UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

KENNETH NEVE, SR., and LINDA NEVE,	)	Case No. 2:20-cv-63
Plaintiffs,	)	Judge Travis R. McDonough
v.	)	Magistrate Judge Cynthia R. Wyrick
ENDOLOGIX, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION

Before the Court is Defendant Endologix, Inc.'s ("Endologix") motion to dismiss (Doc. 39). Plaintiffs Kenneth Neve, Sr., and Linda Neve ("the Neves") failed to timely respond to the motion, triggering the Court's issuance of a show-cause order on August 25, 2022. (Doc. 41.) The order was met with a timely-filed response by Ms. Neve and a subsequent reply by Endologix. (Docs. 42, 43.) For the reasons that follow, the Court will **DENY IN PART** and **GRANT IN PART** Defendant's motion to dismiss (Doc. 39).

I. BACKGROUND

A. Factual Background

Defendant Endologix, Inc., is a Delaware-based corporation that is in the business of designing, manufacturing, and distributing abdominal aortic aneurism ("AAA") repair products. (Doc. 19-1, at 1–2.) One such product, the Endologix AFX Endovascular AAA system ("AFX"), is at the center of this suit. (*Id.*) AAA systems are medical devices designed to protect against ruptured aneurysms in patients with aortic aneurysms, which are caused by the stretching and expansion of the aorta, by siphoning off blood from the damaged artery. (*Id.* at 3.) In other

words, AAA systems typically work by redirecting blood flow so it does not fill, expand, and potentially rupture the already-distended aneurysm. (*Id.* at 6.)

Medical devices, including AAA systems, are subject to an approval process, the stringency of which is commensurate with the devices' relative risk level. *See* 21 U.S.C. § 360, *et. seq.* Devices designated as "Class III" are subject to the highest level of regulation and must undergo a rigorous premarket approval ("PMA") process through the Federal Drug Administration ("FDA") before the device may be put on the market. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–18 (2008). FDA approval is subject to additional labeling, reporting, training, and manufacturing requirements. (Doc. 19-1, at 5.)

Because Endologix's AAA systems received a Class-III designation, it was required to engage in the PMA process before introducing those products to market. (*Id.*) Though this suit concerns the AFX (one type of AAA system), Endologix initially gained FDA approval for a different type of AAA system—one it branded as the "Powerlink AAA System." (*Id.*) A little over five years later, Endologix sought to introduce a new AAA system—the AFX—for which it did not submit a separate PMA application. (*Id.*) Instead, Endologix tacked a PMA Supplement onto its PMA for the PowerLink AAA System, which was subsequently approved by the FDA. (*Id.* at 5–6.) The AFX contained a graft material called "Strata" that was not incorporated into the original Powerlink system. (*Id.* at 6.)

Implantation of an AAA system sometimes results in complications known as "endoleaks." (*Id.* at 3.) An endoleak occurs when blood is not properly siphoned off from the aneurysm cavity and instead continues to flow into it. (*Id.*) There are different classifications of endoleaks, which are sorted into four "Types." (*Id.*) Type-III endoleaks, unlike other endoleak

Types, typically require urgent medical attention because they can result in the aneurysm's expansion and ultimate rupture. (*Id.* at 3–4.)

Shortly after the AFX system went to market, Endologix began receiving increased reports of Type-III endoleaks—totaling 195 reports within the device's first two years in distribution. (*Id.* at 7.) The precursor Powerlink system, by contrast, received reports of approximately eight Type-III endoleaks each year. (*Id.*)

Though Endologix ceased manufacturing the Strata-based AFX in 2016, Endologix did not recall the product until December 30, 2016. (*Id.* at 8.) The FDA categorized the recall as "Class I", a label reserved for devices that may cause serious injury or death, and later concluded that "the Endologix AFX with Strata device is at greater risk for a Type III endoleak compared to other endovascular AAA graft systems." (*Id.* at 8–9.)

Before the Strata-based AFX was removed from the market, Plaintiff Kenneth Neve, Sr., a Tennessee resident, underwent an endovascular AAA repair surgery. (*Id.* at 4.) During that surgery, Mr. Neve received a Strata-based AFX implant. Following a Type-III endoleak, Mr. Neve underwent an additional AAA-repair surgery, during which a second Strata-based AFX was implanted. (*Id.*) Mr. Neve again suffered a Type-III endoleak, this time requiring a thrombectomy, a surgical procedure used to remove blood clots from a patient's arteries, and a fasciotomy, a limb-saving surgical procedure used to relieve swelling in a compartment of the body. (*Id.*) Mr. Neve faced "severe wound healing problems" as a result of undergoing this series of surgeries. (*Id.*) This lawsuit followed.

