IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

UNITED STATES OF AMERICA,
***ex rel.* THOMAS SCHROEDER,**

Plaintiff,

v.

MEDTRONIC, INC., and
HUTCHINSON REGIONAL MEDICAL CENTER,

Defendants.

Case No. 17-2060-DDC-KGG

MEMORANDUM AND ORDER

This Order rules two pending motions: (1) defendant Medtronic, Inc.'s Motion to Dismiss Second Amended Complaint (Doc. 45) and (2) defendant Hutchinson Regional Medical Center's Motion to Dismiss (Doc. 47). For reasons explained below, the court grants in part and denies in part Medtronic's Motion to Dismiss Second Amended Complaint. The court denies Hutchinson's Motion to Dismiss.

I. Background

A. Procedural History

Relator Thomas Schroeder initiated this *qui tam* action on behalf of the United States government in January 2017. *See* Doc. 1 (Compl.). While the government was weighing whether it would intervene in this lawsuit, *see* Docs. 3, 5, 7, 9, 12, 15, Mr. Schroeder amended his Complaint.[1] *See* Doc. 14 (Am. Compl.). After nearly two years and several extensions of time, the government filed a Notice—in April 2020—explaining that it would not intervene. *See*

[1] "A False Claims Act complaint is first served on the Government and remains under seal . . . while the Government decides whether to intervene and take over the action." *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 n.7 (5th Cir. 2009) (citing 31 U.S.C. § 3730(b)(2)).

Doc. 19 at 1. But as the court explained in an Order entered just a few days later, the government, "for good cause," still could intervene in this action "at any time[.]" Doc. 20 at 2.

In July 2020, relator amended his Complaint a second time. *See* Doc. 26 (Second Am. Compl.).[2] Later that year, Medtronic filed its Motion to Dismiss Second Amended Complaint (Doc. 45), along with a Memorandum in Support of Motion to Dismiss Second Amended Complaint (Doc. 46). Hutchinson then filed its own Motion to Dismiss (Doc. 47), plus a Memorandum in Support of Motion to Dismiss (Doc. 48). Relator filed Responses opposing both motions. *See* Docs. 55, 56. Medtronic filed a Reply Memorandum Supporting Motion to Dismiss (Doc. 61), and Hutchinson filed its own Reply Memorandum (Doc. 63). These motions to dismiss are fully briefed, and the court now can rule them both. But first, the court describes the federal statutes and factual allegations underlying this lawsuit. After that, the court overviews the governing legal standards. Then, the court analyzes the parties' competing arguments.

B. The False Claims Act

This lawsuit is a *qui tam* action arising under the False Claims Act (FCA). *See* 31 U.S.C. § 3729(a)(1) – (3). The peculiar sounding phrase referenced above "is an abbreviation for *qui tam pro domino rege quam pro se ipso in hac parte sequitur*," which means "'who as well for the king as for himself sues in this matter.'" *Grubbs*, 565 F.3d at 184 n.5 (quoting *Black's Law Dictionary* 1262 (7th ed. 1999)). In other words, *qui tam* suits are "brought by private persons *on behalf of the Government*" when permitted by statute. *Id.* at 184 (emphasis added); *see also State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 137 S. Ct. 436, 440 (2016) (describing *qui tam* actions as "[a]lmost unique to the FCA"). If the government declines to

[2] Relator's Second Amended Complaint (Doc. 26) is the operative Complaint in this lawsuit. For convenience, this Order will reference his Second Amended Complaint as "the Complaint."

intervene, as it did here, "the relator 'shall have the right to conduct the action.'"[3] *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 735 (10th Cir. 2018), *cert. dismissed*, 139 S. Ct. 2690 (2019) (quoting 31 U.S.C. § 3730(c)(3)). "Depending on the specific circumstances of the *qui tam* suit, the government and the relator divide any proceeds derived from the suit." *Id.* (citing 31 U.S.C. § 3730(d)). "This system is designed to benefit both the relator and the Government." *Rigsby*, 137 S. Ct. at 440; *see also id.* ("A relator who initiates a meritorious *qui tam* suit receives a percentage of the ultimate damages award, plus attorney's fees and costs." (citing 31 U.S.C. § 3730(d)).

As for the False Claims Act itself, that law dates back more than a century to the Civil War. *See Grubbs*, 565 F.3d at 184. The FCA is a remedial statute. *See id.* at 189 ("Put plainly, the statute is remedial[.]"); *see also United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 725 (10th Cir. 2006) (describing congressional intent behind the 1986 amendments to the FCA as "[e]mphasizing that the statute was remedial").[4] It first was passed in 1863 under President Lincoln's leadership. *See Grubbs*, 565 F.3d at 184. Originally, the FCA was "'aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War.'" *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016) (quoting *United States v. Bornstein*, 423 U.S. 303, 309 (1976)). Congress,

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[3] The government's decision not to intervene in an FCA lawsuit means one simple thing: the government declined to intervene. "As other courts have noted, the government 'may have a host of reasons for not pursuing a claim.'" *United States ex rel. El-Amin v. George Washington Univ.*, 533 F. Supp. 2d 12, 21 (D.D.C. 2008) (quoting *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006)). Thus, the court doesn't "'assume that in each instance in which the government declines intervention in an FCA case, it does so because it considers the evidence of wrong doing insufficient[.]'" *Id.* (quoting *Atkins*, 470 F.3d at 1360 n.17). The FCA's text "clearly anticipates that . . . the Government will not necessarily pursue all meritorious claims" because a contrary view would obviate the law's purpose in having a *qui tam* provision at all. *Id.* (internal quotation marks and citation omitted).

[4] *Sikkenga* was abrogated on other grounds by *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507 (2019).

aghast by the "'sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessitates of war[,]'" responded by passing the FCA. *Id.* (quoting *United States v. McNinch*, 356 U.S. 595, 599 (1958)).

"To aid the rooting out of fraud, the Act provides for civil suits brought by both the Attorney General and by private persons, termed relators, who serve as a 'posse of *ad hoc* deputies to uncover and prosecute frauds against the government.'" *Grubbs*, 565 F.3d at 184 (quoting *United States ex rel. Milam v. Univ. of Tex. M.D. Anderson Cancer Ctr.*, 961 F.2d 46, 49 (4th Cir. 1992)). "Congress has repeatedly amended the Act, but its focus remains on those who present or directly induce the submission of false or fraudulent claims." *Escobar*, 136 S. Ct. at 1996 (citation omitted). So, what exactly does the FCA proscribe?

"Today, the FCA generally prohibits private parties from 'knowingly' submitting 'a false or fraudulent claim' for reimbursement." *Polukoff*, 895 F.3d at 741 (quoting 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). "A 'claim' now includes direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs." *Escobar*, 136 S. Ct. at 1996 (citing 31 U.S.C. § 3729(b)(2)(A)). Given the law's focus on fraud, there's a scienter requirement. It "defines 'knowing' and 'knowingly' to mean that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.'" *Id.* (quoting 31 U.S.C. § 3729(b)(1)(A)).

The FCA's scienter requirement, however, "'require[s] no proof of specific intent to defraud[.]'" *Polukoff*, 895 F.3d at 734 (quoting 31 U.S.C. § 3729(b)(1)(B)).

FCA liability can lead to severe penalties. *See United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 795–96 (8th Cir. 2011) (explaining that the FCA "is not concerned with regulatory noncompliance" and instead "serves a more specific function, protecting the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money").[5] Under § 3729(a) of the Act, violation of the statue can mean a person is liable for civil penalties, plus treble damages—*i.e.*, "3 times the amount of damages which the Government sustains because of the act of that person." 31 U.S.C. § 3729(a)(1).

C. The Parties in this Action

The relator in this lawsuit is a Regional Sales Manager for a company who sells medical devices in Kansas and around the country. Doc. 26 at 3 (Compl. ¶ 2). Medtronic also sells medical devices, including some in the same regions where relator's company operates. *See, e.g.*, *id.* at 21 (Compl. ¶ 65) (alleging that relator's company lost out on sales to one hospital because the facility opted to purchase medical devices from Medtronic). In other words, relator's company and Medtronic are competitors in the medical device sales industry. *See, e.g.*, *id.* at 29 (Compl. ¶ 91) (recounting a conversation with a hospital administration official about how relator's company could "compete like Medtronic" by providing "free devices"). Hutchinson Regional Medical Center is a nonprofit hospital located in Kansas. *Id.* at 4 (Compl. ¶ 6). Relator's company and Medtronic both market their services to Hutchinson. *See, e.g.*, *id.* at 30 (Compl. ¶ 93) (describing a conversation between relator's colleague and a Hutchinson

[5] Unrelated to the premise quoted above, *Vigil*'s holding was superseded by statute, as explained in *United States ex rel. Hendrickson v. Bank of America, N.A.*, 343 F. Supp. 3d 610, 620 (N.D. Tex. 2018).

employee discussing Hutchinson's request for a sales proposal, which also was requested from Medtronic).

The Complaint tells a complicated story involving a host of characters. To lend some order to this complicated story, the following three subsections identify some of these key individuals.

1. Medtronic Employees Mentioned in the Complaint

The Complaint references two key Medtronic figures. Doug Winger is "a Sales Representative and Field Trainer" for Medtronic. *Id.* at 12 (Compl. ¶ 34). According to the Complaint, Winger played a central role in the schemes at Dole VA and Hutchinson. *See, e.g.*, *id.* ("Upon information and belief, Winger continuously ran the schemes detailed herein[.]"). The Complaint also mentions a Medtronic employee named Kerri Montgomery Kirk—"Medtronic's Clinical Specialist[.]" *Id.* at 17 (Compl. ¶ 53). Kirk allegedly assisted Winger with the schemes at Dole VA and Hutchinson. *See id.*; *see also id.* at 29 (Compl. ¶ 88).

2. Relevant Individuals at Dole VA

The Complaint's allegations about Medtronic and Dole VA center on the hospital's catherization ("cath") lab. There, "Teri Brinkley worked as the Radiology Technologist and Lab Manager" and "was responsible for ordering, or recommending for ordering, medical devices for the Dole VA cath lab[.]" *Id.* at 17 (Compl. ¶ 52). The Complaint also references Diane Keene, who was Chief of Logistics for Dole VA. *Id.* at 20 (Compl. ¶ 62). The Complaint describes conversations between relator and a Contracting Specialist involved with device orders at Dole VA, Paul Dixon. *Id.* at 20, 21 (Compl. ¶¶ 61, 65). Last, the Complaint discusses a Wichita-based radiology practice, which "had the exclusive contract to provide" treatment for peripheral

artery disease ("PAD"). *Id.* at 32 (Compl. ¶ 100); *see also id.* at 12 (Compl. ¶ 35) (explaining the term PAD).

3. Relevant Individuals at Hutchinson

At Hutchinson Regional Medical Center, the Complaint references Mark Wilson—the hospital's Director of Supply Chain. *Id.* at 27 (Compl. ¶ 82). "Wilson had purchasing responsibility over Medtronic" devices used in the hospital's cardiac procedures. *Id.* at 28 (Compl. ¶ 83). Also, the Complaint alleges that Hutchinson's "Cath Lab Director/Cath Lab Supply Chain Manager Cindy Henning King" benefitted from the alleged kickback scheme. *Id.* (Compl. ¶ 86).

D. Relator's Allegations Under the FCA and Anti-Kickback Statute

Relator's factual allegations begin with a broad sweep, describing the relationship between two federal statutes. Then, the Complaint's allegations narrow their focus, concentrating on Medtronic and Hutchinson. Before turning to the Complaint's allegations against the defendants, the court first reviews its broader assertions. Because the court is reviewing these details on a motion to dismiss, the court accepts as true the Complaint's well-pleaded factual allegations. *See United States ex rel. Ernst v. HCA Healthcare, Inc.*, No. 19-2085-JWL, 2020 WL 6868775, at *1 (D. Kan. Nov. 23, 2020) (Lungstrum, J.) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)) (describing the governing legal standard for a motion to dismiss a *qui tam* action brought under the False Claims Act). But, the court isn't "'bound to accept as true a legal conclusion couched as a factual allegation.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555).

The Complaint focuses on unlawful "kickback schemes" orchestrated by Medtronic at multiple hospitals. *See* Doc. 26 at 3 (Compl. ¶ 1). According to the Complaint, Medtronic

"bribed hospital staff to purchase its devices over competitors and to purchase grossly excessive inventory" so that Medtronic could "increase the sales of its medical devices and create a near monopoly of its product at hospitals[.]" *Id.* One of the hospitals who allegedly enrolled in the scheme is the other defendant in this action, Hutchinson Regional Medical Center. *Id.* ("One such hospital, Defendant Hutchinson Regional Medical Center, readily solicited and accepted such bribes from Medtronic, Inc.").

