UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

VICKI OETJENS and ERIC OETJENS, Plaintiffs, v. COVIDIEN LP, MEDTRONIC USA, INC., and MEDTRONIC, INC., Defendants.	Case No. 22-11220 Honorable Laurie J. Michelson

OPINION AND ORDER GRANTING IN PART DEFENDANTS' MOTION TO DISMISS [17]

Vicki and Eric Oetjens allege that a medical stapler, which was designed, manufactured, and distributed by Medtronic USA, Inc., Medtronic, Inc., and Covidien LP (collectively "Covidien"), malfunctioned during Vicki's surgery, injuring her. So they sued Covidien. Believing most of their claims to be without merit, Covidien moved to dismiss them.

For the reasons that follow, the Court will grant the motion in part.

I.

Because Covidien seeks dismissal under Federal Rule of Civil Procedure 12(b)(6), the Court accepts the factual allegations in the Oetjens' complaint as true and draws reasonable inferences from those allegations in their favor. *See Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 979 F.3d 426, 440 (6th Cir. 2020).

According to the complaint, Covidien designs, manufactures, and distributes the "EEA Circular Stapler With Tri-Staple Technology[.]" (ECF No. 10, PageID.45.) The stapler is a single-use medical device that is shipped in a sterile, tamper-proof package that is intended to be opened inside an operating suite. (*Id.* at PageID.46–47.) This ensures that the stapler "remains in the exact condition it was in when it left the control of [Covidien] until it is opened[.]" (*Id.*) Once in the operating suite, the stapler is designed to "place a circular, triple staggered row of titanium staples while resecting excess tissue and creating a circular anastomosis"—or surgical connection between tubular structures in the body. (*Id.* at PageID.45); *see also* anastomosis, Medical Encyclopedia, National Library of Medicine, https://perma.cc/6QAC-WYA2. In other words, at least as the Court understands it, once the surgeon has removed diseased tissue from an organ like the intestine or colon, he or she would use the circular stapler to create a clean circular cut and then fire staples to reconnect and seal the two healthy segments of tissue.

But the stapler did not work this way during Vicki Oetjens' colectomy on October 13, 2020. On that date, the surgeon removed the stapler from its sterile packaging at the appropriate time in the operating suite. (ECF No. 10, PageID.46–47.) According to the operative report, the stapler was then passed up the rectum and deployed without incident. (*Id.* at PageID.48.) "[H]owever when the [stapler] was removed it became apparent that [it] had cut but not fired staples." (*Id.*) This left a "large hole in [Vicki's] rectum." (*Id.*) Accordingly, the surgeon was forced to perform a "diverting loop ileostomy[,]" i.e., an emergency procedure to remove waste from the

body when the colon is not working properly. (*Id.* at PageID.48, 62); *see also* ileostomy, Medical Encyclopedia, National Library of Medicine, https://perma.cc/9AKD-CCCR.

Following her surgery, Vicki had to use an ileostomy bag and undergo two additional reconstructive surgeries. (ECF No. 10, PageID.49–50.) Vicki suffered permanent surgical scarring, as well as physical, mental, and financial injury. (*Id.* at PageID.52.) For his part, Eric Oetjens suffered a loss of love and companionship from his wife. (*Id.* at PageID.63.)

So the Oetjens sued Covidien. They bring five claims for relief: (1) ordinary negligence; (2) breach of implied warranty; (3) breach of express warranty; (4) product liability; and (5) loss of consortium. (ECF No. 10, PageID.49–63.) The Oetjens have voluntarily dismissed the express-warranty claim. (ECF No. 21, PageID.171.)

Covidien now moves to dismiss the negligence and product-liability claims. (*See* ECF No. 17.) The motion is fully briefed. (ECF Nos. 21, 22.) Given the clear briefing and record, the Court considers it without further argument. *See* E.D. Mich. LR 7.1(f).

II.

Before considering the merits, the Court will address a threshold issue.

After the Oetjens filed their initial complaint, Covidien moved to dismiss it. (ECF Nos. 1, 7.) But before that motion was briefed, the Court stepped in. (ECF No. 9.) Specifically, the Court gave the Oetjens the "opportunity to file a First Amended Complaint in order to remedy the purported defects that Covidien has raised in its motion to dismiss." (*Id.* at PageID.40.)

The Oetjens accepted the Court's invitation and filed a First Amended Complaint with additional facts and clearer claims. (ECF No. 10.) Covidien again moved to dismiss. (ECF No. 17.)

