UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION

MARK LAY, Plaintiff,

v. Civil Action No. 3:20-cv-289-DJH

MEDTRONIC, INC. et al., Defendants.

* * * * *

MEMORANDUM OPINION AND ORDER

Plaintiff Mark Lay alleges that he was injured by the CD Horizon Spinal System designed, manufactured, and distributed by Defendants Medtronic, Inc; Medtronic USA, Inc.; Medtronic Sofamor Danek USA, Inc.; and Medtronic Care Management Services, LLC (collectively "Medtronic"). Lay asserts various product-liability and tort claims against Medtronic. (Docket No. 1-2) Medtronic moves to dismiss, arguing that Lay fails to state a plausible claim for relief. (D.N. 5) For the reasons explained below, Medtronic's motion will be granted in part and denied in part.

I.

The following facts are set out in the complaint and accepted as true for purposes of the motion to dismiss. *See Keys v. Humana, Inc.*, 684 F.3d 605, 608 (6th Cir. 2012). Lay had the CD Horizon system implanted in his spine on May 14, 2018. (D.N. 1-2, PageID # 16) He was part of the patient population for whom the system was intended, and the doctor who performed the surgery complied with applicable standards of care before, during, and after the procedure. (*Id.*, PageID # 16-18) Although Lay used the system "in a normal and reasonably expected manner"—"a manner consistent with, if not less actively than, many of the representations made in 'Patient Testimonials' and 'Patient Stories' that appeared [o]n [Medtronic's] websites"—Lay experienced

increasing pain at the implantation site, and an MRI in April 2019 revealed multiple fractured and displaced screws. (*Id.*, PageID # 18) The following month, Lay underwent a revision surgery performed by the same doctor, who again complied with all applicable standards of care. (*Id.*, PageID # 19) The "postoperative diagnosis was a failure of arthrodesis of lumbar instrumentation." (*Id.*)

Lay alleges that as a result of the failure of the CD Horizon system and the revision surgery, he has suffered various damages and injuries and will need additional surgery in the future. (*Id.*) He asserts claims of negligence, design defect, failure to warn, breach of implied and express warranties, negligent misrepresentation, and misrepresentation by omission. (*Id.*, PageID # 22-28) Medtronic seeks dismissal of all claims under Federal Rule of Civil Procedure 12(b)(6). (D.N. 5)

II.

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Factual allegations are essential; "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice," and the Court need not accept such statements as true. *Id.* A complaint whose "well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct" does not satisfy the pleading requirements of Rule 8 and will not withstand a motion to dismiss. *Id.* at 679.

As an initial matter, the Court agrees with Medtronic that Lay has abandoned his warranty and misrepresentation claims by failing to address them in his response to the motion to dismiss.[1] *See Bazinski v. JPMorgan Chase Bank, N.A.*, 597 F. App'x 379, 380-81 (6th Cir. 2015) (affirming dismissal where district court found several claims abandoned through plaintiff's failure to address them in response to motion to dismiss); *Degolia v. Kenton Cnty.*, 381 F. Supp. 3d 740, 759–60 (E.D. Ky. 2019) (quoting *Rouse v. Caruso*, No. 06-CV-10961-DT, 2011 U.S. Dist. LEXIS 25776, at *58 (E.D. Mich. Feb. 18, 2011)) ("[I]t is well understood . . . that when a plaintiff files an opposition to a dispositive motion and addresses only certain arguments raised by the defendant, a court may treat those arguments that the plaintiff failed to address as conceded."). The Court will therefore consider only Lay's claims of negligence, design defect, and failure to warn. (*See* D.N. 1-2, PageID # 22-24)

According to Medtronic, these claims fail because Lay has not adequately alleged defect or causation. (*See* D.N. 5, PageID # 65-71; D.N. 7, PageID # 91-94) In Kentucky, "all damage claims arising from the use of products" are governed by the state's Product Liability Act "regardless of the legal theory advanced," and under any theory, defect and causation are essential elements of the claim. *Mitchell v. Actavis Pharms.*, 185 F. Supp. 3d 971, 974 (W.D. Ky. 2016) (quoting *Monsanto Co. v. Reed*, 950 S.W.2d 811, 814 (Ky. 1997)); *see* Ky. Rev. Stat. § 411.300; *Prather v. Abbott Labs.*, 960 F. Supp. 2d 700, 706 (W.D. Ky. 2013) (citations omitted).