The schemes trigger liability under the FCA, relator alleges, because the result of this conduct was an inevitable and unlawful act: "Defendants knowingly submitted, caused to be submitted, and/or conspired to be submitted false claims" to the United States government through various departments and benefits programs. *Id.* But the allegations reach their FCA conclusion by looking first to a different federal law, the so-called federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b). *See* Doc. 26 at 5 (Compl. ¶ 10). Relevant here, the AKS prohibits anyone from "offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to induce such person" to "purchase, . . . order, . . . or recommend purchasing, . . . or ordering any good. . . or item for which payment may be made in whole or in part under a Federal health care program[.]" 42 U.S.C. § 1320a-7b(b)(2). In other words, and as described in the Complaint:

> The AKS makes it illegal for individuals or entities to "offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal Healthcare program."

Doc. 26 at 5 (Compl. ¶ 11) (quoting 42 U.S.C. § 1320a-7b(b)(2)). "Violation of the AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation

in Government Healthcare Plans." *Id.* at 6 (Compl. ¶ 11) (citing 42 U.S.C. § 1320a-7b(b)(2) and 42 U.S.C. § 1320a-7(b)(7)).

What does the AKS have to do with the FCA? Under the AKS, "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31." 42 U.S.C. § 1320a-7b(g). That's a roundabout way of stating that violating the AKS can produce FCA liability. *See id.*; *see also Guilfoile v. Shields*, 913 F.3d 178, 189 (1st Cir. 2019) (explaining that "the AKS was amended to create an express link to the FCA[,]" and that "'a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA].'" (quoting 42 U.S.C. § 1320a-7b(g), as amended by the Patient Protection and Affordable Care Act, Pub. L. No. 1110148, 124 Stat. 119 (2010))). To bring things full circle, relator's allegations—generally speaking—look first to the AKS for an alleged violation, which in turn triggers FCA liability.

1. Relator's Allegations Involving Dole VA

Relator's Complaint alleges four different ways Medtronic, in concert with Dole VA, violated the FCA. *First*, he alleges an unlawful kickback scheme under the AKS which triggers FCA liability. *Second*, relator alleges a related scheme involving the purchase of excessive medical devices and their unnecessary use in medical procedures at Dole VA. *Third*, the Complaint alleges FCA liability for off-label marketing of medical devices at Dole VA by Medtronic. *Last*, relator alleges that these claims reveal the existence of a civil conspiracy. The following four subsections review these allegations in more detail.

a. Remunerations Advancing the Alleged Kickback Scheme

Relator devotes most of the Complaint's pages to Medtronic's alleged kickback scheme with Dole VA.[6] Beginning "at least as early as 2007 and continuing to when the Dole VA catheterization lab was shut down in 2018," Medtronic was "providing remuneration to the Radiology Technologist and Lab Manager" at Dole VA, Teri Brinkley, and her staff. *Id.* at 14 (Compl. ¶ 40). "These kickback schemes have been, and continue to be, integral to Medtronic's overall marketing strategy to sell medical devices at the Dole VA," Hutchinson, and other medical facilities nationwide. *Id.* (Compl. ¶ 41).

Although Dole VA has been "one of the nation's smallest vascular surgery providers[,]" the hospital has qualified as a top selling client for Doug Winger, Medtronic's Sales Representative and Field Trainer. *Id.* at 16–17 (Compl. ¶ 51); *see also id.* at 12 (Compl. ¶ 34) ("Medtronic employs a Sales Representative and Field Trainer named Doug Winger[.]"). The Complaint alleges that vascular device sales between Medtronic's Winger and Dole VA "often exceed[ed] $2–3 million dollars in annual revenue for Medtronic[.]" *Id.* at 17 (Compl. ¶ 51). And relator contends these multi-million dollar revenues for Medtronic relate to "remuneration paid to Dole VA employees[,]" which "led to claims submitted to, and paid by, the U.S. VA for well over $10 million dollars[.]" *Id.*

As for those remunerations, the Complaint alleges that a Dole VA employee, Teri Brinkley, placed device orders for the Dole VA. *Id.* (Compl. ¶ 52). And Brinkley—through either Medtronic's Winger or Kirk—was receiving remunerations "to induce Brinkley to purchase, or recommend purchases, of millions of dollars of Defendant Medtronic's PAD

[6] Relator isn't suing Dole VA, but he alleges that this hospital's relationship with Medtronic is relevant to the AKS and FCA. That's because, according to the Complaint, Dole VA provides medical services "to active and retired military members," meaning that "all devices used in [the relevant medical procedures] at Dole VA are paid for by" the Department of Veterans Affairs. *Id.* at 16 (Compl. ¶ 50).

devices by the U.S. VA." *Id.* (Compl. ¶ 53). "The remuneration took the form of weekly/daily lunches for Brinkley and other cath lab employees, ipads, iphones, NASCAR as well as other entertainment event tickets to Brinkley and her staff, weekend parties, as well as frequent nights at bars and restaurants." *Id.*

And, according to relator, there's an unlawful link between these gifts and "Defendant Medtronic [becoming] the near exclusive provider of PAD medical devices to Dole VA's cath lab[.]" *Id.* at 18 (Compl. ¶ 56). For one thing, "Brinkley would exclude access to the cath lab and its physicians for PAD device salespersons other than [Medtronic's] Winger." *Id.* And, "Brinkley would also exclusively purchase or recommend for purchase all Medtronic devices outright, while all other vendors had to provide their devices on consignment." *Id.* Here's the illegal link, says relator: "Due to Defendant Medtronic's kickback scheme, and in exchange for said remuneration paid to Dole VA," the hospital "over-purchased a tremendous amount of unnecessary" medical devices relative to the actual size of Dole VA's cath lab and the frequency of procedures performed there. *Id.* (Compl. ¶ 57).

The Complaint describes data supporting its allegations. During the time at issue, "Dole VA operated just one cath lab with one procedure room and one physician providing services." *Id.* (Compl. ¶ 58). Most of the time, those procedures occurred two or three days each week and typically concluded by mid-afternoon. *Id.* Between 2017 and 2018, Dole VA "purchased approximately 475 atherectomy devices and 775 [drug-coated balloons] from Defendant Medtronic." *Id.* at 19 (Compl. ¶ 60) (emphasis omitted). That's almost twice the number of atherectomy devices and more than three times the number of drug-coated balloons purchased by larger facilities during the same period. *Id.* "Again, Dole VA is one of the nation's smallest vascular surgery providers[.]" *Id.* For instance, the Cleveland Clinic houses 10 rooms dedicated

to the same procedures while the Dole VA has just one room. *Id.* at 20 (Compl. ¶ 60). And yet, compared against Dole VA during the same time, the Cleveland Clinic purchased 84 fewer atherectomy devices and 632 fewer drug-coated balloons. *See id.* at 19 (showing a table reflecting total device sales of these products by Dole VA, Cleveland Clinic, and 14 other large medical facilities in the United States); *see also id.* at 20 (Compl. ¶ 60) (discussing size of Cleveland Clinic's vascular procedure operations and frequency of those procedures).

Relator also alleges that Medtronic sold Dole VA excessive amounts of medical devices even though his employer offered the same or similar products for a better price. *See id.* at 20–22 (Compl. ¶¶ 61–68). One issue tied to these purchases is the products' expiration dates: "Grossly excessive unused Medtronic inventory at Dole VA is tremendously wasteful due to product expiration dates." *Id.* at 22 (Compl. ¶ 70); *see also id.* ("This product cannot sit indefinitely and must be disposed of when it expires."). The Complaint attaches several photos purporting to show stocked shelves at Dole VA containing Medtronic devices that would expire much sooner than hospital staff could use them.[7] *See id.* at 22–24 (Compl. ¶¶ 70–71). "In November 2016, Dole VA had purchased so many Medtronic [devices] that its cath lab did not have enough space in its storage room, and spillover inventory had to be stored in the operating room."[8] *Id.* at 24 (Compl. ¶ 71). In sum, Dole VA purchased about 240 additional devices from Medtronic in January 2017 despite its inventory already including about 130 of the same Medtronic devices. *Id.* at 25 (Compl. ¶ 72). These figures, relator alleges, "dwarf the average

[7] The quality of relator's attached photographs makes it difficult to decipher their key details. But the court can make out enough from these photographs to understand the key premise. And regardless, the Complaint's allegations and photographs, accepted here as true, allege that the Dole VA possessed a large number of these medical devices.

[8] Here again, the Complaint attaches a photograph of what appears to be a filing cabinet containing medical devices. The photograph's quality, however, isn't so refined that the court can identify the shelf's exact contents. But also here again, the photograph provides enough for the court to discern the point of relator's allegations.

annual usage of 120 [drug-coated balloons] per year by much larger providers." *Id.* (citation omitted).

The Complaint alleges other anecdotal examples, but their ultimate premise is the same: Medtronic's "kickback scheme" involving Dole VA resulted in excessive device purchases which, in turn, caused Dole VA to throw out "vast amounts of these devices due to expiration." *Id.* (Compl. ¶ 75). The Complaint notes, as one other example, that "in 2017 or early 2018," Dole VA employees stuffed trash bags full of expired Medtronic devices worth more than $700,000. *Id.* at 25–26 (Compl. ¶ 75).

b. Excessive Supplies and Unnecessary Procedures at Dole VA

Beyond the alleged kickback scheme, the Complaint also states that Medtronic had a hand—through the Dole VA—in marketing, instructing, or encouraging the overuse of Medtronic devices during certain medical procedures. *See id.* at 32 (Compl. ¶ 99). According to relator, a Wichita-based radiology group "had the exclusive contract to provide" certain procedures at Dole VA. *Id.* (Compl. ¶ 100). And, relator alleges, the group's compensation agreement with the federal government and Dole VA provided for payment "based upon time spent performing" these various procedures. *Id.* In other words, the radiology group would earn higher payments when using more Medtronic devices because—with each added device—the procedure's length would grow. *Id.* ("In turn, [the Wichita radiology group] would earn more income by the utilization of excessive medically unnecessary PAD devices under its agreement with Dole VA and the U.S. VA."). Likewise, more Medtronic devices used for each procedure would mean "Medtronic would earn more in said procedures because more of its devices were being utilized than necessary." *Id.*

Relator's allegations about excessive Medtronic devices and unnecessary procedures go something like this: "It is well established within the medical community that a *single* atherectomy device such as Medtronic's are typically used in only 17%" of the relevant procedures. *Id.* at 33 (Compl. ¶ 102) (citation omitted). But at Dole VA, the Wichita radiology group allegedly used three or four of these Medtronic devices per procedure. *Id.* (Compl. ¶ 103). And, the operating physicians "had an unofficial policy of treating both lower limbs" during these procedures, even though this approach "is rare in such procedures and limited to clinical issues for a specific patient[.]" *Id.* (Compl. ¶ 104). This latter strategy, according to the Complaint, "far exceeds the accepted standards of medical practice in treating" the relevant condition, "and is an unreasonable and unnecessary medical procedure." *Id.* (Compl. ¶ 105). Relator makes a similar allegation about these physicians using Medtronic's drug-coated balloons—allegedly exceeding what's typical and appropriate. *Id.* at 34 (Comp. ¶ 107); *see also id.* (Compl. ¶ 108) ("The routine utilization of more than four [drug-coated balloons] per patient procedure far exceeds the accepted standards of medical practice in treating [the relevant condition] and is an unreasonable and unnecessary medical procedure."). To tie all of this together, relator alleges that Medtronic bears some blame here because its "marketing and training, including its scheme of offering or paying remuneration . . . led to Dole VA and [the Wichita radiology group operating at Dole VA] utilizing excessive and medically unnecessary PAD devices paid for by the U.S. VA." *Id.* (Compl. ¶ 109).

c. Off-Label Marketing at Dole VA

That's not all. The Complaint alleges so-called "off label" marketing of Medtronic devices at Dole VA in a way that violates the FCA. Off-label use of a medical device means that the device is used for a purpose "outside their usage as approved by the FDA." *Id.* at 35 (Compl.

