



January 2017. (Doc. 1.) The original Complaint was filed under seal and alleged violations of the False Claim Act, 31 U.S.C. § 3729, *et seq.*, against Defendants Medtronic, Plc (“Medtronic”) and Hutchinson Regional Hospital (“Hutchinson” or “Hospital”). (Doc. 1.) The False Claims Act (“FCA”) generally prohibits private parties from ‘knowingly’ submitting ‘a false or fraudulent claim’ for reimbursement. 31 U.S.C. § 3729(a)(1)(A). The FCA imposes civil liability on “any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” to the United States government. 31 U.S.C. §3729(a)(1)(A).

Medtronic sells medical devices and overlaps to a degree with certain regions in which relator’s company operates, making Relator’s company and Medtronic competitors. (Doc. 26, at 21, 29.) Hutchinson is a nonprofit hospital located in Kansas. (*Id.*, at 4.) Both Relator’s company and Medtronic market their services to Hutchinson. (*Id.*, at 30.)

Relator filed an Amended Complaint in September 2019. (Doc. 14.) During this time, the United States government was in the process of determining whether it would intervene. (Docs. 3, 5, 7, 9, 12, 15.) The government ultimately filed a notice in April 2020 declining intervention. (Doc. 19.) The District Court subsequently entered an Order unsealing the Complaint and Amended Complaint,

but also indicated that the government could intervene in this action “at any time” upon a showing of good cause. (Doc. 20 at 2.)

In July 2020, Relator filed a Second Amended Complaint; the request to do so was unopposed. (Docs. 24, 26.) This pleading removed the States of Oklahoma and Texas as party Plaintiffs in this case. (*Id.*) According to Relator, the Second Amended Complaint also provide more detail “regarding the alleged kickbacks/bribes involving the two Defendants, and further develops and describes claims for medically unnecessary medical treatment and ‘off-label’ devices involving Defendant Medtronic.” (Doc. 24, at 3.)

Thereafter, Medtronic and Hutchinson filed Motions to Dismiss. (Docs. 45 – 48.) In its Memorandum and Order, the District Court denied Hutchinson’s motion while granting Medtronic’s motion in part. (Doc. 67.) As to Medtronic’s motion, the District Court

denie[d] the motion against these claims: (1) illegal kickbacks at Dole VA and Hutchinson and (2) civil conspiracy allegations based on an illegal kickback scheme at Dole VA. However, the court grant[ed] the motion against these claims: (1) medically unnecessary procedures and (2) off-label marketing.

(Doc. 67, at 55.) The District Court granted Relator’s request for leave to amend as to the two claims that did not survive Medtronic’s Motion to Dismiss (medically unnecessary procedures and off-label marketing). (*Id.*)

The Third Amended Complaint was filed on October 12, 2021. (Doc. 72.) This resulted in another Motion to Dismiss filed by Medtronic on November 9, 2021. (Doc. 75.) Therein, Medtronic argues that Relators' allegations of medically unnecessary procedure and off-label promotion fail to state a claim and should be dismissed with prejudice. (*See generally* Doc. 76.) This motion remains pending before the District Court.

On January 24, 2022, the undersigned Magistrate Judge conducted a scheduling conference, resulting in the Scheduling Order. (Doc. 99.) That Order included a deadline of March 14, 2022, for Relator to seek leave to amend or add parties. (*Id.*) The deadline for fact discovery was set for December 30, 2022. Relator then filed a motion, which was subsequently opposed, requesting an extension of the amendment deadline for two weeks from the District Court's ruling on Medtronic's pending motion to dismiss; this motion was granted by the undersigned Magistrate Judge. (Docs. 108, 111.)

Relator timely filed the present motion to amend on April 11, 2022, seeking permission to:

- (i) add Covidien, L.P. – a corporate entity related to Medtronic – as a party defendant; (ii) add Wichita Radiological Group, P.A. as a party defendant; (iii) clarify the description of peripheral arterial disease ('PAD') devices set forth in ¶ 35 of the [operative Complaint]; (iv) include the sale of Medtronic coronary devices under Relator's False Claims Act, 31 U.S.C. § 3729, *et seq.* (the 'False Claims Act' or 'FCA') and anti-

kickback statute, 42 U.S.C. § 1320a-7b(b) (the ‘AKS’), claims; (v) provide additional allegations regarding medically unnecessary and off-label devices in PAD procedures at the Robert J. Dole Veterans Administration Medical Center (‘Dole VA’) and additional evidence of Medtronic’s promoting thereof; and (vi) correct typographical errors in ¶¶ 116 and 131 of the [operative Complaint] regarding dates.

(Doc. 113, at 1-2.) In response, Medtronic argues that the motion must fail on the bases of Relator’s undue delay, dilatoriness, and bad faith while Defendant Hospital argues undue delay and futility. (Doc. 116; Doc. 117.)

