

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF KANSAS**

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

**Relator,**

**Case No. 17-2060-DDC-BGS**

**v.**

**HUTCHINSON REGIONAL MEDICAL  
CENTER, et al.,**

**Defendants.**

**MEMORANDUM AND ORDER**

The motions at issue in this Order ask the court to decide what counts as illegal kickbacks under the Federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b). More specifically, they ask whether a medical device company providing meals to hospital employees violates the AKS. Do those meals constitute illegal remuneration? Does the answer to that question change if educational content accompanied the meals? Could a reasonable jury find those meals induced medical device purchases?

Relator Thomas Schroeder alleges that defendants Medtronic, Inc. and Covidien, LP (collectively Medtronic) provided meals to employees of the Catheterization Laboratory employees at Hutchinson Regional Medical Center (HRMC) and the Robert J. Dole Veterans Administration Medical Center (Dole VA). And, he contends, Medtronic intended to induce medical device purchases with those meals, so that HRMC and Dole VA would prefer Medtronic over competitors' devices. So, Relator asserts, Medtronic violated the AKS by providing the meals. And HRMC violated the statute by accepting them. In other words, the meals constitute

illegal remuneration under the AKS. And that illegal remuneration means that Relator, on behalf of the government, may bring a qui tam action against defendants under the False Claims Act (FCA), 31 U.S.C. §§ 3729–33.

The statutory structure for Relator’s claims works like this. Illegal remuneration under the AKS—a criminal statute—results in civil liability under the FCA in two ways. *First*, the AKS includes an amendment, passed by Congress in 2010, that explicitly links the AKS and FCA. 42 U.S.C. § 1320a-7b(g). Under this 2010 Amendment, claims “resulting from a violation” of the AKS constitute false or fraudulent claims under the FCA. *Id.* More on that later. *Second*, there’s the false certification theory. Under this legal theory, when an illegal kickback results in a false certification of compliance with the AKS—or other false statement or record—it violates the FCA (wholly apart from any violation based on the 2010 Amendment).

Relator includes both mechanisms in his Fifth Amended Complaint. Count I asserts liability under the AKS 2010 Amendment. Count II asserts liability under the false certification theory. Finally, Count III asserts an FCA conspiracy claim. Relator premises all three claims on the same illegal remuneration allegations. This Order addresses all three theories of liability.

Relator kicked off this round of partial summary judgment motions with a narrow request. Doc. 493. He asks the court to grant summary judgment in his favor against three of Medtronic’s affirmative defenses, to the extent those defenses respond to the Dole VA-meals-as-illegal-remuneration allegation. *Id.* at 2–3. Medtronic responded with a more sweeping partial summary judgment motion of its own. Doc. 515. Medtronic seeks summary judgment in its favor against all three claims to the extent Relator premises those claims on any form of illegal kickback. *Id.* at 1. Then, HRMC chimed in with its own Motion for Summary Judgment. Doc.

545. HRMC moves for summary judgment against all of Relator's claims as they apply to HRMC. *Id.* at 1.

Two caveats merit mention. *First*, there's another portion of this case—premised on the use of medically unnecessary devices—that's not at issue in any of these motions. Relator brought the medically unnecessary claims against Medtronic and another defendant, Wichita Radiological Group, P.A. (WRG). But Relator doesn't press this theory of liability against HRMC. So, Medtronic seeks only partial summary judgment because the medically unnecessary claims continue no matter the outcome on the illegal kickback claims currently at issue. And because the medically unnecessary claims don't target HRMC, its Motion for Summary Judgment encompasses all claims against HRMC.

*Second*, much of the summary judgment briefing implicates bundled medical device transactions between Medtronic and HRMC. Relator alleges that Medtronic provided free, no-charge devices to HRMC when HRMC purchased a particular quantity of medical devices. The parties' papers argue whether those free devices amount to an illegal kickback. But the court's earlier Order (Doc. 565)—issued after the parties completed briefing here—rendered the free device theory moot. That Order concluded that the no-charge devices qualify for safe harbor treatment under either the regulatory safe harbor provisions or the statutory discount exception. Doc. 565 at 61. So, the court already has granted summary judgment to Medtronic and HRMC on the no-charge devices claim. The court thus doesn't entertain any no-charge device arguments in this round of briefing. Relator asks the court to reconsider (Doc. 568) its no-charge device ruling and hear oral argument on that reconsideration (Doc. 576). The court declines both of Relator's requests, and explains why, below.

In sum, this Order thus decides whether Medtronic providing meals (and a few gifts) to cath lab employees at HRMC and Dole VA could violate the FCA under either theory of liability—the 2010 Amendment-based claim (Count I) or the false certification theory (Count II). And, separately, this Order takes up whether the meals-as-illegal-remuneration theory can support (or help to support) an FCA conspiracy claim (Count III). The court concludes that the HRMC meals can’t suffice to induce medical device sales. So, no illegal remuneration allegations against HRMC survive summary judgment, and all three claims against HRMC fail as a matter of law. The court thus grants HRMC’s summary judgment motion and dismisses it as a defendant. This conclusion also means that Relator’s claims against Medtronic relying on illegal kickbacks to HRMC likewise fail.

The other claims against Medtronic are a different story, however. Count I—as alleged against Medtronic for its meals and gifts to Dole VA—survives. Genuine issues of material fact preclude summary judgment in Medtronic’s favor. So, the court denies Medtronic’s partial summary judgment motion on the Dole VA claims in Count I. Count II against Medtronic likewise survives, but—as with Count I—just to the extent it relies on meals or gifts provided to Dole VA. That leaves Count III’s conspiracy claim. The portion of this conspiracy claim relying on a Medtronic-HRMC agreement to get false claims paid fails as a matter of law because the court has concluded Medtronic didn’t provide illegal remuneration in any form to HRMC. The portion of the conspiracy claim that relies on a Medtronic-WRG-Teri Brinkley agreement survives, however, because it’s uncontested on the present motions.

Finally, the court denies Relator’s partial summary judgment motion seeking judgment against Medtronic’s affirmative defenses. The court concludes the affirmative defenses aren’t defenses at all. In essence, these “defenses” try to refute elements of Relator’s claims. So, the

court strikes them as affirmative defenses and construes them as denials of elements of Relator's claims. The court thus denies Relator's Motion for Partial Summary Judgment.

After the court explains these various-and-sundry summary judgment rulings, it addresses Relator's Motion for Reconsideration (Doc. 568), Motion for Oral Argument (Doc. 576), and several pending sealing motions. To kick things off, the court recites the background facts.

## **I. Background**

This case has been pending for more than eight years. The court has recited the background facts on several occasions. So, the court assumes some familiarity with the case and just recites the facts necessary to rule the summary judgment motions at issue now. The following facts are uncontroverted for purposes of the parties' summary judgment motions, unless otherwise noted. Where controverted, the court views the facts in the light most favorable to the non-movant. The court first introduces the parties and then explains the alleged illegal remuneration—meals and gifts.

### ***Parties Involved***

Here are the parties involved in the at-issue motions. HRMC is a not-for-profit hospital in Hutchinson, Kansas, organized under the laws of the state of Kansas. Doc. 233 at 5 (Fifth Am. Compl. ¶ 7); Doc. 379 at 1 (HRMC admitting allegation). Medtronic is a medical device company. Doc. 384 at 2. Medtronic, Plc. acquired Covidien, Plc. in 2015. *Id.* Over time, by and through its employees, Medtronic began making, using, selling and/or importing medical devices formerly sold by Covidien. *Id.* Dole VA provides services to veterans in the United States and is located in Wichita, Kansas. Doc. 233 at 8 (Fifth Am. Compl. ¶ 18). Relator Thomas Schroeder was a sales manager for a medical device company who competes with Medtronic. *Id.* at 3 (Fifth Am. Compl. ¶ 2).

Familiarity with two individuals also provides helpful context to the present dispute. They are the person who allegedly purchased Medtronic's devices for Dole VA and the person who allegedly induced those purchases for Medtronic. *First*, Teri Brinkley worked as Dole VA's cath lab manager starting in 2012. Doc. 494-5 at 4 (Brinkley Dep. 23:19–24:10). Before then, she worked as a radiology tech from 2006 to 2011 and as acting manager of the cath lab from 2011 to 2012, both at Dole VA. *Id.* Her job as cath lab manager included some involvement in purchasing medical devices from sales representatives, though the parties dispute the precise nature of that involvement. Brinkley contends she just purchased the devices the physicians wanted. Doc. 516-5 at 7 (Brinkley Dep. 28:13–29:25). But Relator notes testimony by doctors and other sales representatives suggesting Brinkley controlled both the medical device purchase decisions and the sales reps' access to doctors. *See, e.g.*, Doc. 494-6 at 3 (Gonda Dep.); Doc. 381-15 at 6–7, 8 (Valdivia Dep. 13:13–14:13, 18:17–19:24).

*Second*, one of the sales reps Brinkley interacted with was Doug Winger. Doc. 494-5 at 8–9 (Brinkley Dep. 95:17–98:1). Winger worked as a medical device sales representative for Medtronic. Doc. 494-2 at 6 (Winger Dep. 24:20–25). He transferred from his position as a Covidien sales rep when Medtronic purchased Covidien sometime in 2015. *Id.* (Winger Dep. 24:23–25:20). He has held the same position his entire time at Medtronic. *Id.* (Winger Dep. 25:18–20). According to Winger, Brinkley would “try[] every angle” to purchase devices from him for Dole VA. *Id.* at 12 (Winger Dep. 178:5–24)

### ***Meals Medtronic Provided to Dole VA***

Winger, on Medtronic's behalf, provided meals to cath lab employees at Dole VA, including Brinkley. Doc. 494-5 at 9 (Brinkley Dep. 99:17–100:11). The frequency of those meals is disputed. Brinkley testified lunches occurred two or three times a week, though not every week. *Id.* (Brinkley Dep. 99:17–25). Other testimony suggests Medtronic didn't provide

lunches each week, Doc. 381-15 at 22 (Valdivia Dep 75:5–9), but perhaps just once or twice a month, Doc. 516-6 at 10–11 (Hett Dep. 25:22–26:19). Some of those lunches included educational content provided by Winger. Doc. 381-10 at 85 (Winger Dep. 333:12–21) (explaining the educational content provided and testifying that he always included such content with the meals). But the parties dispute whether Winger always provided that content. *Id.*; Doc. 527-19 at 3 (Hett Dep. 33:21–34:1) (estimating Winger would “talk shop” at about half the lunches). Expense reports suggest lunch meals came from restaurants like Chipotle, Panera Bread, and Pizza Hut. Doc. 516-17 at 17, 21.

Winger also took Dole VA cath lab employees, including Brinkley, out to dinner occasionally. Doc. 494-5 at 9 (Brinkley Dep. 100:21–101:24). Some of the restaurants where they dined included Newport Grill, Doc. 527-19 at 4 (Hett Dep. 46:14–18), Chester’s Chophouse, and Scotch & Sirloin, Doc. 516-17 at 8, 17. Again, the frequency and educational content of those dinners is disputed. Doc. 494-5 at 9 (Brinkley Dep. 100:21–101:24) (testifying dinners occurred less than once each month and always included educational content); Doc. 527-19 at 4 (Hett Dep. 45:18–47:11) (estimating the dinners occurred once per month and never included educational content).

Over nine years, from March 2011 to March 2020, Medtronic’s expense reports reveal it spent \$24,603.72 on lunches provided to Dole VA. Doc. 494-14 at 5 (Fox Report). From those expense reports, Medtronic calculated an average cost of \$13.35 per person, per meal. Doc. 516-1 at 5 (Huyser Decl. ¶ 42). Relator contends, however, that the frequency of the meals suggests a much higher figure. His expert utilized the average transaction total from the expense report—\$124.26 per meal—and the meal frequency of two lunches per week and one dinner per month to calculate total meal expenditures of \$101,023.38. Doc. 494-14 at 4 (Fox Report).

### ***Gifts Medtronic Allegedly Provided to Teri Brinkley***

The parties also dispute whether Winger provided gifts to Brinkley. Some testimony indicates Winger gave Brinkley NASCAR tickets, an iPhone, and an iPad. Doc. 381-15 at 22 (Valdivia Dep. 75:18–77:5). Brinkley and Winger both refute that testimony. Winger testified that he never gave Brinkley tickets to any sporting event and only provided Brinkley devices that she borrowed or bought from him. Doc. 381-10 at 85 (Winger Dep. 331:5–23). And Brinkley explained that she purchased Winger’s old iPhone at fair market value. Doc. 516-5 at 18 (Brinkley Dep. 102:25–104:8).

