

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
WESTERN DIVISION**

Randy Warstler,

Case No. 3:16CV00385

Plaintiff,

v.

**ORDER**

Medtronic, Inc., *et al.*,

Defendants.

This is a products liability case in which plaintiff, Randy Warstler, raised claims under Ohio law against defendant, Medtronic, Inc., with respect to an allegedly defective Medtronic-manufactured device.

Jurisdiction is proper under 28 U.S.C. § 1332.

In a previous decision, *Warstler v. Medtronic, Inc.*, 2017 WL 769810 (N.D. Ohio), I granted defendant's motion to dismiss. (Doc. 18).

Pending is plaintiff's motion for reconsideration, which incorporates a request to file an amended complaint containing detail lacking from his original complaint. (Doc. 20). Defendant filed a response, contending my original order was correct and plaintiff fails to cure the defects that led to dismissal, (Doc. 21), to which plaintiff replied. (Doc. 22).

For the following reasons, I deny plaintiff's motion.

## Background

I discussed the facts of this case at length in my original order. *Warstler, supra*, 2017 WL 769810 at \*1-3.

In that order, I held that the Medical Device Amendment’s express preemption provision, 21 U.S.C. § 360k(a), applied and, additionally, that plaintiff failed to state plausible parallel claims to avoid preemption. *Id.* at \*10.

Section 360k(a), which is the core issue disputed by the parties in this case, provides:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

There is, however, a “narrow gap” in § 360k(a) that allows state law claims otherwise premised on a violation of FDA regulations to avoid preemption. According to the Supreme Court, “[n]othing in § 360k denies [states] the right to provide a traditional damages remedy for violations of common-law duties when those duties *parallel federal requirements.*” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) (emphasis added); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (“[T]he state duties in such a case ‘parallel,’ rather than add to, federal requirements.”).

Thus, I applied a two-part analysis to conclude plaintiff’s claims were expressly preempted, thus warranting dismissal. *Warstler, supra*, 2017 WL 769810 at \*5; *see also, e.g., Wolicki-Gables v. Arrow Intern., Inc.*, 634 F.3d 1296, 1300-01 (11th Cir. 2011); *In re Medtronic, Inc., Spring Fidelis*

*Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010); *Thorn v. Medtronic Sofamor Danek, USA, Inc.*, 81 F. Supp. 3d 619, 623-24 (W.D. Mich. 2015).

First, I determined, *per Riegel, supra*, 552 U.S. at 331, “whether the Federal Government has established requirements applicable to [the device at issue].” I concluded it had.

Then, I determined whether plaintiff’s state law claims impose “requirements with respect to the device that are ‘different from, or in addition to’ the federal ones, and that relate to safety and effectiveness.” *Id.* at 321-22 (quoting § 360k(a)); *see also Hafer v. Medtronic Inc.*, 99 F. Supp. 3d 844, 855-56 (W.D. Tenn. 2015). I concluded they did.

Thus, I held § 360k(a) preempted plaintiff’s state law claims. *Warstler, supra*, 2017 WL 769810 at \*6-10.

Now, plaintiff argues that the allegations in his proposed First Amended Complaint cure the deficiencies that led to my order dismissing his claims. Specifically, plaintiff asserts:

In the attached proposed First Amended Complaint, Mr. Warstler provides the detail missing from (and obtained subsequent to) his initial complaint. Specifically, this Complaint better relates the defect plaguing Mr. Warstler’s two Medtronic SynchroMed II devices, Medtronic’s recall of the devices, Medtronic’s violations of manufacturing standards and the [Premarket Approval] itself, and Mr. Warstler’s injuries as a result.

(Doc. 20, 2).

In response, defendant argues that plaintiff fails to satisfy the Rule 59 standard for motions for reconsideration, stating, “Plaintiff cites no new authorities or evidence supporting this drastic remedy, nor does he even attempt to challenge this Court’s well-reasoned decision holding that his claims are expressly preempted by 21 U.S.C. § 360k(a) as set forth in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).” (Doc. 21, 1).

I agree.

### **Standard of Review**

Although the Federal Rules of Civil Procedure do not specifically mention a motion for reconsideration, such a motion is often treated as a motion to alter or amend under Rule 59(e). *See McDowell v. Dynamics Corp. of Am.*, 931 F.2d 380, 382 (6th Cir. 1991); *Smith v. Hudson*, 600 F.2d 60, 62 (6th Cir. 1979).

