

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA ex rel.	)	
TODD LANGER, et al.,	)	
	)	
Plaintiff-Relator,	)	
	)	
v.	)	Civil Action
	)	No. 21-cv-11293-PBS
	)	
ZIMMER BIOMET HOLDINGS, INC.,	)	
	)	
Defendant.	)	
_____	)	

MEMORANDUM AND ORDER

October 21, 2026

Saris, J.

INTRODUCTION

Defendant Zimmer Biomet Holdings, Inc. ("Zimmer Biomet"), an orthopedic medical device company, uses independent contractor sales representatives to sell its products to surgeons and hospitals. Those sales representatives are paid via commissions, i.e., based on a percentage of their sales. Relator Todd Langer ("Relator") brings this qui tam action under the federal False Claims Act ("FCA") and various state and local analogs alleging that Zimmer Biomet's payment of commissions to its independent contractor sales representatives violates the Anti-Kickback Statute ("AKS") and thus renders fraudulent claims for payment to the government for products sold by these sales representatives.

Zimmer Biomet now moves for summary judgment on multiple grounds. Zimmer Biomet contends that no reasonable jury could find that its commission-based payments to its independent contractor sales representatives violate the AKS and that, even if a jury could so find, Relator has not offered sufficient evidence to prove its liability under the FCA.

After hearing and a review of the record, the Court **ALLOWS IN PART** and **DENIES IN PART** Zimmer Biomet's motion for summary judgment (Dkt. 179). In brief, the Court rejects Relator's broad interpretation of the AKS under which commission-based payments to independent contractor sales representatives amount to remuneration paid with the unlawful intent to induce referrals. However, in applying the suspect characteristics outlined by the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG"), the Court concludes that Relator in this case has offered sufficient evidence of various actions of Zimmer Biomet's independent contractor sales representatives -- like their presence during medical procedures; the provision of meals, private jet travel, and travel expenses to surgeons; and "upselling" more expensive products -- so as to present a triable case that Zimmer Biomet paid commissions to its independent contractor sales representatives with the unlawful intent to induce referrals required by the AKS.

BACKGROUND

When evaluating a summary judgment motion, courts “construe the relevant facts in the light most favorable to the non-moving party.” Deaton v. Town of Barrington, 100 F.4th 348, 353 (1st Cir. 2024). The following facts are undisputed except where otherwise noted.

I. Zimmer Biomet’s Sales Force Transition

Zimmer Biomet is a medical device company that designs, manufactures, and sells orthopedic products. Zimmer Biomet was formed in June 2015 upon the merger of Zimmer Holdings, Inc. (“Zimmer”) and Biomet, Inc. (“Biomet”).

Both pre- and post-merger, Zimmer Biomet and its predecessor companies operated two types of sales territories. In “direct” territories, a company employee manages the sales representatives. In “indirect” territories, an independent distributor contracts with the company to market devices on its behalf. Relator’s claims in this case solely concern Zimmer Biomet’s direct territories.

Following the merger, Zimmer Biomet took steps to integrate the two predecessor companies’ sales forces. Both companies had used a mix of W-2 (employee) and 1099 (independent contractor) sales representatives in their direct territories. As part of integrating the sales forces, Zimmer Biomet transitioned the W-2 sales representatives in its direct territories into 1099 independent contractors as of January 1, 2016. It is disputed

whether all orthopedic sales representatives became independent contractors or whether a small percentage of sales representatives working on specialty product lines (such as trauma, foot, and ankle products) remained employees. Since the transition in 2016, Zimmer Biomet has converted the sales representatives in certain direct territories to W-2 employees. Currently, some of Zimmer Biomet's direct territories have all 1099 sales representatives, while others use only W-2 employees. A number of other medical device companies also use 1099 sales representatives.

Zimmer Biomet transitioned its sales representatives into independent contractors to save money, although some within the company did not believe the transition would lower costs; to ensure consistency; and to encourage entrepreneurship among the sales force. In an internal presentation shared with managers of the direct territories, Zimmer Biomet explained that the transition's "primary purpose" was "to reinvigorate the independence and entrepreneurial spirit that ha[d] been a key element of success in the past." Dkt. 193-38 at 4. Zimmer Biomet aimed to grow sales following the merger, in part by phasing out guaranteed pay for sales representatives in favor of performance-based pay, and the company hoped that transitioning its sales force into independent contractors would increase revenue.

During the transition, Zimmer Biomet emphasized to the managers of its direct territories that sales representatives

would have greater independence, flexibility, and income potential as independent contractors. Zimmer Biomet's managers in at least three territories circulated to their sales representatives a presentation, which was drafted by a third party and not approved by the company, that similarly stressed that being independent contractors would increase their independence and income potential and explained that they would be able to employ their spouse and children.

II. Role of Sales Representatives

All of Zimmer Biomet's orthopedic sales representatives work to generate business and increase sales of company products. They develop relationships with their assigned medical facilities and surgeons, meeting with surgeons at their offices and interacting with the surgeons' staff. Sales representative may contact one of their assigned surgeons if that surgeon has not used Zimmer Biomet products recently. They also reach out to new hospitals and surgeons in order to generate business. Some sales representatives pitch more expensive "top-of-the-line" products to doctors.

Sales representatives sometimes take surgeons out to meals or bring food to surgeons' offices in order to discuss Zimmer Biomet products. Sales representatives may also organize meals involving surgeons and Zimmer Biomet leadership. Zimmer Biomet pays reasonable travel expenses for surgeons to attend trainings and workshops at which sales representatives are present. Relator flew

with surgeons on a private plane owned or chartered by the company both before and after the Zimmer-Biomet merger.

All sales representatives assist surgeons in preparing for and performing procedures using Zimmer Biomet products. They may meet with a surgeon to determine what device is required for a given patient, order the necessary device, help schedule the procedure, assist in setting up for the surgery, and then observe the procedure to provide clinical support. They regularly communicate with hospitals to ensure the hospitals are stocked with the appropriate products. Sales representatives generally do not interact with patients during surgeries, although Relator states that on rare occasions he was briefly introduced to a patient while setting up. Sales representatives may also occasionally interact with potential patients during educational events put on by hospitals. One purpose of assisting surgeons with patient cases is to generate more sales.

Zimmer Biomet's sales representatives in direct territories, whether employees or independent contractors, are compensated via commissions based on a percentage of their sales. For fewer than one percent of 1099 sales representatives, the company has guaranteed a minimum amount of compensation for a year or two, although those representatives could earn more than the guarantee if they generated commissions above that amount. All sales representatives have quotas set by the company.

Zimmer Biomet's compliance manual, which applies to all sales representatives, prohibits financial arrangements with and improper payments to healthcare providers, bars the provision of gifts or entertainment to healthcare providers, and authorizes only modest and occasional meals in connection with scientific or educational presentations. The company investigates and disciplines sales representatives for compliance violations in the same manner regardless of their status as employees or independent contractors.

There are some differences between Zimmer Biomet's W-2 and 1099 sales representatives in direct territories. Only independent contractors enter into written agreements with the company. This agreement allows Zimmer Biomet to terminate a sales representative who fails to meet sales goals set by the company. Unlike employees, independent contractors may hire or contract with other individuals, including family members, to assist them in running their own businesses, but such individuals can only engage in sales-related activities with hospitals and surgeons if they are approved by Zimmer Biomet and contract with the company as a "sub-rep." While at least one Zimmer Biomet employee oversees all sales representatives in direct territories, 1099 sales representatives do not have a direct reporting relationship with Zimmer Biomet supervisors like W-2 sales representatives do.

Moreover, it is contested whether W-2 and 1099 sales representatives are subject to the same training requirements. Zimmer Biomet claims that all sales representatives must undergo certain compliance and product safety training, which includes training on the AKS and rules about interacting with healthcare providers, and that other optional product and sales trainings are equally available to both employee and independent contractor sales representatives. Relator, however, has submitted evidence from certain 1099 sales representatives stating that the training offered to them is not mandatory.

