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 Leave to File Granted January 11, 2024

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

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's") Motion to Dismiss Plaintiff-Relator's Amended Complaint, Doc. 36.

The gravamen of Plaintiff-Relator's Amended Complaint is that Zimmer Biomet's practice of employing independent sales agents to market and facilitate the sale of its medical devices—a practice that is widespread within, and vital to, the medical device industry and the patients it serves—constitutes a *per se* violation of the Anti-Kickback Statute ("AKS"). Respectfully, these allegations reflect a fundamental misunderstanding of the AKS, as well as the relevant guidance from the United States Department of Health and Human Services Office of Inspector General ("OIG"). Moreover, any finding that the use of independent sales agents is a *per se* AKS violation would significantly and negatively impact the medical device industry by, *inter alia*, chilling medical innovation and restricting patients' access to critical and often life-saving health care.

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 Amended Complaint alleges that Zimmer Biomet's practice of employing independent sales agents whom it pays by commission *per se* violates the AKS and the False Claims Act ("FCA"). *See* Doc. 33 ¶¶ 178-196. These arguments fundamentally misinterpret the AKS and vastly overstate OIG's relevant guidance on the use of independent sales agents. In fact, in AdvaMed's experience, medical device companies routinely and compliantly utilize independent sales agents to further new and innovative technologies that improve health care and save lives.

At bottom, any finding that Zimmer Biomet's use of independent sales agents 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.

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[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's prohibition against direct and indirect remuneration to induce or reward the referral or generation of federal healthcare business. *See* 42 U.S.C. § 1320a-7b. Plaintiff-Relator's Amended Complaint centers around Zimmer Biomet's practice of employing independent sales agents ("ISAs"), compensated by commission, who market the company's products. Doc. 33 ¶¶ 123-27, 178-96. In Plaintiff-Relator's view, Zimmer Biomet's practice is a *per se* violation of the AKS. *Id*. This is flatly incorrect.

More specifically, Plaintiff-Relator's allegations (1) misunderstand the AKS and OIG's guidance on this issue, which makes clear there is no *per se* prohibition on ISAs, but rather assesses the practice through a nuanced risk-based analysis; (2) ignore the reality that ISAs are prevalent in the medical device industry while playing an critical role in medical innovation and patient access to health care; and (3) overlook OIG's emphasis on oversight and compliance.

ARGUMENT & CITATION OF AUTHORITY

I. There is No *Per Se* Prohibition on the Use of ISAs in the Medical Device Industry.

In his Amended Complaint, Plaintiff-Relator alleges 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. 33 ¶ 190. This argument misunderstands the AKS, how OIG has interpreted the AKS, and the reality of a medical device industry that relies on OIG's guidance.

As a threshold matter, 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[.]" 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 prison terms, treble damages, and automatic exclusion from federal health care programs, including Medicare and Medicaid, which can potentially ruin a medical device company. *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). Compliance is thus not only advisable, but *necessary* for the medical device industry and its members.

Further, and in part due to the broad definition of what can be considered illegal remuneration, OIG has provided 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). One such safe harbor applies to financial relationships with employees who are in a "bona fide employment relationship with employer." 42 C.F.R.§ 1001.952(i). But, even where arrangements do not fit within a statutory safe harbor (such as ISA relationships compensated by commission), they do not automatically violate the AKS. *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"). OIG has written on ISA arrangements extensively in advisory opinions and in guidance on compliance to the health care industry. This history is replete with examples of OIG declining to impose the type of *per se* prohibition Plaintiff-Relator contends applies in the instant case.

Moreover, in OIG Advisory Opinion 98-10, OIG examined an arrangement with a non-employee sales agent who was paid a monthly commission between 1 and 1.25 percent of invoiced amounts. OIG Advisory Opinion 98-10, 1998 WL 35287765, at *1 (Sept. 8, 1998). Although the arrangement involved the payment of commissions to an ISA for the sale of products, OIG did not automatically find AKS liability. *Id.* Rather, OIG explained that ISA relationships can pose a risk because "they are less accountable to the Seller than an employee" and proceeded to analyze the relationship for "suspect characteristics" that are "associated with an increased potential for program abuse, particularly overutilization and excessive program costs." *Id.* at *3. Against that backdrop, OIG provided a list of six non-exhaustive "suspect characteristics":

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; or

6. Marketing of items or services that are separately reimbursable by a federal health care program (*e.g.*, items or services not bundled with other items or

> services covered by a DRG payment), whether on the basis of charges or costs.

Id., at *3-4. OIG then reviewed those factors and found that it would not impose sanctions for this specific arrangement, even though the ISA's compensation was based on a percentage of sales. *Id.* at *4.

