UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

GLENNA C. KISER and WINSTON D. KISER,	)	Case No. 2:21-cv-69
Plaintiffs,	)	Judge Travis R. McDonough
v.	)	Magistrate Judge Cynthia R. Wyrick
TERUMO MEDICAL CORPORATION,	)	
Defendant.	)	

MEMORANDUM OPINION

Before the Court are Defendant's motion for judgment on the pleadings (Doc. 30) and Defendant's motion to stay discovery and for expedited consideration (Doc. 31).[1] For the following reasons, Defendant's motion for judgment on the pleadings (Doc. 30) will be **DENIED** and its motion to stay discovery and for expedited consideration will be **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

Defendant Terumo Medical Center ("TMC") designs, manufactures, and distributes medical equipment. (Doc. 1-2, at 4–5; Doc. 30, at 2.) TMC sells the Angio-Seal VIP Vascular Closure Device ("Angio-Seal device"), which "creates a mechanical seal by sandwiching the arteriotomy between a bioabsorbable anchor and collagen sponge" in patients who have had a

[1] Plaintiffs filed their response to Defendant's motion to stay discovery and for expedited consideration as an "objection" to Defendant's motion to stay discovery and titled it as a "motion in opposition to Defendants' [sic] motion to stay discovery." (*See* Doc. 37.) However, the document responds to Defendant's motion without moving for anything additional. Accordingly, the Court treats it as a response in opposition to Defendant's motion, and the Clerk is **DIRECTED** to terminate the "objection" on the docket.

cardiac catheterization procedure. (Doc. 1-2, at 4–5.) The Angio-Seal device is a Class III medical device that was approved via the Food and Drug Administration's ("FDA") premarket approval ("PMA") process.[2] (Doc. 30, at 2; Doc. 38, at 2.)

On January 8, 2020, Plaintiff Glenna C. Kiser ("Ms. Kiser") underwent a left-heart catheterization, selective coronary angiography, IFR of her right coronary artery, and right iliofemoral angiogram, all performed by Mark Andrew Borsch, M.D. (Doc. 1-2, at 8.) As part of these procedures, Dr. Borsch placed and deployed an Angio-Seal device. (*Id.* at 9.) However, Dr. Borsch observed a "[c]omplication of distal embolization" of the footplate of the device, which resulted in an occlusion of Ms. Kiser's superficial femoral artery and caused her not to have pulses in her right leg. (*Id.*) The Angio-Seal malfunction and resulting occlusion necessitated additional surgery, a right superficial femoral artery cut down, and removal of the foreign body. (*Id.*) Upon Ms. Kiser's inquiry, the medical center where she underwent the initial procedures informed her that her injuries were caused by the malfunctioning of the Angio-Seal device, "an unforeseen event that could not have been prevented by the cardiologist." (*Id.* at 10.)

Sidney W. Collins, M.D. performed the procedure to address the occlusion, creating an eleven-inch incision to remove the defective portion of the Angio-Seal device. (*Id.* at 9.) After her discharge, Ms. Kiser experienced further complications from a seroma at the incision site.

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[2] Pursuant to Federal Rule of Evidence 201(b)(2), the Court takes judicial notice of the information at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P930038 concerning the Angio-Seal Device's premarket approval. *See also Twumasi-Ankrah v. Checkr, Inc.*, 954 F.3d 938, 947 n.3 (6th Cir. 2020) (Bush, J., dissenting) (noting that taking judicial notice of official records from government websites is appropriate at the motion-to-dismiss stage); *Bailey v. City of Ann Arbor*, 860 F.3d 382, 386 (6th Cir. 2017) ("[A] court ruling on a motion to dismiss *may* consider materials in addition to the complaint if such materials are public records or are otherwise appropriate for the taking of judicial notice." (emphasis in original) (citations and internal quotation marks omitted)).