III. Zimmer Biomet's Understanding of the Legality of Its Use of Independent Contractor Sales Representatives

The parties have offered dueling evidence regarding Zimmer Biomet's understanding of the legality of its arrangement with its independent contractor sales representatives. Relator first points to a lawsuit Zimmer filed in 1997 against Nu Tech Medical, Inc. ("Nu Tech"), which provided distribution, marketing, and billing services to Zimmer as an independent contractor. See Zimmer, Inc. v. Nu Tech Med., Inc., 54 F. Supp. 2d 850, 851-52 (N.D. Ind. 1999). Zimmer sought a declaratory judgment that its contract with Nu Tech was void, including on the basis that its volume-based payments to Nu Tech violated the AKS. See id. at 853-54. After filing its lawsuit, Zimmer requested an advisory opinion from the OIG about the legality of the contract under federal healthcare

statutes. In its advisory opinion, the OIG stated that “[p]ercentage compensation arrangements are potentially abusive . . . because they provide financial incentives that may encourage overutilization of items and services and may increase program costs.” OIG Advisory Opinion No. 98-1, 1998 WL 35287756, at *4 (Mar. 19, 1998). The OIG then deemed Zimmer’s commission-based compensation to Nu Tech to be “problematic” because of (1) the significant percentage of revenue allocated to Nu Tech and the fact that Nu Tech charged prices well above Zimmer’s list prices; (2) the opportunity for Nu Tech to market to and unduly influence physicians and patients; and (3) the absence of safeguards against fraud and abuse. Id. The court subsequently concluded that the parties’ contract did violate the AKS. See Zimmer, 54 F. Supp. 2d at 863-64.

Relator also stresses that a Zimmer Biomet sales representative filed a putative class action lawsuit in 2018 alleging that the company misclassified him and other sales representatives as independent contractors rather than employees under federal and California employment law. See Karl v. Zimmer Biomet Holdings, Inc., et al., No. 18-cv-04176, Dkt. 1 (N.D. Cal. July 12, 2018). In opposing summary judgment during that suit, the plaintiff argued that if Zimmer Biomet’s sales representatives were independent contractors, their commission-based compensation would amount to illegal kickbacks under the AKS. Zimmer Biomet

responded that this argument was immaterial to the plaintiff's employment-law claims and that, in any event, using commission-based independent contractor sales representatives is not per se an AKS violation. The court did not address the AKS issue in resolving the summary judgment motion. See Karl v. Zimmer Biomet Holdings, Inc., No. 18-cv-04176, 2019 WL 5677543, at *7 n.3 (N.D. Cal. Oct. 31, 2019). As part of a settlement in the Karl litigation, Zimmer Biomet transitioned its sales representatives to W-2 employees in direct territories in California but not nationwide.

For its part, Zimmer Biomet emphasizes that both of its predecessor companies, Zimmer and Biomet, entered into a Corporate Integrity Agreement ("CIA") and Deferred Prosecution Agreement ("DPA") with the federal government in 2007 following an investigation into consulting arrangements between large surgical implant manufacturers and orthopedic surgeons. Those agreements all referenced Zimmer's or Biomet's use of independent distributors. So did various reports that were either submitted by the companies in connection with the CIAs or produced between 2007 and 2009 by the monitors appointed pursuant to the DPAs. As part of the DPAs, the monitors also reviewed and approved certain company documents and trainings concerning independent distributors and spoke with individuals at a number of distributors. Biomet told federal authorities in 2008 that it used

independent contractor sales representatives. At no point during the terms of Zimmer's and Biomet's CIAs or DPAs did the federal government or the monitors express concern about their uses of independent distributors or independent contractor sales representatives. Zimmer Biomet also publicly disclosed its use of independent contractor sales representatives in various Securities and Exchange Commission ("SEC") filings between 2018 and 2021.

IV. Relator's Work for and Separation from Zimmer Biomet

Relator has worked in medical device sales for many years. In 2006, he became a W-2 employee of Zimmer Rocky Mountain, an independent distributor that conducted sales for Zimmer as an independent contractor. In March 2014, Zimmer terminated its contract with Zimmer Rocky Mountain, and Relator became a W-2 employee of Zimmer. Relator experienced no change in title, supervision, training, or corporate policies when he became a Zimmer employee.

When Zimmer Biomet decided to transition its W-2 sales representatives in direct territories into independent contractors, the company provided Relator and his colleagues with an independent contractor agreement. Relator declined to sign the agreement. Zimmer Biomet therefore told him on November 24, 2015, that his employment would terminate at the end of December 2015.

Around the same time, Relator became concerned that Zimmer Biomet's arrangement with its 1099 sales representatives may

violate the AKS. He expressed this concern to a sales executive at a meeting on November 19, 2015. The executive responded by analogizing Zimmer Biomet's sales representatives to Uber drivers.

On November 30, 2015, Relator emailed his supervisor, Devin Kendall, with concerns about the independent contractor agreement, including that "commissions . . . paid to a non-employee of a medical device company" violate the AKS. Dkt. 193-21 at 3-4. In another email two days later, Relator added that he was "concerned the agreement [was] contrary to OIG Opinion 98-10," id. at 3, which states that "any compensation arrangement between a [s]eller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the" AKS, OIG Advisory Opinion No. 98-10, 1998 WL 35287765, at *3 (Aug. 31, 1998). Kendall responded to both emails by asking Relator to compile his specific concerns so that Kendall could pass them along to the company's attorneys. Kendall also told Relator to stop raising his concerns with others at the company.

After Relator sent a third email stating that the "1099 agreement has previously been found to be invalid because it violates the AKS safe harbor [for employees]," Dkt. 193-21 at 2, Kendall forwarded Relator's emails to an associate general counsel. The associate general counsel emailed Relator on December 14, 2015, explaining that "there should be no concern for [an AKS]

violation since [the company's] sales representatives are explicitly prohibited from entering into business relationships with physicians or hospitals or exerting undue influence over those responsible for making purchasing decisions" and asking Relator to "advise [the company] immediately" if he had "any reason to believe of any instances where this is not true." Dkt. 193-20 at 2. Relator did not respond to this email.

Despite being notified that his employment with Zimmer Biomet would end in December 2015, Relator continued to sell products and service his accounts for a few more months. In early 2016, Relator conveyed his AKS concerns about the independent contractor arrangement to Zimmer Biomet on two further occasions, once in a letter requesting severance and again in a complaint to the compliance office. Zimmer Biomet did not further respond to Relator about his AKS concerns after he submitted this letter and complaint. Relator's work for Zimmer Biomet ended in March 2016.

V. Procedural History

Relator filed this qui tam lawsuit in August 2021. Neither the United States nor any state intervened in the action. Zimmer Biomet filed a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), which the Court denied. See United States ex rel. Langer v. Zimmer Biomet Holdings, Inc., 743 F. Supp. 3d 282, 297 (D. Mass. 2024). The Court concluded that Relator had plausibly alleged that Zimmer Biomet's payments to its independent

contractor sales representatives amounted to illegal remuneration with the intent to induce referrals under the AKS and that Zimmer Biomet had acted knowingly and willfully. See id. at 291-93. The Court also rejected Zimmer Biomet's argument that dismissal was required pursuant to the FCA's public disclosure bar, finding that Relator qualified as an original source. See id. at 293-97. After discovery, Zimmer Biomet filed this motion for summary judgment.

LEGAL STANDARD

Summary judgment is appropriate "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). "A genuine dispute is one which 'a reasonable jury could resolve . . . in the favor of the non-moving party,' and a material issue is one with the 'potential to affect the outcome . . . under the applicable law.'" Kinzer v. Whole Foods Mkt., Inc., 99 F.4th 105, 108 (1st Cir. 2024) (alterations in original) (quoting Cherkaoui v. City of Quincy, 877 F.3d 14, 23-24 (1st Cir. 2017)). In determining whether to grant summary judgment, a court must construe "the facts in the light most favorable to the non-moving party" and "draw[] all reasonable inferences" in its favor. Id. (quoting Harley-Davidson Credit Corp. v. Galvin, 807 F.3d 407, 408 (1st Cir. 2015)).

The party seeking summary judgment "must [first] adumbrate 'an absence of evidence to support the nonmoving party's case.'"