In 1999, OIG examined the propriety of an ISA arrangement where a company utilized ISAs to sell mattresses to skilled nursing facilities and paid them a 20 percent commission on their sales or leases of mattresses. OIG Advisory Opinion 99-3, 1999 WL 34984727, at *1 (Mar. 23, 1999). There, OIG again conducted a case-specific examination of the arrangement, applying the six characteristics OIG articulated in Advisory Opinion 98-10 to assist in determining its propriety. *Id.* at *6-7. OIG found that while "sales agent compensation will be based on a percentage of collections attributable to the Proposed Arrangement and may involve contact between the sales agent and persons in a position to order the services," it would not subject the company to sanctions. *Id.* OIG emphasized that "the risk of overutilization and excessive program costs" was top of mind in making this determination, and that this arrangement did not present these risks. *Id.* Again, OIG did not apply a *per se* prohibition to an ISA arrangement, and instead evaluated whether there were substantive concerns of overutilization and excessive program costs.

In 2003, OIG published "Compliance Program Guidance for Pharmaceutical Manufacturers" in the Federal Register, detailing ways in which pharmaceutical manufacturers can ensure compliance with the litany of federal regulations covering their business. *See* 68 Fed. Reg. 23731-01 (May 5, 2003).[2] In this guidance, OIG set forth "its general views on the value and

[2] While this guidance was directed to pharmaceutical manufacturers, the same principles and risks apply to the medical device field. *See* 68 Fed. Reg. 23732, n. 5 (stating that "the compliance program elements and potential risk areas addressed in this compliance program guidance may

fundamental principles of compliance programs for pharmaceutical manufacturers and the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program." *Id.* at 23731. Speaking to sales agent arrangements, OIG explained that "[s]ales agents, *whether employees or independent contractors*, are paid to recommend and arrange for the purchase of the items or services they offer for sale," articulated that these arrangements should be carefully reviewed to ensure they comply with the AKS, but expressly declined to find them *per se* prohibited. *Id.* at 23739. OIG further provided that while safe harbors can help to show compliance, "a compensation arrangement with a sales agent that fits in a safe harbor can still be evidence of a manufacturer's intent when evaluating the legality of the manufacturer's relationships with persons in a position to influence business for the manufacturer," thereby making clear, once again, that what matters is the substantive risk of overutilization and excessive program costs rather than whether a manufacturer pays their sales agents as W-2 employees or as 1099 independent contractors.

In these guidance documents, OIG has repeatedly advised manufacturers that they are permitted to use ISAs, but should structure their ISA relationships to reduce the risk of overutilization and excessive program costs the AKS is designed to address. In reliance on this guidance, AdvaMed's members have understood that ISA relationships are not *per se* illegal but should be properly structured, managed, and overseen to remain compliant.

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also have application to manufacturers of other products that may be reimbursed by federal health care programs, such as medical devices and infant nutritional products.").

II. ISAs are Prevalent and Play an Important Role in the Medical Device Industry.

Plaintiff-Relator's allegations cast ISAs as an aberration to the norm, in other words, contractors who only benefit a large company's bottom line. On the contrary, medical device companies across the industry, and of all shapes and sizes, routinely utilize ISAs. ISAs play a crucial role for these companies and the patients they serve.

The medical device industry is a complex and rapidly evolving sector that requires its sales personnel to have, *inter alia*, a unique blend of technical knowledge, sales acumen, and regulatory understanding. An effective sales agent must ethically educate health care providers on the safe and effective use of technology, potentially provide technical support during procedures, and help troubleshoot issues. As described in detail by Plaintiff-Relator in his Amended Complaint, this work is hands-on and highly specialized. *See* Doc. 33 ¶¶ 76-88. That said, for a host of reasons it is not always feasible for medical device companies to employ the entirety of their sales personnel in a W-2 fashion.

By way of example, ISAs have the ability to work for multiple medical device companies selling similar or compatible technologies and can cover geographical areas that a medical device company may not otherwise be able to reach with its own dedicated W-2 employees. This is particularly true for early-stage medical device companies that are on the cutting edge of new technologies. These young companies bring about crucial innovations in the medical device industry, but do not yet have the infrastructure to employ a full-scale sales force. ISAs can bridge the gap among new technologies, healthcare providers, and their patients. It follows, then, that a *per se* rule banning these contractors would have a significant chilling effect on medical scientific innovation and would limit patient access to potentially life-changing medical technologies.

Even with more established companies and technologies, there is not always sufficient geographic reach within a company's existing employee sales force. When companies seek to expand their market, particularly to reach less populated or more rural areas, they often rely on ISAs already working in that area. If contractors were deemed *per se* illegal, health care providers and patients in these areas may lose access to even established medical technologies.

Given their unique and important role in the medical device industry, ISAs are used widely—and that use is open and transparent. Medical device companies openly advertise for ISAs in public forums.[3] Many public companies disclose their use in reports filed with the Securities and Exchange Commission.[4] And, the use of ISAs by medical device companies has

[3] For example, a search on Indeed.com for "Independent Medical Device Sales Representative" returns over 750 results across the United States, including from Medical Solutions, Inc., Gateway MD, and Wassenburg Medical, Inc. *See* Search Results on Indeed.com, https://www.indeed.com/jobs?q=Independent+Medical+Device+Sales+Representative&l=&from=searchOnHP&vjk=101c100dad8cc1de (last accessed November 27, 2023). Other websites, such as www.medcepts.com, provide a job forum aimed specifically at independent sales representatives in the medical device and healthcare industry. *See* https://www.medcepts.com/rep-opportunity/ (last accessed November 9, 2023).

[4] *See, e.g.*, Zimmer Biomet Holdings, Inc.'s Annual 10-K Report, filed Feb. 24, 2023, at 5 ("The U.S. sales force consists of a combination of employees and independent sales agents, most of whom sell products exclusively for Zimmer Biomet."); Medtronic PLC's Annual 10-K Report, filed June 22, 2023, at 11 ("We sell our medical devices and therapies through a combination of direct sales representatives and independent distributors globally."); XTant Medical Holdings, Inc.'s Annual 10-K Report, filed Mar. 7, 2023, at 2 ("We promote and sell our products in the United States through independent distributors and stocking agents, supported by direct employees. We have an extensive distribution channel of commissioned independent agents and stocking agents in the United States representing some or all of our products."); Alphatec Holdings, Inc.'s Annual 10-K Report, filed Feb. 28, 2023, at 1 (explaining that the annual report details Alphatec's "ability to maintain an adequate global sales network for our products, including to attract and retain independent sales agents and direct sales representatives").

been exhaustively covered in online articles, blogs, and forums.[5] As is plain from the above, medical device companies do not attempt to disguise or hide their use of ISAs. Instead, companies should (and do) combine their use of ISAs with a strong compliance program to guard against the risks of improper promotion consistent with OIG's guidance.

III. OIG Emphasizes Strong Compliance Programs and Proper Oversight.

What OIG makes clear in its guidance is that—regardless of whether a company employs its sales force directly or through independent contractor arrangements—it should have a strong compliance program. In its Compliance Program Guidance, OIG explained that manufacturers should, among other things, develop "a regular and comprehensive training program for its sales force," ensure the sales force is familiar with compliance standards, and "institute and implement corrective action and disciplinary policies applicable to sales agents who engage in improper marketing." 68 C.F.R. at 23739.

AdvaMed fully endorses and encourages the creation and implementation of strong compliance programs amongst its members and in the industry at large. In fact, AdvaMed publishes an industry-wide 'Code of Ethics On Interactions With Healthcare Providers' ("AdvaMed Code") to provide compliance guidance to its members and set the standard for the industry.[6] The AdvaMed Code repeatedly makes clear that its guidance applies to *all* representatives of medical device companies, including employees and independent agents. *Id.* at 4 ("The Code applies to a Company's interactions and a Company's employees' and agents'

[5] A Google search for "independent sales agent" and "medical device" yields over 17,000 results. (last accessed November 9, 2023).

[6] Available at https://www.advamed.org/wp-content/uploads/2021/05/AdvaMed-Code-of-Ethics-2021.pdf (last accessed November 9, 2023).

interaction with U.S. Healthcare Professionals . . . A Company adopting the Code is required to communicate the Code's provisions to its employees, agents, dealers, and distributors, with the expectation that they will adhere to the Code.").

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.

CONCLUSION

There is no dispute that OIG has been aware of, and has provided guidance on, ISA arrangements for decades. In so doing, OIG has had every opportunity to announce a *per se* prohibition on such arrangements. By consistently and repeatedly declining to do so, OIG has made clear that a medical device company's use of ISAs does not constitute a *per se* AKS violation. Rather, OIG is concerned about insufficient supervision and certain ISA arrangements with increased risk, which can lead to overutilization and excessive program cost. Medical device companies address these concerns through effective compliance programs and thoughtful consideration of the structure and oversight of their ISA relationships.

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.

This 12th day of January, 2024.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 12, 2024, 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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