¶ 110). And relator alleges that Medtronic "claimed, caused a claim to be made, or conspired to have a fraudulent claim be made" through Dole VA and the Wichita radiology group operating there. *Id.* (alleging that "Medtronic marketed, trained, encouraged, and/or coerced" Dole VA and the Wichita group to use "medical devices outside their usage as approved by the FDA"). "In turn, these claims for reimbursement were made to the U.S. VA regarding the devices themselves as well as the time taken" by the Wichita group "to implement said devices." *Id.*

These allegations involve two of Medtronic's medical devices: peripheral drug-coated balloons and a peripheral stent. *See id.* at 35–37 (Compl. ¶¶ 111–16). For the drug-coated balloons, the Complaint briefly outlines the FDA-approved usage. *See id.* at 35 (Compl. ¶ 112); *see also id.* (Compl. ¶ 111) (quoting Medtronic's own published information about the device's usages). Contrary to all of this information, relator alleges that Medtronic somehow induced physicians at Dole VA to use the drug-coated balloons "in cardiac procedures," even though the device is approved only for use in "peripheral treatment." *Id.* (Compl. ¶ 113). The runup to the Complaint's allegations about peripheral stents is similar, recounting what Medtronic has said about appropriate use for the device and what the FDA has approved. *See id.* at 36–37 (Compl. ¶¶ 115–16). The point is that the stents are approved for use only in procedures *above* the knee, but Medtronic "knowingly marketed this device to be used 'off-label' by promoting its usage in arteries at or below the knee for use in all patients being treated." *Id.* at 36 (Compl. ¶ 116). According to the Complaint, Medtronic helped see to it that Dole VA submitted fraudulent claims for reimbursement because, otherwise, the government would owe no such payment back to hospitals for using the devices outside their limited FDA approvals. *See, e.g.*, *id.* at 39–40 (Compl. ¶ 127).

d. Civil Conspiracy at Dole VA

Last, relator's Complaint alleges that these allegations also reveal the existence of a civil conspiracy under the FCA. Specifically, and "[a]s set forth . . . in [other] paragraphs" of the Complaint, "Relator alleges that Defendant Medtronic and Teri Brinkley, [the Wichita radiology group,] and other unnamed co-conspirators entered into an agreement and plan to conspire to violate the FCA[.]" *Id.* at 41 (Compl. ¶ 134). Relator alleges the conspiracy was accomplished through "Medtronic's company policies and practices, which were devised, perpetuated and implemented by" Medtronic, Brinkley, and "other unnamed co-conspirator providers[.]" *Id.* at 42 (Compl. ¶ 134).

2. Relator's Allegations Involving Hutchinson Regional Medical Center

Relator alleges generally fewer claims against Hutchinson. But the Hutchinson claims are similar. *First*, relator alleges an unlawful scheme involving remunerations and kickbacks. *Second*, relator alleges that these kickback allegations evidence a civil conspiracy under the FCA. The next two subsections review his Hutchinson allegations in more detail.

a. Remunerations and Unlawful Kickbacks at Hutchinson

Relator's kickback allegations against Hutchinson follow a similar path as his allegations involving Medtronic's relationship with Dole VA. In short form, it all circles back to alleged remunerations given by Medtronic to Hutchinson staff in exchange for their purchasing Medtronic devices exclusively. *See id.* at 27 (Compl. ¶ 80). According to the Complaint, "Hutchinson draws Medicare patients from a broad geographical area" despite its location in "a rural part of Kansas" because Hutchinson "is the known facility in the region for patients with the most advanced peripheral vascular disease[.]" *Id.* (Compl. ¶ 81). Nearly all of those patients are "covered by Medicare and, to some extent, Medicaid." *Id.*

The key contact at Hutchison, relator alleges, was Mark Wilson—the hospital's Director of Supply Chain. *Id.* (Compl. ¶ 82). "Wilson affected the entire supply chain at the hospital." *Id.* And, "[h]is duties required him to negotiate and purchase hospital supplies, pharmaceuticals and devices including PAD devices" relevant to this case. *Id.*; *see also id.* at 28 (Compl. ¶ 83) (alleging that Wilson's duties including having "purchasing responsibility over" Medtronic's cardiac and other devices relevant to this lawsuit). Just as with the Dole VA, Medtronic's Winger followed a similar "playbook" with Hutchinson's staff. *Id.* (Compl. ¶ 86). Wilson gave them "remuneration such as meals, food, alcohol, gratuities, event sponsorships, NASCAR and other sporting event tickets, golf outings and travel expenses[.]" *Id.* Relator alleges these remunerations went to Wilson, King (Hutchinson's Cath Lab Director/Cath Lab Supply Chain Manager), and other unnamed "Hutchinson cath lab employees." *Id.*

But distinct from the allegations involving Dole VA, relator also alleges that the kickback scheme at Hutchinson "included 'marketing services' for physicians performing PAD procedures[.]" *Id.* (Compl. ¶ 87). For instance, "Winger would host events for referring physicians whereby Winger would promote physicians at Hutchinson such as Dr. Michael Hagley and encourage said referring physicians to send patients to Dr. Hagley at Hutchinson." *Id.* Winger also would "assist Hutchinson physicians" with "the advertising and promotion of their practices." *Id.*

Back to the familiar "playbook," Winger allegedly would offer Hutchinson free Medtronic devices in exchange for Hutchinson purchasing Medtronic's products. *Id.* at 29 (Compl. ¶ 89). This tactic, relator says, "had the effect of creating an illegal 'rebate' under the AKS[,]" in addition to "Medtronic's scheme . . . [of] paying illegal remuneration in exchange for purchases[.]" *Id.* Here, relator claims some direct knowledge because Wilson allegedly solicited

similar deals from relator, telling him "if they wanted to compete, they needed to do the same [as Medtronic]." *Id.* (Compl. ¶ 90). According to relator, Wilson told him that none of his negotiations with Medtronic were ever "'in writing'" because "'Doug [Winger] just has creative ways of getting the devices he needs from other folks in his company.'" *Id.* (Compl. ¶ 91); *see also id.* ("'Nothing is in writing; he just knows how to maneuver the units around.'"). Relator's company wasn't alone, according to the Complaint. "In addition to Relator and Medtronic, Wilson requested bribes from other device providers as well." *Id.* at 30 (Compl. ¶ 94).

Relator alleges that these free device deals could make sense only if something nefarious was afoot because the devices offered by Medtronic are simply too valuable to justify a no-profit exchange. *See id.* (Compl. ¶ 92) (alleging that "[t]en free units" of one such device is worth about $25,000."). But most of all, relator alleges that "Hutchinson would bill Government Healthcare Plans for these 'free' devices from Winger, allowing Hutchinson to capitalize again on the kickback." *Id.* The Complaint contends that Hutchinson's Wilson solicited similar deals from relator's colleague, and that Hutchinson ultimately awarded one particular deal to Medtronic based on "'free' inventory as part of the purchase." *Id.* (Compl. ¶ 93).

"The costs saved at Hutchinson by accepting these bribes is significant and generates a much larger margin on its procedures." *Id.* at 31 (Compl. ¶ 95). The Complaint alleges that "[s]ince 2012 . . . Hutchinson billed just Medicare alone for tens of millions of dollars for reimbursement for the Medtronic devices used and sold as part of the Medtronic kickback scheme with Hutchinson and Wilson." *Id.* (Compl. ¶ 96). In other words, Hutchinson profited off of government payouts because Medtronic provided the devices linked to reimbursement for free. *See id.* at 27 (Compl. ¶ 80).

b. Civil Conspiracy at Hutchinson

As with Medtronic and Dole VA, relator alleges that Medtronic's arrangement with Hutchinson also demonstrates a civil conspiracy under the FCA. As he sees things, the Complaint "alleges that Defendants Medtronic and Hutchinson entered into an agreement and plan to conspire and violate the FCA[.]" *Id.* at 41 (Compl. ¶ 133). This conspiracy allegedly was born of "an illegal kickback scheme whereby Medtronic's . . . Doug Winger would provide remuneration[.]" *Id.* at 42 (Compl. ¶ 135). This remuneration included "free or marketing material or leverage devices to Hutchinson's . . . Mark Wilson to net down the cost of Medtronic's bulk device proposals to Hutchinson." *Id.* (internal quotation marks omitted). In exchange, "Hutchinson would benefit again from the kickbacks, as it would bill Government Healthcare Plans for the free marketing material or leverage devices it received free of charge from Medtronic[.]" *Id.* (internal quotation marks omitted). Essential to the FCA, relator alleges that this conspiracy "caused the submission of false and fraudulent claims to Government Healthcare Plans[.]" *Id.* (Compl. ¶ 137).

II. Legal Standards

Medtronic has moved for dismissal under Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure. *See* Doc. 45 at 1. In contrast, Hutchinson argues that dismissal is merited based on these same Rules, plus Fed. R. Civ. P. 8. *See* Doc. 47 at 1. Below, the court reviews briefly what each of these Rules demands.

A. Fed. R. Civ. P. 8

The court starts with Rule 8 because it's the easiest to explain. Rule 8 prescribes "general rules of pleading[,]" and it doesn't ask for much. Fed. R. Civ. P. 8. Section (a)(2) provides that a complaint must contain "a short and plain statement of the claim showing that the

pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). Although this Rule "does not require 'detailed factual allegations,'" it calls for more than "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of the cause of action'" which, as the Supreme Court explained, "'will not do.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

B. Fed. R. Civ. P. 12(b)(6)

When a defendant makes a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the court must assume that the Complaint's factual allegations are true. *Id.* (citing *Twombly*, 550 U.S. at 555). But the court isn't "'bound to accept as true a legal conclusion couched as a factual allegation.'" *Id.* (quoting *Twombly*, 550 U.S. at 555). "'Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice'" to state a claim for relief. *Bixler v. Foster*, 596 F.3d 751, 756 (10th Cir. 2010) (quoting *Iqbal*, 556 U.S. at 678). Also, the Complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555 (citations omitted).

For relator's Complaint to survive these motions to dismiss under Rule 12(b)(6), his pleading "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the [relator] pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556); *see also Christy Sports, LLC v. Deer Valley Resort Co.*, 555 F.3d 1188, 1192 (10th Cir. 2009) ("The question is whether, if the allegations are true, it is plausible

and not merely possible that the [relator] is entitled to relief under the relevant law." (citation omitted)). The Supreme Court explains the relationship between Rule 8 and Rule 12 this way: "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555).

C. Fed. R. Civ. P. 9(b)

A mine run motion to dismiss under Rule 12 always involves Rule 8 because the dispositive motion's foundational premise is that the pleading party hasn't said enough to establish a claim for relief. But things get trickier in cases involving fraud allegations, like this one. Rule 9 of the Federal Rules of Civil Procedure explains what's required for "pleading special matters" like fraud. Fed. R. Civ. P. 9. For fraud allegations, "a party must state with *particularity* the circumstances constituting the fraud[.]" Fed. R. Civ. P. 9(b) (emphasis added). In other words, Rule 9(b) demands a "heightened pleading standard[.]" *Welch v. Centex Home Equity, Co., L.L.C.*, 323 F. Supp. 2d 1087, 1094 (D. Kan. 2004) (Lungstrum, J.) (citations omitted).

One must read the particularity requirement contained in Rule 9(b) "in conjunction with the principles of Rule 8, which calls for pleadings to be 'simple, concise, and direct[.]'" *Schwartz v. Celestial Seasonings, Inc.*, 124 F.3d 1246, 1252 (10th Cir. 1997) (quoting Fed. R. Civ. P. 8). In other words, "Rule 9(b) joins with 8(a) to form the general pleading requirements for claims under the FCA." *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1171 (10th Cir. 2010) (citations omitted). Our Circuit has explained that "Rule 9(b) supplements 8(a) in setting forth the pleading requirements under the FCA." *Id.* And the Supreme Court's seminal rulings in *Twombly* and *Iqbal* didn't alter Rule 9's primary focus on

"'afford[ing] defendant fair notice of plaintiff's claims and the factual ground upon which [they] are based[.]'" *Id.* at 1172 (quoting *Lawrence Nat'l Bank v. Edmonds*, 924 F.2d 176, 180 (10th Cir. 1991)). On that note, "claims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." *Id.* (first citing *United States ex rel. Duxbury v. Ortho Biotech Prods.*, 579 F.3d 12, 29 (1st Cir. 2009); then citing *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854–55 (7th Cir. 2009); and then citing *Grubbs*, 565 F.3d at 190).[9]

III. Analysis

Before assessing the parties' competing views, the court first reviews briefly what's required for FCA claims to survive a motion to dismiss. According to our Circuit, and in light of Rule 9(b)'s particularity requirement, "'claims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme.'" *Polukoff*, 895 F.3d at 745 (quoting *Lemmon*, 614 F.3d

[9] Our Circuit considered *Sikkenga* before it decided *Lemmon*. In *Sikkenga*, the court agreed with the Eleventh Circuit: Rule 9(b)'s particularity requirement demands that a relator plead, with particularity, both the fraud alleged *and* actual claims—based on that fraud—submitted to the government. *Sikkenga*, 472 F.3d at 727–28 (citing *United States ex rel. Clausen v. Lab'y Corp of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002)). "It appears, however, that the Tenth Circuit may have retreated somewhat from its strict requirement in *Sikkenga*[.]" *Ernst*, 2020 WL 6868775, at *5 (first citing *Lemmon*, 614 F.3d at 1172; then citing *Polukoff*, 895 F.3d at 745). "District courts have noted that the Tenth Circuit has thus seemed to revise its strict standard from *Sikkenga*." *Id.* (first citing *United States ex rel. Allison v. Sw. Orthopedic Specialists, PLLC*, No. CIV-16-0569-F, 2020 WL 5984814, at *6 n.4 (W.D. Okla. Oct. 8, 2020) (collecting cases); then citing *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 838 F.3d 750, 772–73 (6th Cir. 2016) (agreeing with the Tenth Circuit and all others who previously applied an especially strict pleading standard under Rule 9(b) but since have "retreated from such a requirement in cases in which other detailed factual allegations support a strong inference that claims were submitted")).