Pleasantdale Condos., LLC v. Wakefield, 37 F.4th 728, 733 (1st Cir. 2022) (alteration in original) (quoting Brennan v. Hendrigan, 888 F.2d 189, 191 (1st Cir. 1989)). Once the movant does so, “[t]he burden then shifts to the nonmovant to establish the existence of a genuine issue of material fact.” Id. To satisfy this burden, the nonmovant “must present definite, competent evidence” demonstrating that a trialworthy issue exists. Id. (quoting Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991)). “[C]onclusory allegations, improbable inferences, and unsupported speculation” do not suffice. Kinzer, 99 F.4th at 108 (quoting Ellis v. Fid. Mgmt. Tr. Co., 883 F.3d 1, 7 (1st Cir. 2018)).

DISCUSSION

The Court begins by describing the relevant FCA and AKS standards, then turns to the parties’ arguments regarding Zimmer Biomet’s alleged violations of those statutes, and concludes with Relator’s claims under state and local law.

I. Federal FCA and AKS Standards

Relator seeks to hold Zimmer Biomet liable under two provisions of the FCA. First, Relator contends that Zimmer Biomet “knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval” to the federal government. 31 U.S.C. § 3729(a)(1)(A). To establish liability under this provision, a plaintiff must “show (1) that there[is] a ‘false or fraudulent claim’ made to the government, (2) that the

defendant 'presents, or causes to be presented,' that claim, and (3) that the defendant did so 'knowingly.'" United States ex rel. Omni Healthcare Inc. v. MD Spine Sols. LLC, 160 F.4th 248, 258 (1st Cir. 2025) (quoting 31 U.S.C. § 3729(a)(1)(A)). The plaintiff also must demonstrate that the claim's falsity was material to the government's payment decision. See Guilfoile v. Shields, 913 F.3d 178, 187 (1st Cir. 2019). Second, Relator contends that Zimmer Biomet "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). As with § 3729(a)(1)(A), a claim under this provision has "four elements: "(1) . . . statements were made; (2) these . . . statements were false; (3) these falsehoods were material; and (4) these statements were made with scienter of the falsehood." United States ex rel. Mackillop v. Grand Canyon Educ., Inc., 626 F. Supp. 3d 418, 444-45 (D. Mass. 2022).¹

The FCA defines "knowingly" to mean that the defendant "has actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A); see Omni Healthcare, 160 F.4th at 258.

¹ Relator's complaint also alleges that Zimmer Biomet conspired to violate the FCA under 31 U.S.C. § 3729(a)(1)(C). Relator abandoned this claim in his opposition to Zimmer Biomet's summary judgment motion.

"[P]roof of specific intent to defraud," however, is not required. 31 U.S.C. § 3729(b)(1)(B); see Omni Healthcare, 160 F.4th at 258 n.12.

Relator's theory of FCA liability under both provisions is premised on an underlying violation of the AKS. The AKS makes it a criminal offense to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person":

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend 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.

42 U.S.C. § 1320a-7b(b)(2). Congress enacted the AKS "to prevent medical providers from making decisions based on improper financial incentives rather than medical necessity and to ensure that federal health care programs do not bear the costs of such decisions." United States ex rel. Flanagan v. Fresenius Med. Care Holdings, Inc., 142 F.4th 25, 35 (1st Cir. 2025) (quoting United States ex rel. Banigan v. PharMerica, Inc., 950 F.3d 134, 137 (1st Cir. 2020)). The "heartland of what the AKS is intended to prevent" is "the use of payments to improperly influence decisions on the provision of health care that lead to claims for payment to federal

health care programs.” Guilfoile, 913 F.3d at 192-93. “Essentially, the AKS targets any remunerative scheme through which a person is ‘paid in return for referrals’ to a program under which payments may be made from federal funds.” Flanagan, 142 F.4th at 35 (quoting Guilfoile, 913 F.3d at 189).

A necessary element of an AKS violation is the “intent of the person or company providing remuneration.” United States v. Teva Pharms. USA, Inc., 560 F. Supp. 3d 412, 419 (D. Mass. 2021); see United States ex rel. Witkin v. Medtronic, Inc., 189 F. Supp. 3d 259, 268 (D. Mass. 2016). The statute “requires intent to influence physicians to prescribe care reimbursable by the federal government.” Teva, 560 F. Supp. 3d at 419. This “intent requirement may be satisfied as long as ‘at least one purpose of the remuneration was to induce Medicare purchases.’” Id. (quoting United States ex rel. Strunck v. Mallinckrodt ARD LLC, No. 12-cv-175, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020)); see Guilfoile, 913 F.3d at 189 (listing one “[r]elevant consideration[] for identifying an unlawful kickback” as “whether at least one purpose of the payment could be ‘to induce or reward the referral or recommendation of business payable in whole or in part by a [f]ederal health care program’” (third alteration in original) (quoting OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005))).

Liability under the AKS is not triggered, however, “where a company hopes or expects that ‘referrals may ensue from remuneration that was designed wholly for other purposes.’” Teva, 560 F. Supp. 3d at 420 (quoting United States v. McClatchey, 217 F.3d 823, 834 (10th Cir. 2000)).

Establishing an AKS violation also requires proof that the defendant acted “knowingly and willfully.” 42 U.S.C. § 1320a-7b(b) (2). In this context, the term “willfully” refers to knowledge that the conduct was unlawful. See Zimmer Biomet, 743 F. Supp. 3d at 292; Teva, 560 F. Supp. 3d at 421; see also United States ex rel. Hart v. McKesson Corp., 96 F.4th 145, 154-55, 157 (2d Cir. 2024) (adopting this meaning and collecting cases from other circuits doing the same).

An AKS violation may trigger FCA liability via “two pathways,” Flanagan, 142 F.4th at 35, that “run on . . . separate track[s],” United States v. Regeneron Pharms., Inc., 128 F.4th 324, 334 (1st Cir. 2025). One, which rests on 42 U.S.C. § 1320a-7b(g), occurs “when claims for payment are made ‘resulting from’ AKS violations.” Flanagan, 142 F.4th at 35 (quoting 42 U.S.C. § 1320a-7b(g)). Under this pathway, an “AKS violation that results in a federal health care payment is a per se false claim under the FCA.” Guilfoile, 913 F.3d at 190 (quoting United States ex rel. Lutz v. United States, 853 F.3d 131, 135 (4th Cir. 2017)); see 42 U.S.C. § 1320a-7b(g) (providing that “a claim that includes items or services

resulting from a violation of th[e AKS] constitutes a false or fraudulent claim for purposes of" the FCA). To establish liability under this pathway, "the plaintiff 'must show that an illicit kickback was the but-for cause of a submitted claim,'" i.e., that the claim would not have been submitted in the absence of the kickback. Flanagan, 142 F.4th at 35 (quoting Regeneron, 128 F.4th at 336). This theory of liability is viable regardless of the materiality of the AKS violation and regardless of whether there was "any representation -- implied or express -- of AKS compliance" to the government. Regeneron, 128 F.4th at 334.

The second pathway -- the "false certification" theory, id. at 333 -- arises "when someone falsely represents compliance with a material requirement that there be no AKS violation in connection with the claim." Flanagan, 142 F.4th at 35 (quoting Regeneron, 128 F.4th at 333). Under this second pathway, the claim is false not due to "the AKS violation itself" but, rather, because of "the false representation that there is no AKS violation." Regeneron, 128 F.4th at 333. To succeed on a false certification theory, the plaintiff "must show that the . . . misrepresentation of AKS compliance was material to the government's payment decision." Id. at 334. This type of claim does not, though, require that the plaintiff prove that the AKS violation was the but-for cause of a submitted claim. See Flanagan, 142 F.4th at 37; Regeneron, 128 F.4th at 333-34.

II. Alleged AKS Violation

The Court starts with the parties' arguments as to whether Zimmer Biomet's commission-based payments to its independent contractor sales representatives violate the AKS. Zimmer Biomet contends that no reasonable jury could find that it has made the payments with an unlawful intent to induce referrals or that it acted willfully.

A. Intent to Induce Referrals

Zimmer Biomet first asserts that the record does not support a reasonable finding that it has paid its independent contractor sales representatives with the unlawful intent to induce referrals required by the AKS. Zimmer Biomet argues that it transitioned its sales representatives in direct territories from employees to independent contractors to save costs, encourage their entrepreneurial spirit, and ensure consistency across the sales force. A simple desire to increase sales or revenue, Zimmer Biomet continues, does not satisfy the AKS's intent-to-induce requirement.