B. Procedural Background

On March 2, 2020, Mr. Neve and his wife, Linda Neve, brought this action against Endologix in the Circuit Court for Greene County, Tennessee, to recover for injuries sustained as a result of the AFX and for loss of consortium, respectively. (Doc. 1-1.) On April 9, 2022, after the action was removed to this Court, Endologix moved to dismiss Plaintiffs' claims against it. (Doc. 9, at 1.) Before the Court ruled on the motion, Plaintiffs moved to amend the complaint (Doc. 19), which Endologix did not oppose (Doc. 20.) Thereafter, the Court granted Plaintiffs' motion to amend and denied Endologix's motion to dismiss with leave to refile as applicable. (Doc. 22.)

On July 29, 2022, Endologix again moved to dismiss Plaintiffs' complaint for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure. (Doc. 39.) In their amended complaint, Plaintiffs allege claims under Tennessee law for: (1) strict liability for manufacturing defect; (2) strict liability for design defect; (3) strict liability for defective warnings; (4) negligence; (5) negligence per se; (6) breach of express warranty; (7) breach of implied warranty; and (8) negligent misrepresentation. (*See* Doc. 19-1.)

Though Plaintiffs were represented by counsel for the majority of proceedings in this case, Plaintiffs are now proceeding *pro se* following the death of their attorney. (Docs. 35, 37, 38.) Plaintiffs did not timely submit a response to Endologix's newly-filed motion to dismiss, and, on August 25, 2022, the Court ordered Plaintiffs to show case as to why their claims should not be dismissed for waiver of opposition under Local Rule 7.2 and failure to prosecute under Rule 41(b) of the Federal Rules of Civil Procedure. (Doc. 41.) Linda Neve filed a one-paragraph response imploring the Court not to dismiss the case. (Doc. 42.) The response,

however, did not contain any legal arguments responsive to Endologix's motion to dismiss. (*Id.*) Endologix's motion to dismiss is now ripe for the Court's review. (Doc. 43.)

II. STANDARD OF REVIEW

According to Rule 8(a)(2) of the Federal Rules of Civil Procedure, 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.*

A defendant may obtain dismissal of a claim that fails to satisfy Rule 8 by filing a motion pursuant to Rule 12(b)(6). On a Rule 12(b)(6) motion, 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." *Id*. 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*, 484 F.3d at 859. 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

A. Failure to Prosecute

After Plaintiffs, proceeding *pro se*[1], missed the responsive pleading deadline to Endologix's motion to dismiss, the Court alerted Plaintiffs that it was considering summary dismissal of their claims for failure to prosecute and provided an opportunity to show cause as to why their claims should not be dismissed. (*See* Doc. 41.) In response, Plaintiffs "beg[ged] the Court to not allow a dismiss of this case so [they] can have [their] day in court[,]" and lamented the "misinformation" defendants have "told along the way as well as false reports being filed on this matter." (Doc. 42.) This five-sentence paragraph constitutes the entirety of Plaintiffs' response to Defendant's dispositive motion.

Under Local Rule 7.2, a party's "[f]ailure to respond to a motion may be deemed a waiver of any opposition to the relief sought." E.D. Tenn. L.R. 7.2. A plaintiff's failure to

[1] The Court acknowledges that the Neves are proceeding in this action *pro se* following the death of their attorney and is mindful that *pro se* pleadings are to be liberally construed and held to less stringent standards than those prepared by attorneys. *Bridge v. Owen Fed. Bank*, 681 F.3d 355, 358 (6th Cir. 2012). However, those who proceed without counsel must still comply with the procedural rules that govern civil cases, including filing timely responses to dispositive motions. *Lewis v. Hawkins*, No. 3:16-cv-315, 2017 WL 4322825, at *4 (E.D. Tenn. Sept. 28, 2017); *see also Durante v. Fairlane Town Ctr.*, 201 F. App'x 338, 344 (6th Cir. 2006); *Whitson v. Union Boiler Co.*, 47 F. App'x 757, 759 (6th Cir. 2002). Regardless, Plaintiffs had retained counsel at the time they filed the amended complaint Defendant now seeks to dismiss, precluding application of the less stringent *pro se* pleading standards to that amended complaint. (Doc. 19-1, at 40.)

address the substantive arguments raised in a motion may be viewed as a failure to respond to the motion. *See Jarvis v. Hamilton Cnty. Dep't of Educ.*, No. 1:17-cv-172, 2019 WL 1368618, at *9 (E.D. Tenn. Mar. 26, 2019) (finding that a party's failure to address arguments made in motion to dismiss resulted in waiver); *Correa v. Rubin Lublin TN, PLLC*, No. 15-2135, 2015 WL 5232081, at *3 (W.D. Tenn., Sept. 8, 2015 (finding that a party's failure to address an argument raised in a motion to dismiss amounted to a waiver of the issue).

