UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ILONA HILDEBRANDT et al., Plaintiffs, v. MICHAEL J. BAUER et al., Defendants.	Case No. 24-11061 Honorable Shalina D. Kumar Magistrate Judge Anthony P. Patti

OPINION AND ORDER GRANTING DEFENDANT BAUER'S PARTIAL MOTION TO DISMISS (ECF NO. 13)

Plaintiffs Ilona Hildebrandt ("Ilona") and her husband Christian Hildebrandt ("Christian") sued defendants Michael J. Bauer and Keralink International, Inc. (f/k/a Tissue Banks International, Inc.) ("Keralink") for breach of implied and express warranty (Counts I & II), gross negligence (Count IV), "knowledge of defect" (Count V) (collectively, "product liability claims"),[1] and negligence (Count III) related to allegedly contaminated

[1] It is undisputed that these are all product liability claims governed by Michigan's product liability statutes, M.C.L. 600.2945-600.2949a. *See* ECF No. 1, PageID.13-14; ECF No. 19, PageID.188.

FiberCel Fiber Viable Bone Matrix ("FiberCel") that doctors had implanted into Ilona. ECF No. 1.

Bauer moves to partially dismiss the complaint, arguing that the complaint fails to properly plead the product liability claims. ECF No. 13. The motion is fully briefed, ECF Nos. 13, 19-20, and the matter is sufficient for determination without oral argument. *See* E.D. Mich. LR 7.1(f). For the following reasons, the Court grants the motion.

I. Factual Background

This matter is one of many product liability cases concerning allegedly contaminated FiberCel. *See, e.g.*, *Parron v. Aziyo Biologics, Inc.*, Case No. 22-10522; *Hildebrandt v. Aziyo Biologics, Inc.*, Case No. 21-12708; *Sherrill v. SpinalGraft Techs., LLC*, 2024 WL 1979452 (W.D.N.C. May 3, 2024). FiberCel is a human tissue implant sold for use as a bone void filler in orthopedic and spinal procedures to support bone repair. ECF No. 1, PageID.5. According to each FiberCel unit's packaging, the unit "was prepared from a donor determined to be eligible by the Medical Director of Aziyo . . . based on the results of screening and testing" and "has passed bacteriological testing." *Id.*

Non-party Aziyo Biologics, Inc. ("Aziyo") manufactures, sells, and distributes FiberCel, and at all relevant times, Bauer served as Aziyo's musculoskeletal medical director. *Id.* at PageID.3. Bauer was responsible for making Aziyo's FiberCel donor eligibility determinations. *Id.* at PageID.3-4.

Aziyo initiated a voluntary recall of certain FiberCel donor lots in 2021, after patients who had received FiberCel implants during surgery reported post-surgical infections—including tuberculosis.[2] *Id.* at PageID.6. Plaintiffs allege that some of the patients who received the contaminated FiberCel implants died or were otherwise harmed. *See id.* at PageID.7.

Ilona is allegedly one such patient. On April 20, 2021, Ilona underwent neck surgery at a hospital in Michigan. *Id.* at PageID.7. According to plaintiffs, the doctors implanted into Ilona FiberCel that came from the recalled donor lots and were thus contaminated with tuberculosis

[2] Tuberculosis is an infectious disease caused by bacteria known as mycobacterium tuberculosis ("tuberculosis bacteria"). ECF No. 1, PageID.7. Once tuberculosis bacteria is introduced to the body, the bacteria must then proliferate within the new host for the host to develop the disease. *Id.* When the bacteria is introduced in a surgical wound, the patient is already in an immunocompromised position, causing them to have an increased likelihood of developing tuberculosis, which can be fatal. *Id.*

bacteria. *Id.* Plaintiffs allege that several weeks later, Ilona experienced symptoms of tuberculosis and developed in her neck a "significant abscess" and vertebra deterioration caused by the contaminated FiberCel implant. *Id.* at PageID.7-8. Plaintiffs further allege that Ilona had the FiberCel implant surgically removed, quarantined, and took antibiotics for at least nine months. *Id.* at PageID.8.

Allegedly as a result of the FiberCel implant, Ilona faces increased neck injury risks and must undergo additional surgeries and medical treatments to stop and repair the FiberCel implant's damage. *Id.* Plaintiffs allege that due to the contaminated FiberCel, Ilona suffered pain and anxiety, restrictions to her daily activities, medical expenses, and other damages such as "the loss of or impairment of a vital bodily function," while Christian suffered a loss of consortium and Ilona's companionship and other such losses. *Id.* at PageID.8-9.

Hildebrandt subsequently filed this action against Bauer and Keralink, alleging claims for breach of implied and express warranty (Counts I & II), negligence (Count III), gross negligence (Count IV), and "knowledge of defect" (Count V). ECF No. 1. Bauer filed a motion to dismiss the product liability claims, arguing that the complaint fails to plead that he was a

manufacturer or seller of FiberCel and alternatively that the claims are barred by Michigan's "tissue shield" statute, M.C.L. 333.9121. ECF No. 13. Plaintiffs have since stipulated to dismiss Counts I and II. *See* February 6, 2025 Minute Entry. Accordingly, the Court dismisses Counts I and II against Bauer and considers Bauer's motion as to the remaining product liability claims (Counts IV & V).

