BRIAN M. BOYNTON
Acting Assistant Attorney General
TRACY WILKISON
Acting United States Attorney
DAVID M. HARRIS, AUSA
Chief, Civil Division
ABRAHAM C. MELTZER, AUSA
Chief, Civil Fraud Section
FRANK D. KORTUM, AUSA
California State Bar No. 110984
Room 7516, Federal Building
300 North Los Angeles Street
Los Angeles, California 90012
Tel: (213) 894-6841; Fax: (213) 894-7819
E-mail: Frank.Kortum@usdoj.gov
JAMIE ANN YAVELBERG
COLIN M. HUNTLEY
DOUGLAS J. ROSENTHAL
CHRISTOPHER TERRANOVA
Attorneys, Civil Division
United States Department of Justice
P.O. Box 261
Ben Franklin Station
Washington, D.C. 20044
Tel: (202) 616-4203; Fax: (202) 514-0280
E-mail: Christopher.Terranova@usdoj.gov
Attorneys for the United States of America

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA *ex rel.* DR. KUO CHAO, *et al.*,

Plaintiffs,

v.

MEDTRONIC PLC, MEDTRONIC VASCULAR, INC., COVIDIEN LP, COVIDIEN SALES LLC, EV3, INC., and MICRO THERAPEUTICS, INC.,

Defendants.

No. CV 17-1903-ODW (SSx)

UNITED STATES' STATEMENT OF INTEREST REGARDING DEFENDANTS' MOTION TO DISMISS RELATOR'S THIRD AMENDED COMPLAINT

Hearing Date: October 18, 2021
Time: 1:30 p.m.
Judge: Hon. Otis D. Wright II

The United States respectfully submits this Statement of Interest as a real party in interest in this False Claims Act (FCA) case, entitled to the majority of any recovery that relator may obtain on the United States' behalf. *See* 31 U.S.C. § 3730(d); *United States ex rel. Welch v. My Left Foot Children's Therapy, LLC*, 871 F.3d 791, 794 (9th Cir. 2017). The United States has a substantial interest in ensuring the correct application of the FCA, which is the United States' "primary litigative tool for combatting fraud" against the public fisc. *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 745 (9th Cir. 1993) (quoting S. Rep. 99-345, *reprinted in* 1986 U.S.C.C.A.N. 5266).

Contrary to defendants' arguments in support of their motion to dismiss relator's Third Amended Complaint (ECF No. 106) and as addressed below:

(1) the United States' decision to decline intervention in an FCA case is not a statement on the merits of that case;

(2) relators are not required to plead the inapplicability of a safe harbor defense to the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b, in an FCA case based on AKS violations where the face of the complaint does not itself establish the defense; and

(3) lack of fair market value is not an element of the AKS.

Otherwise, the United States takes no position on the merits of defendants' motion.

I. Declination Is Not a Statement on the Merits

Three times in their brief, defendants highlighted the United States' decision to decline intervention. Defs.' Br. at 1, 3, 5. However, it is neither legally nor factually appropriate to construe declination as a statement about the merits of relator's allegations. As the Supreme Court has noted, a "*qui tam* relator is, in effect, suing as a partial assignee of the United States." *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 1514 (2019). "When the government chooses not to take over a *qui tam* action, the relator 'shall have the right to conduct the action.'" *Boeing*, 9 F.3d at 746 (quoting 31 U.S.C. § 3730(c)(3)). Even after an initial declination, the United States retains the right—including in this case—"to intervene at a later date upon a showing of good cause." 31

U.S.C. § 3730(c)(3). Moreover, in cases in which the United States believes the allegations advance noncognizable or frivolous claims, the FCA allows the United States to "dismiss the action notwithstanding the [relator's] objections . . . ." *Id.* § 3730(c)(2)(A). The United States has not sought to have this action dismissed.

