveness are the core of Plaintiff's manufacturing defect claims. And like the Howard plaintiff, Plaintiff Kodger has alleged Defendants' violations of specific CGMP manufacturing requirements, even if those requirements are not specific to the Biomet knee implant itself.[53]

Because Plaintiff entirely bases Defendants' breach of duty on these CGMP violations, his claims do not "add to" federal requirements. They are therefore parallel state claims and are not expressly preempted by the MDA.[54]

2. Implied Preemption

Plaintiff's claims are also not impliedly preempted.

Defendants argue that Plaintiff's claims are impliedly preempted because Plaintiff is usurping the FDA's responsibility to enforce FDA regulations.[55] Plaintiff mostly responds that his claims are based on common-law duties of care that exist independently of FDA regulations.[56]

State law claims can be impliedly preempted when they conflict with federal law and stand in the way of congressional objectives.[57]

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[53] Plaintiff identifies Defendants' failure to (1) comply with design controls under 21 C.F.R. § 820.30; (2) adequately conduct the inspecting and verification activities required under 21 C.F.R. § 820.80; (3) establish appropriate procedures to ensure they could take necessary corrective and appropriate action required under 21 C.F.R. § 820.100; and (4) conduct appropriate investigations into adverse incident reports and returned device parts required under 21 C.F.R. § 820.198. Doc. 16-1 at ¶¶ 34, 51.

[54] Defendants' arguments that we should not follow the holding in Howard are unpersuasive. See Doc. 22 at 10; Doc. 33 at 9-10. Defendants' citation to Hafer v. Medtronic, Inc. is not relevant because that case did not concern similar tort claims based on manufacturing defects. See 99 F. Supp. 3d 844, 853 (W.D. Tenn. 2015), reconsideration denied (June 17, 2015) (concerning tort claims based on off-label promotion that was within FDA's exclusive right to enforce). And unlike in other cases Defendants cite, Plaintiff here has alleged specific violations of federal regulations to survive this motion to dismiss, as well as causation (as explained later). See Aaron v. Medtronic, Inc., 209 F. Supp. 3d 994, 1000-01 (S.D. Ohio 2016); Warstler, 238 F. Supp. 3d at 987-88; Anthony, 2010 WL 1387790, at *3-5; Potolicchio v. Medtronic, Inc., No. 1:15-CV-122, 2016 WL 3129186, at *4 (E.D. Tenn. June 2, 2016), appeal dismissed (Sept. 8, 2016); Kitchen v. Biomet, Inc., No. CIV.A. 13-18-HRW, 2014 WL 694226, at *2, 5 (E.D. Ky. Feb. 21, 2014).

[55] Doc. 22 at 11-12.

[56] Doc. 29 at 9-11.

[57] *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48 (2001).

In *Buckman Co. v. Plaintiffs' Legal Comm.*, the Supreme Court found that plaintiff's state law fraud claims against a defendant medical device manufacturer were impliedly preempted.[58] There, the court reasoned that "[p]olicing fraud against federal agencies" was purely within the FDA's domain.[59] Thus, state law claims premised on such fraud was in conflict with federal law and stood in the way of congressional objectives for FDA regulations.[60]

Unlike the plaintiff in Buckman, however, Plaintiff Kodger does not bring fraud claims. He brings manufacturing defect tort claims related to health and safety, which naturally fall under the state's historic police powers.[61] As a result, Plaintiff's claims are grounded on common-law duties of care, and exist independently of the FDA regulations. Moreover, such tort law claims do not conflict with the FDA's purpose – to ensure the safety and effectiveness of medical devices.[62]

Thus, Plaintiff's claims are not impliedly preempted by the FDA regulatory scheme.

B. OPLA Abrogation

Defendants argue that Plaintiff's common-law negligence and strict liability claims are abrogated by the OPLA. They are not.

In Ohio, product liability claims are governed by the statutory scheme laid out in the OPLA.[63] The OPLA abrogates "all common law product liability claims or causes of action."[64] Product liability claims that are not brought under the OPLA must be dismissed.