So, the Tenth Circuit's more recent opinion in *Lemmon* guides the analysis of FCA claims in light of Rule 9(b)'s particularity requirement. *See Lemmon*, 614 F.3d at 1172 ("[C]laims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." (citation omitted)); *see also Polukoff*, 895 F.3d at 745 (explaining "the principle that 'Rule 9(b) does not require omniscience; rather the Rule requires that the circumstances of the fraud be pled with enough specificity to put defendants on notice as to the nature of the claim'" (quoting *Williams v. Duke Energy Int'l, Inc.*, 681 F.3d 788, 803 (6th Cir. 2012)).

at 1172). In other words, "FCA claims comply with Rule 9(b) when they 'provid[e] factual allegations regarding the who, what, when, where and how of the alleged claims.'" *Id.* (quoting *Lemmon*, 614 F.3d at 1172).

These showings needn't appear all in one place so long as they appear in the aggregate. *See Lemmon*, 614 F.3d at 1173 ("Nor must every allegation, taken in isolation, contain all the necessary information."); *see also id.* ("Rather, to avoid dismissal under Rules 9(b) and 8(a), plaintiffs need only show that, taken as a whole, a complaint entitles them to relief." (citation omitted)). Also, and central to this case's analysis, our Circuit has noted an important caveat: "'in determining whether a plaintiff has satisfied Rule 9(b), courts may consider whether any pleading deficiencies resulted from the plaintiff's inability to obtain information in the defendant's exclusive control.'" *Polukoff*, 895 F.3d at 745 (quoting *George v. Urb. Settlement Servs.*, 833 F.3d 1242, 1255 (10th Cir. 2016)). And to bring things full circle, this rationale permeates from the overarching premise that "'Rule 9(b) does not require omniscience; rather the Rule requires that the circumstances of the fraud be pled with enough specificity to put defendants on notice'" about the claim's "'nature.'" *Id.* (quoting *Williams*, 681 F.3d at 803).

Medtronic and Hutchinson's respective motions to dismiss each deserve individual consideration. But still, the issues here often overlap, and at times, the court reaches conclusions about one of the two motions that applies equally to the other. In those instances, the court chooses not to belabor the same point. But for the sake of due care and consideration, the court addresses these two motions individually. Medtronic was first to file its Motion to Dismiss Second Amended Complaint (Doc. 45), so the court starts there. After that, the court reviews Hutchinson's Motion to Dismiss (Doc. 47). And for reasons explained below, the court grants in part and denies in part Medtronic's Motion to Dismiss Second Amended Complaint (Doc. 45).

Separately, the court denies Hutchinson's Motion to Dismiss (Doc. 47) in its entirety. The court now explains the reasons for these holdings.

A. Medtronic's Motion to Dismiss Second Amended Complaint (Doc. 45)

Medtronic attacks the Complaint from every angle. It argues that relator either has failed to state some claims altogether under Rule 12, or, alternatively that he has failed to adduce particularized details like Rule 9(b) requires. Of relator's four claims against Medtronic, the court agrees with relator on half of them—and denies the motion to dismiss against those claims. But on the other two claims, the court agrees with Medtronic—and thus grants the motion to dismiss targeting those claims. As the court will explain, relator isn't out of the game on his deficient claims just yet. Relator asked for, and the court will grant, leave to amend these claims. The court discusses these issues in more detail, below.

1. Relator's Illegal Kickback Allegations Survive Medtronic's Motion to Dismiss

a. Medtronic Hasn't Shown That a Statutory Safe Harbor Applies

First, Medtronic has argued that relator's kickback allegations are doomed because of a statutory safe harbor provided by the AKS. *See* Doc. 46 at 11; *see also* Doc. 61 at 10 n.1. But the court agrees with relator on this claim. *See* Doc. 55 at 28–32 (arguing that "the AKS 'safe harbor' provision is an affirmative defense[,]" and as such "dismissal of a complaint based on these grounds under Rules 8 or 9(b) is inappropriate"); *see also id.* at 31 (citing *United States v. Medoc Health Servs. LLC*, 470 F. Supp. 3d 638, 651 (N.D. Tex. 2020) (noting that the court "previously held that the 'safe harbors' are affirmative defenses on which the Defendants bear

the burden of proof" and confirming that other courts "have described the safe harbors this way for good reason").[10] So, this argument doesn't end this claim in relator's *qui tam* action.

b. Illegal Kickbacks at Dole VA

Second, Medtronic attacks the Complaint's kickback allegations based on particularity under Fed. R. Civ. P. 9(b). But, again, the court agrees with relator. His allegations are at their clearest resolution as they apply to the Dole VA. There, the Complaint describes *who* was involved: specific, named individuals at Medtronic and at Dole VA's cath lab.[11] *See* Doc. 26 at 17–18 (Compl. ¶¶ 52–56). Likewise, the Complaint details *what* was involved—a two-parter of sorts. Part one is the remuneration allegedly given in the form of various, lavish gifts. *See id.* at 17 (Compl. ¶ 53). And part two is the Complaint's detailed allegations about shelves at Dole VA overflowing with unneeded Medtronic devices, all of them expensive and many of them tagged with soon-to-expire deadlines. *See id.* at 21–26 (Compl. ¶¶ 67–75). As for the *when*, the

[10] Although Medtronic makes this argument, it hasn't done anything to shoulder its burden. Even if the court considered this argument about the statutory safe harbor, the court still would agree with relator because the argument relies on contested facts. *See Midland Pizza, LLC v. Sw. Bell Tel. Co.*, No. 10-2219-CM-GLR, 2010 WL 4622191, at *4 (D. Kan. Nov. 5, 2010) ("Because resolution of contested facts is essential to the resolution of defendants' affirmative defense of voluntary payment, the court cannot grant the motion to dismiss on this basis."); *see also Butcher v. Teamsters Loc. 955*, No. 18-CV-02424-JAR-KGG, 2018 WL 6200027, at *2 (D. Kan. Nov. 28, 2018) (explaining that courts may decide a Rule 12(b)(6) motion based on an argument about affirmative defenses only "[i]f the facts establishing the affirmative defense are apparent on the face of the complaint itself" (citations omitted)).

[11] Medtronic argues that relator's claim should fail, in part, because his allegations don't fix every detail of the alleged scheme on a single individual at Dole VA. *See* Doc. 46 at 12–13. But the court struggles to imagine that every viable FCA claim will entail just one decision maker on either side of the arrangement. Relator's allegations assert a complex scheme, so it's unsurprising that his Complaint identifies more than one responsible actor. And, his allegations—contrary to Medtronic's argument—specify important details about how those named individuals were part of an interwoven scheme. *Compare* Doc. 46 at 13 ("Thus, the [Complaint] pleads specific facts regarding the role that Dixon and Keene played in ordering Medtronic's devices but alleges no specific facts with respect to Brinkley, the alleged recipient of the kickbacks."), *with* Doc. 26 at 20–21 (Compl. ¶ 64) (describing multiple conversations between relator and Dixon in January 2017 about alleged "pressure" that Dixon was facing due to Brinkley and Keene's interest in purchasing devices as quickly as possible, and therefore demonstrating that these individuals worked not in isolation, but rather—to some extent anyway—in conjunction with one another).

Complaint's allegations are more attenuated because they describe a broad timespan, in lieu of specific dates and times. *See id.* at 17 (Compl. ¶ 53) (describing the alleged kickback scheme at Dole VA); *see also id.* at 11 n.4 (defining the relevant time period for this action as "refer[ring] to the permissible period of time under Relator's FCA claims which would be six years from the initiation of this action"). But the Complaint does provide some dates and times. For example, it recites when relator and his colleagues conversed with Dole VA employees about their efforts to solicit business.[12] *See, e.g.*, *id.* at 20 (Compl. ¶¶ 62–63) (alleging that relator communicated directly with Dole VA's Brinkley about a lower cost arrangement for medical devices). And the *how*? The Complaint adduces particularized allegations about how Dole VA staff refused competitive offers from relator's company while purchasing expensive Medtronic devices at a pace beyond the hospital's actual needs. *See id.* at 22–27 (Compl. ¶¶ 70–79). These allegations provide a sufficient basis for an inference that the Dole VA nevertheless billed wasted materials to the federal government. Otherwise, why would Dole VA have purchased so much more from Medtronic than it needed?

The Complaint describes millions of dollars of device sales by Medtronic to Dole VA despite the hospital being "one of the nation's smallest vascular surgery providers." *Id.* at 16 (Compl. ¶ 51). Dole VA was purchasing Medtronic devices—according to the Complaint's

[12] Relator would strengthen the Complaint if he listed specific dates and times when Medtronic allegedly paid these remunerations. But our Circuit has said those details, at least in the context of this case, aren't essential. *See Polukoff*, 895 F.3d at 745 ("[I]n determining whether a plaintiff has satisfied Rule 9(b), courts may consider whether any pleading deficiencies resulted from the plaintiff's inability to obtain information in the defendant's exclusive control." (internal quotation marks and citation omitted)). Medtronic, more than once, faults relator's allegations because he wasn't personally present for some of these alleged events. *See, e.g.*, Doc. 46 at 6 ("Relator is not an insider with personal knowledge of wrongdoing—the traditional False Claims Act . . . whistleblower—and it shows in his complaint, which provides no specific information to support his serious allegations."). But relator's case isn't doomed *per se* because of this wrinkle. To the contrary, his Complaint can survive Medtronic's motion so long as its fraud allegations, in the aggregate, adduce a strong inference that related claims were submitted to the government for payment. *See Lemmon*, 614 F.3d at 1173 (explaining that a relator's allegations needn't be "taken in isolation" and that a relator may "avoid dismissal under Rules 9(b) and 8(a)" by "show[ing] that, taken as a whole, a complaint entitles [him] to relief." (citation omitted)).

allegations—at a rate far exceeding many of the nation's largest facilities for these procedures. *See id.* at 18–20 (Compl. ¶¶ 59–61). Many of these devices went completely to waste, the Complaint alleges with detail. *See id.* at 21–27 (Compl. ¶¶ 67–79).

And so, while a reasonable factfinder could find or infer that Dole VA made a well-intentioned mistake—*i.e.*, it simply purchased far too many medical devices from Medtronic, and then ate the lost profits rather than billing them to the government, another inference also is available. A factfinder could infer from these allegations that something nefarious was afoot. So, relator's kickback allegations about Medtronic and Dole VA will survive the motion to dismiss.[13] *See Perkins v. Kan. Dep't of Corr.*, 165 F.3d 803, 806 (10th Cir. 1999) ("[W]e must accept the allegations of the complaint as true and we must construe those allegations, and any reasonable inferences that might be drawn from them, in the light most favorable to the plaintiff." (citation omitted)); *see also Polukoff*, 895 F.3d at 745 ("'Thus, claims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme.'" (quoting *Lemmon*, 614 F.3d at 1172)).

c. Illegal Kickbacks at Hutchison

Medtronic's motion also attacks the Complaint's allegations about unlawful kickbacks at Hutchinson. These allegations aren't as detailed as relator's claims about Medtronic and Dole VA. But, they say enough to survive the motion to dismiss. Relator's Response argues that Medtronic followed a similar path at both hospitals. *See* Doc. 55 at 22 (arguing that relator's

[13] The court also accepts the Complaint's scienter allegations. A party may plead scienter generally. *See Antonson v. Robertson*, No. 88-2567-V, 1992 WL 220793, at *3 (D. Kan. Aug. 12, 1992) ("Rule 9(b) permits scienter to be averred generally[.]" (citation omitted)). "The pleading requirements of Rule 9(b) with respect to scienter may be satisfied either by alleging facts showing a motive for committing fraud and an opportunity for doing so or by identification of circumstances indicating defendants' conscious behavior." *Id.* (citations omitted).

Complaint "describes the same scheme employed by Medtronic to induce sales at Dole VA" as at Hutchinson (internal quotation marks omitted)); *see also* Doc. 26 at 28 (Compl. ¶ 86) ("Following Medtronic's playbook, Winger's kickback scheme at Hutchinson worked similar to the one at Dole VA."). But these allegations aren't identical to those involving the Dole VA. So, the court reviews these assertions on their own.[14]

Relator's Complaint alleges that Medtronic gave "remuneration such as meals, food, alcohol, gratuities . . . NASCAR and other sporting event tickets," and more "to induce Hutchinson to directly purchase millions of dollars of Defendant Medtronic's PAD devices." Doc. 26 at 28 (Compl. ¶ 86). "Also, part of Medtronic's kickback scheme included [Medtronic's] Winger giving free PAD devices" to Hutchinson "in exchange for [Hutchinson's] Wilson making purchases from Medtronic." *Id.* at 29 (Compl. ¶ 89). So, relator claims, Medtronic committed two AKS violations: (1) "illegal remuneration" and (2) "an illegal rebate under the AKS[.]" *Id.* (internal quotation marks omitted). In other words, this scheme actually involved two distinct mechanisms: remunerations and free products.