### ***Meals Medtronic Provided to HRMC***

Winger, on Medtronic’s behalf, also provided meals to the cath lab at HRMC. Doc. 546-10 at 3 (Winger Dep. 258:24–259:9). He claims he provided educational content with lunch “a lot of the times.” *Id.*; *see also* Doc. 546-2 at 5 (Naab Dep. 92:11–14) (confirming HRMC asked all sales reps to provide educational content with lunch). A sales rep from another company, Todd Brown, testified that he witnessed lunches Winger purchased but didn’t attend. Doc. 551-5 at 7 (Brown Dep 32:3–19). And, Brown testified, when he witnessed Winger’s presence at lunch, he never saw him provide an educational program. *Id.* at 8–9 (Brown Dep. 76:7–77:2).

Based on Medtronic’s expense reports, Medtronic sales reps held an average of about eight lunches per year for HRMC cath lab employees. Doc. 516-1 at 5 (Huyser Decl. ¶ 40). Over nine years, from March 2011 to March 2020, Medtronic’s expense reports reveal it spent \$16,034.54 on lunches to HRMC. Doc. 494-14 at 5 (Fox Report). From those expense reports, HRMC calculated an average cost of \$11.87 per person per lunch. Doc. 516-1 at 5 (Huyser Decl. ¶ 40). Relator doesn’t contest the monetary value of the reported lunches, but questions whether Medtronic employees reported all the meals. Doc. 551 at 21. He never offers a competing monetary value, however. *See generally id.*



The court now turns to the three pending summary judgment motions. HRMC moves for summary judgment in its favor on all Relator's claims against it. Doc 545. Given the court's earlier Order concluding the no-charge devices aren't illegal remuneration, Doc. 565 at 61, all of Relator's claims against HRMC derive from HRMC accepting meals from Medtronic, Doc. 546 at 15. Medtronic moves for partial summary judgment on all three claims in Counts I, II, and III to the extent those claims rest on alleged illegal kickbacks to HRMC and Dole VA. Doc. 515 at 1. Finally, Relator moves for summary judgment on Medtronic's affirmative defenses to the Dole VA meals-as-kickbacks claim. Doc. 493 at 2. Specifically, Relator asks the court to grant him summary judgment against all three of Medtronic's affirmative defenses for the Dole VA meals, namely: (1) Medtronic acted in good faith, not providing the meals with any improper or illegal purpose or intent; (2) Medtronic complied with laws and regulations when it provided the meals; and (3) Relator's claims rely on ambiguous FCA provisions and so aren't viable. Doc. 384 at 23–24.

The court addresses, *first*, alleged kickbacks from Medtronic to HRMC and HRMC's summary judgment motion. *Second*, the court takes up alleged kickbacks from Medtronic to Dole VA and Medtronic's summary judgment motion against Count I. Then, the court considers Relator's summary judgment argument, which also draws on Count I's kickback allegations. Once it wraps up kickbacks and Count I, the court then evaluates Counts II and III. The Order finishes by ruling several other motions, including ones seeking reconsideration of an earlier decision, an oral hearing, and sealing. To start, the court recites the legal standard for summary judgment motions—highlighting that the same standard applies to the whole spectrum of summary judgment motions at issue here—whether full motions, partial motions, or motions attacking affirmative defenses.

## II. Legal Standard

Fed. R. Civ. P. 56(a) contemplates both full and partial summary judgment motions: “A party may move for summary judgment, identifying each claim or defense—or the part of each claim or defense—on which summary judgment is sought.” It also permits a movant to train such a motion on an affirmative defense. *See* 10B Charles A. Wright, Arthur R. Miller, & Adam N. Steinman, *Federal Practice & Procedure* § 2734 (4th ed. 2024) (explaining that a plaintiff may move for summary judgment “to test a defense’s sufficiency”). Rule 56 provides the same standard regardless of a motion’s variety: “The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a).

“An issue of fact is ‘genuine’ ‘if the evidence is such that a reasonable jury could return a verdict for the non-moving party’ on the issue.” *Nahno-Lopez v. Houser*, 625 F.3d 1279, 1283 (10th Cir. 2010) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). “An issue of fact is ‘material’ ‘if under the substantive law it is essential to the proper disposition of the claim’ or defense.” *Id.* (quoting *Adler v. Wal-Mart Stores, Inc.*, 144 F.3d 664, 670 (10th Cir. 1998)). Those “facts must be identified by reference to affidavits, deposition transcripts, or specific exhibits incorporated therein.” *Adler*, 144 F.3d at 671. “Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment.” *Anderson*, 477 U.S. at 248.

The court views the evidence referenced in the parties’ summary judgment papers (and inferences drawn from it) in the light most favorable to the non-moving party. *Nahno-Lopez*, 625 F.3d at 1283. When deciding whether the parties have shouldered their summary judgment burdens, “the judge’s function is not . . . to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.” *Anderson*, 477 U.S. at 249.

The federal courts don't view summary judgment as a "disfavored procedural shortcut[.]" *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986). To the contrary, it's an important procedure "designed 'to secure the just, speedy[,] and inexpensive determination of every action.'" *Id.* (quoting Fed. R. Civ. P. 1).

The court dives into its analysis by assessing Relator's kickback allegations. Relator's Count I FCA claim requires a successfully established AKS violation. These kickbacks allegedly provide the requisite violation. As explained more later, these kickback allegations also inform whether the claims in Counts II and III survive.

### **III. Illegal Remuneration**

Congress intended for the AKS to "to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the Medicare and Medicaid programs." *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 96 (3d Cir. 2018) (quotation cleaned up). To accomplish this end, the AKS sweepingly prohibits illegal remuneration when "payment may be made in whole or in part under a Federal health care program[.]" 42 U.S.C. § 1320a-7b(b)(1)–(2).

At issue here, Relator alleges that Medtronic provided illegal remuneration to HRMC and Dole VA to induce medical device sales. Doc. 233 at 16 (Fifth Am. Compl. ¶ 43). This allegedly illegal remuneration took two forms: (1) free medical devices provided through bundled transactions and (2) other assorted kickbacks—things of value such as sporting event tickets, free technology, and meals. *See id.* at 19 (Fifth Am. Compl. ¶ 56) (alleging Medtronic provided Dole VA cath lab employees with NASCAR tickets, iphones, ipads, weekly/daily lunches, frequent nights out at bars and restaurants); *id.* at 29 (Fifth Am. Compl. ¶ 88) (alleging Medtronic provided HRMC employees with "meals, food, alcohol, gratuities, event sponsorships, NASCAR and other sporting event tickets, golf outings and travel expenses").

Medtronic allegedly provided these kickbacks with the intent of inducing medical device sales. *See id.* at 19, 29 (Fifth Am. Compl. ¶¶ 56, 88).

Relator later abandoned his allegations of Medtronic’s more extravagant kickbacks to HRMC employees—gifts like event tickets, golf outings, alcohol, and gratuities. He expressly limited the alleged Medtronic-HRMC illegal remuneration to free devices and meals. Doc. 381 at 16–18. As clarified earlier, the court already has ruled on free devices as illegal remuneration, holding such transactions qualify for the safe harbor of the AKS. Doc. 565 at 61. Now, the sole surviving kickback allegation from Medtronic to HRMC is meals. Kickback allegations from Medtronic to Dole VA, however, still include alleged gifts as well as meals. The court thus addresses Medtronic providing both meals and gifts to Dole VA in § III.C, below.

#### **A. Violating the AKS**

For Relator to marshal a triable claim that defendants violated the AKS through exchanging illegal remuneration, he must satisfy three elements: Defendants “(1) knowingly and willfully (2) solicited or received remuneration (3) in return for, or to induce” the purchase or ordering of products for which a Federal healthcare program may pay. *U.S. ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568, at \*4 (E.D. Pa. June 19, 2017); *see also U.S. ex rel. Everest Principals, LLC v. Abbot Lab’ys, Inc.*, 622 F. Supp. 3d 920, 930 (S.D. Cal. 2022) (same). Courts have derived these three enumerated elements directly from the AKS’s statutory language. As it applies to the party allegedly *accepting* illegal remuneration—here HRMC—the statute provides

- (1) Whoever *knowingly and willfully* solicits or receives *any remuneration* (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind— . . .
- (B) *in return for purchasing, leasing, ordering, or arranging for or recommending* purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty[.]

42 U.S.C. § 1320a-7b(b)(1)(B) (emphasis added). The statute invokes the same three elements to apply to the party allegedly *proffering* illegal remuneration (here Medtronic). *See id.* § 1320a-7b(b)(2)(B).

So, the court begins its analysis by deciding whether a reasonable jury could find that Medtronic offered—and HRMC received—remuneration knowingly and willfully to induce medical device purchases. After concluding that analysis, the court considers the same three elements for Medtronic’s alleged proffers of illegal remuneration to the Dole VA.

### **B. Meals from Medtronic to HRMC**

As already explained, various rounds of briefing and the court’s discount safe harbor Order (Doc. 565) have whittled down the allegedly illegal remuneration from Medtronic to HRMC. All that’s left are meals. HRMC moves for summary judgment on the meals-as-illegal-remuneration theory, arguing that the “modest in-service lunches do not constitute AKS remuneration because they were of nominal value, both individually, and holistically.” Doc. 546 at 15. HRMC also contends that these meals ““could not reasonably be expected to induce a referral.”” *Id.* (quoting *Miller v. Abbott Lab ’ys*, 648 F. App’x 555, 561 (6th Cir. 2016)). Medtronic likewise moves for summary judgment against Relator’s claim that these meals qualify as illegal remuneration. It explains that what remains “after seven years and millions of dollars of litigation costs, are approximately eight modest in-service lunches provided each year with an average cost of \$11.87 per person.” Doc. 516 at 47.<sup>1</sup>

---

<sup>1</sup> Relator’s Partial Summary Judgment motion (Doc. 493) doesn’t address the alleged HRMC-Medtronic kickbacks. It confines its request for summary judgment to Medtronic’s affirmative defenses based on meals specifically provided to Dole VA. So, in this section, Relator is the non-movant, receiving the benefit of the view of the summary judgment record and all reasonable inferences drawn from it.

Relator initially responds that even such modest lunches are industry-appropriate only when accompanied by in-service educational programs—and these weren’t. Doc. 551 at 20. HRMC and Medtronic disagree. Doc. 546 at 11; Doc. 516 at 48. Relator also suggests discovery didn’t reveal all the lunches because Medtronic possessed incomplete expense reports. Doc. 551 at 21. But, in the end, Relator concedes the lunches—standing alone—can’t satisfy the third element required under the AKS: intent to induce. *See* Doc. 527 at 33. Rather than assess each prong of the illegal remuneration claim, the court jumps straight to the dispositive one. The court grants summary judgment to HRMC and Medtronic on the meals-provided-to-HRMC theory of illegal remuneration. As Relator concedes, no jury could conclude reasonably that these meals induced HRMC to order medical devices from Medtronic.

### **1. Law on Intent to Induce**

“[C]ourts widely agree that the gravamen of Medicare fraud is inducement.” *Jones-McNamara v. Holzer Health Sys.*, 630 F. App’x 394, 400 (6th Cir. 2015) (internal quotation marks and citation omitted). The Tenth Circuit adheres to the one-purpose test for inducement: “[A] person who offers or pays remuneration to another person violates the [AKS] so long as one purpose of the offer or payment is to induce Medicare or Medicaid” payments for the purchased items. *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000). The Office of the Inspector General for the Department of Health and Human Services (HHS OIG) has defined the “term ‘induce’ as the necessary intent ‘to lead or move by influence or persuasion.’” *Jones-McNamara*, 630 F. App’x at 401 (quoting 56 Fed. Reg. 35952, 35938 (July 29, 1991)). In light of this understanding, HHS OIG permits gifts of nominal value under the AKS “because those items or services could not reasonably be expected to induce a referral.” *Miller*, 648 F. App’x at 561; *see also* 68 Fed. Reg. 14245, 14252 (Mar. 24, 2003) (explaining to ambulance suppliers that “token gifts used on an occasional basis to demonstrate good will or appreciation (e.g., logo key

chains, mugs, or pens) will be considered to be nominal in value” and thus won’t violate the AKS). “In short, a kickback violation entails 1) remuneration to a person or entity in a position to refer Federal health care program patients 2) that could reasonably induce the person or entity to refer such patients.” *Jones-McNamara*, 630 F. App’x at 401.