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[58] Id. at 349-50.
[59] Id. at 347.
[60] Id. at 349-50.
[61] See id.at 348; see also Medtronic, Inc. v. Lohr, 518 U.S. 470, 475, 485 (1996) ("Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens;" and finding that courts begin with the presumption that federal law does not preempt such traditional police powers).
[62] Buckman, 531 U.S. at 347-48; see also Bausch, 630 F.3d at 556-57.
[63] Ohio Rev. Code Ann. §§ 2307.71 et seq.
[64] Ohio Rev. Code Ann. § 2307.71(B).

Plaintiff does bring his claims under the OPLA. Plaintiff cites to OPLA provisions to state his claims for negligence[65] and strict liability,[66] as well as his entitlement to damages.[67]

But the OPLA provisions Plaintiff cites relate to design defect claims[68] that are not obviously related to Plaintiff's manufacturing defect claims.[69] "Claims that are authorized by the OPLA should be pled with reference to the applicable provision of the OPLA."[70]

Thus, although the Court does not find Plaintiff's claims are abrogated by the OPLA,[71] it is unclear to the Court which OPLA provisions are applicable to Plaintiff's claims. The Court will therefore direct Plaintiff to amend his complaint to allege the precise basis for his OPLA claims.

C. Pleading Sufficiency

Assuming that Plaintiff brings a manufacturing defect claim under the OPLA, Plaintiff has sufficiently plead causation.

To bring a products liability claim under the OPLA, Plaintiff must establish that the manufacturing defect was the proximate cause of his injuries.[72] Under the OPLA, proximate cause is established when Plaintiff's injuries are a "natural and probable consequence" of Defendants' wrongful conduct.[73]

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[65] Doc. 16-1 at ¶ 37 (citing to Ohio Rev. Code. Ann. § 2307.75).
[66] Id. at ¶ 54 (citing to Ohio Rev. Code. Ann. § 2307.75).
[67] Id. at ¶¶ 42, 59 (citing to Ohio Rev. Code. Ann. § 2307.72).
[68] See Ohio Rev. Code. Ann. § 2307.75.
[69] Doc. 29 at 2-3.
[70] Boroff v. Alza Corp., 685 F. Supp. 2d 704, 709 (N.D. Ohio 2010) (quoting Stratford v. SmithKline Beecham Corp., No. 2:07-CV-639, 2008 WL 2491965, at *5 (S.D. Ohio June 17, 2008)); Tolliver v. Bristol-Myers Squibb Co., No. 1:12 CV 00754, 2012 WL 3074538, at *3 (N.D. Ohio July 30, 2012) ("When bringing claims under the OPLA, plaintiffs should clarify which OPLA provision governs the claims in their complaint.").
[71] See Aaron, 209 F. Supp. 3d at 1011-12 (finding product liability claims abrogated by the OPLA only because there was "no citation to, or even mention of, the [OPLA] in any of the sections of the Omnibus Complaint outlining the claims against Defendants").
[72] Ohio Rev. Code Ann. § 2307.73.
[73] See Eastman v. Stanley Works, 907 N.E.2d 768, 780 (Ohio Ct. App. 2009) (citation omitted).

Defendants are responsible for manufacturing the Biomet knee implant. Plaintiff alleged that 23% of bearing failures since 1999 occurred in Biomet knee implants manufactured in the short window between 2007 and 2008. According to Plaintiff's allegations, these manufacturing failures indicate Defendants' failure to abide by CGMP requirements.

Plaintiff alleges that his injuries likely resulted from Defendants' federal regulation violations because he received his Biomet knee implant in 2008, around the same time Defendants manufactured a large percentage of faulty bearings. The bearing in Plaintiff's Biomet knee implant also collapsed, causing Plaintiff to experience severe pain and undergo full knee replacement surgery.

Assumed as true, these alleged facts sufficiently plead that Plaintiff's injuries were a "natural and probable" consequence of Defendants' federal regulation violations.

IV. CONCLUSION

For the following reasons, the Court **DENIES** Defendants' motion to dismiss but orders Plaintiff to file an amended complaint to precisely identify the applicable OPLA provisions for his negligence and strict liability claims. The Court therefore **GRANTS** Plaintiff leave to amend the complaint to address this deficiency.

IT IS SO ORDERED

Dated: September 29, 2017

s/ James S. Gwin
JAMES S. GWIN
UNITED STATES DISTRICT JUDGE