

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

UNITED STATES OF AMERICA, *et al.*,
Plaintiffs,

ex rel. BEVERLY MARCUS,
Relator,

Case No. 8:18-cv-2915-WFJ-JSS

v.

BIOTEK LABS, LLC, *et al.*,
Defendants.

_____ /

**UNITED STATES' OPPOSITION TO PUBLIC DISCLOSURE DISMISSAL
AND STATEMENT OF INTEREST RE MOTION TO DISMISS**

Pursuant to the False Claims Act, 31 U.S.C. § 3730(e)(4)(A), the United States notifies the Court that it is exercising its right to object to dismissal of Relator's Amended Complaint on the basis of the Public Disclosure Bar. Additionally, as a real party in interest, and pursuant to 28 U.S.C. § 517, the United States of America respectfully submits this Statement of Interest in response to certain other issues raised in Defendants' Motion to Dismiss (Dkt. 90).

INTRODUCTION

Relator Beverly Marcus brought this False Claims Act (FCA) *qui tam* suit, 31 U.S.C. § 3729 *et seq.*, against Defendant Biotek Labs, LLC and related entities and individuals. Defendants have filed a wide-ranging

Motion to Dismiss (Dkt. 90).¹

First, the United States hereby notifies the Court that it is exercising its statutory right to object to dismissal of Relator on the Public Disclosure Bar, mooting that as an issue before this Court.

Additionally, although the United States has not elected to intervene, see Dkt. 27 – permitting Relator to pursue the action on her own, 31 U.S.C. § 3730(c)(3) – the United States remains the real party in interest in this litigation, entitled to a share of any monies recovered. See, e.g., United States ex rel. Hall v. Tribal Development Corp., 49 F.3d 1208, 1212-13 (7th Cir. 1995). Moreover, the United States has a substantial interest in the proper interpretation and application of the FCA and related issues because that statute is the government's primary tool to combat fraud in, and recover losses from, federally-funded programs. The United States thus submits this brief for the limited purpose of providing the Court with its position regarding the issues discussed in Part II. below. See 28 U.S.C. § 517 (providing for Department of Justice participation in any federal court litigation to attend to the interests of the United States).²

¹ The United States assumes the Court's familiarity with the factual and procedural background of this case, as well as the parties' substantial briefing, and so will not add to that unnecessarily.

² That this Statement does not address other arguments raised by Relator or Defendants should not be construed as signaling agreement or disagreement with those arguments.

I. Opposition to Any Public Disclosure Dismissal

Defendants argue Relator's complaint should be dismissed based on the so-called public disclosure bar found in 31 U.S.C. § 3730(e)(4)(A)(i)-(iii). See generally Dkt. 90 at 13-22. Specifically, Defendants contend Relator's allegations were previously disclosed publicly in: (i) the course of a federal criminal investigation / prosecution of an individual physician in Tennessee, in which Biotek personnel were merely witnesses regarding conduct that predated the conduct for which the physician was prosecuted; and (ii) information allegedly available on Biotek's website. See id. at 14.

The relevant FCA section provides that, if the Court finds an applicable public disclosure, and finds that the Relator is not an original source as that term is defined in the FCA, then the "Court shall dismiss . . . , unless opposed by the Government" § 3730(e)(4)(A). The FCA's public disclosure bar was amended substantially in 2010.

The bar found in the pre-2010 FCA was "explicitly a jurisdictional bar" and required dismissal under FRCP 12(b)(1) if there had been such a disclosure; whereas the post-2010 version "creates grounds for dismissal for failure to state a claim." U.S. ex rel. Osheroff v Humana, Inc., 776 F.3d 805, 810 (11th Cir. 2015). Further, "[t]he amended section also provides that the

government can oppose dismissal, allowing the case to proceed even if the public disclosure provision would otherwise apply.” Id. at 811.³