## **2. Analysis**

Here, Relator implicitly concedes that Medtronic’s meals to HRMC can’t suffice to induce device purchases. So, the court concludes Relator’s allegation of illegal kickbacks between HRMC and Medtronic fails at prong three. That’s because, taking all inferences in favor of Relator—as the nonmovant—a reasonable jury might conclude these allegations support the first two elements of illegal remuneration. More specifically, at prong one, a reasonable juror could conclude that the absence of educational content made the meals illegal remuneration. And perhaps, at prong two, a reasonable juror could conclude Medtronic knowingly and willingly provided—and HRMC knowingly and willingly accepted—the meals as illegal remuneration. Nonetheless, Relator’s theory of a meal-based AKS violation grinds to a halt at prong three—intent to induce. That’s because no reasonable jury could conclude that a smattering of modest lunches valued at \$11.87 per person could induce medical device sales. Doc. 516-1 at 5 (Huyser Decl. ¶ 40) (calculating, based on expense reports, average cost of \$11.87 per person, per meal). And, seeing the writing on the wall, Relator implicitly concedes as much in his Response to Medtronic’s motion. Here’s what he concedes:

Relator has also alleged that meals Winger provided to HRMC cath lab staff were illegal remuneration under the AKS—*i.e.*, no educational programs were being provided. Unlike the significant bribes [bundled discounts] paid to HRMC, the meals alone may not have sufficed to evidence inducement of sales under the AKS. However, they still matter and play a role *coupled with Medtronic’s bribes* [bundled discounts] as sufficient evidence to further Relator’s position.

Doc. 527 at 33 (emphasis added). The court already has decided the bundled discounts—which Relator refers to as the “bribes”—excepted under the AKS’s discount safe harbor. *See* Doc. 565. So, the meals now stand alone. They are no longer “coupled,” as Relator puts it. Doc. 527 at 33. And, as Relator also recognizes, no reasonable jury could find that these modest meals—standing alone—could induce sales given their nominal value. Without sufficient inducement power, a reasonable jury couldn’t conclude that Medtronic’s meals to HRMC violated the AKS.

This conclusion wipes out all HRMC-Medtronic illegal remuneration allegations. Initially, Relator alleged three categories of alleged illegal kickbacks: gifts, free devices, and meals. But Relator surrendered his allegations of gifts to HRMC. Doc. 381 at 16–18. The court concluded that the free devices qualified for the AKS’s safe harbor provision and thus don’t violate the AKS. Doc. 565 at 61. And now, even Relator acknowledges the meals—standing alone—can’t suffice to induce purchases. With no surviving kickback allegations, no FCA liability for a false or fraudulent claim can follow. The court thus grants summary judgment to Medtronic and HRMC against the claim advanced by Count I—to the extent this claim relies on the exchange of illegal remuneration between Medtronic and HRMC.

That doesn’t dispose of Count I completely, however. Relator also alleges under Count I that Medtronic provided illegal remuneration to Dole VA. The court takes up the Medtronic-Dole VA illegal remuneration allegations, next. These allegations inform both Medtronic’s motion against the claim in Count I and Relator’s motion attacking Medtronic’s affirmative defenses. The court begins with Medtronic’s motion. It concludes that genuine disputes of material fact surface at each illegal remuneration prong, precluding summary judgment. Then, the court turns to Relator’s arguments about Medtronic’s affirmative defenses.



### **C. Illegal Remuneration from Medtronic to Dole VA Cath Lab**

Relator alleges that Medtronic provided meals and a few gifts to the Dole VA cath lab. The court evaluates the meals first, followed by the gifts. Recall the three prongs for illegal remuneration under the AKS: “Stating an AKS violation . . . requires . . . the defendant (1) knowingly and willfully (2) offered or paid remuneration, (3) to induce the purchase or ordering of products or items for which payment may be made under a Federal healthcare program.” *Everest Principals*, 622 F. Supp. 3d at 930 (quotation cleaned up). So, to secure summary judgment in its favor, Medtronic must establish—as a matter of law—that Relator failed to satisfy one of these three prongs. Because the court just finished discussing this requirement above, the court begins with the third prong: intent to induce.

#### **1. Meals as Illegal Remuneration**

##### **a. Intent to Induce**

Remember one aspect of the intent to induce analysis involves nominal value. The court must assess whether the meals’ value was so nominal that they “could not reasonably be expected to induce” a purchase. *Miller*, 648 F. App’x at 561. As summarized earlier, the parties essentially agreed that a smattering of meals couldn’t induce medical device purchases. *See* § III.B.2. One might think the same holds true when applied to Dole VA’s cath lab. Not so.

The frequency and type of the meals Medtronic allegedly provided to Dole VA’s cath lab differ meaningfully from those allegedly provided to HRMC’s cath lab. Even more problematic at the summary judgment stage, the parties dispute material facts about how often and how extravagant these meals were.

Relator asserts that Medtronic’s meal expenditures over the relevant period far exceed those captured in the expense reports. Those reports capture \$24,603.72 in meal expenditures

between March 15, 2011 and March 24, 2020, according to Relator’s expert. *See* Doc. 494-14 at 5 (Fox Report). Aspiring to expand this figure, Relator invokes Brinkley’s testimony. Brinkley testified that Medtronic would bring in lunch to the cath lab often, “[i]t seemed like it was two or three times a week[.]” Doc. 494-5 at 9 (Brinkley Dep. 99:17–25). Relator then combines that twice-a-week average with Stan Hett’s testimony—another employee at the Dole VA cath lab—that estimated once-a-month dinners out. Doc. 527-19 at 4 (Hett Dep. 45:22–46:4). Using these metrics, Relator’s expert calculated total meal expenditures of \$101,023.38, based on an average transaction total—derived from the expense reports—of \$124.26. Doc. 494-14 at 4 (Fox Report ¶ 8). In short, Relator contends Medtronic spent three times as much on meals than its expense reports reveal.

But Relator’s meal frequency metrics used to calculate this \$101,023 are by no means certain. Even the portion of Brinkley’s testimony Relator cited to establish the twice-a-week lunch average is less definitive than he represents. Brinkley’s full answer includes a significant, omitted qualification: “It seemed like it was two or three times a week, *but not always, not every week.*” Doc. 494-5 at 9 (Brinkley Dep. 99:17–25) (emphasis added). What’s more, Brinkley’s testimony about dinners conflicts with Mr. Hett’s once-a-month average: “[i]f we would go out to dinner . . . *it wasn’t once a month. It wasn’t that frequent.*” *Id.* (Brinkley Dep. 101:22–24) (emphasis added). Add in testimony by Medtronic’s sales representative, Winger, and the fact-finding enterprise gets even messier. He estimated meals occurred even less frequently. Doc. 494-2 at 8 (Winger Dep. 116:18–117:6) (“I think I only bought four dinners the whole time I called on them, and probably lunch a couple times a month[.]”). Simply put, estimates about meal frequency are all over the map. And that matters.

To determine whether the meals reasonably could've induced medical device sales, the court must assess the nominal nature of the meals. But this assessment proves impossible with so much varied testimony about meal frequency, unless the court starts weighing the evidence. But the court can't because it's not the court's job "to weigh the evidence and determine the truth of the matter[.]" *Anderson*, 477 U.S. at 249. The court declines to usurp the jury's role to evaluate the credibility of conflicting testimony.

**b. Knowingly and Willfully**

A similar problem surfaces with the next prong—knowingly and willfully offering illegal remuneration. "An act is done willfully if it is done voluntarily and purposely and with the specific intent to do something the law forbids, that is, with the bad purpose either to disobey or disregard the law." *McClatchey*, 217 F.3d at 829 (affirming jury instruction defining willfully for criminal trial of AKS violation). That is, "to violate the federal AKS, a defendant must act knowing that its conduct is, in some way, unlawful[.]" *U.S. ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 150 (2d Cir. 2024). "Accordingly, with few exceptions, a person who acts willfully need not be aware of the *specific* law that his conduct may be violating." *Id.* at 154 (emphasis in original) (internal quotation marks and citation omitted). Instead, knowing "that the conduct is unlawful is all that is required." *Id.* (quoting *United States v. Henry*, 888 F.3d 589, 599 (2d Cir. 2018)).

Medtronic asserts the summary judgment facts demonstrate that Medtronic—and the cath lab employees—didn't believe they were violating the law. Doc. 516 at 73. To demonstrate Medtronic didn't act willfully, it highlights the Dole VA's apparent acceptance of the practice. *See id.* at 26–27. In particular, Medtronic dwells on manager Brinkley's statements that she did not "think there was anything improper" about allowing lunches to come in. *Id.* at 26 (quoting Doc. 516-5 at 36 (Brinkley Dep. 230:12–231:10)). And Medtronic notes that representatives

from other companies also brought in food. As Winger explained, “[The cath lab] had expectation that someone, some rep would feed them . . . . They got food from us [Medtronic], from Abbott, from Boston, from about every medical device company that went in there.” Doc. 381-10 at 66 (Winger Dep. 254:25–255:4). Dole VA’s acceptance of the meals, Medtronic argues, shows no one knowingly violated the law. Doc. 516 at 26–27.

But Relator strikes back with his own evidence. Perhaps most damning to Medtronic’s willfulness argument is manager Brinkley’s statement—in a different part of her deposition testimony—that she *knew* it was wrong to accept the lunches.

Q: And as far as him bringing in the lunches for the cath lab staff, and as it relates to that training that you’ve described, was it your understanding that doing so violated any VA policies?

A: Yes, I knew it wasn’t right.

Doc. 494-12 at 4 (Brinkley Dep. 14:25–15:4). Medtronic does its best trying to cabin Brinkley’s knowledge to post-2018. *See* Doc. 516 at 26. But, even in the context of earlier lunches from another companies’ sales representative—Monique Lloyd—Brinkley confessed, “I knew that they really weren’t supposed to bring lunches.” Doc. 516-5 at 40 (Brinkley Dep. 248:18–249:1).

Adding on, Relator points to a specific Covidien policy counseling caution when selling devices to a governmental entity.

The sale of goods and services to government organizations is heavily regulated. Covidien employees involved in sales to governmental customers must take necessary steps to ensure that all government-related transactions and relationships comply with the applicable laws and regulations, including the provision of gifts.

Doc. 469-2 at 24 (Rel. Ex. 47). Again, this juxtaposition of contradictory testimony leaves the court to weigh the evidence at summary judgment, a posture it diligently must avoid.

### c. Illegal Remuneration

Finally, the court turns to the last prong—illegal remuneration. The statute defines “remuneration” as “transfers of items or services for free or for other than fair market value.” 42 U.S.C. § 1320a-7a(i)(6). Courts have found “[f]ees, food and drink, travel, and lodging qualify as any remuneration, as long as any part of the remuneration was paid to induce[.]” *United States ex rel. Wilkerson v. Allergan Ltd.*, No. 22 CV 3013, 2024 WL 1242989, at \*11 (N.D. Ill. Mar. 22, 2024) (internal quotation marks and citations omitted). Some courts embrace a broad definition of remuneration, taking it “to mean anything of value,” *Everest Principals*, 622 F. Supp. 3d at 930 (internal quotation marks and citation omitted), or “virtually anything of value . . . in any form whatsoever[.]” *Jones-McNamara*, 630 F. App’x at 400 (internal quotation marks and citation omitted). But other courts caution against an “overly broad” interpretation of the term and explain that remuneration “demands the transfer of something with substantial independent value.” *U.S. ex rel. PCTLS, LLC v. Nw. Mem’l Healthcare*, No. 19-cv-00593, 2023 WL 6388328, at \*5 (N.D. Ill. Sept. 29, 2023) (quotation cleaned up). Other courts also have interpreted AKS remuneration narrowly—in light of the rule of lenity—because the AKS is a criminal statute. *U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1050 (6th Cir. 2023) (“In the context of dual-application statutes . . . we give the same interpretation to the same words, whether applied in a civil or criminal setting. That means that, if ambiguity exists over the meaning of a provision, the rule of lenity favors the narrower definition.”)

Medtronic argues that the meals don’t qualify as illegal remuneration because educational presentations accompanied the meals. And, Medtronic contends, HHS-OIG guidance aligns with this educational-meals approach. According to Medtronic, HHS-OIG doesn’t “advise healthcare providers that *all* meals are prohibited. Rather it expressly advises companies to rely on long-standing industry guidance[.]” Doc. 516 at 47 (emphasis in original). Medtronic then identifies

industry guidance that permits “low-cost meals provided along with information to health care providers[.]” *Id.* at 48.