This case presents a unique issue, as plaintiff, at this stage of the case, requests relief under Rule 15, which addresses amendment of a complaint, *and* Rule 59, which addresses post-judgment motions.

The Sixth Circuit advises district courts on how to approach the overlap of Rules 59 and 15 presented by this case:

[T]his is not a traditional motion to amend the complaint. Rule 15 requests to amend the complaint are frequently filed and, generally speaking, “freely” allowed. But when a Rule 15 motion comes *after* a judgment against the plaintiff, that is a different story. Courts in that setting must “consider[] the competing interest of protecting the finality of judgments and the expeditious termination of litigation.” *Morse*, 290 F.3d at 800. If a permissive amendment policy applied after adverse judgments, plaintiffs could use the court as a sounding board to discover holes in their arguments, then “reopen the case by amending their complaint to take account of the court’s decision.” *James v. Watt*, 716 F.2d 71, 78 (1st Cir. 1983) (Breyer, J.). That would sidestep the narrow grounds for obtaining post-judgment relief under Rules 59 and 60, make the finality of judgments an interim concept and risk turning Rules 59 and 60 into nullities. *See* 6 Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 1489 (3d ed. 2010).

*Leisure Caviar, LLC v. U.S. Fish & Wildlife Serv.*, 616 F.3d 612, 615-16 (6th Cir. 2010); *see also Benzon v. Morgan Stanley Distribs., Inc.*, 420 F.3d 598, 613 (6th Cir. 2005) (instructing courts to consider the “‘finality of judgments and the expeditious termination of litigation’” when determining whether to grant leave to amend a complaint post-judgment under Fed. R. Civ. P. 15) (quoting *Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir. 2002)).

Thus, “[w]hen a party seeks to amend a complaint after an adverse judgment, it . . . must shoulder a heavier burden. Instead of meeting only the modest requirements of Rule 15, the claimant must meet the requirements for reopening a case established by Rules 59 or 60.” *Leisure Caviar, LLC, supra*, 616 F.3d at 616; *see also HDC, LLC v. City of Ann Arbor*, 675 F.3d 608, 615 (6th Cir. 2012); *In re Ferro Corp. Derivative Litig.*, 511 F.3d 611, 624 (6th Cir. 2008); *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 607 (6th Cir. 2008). That “heavier burden” requires “[a] claimant who seeks to amend a complaint *after* losing the case [to] provide a compelling explanation to the district court for granting the motion.” *Leisure Caviar, LLC, supra*, 616 F.3d at 617; *see also Benzon, supra*, 420 F.3d at 613 (instructing courts to “‘be particularly mindful of . . . the movant’s explanation for failing to seek leave to amend prior to the entry of judgment’” when determining whether to grant leave to amend a complaint post-judgment under Fed. R. Civ. P. 15) (quoting *Morse, supra*, 290 F.3d at 800).

According to the Sixth Circuit:

A court acts within its discretion in denying a Rule 15 and a Rule 59 motion on account of “undue delay”—*including delay resulting from a failure to incorporate “previously [ ]available” evidence, GenCorp*, 178 F.3d at 834—and ought to pay particular attention to “the movant’s explanation for failing to seek leave to amend prior to the entry of judgment.” *Morse*, 290 F.3d at 800.

*Leisure Caviar, LLC, supra*, 616 F.3d at 616 (emphasis added).

Under Rule 59, I may alter the judgment based on: “(1) a clear error of law; (2) newly discovered evidence; (3) an intervening change in controlling law; or (4) a need to prevent manifest injustice.” *Intera Corp. v. Henderson*, 428 F.3d 605, 620 (6th Cir. 2005).

However, “[a] plaintiff cannot use a Rule 59 motion (or for that matter a post-judgment Rule 15 motion) ‘to raise arguments which could, and should, have been made before judgment issued.’”

*Leisure Caviar, LLC, supra*, 616 F.3d at 616 (quoting *Sault Ste. Marie Tribe of Chippewa Indians v. Engler*, 146 F.3d 367, 374 (6th Cir. 1998)); *see also Claybrooks v. Am. Broad. Cos., Inc.*, 2013 WL 1435050, \*2 (M.D. Tenn.) (“[A] motion under Rule 59(e) is not a vehicle for presenting new legal arguments that could have been raised before a judgment was issued.”) (citing *Roger Miller Music, Inc. v. Sony/ATV Publ’g, LLC*, 477 F.3d 383, 395 (6th Cir. 2007)); *Sault Ste. Marie Tribe of Chippewa Indians, supra*, 146 F.3d at 374 (“A motion under Rule 59(e) is not an opportunity to reargue a case.”).