But even if relator is right about an AKS violation, his allegations can bridge the gap between that law and the FCA only if he alleges (with particularity) that the government footed the bill. 42 U.S.C. § 1320a-7b(g) ("'[A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act].'").

For the first part of the alleged scheme—remuneration paid to induce an exclusive relationship between Medtronic and Hutchinson—relator hasn't alleged enough. The Complaint describes a broad range of remuneration given to Hutchinson from Medtronic. *See id.* at 28

[14] As with Dole VA, the court agrees with relator that Medtronic hasn't shown the AKS statutory safe harbor applies to the allegations involving Hutchinson. *See Medoc Health Servs., LLC*, 470 F. Supp. 3d at 651; *see also* Doc. 55 at 30–31 (discussing the holding in *Medoc*).

(Compl. ¶¶ 86–87). But it doesn't describe the particulars of how these gifts led Hutchinson to submit false claims to the government. *See Polukoff*, 895 F.3d at 745. Instead, these allegations about remuneration—even if they constitute a violation of the AKS—fall short of alleging particularized details about *how* remuneration ultimately generated false claims for government payment. There's a gap between the AKS and FCA which relator has to bridge. *See* Doc. 26 at 6 (Compl. ¶ 13) ("Falsely certifying compliance with the AKS in connection with a claim submitted to a federally funded insurance program is actionable under the FCA."). But the court can't tell from the Complaint—let alone by particularized allegations—how exactly this arrangement would bridge that gap.

However, the Complaint discusses more than just these remunerations. It also describes a scheme between Medtronic and Hutchinson involving large volumes of free Medtronic devices. *See id.* at 29 (Compl. ¶ 89). And on this front, the Complaint makes allegations that are particularized. They adduce a *who*: specific individuals at Medtronic and Hutchinson in positions to make decisions about device purchases. *See id.* at 27–28 (Compl. ¶¶ 82–83, 86). The Complaint bolsters these allegations by describing specific conversations between these Hutchinson employees, relator and his colleagues, and other medical device industry members about similar efforts to secure large volumes of free, expensive medical devices. *See id.* at 29–31 (Compl. ¶¶ 91–94). These allegations also answer the *when* and *what* questions. *See id.* As for the *how*, the Complaint describes a scheme bound up in these free devices whereby "Hutchinson would bill Government Healthcare Plans for the free devices from [Medtronic's] Winger, allowing Hutchinson to capitalize again on the kickback." *Id.* at 30 (Compl. ¶ 92) (internal quotation marks omitted).

These cost savings were substantial. *See, e.g.*, *id.* (Compl. ¶ 92) ("Ten free units of the 'Outback' re-entry catheters alone would net the price paid by Defendant Hutchinson to Defendant Medtronic down by approximately $25,000."). Also, the savings amounted to nearly half of what a device company needed to recoup for a bulk sale. *See id.* (Compl. ¶ 93) (describing a conversation on August 5, 2019 between relator's colleague and Hutchinson's Wilson in which Wilson requested about $15,000 worth of free product in exchange for purchasing about $37,500 worth of relator's devices).[15] These details matter for Medtronic because the deal was solicited from relator's company "'in order to get close to what Medtronic is offering[.]'" *Id.*

To be certain, these allegations are closer to the margin than relator's claims about Medtronic and Dole VA. Here, a reasonable factfinder might infer from the allegations that Medtronic was doling out free devices for non-culpable reasons while Hutchinson simply wished to cut costs. But the Complaint avers that this scheme entailed Hutchinson submitting false claims to the government for payment. *See id.* (Compl. ¶ 92); *see also id.* at 31 (Compl. ¶ 96) ("Since 2012, Defendant Hutchinson billed just Medicare alone for tens of millions of dollars for reimbursement for the Medtronic devices used and sold as part of the Medtronic kickback scheme with Hutchinson and Wilson."). And at this stage of the litigation, the court must "assume the truth of all well-pleaded facts in the complaint, and draw all reasonable inferences therefrom in the light most favorable" to relator. *Leverington v. City of Colo. Springs*, 643 F.3d 719, 723 (10th Cir. 2011).

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[15] Also, this allegation is particularized because it specifies a precise date when the alleged conversation took place. This level of specificity makes sense because the relator presumably would know this information already. In contrast, relator couldn't know other details bound up in the alleged scheme—at least not yet. *Cf. George*, 833 F.3d at 1255 ("[I]n determining whether a plaintiff has satisfied Rule 9(b), courts may consider whether any pleading deficiencies resulted from the plaintiff's inability to obtain information in the defendant's exclusive control." (citations omitted)).

Also, and critically, "Rule 9(b)'s 'normally rigorous particularity rule has been relaxed somewhat where the factual information is peculiarly within the defendant's knowledge or control'" so long as relator "'accompan[ies] [his] legal theory with factual allegations that make [his] theoretically viable claim plausible[.]'" *George*, 833 F.3d at 1255 (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997)). Relator's allegations might not withstand the next stage of this litigation, where discovery unfolds and the court must decide whether relator has marshaled admissible evidence supporting the elements of his claims. But assuming for present purposes "that plaintiff is unable to obtain essential information in defendant's possession without pretrial discovery[,]" the court won't dismiss these claims. *Id.* (citing *Emery v. Am. Gen. Fin., Inc.*, 134 F.3d 1321, 1323 (7th Cir. 1998)). For now, the theory of the Hutchinson claim is plausible. *See Lemmon*, 614 F.3d at 1173 ("The complaint must provide enough information to describe a fraudulent scheme to support a plausible inference that false claims were submitted.").

2. Medtronic is Right About Relator's Deficient Allegations Involving Medically Unnecessary Procedures at Dole VA

Next, relator alleges that Medtronic also is liable under the FCA for causing Dole VA to perform medically unnecessary procedures. On this claim, the court agrees with Medtronic. "[C]laims for medically unnecessary treatment are actionable under the FCA." *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) (footnote omitted); *see also* Doc. 55 at 32 n.14 ("Relator also alleges with particularity the legal foundation for his claims by outlining how, under the relevant federal regulations, only services and products that are medically necessary are reimbursable[.]"). And relator's Complaint alleges just that: "Medtronic claimed, caused a claim to be made, or conspired to have a fraudulent claim be made . . . for reimbursement for unnecessary medical treatment and devices." Doc. 26 at 32 (Compl. ¶

99); *see also id.* ("This included . . . Winger and/or Kirk being present during procedures whereby they marketed, instructed, or encouraged the overuse of Medtronic atherectomy devices, [drug-coated balloons], and stents in PAD procedures."). Of course, Medtronic disagrees. *See* Doc. 46 at 21–22 ("[T]he allegations about medical necessity lack any specificity and fail to identify a single specific patient, procedure, physician, or communication related to this 'overuse.'"); *see also id.* at 22 ("Critically, Relator fails to identify any specific statements by Winger or Kirk, and he fails to explain the causal link between the alleged 'marketing' and 'encouragement,' and physicians' independent decision-making regarding the use of Medtronic devices.").

Medtronic has the better end of this argument. *See* Doc. 61 at 11 (arguing that relator's medical necessity allegations don't supply the requisite particularity demanded of factual allegations under Fed. R. Civ. P. 9(b)). On one hand, relator avers generally that his medical necessity allegations are "pled in the context of Medtronic paying illegal renumeration at Dole VA" in the sense that medically unnecessary procedures offered operating physicians a chance to dispose of their excessive Medtronic inventory. Doc. 55 at 33; *see also* Doc. 26 at 34 (Compl. ¶ 109). And this theory makes some sense, albeit in a morbid sort of way.

But the Complaint is deficient in other respects. The Complaint's factual allegations don't address the particulars of several key details. For instance, relator alleges that Medtronic's "Winger and/or Kirk" were "present during procedures whereby they marketed, instructed, or encouraged the overuse of Medtronic" devices. Doc. 26 at 32 (Compl. ¶ 99). But the Complaint dives no deeper than those details. The court can't discern from that allegation, for instance, *how* these Medtronic employees influenced medical procedures and the devices that were used. *See* Doc. 61 at 11 (arguing that relator doesn't "describe how Medtronic's sales representatives

marketed, instructed, or encouraged any unnecessary procedure" (internal quotation marks and emphasis omitted)). Likewise, these allegations don't fully answer the *who* question. *See Polukoff*, 895 F.3d at 745 ("Practically speaking, FCA claims comply with Rule 9(b) when they provide factual allegations regarding the who, what, when, where, and how of the alleged claims." (internal quotations marks, alteration, and citation omitted)). Although the Complaint alleges that two Medtronic employees attended some procedures, it doesn't identify any specific physician(s) who performed these procedures. *See* Doc. 61 at 11 (arguing same). As for the *when* question, the Complaint alleges a timespan of more than seven years. *See* Doc. 55 at 33 (arguing that the Complaint's allegations describe a scheme that played out between January 2011 and summer 2018); *see also* Doc. 61 at 11 (arguing that the Complaint lacks specificity on this detail other than to "baldly state" that the scheme transpired throughout this same time period).

Our Circuit considered medical necessity allegations in *Polukoff*. The plaintiff there previously faced defeat when the district court granted the defendants' motions to dismiss. *See Polukoff*, 895 F.3d at 734. But he won his appeal before the Tenth Circuit, which reversed the trial court's ruling and remanded the case for further proceedings. *See id.* In that appeal, our Circuit held that the plaintiff's medical necessity allegations should've survived the motions to dismiss because his allegations included particularized details. *See id.* at 743. *Polukoff*'s plaintiff alleged that a specific physician "performed an unusually large number" of procedures during a specific year compared to other medical providers. *Id.* (citation omitted). Also, he alleged particularized details about specific billing records that would substantiate this allegation. *Id.* (citation omitted). Likewise, the *Polukoff* plaintiff alleged that this physician's employer hospital had audited his performance "and concluded that its guidelines had been violated in

many of the 47 cases reviewed[.]" *Id.* (internal quotation marks and citation omitted). Relator's allegations here simply don't approach this level of particularity.

Relator acknowledges the precise point that concerns the court most about this aspect of his allegations. *See* Doc. 55 at 11 ("The germane question under Rule 9(b) is whether a defendant has 'fair notice' of the factual and legal basis for the claims against it." (quoting *Polukoff*, 895 F.3d at 745)). The court has reviewed his Complaint's allegations in the holistic sense required by precedent. *See Lemmon*, 614 F.3d at 1173 ("Nor must every allegation, taken in isolation, contain all the necessary information."); *see also id.* ("Rather, to avoid dismissal under Rules 9(b) and 8(a), plaintiffs need only show that, taken as a whole, a complaint entitles them to relief." (citation omitted)). And the court recognizes that some key details currently may reside "in the defendant's exclusive control." *Polukoff*, 895 F.3d at 745 (internal quotation marks and citation omitted). But even under this approach, the court can't find enough particularity elsewhere in the allegations to offset the deficiencies noted. And so, the court can't agree that relator's Complaint "put[s] Medtronic on notice of the who, what, when, where, and how it promoted medically unnecessary treatment" at Dole VA. Doc. 55 at 8. In short, the court grants Medtronic's Motion to Dismiss Second Amended Complaint (Doc. 45) against relator's claim for medically unnecessary procedures at Dole VA.[16]

[16] The court doesn't reach this conclusion because relator's allegations aren't troubling. The Complaint alleges performance of unnecessary and potentially dangerous medical procedures at Dole VA. *See* Doc. 26 at 34 (Compl. ¶ 108). But the FCA is a specific statute concerned with specific conduct—submission to the federal government of false claims for payment. Relator has alleged unnecessary medical procedures. But he hasn't alleged particularized details about how Medtronic induced physicians to perform unnecessary procedures that Dole VA ultimately billed to the government. *Cf. United States ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 540 (10th Cir. 2020) ("Simply put, the FCA is not 'an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations.'" (quoting *Escobar*, 136 S. Ct. at 2003)); *see also id.* ("Instead, FCA liability attaches only where the alleged misrepresentations are material to the Government's payment decision." (citing *Escobar*, 136 S. Ct. at 2001–02)).