And so, Medtronic, citing deposition testimony, tries to establish the meals it provided to Dole VA involved the requisite education to avoid the illegal remuneration classification. Winger testified that he provided in-service education with those meals. Doc. 381-10 at 85 (Winger Dep. 333:12–15). When asked to describe the content of this educational component, he explained “I would work with the staff on the TurboHawk device, just showing them how to use it, how to clean it, which one to pull for what vessel size.” *Id.* (Winger Dep. 333:18–21). And he testified that dinners out also involved discussing Medtronic products. *Id.* at 86 (Winger Dep. 334:6–7).

Relator asserts just the opposite. He contends education didn’t accompany the meals. And he points to deposition testimony supporting his version of the events. When asked if Winger gave presentations with each of the lunches, Brinkley answered with an unqualified “no.” Doc. 494-5 at 9 (Brinkley Dep. 100:12–20). And when asked if he ever provided other lunchtime education “[r]egarding his product or his devices” Brinkley replied: “Maybe a few times, but not every time, no.” *Id.* Brinkley’s answer shifted when it came to dinners outside the office, however: “if we would go out to dinner, there would always be something educational discussed[.]” *Id.* (Brinkley Dep. 101:22–24).

Another individual who worked in the Dole VA cath lab recalled it differently. *See id.* (Brinkley Dep. 101:10–12) (establishing Mr. Hett was a radiology tech in Dole VA’s cath lab during period when Medtronic brought meals in). Mr. Hett recalled “talk[ing] shop” about “50 percent” of the time when Medtronic brought in lunch. Doc. 527-19 at 3 (Hett Dep. 33:21–34:1). But when it came to dinners out, he didn’t remember any “educational discussion” about

“products or devices or procedures.” *Id.* at 4 (Hett Dep. 47:3–11). They just discussed “everyday life.” *Id.*

These vastly different accounts of the degree of mealtime educational content manifest yet another genuine dispute over a material fact. Taking stock, these disputes are genuine, they matter, and they surface at each prong of the AKS meals-as-illegal-remuneration analysis. The court concludes that Relator has adduced enough evidence to permit a reasonable jury to find for Relator. This conclusion precludes the court from granting summary judgment in Medtronic’s favor.

## **2. Gifts as Illegal Remuneration**

Though Relator and Medtronic give it little attention in the argument sections of their papers, another alleged form of illegal remuneration remains in dispute as well: gifts to Teri Brinkley. Relator has alleged that Medtronic (through Winger) provided gifts—NASCAR tickets, an iPhone, and an iPad—to Teri Brinkley at Dole VA. *See* Doc. 233 at 19 (Fifth Am. Compl. ¶ 56). The summary judgment briefing refers to these alleged gifts, but almost exclusively in the fact sections. *See* Doc. 516 at 24–26; Doc. 527 at 9, 17. Medtronic’s argument section includes just one reference to these gifts, and it’s a perfunctory one. *See* Doc. 516 at 44 (“[T]here is no evidence that gifts, tickets, trips, or other alleged extravagant kickbacks occurred.”). Relator’s argument sections—not to be outdone—never reference these gifts at all. *See generally* Doc. 494; Doc. 527. That is, the parties don’t debate whether these gifts would induce purchases, were provided knowingly, or qualify as illegal remuneration. Medtronic just says the evidence doesn’t prove the gifts existed. Doc. 516 at 44. And Relator cites testimony indicating that they did. Doc. 527 at 17.

In the end, the court’s analysis of the alleged gifts mirrors that of the alleged meals—ending with a genuine dispute of material fact. And, following the parties’ lead, the court addresses it but briefly.

Two witnesses purportedly support Relator’s allegation that Brinkley received gifts—Mary Bunting and Larry Valdivia. According to Bunting, Brinkley got an iPhone from a sales rep, though Bunting didn’t know which representative. Doc. 516-18 at 7 (Bunting Dep. 23:2–20). Ms. Bunting also didn’t know whether Brinkley had paid for the phone or gotten it for free. *Id.* at 11 (Bunting Dep. 42:15–43:7). Mr. Valdivia testified that Brinkley told him in 2010 or 2011 that she’d received NASCAR tickets, an iPhone, an iPad, and a backpack from Medtronic’s sales rep. Doc. 381-15 at 22 (Valdivia Dep. 75:23–77:5). When asked about it again later, Valdivia identified the time when these gifts were made as anywhere from 2016 to 2018. *Id.* at 32–33 (Valdivia Dep. 114:6–118:10).

On the other side of the scale, two witnesses purportedly disprove Relator’s gift allegation—Brinkley and Winger. Brinkley testified that she never received any NASCAR tickets from Winger. Doc. 516-5 at 18 (Brinkley Dep. 102:20–24). She also testified that she got an iPhone from Winger but she “paid fair market value for it” and “didn’t get anything as a favor . . . it wasn’t a discount.” *Id.* (Brinkley Dep. 102:25–104:8). Winger, the allegedly complicit sales rep, denied providing any tickets to Brinkley. Doc. 381-10 at 85 (Winger Dep. 331:16–23). He also denied ever providing her with an iPhone or iPad, apart from an old one he either loaned or sold to her. *Id.* (Winger Dep. 331:5–15).

Medtronic, in the fact section of its filing, tries to undermine Bunting and Valdivia’s testimony. *See* Doc. 516 at 25. Medtronic notes, for example that Valdivia’s deposition was inconsistent about the year of the gifts. *Id.*; *See* Doc. 381-15 at 22, 32–33 (first identifying the



gifts timeframe as 2010 or 2011 and later as 2016 to 2018). And Medtronic contrasts this inconsistency with Brinkley’s “more specific recollection.” Doc. 516 at 25. But that argument is indeed the point. Medtronic’s argument invites the court again to weigh the evidence. That’s not the court’s job at summary judgment. Indeed, it’s more than that: it’s an endeavor that the court must not undertake at summary judgment. And given that Medtronic presents no other argument—apart from questioning the credibility of the opposing witnesses—the court bows out. The trier-of-fact will have to determine whether Bunting and Valdivia or Brinkley and Winger are more reliable. Finding genuine dispute over a material fact, the court can’t grant summary judgment to Medtronic on the gifts-to-DoleVA-as-illegal-remuneration claim.

Undeterred, Medtronic tries one final tack. Assuming the court finds a dispute about an AKS violation, Medtronic asserts it still deserves summary judgment because Relator hasn’t established the requisite causal relationship to move from an AKS violation to an FCA claim. Doc. 516 at 78. The court engages this causation argument, below, before reaching its conclusion about the claim in Count I.

### **3. But-For Causation**

As outlined earlier, there is more than one mechanism for a Relator to bring an FCA claim premised on an AKS violation. The mechanism for Count I here relies on an amendment to the AKS, 42 U.S.C. § 1320a-7b(g). In 2010, Congress amended the AKS to add the following words: “[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].” *Id.* (emphasis added); *see also Stop Ill. Health Care Fraud, LLC v. Sayeed*, 100 F.4th 899, 904 (7th Cir. 2024) (explaining how Congress amended the AKS in 2010). The parties here debate the kind of causal connection required by the statutory phrase “resulting from.” Medtronic contends that “to prove an AKS-based FCA case” Relator must “show a but-for causal link between an anti-

kickback violation and the items or services included in the claim.” Doc. 516 at 78 (quotation cleaned up). And Medtronic argues that Relator can’t establish that kind of “but-for” causation here. *Id.* at 78–79. To address this argument, the court first surveys the but-for causation landscape as things stands today. The court begins with the circuit split on the question.

Three Circuits have interpreted the “resulting from” language in the 2010 Amendment as requiring “but-for” causation. *See U.S. ex rel. Cairns v. D.S. Med. LLC*, 42 F.4th 828, 836 (8th Cir. 2022) (“[W]hen a plaintiff seeks to establish falsity or fraud through the 2010 amendment, it must prove that a defendant would not have included particular items or services but for the illegal kickbacks.”) (quotation cleaned up); *Martin*, 63 F.4th at 1052 (“Congress added the ‘resulting from’ language in 2010, against the backdrop of a handful of cases that observed similar language as requiring but-for causation.”); *United States v. Regeneron Pharms., Inc.*, 128 F.4th 324, 328 (1st Cir. 2025) (“[T]o treat an AKS violation as a false or fraudulent claim under the FCA, the government must prove that the AKS violation was a but-for cause of the false claim.”). These three Circuits all rely on *Burrage v. United States*, a United States Supreme Court case interpreting similar language—“results from,” albeit in a different criminal statute—as requiring but-for causation. 571 U.S. 204, 216 (2014). *Burrage* explains that “it is one of the traditional background principles against which Congress legislates that a phrase such as ‘results from’ imposes a requirement of but-for causation.” *Id.* at 214 (quotation cleaned up).

The Third Circuit—ruling before the other three Circuits—rejected the “but-for” standard. *See Greenfield*, 880 F.3d 89. To reach its conclusion, *Greenfield* consulted “the drafters’ intentions[.]” *Id.* at 96. The Third Circuit explored the legislative history because it feared incongruous results if it applied *Burrage*—namely, it feared that requiring but-for causation would make it more difficult to prove FCA liability than to prove AKS criminal

conduct. *Id.* *Greenfield* thus concluded but-for causation would prove “inconsistent with the drafters’ intentions” *Id.* Instead, “a ‘link’ is required,” but that causal link “is less than” but-for causation. *Id.* at 98.

So, there’s the circuit split. And our Circuit hasn’t weighed in yet.

This court took up the issue at the motion-to-dismiss stage in 2021. *See U.S. ex rel. Schroeder v. Medtronic, Inc.*, No. 17-2060-DDC-KGG, 2021 WL 4168140, at \*23–24 (D. Kan. Sept. 14, 2021). At that point, the circuit split hadn’t emerged. The court only had the benefit of the Third Circuit’s *Greenfield* opinion. And the court adopted *Greenfield*’s reasoning, though it did so relying heavily on the litigation’s preliminary stage. *See id.* (“But *Greenfield* is a summary judgment case. . . . [Defendant] asks the court to apply a pleading standard that isn’t appropriate before discovery. . . . The court thus rejects . . . this argument *at the motion to dismiss stage*.” (emphasis added)).

Revisiting the causation standard isn’t necessary to decide the motion presently before it. If it were, the court wouldn’t rely on its previous analysis alone. Instead, it would engage in a thorough review of the other Circuits’ reasoning. And it would re-evaluate, in light of the new case law, producing this circuit split. But here’s the thing: even if the court were persuaded by these three new Circuit opinions—requiring but-for causation—it wouldn’t matter here. That’s so because even if the 2010 Amendment requires but-for causation, the summary judgment facts don’t establish conclusively that Relator has failed to adduce a triable claim of but-for causation. The summary judgment facts that control this causation question turn facts that are disputed genuinely. And again, this dispute precludes summary judgment in Medtronic’s favor.

In the context of this case, here’s what but-for causation means: Relator must show that Dole VA wouldn’t have purchased the at-issue Medtronic devices but for Medtronic’s

remuneration to cath lab employees. That is, if Medtronic hadn't provided meals and gifts, Dole VA wouldn't have bought Medtronic's devices, or at least not so many of them. Relator contends a reasonable jury could find but-for causation. He argues, "Medtronic directly made bribes to the VA to induce sales. 'But for' doing so, the sales of their devices arguably would not have occurred." Doc. 527 at 42. And he suggests that "[c]ompetitors were shut out due to these bribes." *Id.*

Medtronic, for its part, contends that "there is no evidence that any food actually influenced any order." Doc. 516 at 79. It argues, *first*, that the recipients of the alleged remuneration weren't decisionmakers. *Id.* Physicians—who didn't receive meals or gifts—drove product choice. *See id.* The cath lab staff simply monitored product levels and re-ordered them, as necessary, Medtronic asserts. *Id.* And providing remuneration solely to non-decisionmakers can't support but-for causation. *Second*, Medtronic contends, the purchasing processes at the VA also precluded but-for causation. That is, others—besides Brinkley—had to sign off on product purchases. *Id.* at 78–79. Because Brinkley didn't purchase devices single-handedly, meals or gifts to Brinkley didn't determine those purchases.

In essence, the causation question here asks this question: were the people receiving the alleged remuneration the ones who decided to buy Medtronic's devices? Narrowing the question even further, it really comes down to one person's role—Brinkley, the cath lab manager. The theory of Relator's claim relies on Medtronic's meals (and other alleged gifts) inducing Brinkley to buy devices from Medtronic, instead of from other companies. *See* Doc. 527 at 9 ("Relator is claiming that Dole VA cath lab *Manager* Teri Brinkley (recipient of the meals, i-phone, i-pad, NASCAR tickets) decided what medical devices were purchased at the Dole VA's cath lab." (emphasis in original)).