Plaintiff seems to argue that the judgment should be altered to allow him to amend his complaint based on newly discovered evidence, which allegedly turned up for the first time after filing his initial complaint.

### **Discussion**

Pursuant to Rule 59, “newly discovered evidence” is evidence that was previously unavailable to the movant. *CGH Transport, Inc. v. Quebecor World, Inc.*, 261 F. App’x 817, 823 (6th Cir. 2008) (“‘Newly discovered evidence’ must have been previously unavailable.”); *GenCorp, Inc. v. Am. Intern. Underwriters*, 178 F.3d 804, 834 (6th Cir. 1999). “Newly discovered evidence” is “*not* evidence that was available to the movant before the judgment in question issued, but which the movant did not discover until post judgment.” *Lonardo v. Travelers Indem. Co.*, 706 F. Supp. 2d 766, 809 (N.D. Ohio 2010).

Additionally, as noted above, the Sixth Circuit instructs that I must consider plaintiff’s “explanation for failing to seek leave to amend prior to the entry of judgment” when determining whether to grant leave to amend a complaint post-judgment under Fed. R. Civ. P. 15. *Benzon, supra*, 420 F.3d at 613.

With respect to the “newly discovered evidence” argument, plaintiff simply states that the Proposed First Amended Complaint “provides the detail missing from (*and obtained subsequent to*) his initial complaint.” (Doc. 20, 2) (emphasis added).<sup>1</sup> This is the extent to which plaintiff goes to explain *why* or *how* the evidence he now seeks to include in his Proposed First Amended Complaint was previously unavailable. Other than the rather unclear and unexplained “obtained subsequent to” statement, plaintiff fails to tell me why he did not, or could not, learn of and include this information in his initial complaint. In both his motion for reconsideration and his reply to defendant’s opposition, plaintiff says nothing about this information being previously unavailable to justify granting a Rule 59 motion.

Plaintiff asserts that the allegations in his Proposed First Amended Complaint “better relate[] the defect plaguing [his] two Medtronic SynchroMed II devices, Medtronic’s recall of the devices, Medtronic’s violations of manufacturing standards and the [Premarket Approval] itself, and [his] injuries as a result.” (*Id.*). While this may be true, plaintiff, again, does not explain *why* or *how* this evidence was previously unavailable for inclusion in his initial complaint. For example, plaintiff fails to explain why he could not have previously learned about the alleged defects in the two SynchroMed II devices he received and his resulting injuries or defendant’s recall and violations of manufacturing standards and the FDA’s Premarket Approval. I see no reason, and plaintiff points me to none, why plaintiff could not have familiarized himself with these details prior to filing his initial complaint and certainly prior to my order dismissing his claims. Simply put, plaintiff fails to demonstrate that this “newly discovered” evidence was previously unavailable to him.

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<sup>1</sup> I note that plaintiff does not even address the “newly discovered evidence” argument in his motion for reconsideration. This terminology is nowhere in the motion. Instead, I presumed this is his argument for satisfying Rule 59, as the other three grounds do not apply.

Further, there is simply no explanation, let alone a “compelling explanation,” for why plaintiff did not seek leave to amend his complaint to include this detail prior to my judgment granting defendant’s motion to dismiss. Plaintiff had more than enough time to seek leave to file an amended complaint *prior* to my dismissal order; yet, plaintiff failed to do so and now wants to change his complaint in light of that order. I see no reason why plaintiff did not seek leave to amend before my order to include the same information he now seeks to include after my order. Having considered the “competing interest of protecting the finality of judgments and the expeditious termination of litigation,” as well as plaintiff’s utter lack of explanation for not seeking leave to amend prior to my order, I conclude plaintiff does not satisfy the “heavier burden” he must satisfy to warrant post-judgment leave to amend. *Leisure Caviar, LLC, supra*, 616 F.3d at 615-16.

Therefore, I deny plaintiff’s motion for reconsideration.

### **Conclusion**

Because plaintiff failed to meet the Rule 59(e) standard, plaintiff’s motion for reconsideration (or for leave to amend his complaint) is not well-taken.

It is hereby,

ORDERED THAT: plaintiff’s motion for reconsideration (Doc. 20) be, and the same hereby is, denied.

So ordered.

/s/ James G. Carr  
Sr. U.S. District Judge