(*Id.* at 10.) The swelling ultimately required additional surgical intervention and a wound-vacuum-assisted closure. (*Id.*) Ms. Kiser continued to suffer leg pain and nerve damage several months after the procedure. (*Id.*)

On January 8, 2021, Ms. Kiser and her husband, Plaintiff Winston D. Kiser ("Mr. Kiser"), filed this action in the Circuit Court for Sullivan County, Tennessee. (*See* Doc. 1, at 1.) Plaintiffs assert claims for negligence and strict products liability under the Tennessee Products Liability Act based on a manufacturing defect in the Angio-Seal device. (Doc. 1-2, at 10–13.) Plaintiffs also reference TMC's failure to comply "with FDA requirements" in manufacturing the device and allege that TMC should have updated its advertising materials to indicate that at least 500 "adverse events" resulting from the device had been reported to the FDA. (*Id.*) Plaintiffs seek compensatory damages, punitive damages, and damages for loss of consortium. (*Id.*) On April 7, 2021, Defendant[3] removed the action to this Court. (*See* Doc. 1.) On July 21, 2021, TMC moved for judgment on the pleadings, arguing Plaintiffs' claims are expressly preempted by federal law. (*See* Doc. 30.) TMC's motion is ripe for review.

II. STANDARD OF REVIEW

According to Federal Rule of Civil Procedure 8, a plaintiff's complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Though the statement need not contain detailed factual allegations, it must contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Rule 8 "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.*

[3] At the time of removal, there were two additional Defendants—Terumo Cardiovascular Systems, Corporation, and Terumo BCT, Inc.—who have since been dismissed. (*See* Doc. 24.)

A defendant may obtain dismissal of a claim that fails to satisfy Rule 8 by filing a motion pursuant to Rule 12(c). A Rule 12(c) motion for judgment on the pleadings is analyzed using the same standards that apply to Rule 12(b)(6) motions for failure to state a claim. *Lindsay v. Yates*, 498 F.3d 434, 438 (6th Cir. 2007). Thus, the Court considers not whether the plaintiff will ultimately prevail, but whether the facts permit the court to infer "more than the mere possibility of misconduct." *Iqbal*, 556 U.S. at 679. For purposes of this determination, the Court construes the complaint in the light most favorable to the plaintiff and assumes the veracity of all well-pleaded factual allegations in the complaint. *Thurman v. Pfizer, Inc.*, 484 F.3d 855, 859 (6th Cir. 2007). This assumption of veracity, however, does not extend to bare assertions of legal conclusions, *Iqbal*, 556 U.S. at 679, nor is the Court "bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

After sorting the factual allegations from the legal conclusions, the Court next considers whether the factual allegations, if true, would support a claim entitling the plaintiff to relief. *Thurman*, 484 F.3d at 859. This factual matter must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Plausibility "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

III. ANALYSIS

TMC seeks dismissal of Plaintiffs' claims on the grounds that they are preempted under the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic

Act of 1938 ("FDCA"). (*See* Doc. 30, at 4–9.) TMC relies on 21 U.S.C. § 360k(a), which states:

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

Section 360k(b) provides:

> Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—
>
> > (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
> >
> > (2) the requirement—
> >
> > > (A) is required by compelling local conditions, and
> > >
> > > (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360k(b).

The Supreme Court has outlined a two-part inquiry for preemption determinations under § 360k.[4] *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321 (2008). First, the Court "must

[4] The Supreme Court has also recognized that private actions to directly enforce the MDA's provisions are impliedly preempted by 21 U.S.C. § 337(a), which authorizes only the United States to enforce the provisions of the FDCA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4, 352–53 (2001) ("[W]e have clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government."). However, because TMC does not argue that Plaintiffs' claims are impliedly preempted by the FDCA, this Court's analysis focuses only on express preemption under 21 U.S.C. § 360k.

determine whether the Federal Government has established requirements applicable to" the device at issue. *Id.* If it has, the Court "must then determine whether [the Plaintiffs'] claims are based upon [state-law] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* (quoting 21 U.S.C. § 360k(a)). If Plaintiffs' claims are based on state-law requirements that do not differ from or add to the federal requirements, those "parallel" claims survive the MDA's preemption provisions. *Id.* at 330 ("§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." (citing *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