The United States hereby informs the Court that it opposes dismissal of Relator’s complaint on alleged public disclosure grounds, respectfully rendering “moot” Defendants’ arguments for dismissal under § 3730(e)(4)(A). U.S. ex rel. Arvin v. Florida Birth-Related NICA, Case No. 19-61053, 2020 WL 5540367, at *4 n.1 (S.D. Fla. Sept. 8, 2020); see also U.S. ex rel. Conroy v. Select Med Corp., 3:12-cv-00051-RLY-DML, 2017 WL 468276, at *4 (S.D. Ind. Feb. 3, 2017) (recognizing, if Government objects to public disclosure dismissal, Court need “not even address the issue”); U.S. ex rel. Berntsen v. Prime Healthcare Servs, Inc., Case No. 11-CV-8214 PJW, 2014 WL 12480026, at **2-3 (C.D. Cal. Nov. 20, 2014) (rejecting defense argument public disclosure bar dismissal was within Court’s discretion after United States objected; agreeing such dismissal was “precluded in the face of the Government’s opposition”); U.S. ex rel. Baker v Community Health Sys., Inc., Civil No. 05–279 WJ/ACT, 2014 WL 10212574, at *25 (D.N.M. May 16, 2014)(“Under this post-amendment provision, the Government’s opposition precludes application of the public disclosure bar as to claims [accruing after the date of the amendment.]”)

³ That amended section applies here, as Defendants’ were not founded until 2011 - 2012. See Dkt. 85 at ¶¶ 24, 26.

II. "Remuneration" Need Not Exceed Fair Market Value or be Commercially Unreasonable

Among their arguments seeking dismissal of Relator's claims premised on alleged violations of the Anti-Kickback Statute (AKS), Defendants rely on the unpublished Eleventh Circuit decision in Bingham v. HCA, Inc., 783 F. App'x 868, 873-74 (11th Cir. 2019). See Dkt. 90 at 28 (contending Relator must allege "remuneration in the form of a benefit conferred in excess of fair market value, or that items or services provided for less than fair market value"); see also id. at 1-2.⁴

As an initial premise, to state an FCA violation the United States or a relator must allege that defendants (1) made a false statement, (2) with scienter, (3) that was material, (4) causing the Government to make a payment. Ruckh v. Salus Rehab., LLC, 963 F.3d 1089, 1106 (11th Cir. 2020) (citations and quotations omitted). Falsely certifying compliance with the Anti-Kickback Statute (AKS) in connection with the submission of Medicare claims is actionable under the FCA. See, e.g., United States ex rel. Lutz v. United States, 853 F.3d 131, 135 (4th Cir. 2017) (citing 42 U.S.C. 1320a-7b(g)); United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., 675 F.3d 394, 396 n.2 (4th Cir. 2012).

⁴ Defendants' prior Motion to Dismiss contained expanded argument that Relator is required to allege remuneration in excess of fair market value, see Dkt. 59 at 27-30, including additional citation to Bingham. See id. at 30. The latest Motion to Dismiss presents a pared-back version that nevertheless still merits addressing.

Enacted in 1972, the AKS makes it a felony to "knowingly and willfully" offer or pay remuneration to induce someone to make, arrange for, or recommend a referral "of any item or service 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). Remuneration is not defined in the AKS but includes "any kickback, bribe or rebate," and broadly applies to anything of value provided "directly or indirectly, overtly or covertly, in cash or in kind." *Id.* § 1320a-7b(b)(1), (2); 56 Fed. Reg. 35952 (Jul. 29, 1991). The AKS recognizes certain exclusions, called "safe harbors," from the broad definition of "remuneration." See 42 U.S.C. § 1320a-7b(b)(3).

To establish a prima facie violation of the AKS, the United States or a relator must show (1) that "the defendant [offered or paid] any remuneration, including any kickback or bribe, directly or indirectly, overtly or covertly, in cash or in kind, to any person"; (2) "that the remuneration was [offered or paid] to induce such person to refer an individual to a person for furnishing or arranging of an item or service"; (3) "that the item or service was one for which payment may be made in whole or in part under a federal health care program"; and (4) "that the defendant acted knowingly and willfully." United States v. Thompson, 761 F. App'x 283, 289-90 (5th Cir. 2019). A defendant may invoke and attempt to prove that it satisfied all of the requirements of an applicable AKS safe harbor as an affirmative defense to an alleged violation of the statute. For certain safe harbors, those requirements include that the

arrangement at issue was commercially reasonable and involved the payment of fair market value for services rendered.

