

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF KANSAS

UNITED STATES OF AMERICA )  
*ex rel.* THOMAS SCHROEDER, )  
 )  
 Relator, )  
 )  
 vs. )  
 )  
 MEDTRONIC, INC., *et al.*, )  
 )  
 Defendants. )  
\_\_\_\_\_ )

Case No. 17-2060-DDC-BGS

**MEMORANDUM & ORDER DENYING  
MOTION TO AMEND SCHEDULING ORDER**

Now before the Court is Relator’s “Motion to Amend Scheduling Order to Reopen Fact Discovery for Limited Purposes.” (Doc. 390.) Having reviewed the submissions of the parties, Relator’s motion is **DENIED** for the reasons set forth herein.

**BACKGROUND**

Relator Thomas Schroeder (“Relator”) brings this action against Defendants Medtronic, Inc. (“Medtronic”), Covidien L.P. (“Covidien”), Hutchison Regional Medical Center (“HRMC”) and Wichita Radiological Group, P.A. (“WRG”) under the False Claims Act, 31 U.S.C. § 3729, alleging Defendants Medtronic and Covidien paid illegal remuneration to induce purchase of medical devices in an effort to recover monies for the Veterans Administration. Relator further alleges that Medtronic employees were rewarded for marketing or encouraging the “overuse” and “off label” use of Peripheral Disease devices. (*Id.*)

Relator’s Fifth Amended Complaint (“operative Complaint” or “the Complaint”) was filed on October 24, 2022. (Doc. 233.) Therein, Relator alleges that HRMC and Medtronic violated the Federal anti-kickback statute, 42 U.S.C § 1320a-7b(b) (“AKS”), “by exchanging medical devices free

of charge as part of larger bulk purchases of other devices.” (Doc. 390, at 2.) According to Relator, these devices were “illegal remuneration provided to induce these sales.” (*Id.*)

HRMC and Medtronic filed their Answers to the operative Complaint on August 24, 2023, and August 31, 2023 (Docs. 379, 384), several months after the close of fact discovery on April 30, 2023.<sup>1</sup> (Doc. 301, text Order.) The case progressed this way because HRMC and Medtronic filed Motions to Dismiss in response to the operative Complaint (Docs. 243, 244) on November 21, 2022. The District Court, however, permitted discovery to proceed while these dispositive motions were pending. The motions were ruled upon by the District Court on August 10, 2023. (Doc. 368.)

Thereafter, HRMC and Medtronic filed the above-referenced Answers to the operative Complaint, which contain the “safe harbor” affirmative defense to liability under the AKS. (Doc. 379, at 25; Doc. 384, at 24.) The defense relates to certain exceptions – or “safe harbors” – to sales between device manufacturers and buyers. This affirmative defense had also been included in HRMC’s Answer to Relator’s Third Amended Complaint, which was filed on November 23, 2021.<sup>2</sup> (Doc. 77, at 23.)

Relator brings the present motion, arguing that because discovery closed before Defendants pled the safe harbor affirmative defense, he should be allowed “very brief and limited discovery” into the basis for this affirmative defense. (Doc. 390, at 2.) Defendants generally argue that Relator’s motion should fail because he has failed to establish the requisite good cause to amend the

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<sup>1</sup> The case remains in the expert discovery phase until April 12, 2024. (Doc. 361, at 2.) The Pretrial Conference is set for May 8, 2024, with dispositive motions due June 7, 2024. (*Id.*)

<sup>2</sup> Medtronic did not answer the Third Amended Complaint, but instead filed a Partial Motion to Dismiss. (Doc. 75.) The Fourth Amended Complaint was filed on May 25, 2022. (Doc. 127.) All Defendants filed partial or full motions to dismiss the Fourth Amended Complaint. Therefore, Defendants did not answer (and plead affirmative defenses to) the Fourth Amended Complaint. Before the dispositive motions relating to the Fourth Amended Complaint were ruled upon, Relator was granted leave (Doc. 232) to file the Fifth Amended Complaint, which was entered on October 24, 2022 (Doc. 233). Thus, prior to answering the Fifth Amended Complaint, the last operative Answer by HRMC was the Answer to the Third Amended Complaint – which included the safe harbor affirmative defense.