A. Whether the Federal Government Has Established Requirements Applicable to the Angio-Seal Device

The parties do not dispute that the Federal Government has established requirements for the Angio-Seal device. (*See* Docs. 30, 38, 40.) When a device underlying a state-law claim was subject to the FDA's PMA process, the first step of the *Riegel* test is satisfied. *See* 552 U.S. at 322–23 ("Premarket approval . . . imposes 'requirements' under the MDA[.]"); *Bass v. Stryker Corp.*, 669 F.3d 501, 508 (5th Cir. 2012) ("[T]he district court did not err in determining that the [device] in its entirety was subject to PMA approval and therefore satisfied the 'federal requirement' prong of *Riegel*.'"). Because the Angio-Seal device was approved through the PMA process, there are federal requirements applicable to the device.

B. Whether Plaintiffs' TPLA Claims Are Based Upon Requirements that Differ From or Add to the Federal Requirements

The Court next asks whether the state requirements at issue relate to safety and effectiveness and are "different from, or in addition to," the federal requirements. *Riegel*, 552 U.S. at 321. Because Plaintiffs' TPLA claims relate to the safety and effectiveness of the Angio-

Seal device, "the crucial question . . . is whether these claims are parallel claims that avoid preemption because they would not impose state requirements 'different from, or in addition to,' the federal requirements established by PMA approval." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010) [hereinafter "*Sprint Fidelis*"].

TMC argues that Plaintiffs have not pled a "parallel" Tennessee claim that is coextensive with violations of FDA regulations in a manner that survives Federal Rule of Civil Procedure 8, *Twombly*, and *Iqbal*. (Doc. 30, at 5.) In particular, it argues that, although Plaintiffs reference "FDA requirements," they have not pled factual allegations that support a parallel claim. (*See id.* at 6.) Plaintiffs respond that they "clearly and specifically pled that Defendant deviated from the MDA in its production of . . . the Angio-Seal Device at issue by failing to ensure the tensile strength of [the device] was consistent with what had been approved by the FDA in the PMA process." (Doc. 38, at 5.)

In their complaint, Plaintiffs allege the following with respect to FDA regulations:

- "Defendan[t] failed to properly manufacture the Angio-Seal Device at issue in compliance with FDA requirements."
- "Defendan[t's] manufacturing deficiencies in complying with FDA requirements in the production of the Angio-Seal Device include, but are not limited to, failing to ensure the components had sufficient strength to not break during use."
- "Defendan[t's] deviations from the FDA productions requirements resulted in a device which was not safe for its foreseeable use[.]"
- "Defendan[t's] deviation from FDA specifications in the production process caused the Angio-Seal Device to fail."
- "Defendan[t's] failure to adhere to FDA specifications for the production of the Angio-Seal Device caused the wire utilized by the Device to break during Ms. Kiser's January 8, 2020 procedure and resulted in her suffering the injuries set out herein."
- "Defendan[t] [was] negligent in the production and inspection of the Angio-Seal device at issue in that they failed to manufacture it in compliance with FDA requirements."

- "Defendan[t] manufactured and distributed the Angio-Seal Device when they knew, or should have known, that based upon their failure to comply with the FDA's manufacturing requirements that the product would fail under normal, foreseeable use."

- "Defendan[t] negligently tested, sold, marketed, and manufactured the subject Angio-Seal device by virtue of [its] failure to comply with FDA requirements."

(Doc. 1-2, at 11–12.)

Courts are divided as to the level of specificity required to plead a parallel claim, and the Seventh and Eleventh Circuits occupy the ends of the spectrum. In *Bausch v. Stryker Corporation*, 630 F.3d 546 (7th Cir. 2010), the Seventh Circuit rejected the defendants' argument that the plaintiff's product-liability claims should be dismissed for failure to "specify the precise defect or the specific federal regulatory requirements that were allegedly violated." *Id.* at 560. The court held that, "[a]lthough the complaint would be stronger with such detail," the absence of those details did not run afoul of Rule 8. *Id.* In so holding the Seventh Circuit emphasized: (1) "[t]here are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular"; (2) "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"; and (3) "in the context of Class III medical devices, much of the critical information"—including "[t]he specifications of the FDA's premarket approval documents"—"is kept confidential as a matter of federal law." *Id.* at 558–60. Similarly, the Eighth Circuit has noted in dicta that, if appropriately raised, a plaintiff's argument that she lacked access to PMA files "would have considerable force in a case where a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit." *Sprint Fidelis*, 623 F.3d at 1206.