[1] Lay does mention the negligent-misrepresentation claim in his response, but only to assert that the claim is not subject to the heightened pleading standard set out in Federal Rule of Civil Procedure 9(b). (D.N. 6, PageID # 83) As Medtronic observes, Sixth Circuit precedent is to the contrary. *See, e.g.*, *Morris Aviation, LLC v. Diamond Aircraft Indus.*, 536 F. App'x 558, 562 (6th Cir. 2013) ("As with fraudulent-misrepresentation and fraudulent-concealment claims, negligent-misrepresentation claims under Kentucky law are subject to Rule 9(b)'s heightened pleading standards." (citing *Republic Bank & Tr. Co. v. Bear Stearns & Co.*, 683 F.3d 239, 247-48 (6th Cir. 2012))). Lay does not contend that he has met this standard. (*See* D.N. 6, PageID # 83)

Throughout its motion and reply, making ample use of italics, Medtronic insists that Lay has failed to identify a specific defect or allege how the system injured him. (*See, e.g.*, D.N. 5, PageID # 66-71; D.N. 7, PageID # 91-94) It dismisses Lay's allegations about fractured screws as "vague" and "conclusory" and otherwise ignores the factual allegations supporting Lay's claims. (*See* D.N. 5, PageID # 66-71; D.N. 7, PageID # 91-94)

Medtronic relies heavily on *Red Hed Oil, Inc. v. H.T. Hackney Co.*, 292 F. Supp. 3d 764 (E.D. Ky. 2017), in support of its contention that Lay's complaint is deficient. (*See, e.g.*, D.N. 7, PageID # 93-94 & nn.3-4) In *Red Hed*, however, the complaint's primary shortcoming was its failure to specify which of several defendants was responsible for the fire that caused the plaintiffs' injuries. *See* 292 F. Supp. 3d at 774-77. While the court also found that the complaint "fail[ed] to adequately plead how the fire started," *id.* at 775, the plaintiffs had only "vaguely assert[ed] that e-cigarettes spark fires" and that a defective product was to blame, without "specify[ing] what defect, which product was defective, or how the defect sparked the fire." *Id.* Likewise, in *Vanden Bosch v. Bayer Healthcare Pharms., Inc.*, 13 F. Supp. 3d 730 (W.D. Ky. 2014), another case cited by Medtronic (D.N. 7, PageID # 93), the plaintiffs "only assert[ed] that their Mirena® products were in an 'unsafe, defective, and inherently dangerous condition,' and that Mirena® was defectively designed because it was 'not reasonably fit, suitable, or safe for its intended purpose.'" 13 F. Supp. 3d at 743 (internal citation omitted). The Court distinguished *Foust v. Stryker Corp.*, No. 2:10-cv-00005, 2010 U.S. Dist. LEXIS 69771 (S.D. Ohio June 22, 2010), where "the plaintiff alleged how the product was defective" by "alleg[ing] that her hip replacement parts broke while implanted, causing the replacement to fail." *Vanden Bosch*, 13 F. Supp. 3d at 743. Since the *Vanden Bosch* plaintiffs "d[id] not allege what part of their Mirena® devices failed—or that their devices broke or malfunctioned once inserted," their design-defect claim was dismissed. *Id.*