The court again concludes that genuinely disputed material facts preclude summary judgment here. The summary judgment facts don't settle the extent of Brinkley's independent decision-making authority—at least not definitively. For starters, Brinkley herself disavows having functioned as a decisionmaker:

Q: As far as the decision, though, that the cath lab needed to get more of a particular type of device to serve future patients, who was it in the cath lab that made that decision? . . .

A: It was pretty much the physician using it, would let me know if we were going—if we needed to stock more.

Q: And then in turn, would you then start filling out this paperwork that you've referenced?

A: Yes. Or I'd—if it had already been done, I'd contract—contact logistics and contracting to order more.

Q: And what you've just described to me, is that how it played out the entire time that you worked as either the assistant—I'm sorry, the acting manager or the manager at the cath lab?

A: Yes.

Q: So I want to make sure it's your testimony here that you're stating that you never made any decisions on the volume or quantity of devices to be ordered at the lab. It's your testimony that it was the physicians that did this? . . .

A: It was—it was my job to make sure we had product on the shelf. So knowing what the physicians wanted and what they used, it was my job to make sure they had what they needed.

Q: So you were the person then that would make the decision as to the quantity and the types of devices that the physicians were wanting. Is that a fair statement? . . .

A: No, because the doctor would usually tell me like, "We need X, we need to keep X amount of this on the shelf."

Doc. 516-5 at 7 (Brinkley Dep. 28:13–29:25).

Aiming to dispute Brinkley’s testimony, Relator highlights what doctors from Dole VA testified about device ordering. Many of them clarified that, when it came to *volume* or *quantity*, they had nothing to do with ordering; but perhaps they had a say in the *type* of devices. *See, e.g.*, Doc. 494-6 at 3 (Gonda Dep. 124:15–16) (“I never had any input on the . . . quantity purchased. Never.”); Doc. 494-7 at 5 (Winblad Dep. 98:19–23) (“Q: Did you play any role in making any decisions regarding the volume of drug-coated balloons that were ordered at the Dole VA? A: The volume, no. Maybe the type.”). One doctor expounded at greater length about this distinction between quantity and type:

If the question is was I involved in ordering devices, the answer is no, I did not order devices for the VA. Would they ask me my opinion? I do recall being asked should we use a Bard balloon versus a—a Medtronic balloon, and the data that I remember receiving and learning from the LEARN conference was that at that time the [Medtronic] balloon was showing better a little bit better data than the Bard balloon, and I remember conveying that to . . . someone in the cath lab who may—may have been involved in—in that—in that process in some manner. I do not recall.

Doc. 494-8 at 5 (Baalmann Dep. 186:14–187:5). All of this suggests that the doctors didn’t place the orders or determine the quantity of products to purchase. But the doctors may have influenced brand choice, in some fashion.

Adding more mud to the waters is testimony by competing sales representatives. Sales reps from medical device companies other than Medtronic testified that Brinkley controlled their access to the cath lab and the doctors. For example, Larry Valdivia—at that time selling for Medtronic’s competitor, Abbott—explained that “everything went through Teri Brinkley” when introducing a product at the Dole VA cath lab. Doc. 381-15 at 6–7, 8 (Valdivia Dep. 13:13–14:13, 18:17–19:24). He confirmed that she was “the person that allowed [him] to have access to the physicians” and was the “first-line person to talk to.” *Id.* at 8 (Valdivia Dep. 19:16–24, 20:9–10). Relator thus contends that Brinkley’s alleged preferential treatment of Medtronic’s

sales rep restricted other reps' ability to compete. Doc. 527 at 42 ("Competitors were shut out due to these bribes."). And but-for those alleged bribes, Relator theorizes, Brinkley would have allowed more equitable access and different purchasing outcomes.

Medtronic responds with conflicting testimony. *See* Doc. 534 at 5. Medtronic notes that Mr. Valdivia also testified that he physically attended procedures and did in-person sales work at the Dole VA cath lab "'maybe two or three times a week[.]'" *Id.* (quoting Doc. 381-15 at 7 (Valdivia Dep. 16:21–17:9)). That, Medtronic contends, doesn't sound like inhibited access. And Valdivia cited instances where he went "around Ms. Brinkley," in that he "spoke to physicians and Brinkley at the same time[.]" Doc. 381-15 at 8 (Valdivia Dep. 19:25–20:10). Apparently, Brinkley didn't have to grant him access to the physicians—at least not all the time.

Finally, there's the question of other processes in place at the VA. If other processes could block or overrule Brinkley's choices, those processes would intervene and thereby disrupt but-for causation between the meals/gifts and the device purchases. Medtronic identifies, for example, the oversight of device orders imparted by the Clinical Products Review Committee (CPRC). Doc. 516 at 14 (citing Doc. 516-10 at 27–28 (Keene Dep. 33:1–34:8)). The CPRC reviewed and approved products before stocking. *Id.* And Medtronic points to Diana Keene's testimony, who served as the Head of Logistics until 2017, to explain the CRPC oversight process. *Id.* at 15 (citing Doc. 516-10 at 18–19 (Keene Dep. 24:17–25:15)).

Relator counters with Keene's testimony that the cath lab had considerable independence, at least initially. Doc. 527 at 10 (citing Doc. 516-10 at 32–34 (Keene Dep. 38:6–40:23)). Keene explained that when the cath lab first started "they were kind of like their own thing" and so Logistics wasn't involved in "their inventory for a lot of years." Doc. 516-10 at 32 (Keene Dep. 38:10–23). And she concedes there was likely cath lab inventory that Logistics "didn't know"

was there. *Id.* So, the parties agree. There were purchasing processes in place at the Dole VA, like the CPRC. *See* Doc. 516 at 15; Doc. 527 at 11. But they disagree about the extent to which the cath lab followed those processes. Doc. 516 at 78–79; Doc. 527 at 11.

In sum, the picture captured by the evidence in the summary judgment record is a fuzzy one. A reasonable jury could find that Brinkley exercised sufficient control and influence over device purchases to qualify as a decisionmaker. If so, such a jury also could find that, but for the provided meals and gifts, Brinkley would have made different purchasing decisions. But a reasonable jury equally could come down on the other side, as well. Citing the doctors’ influence and the other VA processes, a reasonable jury might find that Brinkley wasn’t a decisionmaker. In that outcome, the meals couldn’t suffice as a but-for cause of the device purchases because Brinkley didn’t make the decision to purchase them. Our Rules of Civil Procedure make it so that the jury, not the court, decides between fuzzy facts.

#### **4. Summary**

Recall that a “dispute over a material fact is genuine if a rational jury could find in favor of the nonmoving party on the evidence presented.” *Laul v. Los Alamos Nat’l Lab’ys*, 765 F. App’x 434, 440 (10th Cir. 2019). Relator—as the nonmoving party—paints a factual picture of frequent meals and other gifts provided directly to Dole VA’s medical-device-purchase decisionmaker to induce sales. The factfinder reasonably could find that picture persuasive and adopt it. This result means that Medtronic’s summary judgment motion on Count I for Dole VA kickbacks must fail.

The court next addresses Relator’s summary judgment motion. Relator asks the court to preclude Medtronic from asserting three affirmative defenses against these same kickbacks-to-Dole VA allegations.



## 5. Relator's Motion

Relator moves for summary judgment against three of Medtronic's affirmative defenses. Doc. 493 at 2. These defenses purport to justify the meals Medtronic provided to Dole VA. The three affirmative defenses, put succinctly, are as follows: (1) Medtronic acted with good faith, not with any improper or illegal purpose or intent; (2) Medtronic conducted itself in compliance with, or as authorized by laws and regulations; and (3) Relator relies on ambiguous provisions of the False Claims Act and this reliance bars Relator's claims. Doc. 384 at 23–24 (reciting these as the fifth, eighth, and ninth affirmative defenses in Medtronic's Answer). Relator limits his request for summary judgment to the issue of meals. Doc. 493 at 2. That is, he asks the court to prohibit Medtronic from asserting that it provided meals to Dole VA employees in good faith, in compliance with laws and regulations, or in light of ambiguous FCA provisions. *Id.* Relator asks the court to find “as a matter of law that Medtronic's free meal gifts violated 5 C.F.R. § 2635.201 [the Executive Branch Ethics Standard], and in turn, prohibit Medtronic from asserting [these] affirmative defenses[.]” Doc. 494 at 30.

Relator's motion is a narrow one. He clarifies that he isn't “seeking summary judgment on this AKS/FCA claim—*i.e.*, whether the free meals provided by Medtronic induced its device sales to Dole VA. Instead, he is seeking summary judgment on Medtronic's three affirmative defenses applying to this claim.” *Id.* at 4. So, Relator contends, it doesn't matter that there are controverted facts about how often and how much Medtronic spent on meals provided to Dole VA cath lab staff. *Id.* at 30. Draw all inferences in Medtronic's favor and assume (for example) that Medtronic only spent the \$24,603.72 identified in its expense reports. Doc. 494-14 at 5 (Fox Report). Even then, Relator contends, this level of meals is impermissible under federal regulations and, therefore Medtronic's affirmative defenses fail as a matter of law. Doc. 494 at 30.

Somewhat curiously, Medtronic responds that its defenses aren't affirmative defenses at all even though that's what Medtronic calls them in its Answer. "Affirmative defenses do not negate the elements of a claim but allow a party to avoid liability even if all the elements of the claim are met." *EEOC v. A&A Quality Appliances, Inc.*, 23-cv-02456-DDD-MEH, 2024 WL 5455801, at \*6 (D. Colo. June 11, 2024), *report and recommendation adopted sub nom. EEOC v. A & A Quality Appliance, Inc.*, 2024 WL 5455799 (D. Colo. July 3, 2024). In contrast, a "defense which demonstrates that plaintiff has not met its burden of proof as to an element plaintiff is required to prove is not an affirmative defense." *Muller v. Vilsack*, No. CV 13-0431 MCA/SMV, 2014 WL 12787957, at \*4 (D.N.M. Sept. 30, 2014) (quoting *Barnes v. AT&T Pension Ben. Plan*, 718 F. Supp. 2d 1167, 1173 (N.D. Cal. 2010)). In other words, "[a]ffirmative defenses plead matters extraneous to the plaintiff's prima facie case which deny plaintiff's right to recover, even if the allegations of the complaint are true. In contrast, denials of the allegations in the Complaint or allegations that the Plaintiff cannot prove the elements of his claims are not affirmative defenses." *McMahan v. Total Trucking, Inc.*, No. CIV-22-243-J, 2023 WL 3476159, at \*2 (W.D. Okla. Feb. 16, 2023) (citation and internal quotation marks omitted).

"Where a so-called 'affirmative defense' does nothing more than rebut a plaintiff's claims directly, the defense should be stricken." *Id.* (internal quotation marks and citation omitted). But striking something pleaded as an affirmative defense shouldn't eliminate it from the case; instead, the court should construe it as a denial. 5 A. Benjamin Spencer, Charles A. Wright & Arthur R. Miller, *Fed. Prac. & Proc. Civ.* § 1269 (4th ed.) (June 2024 Update) ("The federal courts have accepted the notion of treating a specific denial that has been improperly denominated as an affirmative defense as though it were correctly labeled."); *id.* ("[A]n improper

designation of a denial as an affirmative defense should be disregarded and the plaintiff put to his proof as if the defendant's negative averment had been properly labeled a specific denial.”).

Here, Relator's case requires him to prove the meals were illegal remuneration—the first element of an AKS violation. *See* § 1320a-7b(b)(2)(B); *Everest Principals*, 622 F. Supp. 3d at 930 (reciting three elements of AKS violation). Medtronic rebuts this element with the defense that it complied with the governing law and that the law is ambiguous. Doc. 384 at 24 (reciting eighth affirmative defense as compliance and ninth affirmative defense as ambiguous law).

Relator also must demonstrate that Medtronic violated the law knowingly and willingly, with an intent to induce—the other two elements of an AKS violation. *See* § 1320a-7b(b)(2)(B); *Everest Principals*, 622 F. Supp. 3d at 930 (reciting three elements of AKS violation). Medtronic tries to refute these elements with a “defense” that it provided the meals in good faith, not knowingly violating the law or intending to induce. Doc. 384 at 23 (reciting fifth affirmative defense as good faith). Each challenged affirmative defense thus directly correlates to an element of Relator's AKS-based claim. This correlation aligns with denials, not affirmative defenses. *See McMahan*, 2023 WL 3476159, at \*2. (“[A]llegations that the Plaintiff cannot prove the elements of his claims are not affirmative defenses.” Because the content of Medtronic's fifth, eighth, and ninth “affirmative defenses” are rebuttal defenses, the court strikes them as affirmative defenses. But, the court construes them as denials and treats them as though “correctly labeled.” 5 A. Benjamin Spencer, Charles A. Wright & Arthur R. Miller, *Fed. Prac. & Proc. Civ.* § 1269 (4th ed.) (June 2024 Update).