Courts widely recognize that the government's declination does not reflect on the merit of the relator's allegations because "[i]n any given case, the government may have a host of reasons for not pursuing a claim." *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006). "There is no reason to presume that a decision by the Justice Department not to assume control of the suit is a commentary on its merits. The Justice Department may have myriad reasons for permitting the private suit to go forward including limited prosecutorial resources and confidence in the relator's attorney." *United States ex rel. Chandler v. Cook Cty.*, 277 F.3d 969, 974 n.5 (7th Cir. 2002), *aff'd*, 538 U.S. 119 (2003). "Indeed, assuming the government looked unfavorably upon each *qui tam* action in which it did not intervene would seem antithetical to the purpose of the *qui tam* provision—to encourage private parties to litigate on behalf of the government." *United States ex rel. El-Amin v. Geo. Wash. Univ.*, 533 F. Supp. 2d 12, 21 (D.D.C. 2008). "[T]he simple fact that the government did not intervene has no probative value and is not relevant." *Id.* at 22.

Finally, to the extent that defendants suggest that the government's declination bears on materiality specifically, this is incorrect. When the Supreme Court discussed FCA materiality in *Universal Health Servs., Inc. v. United States ex rel. Escobar* ("*Escobar*"), it did so in the context of a declined case. 136 S. Ct. 1989, 1998 (2016). Yet despite the government's decision not to intervene, the Supreme Court did not mention the declination decision as a factor in its materiality analysis. *Id.* at 2001–04. Nor did the First Circuit, on remand, consider the government's declination as relevant to the materiality inquiry. *United States ex rel. Escobar v. Universal Health Servs. Inc.*, 842 F.3d 103, 112 (1st Cir. 2016). Other courts since *Escobar* have properly rejected invitations by defendants to draw negative inferences with respect to materiality from the government's decisions not to

intervene, particularly at the pleadings stage. *See, e.g., United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822, 836 (6th Cir. 2018) ("If relators' ability to plead sufficiently the element of materiality were stymied by the government's choice not to intervene, this would undermine the purposes of the Act.").

II. Defendants Bear the Burden as to Applicability of AKS Safe Harbors

As a matter of law, "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). The AKS is violated by whoever knowingly and willfully offers or pays "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" to any person to induce a referral for an item or service for which payment may be made in whole or in part by a Federal health care program. 42 U.S.C. § 1320a-7b(b)(2).

Here, relator has alleged that (a) defendants made offers or payments, *e.g.*, Compl., ECF No. 96-3 ¶¶ 108–10, 128–36, 141–42, 170, 174; (b) of remuneration (monetary payments), *e.g.*, *id.*; and (c) with at least one purpose to induce referrals for Pipeline devices paid for by Federal health care programs (sales personnel co-opting purported clinical programs to pay high-volume physicians to secure and maintain sales and referrals), *e.g.*, *id.* ¶¶ 82, 89, 109–110, 133–37, 160–61, 172–73, 195.

In addition, relator alleged that defendants acted knowingly and willfully (aware that kickbacks were illegal, and seeking to conceal their conduct), *e.g.*, *id.* ¶¶ 81–82, 90–91, 93, 163, 267, even though for pleading purposes "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); *accord United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr.*, 953 F.3d 1108, 1122 (9th Cir. 2020) ("A complaint needs only to allege facts supporting a plausible inference of scienter.") (citing *United States ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 997 (9th Cir. 2011)).

Relator has thus alleged the elements of an AKS violation that resulted in false claims to Federal health care programs in violation of the FCA. Compl. ¶¶ 250–294.

At trial, as an affirmative defense, defendants may invoke and attempt to prove all of the elements of an AKS safe harbor. "Once the plaintiff or the government has established proof of each element of a violation under the [AKS], the burden shifts to the defendant to establish that the conduct was protected by an exception." *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009). Here, defendants have invoked the personal services safe harbor, 42 C.F.R. § 1001.952(d) (2012). Defs.' Br. at 7, 9, 16. During the relevant period, a defendant qualified for that safe harbor only if "all of the [seven specified] standards [we]re met." 42 C.F.R. § 1001.952(d) (2012).[1] Thus, the condition that payments be "consistent with fair market value" was merely a subset of one of the seven requirements for the personal services safe harbor. *Id.* § 1001.952(d)(5).