Despite Local Rule 7.2's permission to dismiss an action on account of a plaintiff's non-responsiveness, a district court cannot dismiss a plaintiff's complaint *solely* on this basis. *See Carver v. Bunch*, 946 F.2d 451, 455 (6th Cir. 1991) ("[A] district court cannot grant summary judgment in favor of a movant simply because the adverse party has not responded.") Instead, a court must "examine the movant's motion for summary judgment [or motion to dismiss] to ensure that he has discharged [his] burden" under Federal Rules of Civil Procedure 56(c) or 12(b). *Id.* In other words, "where the adverse party has not responded to a motion to dismiss, the district court must [still] consider the [motion] and make a determination accordingly." *Green v. City of Southfield, Michigan*, 759 F. App'x 410, 417 (6th Cir. 2018) (citing *Carver*, 946 F.2d at 455).

A court may also dismiss a plaintiff's action under Rule 41(b) of the Federal Rules of Civil Procedure for failure to prosecute, but, again, not if a plaintiff's failure to respond to a motion is the *only* basis for doing so. *See Carver*, 946 F.2d at 454. And the Sixth Circuit cautions dismissal for failure to prosecute "is a harsh sanction" reserved only for "extreme situations showing a clear record of delay or contumacious conduct by the plaintiff." *Id.* (citing *Carter v. City of Memphis, Tennessee,* 636 F.2d 159, 161 (6th Cir.1980)) (internal quotations omitted).

Having not yet evaluated whether Endologix has discharged its burden under Rule 12(b), the Court does not find dismissal is warranted under Local Rule 7.2. The Court is also unable to find Plaintiffs, who suddenly and unexpectedly found themselves without counsel mid-way through litigation, have demonstrated a track-record of delay or contumacious conduct deserving of dismissal under Rule 41(b).

B. Endologix's Motion to Dismiss

Endologix moves to dismiss Plaintiffs' claims under 12(b)(6), arguing: (1) the claims are preempted by federal law and, (2) even if Plaintiffs managed to avoid preemption by pleading parallel state claims, the complaint did not contain sufficient facts to entitle Plaintiffs to relief.

i. Whether Plaintiffs' Claims are Preempted

Endologix first argues Plaintiffs' claims are all preempted by federal law because the Food and Drug Administration ("FDA") has the exclusive authority to regulate Class-III medical devices, which includes the AFX system. (Doc. 40, at 1.)

The Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA") "impose a regime of federal oversight" on medical devices, which includes the aforementioned three-tiered, risk-based classification system. *Riegel*, 552 U.S., at 315–16. Within the MDA is a provision preempting any state law "relat[ing] to the safety or effectiveness of [a medical] device" that is "different from, or in addition to, any requirement applicable under [the MDA]." 21 U.S.C. § 360k(a). The provision, though restrictive, allows for a narrow gap through which certain otherwise-preempted state-law-based claims—"parallel claims"—can slip. *Medtronic Inc. v. Lohr*, 518 U.S. 470, 495 (1996) ("Nothing in § 360(k) denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.") The simultaneously complex and nebulous terrain of parallel-

claim allegations has been well-worn by post-*Lohr* precedent, yet without producing an accordant answer to the question: when has a parallel claim been sufficiently pled? *See White v. Stryker Corp.*, 818 F.Supp.2d 1032 (W.D. Ky. 2011) (taking stock of appellate courts' varying positions on the matter, with pleading requirements ranging from the Seventh Circuit's plaintiff-sympathetic approach to the Eleventh Circuit's detail-heavy standard).

Though the Sixth Circuit has not taken a firm stance as to the specificity required by a parallel-claim pleading, recent decisions of district courts—including one involving the same Defendant and medical device—provide some guidance. In *Hayes v. Endologix*, a case with a factual and procedural posture nearly identical to the present case, the district court explained that "to overcome the 12(b)(6) hurdle, there must be specific allegations as to how the Defendant deviated from the specifications in the PMA . . . [i]n other words, referring to a broad category of regulations without alleging how the device violated a particular regulation is not enough." *Hayes v. Endologix, Inc.*, 449 F.Supp.3d 676, 680 (emphasis removed) (drawing from *Waltenburg v. St. Jude Medical, Inc.*, 33 F.Supp.3d 818 (W.D. Ky. 2014); *White v. Stryker Corp.*, 818 F. Supp. 2d 1032 (W.D. Ky. 2011); *Steiden v. Genzyme Biosurgery*, 2012 WL 2923225 (W.D. Ky, July 18, 2012); and *Kitchen v. Biomet*, 2014 WL 694226 (E.D. Ky. Feb. 21, 2014)). Applying this principle, the *Hayes* court found "[p]laintiff's Complaint [to be] replete with citations to pertinent federal regulations and, how, specifically, [the Strata-based AFX] deviated from or violated" those regulations. *Id*. Satisfied that the complaint contained sufficiently-specific allegations as to how Endologix ran afoul of FDA-prescribed standards, the court found all but one state-law claim escaped preemption. *Id.*