Zimmer Biomet's argument about its intent in paying commissions to its independent contractor sales representatives implicates the difficult question of when such payments violate the AKS. As an initial matter, the Court notes that while the AKS contains a safe harbor for payments "by an employer to an employee (who has a bona fide employment relationship with such employer)

for employment in the provision of covered items or services,” 42 U.S.C. § 1320a-7b(b)(3)(B); see 42 C.F.R. § 1001.952(i); United States v. Cockerell, 140 F.4th 213, 222 (5th Cir. 2025); United States v. Sorensen, 134 F.4th 493, 500 n.5 (7th Cir. 2025), this safe harbor does not protect payments to independent contractors, see United States v. Mallory, 988 F.3d 730, 738 (4th Cir. 2021); Zimmer Biomet, 743 F. Supp. 3d at 290.

The Office of Inspector General (“OIG”) has recognized that “any compensation arrangement between a [s]eller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the” AKS. OIG Advisory Opinion No. 98-10, supra, at *3 (emphasis added). The OIG has offered two sets of factors that bear on the permissibility of such arrangements. The first set of “suspect characteristics,” which the OIG laid out in 1998, are (1) “compensation based on percentage of sales”; (2) “direct billing of a Federal health care program by the Seller for the item or service sold by the sales agent”; (3) “direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a Federal health care program”; (4) “direct contact between the sales agent and Federal health care program beneficiaries”; (5) “use of sales agents who are health care professionals or persons in a similar position to exert undue influence on

purchasers or patients”; and (6) “marketing of items or services that are separately reimbursable by a Federal health care program.” Id. at *3-4.

In 2003, the OIG offered a second set of factors: (1) the “amount of compensation”; (2) the “identity of the sales agent engaged in the marketing or promotional activity (e.g., is the agent a ‘white coat’ marketer or otherwise in a position of exceptional influence)”; (3) the “sales agent’s relationship with his or her audience”; (4) the “nature of the marketing or promotional activity”; (5) the “item or service being promoted or marketed”; and (6) the “composition of the target audience.” OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23739 (May 5, 2003).

The Fourth Circuit has interpreted the AKS to broadly criminalize any commissions based on volume or value of sales paid to independent contractors who are hired to influence those who make healthcare decisions on behalf of providers by promoting a company’s product or service that is reimbursable by the federal government. See United States ex rel. Nicholson v. MedCom Carolinas, Inc., 42 F.4th 185, 194 (4th Cir. 2022); Mallory, 988 F.3d at 738. Both Relator and the federal government, which declined to intervene in this case but participated at oral argument on Zimmer Biomet’s summary judgment motion, essentially urge the Court to adopt this approach. While they dispute that

they are advocating for a “per se” rule that commission-based payments to independent contractor sales representatives violate the AKS, they contend that such payments amount to an AKS violation whenever the elements of the AKS -- remuneration, intent to induce referrals, and willfulness -- are satisfied. And in Relator’s view, the payor of such commissions has an intent to induce referrals when it makes the payments with an intent to influence the products the sales representatives promote to physicians. Under this interpretation, the AKS’s intent-to-induce requirement would be satisfied in every case involving commission-based payments to independent contractor sales representatives because promoting the company’s products is always “why they [are] hired.” Omni Healthcare, Inc. v. MD Spine Sols. LLC, 761 F. Supp. 3d 356, 361 (D. Mass. 2025), aff’d, 160 F.4th 248.² The Court disagrees with Relator’s position that the intent-to-induce requirement is met by the mere payment of commissions.

As noted, Zimmer Biomet rejects the notion that a mere desire to increase sales or revenue satisfies the AKS’s intent-to-induce requirement. In Zimmer Biomet’s view, the AKS requires an intent

² The federal government stressed that it views the AKS’s willfulness requirement and the difficulty of proving that a party knew its commission-based payments to independent contractor sales representatives were illegal as a significant limitation on the scope of criminal liability in this context.

to improperly influence the decisions of providers purchasing the products reimbursable by the federal government. The Court agrees.

Zimmer Biomet's position mirrors the approach taken by the Fifth, Seventh, and Ninth Circuits in cases involving payments to independent contractor sales representatives or marketing agents, which focuses on a defendant's intent in making the payments. This approach "dr[aws] a distinction . . . between . . . [the] intent to induce 'referrals,' which is illegal, and the intent to compensate advertisers, which is permissible." Cockerell, 140 F.4th at 218 (alterations in original) (quoting United States v. Shoemaker, 746 F.3d 614, 628 (5th Cir. 2014)); see Sorensen, 134 F.4th at 501 (distinguishing between lawful "payments for aggressive advertising efforts" and unlawful "payments to individuals who take advantage of their existing relationships with patients or other health care providers"). The "mere fact that the good or service provider compensates the advertiser following each purchase is insufficient" to establish an AKS violation, Cockerell, 140 F.4th at 218 (quoting Shoemaker, 746 F.3d at 628), as is, "without more," a "percentage-based compensation structure for marketing agents," United States v. Schena, 142 F.4th 1217, 1224 (9th Cir. 2025) (interpreting materially identical language in the Eliminating Kickbacks in Recovery Act ("EKRA")), cert. denied, 146 S. Ct. 1824 (2026); see Sorensen, 134 F.4th at 502. No AKS violation occurs when

"physicians always ha[ve] ultimate control over their patients' healthcare choices and appl[y] independent judgment in exercising that control." Sorensen, 134 F.4th at 502.

Rather, liability under the AKS attaches under this approach only when the "payments to a marketing agent reflect a wrongful effort to unduly influence the decisions of doctors and medical professionals making referrals." Schena, 142 F.4th at 1225 (emphasis added); see Cockerell, 140 F.4th at 218 (asking whether the defendant "intended 'improperly [to] influence[]' those who make healthcare decisions on behalf of patients" (alterations in original) (quoting United States v. Marchetti, 96 F.4th 818, 827 (5th Cir. 2024))); Sorensen, 134 F.4th at 501 (asking whether the defendant "leveraged any sort of informal power and influence over healthcare decisions"). Courts have found this type of undue influence "when a marketing intermediary effectively takes over the role of the referring physician" by selecting which provider or product to use, Schena, 142 F.4th at 1225-26; see Sorensen, 134 F.4th at 501-02; Marchetti, 96 F.4th at 827; "when percentage-based payments are made to marketing agents who are directed to mislead those making the referrals about the nature of and need for the covered medical services," Schena, 142 F.4th at 1226; and when marketers "provid[ed] physicians with . . . prescription pads with profitable compounds already written out," "promotional

dinners," "lavish vacations," and "offerings of investment in management service organizations," Cockerell, 140 F.4th at 220.

The First Circuit has not addressed how the AKS applies to commission-based payments to independent contractor sales representatives. In the absence of controlling precedent, this Court adopts the approach taken by the Fifth, Seventh, and Ninth Circuits that focuses on an intent to improperly influence physicians' decisionmaking rather than to simply increase sales. That approach is consistent with the First Circuit's statement that "the heartland of what the AKS is intended to prevent" is "the use of payments to improperly influence decisions on the provision of health care that lead to claims for payment to federal health care programs." Guilfoile, 913 F.3d at 192-93 (emphasis added). Similarly, another court in this district has defined the AKS's intent-to-induce requirement to "mean[] an intent 'to gain influence over the reason or judgment' of the physicians" to whom a defendant provided remuneration. Witkin, 189 F. Supp. 3d at 271 (quoting McClatchey, 217 F.3d at 834). Distinguishing between lawful payments meant to compensate advertisers for making sales and unlawful payments meant to encourage undue influence over physician referrals reflects this focus on improper influence over physicians' reason or judgment.

This approach also finds textual support in the AKS's use of the term "induce." 42 U.S.C. § 1320a-7b(b) (2). As the Ninth Circuit

has cogently explained regarding materially identical language in EKRA:

"[I]nduce" has a "longstanding history" in criminal law. United States v. Hansen, 599 U.S. 762, 778 (2023). Although "in ordinary parlance, 'induce' means to lead on; to influence; to prevail on; to move by persuasion or influence," it has a "specialized, criminal-law" meaning that "incorporates common-law liability for solicitation and facilitation." Id. at 774 (internal quotations omitted). Criminal solicitation "is the intentional encouragement of an unlawful act," and criminal facilitation (also known as aiding and abetting) "is the provision of assistance to a wrongdoer with the intent to further an offense's commission." Id. at 771. We take from Hansen that the term "induce" connotes not mere causation, but wrongful causation. And it makes sense to read EKRA as incorporating the "well-established legal meaning" of "induce," because "when Congress 'borrows terms of art in which are accumulated the legal tradition and meaning of centuries of practice, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word.'" Id. at 774 (quoting Morrisette v. United States, 342 U.S. 246, 263 (1952)).