3. Medtronic is Right that Relator's Off-Label Marketing Allegations Fail Under Rule 9(b)

Now, the court addresses Medtronic's argument that relator's off-label marketing allegations fail to state a viable claim. On this front, the court agrees with Medtronic. Although device manufacturers can't market their devices for an off-label purpose, health care providers still can use them in accordance with their medical judgment—even if that use constitutes an off-label use. *See United States ex rel. George v. Bos. Sci. Corp.*, 864 F. Supp. 2d 597, 600 (S.D. Tex. 2012) (explaining that manufacturers are "generally prohibited . . . from marketing products for off-label uses[,]" but it's also true that "off-label use of many medical devices and drugs is an accepted medical practice." (footnote omitted)). In other words, there's a big difference between permissible off-label *use* and prohibited off-label *promotion*. *See Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977, 990 (D. Ariz. 2013) ("While permitting health care providers to use devices in ways other than those anticipated by the FDA, the FDA prohibits device manufacturers from promoting the off-label use of their product.").

"FCA liability does not attach to violations of federal law or regulations, such as marketing of drugs . . . that are independent of any false claim." *United States ex rel. Gardner v. Vanda Pharms., Inc.*, No. 17-cv-00464 (APM), 2020 WL 2542121, at *7 (D.D.C. May 19, 2020) (internal quotation marks and citation omitted). Thus, proving "unlawful off-label promotion alone cannot sustain a successful FCA action; the FCA does not impose liability for all fraudulent acts, only for fraudulent claims." *United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 345 (D. Mass. 2011) (citations and emphasis omitted). So, "to state a claim for relief under the FCA," relator "must also allege that the promotion knowingly included false statements or misrepresentations in connection with the submission of false claims." *Id.* at 346.

Medtronic's Motion to Dismiss Second Amended Complaint (Doc. 46) argues that relator fails to state this claim with the requisite particularity. *See* Doc. 46 at 23–27; *see also* Doc. 61 at 12. Relator sees things differently. *See* Doc. 55 at 39 (arguing that his Complaint "satisfies Rule 9(b) and identifies the 'who, what, when, where, and how' of the off-label claims alleged against Medtronic for two different devices"). In relator's view, it matters not whether his allegations pinpoint particular claims submitted to the government. *Id.* at 38–39 (first citing *Duxbury*, 579 F.3d at 30; then citing *United States ex rel. Bergman v. Abbot Lab'ys*, 995 F. Supp. 2d 357, 371 (E.D. Pa. 2014); and then citing *United States ex rel. Zverev v. USA Vein Clinics of Chi., LLC*, 244 F. Supp. 3d 737, 745 (N.D. Ill. 2017)). Instead, he argues his allegations survive because he alleges the particulars of Medtronic's scheme to promote off-label use of its devices, which produced false claims to the government. *See id.* at 38–39 (citations omitted).

Relator argues his Complaint satisfies Rule 9(b) because it supplies particularized allegations showing (if proved true) how Medtronic employees marketed off-label uses for its devices during medical procedures at Dole VA. *Id.* at 40 (citing Doc. 26 at 14, 32–34, 36–37 (Compl. ¶¶ 40, 99–100, 103–105, 107, 114, 116)). And he argues that Dole VA staff actually used the devices in an off-label sense during medical procedures there. *Id.* (citations omitted). If the Complaint substantiated his argument, the court likely would agree with his broader premise about Rule 9(b). *See Polukoff*, 895 F.3d at 745 ("[C]laims under the FCA need only show the specifics of a fraudulent scheme and provide an adequate basis for a reasonable inference that false claims were submitted as part of that scheme." (internal quotation marks and citation omitted)); *see also Grubbs*, 565 F.3d at 190 (explaining that Rule 9(b)'s particularity requirement "is context specific and flexible and must remain so to achieve the remedial purpose of the False Claims Act").

But relator's papers cite sections of his Complaint where no such specifics are found. For example, one of relator's cited passages merely parrots the premise mentioned in his Response. *Compare* Doc. 55 at 40 ("Relator's [Complaint] specifically alleges how Medtronic employees Winger and Kirk unlawfully marketed PAD devices to [the Wichita] physicians, Brinkley, and Dole VA catherization lab employees *during* procedures for unlawful, off-label use."), *with* Doc. 26 at 32 (Compl. ¶ 99) ("This included, but is not limited to, Winger and/or Kirk being present during procedures whereby they marketed, instructed, or encouraged the overuse of Medtronic atherectomy devices, [drug-coated balloons], and stents in PAD procedures."). Neither from these allegations nor from any others in the Complaint can the court find particularized details about when these events unfolded, what was said, or how Medtronic employees marketed their devices for off-label use in medical procedures.

"Practically speaking, FCA claims comply with Rule 9(b) when they provide factual allegations regarding the who, what, when, where and how of the alleged claims." *Polukoff*, 895 F.3d at 745 (internal quotations marks, alteration, and citation omitted). Some of these details might rest within "the defendant's exclusive control[,]" at least without pretrial discovery. *Id.* (internal quotation marks and citation omitted). And the court is mindful of our Circuit's view "that Rule 9(b) does not require omniscience; rather the Rule requires that the circumstances of the fraud be pled with enough specificity to put defendants on notice as to the nature of the claim." *Id.* (internal quotation marks and citation omitted). But still, the Rule does require that relator "state with particularity the circumstances constituting fraud[.]" Fed. R. Civ. P. 9(b). These allegations in the Complaint about off-label marketing, if not conclusory, are generalized.

So, the court grants Medtronic's Motion to Dismiss Second Amended Complaint (Doc. 45) against relator's off-label device marketing allegations.[17]

4. Relator's Civil Conspiracy Allegations About Medtronic and Dole VA Survive Medtronic's Motion to Dismiss

Last, Medtronic's motion to dismiss attacks the Complaint's civil conspiracy allegations. *See* Doc. 46 at 27–29; *see also* Doc. 61 at 17–18. On this front, the court agrees with relator and thus denies the motion to dismiss.

Medtronic advances two arguments. *First*, Medtronic argues the "conspiracy claim fails for the same reasons his underlying FCA claims fail." Doc. 46 at 28; *see also* Doc. 61 at 17 ("[B]ecause Relator has failed to adequately plead an underlying FCA violation, his FCA conspiracy claims also, and necessarily, should be dismissed." (citation omitted)). *Second*, and "[e]ven if that weren't true as a logical or legal matter," Medtronic argues that these civil conspiracy allegations aren't particularized. Doc. 61 at 18; *see also* Doc. 46 at 28–29. Relator provides a robust defense of these claims. *See* Doc. 55 at 41–45.

In relator's view, the civil conspiracy allegations "are clear, plausible, particularized and state a claim for conspiracy." *Id.* at 41. More specifically, relator argues that his civil conspiracy allegations survive the motion to dismiss because his other viable claims demonstrate that there must have been some agreement behind all of this. *See id.* at 43–44 (arguing that this "detailed scheme . . . whereby all parties financially benefitted via fraudulent claims" must have "exist[ed] via agreement among the parties involved" (internal quotation marks omitted)). And, relator repeats a point raised throughout his papers: "the specific claims need not be identified to

[17] Medtronic also raises an argument that relator's off-label marketing allegations fail for First Amendment reasons. *See* Doc. 46 at 26. Relator disagrees. *See* Doc. 55 at 40–41. The court doesn't need to address either side's view of this issue. Relator's off-label marketing allegations fail for the independent and narrower reason that they aren't particularized, as Rule 9(b) requires. *See* Fed. R. Civ. P 9(b).

meet the Rule 9(b) particularity requirement for a conspiracy claim." *Id.* at 44–45 (first citing *Duxbury*, 579 F.3d at 30; then citing *United States ex rel. Baltazar v. Warden*, 635 F.3d 866, 870 (7th Cir. 2011) ("A relator need not have seen the claims submitted to the federal government, but must know enough to make fraud a likely explanation for any overbilling." (citation omitted))).

The parties agree on one thing at least: the legal standard for alleging a viable civil conspiracy claim under the FCA. Each relies on the Fifth Circuit's view in *Grubbs* that "a relator must show (1) the existence of an unlawful agreement between defendants to get a false or fraudulent claim allowed or paid by the Government and (2) at least one act performed in furtherance of that agreement." *Grubbs*, 565 F.3d at 193 (internal quotation marks, alteration, and citation omitted); *see also* Doc. 46 at 28 (quoting same); Doc. 55 at 41–42 (reciting same). But things diverge from there. The court already has concluded that at least some of the Complaint's allegations state a viable FCA claim. So, Medtronic's first argument—that flimsy allegations about a primary FCA violation doom the conspiracy claim—won't help it on the conspiracy issue. But this conclusion doesn't necessarily defeat Medtronic's second argument—about particularity.

Medtronic identifies a few courts who have agreed with this argument. The Eighth Circuit, for example, has held that just because a relator alleges a viable unlawful kickback scheme doesn't mean the relator necessarily has alleged a civil conspiracy under the FCA. *United States ex rel. Strubbe v. Crawford Cnty. Mem'l Hosp.*, 915 F.3d 1158, 1166 (8th Cir. 2019) ("Because the complaint does not include any details about an agreement, the relators fail to plead the conspiracy with particularity."). The Eastern District of Louisiana also has agreed with the Eighth Circuit's view of this issue. *United States ex rel. McLain v. Fluor Enters., Inc.*,

Nos. 06-11229, 09-4191, 2013 WL 3899889, at *10 (E.D. La. July 29, 2013) (observing that while plaintiffs specified the alleged conspirators, the nature of the conspiracy, the claims submitted as part of the conspiracy, and the timeframe when the conspiracy unfolded, "plaintiffs have not provided . . . any indication that any of the parties actually agreed to enter into the alleged conspiracy").

But relator adduces a few examples when courts have agreed with his view. He cites the Southern District of Florida. *United States v. Marder*, No. 13-cv-24503-KMM, 2015 WL 13264207, at *5 (S.D. Fla. May 14, 2015) (concluding "that the scheme that is detailed in the Complaint would not have been possible without agreement and coordinating among all Defendants"). Likewise, the Eastern District of Pennsylvania has reached a similar conclusion. *United States ex rel. Gohil v. Sanofi-Aventis U.S. Inc.*, 96 F. Supp. 3d 504, 523 (E.D. Pa. 2015) ("Viewing the pleadings in the light most favorable to Mr. Gohil, as I must, I can easily infer the existence of an agreement." (citation omitted)).

Forced to choose between two divergent arguments about appropriate inferences, the court agrees with relator. At this stage of the litigation, the court must "assume the truth of all well-pleaded facts in the complaint, and draw all reasonable inferences therefrom in the light most favorable" to relator. *Leverington*, 643 F.3d at 723 (internal quotation marks and citation omitted). And here, a factfinder could infer at least two disparate narratives from the facts alleged.

On the one hand, a trier of fact might infer that Medtronic and the relevant hospitals shared mutual-but-separate interests in financial gain. In other words, it's plausible to infer that these facts played out not because of an agreement to perpetuate a fraudulent scheme, but rather resulted from lucrative benefits appealing to both sides of the arrangement. That storyline

wouldn't amount to a conspiracy under the FCA. *See Grubbs*, 565 F.3d at 193. But, on the other hand, there's another reasonable inference within reach. Plaintiff has alleged with particularity that Medtronic, Dole VA, and Hutchinson entered into a business relationship involving illegal remuneration under the AKS which ultimately involved government payouts. These transactions entailed large sums of money. Allegedly, they played out over the course of several years. According to the Complaint, it wasn't a simple or one-off sort of thing. And so, as relator avers, it's plausible to infer an "agreement among the parties involved." Doc. 55 at 44; *see also Gohil*, 96 F. Supp. 3d at 523; *Marder*, 2015 WL 13264207, at *5.

For now, the court accepts the inference most beneficial to relator. It's plausible. *See Gohil*, 96 F. Supp. 3d at 523; *Marder*, 2015 WL 13264207, at *5; *see also Leverington*, 643 F.3d at 723. And it also heeds our Circuit's directive about the limited evidence that this relator can access without discovery. *See Polukoff*, 895 F.3d at 745. If Medtronic is correct that no conspiracy existed, it still can prove that point and reject relator's case. *See Grubbs*, 565 F.3d at 191 ("Discovery can be pointed and efficient, with a summary judgment following on the heels of the complaint if billing records discredit the complaint's particularized allegations."). In short, the court declines to shutter this claim before relator has had an opportunity to discover the facts thoroughly.

5. Relator is Granted Leave to Amend His Deficient Allegations About Medically Unnecessary Procedures and Off-Label Marketing at Dole VA

Neither party will walk away from this motion with everything they've requested. The court denies Medtronic's Motion to Dismiss Second Amended Complaint (Doc. 45) 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.[18] But, the court agrees with Medtronic that some of relator's allegations fail to satisfy Fed. R. Civ. P. 9(b)'s particularity requirement, meaning they don't allege particularized, plausible claims. For these allegations—(1) medically unnecessary procedures and (2) off-label marketing—the court grants the motion to dismiss. But this leaves another question: how should the lawsuit proceed from here?