## ANALYSIS

### **I. Standards for Motions to Amend.**

Motions to amend pleadings are governed by Fed.R.Civ.P. 15(a), which provides that a pleading may be amended “once as a matter of course within ... 21 days after service of a responsive pleading.” Fed.R.Civ.P. 15 (a)(1)(B). Because more than 21 days have elapsed since Defendants filed their Answers, Relator may amend “only with the opposing party’s written consent,” which has not been provided, “or the court’s leave.” Fed.R.Civ.P 15(a)(2). Courts are to “freely give leave when justice so requires.” *Id.* “The liberal granting of motions for leave to amend reflects the basic policy that pleadings should enable a claim to be heard on its merits.” *Calderon v. Kan. Dept. Soc. & Rehab. Servs.*, 181 F.3d 1180, 1186 (10th Cir. 1999).

“Refusing leave to amend is generally only justified upon a showing of undue delay, undue prejudice to the opposing party, bad faith or dilatory motive, failure to cure deficiencies by amendments previously allowed, or futility of amendment.” *Frank v. U.S. West, Inc.*, 3 F.3d 1357, 1365 (10th Cir. 1993) (citation omitted). “The proposed pleading is then analyzed using the same standard as a motion to dismiss under Fed.R.Civ.P. 12(b)(6).” *Causer v. Somers*, No. 18-1221-JWB-GEB, 2020 WL 6742790, at \*8 (D. Kan. Nov. 17, 2020).

“[T]o 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.’” *Williamson v. United Parcel Service, Inc.*, 2020 WL 1638063, at \*2 (D. Kan. April 2, 2020) (citation omitted). The complaint or amendment need only make a statement of the claim and provide some factual support. *Bell Atlantic v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 1965, 167 L.Ed.2d 929 (2007)). “It does not matter how likely or unlikely the party is to actually receive such relief, because for the purposes of dismissal all allegations are considered to be true.” *Williamson*, 2020 WL 1638063, at \*2 (citing *Twombly*, 550 U.S. at 556). In other words, applying this standard, “the court must accept as true all well-pleaded factual allegations and view them in the light most favorable to the pleading party.” *Carefusion 213, LLC v. Professional Disposables, Inc.*, No. 09-2626-KHV-DJW, 2010 WL 4004874, at \*5 (D. Kan. Oct. 12, 2010).

The proposed amendment should be found futile only if the court finds “the proposed claims do not contain enough facts to state a claim for relief that are plausible on their face or the claims otherwise fail as a matter of law.” *Id.* (citing *Raytheon Aircraft Co. v. U.S.*, 501 F. Supp. 2d 1323, 1327 (D. Kan. 2007).) The party opposing amendment has the burden of showing the proposed amendment is futile. *Williamson*, 2020 WL 1638063, at \*2 (citing *Layne Christensen Co. v. Bro-Tech Corp.*, No. 09-CV-2381-JWL-GLR, 2011 WL 3847076, at \*5 (D. Kan. Aug. 29, 2011)).

## **II. Rule 15 Factors.**

In opposition to Relator’s motion, Defendants argue that the proposed amendment is precluded by Rule 15 because of undue delay, dilatoriness, bad faith, and futility. (Doc. 116, 117.) The Court will address each of these factors.

### **A. Undue Delay, Dilatoriness, and Bad Faith.**

In determining whether a delay is undue, the Tenth Circuit focuses primarily on the reasons for the delay. Denial of leave to amend is appropriate “when the party filing the motion has no adequate explanation for the delay.”” *Minter v. Prime Equip. Co.*, 451 F.2d 1196, 1206 (10th Cir. 2006) (citations omitted)). An unexplained delay by itself can be adequate justification for the denial of a motion to amend. *Durham v. Xerox Corp.*, 18 F.3d 836, 840 (10th Cir. 1994).

In arguing unduly delay, Defendant Medtronic first relies on the obvious fact that this case was filed in 2017, more than five years ago. (Doc. 116, at 3.)

Medtronic contends that during these five years,

Relator has already filed four complaints. The first two complaints were filed under seal. (Docs. 1, 14). The United States undertook a two-year investigation and, when it declined to participate, Relator filed a third public complaint on nearly two years ago, amending to account for the investigation. (Doc. 26). For the past two years, the case procedure has been driven almost entirely by motion practice on Relator's third and fourth complaints. (Doc. 72). Far from a new case, Relator has been adjusting and shifting his claims for five years. This history shows that Relator is attempting to make the complaint 'a moving target,' *Viernow [v. Euripedes Dev. Corp.]*, 157 F.3d 785, 800 (10th Cir. 1998), and to present 'theories seriatim' to drag the litigation out, *Pallottino v. City of Rio Rancho*, 31 F.3d 1023, 1027 (10th Cir. 1994).