The Eleventh Circuit has adopted a more restrictive approach, holding that a plaintiff "must allege that '[the] defendant violated a particular federal specification referring to the device at issue.'" *Wolicki-Gables v. Arrow Int'l, Inc.*, 624 F.3d 1296, 1301 (11th Cir. 2011) (quoting *Ilarraza v. Medtronic, Inc.*, 667 F. Supp. 2d 582, 589 (E.D.N.Y. 2009)) (alteration in original). In *Wolicki-Gables*, the Eleventh Circuit upheld the district court's preemption finding because the complaint's allegations did not "set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged." *Id.* at 1301–02 (quoting *Ilarraza*, 667 F. Supp. 2d at 589)). "Plaintiffs cannot simply incant the magic words '[Defendants] violated the FDA regulations' in order to avoid preemption." *Id.* at 1301 (quoting *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009)).

Unsurprisingly, TMC cites the *Wolicki-Gables* standard (Doc. 30, at 5), and Plaintiffs cite *Bausch* (Doc. 38, at 6–7). But the Sixth Circuit has not recognized either *Bausch* or *Wolicki-Gables* as more compelling.[5] Other circuits have attempted to reconcile the Seventh and Eleventh Circuit standards or at least to glean commonalities between them:

[5] In one unpublished case, the Sixth Circuit affirmed the dismissal of some of the plaintiff's product-liability claims under 21 U.S.C. § 360k because the plaintiff had failed to identify "a single parallel federal statute or regulation" underlying the claims. *White v. Medtronic, Inc.*, 808 F. App'x 290, 295 (6th Cir. 2020) (quoting *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1337 (10th Cir. 2015)). But *White* is distinguishable from this case because, there, the plaintiff did "not challenge . . . the actual manufacture of [the device] but instead [sought] relief pursuant to state law claims challenging [the defendants'] alleged promotion of the off-label use of the device." *Id.* And the court held that the plaintiff failed to allege a parallel requirement because the FDCA embraces off-label use of medical devices. *See id.* at 295–96; *see also White v. Medtronic, Inc.*, No. 18-11590, 2019 WL 1339613, at *3–4 (E.D. Mich. Feb. 20, 2019) (outlining each count of the complaint). Thus, *White* dealt with the inexistence of a parallel federal requirement rather than the failure to adequately plead a violation of a parallel federal requirement. Accordingly, the little Sixth Circuit guidance on the issue is not applicable here.

> The 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.

Bass, 669 F.3d at 511–12 (emphasis in original). In *Bass*, the Fifth Circuit held "that if a plaintiff pleads that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the [Current Goods Manufacturing Practices] themselves *and* that this failure caused the injury, the plaintiff will have pleaded a parallel claim." *Id.* at 12.

District courts in this circuit have acknowledged the lack of clarity among the Courts of Appeals. *See, e.g.*, *White v. Stryker Corp.*, 818 F. Supp. 2d 1032, 1039 (W.D. Ky. 2011) (noting the circuits' disagreement "on the degree of specificity required to establish a plausible claim," "about whether asserting the violation of a [Current Goods Manufacturing Practice] is sufficient to avoid preemption," and "about the circumstances in which discovery should proceed before determining preemption"). Nevertheless, many district courts have agreed that allegations that a manufacturer deviated from the terms of the device's premarket approval or a particular FDA regulation are sufficient to survive dismissal at the pleadings stage. *See, e.g.*, *Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 832 (W.D. Ky. 2014) (finding sufficient the plaintiff's allegations that a particular component of the device was defective "because the actual manufacture of [that component] deviated from the specifications and protocols set forth in the federal regulations and the PMA"); *Steiden v. Genzyme Biosurgery*, No. 3:11 CV-441-S, 2012 WL 2923225, at *5 (W.D. Ky. July 18, 2012) (finding "that the allegation of adulteration based on the occurrence of an immediate adverse reaction [to the device] contains sufficient specificity to satisfy *Iqbal* and *Twombly*").