Here, by contrast, Lay alleges that Medtronic's CD Horizon Spinal System caused his injuries when screws that were part of the system fractured. (D.N. 1-2, PageID # 18-19) While Lay does not specify exactly how the screws became fractured, his complaint rules out the alternative causes suggested by Defendants, namely "(1) natural complications flowing from a surgical procedure; (2) surgical technique; and (3) co-morbidities that affect Plaintiff's ability to heal or fuse appropriately." (D.N. 7, PageID # 94; *see* D.N. 1-2, PageID # 16-19 (alleging that surgery and postoperative treatment were performed in accordance with applicable standards of care and that Lay was an appropriate candidate for the CD Horizon system)) In any event, "the fact that [the screws] could have failed for multiple reasons is not relevant at this stage" of the case. *Foust*, 2010 U.S. Dist. LEXIS 69771, at *11-*12 (citing *Redinger v. Stryker Corp.*, No. 10-cv-104, 2020 U.S. Dist. LEXIS 49465, at *7 (N.D. Ohio May 19, 2010)); *cf. Minisan v. Danek Med., Inc.*, 79 F. Supp. 2d 970, 977 (N.D. Ind. 1999) (defect claim failed at summary-judgment stage where plaintiff "made no attempt to rule out any other cause for her pain and alleged injury"). And though Medtronic is correct that many courts have found that a broken spinal screw "[did] not mean *ipso facto* the device was defective," every case cited by Medtronic on that point was at the summary-judgment stage, where the plaintiffs' proof—usually expert testimony—was found to be deficient. (D.N. 5, PageID # 63 (alteration in original) (citing *Minisan*, 79 F. Supp. 2d at 977; *Menges v. DePuy Motech, Inc.*, 61 F. Supp. 2d 817, 822 (N.D. Ind. 1999); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 257 (E.D.N.Y. 1999); *Savage v. Danek Med., Inc.*, 31 F. Supp. 2d 980 (M.D. Fla. 1999))) Medtronic cites no cases applying this "ipso facto" rule at the motion-to-dismiss stage, and the Court has found none.

A plaintiff need not support his claims with evidence to survive a motion to dismiss. *See Smith v. Zoll Med. Corp.*, No. 1:20-cv-02204-STA-jay, 2020 U.S. Dist. LEXIS 230245, at *16

(W.D. Tenn. Dec. 8, 2020). From the facts alleged in Lay's complaint, the Court can reasonably infer that the screws in the CD Horizon system were defective, resulting in Lay's claimed injuries: Lay was implanted with the system as intended by Medtronic, yet the screws fractured and loosened, injuring Lay and necessitating a second surgery. (*See* D.N. 1-2, PageID # 16-19) These allegations go beyond a "mere recitation of the elements" of Lay's claims and are sufficient at this stage of the litigation. *Foust*, 2010 U.S. Dist. LEXIS 69771, at *11; *see Iqbal*, 556 U.S. at 678; *Clark v. Wright Med. Tech., Inc.*, No. 3:11-cv-00162, 2011 U.S. Dist. LEXIS 74248, at *2, *5-*6 (N.D. Ohio July 11, 2011)) (finding defect claim sufficient to withstand motion to dismiss where complaint alleged that a particular part of plaintiff's hip replacement fractured during normal activity); *cf. Vanden Bosch*, 13 F. Supp. 3d at 743.

III.

For the reasons set forth above, and the Court being otherwise sufficiently advised, it is hereby

ORDERED as follows:

(1) Medtronic's motion to dismiss (D.N. 5) is **GRANTED** as to Lay's claims of breach of express warranty, breach of implied warranty, negligent misrepresentation, and misrepresentation by omission. Counts 4, 5, 6, and 7 of Lay's complaint are **DISMISSED**. The motion to dismiss is **DENIED** as to Counts 1, 2, and 3.

(2) Pursuant to 28 U.S.C. § 636(b)(1)(A), this matter is hereby **REFERRED** to U.S. Magistrate Judge Colin H. Lindsay for resolution of all litigation planning issues, entry of scheduling orders, consideration of amendments thereto, and resolution of all non-dispositive matters, including discovery issues. Judge Lindsay is further authorized to conduct a settlement conference in this matter at any time.

March 31, 2021

David J. Hale, Judge
United States District Court