(*Id.*) Defendant Hospital makes a similar argument. (*See generally*, Doc. 117.) In the Court's purview, this argument is too simplistic in light of the complicated procedural history of this case.

As Relator argues in his reply,

the three years this case was under seal and the investigatory purview of the U.S. Department of Justice – three years Relator was not permitted to litigate or investigate. Second, the additional year consumed by Defendants' motions to dismiss – another year Relator was not permitted to conduct any discovery.



(Doc. 118, at 1.) As Relator points out, these delays were beyond his control. (*Id.*, at 1-2.) The District Court recently validated this argument in its Memorandum & Order on Defendants' prior motions to dismiss Relator's Second Amended Complaint, stating that "Relator's point is a good one." (Doc. 67, at 43.)

Explained another way, at the time Relator filed the present motion, the discovery phase was less than four months old. Discovery cannot commence until the parties conduct their Rule 26(f) planning conference. *See* Fed.R.Civ.P. 26(d)(1), (f). A deadline of December 23, 2021, for the planning conference was set by the Court. (Doc. 78.) The present motion to amend was filed on April 11, 2022, approximately three and a half months after discovery commenced. Further, this was within the deadline set by the Court for filing motions to amend. (*See* Doc. 111, text entry (stating that "[a]ny such motion shall be filed within 2 weeks of the District Court's ruling on the currently pending dispositive motion).) The Court rejects Defendants' argument that Relator unduly delayed making the proposed allegations because of the time passed since this case was filed.

Defendants also contend that Relator is unable to establish that the facts on which he bases the proposed amendment were previously unknown to him. (Doc. 116, at 3-4; Doc. 117, at 2-4.) Medtronic contends that Relator had "long-standing knowledge" of each of the newly proposed Defendants (Covidien and Wichita Radiological Group). (Doc. 116, at 4.)

As to allegations about additional Medtronic devices, Medtronic argues that it “has already produced comprehensive information on every at-issue device sold to the Dole VA from 2011 to 2018 and Hutchinson from 2011 to 2020, including contracts, invoices, sales data, consignment data, and trunk stock data, among other things.” (Doc. 116, at 5.) Medtronic contends that Relator has provided “no explanation for why claims associated with those devices were not asserted in the first four complaints.” (*Id.*) The Hospital argues that Relator has provided “no justification” for “wait[ing] so long to clarify what devices he *believes* were involved in the alleged illegal scheme.” (Doc. 117, at 4 (emphasis in original).)

Relator has established, however, that inclusion of the newly proposed Defendants is based on information it recently received in discovery. (Doc. 118, at 4-5.) Relator contends that while it have had a good faith belief as to allegations regarding the proposed Defendants, “only the VA contracts and monthly invoices,” which were recently received by Relator via discovery, established the potential claims to Relator’s satisfaction. (Doc. 118, at 5.)

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Relator has provided “no explanation for why claims associated with those devices were not asserted in the first four complaints.” (*Id.*)

Relator counters that Medtronic has failed to produce “‘comprehensive information’ on all PAD devices it sold to Hutchinson or Dole VA ... .” (Doc. 118, at 6.) According to Relator, “[i]t has been clear from the first complaint that this case deals with the sale of PAD devices by Medtronic to Dole VA and Hutchinson” and it is merely “ensuring that all of these PAD devices are covered in discovery.” (*Id.*)

The Court will not find that Relator’s course of action – to wait for certain discovery before moving to amend rather than rely on his mere beliefs – was dilatory or improper. As Relator argues, “[a]t best, Relator exercised sound discretion before joining a medical practice into a serious and complex legal case. At worst, Relator exercised ‘some’ delay in adding WRG as a defendant, but certainly not ‘undue’ delay.” (*Id.*, at 6.) The Court agrees.

The party requesting the amendment has not been unduly delayed in doing so “when knowledge of the facts behind the new claim is gained only after recent discovery and then confirmed after a reasonable investigation.” *Deghand v. Wal-Mart Stores, Inc.*, 904 F. Supp. 1218, 1221–22 (D. Kan. 1995) (citations omitted). Relator has established that situation herein. Relator’s attempts to glean and verify relevant information via discovery before moving to amend constitutes neither

undue delay, dilatory motive, nor bad faith. These objections of Defendants' are **overruled.**

**B. Futility.**

A court is justified in denying a motion to amend as futile if the proposed amendment could not withstand a motion to dismiss or otherwise fails to state a claim. *Ketchum v. Cruz*, 961 F.2d 916, 920 (10th Cir. 1992); *see* 6 Wright, Miller & Kane, FEDERAL PRACTICE AND PROCEDURE § 1487 at 642 (1990). “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face.’” *ConAgra Foods Food Ingredients Co., Inc. v. Archer-Daniels-Midland Co.*, No. 12-2171-EFM-KGS, 2014 WL 359566, at \*2 (D. Kan. Feb. 3, 2014) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citation omitted)). The burden is on Defendants to establish the futility of Relator’s proposed amendment. *Pekareck v. Sunbeam Products*, No. 06–1026–WEB, 2006 WL 1313382, at \*3 (D.Kan. May 12, 2006).