Scheduling Order because he was aware of the affirmative defense long before the close of fact discovery. The Court notes that Magistrate Gale’s Memorandum & Order granting Relator’s previous Motion to Amend Revised Scheduling Order for Extension of Expert Deadlines emphatically stated that “**fact discovery has ended. No party may issue additional fact discovery without leave of court.**” (Doc. 353, at 11 (emphasis in original).)

### ANALYSIS

#### **I. Standards for Amending Scheduling Order.**

Rule 16(b)(4) provides that “[a] schedule may be modified only for good cause and with the judge's consent.” “In practice, this standard requires the movant to show the ‘scheduling deadlines cannot be met despite [the movant’s] diligent efforts.’” *Gorsuch, Ltd., B.C. v. Wells Fargo Nat’l Bank Ass’n*, 771 F.3d 1230, 1240 (10th Cir. 2014) (citing *Pumpco, Inc. v. Schenker Intern., Inc.*, 204 F.R.D. 667, 668 (D. Colo. 2001) (quotations omitted)). *See also Pfeiffer v. Eagle Mfg. Co.*, 137 F.R.D. 352, 355 (D. Kan. 1991); Fed.R.Civ.P. 16 advisory committee note to 1983 Amendment. The Court is “afforded broad discretion in managing the pretrial schedule.” *Rimbert v. Eli Lilly & Co.*, 647 F.3d 1247, 1254 (10th Cir. 2011); *see also Smith v. US*, 834 F.2d 166, 169 (10th Cir. 1987).

In determining whether to reopen discovery, the Court’s analysis is guided by the following six factors:

- 1) whether trial is imminent, 2) whether the request is opposed, 3) whether the non-moving party would be prejudiced, 4) whether the moving party was diligent in obtaining discovery within the guidelines established by the court, 5) the foreseeability of the need for additional discovery in light of the time allowed for discovery by the district court, and 6) the likelihood that the discovery will lead to relevant evidence.

*Smith*, 834 F.2d at 169; *see also Rutledge v. Bd. of Cnty. Commissioners of Johnson Cnty.*, No. 20-2012-DDC-GEB, 2021 WL 274514, \*3 (D. Kan. Jan. 27, 2021) (citation omitted) and *Benjamin v. Bd. of Trustees of Barton Cnty. Cmty. Coll.*, No. 17-2557-JAR, 2020 WL 4785107, \*2 (D. Kan. Aug. 18, 2020) (citation

omitted). That stated, the lack of prejudice to the nonmovant does not, in itself, establish “good cause.” *Degband v. Wal-Mart Stores, Inc.*, 904 F.Supp. 1218, 1221 (D. Kan. 1995) (citations omitted).

## II. Application of Legal Standard to Facts of Case.

In seeking to amend the Scheduling Order to reopen discovery, Relator specifically seeks permission

to take one Rule 30(b)(6) deposition from Medtronic regarding where the ‘no charge’ devices given by Medtronic to HRMC would have physically come from. These no charge devices impacted the sale price of other devices, and therefore, play an essential role in any alleged ‘safe harbor’ defense under the AKS. Assuming Medtronic’s designated corporate representative has been prepared as required by Rule 30(b)(6). Relator anticipates the deposition should take no more than a few hours to complete. That is the extent of the requested discovery.

(Doc. 390, at 2-3 (footnote omitted).) Relator concedes that “some discovery” regarding the safe harbor affirmative defense occurred prior to the fact discovery deadline. (*Id.*, at 3.) Relator opines, however, that “until defendants actually filed their Answers [in August 2023], Relator did not, and could not, know for sure whether the safe harbor affirmative defense would be invoked,” thus “not all discovery was performed on it prior to the cutoff date (i.e., discovery on where the free devices behind the ‘no charge’ discounts came from).” (*Id.*) Relator continues that it was “under no legal obligation to ‘anticipate’ what defenses the defendants ‘might’ eventually plead and conduct prophylactic discovery on them.” (*Id.*) Relator contends that allowing the requested deposition will not delay this case or otherwise impact the deadlines in the Scheduling Order. (*Id.*)