Despite the Court's prior warning that it did "not anticipate allowing the Oetjens another opportunity to amend [their complaint] to add factual allegations that it could now include against Covidien" (ECF No. 9, PageID.40), the Oetjens provided additional facts and exhibits in response to the second motion to dismiss (*see* ECF No. 21, PageID.160–165; ECF No. 21-1 (listing five new exhibits)). Covidien protests. (ECF No. 22, PageID.242–244.) And it has good reason to. It is "black-letter law" that a court evaluating a motion to dismiss "must focus only on the allegations in the pleadings." *Bates v. Green Farms Condo. Ass'n*, 958 F.3d 470, 483 (6th Cir. 2020). So the additional facts raised in the response brief are improper and will not be considered. *See Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 979 F.3d 426, 440 (6th Cir. 2020).

III.

On to the merits. In deciding this motion to dismiss, the Court "construes the complaint in the light most favorable" to the Oetjens and determines whether their "complaint 'contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *See Heinrich v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 403 (6th Cir. 2012) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). Detailed factual allegations are not required to survive a motion to dismiss, *HDC, LLC v. City of Ann Arbor*, 675 F.3d 608, 614 (6th Cir. 2012), but they must

"raise a right to relief above the speculative level," *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). What is plausible is "a context-specific task" requiring this Court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679.

IV.

The parties agree that Michigan law applies to this dispute. (ECF No. 10, PageID.44; ECF No. 17, PageID.96 n.1.) With that in mind, the Court considers both claims that Covidien challenges in its motion to dismiss.

A. Ordinary Negligence

As to Count 1, Covidien argues that "[e]ven with the label of 'Ordinary Negligence' . . . Covidien has no understanding of what claims [the Oetjens] are bringing against it." (ECF No. 17, PageID.97.) Instead of laying out their claims as required by the Federal Rules of Civil Procedure, says Covidien, the Oetjens make "kitchen sink" pleadings that merely gesture at a number of potential claims. (ECF No. 17, PageID.95–98 (listing failure-to-inspect, failure-to-warn, and negligent-manufacturing as potential claims against it).) In response to the motion to dismiss, the Oetjens clarify that Count I is a common law negligence claim only. (*See* ECF No. 21, PageID.168.)

Nonetheless, Covidien hints at a larger problem. As the Oetjens recognize in their response brief, this is a "products liability case aris[ing] under Michigan law[.]" (ECF No. 21, PageID.166.) Michigan law defines a "product liability action" as an "action based on a legal or equitable theory of liability brought for . . . the injury to a person . . . caused by or resulting from the production of a product." *See* Mich. Comp.

Laws § 600.2945(h). "Production" includes the "manufacture . . . assembly, [or] inspection" of a product. *Id.* at § 600.2945(i). Putting that together, this is an action brought for injuries to Vicki, which were caused by or resulting from the manufacture, assembly, or inspection of the stapler. So the Court agrees that this is indeed a product-liability case.

Michigan law forbids plaintiffs from bringing common law negligence claims as separate causes of action in product-liability cases. *See Heaton v. Benton Const. Co.*, 780 N.W.2d 618, 623 (Mich. Ct. App. 2009) ("[T]he fact that plaintiffs' theory of liability was one of negligence does not preclude its action from coming within the statutory definition of a products liability action[.]"); *Johnson v. Jenkins*, No. 334452, 2017 WL 4699753, at *3 (Mich. Ct. App. Oct. 19, 2017) ("Although he may allege negligence as part of his product liability action, such an assertion serves as a theory of liability, rather than a separate claim."); *Holbrook v. Prodomax Automation Ltd.*, No. 1:17-219, 2021 WL 4260622, at *4 (W.D. Mich. Sept. 20, 2021) ("Therefore, he could only prosecute the . . . purportedly defective design through a product liability claim; he cannot assert a claim for common law negligence here."). Instead, as will be explained below, negligence is a theory of liability within a product-liability claim. *See Johnson*, 2017 WL 4699753, at *3.

So the separate ordinary negligence claim will be dismissed.

B. Product Liability

Covidien next argues that the Oetjens have failed to state a product-liability claim. In particular, it says they failed to plead a "design defect" and to identify an

"economically feasible alternative design[.]" (ECF No. 17, PageID.100–101.) True enough. But that is not the type of product-liability claim the Oetjens are bringing.