Schena, 142 F.4th at 1224 (cleaned up). Any commission-based payments to independent contractor sales representatives are meant to "induce" referrals in the colloquial sense, but only when such payments are accompanied by a fraudulent intent or an effort to improperly influence physicians' decisionmaking do they reflect the wrongful causation connoted by the criminal-law definition of "induce."

Finally, the Court is cognizant that "[p]lainly, . . . sales representatives . . . s[ee]k to influence referral of [products] . . . -- that's why they [are] hired." Omni Healthcare,

761 F. Supp. 3d at 361; see Schena, 142 F.4th at 1225 (“All marketing efforts are intended to influence the recipient.”). While the AKS uses broad language, “[i]n the absence of a clearer indication in the statute,” the Court is “hard-pressed to read [the AKS] to criminalize (with major federal penalties) a standard payment structure for marketing personnel, even when the marketing personnel are persuasive in driving business.” Schena, 142 F.4th at 1225.

While the Court largely agrees with Zimmer Biomet about the meaning of the AKS’s intent-to-induce requirement in the context of commission-based payments to independent contractor sales representatives, the Court concludes that a reasonable jury could find such an intent in this case. It is true that much of the evidence Relator cites reflects a lawful intent on Zimmer Biomet’s part to structure and incentivize its sales force to engage in more and better marketing efforts, to sell more products in turn, and thereby to increase revenue for the company. For example, the main goal of Zimmer Biomet’s sales representatives is to sell more products to physicians, and they are incentivized to do so by commission-based pay; the company sets quotas for its sales representatives and may fire those who fail to meet those quotas; and Zimmer Biomet transitioned its sales force to independent contractors at least partially to improve their sales performance by giving them more autonomy, including by hiring family members.

By themselves, these practices merely evince a lawful intent to compensate sales representatives for marketing services that drive sales.

That said, in light of the above-cited caselaw and the OIG guidance, other facts in the record support a reasonable inference that Zimmer Biomet has paid its independent contractor sales representatives with an unlawful intent to improperly influence physicians' decisionmaking. In so concluding, the Court is guided by the factors set forth by the OIG. While those factors are not binding on this Court with respect to the meaning of the AKS, see 42 C.F.R. § 1008.53 ("An advisory opinion issued by the OIG will have no application to any individual or entity that does not join in the request for the opinion."); OIG Compliance Program Guidance, 68 Fed. Reg. at 23733 (providing that the 2003 "guidance does not create any new law or legal obligations"); cf. Loper Bright Enters. v. Raimondo, 603 U.S. 369, 406 (2024) (explaining that courts must "exercise independent judgment in construing statutes administered by agencies"), they provide useful guideposts in assessing when a commission-based compensation arrangement with independent contractor sales representatives reflects an intent to improperly influence physicians.

A reasonable jury could find many of the OIG factors satisfied in this case. Zimmer Biomet concedes that its sales representatives are compensated almost exclusively via commissions and interact

directly with the surgeons who order the products. See OIG Compliance Program Guidance, 68 Fed. Reg. at 23739 (the "amount of compensation" and the "sales agent's relationship with his or her audience"); OIG Advisory Opinion No. 98-10, supra, at *3 ("compensation based on percentage of sales" and "direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a Federal health care program"). It is undisputed that sales representatives are present with surgeons during surgical procedures in the operating room, placing them in a position of exceptional influence to directly influence the surgeons' decisionmaking. See OIG Compliance Program Guidance, 68 Fed. Reg. at 23739 (the "identity of the sales agent engaged in the marketing or promotional activity (e.g., is the agent a 'white coat' marketer or otherwise in a position of exceptional influence)"); OIG Advisory Opinion No. 98-10, supra, at *3 ("use of sales agents who are health care professionals or persons in a similar position to exert undue influence on purchasers or patients"). Relator has offered evidence that sales representatives occasionally interact with patients. See OIG Advisory Opinion No. 98-10, supra, at *3 ("direct contact between the sales agent and Federal health care program beneficiaries"). There is also evidence that some sales representatives try to "upsell" doctors by encouraging them to buy a top-of-the-line product simply because it is more expensive; that Relator flew

with surgeons on a private jet owned or chartered by Zimmer or Zimmer Biomet both before and after the Zimmer-Biomet merger and the company pays for surgeons' travel expenses to attend workshops; and that sales representatives take surgeons out to meals, bring food to surgeons' offices, and organize dinners involving surgeons and Zimmer Biomet leadership in order to promote the company's products. See OIG Compliance Program Guidance, 68 Fed. Reg. at 23739 (the "nature of the marketing or promotional activity").

A reasonable jury could infer from the collective weight of these facts that Zimmer Biomet has paid its independent contractor sales representatives with an unlawful intent to induce referrals as required by the AKS rather than simply with a desire to drive sales. Summary judgment is therefore not warranted for Zimmer Biomet on this basis.

B. Willfulness

Zimmer Biomet next argues that the record contains insufficient evidence that any violation of the AKS via its commission-based payments to its independent contractor sales representatives was done knowingly and willfully. Zimmer Biomet stresses that it disclosed its use of independent contractor sales representatives in various SEC filings, the federal government was aware from its investigations in the 2000s that Zimmer and Biomet used independent contractor sales representatives, and the federal government never expressed concern about the structure of

Zimmer's, Biomet's, or Zimmer Biomet's sales forces. Zimmer Biomet also asserts that its arrangement with its independent contractor sales representatives is consistent with those the OIG has approved in various advisory opinions, thereby negating any inference of willfulness.

To satisfy the AKS's willfulness requirement, a plaintiff must show that the defendant acted with knowledge that its conduct was unlawful. See Hart, 96 F.4th at 157; Zimmer Biomet, 743 F. Supp. 3d at 292; Teva, 560 F. Supp. 3d at 421. Zimmer Biomet's and its predecessor companies' open use of independent contractor sales representatives does cut against the conclusion that Zimmer Biomet knew its payments to those sales representatives were unlawful. See United States ex rel. Hart v. McKesson Corp., 602 F. Supp. 3d 575, 596 (S.D.N.Y. 2022); United States ex rel. Suarez v. AbbVie, Inc., 503 F. Supp. 3d 711, 735 (N.D. Ill. 2020). So does the fact that the federal government was aware that Zimmer and Biomet were using independent contractor sales representatives. See United States ex rel. Spay v. CVS Caremark Corp., 875 F.3d 746, 755 (3d Cir. 2017).

But "[c]ourts use special caution in granting summary judgment" on issues of scienter because scienter "is often proved by inference . . . , and on a motion for summary judgment, all reasonable inferences must be drawn in favor of the nonmoving party." Daniels v. Agin, 736 F.3d 70, 83 (1st Cir. 2013); see Omni

Healthcare, 160 F.4th at 259 n.13 (explaining that while “the presence of issues involving state of mind, intent, or motivation does not automatically preclude summary judgment,” a “resort to summary judgment is vested with more than usual difficulty” in cases where “the state of mind of one of the parties is crucial to the outcome” (quoting Stepanischen v. Merchs. Despatch Transp. Corp., 772 F.2d 922, 928-29 (1st Cir. 1983))). Here, Relator has offered sufficient evidence to create a genuine dispute about whether Zimmer Biomet understood the illegality of its commission-based payments to its independent contractor sales representatives when coupled with the sales tactics used by them.

