

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
AT LEXINGTON**

**DONALD HAWN and PAM HAWN,
Plaintiffs,**

V.

**MEDTRONIC MINIMED, INC.,
MEDTRONIC, INC.,
UNOMEDICAL A/S, and
DOES 1-100
Defendant.**

CIVIL ACTION NO. 5:16-93-KKC

OPINION AND ORDER

*** **

This matter is before the Court on the motions to dismiss filed by the named defendants in this action (DE 71, 74) and the plaintiffs' motion to amend their complaint (DE 79), which they filed in response to the motions to dismiss. For the following reasons, the Court will grant the motion to amend the complaint and will deny the motions to dismiss as moot.

In their complaint, plaintiffs Donald and Pam Hawn allege that the defendants design, manufacture and sell the MiniMed Paradigm Quick-Set Infusion Sets. The Minimed infusion set is intended to help diabetics regulate their blood sugar by providing a constant source of insulin and an alternative to multiple daily injections of insulin. The Hawns allege that the infusion set is used in conjunction with an insulin pump. Diabetics set the pump to deliver a steady trickle of insulin throughout the day and may program the pump to release higher doses at meals or when their blood sugar is high.

The Hawns allege that the infusion sets were defective in their design, manufacture, and marketing and that they were prone to deliver incorrect and life-threatening doses of

insulin. They allege that Donald was correctly using the infusion set at various times in 2013 but that it failed to deliver the correct dose of insulin. The Hawns allege that the device caused Donald to suffer a seizure, a dislocated shoulder and broken bones, back pain, diabetic ketoacidosis, and vomiting. They allege that, ultimately, the infusion set caused Donald to lose his job as a nurse.

The Hawns assert four causes of action against the defendants: strict liability, breach of express warranty, breach of implied warranty, and negligence.

This case was originally filed in the Southern District of Texas. The Texas court entered an order dismissing defendant Unomedical Devices S.A. de C.V. (DE 32, Opinion.) The three remaining named defendants – Medtronic MiniMed, Inc. and Medtronic, Inc. (together, “Medtronic”) and Unomedical A/S (“Unomedical”) – then jointly moved to transfer the case to this Court. The Hawns, who reside in Kentucky, did not oppose the motion. By order dated March 29, 2016, the Texas court transferred this action here.

Medtronic then moved to dismiss the action for failure to state a claim. Unomedical also moved to dismiss the complaint, largely adopting Medtronic’s arguments but asserting an additional defense to the breach of warranty claim. The Hawns responded to the motion to dismiss but have also filed a motion to amend their complaint. The proposed amended complaint would add substantial allegations to the complaint.

Because the window for amending their complaint as a matter of course has closed, see Fed. R. Civ. P. 15(a)(1)(A)-(B), the Hawns may only amend with written consent from the defendants or the Court’s permission. Fed. R. Civ. P. 15(a)(2). The defendants oppose the motion. Accordingly, this Court must determine whether to permit amendment. Rule 15(a)(2) provides that leave to amend a pleading shall be freely given when justice so requires. Fed. R.

Civ. P. 15(a)(2). The granting or denial of a motion to amend is within the sound discretion of the Court. *Marks v. Shell Oil Co.*, 830 F.2d 68, 69 (6th Cir. 1987).

A district court should consider the following factors in ruling on a party's motion to amend: (1) undue delay in filing the motion; (2) lack of notice to adverse parties; (3) whether the movant is acting in bad faith, or with a dilatory motive; (4) failure to cure deficiencies by previous amendments; (5) the possibility of undue prejudice to adverse parties; and (6) whether the amendment is futile. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Robinson v. Michigan Consol. Gas Co.*, 918 F.2d 579, 591 (6th Cir. 1990); see also *Birchwood Conservancy v. Webb*, 302 F.R.D. 422, 424 (E.D. Ky. 2014) (listing *Foman* factors).

The defendants do not address the first five of these factors. Instead, they argue that the Court should prohibit the proposed amendment because the amendment would be futile. An amendment is “futile” if “the proposed amendment would not permit the complaint to survive a motion to dismiss.” *Miller v. Calhoun Cnty.*, 408 F.3d 803, 817 (6th Cir. 2005). “If a proposed amendment is not clearly futile,” then the court should allow the amendment. *United States ex rel. Griffith v. Conn*, No. CV 11-157-ART, 2015 WL 8682294, at *3 (E.D. Ky. Dec. 11, 2015) (quoting *Wright & Miller*, 6 Fed. Prac. & Proc. Civ. § 1487 (3d ed.) (emphasis added)). “The proper vehicle to address an amendment that is subject to dismissal—but not clearly so—is a standalone motion to dismiss, rather than a motion for leave to amend a complaint.” *Id.*

At this juncture, the Court cannot find that the proposed amendments are so clearly futile that they must be prohibited. This is a product liability case. The *Hawns* seek to add 25 paragraphs to the current complaint, which consists of 109 paragraphs. The defendants argue that the amendments are futile, not only because these allegations are not sufficient to state a claim, but also because the claims themselves are preempted, time barred, and prohibited under

comment k to Section 402A of the Restatement of Torts. The Court finds that the best and most appropriate course to resolve the viability of the claims is to permit the Hawns to amend them, which would still allow the defendants to present their arguments in favor of dismissal through a motion to dismiss under Rule 12 of the Federal Rules of Civil Procedure specifically aimed at the amended complaint.

Accordingly, the Court hereby ORDERS as follows:

- 1) the Hawns motion to amend their complaint (DE 79) is GRANTED;
- 2) the Clerk of the Court SHALL FILE the tendered amended complaint into the record;
and
- 3) the motions to dismiss (DE 71, 74) and motion for a hearing (DE 71) are DENIED as moot.

Dated March 27, 2017.



A handwritten signature in cursive script that reads "Karen K. Caldwell".

KAREN K. CALDWELL, CHIEF JUDGE
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY