IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al.*, *ex rel.* TODD LANGER, *et al.*, Plaintiff-Relator, v. ZIMMER BIOMET HOLDINGS, INC., Defendant.	)	Civil Action No. 1:21-cv-11293-PBS

PROPOSED BRIEF FOR ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF ZIMMER BIOMET HOLDINGS, INC.'S MOTION FOR SUMMARY JUDGMENT

COMES NOW Advanced Medical Technology Association ("AdvaMed"), pursuant to this Court's leave and Federal Rule of Appellate Procedure 29, and hereby submits its Amicus Brief in Support of Zimmer Biomet Holdings, Inc.'s ("Zimmer Biomet") Motion for Summary Judgment, Doc. 180.

Following the completion of fact discovery, the gravamen of Plaintiff-Relator's case remains whether the use of independent sales agents ("ISAs") to market and facilitate the sale of medical devices is a *per se* violation of the Anti-Kickback Statute ("AKS"). This proposed legal theory—which Plaintiff-Relator initially sought to disclaim in his response to Zimmer Biomet's Motion to Dismiss (*see* Doc. 56 at 7-8) and AdvaMed's initial Amicus Brief (*see* Doc. 67 at 1-3), but which Plaintiff-Relator purportedly now adopts in his voluntary disclosure (*see* Doc. 180 at 34)—reflects a fundamental misunderstanding of the AKS, as well as the guidance from the Office of Inspector General for the Department of Health and Human Services ("OIG"). The use of ISAs is a practice that is widespread within, and vital to, the medical device industry and the patients it

serves. This practice provides valuable benefits to health care companies, physicians, and patients by increasing access to cutting-edge health care products and incentivizing health care companies to innovate and move health care forward.

At bottom, AdvaMed's Amicus Brief seeks to correct the negative impact and potential chilling effect of these misunderstandings by providing the perspective of an organization that assists medical device companies in navigating complex state and federal regulations to help advance the health care industry's ability to provide patients with access to critical—and often life-saving—health care.

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INTEREST OF AMICUS[1]

AdvaMed is the world's largest medical technology association representing device, diagnostics, and digital technology manufacturers that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Its more than 400 members span medical technology companies around the world, ranging from cutting-edge startups to multinational manufacturers. AdvaMed acts as a common voice for these members to foster high ethical standards, encourage innovation, and expand access to safe and effective medical technology.

AdvaMed's members operate in a heavily regulated field, and they seek in good faith to comply with all applicable federal and state laws. The regulatory scheme governing the health care and life sciences sectors is immensely complex. Plaintiff-Relator's misplaced legal theory that the practice of contracting with ISAs is a *per se* violation of the AKS both fundamentally misinterprets the AKS and vastly overstates OIG's guidance. In fact, in AdvaMed's experience, medical device companies routinely and compliantly utilize ISAs to further the development of new and innovative technologies that improve health care and save lives.

At bottom, any finding that Zimmer Biomet's use of ISAs constitutes a *per se* violation of the AKS would have a significantly negative impact on the medical device industry and deprive patients of innovative and transformative treatments.

[1] No counsel for any party authored this brief in whole or in part, and no person or entity, other than amicus curiae or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

SUMMARY OF ARGUMENT

AdvaMed's members, which is to say manufacturers of medical technologies, operate within a vast and intricate regulatory framework. One of the most important, and most frequently enforced, laws within this framework is the AKS' prohibition against direct and indirect remuneration to induce or reward the referral or generation of federal health care business. *See* 42 U.S.C. § 1320a-7b. Plaintiff-Relator's theory of liability, even now that fact discovery is closed, remains focused on the fact that Zimmer Biomet employs ISAs, compensated by commission, who market the company's products. (*See* Doc. 117 ¶¶ 123-27, 178-96). Based on this, Plaintiff-Relator seeks to establish that the mere fact that Zimmer Biomet contracts with ISAs, flatly and by itself, is a *per se* violation of the AKS. (*Id*., *see also* Doc. 180 at 34). Notably, this is contrary to Plaintiff-Relator's earlier position in this case, when he was able to escape dismissal, in part, because he disclaimed this very theory on which he now relies. (*See* Doc. 56 at 7-8; Doc. 67 at 1-3; Doc. 74 at 12-13). Regardless, this theory is incorrect. In fact, this Court held just this year that another company's use of ISAs in a manner similar to Zimmer Biomet's was *not* an AKS violation. *See Omni Healthcare, Inc. v. MD Spine Solutions, LLC* 761 F. Supp. 3d 356, 368-69 (D. Mass. 2025) (Saris, J.).