The parties' papers contemplate this scenario, but each makes quite different recommendations. Medtronic argues that the court should dismiss the Complaint (or its respective claims) with prejudice. *See* Doc. 46 at 29; *see also* Doc. 61 at 19. To this end, Medtronic mentions that relator already has amended his Complaint twice. *See* Doc. 46 at 29 ("Relator has had years to develop any additional facts to allege in his complaint."). And, the company argues, "'[a] dismissal with prejudice is appropriate where a complaint fails to state a claim under Rule 12(b)(6) and granting leave to amend would be futile.'" *Id.* (quoting *Brereton v. Bountiful City Corp.*, 434 F.3d 1213, 1219 (10th Cir. 2006)). Relator recommends exactly the opposite. In his view, and if the "Court finds that Relator was deficient in sufficiently pleading any of the claims in his [Complaint], he asks this Court to grant leave to amend." Doc. 55 at 45.

The court agrees with relator for several reasons. *First*, Federal Rule of Civil Procedure 15(a)(2) directs courts to "freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). And, refusing to grant leave to amend "is generally only justified upon a showing of undue delay, unique 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. W., Inc.*, 3 F.3d 1357, 1365 (10th Cir. 1993). The court agrees with relator that Medtronic cites only the notion of futility in arguing for a dismissal with prejudice. *See* Doc. 55 at 45 ("Medtronic's

[18] Relator also alleges a civil conspiracy involving Medtronic and Hutchinson. The court addresses this claim in the next section of this Order.

only basis for denying a potential leave is futility of amendment." (internal quotation marks omitted)). But, also as relator argues, Medtronic hardly expands its point—it's a conclusory assertion. That's a problem. *See id.*; *see also Williams v. Corecivic, Inc.*, No. 17-2310-JAR, 2018 WL 1848701, at *2 (D. Kan. Apr. 18, 2018) ("The party opposing amendment bears the burden of establishing its futility." (citation omitted)). As the party asserting futility, Medtronic hasn't shouldered its burden, so the court rejects this argument.

Second, and on a similar note, Medtronic has argued that amendment is pointless because relator already has amended his Complaint twice, and if "he had facts to support his claims, he presumably would have pleaded them by now." Doc. 46 at 29. But relator points out that his "case was filed under seal in January 2017 and remain[ed] under seal until lifted by the Court on April 13, 2020." Doc. 55 at 45. Throughout those three years, "the United States Justice Department and its investigatory agencies conduct[ed] the only investigation[,]" meaning that relator "has not had years to 'develop' this matter." *Id.*; *see also id.* ("Relator could not investigate or conduct discovery during this time frame."). Relator's point is a good one.

Third and finally, the court takes note of a similar scenario that played out in our court already. Here, Medtronic has filed a Notice of Supplemental Authority (Doc. 65). Its filing references a decision from our court where "Judge Lungstrum found the . . . plaintiff's claims lacked the requisite particularity[.]" *Id.* at 1 (citing *Ernst*, 2020 WL 6868775, at *1). But that case also involved arguments about futility of amendment. *See Ernst*, 2020 WL 6868775, at *7. And like this case, the *Ernst* defendants argued "that plaintiff should not be afforded such opportunity [to amend] because he has already amended once in response to a motion to dismiss." *Id.* Judge Lungstrum disagreed. "This is the first ruling by the Court on the sufficiency of the allegations . . . and thus the Court will grant plaintiff one additional

opportunity to attempt to state cognizable claims under the FCA." *Id.* The same is true in this case. Relator has amended his Complaint twice already, and he had every right to do so.[19] *See* Docs. 1 (Compl.), 14 (Am. Compl.), 26 (Second Am. Compl.). But as in *Ernst*, "[t]his is the first ruling by the Court on the sufficiency of the allegations[.]" *Ernst*, 2020 WL 6868775, at *7. And so, as in *Ernst*, "the Court will grant plaintiff one additional opportunity to attempt to state cognizable claims under the FCA" where this Order rules he has come up short. *Id.*

The court construes relator's argument to mean that he requests leave to amend his Complaint (Doc. 26). *See* Doc. 55 at 46 ("[T]he Court should deny Medtronic's motion in its entirety, or alternatively, grant Relator leave to amend to correct any deficiencies found by this Court."). The court grants the request, and grants relator **30 days from the date of this Order** to amend these claims.

B. Hutchinson's Motion to Dismiss (Doc. 47)

The other defendant in this FCA controversy—Hutchinson Regional Medical Center—has filed its own Motion to Dismiss (Doc. 47). And as this Order already has noted, its motion is fully briefed as well. *See* Docs. 48, 56, 63.

Hutchinson's Motion to Dismiss hinges on this central premise: "the Second Amended Complaint . . . fail[s] to state a claim under Federal Rules of Civil Procedure 8, 9(b), and

[19] *See, e.g.*, *Watkins v. Genesh, Inc.*, No. 19-2486-GEB, 2020 WL 5993641, at *2 (D. Kan. Oct. 9, 2020) ("A party may amend its pleading as a matter of course under Fed. R. Civ. P. 15(a)(1), either before the responding party answers or within 21 days after service of a responsive pleading."); *see also* Doc. 25 (granting relator leave to file his Second Amended Complaint before either defendant had filed their motions to dismiss). In this case, relator filed his First Amended Complaint (Doc. 14) before any defendant answered or filed a responsive pleading. And relator filed his Second Amended Complaint (Doc. 26)—the operative pleading in this lawsuit—after securing leave of court. The court won't infer from these facts anything more than their literal meaning: relator amended his pleading twice in accordance with the rules.

12(b)(6)."[20] Doc. 47 at 1; *see also* Doc. 48 at 8 (arguing that the Complaint "fails to meet the basic pleading standard under Rule 8 and does not come close to satisfying the heightened pleading requirements of Rule 9(b)"). Below, the court analyzes the specific issues implicated by Hutchinson's motion.

1. Relator's Illegal Kickback Allegations Survive Hutchinson's Motion to Dismiss

Hutchinson argues that relator's claims about illegal kickbacks "fail at the outset because they lack support through specific factual allegations." Doc. 48 at 5. Relator's Complaint, Hutchinson asserts, is replete with red flags: "threadbare allegations and conclusory statements" that "are insufficient to satisfy the heightened standard requiring him to plead fraud claims with particularity—the who, what, when, where, and how." *Id.* And Hutchinson grounds its arguments in three main anchors: (1) "that discounts are proper and explicitly allowed under the Anti-Kickback Statute[,]" (2) that relator "fails to show that any alleged kickback caused the submission of a false claim to a federal healthcare program[,]" and (3) that relator "offers no facts to establish the scienter element required explicitly by the Anti-Kickback Statute and False Claims Act."[21] *Id.* The court addresses all of these arguments, below. The court concludes that

[20] The legal standards recited near the beginning of this Order also apply to Hutchinson's Motion to Dismiss (Doc. 47). To summarize, "Rule 9(b) has long played [a] screening function, standing as a gatekeeper to discovery, a tool to weed out meritless fraud claims sooner than later." *Grubbs*, 565 F.3d at 185. But Rule 9(b) "supplements" rather than "supplant[s]" Rule 8(a)'s requirements about notice pleadings. *Id.* at 186. So, as with Medtronic's motion to dismiss, the legal standard for Hutchinson's motion blends the pleading requirements in Fed. R. Civ. P. 8 and 9 in light of what the Supreme Court requires more generally under Fed. R. Civ. P. 12(b)(6). *See Grubbs*, 565 F.3d at 186 ("Rule 9(b) does not reflect a subscription to fact pleading and requires only simple, concise, and direct allegations of the circumstances constituting fraud, which after *Twombly* must make relief plausible, not merely conceivable, when taken as true." (internal quotation marks and footnote omitted)).

[21] Like Medtronic, Hutchinson makes much ado over the government's decision to decline intervention in this lawsuit. *See* Doc. 48 at 6. And Hutchinson's Motion to Dismiss makes note of relator's previous amendments to his Complaint. *See id.* To the first point, the court already has explained why the government's decision about intervention has no bearing on the merits of an FCA case. *See El-Amin*, 533 F. Supp. 2d at 21 (citation omitted). As for the second theme, the court likewise

Hutchinson's assertions—although well presented—aren't adequate to justify dismissing the lawsuit.

a. Hutchinson Hasn't Shown That a Statutory Safe Harbor Applies

For reasons explained already, the court agrees with relator and rejects the argument that his Complaint fails outright because the AKS contains a statutory safe harbor provision. This provision applies to:

> a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(3)(A). In simpler terms, the safe harbor applies when a price reduction is recorded, "disclosed and appropriately reflected in the costs claimed or charges made" so that the government doesn't pay the full bill for a device that actually costed less. *Id.*; *see also* Doc. 56 at 13 (arguing that these qualifiers in the provision work to ensure "that a buyer does not charge full price to a Federal healthcare program for a device it received at a discount" (citation omitted)). Relator's Complaint alleges plainly that Hutchinson and Medtronic engaged in transactions that wouldn't qualify under the statutory safe harbor provision. *See* Doc. 26 at 31 (Compl. ¶ 95).

Regardless, the court agrees with relator that this argument amounts to an affirmative defense. So, it's an inappropriate basis granting a motion to dismiss. *See* Doc. 56 at 14–16; *see also Medoc Health Servs. LLC*, 470 F. Supp. 3d at 651; *Marder*, 208 F. Supp. 3d at 1318; *Medicor*, 2017 WL 4867614, at *3. Hutchinson argues that "labels applied in a complaint do not transform all business transactions into an illegal kickback." Doc. 48 at 10–11 (citation omitted). And, it argues, relator alleges nothing more than "typical bulk-discount arrangements protected

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declines to read subtext into relator's decision to amend his pleadings consistent with the rules for doing so. *See Watkins*, 2020 WL 5993641, at *2; *see also* Doc. 25.

by federal statutes and regulations." *Id.* at 11. But Hutchinson doesn't elaborate on its arguments. It hasn't acknowledged the burden it bears in the context of arguing an affirmative defense. *Cf. Medoc Health Servs. LLC*, 470 F. Supp. 3d at 651 ("This Court previously held that the safe harbors are affirmative defenses on which the Defendants bear the burden of proof." (internal quotation marks and citation omitted)).

Are there bulk discounts and other rebates in the medical device industry that won't violate the AKS? Of course there are—the statute anticipates them. *See* 42 U.S.C. § 1320a-7b(b)(3)(A) (explaining that the statute's restrictions don't apply to "a discount or other reduction in price" where "the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made" to "a Federal health care program"). But relator alleges facts about a scenario that the statute doesn't cover. For instance, his Complaint describes a conversation with Hutchinson's Wilson where this hospital employee stated that none of Hutchinson's business deals with Medtronic ever were "in writing[.]" Doc. 26 at 29 (Compl. ¶ 91); *see also* Doc. 56 at 15 (noting that the AKS "requires Hutchinson and Medtronic to disclose and record in writing any discounted or free product" and observing that relator's Complaint "alleges that Wilson confirmed that none of Medtronic's free product is ever in writing" (internal quotation marks and citation omitted)).

Hutchinson argues that these allegations describe only "typical bulk-discount arrangements protected by federal statutes and regulations." Doc. 48 at 11. But Hutchinson's papers say nothing to substantiate this assertion. And regardless—if Hutchinson is right—"then discovery should expose the detailed documenting of all such transactions required under the safe harbor provisions." Doc. 56 at 13.

Perhaps Hutchinson will prevail in this dispute for any number of reasons. These reasons could include a showing of proof that its transactions with Medtronic qualify under the AKS safe harbor provision. But the court won't—and can't—grant Hutchinson's Motion to Dismiss (Doc. 47) based simply on Hutchinson's assertion that it has and will assemble such proof. As the law school bromide puts it, "Saying it's so doesn't make it so."[22]

b. Relator's Complaint Adequately Alleges Causation

Next, Hutchinson contends that relator's Complaint falls short for the independent reason that it "fails to allege any facts supporting a conclusion that an illegal kickback caused the submission of a false claim." Doc. 48 at 12. This detail matters because even an unlawful kickback isn't an FCA violation, *per se*. As Hutchinson argues, "the statute only makes actionable the submission of a claim to the government 'resulting from' a violation of the Anti-Kickback Statute[.]" Doc. 63 at 16 (quoting 42 U.S.C. § 1320a-7b(g)).