Just as in the *Hayes* complaint, Plaintiffs' amended complaint cites to a number of federal rules and details how Endologix violated those rules. For instance, Plaintiffs allege Endologix

violated 21 C.F.R. § 820.30(g) by failing to "conduct any adequate clinical studies to establish the safety of the AFX System under actual or simulated use conditions." (Doc. 19-1, at 24.) In support of this claim, Plaintiffs rely on a statement made by the President and CEO of Endologix at a quarterly-earnings call: "[O]ur hope is that the clinical studies will not be required and we will be able to enter both the Europe and U.S. in 2011." (*Id.*) Because Plaintiffs' complaint is "replete" with citations to federal law and descriptions of how Endologix violated them, Plaintiffs' claims—with two exceptions—are not preempted.

The *Hayes* court concluded that the plaintiff's negligence-per-se claim was preempted. 449 F. Supp. 3d at 680–81. Because it is clear under Kentucky precedent—the state law applicable to the parallel claims—that a negligence-per-se claim cannot be based on violations of federal law and regulations, the court found the claim to be necessarily preempted. *Id.* Though Tennessee law does not pose the same sort of restraint on negligence-per-se claims, multiple Tennessee district courts have held that certain negligence-per-se and misrepresentation claims based on FDCA statutes are nonetheless preempted. *See Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 862 (W.D. Tenn. 2015) ("[T]o the extent that Plaintiff seeks to ground her negligence-per-se and misrepresentation claims on allegations that Defendant violated the FDCA—namely, by selling a misbranded and adulterated product—these claims are impliedly preempted pursuant to 21 U.S.C. § 337(a)") (internal citations omitted); *Heath v. C.R. Bard Inc.*, No. 3:19-CV-803, 2021 WL 3172315, at *10 (M.D. Tenn. July 27, 2021). For this reason, Plaintiffs' negligence-per-se and misrepresentation claims are preempted.

ii. Whether Plaintiffs Sufficiently Alleged Parallel State Claims

Endologix also argues that, even if Plaintiffs' claims are not preempted, the Court should still dismiss their complaint for failing to allege a causal connection between the medical device and Plaintiffs' injuries. (Doc. 40, at 9.)

A party pleading a parallel claim must adequately identify: (1) "the federal regulation violated by Defendant[]"; (2) "how the product deviated from the FDA approved process"; and (3) "how such deviation caused [the party's] injury[.]" *Kitchen*, 2014 WL 694226, at *3, 6–7. As this third directive makes plain, "parallel claims are not exempted from the causation requirements ordinarily applicable to the asserted causes of action . . . Plaintiff must also plead facts that show a causal connection between the alleged violation of the federal requirements and the injury suffered." *Potolicchio v. Medtronic, Inc.*, No. 1:15-cv-122, 2016 WL 3129186, at *3 (E.D. Tenn. June 2, 2016) (citation omitted). Thus, a plaintiff pleading parallel claims cannot do so successfully if she fails to draw a causal nexus between the alleged federal-law violations and the injuries she suffered.

In this case, Plaintiffs sufficiently link Mr. Neve's injury to Endologix's violations of relevant federal law. Plaintiffs argue throughout their complaint that Mr. Neve suffered Type-III endoleaks as a result of the Strata-based AFX's implantation, which was directly and proximately caused by Endologix's failure to comply with FDA regulations and statutes. (Doc. 19-1, at 24.) For instance, Plaintiffs argue that Endologix's failure to properly recall the Strata-based AFX system or to more expediently notify physicians of the system's markedly-high failure rate led to its implantation in Mr. Neve, and, consequently, his injuries. (*Id.*) Had Endologix complied with the federal rules requiring it to take these actions, Plaintiffs argue, the unreasonably dangerous Strata-based AFX would not have entered the market and ultimately

caused Mr. Neve to suffer Type-III endoleaks. (*Id*.) The Court finds Plaintiffs have met their burden under Rule 8(a) to demonstrate a causal connection between the alleged violation of the federal requirements and the injury suffered.

IV. CONCLUSION

For the aforementioned reasons, the Court finds that the majority of claims in Plaintiffs' first amended complaint satisfy Rule 8(a)(2)'s pleading standard. *See* Fed. R. Civ. P. 8(a)(2). Accordingly, the Court hereby **DENIES IN PART** Defendants' motions to dismiss Plaintiffs' strict liability, negligence, and breach of warranty claims and **GRANTS IN PART** Defendant's motion to dismiss Plaintiffs' negligence per se and misrepresentation claims. (Doc. 39).

SO ORDERED.

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