II. Standard of Review

When deciding a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the Court must "construe the complaint in the light most favorable to plaintiff and accept all allegations as true." *Keys v. Humana, Inc.*, 684 F.3d 605, 608 (6th Cir. 2012). "To survive a motion to dismiss, 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) (internal quotation marks omitted); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (concluding that a plausible claim need not contain "detailed factual allegations," but it must contain more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action").

III. Analysis

Bauer argues that the product liability claims fail because plaintiffs have not plausibly pled that Bauer manufactured or sold FiberCel. In Michigan,[3] product liability claims are creatures of statute. *Klein v. Caterpillar Inc.*, 581 F. Supp. 3d 912, 922 (E.D. Mich. 2022). Michigan's product liability statutes contemplate product liability actions brought against only "manufacturer[s]" and "seller[s]." M.C.L. 600.2946; M.C.L. 600.2947. Indeed, "[a] plaintiff bringing a products liability action must show that the defendant supplied a product that was defective and that the defect caused the injury." *Auto Club Ins. Ass'n v. GMC*, 552 N.W.2d 523, 527 (Mich. Ct. App. 1996). To state a claim for product liability under a breach-of-warranty theory, a plaintiff must allege that "a seller . . . set[] forth a promise or affirmation, description, or sample with the intent that the goods will conform" or that "goods were defective when they left the possession of the manufacturer or seller." *Guaranteed Constr. Co. v. Gold Bond Prods.*, 395 N.W.2d 332, 334, 336 (Mich. Ct. App. 1986).

[3] Where, as here, a federal court sits in diversity, the court must "apply state substantive law and federal procedural law." *Saab Auto. AB v. GM Co.*, 770 F.3d 436, 440 (6th Cir. 2014).

Here, the complaint alleges that Bauer served as Aziyo's medical director and in that capacity determined whether donor tissue was eligible for use in FiberCel. ECF No. 1, PageID.3-4; *see also id.* at PageID.6 ("Donor eligibility determination[s] [were] made by Aziyo Biologics."). Although Bauer assessed donor tissue, the complaint contains no allegations indicating that Bauer himself supplied, manufactured, or sold FiberCel, let alone made personal promises or warranties related to FiberCel.

Plaintiffs do not dispute that to state their product liability claims, the complaint must allege that Bauer is a manufacturer or seller of FiberCel. Instead, they argue that Bauer did indeed manufacture FiberCel. According to plaintiffs, FiberCel's packaging—which says that FiberCel was produced with donor material that was screened, tested, and approved by Aziyo's medical director, Bauer—shows that Bauer was "central . . . to the manufacturing process" and that FiberCel "could not be made without [him]." ECF No. 19, PageID.187-88. Without any authority or further explanation, plaintiffs contend that these inferences show that Bauer was a manufacturer of FiberCel.

However, that Bauer screened, tested, and approved the raw materials from which FiberCel is ultimately produced does not establish that he himself produced or assembled FiberCel as a manufacturer for product liability purposes. *See Kraft v. Leonard's Healthcare Corp.*, 646 F. Supp. 2d 882, 888 (E.D. Mich. 2009) (defining "manufacturer" under Michigan product liability statutes as an "entity engaged in producing or assembling new products") (internal citation omitted); *see also Tubelite Inc. v. Lakeshore Glass & Metals, Inc.*, 2000 WL 33529759 at *3 (Mich. Ct. App. February 18, 2000) ("[T]he verb manufacture means 'to make up or produce by hand or machinery,' 'to work up (material) into form for use,' 'to fabricate,' 'to produce in a mechanical way,' or 'the making of goods by manual labor or machinery.'" (citing *Random House Webster's College Dictionary* (2d ed.)). Merely approving donor tissue or participating in quality control of that tissue—which is the extent of Bauer's alleged role in Aziyo's production of FiberCel—does not by itself allow a reasonable inference that Bauer produced or assembled units of FiberCel.

Without more, the complaint does not show that Bauer is a "manufacturer" or "seller" of FiberCel. M.C.L. 600.2946; M.C.L. 600.2947. Because the complaint does not adequately plead the product liability

claims against Bauer, the Court dismisses the remaining product liability claims (Counts IV & V) against him.[4]

IV. Conclusion

For the reasons above, the Court **GRANTS** Bauer's partial motion to dismiss. ECF No. 13. The Court **DISMISSES** the product liability claims as to Bauer (Counts I, II, IV, V). The remaining claims, for breach of express warranty against Keralink (Count I), breach of implied warranty against Keralink (Count II), negligence against Bauer and Keralink (Count III), gross negligence against Keralink (Count IV), and "knowledge of defect" against Keralink (Count V) survive and may proceed to discovery.

s/ Shalina D. Kumar
SHALINA D. KUMAR
United States District Judge

Dated: March 21, 2025

[4] As a result, the Court need not consider Bauer's alternative argument that these claims are barred by Michigan's "tissue shield" statute, M.C.L. 333.9121.