Relator doesn't seek summary judgment against the elements of the meals-as-illegal-kickbacks claim, but only as presented as affirmative defenses. Doc. 494 at 4. He never asserts that the undisputed facts prove these elements of his claim as a matter of law. *See generally*

Doc. 494. In fact, he explicitly forsakes any note he’s seeking such a judgment: “At this time, Relator is not seeking judgment on this AKS/FCA claim—*i.e.*, whether the free meals provided by Medtronic induced its device sales to Dole VA. Instead, he is seeking summary judgment on Medtronic’s three affirmative defenses applying to this claim.” *Id.* at 4. So, by this ruling, the court isn’t granting Relator summary judgment on the disputes joined by Medtronic’s denial of these elements. Relator’s disclaimer is a wise choice given the litany of disputes already discussed.

Concluding that the challenged defenses aren’t affirmative defenses, the court needn’t provide the relief Relator requests. Indeed, it can’t because the disputes of fact remain. So, the court denies Relator’s Partial Motion for Summary Judgment (Doc. 493), and instead strikes them because they’re not affirmative defenses at all.

The court rounds out its summary judgment decisions by briefly addressing Relator’s other two claims, False Certification and Conspiracy.

#### **IV. Count II: False Certification**

HRMC and Medtronic’s motions also seek summary judgment against Relator’s false certification claim (Count II). *See* Doc. 546 at 23; Doc. 516 at 84. This claim asserted against both HRMC and Medtronic relies on many of the same allegations but invokes a different legal theory of liability.

As mentioned at the outset, the FCA contemplates a second mechanism linking the FCA and AKS—one which doesn’t rely on the 2010 Amendment addressed in Count I. *See Regeneron*, 128 F.4th at 332. This other mechanism—commonly called the “false certification theory”—predates the 2010 Amendment. *Id.* at 332–33.

“Under this theory, a defendant violates the FCA when presenting (or causing to be presented) a claim that misrepresents compliance with a ‘statutory, regulatory, or contractual

requirement’ that ‘the defendant knows is material to the [g]overnment’s payment decision.’” *Id.* at 332 (quoting *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 181 (2016)). For example, “a defendant who falsely represented AKS compliance when seeking a payment from Medicare could be liable under the FCA.” *Id.* To clarify the distinction between Count I’s theory and the theory in Count II, under Count I FCA liability follows from violating the AKS. Under Count II, FCA liability follows from falsely certifying compliance with the AKS or submitting false records—not the AKS violation itself.

Title 31 U.S.C. § 3729(a)(1) supplies the statutory basis for the false certification theory. *See U.S. ex rel. Sorenson v. Wadsworth Bros. Constr. Co.*, 48 F.4th 1146, 1151 (10th Cir. 2022) (“Falling within the umbrella of liability created by § 3729(a)(1) are false certifications.” (quotation cleaned up)). Relevant here, the FCA provides liability for “any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]” § 3729(a)(1)(B). “A false claim within the meaning of § 3729(a)(1) can be either factually false or legally false.” *Sorenson*, 48 F.4th at 1151. “Legally false requests for reimbursement ‘generally require knowingly false certification of compliance with a regulation or contractual provision as a condition of payment.’” *Id.* (citing *U.S. ex rel. Polukoff v. St. Mark’s Hosp.*, 895 F.3d 730, 741 (10th Cir. 2018)). The court evaluates, first, HRMC’s and, then, Medtronic’s arguments supporting summary judgment on false certification.

#### **A. False Certification Claim against HRMC**

Here, Relator alleges that HRMC falsely certified compliance, and thus violated the FCA in three ways. *One*, HRMC falsely certified AKS compliance when securing reimbursement for allegedly tainted no-charge devices. *Two*, HRMC’s AKS violation created “*per se* FCA liability[.]” And *last*, HRMC provided false records/statements based on those allegedly tainted no-charge devices “outside the AKS context.” Doc. 551 at 31–32 (emphasis in original). The

first and third of these theories rest on the alleged taint of the no-charge devices. If the no-charge devices aren't tainted, HRMC didn't certify compliance falsely or provide false records/statements. The court has granted summary judgment to HRMC on the no-charge devices claim. This ruling held the no-charge bundled devices qualified for the AKS statutory discount exception. So, they didn't violate the AKS (*i.e.*, there was no taint). Doc. 565 at 61.

The second false certification theory of liability against HRMC—per se FCA liability—rests on HRMC violating the AKS. But the court has granted summary judgment to HRMC on all other surviving AKS violation allegations, as well.<sup>2</sup> *See above* § III.B. So, because there's no AKS violation, there's no basis for per se FCA liability. The court thus grants summary judgment to HRMC on Relator's false certification claim (Count II).

#### **B. False Certification Claim against Medtronic**

Relator also asserts a false certification claim against Medtronic. This claim rests on three bases. *See* Doc. 233 at 62–64 (Fifth Am. Compl. ¶¶ 166–73). Two of those bases—inducing purchases of medically unnecessary goods and off-label promotion—aren't at issue in Medtronic's partial summary judgment motion here. *See generally* Doc. 516. So, this ruling doesn't affect those two bases of liability. The third basis—paying remuneration to induce sales of Medtronic devices—is a different story.

Even after the current batch of summary judgment filings, the precise boundaries of Relator's remuneration-based false certification claim against Medtronic remain unclear. Does it apply to both the alleged no-charge device kickbacks to HRMC and the kickbacks to Dole VA? The parties' briefing addresses false certification almost exclusively in the no-charge device

---

<sup>2</sup> Recall that Relator chose not to pursue AKS violations based on the alleged gifts. *See* § III. All that remains, therefore, are the meals and no-charge device bundle allegations. The court has granted summary judgment to HRMC on both theories.

context. *See, e.g.*, Doc. 527 at 24–25, 32 (“Medtronic knowingly violated the FCA by causing HRMC to submit false claims, statements and records for reimbursement.”); Doc. 534 at 12 (“Relator also provides no evidence that HRMC submitted false claims or false certifications at all.”). Any mention of false certification in the context of meals and gifts that Medtronic provided to Dole VA is, at most, perfunctory.

Here’s all that the parties have to say about false certification for Dole VA kickbacks: One sub-heading in Relator’s Response suggests his false certification claim applies also to the meals Medtronic provided to Dole VA. Doc. 527 at 41 (“Medtronic’s Conduct at Dole VA Resulted in False Claims[.]”). But the section that follows merely focuses on “but for” causation. Medtronic—presumably replying to this sub-heading—responds simply, “Relator does not try to identify any certification or claim made by Medtronic to the VA that was false.” Doc. 534 at 15. That’s it. And so, as did the parties, the court confines its summary judgment analysis to the no-charge device context. *See Lebahn v. Owens*, 813 F.3d 1300, 1307–08 (10th Cir. 2016) (clarifying that a party mustn’t “ignore his obligation to bring relevant issues to the district court’s attention. It is not the court’s job to comb the record in order to make [a party’s] arguments for him.” (quotation cleaned up)).

Anyone who’s followed along to this point can predict the court’s ruling. For clarity’s sake, though, the court outlines it explicitly: Relator’s allegation that Medtronic caused HRMC to present false claims by offering no-charge devices fails as a matter of law. *See* Doc. 233 at 62 (Fifth Am. Compl. ¶ 168). As the court has recited—perhaps ad nauseum—it granted summary judgment in defendants’ favor on the no-charge device issue. Doc. 565. So, no claim flowing from the allegedly tainted no-charge devices survives. The court thus grants summary judgment

to Medtronic against Relator’s false certification claim (Count II) to the extent that this claim rests on allegations relying on no-charge devices.<sup>3</sup>

## V. Count III: Conspiracy

At long last, the court turns to Count III—a claim that HRMC and Medtronic conspired to violate the FCA. Both HRMC and Medtronic move for summary judgment against this claim. The FCA also imposes liability on anyone who “conspires to commit a violation” of the provisions in § 3729(a)(1). *Sorenson*, 48 F.4th at 1151. “The elements of an FCA conspiracy claim are [1] an agreement to get false claims paid and [2] an overt act taken toward that purpose.” *U.S. ex rel. Edalati v. Sabharwal*, No. 17-cv-02395-HLT, 2023 WL 5334621, at \*12 (D. Kan. Aug. 18, 2023) (citing *U.S. ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*, 459 F. Supp. 2d 1081, 1091 (D. Kan. 2006)).

---

<sup>3</sup> In their briefing on false certification, the parties dispute the requisite elements of an FCA claim, namely, whether those elements include damages. Medtronic contends that “Relator must prove the United States incurred damages as a result of a false claim.” Doc. 516 at 80. But the court declines to entertain that argument in earnest. Here’s why.

A number of courts have held that damages are not an element of an FCA claim. *U.S. ex rel Trim v. McKean*, 31 F. Supp. 2d 1308, 1315–16 (W.D. Okla. 1998) (“Several jurisdictions have previously held that actual damages are not a necessary element of the FCA claim.”) (collecting cases). Other courts have held the same. *See, e.g., U.S. ex rel. Feldman v. Van Gorp*, 674 F. Supp. 2d 475, 481 (S.D.N.Y. 2009) (“The False Claims Act provides for recovery of both (a) two to three times the damages to the government and (b) a civil penalty for the false or fraudulent claims. 31 U.S.C. § 3729(a). This civil penalty provision allows courts to find a violation even in the absence of proof of damages to the United States.”); *United States v. Kensington Hosp.*, 760 F. Supp. 1120 (E.D. Pa. 1991). (“It is clear that the focus of the inquiry, in a claim under the FCA, is to the claim and the conduct of the claimant, rather than its effect on the government, and the Court finds proof of damage as a result of the claim is not a necessary element.”).

The Tenth Circuit has declined to decide this question. *See U.S. ex rel. Aakhush v. Dynacorp, Inc.*, 136 F.3d 676, 681 (10th Cir. 1998) (“Although Stinson suggests a plaintiff must also prove damages suffered by the government, there is authority to the effect that the government need not prove damages to establish liability under the FCA, but can instead recover statutory penalties for a violation even absent any damages. . . . We find it unnecessary to decide whether proof of damages is an essential element[.]”). Nonetheless, our Circuit alluded to “authority to the effect that the government need not prove damages to establish liability under the FCA[.]” *Id.* And, when it listed the elements of an FCA claim, our Circuit didn’t include damages in that list. *Id.*



Here, Relator alleges two distinct FCA conspiracies. He premises one of them on the medically unnecessary claims not at issue here. *See* Doc. 233 at 65 (Fifth Am. Compl. ¶¶ 178, 180). In the second, Relator contends that defendants Medtronic and HRMC “entered into an agreement and plan to conspire to violate the FCA through their company policies and practices[.]” Doc. 233 at 64–65 (Fifth Am. Compl. ¶ 177). He then specifies that those allegedly fraudulent company practices “included engaging in an illegal kickback scheme whereby Medtronic/Covidien’s Sales Representative . . . would provide remuneration including ‘free’ . . . devices[.]” *Id.* at 65 (Fifth Am. Compl. ¶ 179).

HRMC and Medtronic move for summary judgment against this conspiracy claim in its entirety. Doc. 546 at 19–23; Doc. 516 at 77–79. Medtronic argues that “there cannot be liability for conspiracy where there is no underlying violation of the FCA.” Doc. 516 at 79 (citing *U.S. ex rel. Amin v. George Wash. Univ.*, 26 F. Supp. 2d 162, 165 (D.D.C. 1998)). The court agrees.

The court’s earlier Order held the no-charge devices lawful under the AKS’s safe harbor. Doc. 565 at 61. And this Order concludes meals Medtronic provided to HRMC were insufficient to induce device purchases. Both illegal kickback theories that could’ve produced HRMC false claims thus wither. An agreement to get a false claim paid is an obligatory element of an FCA conspiracy claim. *Edalati*, 2023 WL 5334621, at \*12. But the court has concluded the underlying transactions allegedly supporting any false claim lawful. So, this arm of Relator’s conspiracy claim can’t survive summary judgment. Succinctly, no basis for a false claim means no conspiracy. The court thus grants summary judgment in favor of HRMC and Medtronic on Count II to the extent Relator premises his conspiracy claim on an agreement between HRMC and Medtronic.