Generally, plaintiffs are not required to "plead around affirmative defenses." *U.S. Commodity Futures Trading Comm'n v. Monex Credit Co.*, 931 F.3d 966, 972 (9th Cir. 2019), *cert. denied*, 141 S. Ct. 158 (2020) (citing *Jones v. Bock*, 549 U.S. 199, 216 (2007)). And "'[o]rdinarily, affirmative defenses . . . may not be raised on a motion to dismiss.'" *Id.* (quoting *Lusnak v. Bank of Am., N.A.*, 883 F.3d 1185, 1194 n.6 (9th Cir. 2018)). "Placing the burden on the defendant is, after all, the 'general rule where [the defendant] claims the benefits of an exception to the prohibition of a statute.'" *Id.* (quoting *United States v. First City Nat'l Bank of Houston*, 386 U.S. 361, 366 (1967)). As the Ninth Circuit re-affirmed in 2019, "this 'longstanding convention is part of the backdrop against which Congress writes laws,' so courts must 'respect it unless we have compelling reasons to think that Congress meant to put the burden of persuasion on the other side.'" *Id.* (quoting *Meacham v. Knolls Atomic Power Lab.*, 554 U.S. 84, 91–92 (2008)).

Although an AKS safe harbor is an affirmative defense that ordinarily may not be raised on a motion to dismiss, courts may "consider an affirmative defense on a motion to dismiss when there is 'some obvious bar to securing relief on the face of the complaint.'" *Id.* (quoting *ASARCO, LLC v. Union Pac. R.R. Co.*, 765 F.3d 999, 1004 (9th Cir. 2014)).

[1] The personal services safe harbor was amended effective January 19, 2021. 85 Fed. Reg. 77,684 (Dec. 2, 2020). The amended safe harbor did not apply during the relevant period in this case. *Id.*

"In other words, dismissal based on an affirmative defense is permitted when the complaint establishes the defense." *Id.* (citing *Sams v. Yahoo! Inc.*, 713 F.3d 1175, 1179 (9th Cir. 2013)). This exception to general pleading standards was applied in *Corinthian Colleges*, in which relators' complaint admitted that one element of a two-element safe harbor (under a different regulatory regime, not the AKS) had been met and relators "attached to the Complaint" an exhibit that the district court found "makes clear" that the second element of that safe harbor also was met. No. 07-cv-1984, 2009 WL 4730890, at *1, *3 (C.D. Cal. Dec. 4, 2009), *rev'd*, 655 F.3d 984, 993–94 & n.6 (9th Cir. 2011) (reversing Rule 12(b)(6) dismissal and remanding to district court).[2]

Here, the face of relator's complaint does not establish the defense of the personal services safe harbor. In fact, the complaint alleges multiple reasons why the safe harbor does not apply. Compl. ¶¶ 66, 164–69, 201–03. Among other reasons, during the relevant period, the safe harbor required that "[t]he aggregate compensation paid to the agent over the term of the agreement is set in advance," with a term of "not less than one year," 42 C.F.R. § 1001.952(d)(4)–(5) (2012), but the proctoring and data collection payments were paid per proctoring event, travel, or data submission, and thus the aggregate amount paid over the term of the agreement was not set in advance.

III. Lack of Fair Market Value Is Not an Element of the AKS

The AKS does not require proof of the lack of fair market value (FMV). 42 U.S.C. § 1320a-7b(b). Indeed, the AKS does not use the words "fair market value" at all. *Id.* Rather, the AKS broadly covers "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind." *Id.* § 1320a-7b(b)(1)–(2). Added to the AKS in 1977, "[t]he phrase 'any remuneration' was intended to broaden the reach of the law which previously referred only to kickbacks, bribes, and rebates." *United States v. Shoemaker*, 746 F.3d 614, 630 n.22 (5th Cir. 2014) (quotations omitted).