HRMC generally responds that Relator cannot establish the requisite good cause to amend the Scheduling Order. (Doc. 393.) According to HRMC, Relator had “ample time and opportunity to conduct discovery into the safe harbors” because “Relator knew from the beginning of this case that Defendants would assert the safe harbors as affirmative defenses.” (*Id.*, at 1, 2.) In support of this argument, HRMC references the December 2021 Report of Parties’ Planning Conference, in

which “‘safe harbor’ paperwork” was “jointly propose[d]” as a subject matter in the parties’ plan for discovery. (*Id.*, at 1 (citing (Doc. 393-9, at 6).) Interestingly, the parties’ report jointly proposed that fact discovery regarding safe harbor and other listed issues should be completed by December 30, 2022 – almost nine months before the filing of the present motion wherein Relator argues he could not reasonably have been expected to conduct discovery on safe harbor issues until August 2023. (Doc. 393-9, at 6.) HRMC continues that Relator served numerous written discovery requests regarding the safe harbors. (Doc. 393, at 4 (referencing Doc. 393-1, at 9, Doc. 393-2, at 5, and Doc. 393-3, at 5-10).)

Further, on April 27, 2023, Relator noticed a Rule 30(b)(6) deposition that specifically enumerated “facts that would support HRMC’s use of Safe Harbor regulations in this case” as a matter about which the designated officer was expected to testify. (Doc. 338, at 4-5.) It is uncontested that Relator in fact questioned two deponents about safe harbor issues. (*See* Doc. 393-5, at 3-16; Doc. 393-6, at 3.)

Particularly damaging to Relator’s position is the fact that HRMC included safe harbors in the affirmative defenses contained in its Answer to Relator’s Third Amended Complaint. (Doc. 77, at 23.) This Answer was filed on November 23, 2021 – 17 months prior to the close of fact discovery.<sup>3</sup> This clearly runs counter to Relator’s argument that it could not have been expected to engage in discovery regarding safe harbors “until defendants actually filed their Answers last month” (in August 2023) because “Relator did not, and could not, know for sure whether the safe harbor affirmative defense would be invoked.” (Doc. 390, at 3.)

Counsel for HRMC also points out that “while negotiating topics for Hutchinson’s corporate representative deposition” on March 17, 2023, Relator’s counsel “specifically asked whether [HRMC] planned to assert an affirmative defense based on the safe harbor.” (Doc. 393, at

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<sup>3</sup> As discussed above, this was the last Answer filed by HRMC prior to the close of fact discovery.

4 (citing Doc. 393-4, at 2 (wherein counsel inquired “Can we discuss if HRMC is going to bring an affirmative defense based on the Safe Harbor provisions in 42 CFR 1001.952. If so, perhaps we can talk about the records that apply here and if we need to do more discovery.”)).) This occurred approximately six weeks before the close of fact discovery on April 30, 2023. (Doc. 301, text Order.) HRMC asserts that it replied to this inquiry “that it would in fact be pursuing the safe harbor affirmative defense,” which lead to the parties “negotiating a Rule 30(b)(6) Witness topic covering the defense.”<sup>4</sup> (Doc. 393, at 4 (referencing Doc. 338).)

Medtronic makes a similar “lack of good cause” argument. (Doc. 392.) According to Medtronic,

Relator was fully aware that the safe harbor defense was at issue in the case by no later than December 2021, when the safe harbor was identified by name as a subject for discovery in the parties’ December 2021 Joint Planning Report which Relator’s counsel signed. Moreover, Relator also already conducted extensive discovery on the discount safe harbor – including approximately 25 Requests for Production and deposition questions for both fact and Rule 30(b)(6) witnesses. Finally, the specific topic on which Relator seeks discovery – namely, where the devices Medtronic sold HRMC in bulk deals physically came from – is not even germane to the AKS factors used to analyze the safe harbor exemption.

(*Id.*, at 1-2.)