For one, Zimmer Biomet was put on notice of the potential unlawfulness of its use of independent contractor sales representatives in the Nu Tech litigation in late 1990s. In that litigation, Zimmer, one of Zimmer Biomet’s predecessor companies, itself argued that its volume-based payments to an independent contractor distributor and marketer called Nu Tech violated the AKS. See Zimmer, 54 F. Supp. 2d at 854. The OIG agreed in an advisory opinion that explained that “[p]ercentage compensation arrangements are potentially abusive,” OIG Advisory Opinion No. 98-1, supra, at *4, as did the district court in granting Zimmer’s summary judgment motion in the case, see Zimmer, 54 F. Supp. 2d at 863-64. While Zimmer Biomet stresses that the OIG highlighted certain problematic aspects of the Zimmer-Nu Tech contract that

are not present here -- such as Nu Tech's charging of prices substantially in excess of Zimmer's list prices -- whether Zimmer Biomet believed those differences rendered permissible its post-merger payments to its independent contractor sales representatives is a factual question for a jury to resolve.

Zimmer Biomet also received more recent warnings that its arrangement with its independent contractor sales representatives may violate the AKS. On multiple occasions shortly before Relator left Zimmer Biomet in 2016, he expressed concern to his supervisor and to the company's compliance office about whether the use of independent contractor sales representatives complied with the AKS and the OIG's advisory opinions. A few years later, the plaintiff in the Karl litigation argued that classifying Zimmer Biomet's sales representatives as independent contractors would mean that their commission-based compensation constituted an illegal kickback. The record contains no evidence that Zimmer Biomet agreed with either Relator or the Karl plaintiff that the company's arrangement with its independent contractor sales representatives violated the AKS. But the multiple warnings that Zimmer Biomet received over time regarding the legality of that arrangement, coupled with the position Zimmer took in the Nu Tech litigation regarding commission-based payments to an independent contractor distributor and marketer, is sufficient for a reasonable jury to

find that the company's alleged AKS violation was willful and knowing.

The contrary evidence offered by Zimmer Biomet is insufficient to establish as a matter of law that it did not act with the requisite state of mind. With respect to the federal government's knowledge of Zimmer's and Biomet's use of independent contractor sales representatives during its investigation in the 2000s, courts have held in FCA cases "that when 'the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim.'" United States ex rel. Streck v. Eli Lilly & Co., 152 F.4th 816, 845 (7th Cir. 2025) (quoting United States ex rel. Durcholz v. FKW Inc., 189 F.3d 542, 545 (7th Cir. 1999)), cert. denied, 146 S. Ct. 2667 (2026). "But 'merely showing some government knowledge' of the falsity is not enough; there must be evidence of the government's 'cooperation and collaborative problem-solving' or 'explicit approval' to undercut scienter." Id. (quoting Spay, 875 F.3d at 757, 759). Here, while both the federal government and the monitors appointed pursuant to Zimmer's and Biomet's DPAs were generally aware of the companies' use of independent contractor sales representatives and did not expressly disapprove of the arrangement, Zimmer Biomet has not shown that they knew about the specific aspects of the arrangement that raise questions about its

intent to improperly influence physicians' decisionmaking. Moreover, the federal government's investigation was focused on consulting arrangements between large surgical implant manufacturers and orthopedic surgeons, not on the manufacturers' use of independent contractor sales representatives. A reasonable jury could view these circumstances as falling short of the "explicit approval" that would undercut Zimmer Biomet's knowledge of the unlawfulness of its conduct as a matter of law. Id. (quoting Spay, 875 F.3d at 759).

Nor do the OIG's advisory opinions conclusively establish, as Zimmer Biomet argues, that the company did not act willfully. The six "suspect characteristics" identified by the OIG with respect to compensation for independent contractor sales representatives do not irrefutably point in Zimmer Biomet's favor. OIG Advisory Opinion No. 98-10, supra, at *3-4. The OIG has approved arrangements that implicate no more than two of these characteristics, see OIG Advisory Opinion No. 99-3, 1999 WL 34984727, at *7 (Mar. 16, 1999); OIG Advisory Opinion No. 98-10, supra, at *4, and, for the reasons previously discussed, Zimmer Biomet's use of independent contractor sales representatives arguably implicates at least four.

Accordingly, the Court concludes that a reasonable jury could find that Zimmer Biomet made commission-based payments to its independent contractor sales representatives with knowledge that

doing so was unlawful. As there is a genuine dispute on this record as to whether Zimmer Biomet violated the AKS, Zimmer Biomet is not entitled to summary judgment on this ground.

III. Alleged FCA Violation

Having determined that Relator has presented a triable case that Zimmer Biomet's commission-based payments to its independent contractor sales representatives violate the AKS in light of the factors set forth by the OIG, the Court now turns to the parties' arguments as to whether this violation supports liability under the FCA. Zimmer Biomet contends that (1) Relator has failed to put forth competent evidence of an actual false claim, (2) no reasonable jury could find that any AKS violation was the but-for cause of a false claim, (3) Relator cannot proceed on a false certification theory, (4) there is insufficient evidence of scienter, and (5) the public disclosure bar defeats the FCA claims because Relator does not qualify as an original source. The Court addresses these arguments in turn.

A. Evidence of a False Claim and Damages

Zimmer Biomet asserts that Relator has failed to offer sufficient evidence of an actual false claim. "It is well settled that '[e]vidence of an actual false claim is "the sine qua non of a False Claims Act violation."' " United States ex rel. Booker v. Pfizer, Inc., 847 F.3d 52, 57 (1st Cir. 2017) (alteration in original) (quoting United States ex rel. Karvelas v. Melrose-

Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004)). In other words, "even when a relator can prove that a defendant engaged in 'fraudulent conduct affecting the government,' FCA liability attaches only if that conduct resulted in the filing of a false claim for payment from the government." Id. (quoting United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 727 (1st Cir. 2007)). It follows that "at the summary judgment stage, relators must produce competent evidence of an actual false claim made to the government." Id. at 58.

Zimmer Biomet first argues that the Court should preclude all of the relevant data regarding claims for payments from the federal government because that data was produced after the close of discovery. Zimmer Biomet further argues that the Court should not consider declarations about that claims data submitted by Relator. The Court has already rejected these arguments in resolving Zimmer Biomet's motion to strike and Relator's motion for leave to supplement the record. See Dkt. 228.

Zimmer Biomet next contends that the evidence Relator has offered about claims for payment to the federal government fails to show any specific claim in connection with which Zimmer Biomet paid a commission to an independent contractor sales representative. The Court disagrees. Relator analyzed Zimmer Biomet's sales, inventory, and scheduling data to compile a list of orthopedic-related procedures using the company's products that

occurred after the transition of the sales force to independent contractors in January 2016. Relator excluded from this list the procedures that occurred in indirect territories and in territories where Zimmer Biomet later converted its sales representatives to employees. Relator's Touhy request to the federal government sought claims and payment data related to the procedures on this list. Relator received that data from the federal government, and a declaration from a consultant for Relator describes a specific claim submitted to and paid by the Centers for Medicare & Medicaid Services ("CMS") for a hip replacement that matches one of the procedures in Zimmer Biomet's orthopedic sales records and took place in a direct sales territory where the company used independent contractor sales representatives. This evidence suffices to satisfy Relator's obligation at this stage to show an actual false claim submitted to the federal government.

Zimmer Biomet correctly points out that Relator has not identified an independent contractor sales representative who sold the product used in this specific procedure or offered direct evidence of the commission paid to that individual for this sale. But because Zimmer Biomet pays its sales representatives on a commission basis for each sale they make, a jury could reasonably infer that the company paid a commission in connection with the specific claim identified by Relator. And because Relator excluded procedures performed in direct territories where Zimmer Biomet

later converted its sales force to employees, a jury could reasonably infer that the sales representative to whom the commission was paid was an independent contractor.³

Additionally, Zimmer Biomet argues that it is entitled to summary judgment with respect to damages because Relator did not disclose a damages computation during discovery. Federal Rule of Civil Procedure 26(a)(1)(A)(iii) requires that a party's initial disclosure include "a computation of each category of damages claimed by the disclosing party." Here, Relator did disclose during discovery the categories of damages he is seeking in this lawsuit and the basic methodology for calculating those damages, but he could not provide actual computations of damages because he only received relevant data on claims for payment after discovery closed. Under such circumstances, Relator did not violate Rule

³ Zimmer Biomet has put forth evidence that a small percentage of sales representatives working on specialty product lines (such as trauma, foot, and ankle products) remained employees after the sales force transition. Zimmer Biomet also guaranteed a certain level of pay to fewer than one percent of its independent contractor sales representatives rather than paying them purely on commissions. These aspects of the record do not undermine the reasonable inference that Zimmer Biomet paid a commission to an independent contractor sales representative in connection with the specific claim for payment cited by Relator. It is disputed whether Zimmer Biomet converted all or only most of its sales representatives to independent contractors and, in any event, the specific claim for payment involved a hip product rather than one of the specialty product lines. Moreover, the percentage of sales representatives receiving guarantees is so small that a reasonable jury could infer that the sales representative involved in the procedure at issue was paid on a commission.