District courts have also outlined the minimum level of specificity—regardless of which circuit's precedent applies—that must be included in the complaint in order to survive a motion to dismiss or motion for judgment on the pleadings. *See, e.g.*, *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1001 (S.D. Ohio 2016) ("[E]ven were the Court to apply the lower pleading standard from *Bausch*, several of Plaintiffs' claims would still be deficient because . . . Plaintiffs simply do not allege—or provide any factual support for an allegation of—violations of federal law with respect to several of their claims." (citations and internal quotation marks omitted)); *Anderson v. Boston Sci. Corp.*, No. 1:12-CV-00762, 2013 WL 632379, at *4 n.1 (S.D. Ohio Feb. 20, 2013) (noting that *Bausch* could not save the plaintiffs' complaint because it "[was] expressly premised on violations of *state* law" and did not allege any violation of federal law); *White*, 818 F. Supp. 2d at 1039 ("In our case, one must question whether any of these disagreements are consequential because Plaintiff has not alleged any specific manufacturing failure, has not alleged the violation of any specific federal standard, including GMPs, and has already amended his complaint once in response to the motion to dismiss.").

Plaintiffs' complaint narrowly meets the minimum level of specificity required to survive TMC's motion. Although Plaintiffs could have more easily satisfied their burden under Rule 8 if they had referenced in their complaint the particular issues and PMA specifications they now assert, the Court is persuaded by the reasoning of other courts that have allowed discovery prior to deciding the preemption issue. *See, e.g.*, *Engle v. Medtronic, Inc.*, No. 3:19-cv-909-RGJ, 2021 WL 1318322, at *5 (W.D. Ky. 2021) ("Given the disagreement among courts and the inability of PMA plaintiffs to gather all necessary information prior to engaging in discovery, the Court is not inclined to dismiss all of [Plaintiff's] claims at this early stage."); *Oblak v. Integra LifeSciences Corp.*, No. 1:16-CV-132, 2017 WL 1831098, at *3 (N.D. Ohio May 4, 2017)

("While [Plaintiff] alleges generally that one or more of the pieces of medical hardware . . . failed, discovery will serve to clarify the exact nature and cause of the hardware failure."); *Brook v. sanofi-aventis U.S., LLC*, No. 2:14-cv-976, 2014 WL 7272243, at *4 (S.D. Ohio Dec. 18, 2014) ("It . . . would require too much to demand that Plaintiff allege specific defects that violate the FDA standards when such information is not necessarily within her control."). Here, Plaintiffs do allege—albeit in a somewhat cursory manner—that TMC violated federal law in its manufacture of the Angio-Seal device by failing to ensure the wire in the device was adequately strong not to break during use. (*See* Doc. 1-2, at 11–12.) Plaintiffs also allege that the failure to comply with federal law in ensuring the strength of the wire caused the device to break, which in turn caused Ms. Kiser's injuries. (*See id.*) This is enough to satisfy Rule 8 in this context. *See Bass*, 669 F.3d at 511–12 (requiring only that plaintiffs allege "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" (emphasis removed)).

Nevertheless, Plaintiffs are strongly cautioned that if they cannot show a particular manufacturing defect and a violation of a particular federal requirement, their complaint will be subject to preemption and dismissal at summary judgment. *See Engle*, 2021 WL 1318322, at *5 ("After the parties have engaged in discovery, [Plaintiff] will be required to connect a specific federal violation to her alleged defect in order to state a sufficient claim."). And insofar as Defendants deny that there was any violation of federal law, they are free to present that theory to the Court at summary judgment.

IV. CONCLUSION

For these reasons, TMC's motion for judgment on the pleadings (Doc. 30) is **DENIED**. TMC's motion for expedited ruling and to stay discovery is **GRANTED IN PART** to the extent

this opinion rules on the Rule 12(c) motion and is **DENIED IN PART** to the extent TMC seeks a stay of discovery.

SO ORDERED.

/s/ Travis R. McDonough
TRAVIS R. MCDONOUGH
UNITED STATES DISTRICT JUDGE