In his reply brief, Relator reiterates that he could not have been expected to conduct discovery on this defense until it was plead. (Doc. 394, at 1.) In support of this argument, Relator cites the case of *New York v. Micron Tech., Inc.*, No. C 06-6436-PJH, 2009 WL 29883, at \*6 (N.D. Cal. Jan. 5, 2009) (granting the plaintiff’s request to reopen discovery of the defendants’ affirmative defenses plead after close of discovery and rejecting defendants’ argument that plaintiff was “on

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<sup>4</sup> The Court notes that HRMC does not include an email memorializing this reply as an exhibit to its response brief. It is possible counsel’s reply occurred by telephone. Regardless, Relator does not address this fact in his reply brief. As such, it is uncontroverted.

notice” of those defenses before they were plead and therefore should have conducted discovery on them).

The Court finds Relator’s reliance on this case to be unpersuasive. Because multiple motions to dismiss were filed in *Micron Tech.*, the defendants therein did not file Answers to any Complaint filed in that case until after the discovery deadline had passed. *Id.*, at 1-2. Therefore, the affirmative defenses about which the plaintiff sought discovery had never specifically been raised in the case until after the close of discovery.

That is clearly distinguishable from the circumstances existing herein. It is uncontested that the safe harbor affirmative defense was raised by HRMC in its “Answer and Affirmative Defenses to Relator’s Third Amended Complaint” in November 2021. (Doc. 77, at 23.) This put Relator on notice about the affirmative defense for purposes of ongoing discovery.

Further, it is uncontested that Relator was aware that discovery would need to be conducted in this case regarding safe harbor issues as early as December 2021 when the parties submitted their Report of Parties’ Planning Conference. (*See* Doc. 393-9, at 6). It is also uncontested that Relator engaged in significant discovery regarding safe harbor issues – both written and by deposition – prior to the discovery deadline. (*See* Doc. 393-1, at 9, Doc. 393-2, at 5, and Doc. 393-3, at 5-10; Doc. 338, at 4-5; Doc. 393-5, at 3-16; and Doc. 393-6, at 3.)

Relator argues in his reply brief that “the particular discovery sought in this requested deposition (where the “no charge” devices given by Medtronic to HRMC physically came from) has not been a topic of any discovery conducted to date.” (Doc. 394, at 2.) The Court is not persuaded by this reasoning. The fact that Relator failed to – or chose not to – seek discovery on a specific aspect of the safe harbor affirmative defense does not negate the fact that he was admittedly aware that safe harbor issues would need to be addressed as far back as November/December 2021 when HRMC included the safe harbor affirmative defense in its November 2021 Answer and the parties

jointly identified safe harbor issues as a matter about which discovery would be sought in their December 2021 Report of Parties' Planning Meeting. (Doc. 77, at 23; Doc. 393-9, at 6.)

Given the *Smith* factors listed *supra*, the Court finds that Relator has failed to establish good cause for the requested extension of the fact discovery deadline. 834 F.2d at 169. While trial is not imminent and the discovery *may* lead to relevant evidence, as set forth herein, the other factors do not weigh in favor of granting the extension. *Id.*

Defendants have opposed the request, Relator was not diligent in obtaining discovery, and the need for discovery on this issue was clearly foreseeable long before the close of discovery. *Id.*; *see also Gorsuch, Ltd.*, 771 F.3d at 1240 (holding that the “standard requires the movant to show the ‘scheduling deadlines cannot be met despite [the movant’s] diligent efforts.’”). In addition, Defendants have established that they would be prejudiced by allowing the discovery to proceed given the fact that Relator has already deposed at least two witnesses on safe harbor issues and submitted extensive written discovery on the topic, discussed *supra*. (Doc. 392, at 11.)

On balance, Relator has failed to establish good cause and the circumstances of this case do not warrant the reopening of discovery. Relator’s motion is, therefore, **DENIED**.

**IT IS THEREFORE ORDERED** that Relator’s Motion to Amend Scheduling Order (Doc. 390) is **DENIED**.

**IT IS SO ORDERED.**

Dated this 5<sup>th</sup> day of October 2023, at Wichita, Kansas.

/s/BROOKS G. SEVERSON  
Brooks G. Severson  
U.S. Magistrate Judge