To be facially plausible, a claim must include sufficient factual matter “that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Suture Express, Inc. v. Cardinal Health 200, LLC*, 963 F. Supp. 2d 1212, 1218 (D. Kan. 2013) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937 (2009)). This requires “more than labels and conclusions, and a

formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.” *Id.* (citing *Bell Atlantic v. Twombly*, 550 U.S. 544, 555, 127 S.Ct. 1955, 1965, 167 L.Ed.2d 929 (2007)).

In determining the facial plausibility of an asserted claim, the Court need consider “conclusory allegations, unwarranted inferences, or legal conclusions.” *Hackford v. Babbitt*, 14 F.3d 1457 (10th Cir. 1994). As discussed above, however, “the court must accept as true all well-pleaded factual allegations and view them in the light most favorable to the pleading party.” *Carefusion 213, LLC v. Professional Disposables, Inc.*, No. 09-2626-KHV-DJW, 2010 WL 4004874, at \*5 (D. Kan. Oct. 12, 2010).

Defendant Medtronic initially argues that Relator has failed to identify “a single source” for its allegations regarding alleged kickbacks. (Doc. 116, at 8-9.) The Court reiterates, however, that for the purposes of futility analysis, however, it must accept all well-plead allegations as true. *Carefusion 213*, 2010 WL 4004874, at \*5. As such, Medtronic’s argument is irrelevant to the present motion.

Medtronic next argues that Relator has failed to allege facts supporting a claim under the Anti-Kickback Statute because he “has pled no facts about the use or sale of Medtronic coronary devices at either the Dole VA or Hutchinson” hospital. (Doc. 116, at 10.) Medtronic continues that Relator “has not added any

factual allegations about coronary procedures; coronary doctors and staff; the selection, purchase or use of coronary devices; nor how any alleged kickbacks induced the use of Medtronic devices,” but instead simply “added ‘and coronary’ to the descriptions of devices sold.” (*Id.*, at 11.) A similar argument is made by the Hospital. (*See* Doc. 117, at 5.)

Relator replies that the proposed amendment ties sales of coronary devices “to ongoing illegal remuneration (e.g., free lunches, free dinners, free devices, free marketing services) that occurred between Medtronic employees and employees at Dole VA and Hutchinson.” (Doc. 118, at 11.) In other words, Relator contends that the illegal remuneration alleged regarding sales of peripheral arterial disease treatment devices “applied equally to the same Medtronic employees selling the coronary devices as well.” (*Id.*) The Court finds Relator’s allegations to be sufficient in the context of futility analysis for a motion to amend.

Finally, Medtronic argues that Relator “has not pled viable claims based on lack of medical necessity and off-label promotion.” (Doc. 116, at 12.) In so doing, Medtronic refers to the Court to the arguments contained in its Motion to Dismiss (Docs, 76, 80), currently pending before the District Court. Medtronic’s arguments are summarized as Relator failing to plead sufficient facts to establish “1) there was at least one identifiable procedure at the Dole VA that was medically unnecessary; and 2) [Medtronic’s employees at issue in this lawsuit] caused this

medically unnecessary procedure to be performed.” (Doc. 116, at 12.) The undersigned Magistrate will defer any substantive decision on these arguments to the District Court as it decides the pending motion to dismiss.

That stated, the Court notes that in support of its position, Medtronic relies on a sworn declaration of its attorney in an attempt to discredit allegations Relator has included in the proposed amended pleading. (See Doc. 116, at 13-14, chart; Doc. 116-1.) The Court agrees with Relator that this is an “inappropriate exercise at this stage of the proceedings” (Doc. 118, at 11 (citation omitted)) because “the court must accept as true all well-pleaded factual allegations and view them in the light most favorable to the pleading party.” *Carefusion 213*, 2010 WL 4004874, at \*5. Medtronic’s tactic is more appropriate for a motion for summary judgment.

As such, for purposes of the present motion, the Court finds that Defendants have not established the futility of Relator’s proposed amendment. Relator’s Motion to Amend (Doc. 113) is, therefore, **GRANTED**.

### **CONCLUSION**

IT IS THEREFORE ORDERED that Relator’s Motion for Leave to File Fourth Amended Complaint (Doc. 113) is **GRANTED**. Relator shall file his Second Amended Complaint, as attached to his motion, **within 14 days of the date of this Order**.

**IT IS SO ORDERED.**

Dated at Wichita, Kansas, on this 25<sup>th</sup> day of May, 2022.

/s KENNETH G. GALE  
KENNETH G. GALE  
United States Magistrate Judge