With that, the court rounds out its summary judgment analysis. To sum up, here's where things stand.

- The court grants summary judgment to HRMC against all claims asserted by Relator. This ends the case against HRMC.
- The court grants summary judgment to Medtronic on Counts I and II to the extent Relator premises those claims on kickbacks to HRMC.
- Counts I & II against Medtronic survive to the extent Relator premises those claims on kickbacks allegedly provided to Dole VA. Genuine disputes of material fact preclude summary judgment.
- The court strikes Medtronic's affirmative defenses 5, 8, and 9, and construes them instead as denials of elements of Relator's claims.
- The court denies Relator's summary judgment motion against Medtronic's affirmative defenses.
- The court grants summary judgment to Medtronic on Count III to the extent Relator premised that claim on an agreement between Medtronic and HRMC.

Next up, Relator's Motion to Reconsider (Doc. 568) and Request for Oral Argument (Doc. 576). And then, to tie up loose ends, the court addresses several unrul'd sealing motions before reciting its conclusions.

#### **VI. Motion to Reconsider (Doc. 568) and Request for Oral Argument (Doc. 576)**

Relator filed a Motion to Reconsider (Doc. 568) the court's Order (Doc. 565) granting summary judgment to defendants Medtronic and HRMC on their safe harbor affirmative defense. Relator later filed a motion asking the court to hear oral arguments on his reconsideration motion. Doc. 576. The court denies both requests.

Begin with a quick review. Congress implemented safe harbor exceptions to the AKS. It deemed discounts permissible under the AKS when they qualify either under a regulatory safe harbor provision, 42 C.F.R. § 1001.952(h) (2023), or the statutory discount exception, 42 U.S.C. § 1320a-7b(b)(3)(A). The regulatory safe harbor protects discounts when certain specifications are met. 42 C.F.R. § 1001.952(h). And the statutory exception similarly provides that discounts and price reductions—if properly disclosed and appropriately reflected—don’t constitute illegal remuneration. 42 U.S.C. § 1320a-7b(b)(3)(A). The court concluded that Medtronic’s bundled device sales to HRMC qualified for safe harbor under the regulatory provisions. Doc. 565 at 53. And it concluded that HRMC’s bundled device purchases qualified for safe harbor under the statutory discount exception. *Id.* at 60–61.

Most importantly for present purposes, the court concluded that HRMC accurately reported the discount bundles. *Id.* at 42. This accurate reporting allowed HRMC’s bundled device purchases to qualify for the statutory discount exception. *Id.* at 59, 60–61. The court determined HRMC’s reporting was accurate because it reported the actual purchase price of the bundles on its cost report. *Id.* at 42. Relator primarily takes issue with this conclusion in his reconsideration motion. He argues that accurate reporting necessarily involves the *charges* for each device, not just their cost. Doc. 568 at 1–5. And he identifies as support his experts’ contention that the unit price of each device needed to reflect the discount. *Id.*

#### **A. Legal Standard**

“A motion to reconsider must be based on: (1) an intervening change in controlling law; (2) the availability of new evidence; or (3) the need to correct clear error or prevent manifest injustice.” D. Kan. Rule 7.3. That is, “a motion for reconsideration is appropriate where the court has misapprehended the facts, a party’s position, or the controlling law.” *Servants of*

*Paraclete v. Does*, 204 F.3d 1005, 1012 (10th Cir. 2000). But it “is not appropriate to revisit issues already addressed or advance arguments that could have been raised in prior briefing.” *Id.*; see also *Banister v. Davis*, 590 U.S. 504, 508 (2020) (explaining that, on a Rule 59(e) motion, “courts will not address new arguments or evidence that the moving party could have raised before the decision issued”). A district court has discretion when deciding whether to grant or deny a motion to reconsider. *Hancock v. City of Okla. City*, 857 F.2d 1394, 1395 (10th Cir. 1988).

## **B. Analysis**

Relator contends his motion is based on the third ground for reconsideration—the need to correct clear error. Doc. 568 at 3. First and foremost, Relator takes issue with the court’s focus on costs—and not charges—in its discount safe harbor analysis. *Id.* at 1. He contends that his other arguments flow from the court’s purported error, failing to consider the charges. *Id.* at 1–2. Relator suggests that since his expert had demonstrated that both claims and costs are included in a cost report, accurate reporting necessarily must include both costs and charges. *Id.* at 4–5. But that’s just not what the legal authorities conclude, as reiterated below.

### **1. The Court’s Ruling About Costs Versus Charges**

The court already conducted a robust costs-versus-charges analysis in its earlier Order (Doc. 565). The court considered, at length, Relator’s suggested approach. Relator suggests that a buyer should decrease the charge for each individual device (a line-item approach) to reflect accurately a discount. Doc. 565 at 43–46. The court rejected this approach, explaining:

Relator’s argument has some logical appeal. But here’s the problem. Relator never cites any authority hinting even that Medicare requires reporting these sorts of unit-based price reductions to qualify for fully disclosing and accurately reflecting a discount. And the court has found none. The sole authority Relator invokes are two HHS OIG Advisory Opinions. And neither of those opinions says what Relator wants it to say.

*Id.* at 43 (internal citation omitted). The court then evaluated—again, at length—Relator’s only legal “authority” for this line-item approach: two HHS OIG advisory opinions that explicitly forsake any authoritative effect. *Id.* at 43–44. The court concluded its analysis by quoting HHS OIG guidance that confirmed the court’s cost-only focus: “[P]arties who were uncertain about how or where to report on a particular form the fact that the price was due to a discount need not be concerned with reporting that fact, as long as the actual purchase price accurately reflects the discount.” *Id.* at 42 (emphasis omitted) (quoting 64 Fed. Reg. 63518, 63527 (Nov. 19, 1999) (to be codified at 42 C.F.R. § 1001.952)).

Later, the court bolstered its cost-focused approach by interpreting the disjunctive “or” within the key statutory language. The court concluded that Congress’s choice of “or” signifies that a buyer need report just its costs (and a seller its charges). *Id.* at 59–60. But the court didn’t conclude based solely on its own reasoning. Instead, it quoted another court who had considered the same question—and reached the same answer. *Id.* at 60 (quoting *United States v. Shaw*, 106 F. Supp. 2d 103, 120 (D. Mass. 2000)). In sum, the court deployed a litany of legal tools to address this costs-versus-charges question—case law, rules of statutory construction, HHS OIG guidance, and HHS OIG advisory opinions.

The court concluded then that what matters is an accurate report of the actual costs paid for bundled devices. Buyers needn’t engage in a device-by-device breakdown of the discount—a method which cost reports don’t accommodate, and the regulations never require. *See id.* at 44–46. Relator’s expert herself admits that *individual* charges (*i.e.*, charges not in aggregate) aren’t included in the cost report. Doc. 561-1 at 3 (Schmor Dep. 108:4–25). And Relator concedes that safe harbor regulations don’t “spell out” how a buyer should report charges. Doc. 568 at 8. If

the regulations don't require the reporting envisioned by Relator's expert, then neither can the court.

## **2. Relator's Argument to Include Charges in Accurate Reporting**

Relator endorses a line-item charging system—where each time a buyer-provider uses a device, it has to calculate the portion of the discount it should apply to that one single device. Such a system is far more onerous than the regulations demand. *See id.* at 44–46. The discount exception aims to *encourage* lower costs, which onerous reporting requirements wouldn't do. *Shaw*, 106 F. Supp. 2d at 120. Those lower prices benefit the Federal health care programs. *See id.* (explaining that the “discount exception should encourage providers to seek discounts as a good business practice which results in savings to medicare and medicaid program costs” (quotation cleaned up)).

Relator's motion revisits the same legal sources the court already considered, and he looks for nuggets of “charges” or “claims” language. He contends this language proves that the court's focus on costs was misplaced. The court provides a few examples.

Relator returns to *Shaw* and hangs his hat on this sentence: “The statute aims at reduction of the price of the goods or services *through disclosure*, so a lower price can be reflected in lower costs *claimed from or charged to* a federal health care program.” Doc. 568 at 7 (emphasis in original) (quoting *Shaw*, 106 F. Supp. 2d at 119). Relator argues that this language demonstrates that charges must enter the disclosure analysis. But, pulling back for a broader view, the context of this sentence supports the court's emphasis on the buyer's lowered costs—not an itemized discount-per-device approach.

The statute requires disclosure *and reflection of the costs incurred* in order to satisfy the purposes of the statute—to pass on the benefits of the price reduction to Medicare or Medicaid. . . . The statute aims at reduction of the price of the goods or services through disclosure, so *a lower price can be reflected in lower costs claimed from or charged to* a federal health care program. In this way, the federal

health program *may benefit from a reduction in price* offered and received. *Shaw*, 106 F. Supp. 2d at 119 (emphasis added). The purpose of disclosure is that Medicare or Medicaid knows the “costs incurred” and benefits from those “lower costs” and from “a reduction in price.” *Id.* Notice the focus on the costs. A similar pattern emerges in another of Relator’s arguments, addressed next.

Relator also contends that the “claim” language in the HHS OIG guidance below suggests the court misapplied the guidance. The court doesn’t think so. Look for the language’s emphasis on actual purchase price, which mirrors the emphasis on costs in the *Shaw* passage just discussed. Here’s the whole paragraph, for fulsome context:

The preamble to the 1991 final rule stated that when reporting a discount, *one only need report the actual purchase price* and note that it is “net discount.” However, for purposes of submitting a claim or request for payment, we proposed clarifying that what is necessary is that the value of the discount be *accurately reflected in the actual purchase price*. It is *not necessary to distinguish whether this price is the result of a discount* or to state “net discount.” Consequently, parties who were uncertain about how or where to report on a particular form the fact that the price was due to a discount need not be concerned with reporting that fact, *as long as the actual purchase price accurately reflects the discount*.

64 Fed. Reg. 63518, 63527 (emphasis added). Relator leans into the portion of this language about “submitting a claim or request for payment” to argue that charges matter when reporting a discount. Doc. 568 at 6–7. But in context, the thrust of this guidance is that one no longer need designate “net discount” or indicate that the price was due to a discount. *Id.* What matters is reporting accurately the actual purchase price. *Id.* And that’s the very conclusion the court reached in its earlier Order.

Relator also cites policy concerns, which he highlights in more detail in his Motion for Oral Argument (Doc. 576). He worries that “the Court’s decision has opened a door in the industry for manufacturers to hide bribes in the form of no-charge device discounts.” Doc. 576

at 1. Policy discussions, while “always fascinating,” “are beside the point.” *Burrage*, 571 U.S. at 218 (quotation cleaned up). The court mustn’t consider whether “some other approach might accord with good policy.” *Id.* (quotation cleaned up). It must decide what the law—as written—requires and then apply it. *Id.*

In a nutshell, the court remains unpersuaded that it erred in focusing on costs for accurate reporting. And so, the court denies Relator’s Motion to Reconsider (Doc. 568).

### **C. Motion for Oral Argument (Doc. 576)**

The court also denies Relator’s Motion for Oral Argument (Doc. 576). Relator had an opportunity to present his arguments in his papers. Oral argument isn’t required. *Barrett-Taylor v. Birch Care Cmty., LLC*, No. 22-1013, 2023 WL 2823531, at \*3 (10th Cir. Apr. 7, 2023) (“A formal evidentiary hearing with oral argument is not necessarily required. Rather, the parties’ right to be heard may be fulfilled by the court’s review of the briefs and supporting affidavits and materials submitted to the court.” (quotation cleaned up)). Our local rules clarify that whether to hear oral argument rests in the court’s discretion. *See* D. Kan. Rule 7.2 (“The court *may* set any motion for oral argument or hearing at the request of a party or on its own initiative.” (emphasis added)). The court, in its discretion, denies Relator’s motion.

## **VII. Sealing Motions**

As a final housekeeping matter, the court decides five pending sealing motions. First, the court recites the standard for maintaining documents under seal. Then, it applies this standard to the five motions.

### **A. Sealing Standard**

A “party seeking to file court records under seal must overcome a presumption, long supported by courts, that the public has a common-law right of access to judicial records.” *Luo v. Wang*, 71 F.4th 1289, 1304 (10th Cir. 2023) (citation and internal quotation marks omitted).