"Traditional principles of products liability law recognize three types of defects: manufacturing defects, defects due to faulty design, and defects due to inadequate instructions or warnings." *Teal v. Argon Med. Devices, Inc.*, 533 F. Supp. 3d 535, 543 (E.D. Mich. 2021) (citing *Fleck v. Titan Tire Corp.*, 177 F. Supp. 2d 605, 613 (E.D. Mich. 2011)). In response to the motion to dismiss, the Oetjens clarify that they bring a manufacturing-defect claim, not a design-defect claim. (*See* ECF No. 10, PageID.60 ("[T]he defect . . . [was that the stapler] fired and there were no staples packaged with the device."); ECF No. 21, PageID.167 ("Plaintiff's FAC also alleges that when the . . . stapler left defendant's control there were no staples loaded in the stapler. This is the 'production defect' that caused plaintiff's harm.").) And an "allegation of a manufacturing defect is analyzed very differently than an allegation of a design defect." *Johnson v. Black & Decker (U.S.), Inc.*, 408 F. Supp. 2d 353, 357 (E.D. Mich. 2005). "[A] manufacturing defect alleges that a product's defect or malfunctioning was caused by some imprecision in the manufacturing process, rather than from any negligent conduct of the manufacturer in designing the product." *Id.*

But that is not the end of the analysis. In order "[t]o provide compensation for injuries caused by such defects, Michigan recognizes two distinct causes of action for product failures: negligence and implied warranty." *Meemic Ins. Co. v. Hewlett-Packard Co.*, 717 F. Supp. 2d 752, 767 (E.D. Mich. 2010) (citing *Gregory v. Cincinnati, Inc.*, 538 N.W.2d 325, 329 (Mich. 1995); *Hollister v. Dayton Hudson Corp.*, 201 F.3d

731, 736–37 (6th Cir. 2000)). The "negligence theory generally focuses on the defendant's conduct, requiring a showing that it was unreasonable," whereas the implied warranty theory "generally focuses upon the fitness of the product, irrespective of the defendant's conduct." *Id.* (quoting *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 186 (Mich. 1985)).

Count IV asserts a product-liability claim for a manufacturing defect under a negligence theory.[1] (ECF No. 10, PageID.61 ("COVIDIEN LP was negligent in its inspection and quality control measures in failing to discover the lack of staples . . . prior to selling the device[.]").)

The negligence theory of liability "recognizes that manufacturers have a duty to use reasonable care to produce a product that is reasonably safe for its intended, anticipated, or reasonably foreseeable use." *Meemic*, 717 F. Supp. 2d at 768. To establish a manufacturing defect under this theory, "the plaintiff must show that: (1) the product was defectively manufactured; (2) the product reached the plaintiff in the same condition as it was when it left the manufacturer; and (3) the defect was the proximate cause of the plaintiff's damages." *Genaw v. Garage Equip. Supply, Inc.*, 604 F. Supp. 3d 653, 660 (E.D. Mich. 2022).

Taking the Oetjens' factual allegations as true, they have satisfied their burden at this stage. They allege that Covidien negligently manufactured the stapler

[1] Though not a subject of the motion to dismiss, it appears that Count II is a product-liability claim for a manufacturing defect under the implied-warranty theory. (ECF No. 10, PageID.54 (alleging that the stapler "was defective" and "did not deploy any staples, nor create the expected anastomosis in plaintiff's colon, and accordingly, was not fit, safe, or merchantable for its intended use").)

because (1) it "fail[ed] to load . . . [the stapler] with staples[;]" (2) the stapler was "packaged inside of a tamper proof sterile package" from the time it left Covidien's control to the time it was opened in the operating suite; and (3) the stapler caused Vicki's injury when it perforated her colon but did not fire any staples. (ECF No. 10, PageID.61–62.) In addition, the Oetjens allege that the stapler was not reasonably safe when it left Covidien's control and that a feasible alternative production practice was available to prevent the harm—namely, proper inspection and quality control practices. (ECF No. 10, PageID.61); *see also* Mich. Comp. Laws § 600.2946(2). And this conclusion is in line with an extremely factually similar case in another district. *See Johnson v. Medtronic Inc.*, No. 6:20-00599, 2021 WL 2669560, at *3 (D. Or. June 10, 2021), *report and recommendation adopted*, No. 6:20 CV 00599, 2021 WL 2668793 (D. Or. June 29, 2021) (denying motion to dismiss product-liability claims where plaintiffs alleged that "Defendants' EEA Stapler was defectively manufactured, that the Stapler malfunctioned during Ms. Johnson's surgery, and that due to this malfunction Ms. Johnson underwent an otherwise unnecessary ileostomy and will require additional surgery to remove the ileostomy bag").

So the Oetjens' negligent-manufacture claim survives.

V.

For the foregoing reasons, the Court will GRANT IN PART Covidien's motion to dismiss. (ECF No. 17.) The ordinary negligence claim will be dismissed. The implied-warranty, negligent-manufacture, and loss-of-consortium claims survive.

SO ORDERED.

Dated: May 22, 2023

s/Laurie J. Michelson
LAURIE J. MICHELSON
UNITED STATES DISTRICT JUDGE