[2] On remand, the *Corinthian Colleges* relators amended their complaint to eliminate the ambiguity caused by the complaint's exhibit, and the district court denied defendants' motion to dismiss, except for claims outside the limitations period. No. 07-cv-1984, 2012 WL 12878361, at *3–4 (Apr. 19, 2012).

Congress intended "to cover the transferring of anything of value in any form or manner whatsoever." *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 68 (D. Mass. 2011) (quoting 56 Fed. Reg. 35,952, 35,958 (July 29, 1991)).

As the Ninth Circuit held in *United States v. Kats*, the AKS "is violated if 'one purpose of the payment was to induce future referrals,' 'even if the payments were also intended to compensate for professional services.'" 871 F.2d 105, 108 (9th Cir. 1989) (quoting *United States v. Greber*, 760 F.2d 68, 69, 72 (3d Cir. 1985)). That is, "[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." *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 29–30 (1st Cir. 1989) (rejecting argument that plaintiff "had to prove that the payments received were not reasonable for the actual work done"). As the Ninth Circuit has explained, "[e]ven if the physician performs some service for the money received, the potential for unnecessary drain on the Medicare system remains." *Katz*, 871 F.2d at 108 (quoting *Greber*, 760 F.2d at 71).

In 2019, the Ninth Circuit re-affirmed its holding in *Katz*, upholding an AKS conviction where "referrals were one purpose" for the remuneration. *United States v. Hong*, 938 F.3d 1040, 1048 (9th Cir. 2019) (holding that "remunerations" for services or expenses may violate AKS if one purpose of payment was "to induce future referrals"). This is consistent with HHS-OIG's longstanding warning to those in the healthcare industry, like defendants, 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)." 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005); *accord United States ex rel. STF LLC v. Vibrant Am. LLC*, No. 16-cv-2487, 2020 WL 4818706, at *7, *12 (N.D. Cal. Aug. 19, 2020) (cited with approval by Judge Scarsi and defendants) (noting that payment may violate AKS "regardless of whether the payment is fair market value for services rendered," and fact payment exceeds FMV may be evidence of "an illegitimate purpose"); *id.* at *16 (FMV will not "legitimize" otherwise improper payments).

While the AKS may be violated by "reasonable payments for actual work done" if the payments were knowingly and willfully made to induce referrals, *Bay State*, 874 F.2d at 31, HHS had promulgated regulatory safe harbors during the relevant period, as noted above, which exempted certain arrangements that did not present a substantial risk for fraud and abuse. 42 C.F.R. § 1001.952 (2012). Although certain safe harbors required payments to be at "fair market value," *e.g.*, *id.* § 1001.952(b)–(d) (2012), each of those safe harbors included many other required elements, *id.*, causing "only a small subset of [FMV] transactions" to be exempt from the AKS. *Bay State*, 874 F.2d at 31 ("Congress did not explicitly change the statute to exclude [from AKS liability] reasonable payments for actual work done.").

Thus, contrary to defendants' arguments, FMV, standing alone, is not a defense to the AKS, nor is lack of FMV an element of an AKS violation. To the extent that FMV has any relevance at all, it is one element among others that defendants have the burden of demonstrating if they seek to avail themselves of certain safe harbor defenses. In any event, relator's complaint alleges that defendants' payments exceeded fair market value. *E.g.*, Compl. ¶¶ 109–110, 133–37, 167, 172, 177, 202.

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CONCLUSION

For the above reasons, the United States respectfully requests that in ruling on defendants' motion the Court should hold that:

(1) the United States declining to intervene is not a statement of the case's merits;

(2) relator need not plead the inapplicability of any AKS safe harbor, and defendants bear the burden of establishing any AKS safe harbor; and

(3) lack of fair market value is not an element of the AKS.

Respectfully submitted,

Dated: August 31, 2021

TRACY WILKISON
Acting United States Attorney
DAVID M. HARRIS
Assistant United States Attorney
Chief, Civil Division
ABRAHAM C. MELTZER
Assistant United States Attorney
Chief, Civil Fraud Section

Frank Kortum

FRANK D. KORTUM
Assistant United States Attorney
Attorneys for the United States of America