For the reasons discussed herein, this Court should grant summary judgment in favor of Zimmer Biomet on Counts One and Three of Plaintiff-Relator's Third Amended Complaint.

ARGUMENT & CITATION OF AUTHORITY

I. Plaintiff-Relator's Bare Assertions Do Not Raise A Genuine Dispute Of Material Fact And Zimmer Biomet Is Therefore Entitled To Judgment As A Matter Of Law.

It is axiomatic that claims may survive a Motion to Dismiss even if they are unlikely to survive a motion for summary judgment. *See, e.g.*, *Schoendorf v. RTH Mechanical Contractors, Inc.*, No. 2:12-CV-00179-GZS, 2012 WL 3229333, at *8 (D. Me. Aug. 6, 2012); *see also El*

Hadidy, D.M.D. v. RBS Citizens, N.A., No. CV-12-11618-JCB, 2013 WL 12329347, at *4 (D. Mass. Oct. 9, 2013) (noting that while the plaintiff's claim "survives [the defendant's] motion to dismiss, it will be subject to a higher standard at the summary judgment stage").

At the summary judgment stage, Plaintiff-Relator must provide admissible evidence to establish the existence of a genuine issue of material fact. *See Rivera-Marcano v. Normeat Royal Dane Quality*, 998 F.2d 34, 37 (1st Cir. 1993). Summary judgment is therefore appropriate when "the party against whom judgment is sought fails to show sufficient basis for the establishment of an essential element of [his] case." *Carlson v. Grobman*, 136 F.R.D. 31, 33 (D. N.H. 1990) (citing *Kauffman v. Puerto Rico Tel. Co.*, 841 F.2d 1169, 1172 (1st Cir. 1988)).

As discussed in Zimmer Biomet's Motion for Summary Judgment, and further below, Plaintiff-Relator's bare assertion that the practice of using ISAs constitutes a *per se* violation of the AKS (*see, e.g.*, Doc. 180 at 34) is insufficient to defeat summary judgment. ISAs are commonly used throughout the industry to help expand access to cutting-edge medical devices and incentivize innovation. Against this backdrop, this Court should hold as a matter of law that simply employing ISAs does not, by itself, amount to a violation of the AKS or the False Claims Act ("FCA").

II. There Is No *Per Se* Prohibition On The Use Of ISAs In The Medical Device Industry.

As detailed in Zimmer Biomet's Motion for Summary Judgment, Plaintiff-Relator claims that Zimmer Biomet's employment of ISAs is a *per se* violation of the AKS because it does not fit into a statutory safe harbor. (*See* Doc. 180 at 34). This argument fundamentally misunderstands the AKS, how OIG has interpreted the AKS, and the reality that the medical device industry relies on OIG's guidance.

The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, makes it a criminal offense to offer or pay another person "any remuneration . . . in return for purchasing, leasing, ordering, or arranging for or recommending . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program[.]" (*See* Doc. 62 at 3-4). Violations of this statute can lead to liability under the FCA when a company knowingly violates the AKS, thereby causing false claims to be made for reimbursement under a federal health care program. *See Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) ("[A]n AKS violation that results in a federal health care payment is a *per se* false claim under the FCA"). Violations of these statutes carry hefty and, in some cases, business-ending penalties, making compliance not only advisable, but necessary for medical device companies. *See* 31 U.S.C. § 3729(a)(1), (3) (treble damages plus costs of the action for FCA violations); 42 U.S.C. § 1320a-7b(a) (prison terms and automatic exclusion from federal health care programs for AKS violations).

Because the AKS is broad, including its definition of "illegal remuneration," OIG provides statutory "safe harbors" that operate to protect "certain arrangements that might otherwise technically violate the anti-kickback statute[.]" *See* 42 C.F.R. § 1001.952; OIG Advisory Opinion 98-10, 1998 WL 35287765, at *2 (Aug. 31, 1998). It must be noted, however, that arrangements that do not fit squarely within a statutory safe harbor do not automatically create an AKS violation. *See* 56 Fed. Reg. 35952, 35971 (OIG rejecting a surgical center's request for an additional safe harbor, explaining that an arrangement's lack of qualification "under one of the safe harbor provisions . . . does not mean that prosecution is imminent. The business arrangement may not even violate the statute, or, after examination on a case-by-case basis, we may conclude that prosecution is not warranted."); *see also U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp.