“The Court may order the sealing of documents if competing interests outweigh the public’s interest.” *Parker v. United Airlines, Inc.*, 49 F.4th 1331, 1343 (10th Cir. 2022). However, when documents “inform [the court’s] decision-making process[,]” the movant ““must articulate a real and substantial interest that justifies depriving the public of access[.]”” *JetAway Aviation, LLC v. Bd. of Cnty. Comm’rs*, 754 F.3d 824, 826 (10th Cir. 2014) (quoting *Eugene S. v. Horizon Blue Cross Blue Shield of N.J.*, 663 F.3d 1124, 1135–36 (10th Cir. 2011)).

For example, the Tenth Circuit has “allowed sealing of documents reflecting a party’s finances and business practices.” *Parker*, 49 F.4th at 1343. And our court has granted motions to seal “confidential business information or non-public financial information, including information about contract negotiations, pricing, profits, and sales strategy.” *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, No. 17-md-2785-DDC-TJJ, 2020 WL 7396915, at \*9 (D. Kan. Dec. 17, 2020); *see also AH Aero Serv., LLC v. Heber City*, No. 17-CV-01118-HCN-DAO, 2020 WL 6135819, at \*5 (D. Utah Oct. 19, 2020) (collecting cases and explaining that “[c]onfidential financial information is often sealed where its disclosure could cause competitive harm.”) (collecting cases); *Melnick v. Tamko Bldg. Prods. LLC*, No. 19-CV-2630-JAR-BGS, 2023 WL 5574188, at \*2 (D. Kan. Aug. 29, 2023) (“Such competing interests may include trade secrets to be protected from disclosure and confidential business information that may harm a business’s competitive standing.”).

## **B. Doc. 498**

*First*, Medtronic moves to maintain under seal Doc. 495-1 (Ex. A), Doc. 495-3 (Ex. D), and Doc. 495-4 (Ex. L). Doc. 498 at 1. Medtronic contends these exhibits include its “confidential, business sensitive information.” *Id.* at 2. And, it alleges, Relator’s past contact with the media raises concerns that Relator will place these internal documents in the hands of the media. *Id.* at 3. Relator opposes sealing Doc. 495-1 (Ex. A). Doc. 499 at 1–2.

Doc. 495-1 (Ex. A) contains emails and text messages. And, Relator argues, any objectionable information, like the credit card information of a Medtronic sales representative, Relator preemptively redacted. Doc. 499 at 2. The court has reviewed Doc. 495-1 (Ex. A) and agrees with Relator. These emails and text messages don't contain the sort of "confidential financial information" that, if disclosed, "could cause competitive harm." *AH Aero Serv.*, 2020 WL 6135819, at \*5. Instead, they contain informal communications between employees. *See, e.g.*, Doc. 495-1 at 13 ("FYI—terri at VA—is sick[.]"). And these communications illuminate questions of who made purchasing decisions at the Dole VA cath lab—a question relevant to the court's "decision-making process." *JetAway Aviation*, 754 F.3d at 826 (quotation cleaned up).

Doc. 495-3 (Ex. D) and Doc. 495-4 (Ex. L), by contrast, include sales data—tables or spreadsheets of specific products, sold in specific quantities, at specific prices. These warrant sealing.

The court thus grants in part and denies in part Medtronic's Partially Unopposed Motion to Seal. Doc. 498. The court directs the Clerk of the Court to remove the provisional designation and maintain permanently under seal Doc. 495-3 and Doc. 495-4. The Clerk must unseal the other documents filed under Doc. 495.

### **C. Doc. 517**

*Second*, Medtronic moves to maintain under seal purchasing agreements, price lists, consignment inventory lists, and the like. Doc. 517 at 1. These are attached as Exhibits 4–25, 38, 43, 46–48. *See* Doc. 518 at 2. Relator opposes. Doc. 519. He contends Medtronic didn't comply with the service requirement under D. Kan. Rule 5.4.2(a), and so failed to satisfy the requisite elements for sealing. *Id.* at 1–2. But Relator never identifies any rule or part of any rule or case law suggesting such a failing means the court should unseal the documents. *See generally id.* So, the court rejects unsealing on that basis.

Next, Relator argues several exhibits don't contain any of the requisite confidential information to deserve sealing. *Id.* at 2–3 (opposing sealing of Exhibits 4–14, 21, 46). Upon review, however, the court found that most of the exhibits contain specific product and inventory information. Most are emails asking for replacement of particular expired products, complete with lot numbers or detailed descriptions. *See, e.g.*, Doc. 518-1 at 2 (Ex. 4); Doc. 518-8 (Ex. 11). Those documents warrant sealing under our Circuit's practice of permitting "sealing of documents reflecting a party's finances and business practices." *Parker*, 49 F.4th at 1343.

A few exhibits contain no product or other confidential business information, however. These include: Doc. 518-5 (Ex. 8) (email referencing "8 expired items" but providing no other identifying information); Doc. 518-25 (Ex. 46) (email explaining purchase of lunch and cookies). Medtronic offers no other argument to warrant sealing. So, the court concludes Doc. 518-5 and Doc. 518-25 shouldn't remain sealed. The court directs the Clerk of the Court to remove the provisional designation and leave permanently under seal all exhibits filed under Doc. 518 except these two. The Clerk of the Court should unseal Doc. 518-5 and Doc. 518-25 only.

#### **D. Doc. 532**

*Third*, Medtronic moves to maintain under seal exhibits Relator filed in his summary judgment Response and Reply. Doc. 532 at 1 (requesting sealing of exhibits in Doc. 528 and Doc. 531). Medtronic contends that the exhibits include its sales data and, thus, warrant protection. Relator opposes sealing three of these exhibits: Doc. 528-5 (Ex. K), Doc. 528-7 (Ex. S), and Doc. 531-3 (Ex. W). Doc. 533 at 2–3. He argues that the email and text communications in these exhibits don't include confidential business information. *Id.*

After review, the court agrees with Relator. The emails and text messages in the contested exhibits include communication about food, not confidential business information. *See* Doc. 528-5; Doc. 528-7; Doc. 531-3. What's more, such communication has "informed the

court’s decision-making process” as it evaluated the role of meals in any alleged illegal remuneration. *JetAway Aviation*, 754 F.3d at 826 (quotation cleaned up). The other exhibits Medtronic requests to maintain under seal include “confidential business information or non-public financial information” that merits sealing. *In re EpiPen*, 2020 WL 7396915, at \*9. So, the court grants Medtronic’s motion for those other exhibits. Finally, Medtronic never requested the court leave under seal one other provisionally sealed exhibit, Doc. 528-3 (Ex. G). It thus won’t remain sealed.

So, the court directs the Clerk of the Court to remove the provisional designation and leave permanently under seal all exhibits filed under Doc. 528 and Doc. 531 except for the four documents specified in this paragraph. The Clerk of the Court must unseal Doc. 528-3, Doc. 528-5, Doc. 528-7, and Doc. 531-3.

**E. Doc. 550**

*Fourth*, Medtronic and HRMC jointly move to seal Doc. 547-1 (Ex. F) and Doc. 547-2 (Ex. H). The documents are expert reports, both of which the court has sealed earlier. *See* Doc. 550 at 1. The reports include defendants’ financial information, including specific information about purchases and billing. The motion is unopposed. Our court’s practice includes sealing “confidential business information or non-public financial information[.]” *In re EpiPen*, 2020 WL 7396915, at \*9. And so, the court grants Medtronic and HRMC’s Motion to Seal (Doc. 550). The court directs the Clerk of the Court to remove the provisional designation and leave permanently under seal Doc. 547-1 and Doc. 547-2.

**F. Doc. 555**

*Fifth*, Medtronic moves to maintain under seal four documents Relator filed in his Response to HRMC’s summary judgment motion (Doc. 545). Doc. 555. Medtronic notes that these expert reports and purchase orders include Medtronic’s detailed financial information. *Id.*

at 1. And it highlights that the court sealed the two at-issue expert reports already. *Id.* at 1–2.

The motion is unopposed. The court reviewed the documents and agrees with Medtronic. These documents merit sealing.

Medtronic doesn't request that the court seal Doc. 552-5 (Ex. M). So, the court directs the Clerk of the Court to remove the provisional designation and leave permanently under seal all exhibits filed under Doc. 552 except one. The Clerk must unseal Doc. 552-5.

## **VIII. Conclusion**

The court concludes no allegations of illegal remuneration against HRMC survive. Relator surrendered on the gifts as illegal kickback theory, the court held the no-charge devices qualify for the AKS's safe harbor protection, and, consistent with Relator's concession, the meals alone can't suffice to induce purchases. The court thus grants HRMC's Motion for Summary Judgment (Doc. 545) and dismisses HRMC as a defendant.

The court also grants, in part, Medtronic's Motion for Partial Summary Judgment (Doc. 515). To the extent that Relator's claims rely on Medtronic providing illegal remuneration to HRMC (Count I), Medtronic causing HRMC to certify or report falsely (Count II), and conspiring with HRMC (Count III), Medtronic deserves summary judgment.

The court denies Medtronic's motion (Doc. 515) as it applies to all other claims. Genuine disputes of material fact preclude summary judgment.

The court also strikes Medtronic's affirmative defenses, construing them to deny aspects of Relator's claims, and also denies Relator's Motion for Partial Summary Judgment (Doc. 493) against those defenses. Finally, the court denies Relator's Motion for Reconsideration (Doc. 568) and Motion for Oral Hearing (Doc. 576). And it grants—at least in part—various sealing motions.

**IT IS THEREFORE ORDERED BY THE COURT THAT** Relator's Motion for Partial Summary Judgment (Doc. 493) is denied.

**IT IS FURTHER ORDERED THAT** Medtronic, Inc. and Covidien, L.P.'s Motion for Partial Summary Judgment (Doc. 515) is granted in part and denied in part, as set forth above.

**IT IS FURTHER ORDERED THAT** Hutchinson Regional Medical Center's Motion for Summary Judgment (Doc. 545) is granted. The court directs the Clerk of the Court to terminate Hutchinson Regional Medical Center as a defendant.

**IT IS FURTHER ORDERED THAT** Relator's Motion to Reconsider (Doc. 568) and Motion for Oral Argument for Hearing (Doc. 576) are denied.

**IT IS FURTHER ORDERED THAT** Medtronic, Inc. and Covidien, L.P.'s Motion to Seal (Doc. 498) is granted in part and denied in part. The court directs the Clerk of the Court to remove the provisional designation and leave permanently under seal Doc. 495-3 and Doc. 495-4. The Clerk must unseal Doc. 495-1; Doc. 495-2; Doc. 495-5.

**IT IS FURTHER ORDERED THAT** Medtronic, Inc. and Covidien, L.P.'s Motion to Seal (Doc. 517) is granted in part and denied in part. The court directs the Clerk of the Court to remove the provisional designation and leave permanently under seal Doc. 518-1, Doc. 518-2, Doc. 518-3, Doc. 518-4, Doc. 518-6, Doc. 518-7, Doc. 518-8, Doc. 518-9, Doc. 518-10, Doc. 518-11, Doc. 518-12, Doc. 518-13, Doc. 518-14, Doc. 518-15, Doc. 518-16, Doc. 518-17, Doc. 518-18, Doc. 518-19, Doc. 518-20, Doc. 518-21, Doc. 518-22, Doc. 518-23, Doc. 518-24, Doc. 518-26, and Doc. 518-27. The Clerk must unseal Doc. 518-5 and Doc. 518-25.

**IT IS FURTHER ORDERED THAT** Medtronic, Inc. and Covidien, L.P.'s Motion to Seal (Doc. 532) is granted in part and denied in part. The court directs the Clerk of the Court to remove the provisional designation and leave permanently under seal Doc. 528-1, Doc. 528-2,

Doc. 528-4, Doc. 528-6, Doc. 531-1, Doc. 531-2, Doc. 531-4 and Doc. 531-5. The Clerk must unseal Doc. 528-3, Doc. 528-5, Doc. 528-7, and Doc. 531-3.

**IT IS FURTHER ORDERED THAT** Medtronic, Inc., Covidien, L.P. and Hutchinson Regional Medical Center's Joint Motion to Seal (Doc. 550) is granted. The court directs the Clerk of the Court to remove the provisional designation and leave permanently under seal Doc. 547-1 and Doc. 547-2.

**IT IS FURTHER ORDERED THAT** Medtronic's Motion to Seal (Doc. 555) is granted. The court directs the Clerk of the Court to remove the provisional designation and leave permanently under seal Doc. 552-1, Doc. 552-2, Doc. 552-3, and Doc. 552-4. The Clerk must unseal Doc. 552-5.

**IT IS SO ORDERED.**

**Dated this 20th day of March, 2025, at Kansas City, Kansas.**

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