As noted, Defendants rely on Bingham, and otherwise argue, that Relator's AKS-based claims should be dismissed because she has failed to allege that the payments received by Biotek from providers exceeded fair market value. For several reasons, these arguments, including Defendants' reliance on Bingham for such, is misplaced.

To start, Bingham is an unpublished Eleventh Circuit decision and is thus not binding precedent. See Moore v. Barnhart, 405 F.3d 1208, 1211 n.3 (11th Cir. 2005) ("Unpublished decisions of this court are not binding precedent") (citing 11th Cir. R. 36-2, which provides "Unpublished opinions are not considered binding precedent, but they may be cited as persuasive authority."). Indeed, several courts from within this Circuit -- none of which were cited by Defendants -- have declined to apply the "Bingham standard" when considering FCA liability premised on alleged AKS violations. See, e.g., United States ex rel. Heller v. Guardian Pharmacy, LLC, 521 F. Supp. 3d 1254, 1267 n.50 (N.D. Ga. 2021) (noting that there is no Eleventh Circuit opinion directly on point for the "open question" of whether a relator must show evidence that alleged remuneration was above or below fair market value); see also United States ex rel. Raven v. Georgia Cancer Specialists I, P.C., No. 1:11-CV- 00994-CAP, 2020 WL 10973945, at *4 n.5 (N.D. Ga. May 29, 2020) (finding Bingham "has no implication on [the court's] rulings

regarding the AKS claims" and stating, "Fair market value evidence will not absolve a defendant if one purpose of the exchange is directed towards referrals"). Accordingly, Defendants' reliance on Bingham as setting the standard by which Relator's AKS claims must be resolved is misguided.

Moreover, Bingham notwithstanding, Defendants' argument that Relator must allege that remuneration offered or paid to induce federal health care program referrals was commercially unreasonable or inconsistent with fair market value misstates the law and is inconsistent with the language of the AKS. The purported requirements of fair market value and commercial reasonableness are simply not found in the plain language of the AKS; the statute's description of the proscribed conduct does not expressly or impliedly reference those as elements of the offense(s). See 42 U.S.C. § 1320a-7b(b)(1)(B); see also, e.g., Health Choice, LLC v. Bayer Corp., No. 5:17- CV-126 RWS-CMC, 2018 WL 3637381, at *14 (E.D. Tex. June 29, 2018); 56 Fed. Reg. 35952 (Jul. 29, 1991) (in using the term "remuneration," Congress intended "to cover the transferring of anything of value in any form or manner whatsoever").

However, as noted, certain safe harbors do include requirements that remuneration be commercially reasonable and consistent with fair market value. See, e.g., 42 C.F.R. § 1001.952(b)-(d). That inclusion further undercuts Defendants' argument in at least two ways. First, it would make no sense to require the United States or a relator to allege (or prove) the absence of fair

market value or commercial reasonableness as part of their prima facie case, and then to have a defendant allege (or prove) the satisfaction of those same elements as part of an affirmative defense. Second, the safe harbors that include those elements have additional requirements, thereby causing "only a small subset of such [fair market value] transactions" to be exempt from the AKS. See United States v. Bay State Ambulance and Hosp. Rental Serv., Inc., 874 F.2d 20, 31 (1st Cir. 1989) ("Congress did not explicitly change the statute to exclude [from all AKS liability] reasonable payments for actual work done").