26(a)(1)(A)(iii) by not disclosing damages computations during discovery. See Fed. R. Civ. P. 26 advisory committee's note to 1993 amendment ("[A] party would not be expected to provide a calculation of damages which . . . depends on information in the possession of another party or person."); AVX Corp. v. Cabot Corp., 252 F.R.D. 70, 77-78 (D. Mass. 2008) (finding no disclosure violation with respect to late damages calculations based on information produced only after the close of discovery). And even if there were a disclosure violation, it would have been substantially justified. See Fed. R. Civ. P. 37(c)(1) (providing that preclusion is not warranted for a disclosure violation that "was substantially justified or is harmless"). As the Court has previously explained, Realtor "acted diligently in seeking the federal and state claims data[,] and . . . the late productions [of that data] were justified by the need to conduct discovery in order to draft a tailored Touhy request." Dkt. 228 at 3. Without that claims data, Relator could not disclose damages computations.

B. But-For Causation

Zimmer Biomet next challenges Relator's reliance on 42 U.S.C. § 1320a-7b(g)'s pathway for proving FCA liability based on an alleged AKS violation. Recall that under this pathway, "the plaintiff 'must show that an illicit kickback was the but-for cause of a submitted claim.'" Flanagan, 142 F.4th at 35 (quoting Regeneron, 128 F.4th at 336). Zimmer Biomet contends that Relator

cannot satisfy this requirement with respect to its commission-based payments to independent contractor sales representatives.

Zimmer Biomet does not dispute that a reasonable jury could find that those commission-based payments were the but-for cause of submitted claims in the sense that, without those payments and the associated marketing and clinical services provided by the independent contractor sales representatives, surgeons would not have purchased the company's products. Instead, Zimmer Biomet rests its argument on this Court's decision in Omni Healthcare, which addressed a similar claim alleging that a medical testing laboratory's commission-based payments to its independent contractor sales representatives constituted an AKS violation that, in turn, resulted in the submission of false claims under the FCA. See 761 F. Supp. 3d at 360-61, 366. There, the Court held that no reasonable jury could find but-for causation where the relator "offered no evidence that the independent[]contractor status of some of [the laboratory's] sales representatives unduly influenced any provider's decision to order . . . testing from" the laboratory. Id. at 369. The Court stressed that the laboratory "submitted un rebutted evidence that [it] trained, managed, disciplined, and paid its sales representatives identically whether they were employees or independent contractors" and that nothing in the record suggested that "independent[]contractor sales representatives acted any differently than the employees

receiving commission-based payments from" the laboratory. Id. The Court also noted that the record did not "support a reasonable finding that any independent[]contractor sales representative engaged in conduct that improperly or unduly influenced a provider's decision to purchase the product." Id.

The parties debate at length whether there are material differences between the training, oversight, discipline, and compensation of Zimmer Biomet's employee and independent contractor sales representatives. There appears to be no material distinction at least in terms of compensation, oversight, and discipline. Regardless, the Court need not weigh into this debate because, unlike in Omni Healthcare, Relator has offered evidence in this case that Zimmer Biomet's "independent[]contractor sales representative[s] engage[] in conduct that improperly or unduly influence[s] a provider's decision to purchase the product." Id. As previously discussed with respect to the AKS's intent-to-induce requirement, Zimmer Biomet's independent contractor sales representatives are present with surgeons during procedures. Relator has also put forth evidence that sales representatives occasionally interact with patients; that some try to "upsell" doctors to buy more expensive top-of-the-line products; that Relator accompanied surgeons on private jet flights; and that sales representatives provide surgeons and their staff with meals. Together with the common-sense inference that surgeons would not

purchase Zimmer Biomet products without the marketing and clinical services provided by sales representatives that result from the company's payment of commissions, this evidence of improper influence is sufficient to support a triable case that the payment of commissions was the but-for cause of submitted claims for Zimmer Biomet products as required for FCA liability under § 1320a-7b(g)'s pathway.

C. False Certification Pathway

Relator also argues that he has established a triable FCA claim based on an alleged AKS violation via the separate false certification pathway. This pathway authorizes FCA liability "when someone falsely represents compliance with a material requirement that there be no AKS violation in connection with the claim." Flanagan, 142 F.4th at 35 (quoting Regeneron, 128 F.4th at 333).

Zimmer Biomet contends that summary judgment is warranted in its favor on the false certification theory because Relator has produced no evidence that it or any provider who submitted a claim for payment for one of its products falsely certified compliance with the AKS. Relator responds that a jury could reasonably infer that providers certified compliance with the AKS in connection with claims for payment for Zimmer Biomet products because "[a]ll healthcare providers must certify that the claims submitted comply with the AKS, as it is printed on the back of the CMS Form 1500 paper claim form." Dkt. 191 at 36; see Ctrs. for Medicare &

Medicaid Servs., CMS Form 1500, at 2 (2012), <https://perma.cc/8JPD-6PEY> ("In submitting this claim for payment from federal funds, I certify that this claim complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute"). Zimmer Biomet retorts that the record contains no actual certifications of this sort.

Zimmer Biomet has the better of the argument. The First Circuit addressed a similar issue in Flanagan, which also involved an FCA claim premised on a purported AKS violation. See 142 F.4th at 32. There, the relator argued that his complaint sufficed to survive a motion to dismiss with respect to his false certification theory because he alleged that the defendant "falsely certif[ied] its compliance with the AKS annually." Id. at 37. The First Circuit disagreed, noting that the relator had merely "allege[d] that submitting certain certifications . . . in forms is required under the Medicare program and . . . that [the defendant] submits these forms every year," without offering "any allegations . . . that address what [the defendant] actually submitted in those" forms. Id. In this case, Relator likewise points only to the requirement to certify compliance with the AKS when submitting a claim without offering any competent evidence -- such as a copy of a claim form -- about what any provider actually certified about compliance

with the AKS in connection with a claim for a Zimmer Biomet product.

Although Flanagan arose on a motion to dismiss, its reasoning applies a fortiori at the summary judgment stage too. After all, a relator “must produce competent evidence of an actual false claim made to the government” to survive summary judgment and “certainly must make a greater showing than is required in a pleading in order ‘to get in front of a jury.’” Booker, 847 F.3d at 58 (quoting Jakobiec v. Merrill Lynch Life Ins. Co., 711 F.3d 217, 226 (1st Cir. 2013)). Without competent evidence of the contents of any certification of compliance with the AKS submitted by a provider in connection with a claim for payment for a Zimmer Biomet product, Relator has not raised a triable case under the false certification theory. The Court therefore grants summary judgment to Zimmer Biomet on this theory.

D. Scienter

Zimmer Biomet further contends that no reasonable jury could find that it acted knowingly as required by the FCA. This contention tracks the argument the Court has already rejected that Relator lacks sufficient evidence that Zimmer Biomet willfully violated the AKS via its commission-based payments to independent contractor sales representatives. See supra Section II.B. For the same reasons, Zimmer Biomet’s contention regarding the FCA’s scienter requirement fails. The Court adds briefly that it is

unpersuaded by Zimmer Biomet's argument that Relator cannot prove scienter because of the ubiquity of independent contractor sales representatives paid on a commission basis in the medical device industry and because of its robust compliance program and oversight of its sales representatives.⁴ Evidence of industry practice and Zimmer Biomet's compliance and oversight is relevant to whether the company acted knowingly, but it is not dispositive on the issue. Cf. Berckelely Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 218-19 (3d Cir. 2006) (deeming industry practice to be admissible but not dispositive with respect to scienter for a securities fraud claim).