2d 39, 47 (D. Mass. 2011) (noting that "failure to comply [with a statutory safe harbor] is not a *per se* violation of the statute").

AdvaMed's prior Amicus Brief provides a discussion of OIG statutory safe harbors, OIG Advisory Opinions, and guidance relevant to ISAs. (*See* Doc. 62 at 5-6). More specifically, OIG has consistently declined to impose a *per se* prohibition on the use of ISAs. Rather, OIG advises manufacturers to carefully structure their ISA relationships to reduce the risk of overutilization and excessive program costs the AKS is designed to address. While OIG recognizes that ISAs can pose a risk, it provided the industry with a list of six non-exhaustive "suspect characteristics" to use as a guidepost for examining ISA arrangements. *See* Advisory Opinion 98-10; *see also* Doc 62 at 5-6. While it is true that OIG Advisory Opinions and guidance are not binding authority, they provide critical guidance for the health care industry. In reliance on OIG's guidance, manufacturers that include AdvaMed's members understood that their open and transparent use of ISAs is not *per se* illegal, but rather requires proper structure, management, and oversight to remain compliant.

III. This Court Has Conclusively Determined That Summary Judgment Is Appropriate Without Evidence Establishing Causation.

As this Court noted in *Omni Healthcare*, its analysis can begin and end with the causation argument. *See* 761 F. Supp. 3d at 368-69 (Saris, J.) (finding that a normal, law-abiding ISA arrangement did *not* cause an AKS violation). Here, Plaintiff-Relator must offer admissible evidence to establish that Zimmer Biomet's ISA relationship actually caused an AKS (or FCA) violation. As set forth in Zimmer Biomet's Motion, he has not, and such lack of causation evidence is fatal to Plaintiff-Relator's claims. (*See* Doc. 180 at 14-20).

In *Omni Healthcare*, this Court found that commission-based payments to ISAs did not cause any sales representative to unduly influence any provider's decision to order testing. On the

AKS claims, this Court expressly held that no reasonable jury could find that the ISA arrangement in *Omni Healthcare* caused a provider to order more expensive tests than they otherwise would have ordered in part because the company "trained, managed, disciplined, and paid its sales representatives identically whether they were employees or sales representatives." 761 F. Supp. 3d at 360-61. This follows with general industry practices: medical device companies have compliance programs and obligations that apply regardless of whether a sales representative is a W-2 employee or an independent contractor. Indeed, and as AdvaMed highlighted in its prior Amicus Brief:

> In AdvaMed's experience, companies in the medical device industry have put compliance measures in place that apply to both employees and agents to ensure appropriate promotion. This includes pre-contractual screening and diligence, training, ongoing monitoring, and contractual compliance obligations providing a right to terminate for breach of those obligations. These tools provide medical device companies with the power to ensure that ISAs properly promote their products in line with OIG's guidance and expectations.

(Doc. 62 at 11). This Court's recent ruling in *Omni Healthcare* tracks AdvaMed's views of the industry standard, and indeed follows with how Zimmer Biomet trains, manages, disciplines, and pays its sales representatives. (*See* Doc. 180 at 14-20). Zimmer Biomet treats its ISAs the same as it treats W-2 employees—not with unlawful intent to induce referrals, but as an important resource to expand access to health care throughout the United States. (*Id.*)

CONCLUSION

ISAs are an integral part of the medical device industry, and a determination that they are *per se* illegal would have a significant harmful impact on the industry, the development of new medical technology, and patients' access to health care. The facts as presented by Zimmer Biomet make clear what AdvaMed has identified across the industry, *i.e.*, ISAs are used in a lawful manner to help expand health care access and incentivize innovation.

This Court should rule as a matter of law that these arrangements do not—by themselves—violate the AKS and, accordingly, grant summary judgment in Zimmer Biomet's favor.

This 29th day of August, 2025.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2025, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which sent notification of the filing to all counsel of record.

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