Courts have thus repeatedly rejected the argument Defendants make here, instead recognizing that something of value can amount to "remuneration" that violates the AKS even if it is offered at market price. See, e.g., Bay State Ambulance, 874 F.2d at 29-30 (rejecting argument government "had to prove that the payments received were not reasonable for the actual work done"); United States ex rel. Hanvey v. Sutter Health, No. 14-cv-04100, ECF No. 131 at 17 (N.D. Cal. March 17, 2021) (holding AKS "does not have a fair market value requirement as an element of the offense"); United States ex rel. Perri v. Novartis Pharms. Corp., No. 15-6547, 2019 WL 6880006, at *13 n.14 (D.N.J. Feb. 21, 2019) ("... there may be situations where an exchange is an illegal 'remuneration' within the meaning of the AKS, even though the exchange itself is for 'fair market value.' "); United States ex rel. Patel v. Catholic Health Initiatives, 312 F.

Supp. 3d 584, 596 (S.D. Tex. 2018) ("The presence of a legitimate business purpose for the arrangement or a fair market value payment will not legitimize a payment if there is also an illegal purpose.") (internal citations omitted); United States ex rel. Boise v. Cephalon, Inc., No. 08-287, 2015 WL 1724572, at *10 (E.D. Pa. Apr. 15, 2015) ("... relators need not allege that speaker fees were provided at higher than market rates for similar speaking engagements in order to constitute kickbacks underlying a theory of FCA liability."); United States ex rel. Bartlett v. Ashcroft, 39 F. Supp. 3d 656, 678 (W.D. Pa. 2014) ("the crux of whether the [AKS] ... [is] violated" is whether the defendant "had the requisite intent to violate the statute," namely, "whether the parties entered business arrangements in exchange for, or to induce, patient referrals"); United States ex rel. Health Dimensions Rehab., Inc. v. RehabCare Group, Inc., No. 4:12-CV-00848, 2013 WL 4666338, at *5 (E.D. Mo. Aug. 30, 2013) ("Lack of fair market value, per se, is not an element the Government must provide."); see also 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005) (HHS-OIG explanation that "under the [AKS], neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business)").

Defendants' contrary position is based on certain decisions, such as Bingham, where courts have accepted others' invitations to graft additional elements onto the AKS. The Bingham Court, for example, ruled

compensation may confer "value" only if it exceeds the market rate for the services rendered. However, that analysis ignores the reality, persuasively explained by the First and Third Circuits, that even "[g]iving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient." Bay State Ambulance, 874 F.2d at 29 (holding "[t]he trial court did not err in not specifically instructing the jury that the government had to prove that the payments received were not reasonable for the actual work done," as "[t]he gravamen of Medicare Fraud is inducement," and "[g]iving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient") (citing United States v. Greber, 760 F.2d 68, 71 (3d Cir. 1985) ("Even if the physician performs some service for the money received, the potential for unnecessary drain on the Medicare system remains. The statute is aimed at the inducement factor."))).

Thus, to state a violation of the AKS, it is sufficient that a relator allege the defendant (1) knowingly and willfully (2) offered, paid, solicited, or received remuneration (3) intended to induce patient referrals. Even assuming arguendo that the remuneration at issue in this case was at fair market value or commercially reasonable (elements of an affirmative defense on which Defendants have the burden, and on which the United States takes

no position here), such findings alone would not be determinative of whether Relator has sufficiently alleged Defendants violated the AKS.

CONCLUSION

The United States respectfully submits its objection to dismissal of Relator on public disclosure grounds and, further, requests the Court consider its statement of interest on the legal issues discussed above when ruling on Defendants' Motion. The United States otherwise takes no position on Defendants' Motion.

WHEREFORE, the Court should deny Defendants' Motion to Dismiss as argued above.

ROGER HANDBERG
United States Attorney

November 17, 2022

By: */s Charles T. Harden III*
CHARLES T. HARDEN III
Assistant United States Attorney
Florida Bar No. 97934
400 North Tampa Street, Suite 3200
Tampa, Florida 33602
Tel: (813) 274-6000
Fax: (813) 274-6200
Email: Charles.Harden@usdoj.gov
Counsel for the United States

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that, on November 17, 2022, I filed the foregoing document using the CM/ECF system, which will send notice of electronic filing to all counsel of record.

By: /s Charles T. Harden III
CHARLES T. HARDEN III
Assistant United States Attorney