E. Original Source

In its final argument in support of summary judgment on Relator's FCA claim, Zimmer Biomet renews its argument from its motion to dismiss that Relator's lawsuit cannot proceed pursuant to the FCA's public disclosure bar. Under this bar, a "court shall dismiss" a qui tam claim "if substantially the same allegations or transactions as alleged in the . . . claim were publicly disclosed" during "a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party," as part of "a congressional, Government Accountability Office, or other Federal

⁴ The Advanced Medical Technology Association has submitted an amicus brief that explains that use of independent sales agents is widespread in the medical device industry.

report, hearing, audit, or investigation,” or “from the news media.” 31 U.S.C. § 3730(e)(4)(A); see Banigan, 950 F.3d at 142-43 (discussing the public disclosure bar). This bar does not apply, however, if “the person bringing the action is an original source of the information.” 31 U.S.C. § 3730(e)(4)(A); see Banigan, 950 F.3d at 144. The FCA defines “original source” to refer to “an individual who either” (1) “prior to a public disclosure . . . has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based” or (2) “has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and . . . has voluntarily provided the information to the Government before filing an action.” 31 U.S.C. § 3730(e)(4)(B).

In denying Zimmer Biomet’s motion to dismiss, the Court concluded that this action triggered the public disclosure bar because “the essential elements of Relator’s claims” -- namely, Zimmer Biomet’s use of independent contractor sales representatives paid on a commission basis and those sales representatives’ interactions with surgeons -- “were previously disclosed and are substantially the same as information contained in public sources.” Zimmer Biomet, 743 F. Supp. 3d at 295. Nonetheless, the Court held that dismissal of the action was not warranted because Relator qualified as an original source under the second statutory definition, as he “has knowledge that is

independent from public disclosures” that “materially add[s] to information already publicly disclosed.” Id. at 296-97. This relevant knowledge consisted of information about “the close relationships that developed between orthopedic sales rep[resentatives] and their customers”; details of various internal documents, such as a November 2015 PowerPoint presentation about the transition to an independent contractor sales force, the company’s Sales Associate Agreement, and reports on the company’s sales; and the fact that the company had imposed a sales growth quota. Id.

Zimmer Biomet received Relator’s prefiling voluntary disclosure to the government during discovery, see United States ex rel. Langer v. Zimmer Biomet Holdings, Inc., No. 21-cv-11293, 2025 WL 2529827, at *1 (D. Mass. July 31, 2025) (compelling production of this document), and now argues that Relator does not qualify as an original source because his disclosure did not contain some details that he alleges in his amended complaint and that form the basis of his current theory of FCA liability. It is true that Relator’s disclosure did not contain specifics about the relationship between Zimmer Biomet sales representatives and surgeons or mention the company’s sales growth quota. Zimmer Biomet does not, however, cite any authority holding that a relator only qualifies as an original source if his prefiling voluntary disclosure to the government includes all information on which he

later relies in the course of his qui tam lawsuit. See United States ex rel. Colquitt v. Abbott Lab'ys, 864 F. Supp. 2d 499, 527 (N.D. Tex. 2012) (“[A] relator need not be the source of information underlying every element of the complaint’s allegations in order to be an original source of information on which those allegations are based.” (emphasis omitted)), aff’d, 858 F.3d 365 (5th Cir. 2017); cf. United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 656-67 (D.C. Cir. 1994) (holding that the original source exception applies to individuals with “direct and independent knowledge of any essential element of the underlying fraud transaction,” not “all of the vital ingredients”).

Here, in the process of explaining his allegations that Zimmer Biomet’s commission-based payments to independent contractor sales representatives violate the AKS, Relator’s disclosure described an internal complaint he made about the arrangement, which is significant in assessing whether Zimmer Biomet acted with the culpable state of mind required by the AKS and FCA. He also provided information about the commission structure and the amount of commissions he was paid, which are pertinent to assessing the OIG factors and, thus, Zimmer Biomet’s alleged intent to induce referrals. The disclosure of this information, which was independent of and materially added to the publicly disclosed facts, suffices to qualify Relator as an original source. See

United States ex rel. Godecke v. Kinetic Concepts, Inc., No. 08-cv-6403, 2016 WL 11673222, at *11-13 (C.D. Cal. Nov. 16, 2016) (rejecting argument that a prefiling disclosure was insufficient to qualify for the original source exception because the relator did not disclose all relevant knowledge she possessed); cf. In re Nat. Gas Royalties, 562 F.3d 1032, 1044 (10th Cir. 2009) (explaining that qui tam suits should be “limited to those in which the relator has contributed significant independent information” to the government (emphasis omitted) (quoting United States ex rel. Findley v. FPC-Boron Emps.’ Club, 105 F.3d 675, 686 (D.C. Cir. 1997))).

IV. State-Law Claims

Finally, Zimmer Biomet contends that it is entitled to summary judgment on Relator’s claims under twenty-eight state and local analogs of the federal FCA for the same reasons as the federal claims. In response, Relator abandons his claims under sixteen of these states and local analogs.⁵

As for the remaining twelve state-law claims, Relator has not received any data regarding claims for payment related to Zimmer

⁵ These abandoned claims are brought under the laws of Connecticut, Delaware, the District of Columbia, Hawaii, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Oklahoma, Rhode Island, Tennessee, Vermont, and Washington.

Biomet products from ten of those state governments.⁶ Except for his claim under Texas law, Relator does not contend that his claims under these respective state FCA analogs can survive summary judgment without evidence of an actual claim for payment, which, as discussed above, is required under the federal FCA. See Booker, 847 F.3d at 57-58. Rather, Relator asserts that these state governments may produce claims data before the pre-trial deadline for expert disclosures and that, even if they do not, he can extrapolate from the claims data produced for other states. “[S]ummary judgment,” however, “is ‘the put up or shut up moment in litigation.’” Guldseth v. Fam. Med. Assocs. LLC, 45 F.4th 526, 533 (1st Cir. 2022) (quoting Jakobiec, 711 F.3d at 226). And Relator has not identified any particular “statistical methodology” for extrapolation that “is appropriate.” United States ex rel. Loughren v. UnumProvident Corp., 604 F. Supp. 2d 259, 261 (D. Mass. 2009). Without evidence of any claims for payments from these state governments, the claims under these state analogs cannot proceed to trial.

Relator does assert that Texas law “sets out several unlawful acts that each proscribe specific conduct generally involving the Medicaid program” and does not require “the submission of false claims . . . for the majority of unlawful acts.” Dkt. 191 at 37

⁶ California, Florida, Iowa, Nevada, New Jersey, New Mexico, New York, North Carolina, Texas, and Virginia.

n.20. But Relator's claim under Texas law is pled in terms of the submission of false claims. Moreover, Relator has not explained with any specificity what act Zimmer Biomet committed that is unlawful under Texas law without proof of the submission of a false claim. Relator's claim under Texas law therefore fails too.

That leaves Relator's claims under Colorado and Illinois law. Relator has received claims data from both the Colorado and Illinois state governments related to Zimmer Biomet products. As with the federal claims data, Relator has submitted a declaration describing a claim submitted to and paid by the Colorado Medicaid program for a knee replacement that matches a Zimmer Biomet orthopedic sales record and took place in a direct territory where the company used independent contractor sales representatives.⁷ Zimmer Biomet does not identify any aspect of Colorado law that differs from the federal FCA, so Relator's claim under Colorado law survives summary judgment for the same reasons as his federal claim. As for the claim under Illinois law, however, Relator has not put into the record a comparable declaration or any other information about a specific claim for payment submitted to the Illinois state government. Summary judgment is therefore warranted in Zimmer Biomet's favor on Relator's claim under Illinois law.

⁷ The Court denied Zimmer Biomet's motion to strike this declaration. See Dkt. 228.

ORDER

For the foregoing reasons, Zimmer Biomet's motion for summary judgment (Dkt. 179) is **ALLOWED** with respect to (1) the substantive FCA claims (Counts One and Two) insofar as those claims rest on a false certification theory of liability, (2) the FCA conspiracy claim (Count Three), and (3) the state- and local-law claims except the claim under Colorado law (Counts Four and Six to Thirty-One). The motion is **DENIED** with respect to (1) the substantive FCA claims (Counts One and Two) insofar as those claims rest on a theory of liability under 42 U.S.C. § 1320a-7b(g) and (2) the claim under Colorado law (Count Five).

SO ORDERED.

/s/ PATTI B. SARIS
Hon. Patti B. Saris
United States District Judge