As Hutchinson sees things, relator's Complaint alleges only that a Hutchinson employee tasked with leading the hospital's supply chain operations transacted for medical devices with Medtronic. *See* Doc. 48 at 13. But, Hutchinson says, this individual "is not a doctor" nor did he "perform surgeries, decide what surgeries would be performed, or determine what specific medical devices would be used during surgeries." *Id.* Thus, Hutchinson argues, relator hasn't "connect[ed] the dots" between this employee's relationship with Medtronic for purchasing

[22] Hutchinson argues, albeit unsuccessfully, that rejecting its assertions about the safe harbor provision will flip Rule 9(b) on its head and create a race to the bottom for FCA plaintiffs. *See* Doc. 63 at 15. This argument misapprehends legal burdens. Contrary to Hutchinson's view, the court would not permit "any plaintiff [to] get a ticket to conduct discovery by intentionally not pleading facts sufficient to satisfy the safe harbor." *Id.* Hutchinson is the party who raised this affirmative defense, so it must produce facts "sufficient to satisfy the safe harbor." *Id.* And if the facts and analysis are as simple as Hutchinson asserts, the Federal Rules of Civil Procedure permit Hutchison to file a motion for summary judgment "at any time[.]" Fed. R. Civ. P. 56(b).

devices and any "decision to use those devices in a procedure" or with any claim submitted to the government. *Id.*

But again, the law favors relator on this point. *First*, the phrase "resulting from" does suggest a connection between violating the AKS and submitting a false claim. *See* 42 U.S.C. § 1320a-7b(g). This language does not expressly summon a but-for causation standard, however, as Hutchinson seems to argue. *See* Doc. 48 at 13 ("The [Complaint] fails to plausibly and specifically allege that any purported kickback caused the submission of a false claim to a federal healthcare program."). Hutchinson references a Third Circuit decision for support. Doc. 48 at 12 (citing *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 100 (3d Cir. 2018)). But *Greenfield* is a summary judgment case. *See Greenfield*, 880 F.3d at 91.

And regardless, the Third Circuit endorsed exactly the opposite of Hutchinson's argument. It found, based on the legislative history of both the AKS and FCA, that "Congress intended both statutes to reach a broad swath of fraud and abuse in the federal healthcare system" and not "to cabin healthcare providers' liability for certain types of false claims or . . . illegal kickbacks." *Id.* at 96 (internal quotation marks and citation omitted). *Greenfield* thus refused to read a direct causation requirement into the AKS. *Id.*; *see also id.* at 97 ("[T]he broad statutory context of the False Claims Act and the Anti-Kickback Statute supports the Government's reading, as neither requires a plaintiff to show that a kickback directly influenced a patient's decision to use a particular medical provider."). In sum, *Greenfield* lends more support to relator's position—not Hutchinson's argument. *Compare* Doc. 48 at 13 ("Schroeder does not identify a single false claim submitted by [Hutchinson] throughout his 139-paragraph [Complaint]."), *with Greenfield*, 880 F.3d at 99 ("Our sister circuits have applied the same

analysis, holding that plaintiffs must provide evidence of at least one false claim to prevail on *summary judgment*." (emphasis added and citations omitted)).

Second, the question the court must answer at this stage of the litigation is this one: Has relator alleged facts with particularity "provid[ing] an adequate basis for a reasonable inference that false claims were submitted as part of that scheme[?]" *Polukoff*, 895 F.3d at 745 (internal quotation marks and citation omitted). Relator alleges a suspicious arrangement between Hutchinson and Medtronic involving unlawful kickbacks under the AKS. For instance, Hutchinson and Medtronic allegedly conducted business without ever recording device discounts. Doc. 26 at 29 (Compl. ¶ 91). Based on this alleged fact, a reasonable factfinder could infer that submitting a false claim to the government was an inevitable byproduct. *See Polukoff*, 895 F.3d at 745; *see also* Doc. 56 at 20 (citing *United States ex rel. Simpson v. Bayer Corp.*, No. 05-3895 (JLL), 2013 WL 4710587, at *14 (D.N.J. Aug. 30, 2013) (holding that "[p]laintiff need not identify a particular false claim submitted to the Government to withstand a motion to dismiss" because the allegations detailed a scheme "which would inevitably cause false claims to be submitted to the government by healthcare providers" (citations omitted))).[23]

In sum, Hutchinson asks the court to require a causal link that's not found in the pertinent statutes. It also asks the court to apply a pleading standard that isn't appropriate before discovery. *Cf. Greenfield*, 880 F.3d at 97 ("Moreover, it would dilute the False Claims Act's requirements via-a-vis the Anti-Kickback Statute, as direct causation would be a precondition to bringing a False Claims Act case but not an Anti-Kickback Statute case." (footnote omitted)); *see also Polukoff*, 895 F.3d at 745 ("[C]ourts may consider whether any pleading deficiencies

[23] *Simpson* was abrogated on other grounds by *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017).

resulted from the plaintiff's inability to obtain information in the defendant's exclusive control." (internal quotation marks and citation omitted)).

As with Hutchinson's arguments about the statutory safe harbor provision, relator may not prevail on the merits. But at the motion to dismiss stage—construing the allegations and drawing reasonable inferences in the light most favorable to relator—he has alleged enough to move forward. *Cf. Grubbs*, 565 F.3d at 190 (holding that details such as "exact dollar amounts, billing numbers, or dates to prove to a preponderance that fraudulent bills were actually submitted" aren't required at the pleading stage of litigation because "requir[ing] these details at pleading is one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates" (footnote omitted)). The court thus rejects Hutchinson's effort to prevail on this argument at the motion to dismiss stage.

c. Relator's Complaint Adequately Alleges Scienter

Last, Hutchinson hones in on scienter. It argues relator "must allege two levels of scienter." Doc. 48 at 14. According to Hutchinson, first "he must allege that [Hutchinson] 'knowingly and wilfully' solicited a kickback 'in return for' certain actions." *Id.* (quoting 42 U.S.C. § 1320a-7b(b)(1)). And second, he "must also allege that [Hutchinson] knowingly presented a false claim to a federal healthcare program." *Id.* (citing 31 U.S.C. § 3729(a)). Hutchinson argues that relator fails on both fronts. *See id.* The court disagrees.

To be sure, courts speak often about the FCA including a "strict" scienter requirement. *See Escobar*, 136 S. Ct. at 2002 ("[C]oncerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements." (internal quotation marks and citation omitted)); *see also Polukoff*, 895 F.3d at

743 (quoting same). Essentially, FCA plaintiffs must allege knowledge, which the FCA defines to mean "that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information[.]" 31 U.S.C. § 3729(b). Also, FCA plaintiffs needn't prove a specific intent to defraud. *Id.*

At this stage, the operative inquiry isn't whether relator has alleged scienter with such strength that it's established by a preponderance of the evidence. *See Grubbs*, 565 F.3d at 190. Here, the court doesn't weigh any evidence because it's not allowed to do so. For now, all that's required is that relator allege particularized details from which a reasonable factfinder could draw the inference that Hutchinson violated the FCA. *Polukoff*, 895 F.3d at 745. "At the pleading stage" of an FCA case, "'knowledge, and other conditions of a person's mind may be alleged generally.'" *United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1224 (11th Cir. 2012) (quoting Fed. R. Civ. P. 9(b)); *see also* Doc. 56 at 21 (quoting same). As relator acknowledges, "'courts have repeatedly required plaintiffs to plead the factual basis that gives rise to a strong inference of fraudulent intent.'" Doc. 56 at 21 (quoting *In re United Telecomms., Inc., Sec. Litig.*, 781 F. Supp. 696, 701–02 (D. Kan. 1991)). But in this case's context, the court "may consider whether any pleading deficiencies resulted from the plaintiff's inability to obtain information in the defendant's exclusive control." *Polukoff*, 895 F.3d at 745 (internal quotation marks and citation omitted). In sum, and despite some "pleading deficiencies" where it's probable that relator could access information only through discovery, he has satisfied the standard adopted by our Circuit in *Polukoff*. *Id.*

First, relator's allegations about an illegal kickback scheme violating the AKS say enough to produce this logical outcome under *Polukoff*'s standard. *See id.* *Second*, and in light

of this first conclusion, the court also easily can infer from these facts that individuals at Medtronic and Hutchinson acted either with actual knowledge, willful ignorance, or reckless disregard for the truth or falsity of the relevant transactions and any related claims for payment. *See* 31 U.S.C. § 3729(b); *see also* Doc. 26 at 29 (Compl. ¶ 91). This doesn't mean relator *will* prove his case. It means simply that he has alleged plausibly—"above the speculative level"—that he *could* prove his case. *Twombly*, 550 U.S. at 555 (citation omitted); *see also Iqbal*, 556 U.S. at 678 ("A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." (citation omitted)). So, the court disagrees with Hutchinson on the issue of scienter.

2. Relator's Civil Conspiracy Allegations About Medtronic and Hutchinson Survive the Motion to Dismiss

These conclusions leave Hutchinson's attack on relator's civil conspiracy claim. *See* Doc. 48 at 15; *see also* Doc. 63 at 20. Hutchinson barely briefed this argument—devoting a total of four paragraphs combined in its Memorandum and Reply briefs. *See id.* To make its short remarks even more concise, it argues a two-part basis for why the Complaint should fail. *First*, and because Hutchinson believes that relator fails to allege even an unlawful kickback, it says the conspiracy claim also is doomed. *See* Doc. 48 at 15. *Second*, and regardless, Hutchinson says his "allegations lack the required particularity to survive under Rule 9(b)." *Id.*

Here, the court uses the same basic formulation for an FCA conspiracy as before because the parties offer different citations to an analogous premise. *Compare id.* ("Schroeder must show that: (1) [Hutchinson] agreed with [Medtronic] to get a false or fraudulent claim paid by the United States; and (2) [Hutchinson] or [Medtronic] performed an act to effect the object of the conspiracy." (internal quotation marks and citation omitted)), *with* Doc. 56 at 23 ("Relator must

plead: (1) an unlawful agreement to submit a false claim for payment, and (2) an act in furtherance of this agreement." (citation omitted)). And as before, the court agrees with relator.

The Complaint alleges an unlawful scheme for free and discounted medical devices. It references specific conversations that suggest the scheme's existence. The Complaint alleges that these devices are worth large sums of money, and that the discounts exchanged between Medtronic and Hutchinson also amounted to large sums of money. The Complaint names specific individuals at Medtronic and Hutchinson who allegedly facilitated these transactions. And it describes circumstances from which a trier of fact can infer that at least one false claim was submitted to the government.

It isn't hard to infer one more link in this sequential chain: that the involved actors agreed to all of this. The notion that at least one of them acted in furtherance of such an agreement is self-evident from the overall allegations about these circumstances. And so, it's reasonable to infer from these allegations "that the scheme that is detailed in the Complaint would not have been possible without agreement and coordinating among all Defendants." *Marder*, 2015 WL 13264207, at *5; *see also Gohil*, 96 F. Supp. 3d at 523 ("Viewing the pleadings in the light most favorable to Mr. Gohil, as I must, I can easily infer the existence of an agreement." (citation omitted)).

The court reaches this conclusion for the same reason as it did on the claim involving Dole VA. A factfinder could surmise at least two divergent inferences based on the facts alleged. One of those inferences favors Hutchinson's narrative. The other accepts relator's version of the story. Giving relator the benefit of any reasonable doubts—as the court must at this stage of the case—it chooses the inference that permits his civil conspiracy allegation to survive. *See Leverington*, 643 F.3d at 723 ("We assume the truth of all well-pleaded facts in the

complaint, and draw all reasonable inferences therefrom in the light most favorable to the plaintiffs." (internal quotation marks and citation omitted)).

IV. Conclusion

In sum, Medtronic's Motion to Dismiss Second Amended Complaint (Doc. 45) is a split ticket. The court denies the motion in part and grants it in part. Specifically, the court denies 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 grants the motion against these claims: (1) medically unnecessary procedures and (2) off-label marketing. For the two claims that do not survive Medtronic's motion to dismiss, the court grants relator's request for leave to amend. And, the court grants relator **30 days from the date of this Order** to amend these claims. If he fails to amend these claims in a way addressing their current shortcomings, the court will deem them dismissed. Last, the court denies Hutchinson's Motion to Dismiss (Doc. 47).

IT IS THEREFORE ORDERED BY THE COURT THAT defendant Medtronic, Inc.'s Motion to Dismiss Second Amended Complaint (Doc. 45) is granted in part and denied in part. The court denies the motion against relator's claims involving (1) illegal kickbacks at Dole VA and Hutchinson and (2) civil conspiracy allegations based on an illegal kickback scheme at Dole VA. The court grants the motion against relator's claims involving (1) medically unnecessary procedures at Dole VA, and (2) off-label marketing at Dole VA.

IT IS FURTHER ORDERED BY THE COURT THAT relator is granted leave to amend his claims that do not survive Medtronic's Motion to Dismiss Second Amended Complaint (Doc. 45). The court grants relator **30 days from the date of this Order** to file a Third Amended Complaint that corrects the deficiencies that this Order identifies. If relator fails

to amend these claims in a way addressing their current shortcomings, the court will deem them dismissed.

IT IS FURTHER ORDERED BY THE COURT THAT defendant Hutchinson Regional Medical Center's Motion to Dismiss (Doc. 47) is denied.

IT IS SO ORDERED.

Dated this 14th day of September, 2021, at Kansas City, Kansas.

s/ Daniel D. Crabtree
Daniel D. Crabtree
United States District Judge